Missouri Medicine

The Journal of the Missouri State Medical Association www.msma.org/missouri-medicine May/June 2020



Telehealth: The Post-COVID Era

COVID-19: Impact, Response, Comprehensive Research, Review

"We shall draw from the heart of suffering itself the means of inspiration and survival."
– Winston Churchill

Give them focus.

Give to the Missouri State Medical Foundation.



Helping students focus on their medical education for over 50 years, the Missouri State Medical Foundation has benefitted thousands of medical students statewide. We thank the many donors who have committed their energy and resources to fulfilling the Foundation's mission, and we are grateful for their generosity.

For over 15 years, MSMA Scholarships have been funded by the Foundation for students at each of Missouri's medical schools.

The Foundation has also facilitated the creation of scholarship funds through a matching grant program. Our scholarship partners include:

- Boone County Medical Society
- Cole County Medical Society
- Kansas City Medical Society
- Northeast Missouri Medical Society
- Quad Counties Medical Society
- Saint Charles-Lincoln County Medical Society
- MSMA Alliance

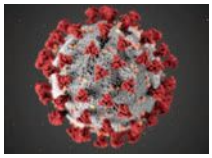
Donations may be sent to:
Missouri State Medical Foundation | P.O. Box 1028 | Jefferson City, MO 65102
Contact Patrick Mills at 800-869-6762 | Email pmills@msma.org

The Missouri State Medical Foundation is a 501(c)3 organization.

Missouri Medicine

The Journal of the Missouri State Medical Association - Since 1904

Volume 117 | Number 3 | May/June 2020 **www.msma.org/missouri-medicine**



Missouri Medicine
Special Report:
Telehealth
in the Post-Covid Era

PRESIDENT'S FORUM

COVID-19 Pandemic: Impact on Healthcare in Missouri
by **George J. Hruza, MD** 168

COVID-19: A Different Kind of Warfare
by **Col. James DiRenna, (Ret) DO** 170

GUEST EDITORIAL

Politics, Economics, and the Science in Public Health
by **Elie Azrak, MD** 171

PERSPECTIVE

State of Missouri Supported by Four Essential Pillars for COVID-19 Response
by **Randall W. Williams, MD** 173

MEDICAL SCHOOL PERSPECTIVE

Patient-Doctor Telemedicine: Virtual Care in the Era of COVID-19 and Beyond
by **Steven Zweig, MD, MSPH** 175

SCIENCE PERSPECTIVE

Missouri Rapid Rural Population Health Response to the COVID-19 Pandemic
by Kathleen Quinn, PhD, Jennifer L. Eldridge Houser, PhD
& Julie M. Kapp, PhD 177

PERSPECTIVE

COVID-19 Response in Mid-Missouri
by Christopher Sampson, MD, **Amy Zguta, MD** & **Albert Hsu, MD** 180

SCIENTIFIC

Laboratory Tests for COVID-19: A Review of Peer-Reviewed Publications and Implications for Clinical Use
by Daniel Shyu, James Dorroh, Caleb Holtmeyer, Detlef Ritter, MD, Anandhi Upendran, PhD, Raghuraman Kannan, PhD, Dima Dandachi, MD, Christian Rojas-Moreno, MD, Stevan P. Whitt, MD & **Hariharan Regunath, MD** 184

PERSPECTIVE

The Feds Act to Boost Competition in the Biosimilars Market
by Henry I. Miller, MD 196

MEDICAL | LEGAL

COVID-19: Has the Standard of Care Changed and Are Providers Immune from Liability?
by Lorinda Holloway, JD 199

AS I SEE IT

The Perilous Blessing of Opioids
by Travis N. Rieder, PhD 202

SCIENCE OF MEDICINE | FEATURE SERIES

Missouri Telehealth Network
University of Missouri

Telehealth and Outreach in the Post COVID-19 World: The MU Show-Me ECHO Program as a National Model
by **Karen Edison, MD** 214

Embracing the Power of Show-Me ECHO Learning Communities to Transform Clinical Practice in Missouri
by Lea Brandt, PhD, Melissa Warne-Griggs, PhD, Kimberly Hoffman, PhD, Lori Popejoy, PhD & E. Rachel Mutrux, BA 216

Building Regional Expertise: Perspectives from Show-Me ECHO Participants
by Melissa Warne-Griggs, PhD, Lea Brandt, PhD, Kimberly Hoffman, PhD, Tracy Greever-Rice, PhD & E. Rachel Mutrux, BA 222

Telehealth and Telemedicine in Missouri
by Mirna Becevic, PhD, Lincoln R. Sheets, MD, Emmanuelle Wallach, MA, Anne McEowen, MS, Angie Bass, MHA, E. Rachel Mutrux, BA
& **Karen E. Edison, MD** 228

Accelerating Care Through ECHO: Case Examples from the Field
by Mirna Becevic, PhD, Emmanuelle Wallach, MA, Lincoln R. Sheets, MD, Hope Misterovich, DO, Susan Norris, FNP-C, Evelyn Aboagye, MD, Jonathan A. Dyer, MD, Bruce R. Bacon, MD, **Karen Edison, MD** & Kristin Sohl, MD 235

Integrating the Lived Experience Conditions and Care in the ECHO Model
by Tracy Greever-Rice, PhD, Lea Brandt, PhD, Melissa Warne-Griggs, PhD & Kimberly Hoffman, PhD 241

Assessing Impact of Show-Me ECHO on the Health of Missourians: Two Examples
by Mirna Becevic, PhD, Tracy Greever-Rice, PhD, Emmanuelle Wallach, MA, Lincoln R. Sheets, MD, Kara Braudis, MD,Benjamin Francisco, PhD, Kimberly Hoffman, PhD & **Karen E. Edison, MD** 245

SCIENCE OF MEDICINE MINISERIES

Colorectal Surgery Review for Primary Care Providers: Part II
by Rakesh Hegde, MD, John M. Trombold, MD
& **José M. Dominguez, MD** 254

SCIENCE OF MEDICINE

Factors Associated with Adherence to Screening Guidelines for Diabetic Retinopathy Among Low-Income Metropolitan Patients
by Jessica Kuo, MD, James C. Liu, MD, Ella Gibson, P. Kumar Rao, MD, Todd P. Margolis, MD, PhD, Bradley Wilson, MA, Mae O. Gordon, PhD, Emily Fondahn, MD & Rithwick Rajagopal, MD, PhD 258

Patient Perception of Vaping in the Midst of the Electronic Cigarette and Vaping Product Associated Lung Injury (EVALI) Epidemic
by Tarang Patel, MD, Ethan Karle, DO, Tamar Gubeladze, MD, Genevieve Pentecost, MS4 & Armin Krvavac, MD 265

FROM YOUR ASSOCIATION

Correspondence 205
Missouri Medicine in the News 207
Alliance Report 208
Medical Society Spotlight 211

162ND ANNUAL CONVENTION/REPORTS & HIGHLIGHTS

Meet MSMA's President 272
Credentials & Appointments 273
Elections 274
Awards 275
Council Minutes Summary 275
Reports of the Delegate Handbook 282
Financial Statements: Missouri State Medical Association 291
Financial Statement: Missouri State Medical Foundation 291
Financial Statement: Missouri Physicians Health Program 291

ON THE COVER

Quote on the cover attributed to Winston Churchill, September 11, 1940, in a broadcast to London during the Battle of Britain, World War II.

www.msma.org/engage

momedical @momedicalassn mostatemedicalassociation momedical momedical

MSMA member names in bold

Missouri Medicine

The Journal of the Missouri State Medical Association - Since 1904

www.msma.org/missouri-medicine









About Missouri Medicine

In publication since 1904, the peer-reviewed, award-winning, bi-monthly *Missouri Medicine: The Journal of the Missouri State Medical Association*, is indexed by Index Medicus, MEDLINE, and PubMed. Complete issues archived at PubMed Central since 2010. Content appears on EBSCO Host Research databases.

With a large and respected editorial board and regular participation by Missouri's six medical schools on eight campuses, *Missouri Medicine* is among the nation's foremost state medical journals.

Articles are frequently cited in impact factor journals and regularly featured in the national media including: *Wall Street Journal*, CSPAN-2, KevinMD, *Outside Magazine*, *Runner's World*, *NBC News*, *General Surgery News, Ophthalmology Times*, and many others. Issues of *Missouri Medicine* are printed on acid-free paper with open access to digital issues available at www.msma.org/missouri-medicine-library.

Copyright & Postal Entry

Missouri Medicine, the Journal of the Missouri State Medical Association, is owned and copyrighted by the Missouri State Medical Association. Published at 113 Madison Street, Jefferson City, Missouri 65101. Printed by the Ovid Bell Press, Inc., Fulton, Missouri. Periodicals postage paid at Jefferson City, Missouri, and at additional mailing offices. Postmaster: Send address changes to Missouri State Medical Association, c/o Membership Dept., P.O. Box 1028, Jefferson City, MO 65102. Annual subscription is included in membership dues; non-members pay $75.00.

Disclaimer

All articles, editorials, letters, and advertisements published represent the opinions of the authors and advertisers, and do not necessarily reflect the official policy or endorsement of the Missouri State Medical Association or the institution with which the author or product or service is affiliated unless clearly specified. *Missouri Medicine* reserves the right to make the final decision on all content and advertisements.

Missouri Medicine Editor

John C. Hagan, III, MD, FACS, FAAO

Managing Editor

Lizabeth R. S. Fleenor, BJ, MA

Contributing Editors & Publication Committee

Justin M. Albani, MD
Jessica D. Bauerle, MD
Jeffrey G. Copeland, MD
Betty M. Drees, MD
David A. Fleming, MD
Arthur H. Gale, MD
William R. Reynolds, DDS, MD
Charles W. Van Way, III, MD

Editorial Board

Allergy & Immunology: Jacqueline L. Reiss, MD
Anesthesiology: Kathy M. Perryman, MD
Cardiac Surgery: Michael C. Murphy, MD
Cardiology: Jerry D. Kennett, MD
Colon & Rectal Surgery: Jose M. Dominguez, MD
Dermatology: Jon A. Dyer, MD
Emergency Medicine: Mark T. Steele, MD
Endocrinology: Howard M. Rosen, MD
Family Practice: Michael L. O'Dell, MD
Gastroenterology: David H. Cort, MD
General Surgery: Joseph A. Corrado, MD
Hematology & Oncology: Stephanie L. Graff, MD
Hospital Medicine: Lancer G. Gates, DO
Infectious Disease: Hariharan Regunath, MD
Internal Medicine: John S. Daniels, MD
Medical Genetics: Patricia I. Dickson, MD
Medical Student Section: Alex Shimony, BS
Military Medicine: Michael S. Clarke, MD
Neonatology: Joshua E. Petrikin, MD
Nephrology: Gary G. Singer, MD
Neurology: Pradeep K. Sahota, MD
Neurosurgery: Keith M. Rich, MD
Obstetrics & Gynecology: Octavio R. Chirino, MD
Ophthalmology: John B. Holds, MD
Orthopaedics: Gregory R. Galakatos, MD
Otolaryngology: John F. Eisenbeis, MD
Pathology: Louis P. Dehner, MD
Pediatrics: Nancy J. Bunge, MD
Physical Medicine & Rehabilitation: Gregory M. Worsowicz, MD
Plastic Surgery: Edmond B. Cabbabe, MD
Preventive Medicine: James H. O'Keefe, MD
Psychiatry: Laine M. Young-Walker, MD
Public Health: Katherine R. Lichtenberg, DO
Pulmonary Medicine: Gary A. Salzman, MD
Radiology: John H. Niemeyer, MD
Resident & Fellow Section: Frances Mei Hardin, MD
Retired Physicians: Juan C. Corvalan, MD
Rheumatology: Anne E. Winkler, MD
Sports Medicine: Brian L. Mahaffey, MD
Statistics & Methodology: Christopher R. Carpenter, MD
Toxicology & Addiction Medicine: Evan S. Schwarz, MD
Urology: Elizabeth A. Piontek, MD
Vascular Surgery: W. Kirt Nichols, MD
Women Physicians Section: Joanne Loethen, MD
Young Physician Section: Marc Mendelsohn, MD

Editors Emeritus

Donald G. Sessions, MD, 1988-1992
J. Regan Thomas, MD, 1992-2000

Contact

Editor: John C. Hagan, III, MD / drjhagan3@gmail.com / 816-478-1230
Managing Editor: Lizabeth R.S. Fleenor / lfleenor@msma.org / 800-869-6762
Instructions for Authors: www.msma.org/missouri-medicine
Missouri Medicine **Library: www.msma.org/missouri-medicine-library**

ISSN 0026-6620 / Established 1904 / ©2020 Missouri State Medical Association



What are the risks associated with **telemedicine?**

We're barely making payroll, what if we **can't make a payment?**

I'm a retired doc that wants to help, **will I be covered?**

Will my premium be lower **while I'm closed or not doing certain surgeries?**

What do you do to help burned out physicians **serving on the frontline?**

Am I covered if I get infected?

How do we keep our practice safe?

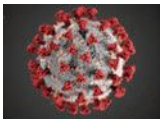
Visit the **ProAssurance COVID-19 Information Center** to find frequently updated information gathered to support your medical professional liability coverage decisions.

You'll find helpful risk guidelines, policy updates, and crisis support at **ProAssurance.com/COVID-19**.

ProAssurance®
Treated Fairly

Healthcare Professional Liability Insurance

For ProAssurance policyholder information and resources ››› **ProAssurance.com/COVID-19**



PRESIDENT'S FORUM

COVID-19 Pandemic: Impact on Healthcare in Missouri

by George J. Hruza, MD

Everyone will remember what they were doing when the reality of the COVID-19 pandemic hit home with the associated feelings of foreboding and panic.

At first, I felt like I was surfing at the crest of a wave having been in China toward the end of November, in Japan toward the end of January, and in northern California on February 29, 2020. I finally landed in St. Louis to the difficult decision. As I was the national president for the American Academy of Dermatology (AAD), I would have to cancel AAD's annual meeting in Denver in mid-March with 20,000 attendees. During my forced two-week staycation, I went through the feelings of fear, panic, worry, helplessness, concern about the damage COVID-19 was wreaking across the world, and compassion for all the people dying and their grieving families.

I picked myself up from the floor and proceeded to learn everything I could about COVID-19 and set up an ad-hoc task force for AAD. The task force has been putting together recommendations and resources as to how we can take care of our patients safely during this time.

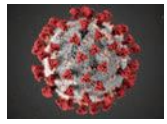
The MSMA has likewise collected resources as to how you can function in the brave new world we now live in. At msma.org you will find dozens of resources on the new waivers for doing telemedicine, infection control, conservation and proper use of PPE, educational modules on various aspects of COVID-19, and HHS, CDC, WHO, CMS, Missouri DHSS, AMA, ACP, ACEP, MHA, and Johns Hopkins recommendations and waivers. The MSMA has been highly active in advocacy for telehealth regulation waivers, civil immunity during the pandemic, financial support for physician practices, and expanded COVID-19 testing capability. We called on the governor to issue a shelter-in-place order early on, and asked that opening up be done in a carefully considered manner. To keep members updated on current issues, the Association arranged for ongoing conference calls between MSMA and the director of MoDHSS, Randall Williams, MD, who is also an MSMA member.

Most elective and "non-essential" procedures and in-person visits were deferred in Missouri based on CDC and CMS recommendations in order to preserve PPE, and free up equipment, ORs, hospital beds, ICUs and ventilators for an expected surge of COVID-19 cases (as was seen in Italy and New York City), and to prevent the spread of the virus in the healthcare setting. As Homeland Security considers all healthcare services to be essential, Missouri was never under a state order to not perform these procedures. Fortunately, due to the shelter-in-place order and social distancing in general, the surge never materialized. Missouri successfully "flattened the curve," just like St. Louis did during the influenza pandemic one hundred years ago.

A dramatic effect of limiting visits and procedures to only the very essential ones across the state has been a 50-100% drop in office visits and hospital activity, putting many practices and hospitals, especially in the rural part of the state, on the verge of financial ruin. The federal government has stepped up with temporary help in the form of loans and grants through Coronavirus 1-4 legislation (the last two called CARES Act I and II). The state has also received some of the CARES Act funds to distribute to healthcare providers in Missouri. This is welcome temporary relief, but not sustainable. Based on CDC definitions, most elective procedures and regular doctor visits with appropriate precautions, are "low-risk" encounters. A trip to the supermarket, hardware store, or gas station may well be "riskier" than going to the doctor's office or an outpatient surgery center, which are much better controlled environments.



George J. Hruza, MD, MBA, FAAD, FACMS, MSMA member since 1989, is the 2020-2021 President. He practices Dermatology in St. Louis.



MSMA Delivers "DocPlates" to Frontline Healthcare Workers



In appreciation of Missouri physicians and healthcare workers, MSMA is calling in food for those providing care during the COVID-19 crisis. MSMA launched DocPlates on April 27 in Jefferson City, providing lunch to Dr. Randall Haight's COVID-19 team at Capital Region Medical Center (CRMC). If you know of a COVID-19 team who deserves to be treated, email Haley Wansing at hwansing@msma.org. Tell us why they are your heroes.

Left: MSMA Council Chair George Hubbell, MD, delivers lunch to Amy Hamacher at Capital Regtion Medical Center.

Another concern of the healthcare system near shutdown is starting to become apparent. Patients are afraid to go to the hospital. There has been a dramatic drop of patients coming to the hospital for heart attacks and strokes. I do not think many us believe that those diseases have just miraculously disappeared. We are starting to see cases of patients with heart attacks dying or patients with strokes suffering irreversible damage due to delaying coming to the hospital for fear of getting COVID-19.

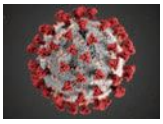
Are some of the excess deaths we are reading about due to undocumented COVID-19 or due to other conditions that were not treated due to fear of COVID-19? Patients are deferring (or are being asked by their doctors to defer) getting chemotherapy or radiation therapy for cancer. In dermatology, NCCN recommended deferring treatment of thin melanomas for months. What do we tell such a melanoma patient that later develops metastatic disease when they ask if the delay may have allowed the metastasis to develop?

The economic damage caused by the virus in the U.S., with record unemployment expected to reach more than 20%, is and will cause a lot of hardship, which will fall on those least able to afford it. The layoffs are concentrated in jobs at the lower end of the wage scale. The impact will be huge. Fortunately, our safety net will help tide most over. My bigger concern is with the developing world where there is little or no safety net. What will happen in those areas with massive unemployment? I would anticipate widespread starvation, civil unrest, and death from non-COVID-19 causes.

As I write this, Missouri is a couple of weeks past its peak of new cases, Governor Parsons has relaxed the shelter-in-place order allowing all businesses to reopen with appropriate social distancing and other safety precautions in place on May 4, 2020. Kansas City started reopening on May 15 and St. Louis County and City May 18. All healthcare services can now be offered. Hopefully, it is not too late for our rural hospitals and clinics. For a successful restart, patients and staff must feel reassured that the clinic/hospital is taking reasonable precautions to keep everyone safe.

The AMA and many other professional societies have posted "restarting your practice" documents to do just that. In our office, patients and staff are screened, both patients and staff wear masks, all doors are open, social distancing is enforced, patients wait in their car until they are called, they don't bring companions with them, surfaces are constantly cleaned, etc. I have found that patients really appreciate the steps we are taking to keep them safe and that we are there to take care of their medical needs. By having a detailed, written COVID-19 pandemic preparedness plan in place, we have been able to bring back staff who were leery of working during these uncertain times.

Until there is a vaccine or some highly effective treatment, COVID-19 will be with us. We will have to get used to a new normal and learn to work and play in that environment for many months, if not years. I have worked through all my negative emotions by gaining knowledge and taking actions along with many of you. It is up to us, the physicians of Missouri, to convey that rational, yet optimistic outlook to our fellow Missourians. With sensible precautions and our American ingenuity, we will persevere and thrive again. **MM**



PRESIDENT'S FORUM

COVID-19: A Different Kind of Warfare

by Col. James DiRenna, (Ret) DO

Irony – a state of affairs defined as incongruity between the actual result of a sequence of events and the normal or expected result.

We've all heard "Beware the Ides of March." On March 15, 2020, the city of Kansas City, Missouri, was shut down by order of the Mayor due to COVID-19. This date would also take me back 49 years to March 15, 1971, at the hills of Khe Sahn Valley in North Vietnam where I knew my enemy. Thus, March 15 is one of those ironic dates in one's reflection of life for me as a soldier in Vietnam and in the United States as a physician. In 1971 I found myself in an intense battle. I was injured, received the Purple Heart and returned to duty. In 2020 I question the virus being an act of God vs. a hidden agenda. Is COVID-19 an actual incident of germ warfare?

As I stated numerous times during my presidency, I am very appreciative for the opportunity to lead our Missouri State Medical Association this past year. I want to thank the administration, the staff, and associated affiliates with our organization. Their continual dedication and purpose gives me great hope to keep medicine alive and successful.

My year started with the vaping crisis and ended with the formation of DocPlates (providing lunches by MSMA representatives to physicians in rural areas) due to the COVID-19 crisis. This is the third time in its 161 years that the Association didn't have a face to face Annual Meeting or Convention. The first was the Civil War; the second was during WWII, and the third was s different kind of war, the COVID-19 crisis.



James DiRenna, DO, MSMA Immediate Past President and member since 1996, is from Kansas City, Mo., and practices Family Medicine for the MOSAIC Lifecare Organization.

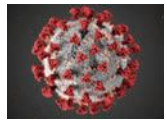
MSMA's Annual Meeting still took place by video and phone conferencing. I wish George Hruza, MD, the best as your incoming state president, and pledge my support. I want to acknowledge and give special recognition not only to the entire MSMA staff, but the departments of legislation, membership, and insurance. Our MSMA staff members work tirelessly in support of physicians and our member's problems by providing resources and services. I also want to acknowledge my ongoing respect and gratitude to our Missouri State Medical Association Alliance for their dedication and support of our advocacy.

The future of MSMA as I see it is to continue avocation, education, and participation. Our organization is only as good as its membership. The teaching of medicine will continue to have its standards of foundation, however curriculums will be challenged. Telemedicine will continue to grow at an impressive rate. Half of all the U.S. hospitals use some sort of form of telemedicine now. This alone is favorable to all state and federal legislation. Telemedicine comes with its own learning curve due to issues concerning privacy, confidentiality, credentialing, and liability. It will be interesting to see what happens after the Missouri Governor's executive order expires this summer relating to how a physician will be allowed to practice under the present law as it relates to telemedicine. It is a priority that physicians of Missouri understand the state law and how it is implemented.

We continue to live in uncharted waters. One must totally believe in organized medicine to achieve professional goals, patient health and safety, and create a balance that leads to making a difference.

I hope our paths cross in the future. To all of my family, friends, and colleagues: "May you live as long as you want, but never want as long as you live."

MM



Politics, Economics, and the Science in Public Health

by Elie Azrak, MD

There needs to be an optimized avenue through which effective public health measures in the U.S. can be adopted in order to effect maximal protection of lives.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020, recently signed into law by President Trump, includes a provision for a $100 billion package for the Public Health and Social Services Emergency Fund designed to provide cash flow to hospitals grappling with the Coronavirus pandemic.[1]

Other provisions of the Act secure loans to large and small businesses, and implement direct cash transfers to individuals, amounting to a total of $2.2 trillion, or 10% of the U.S. GDP. It is not yet clear how some of the relief funds will be distributed and used, and thus some assumptions of potential unfairness, including waste, fraud and abuse alas are inherent to this calculation. Nonetheless, as a bipartisan effort this Congressional action and the swift subsequent Presidential sign-off seem an effective outcome of the political process: prompt action during a crisis.

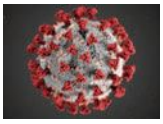
As the COVID-19 pandemic rages on and the economy is frozen, many have asked the question in the manner an economist may do so: "What is the Value of a Statistical Life (VSL) under the conditions of the current pandemic."[2,3] In other words what is the tradeoff between economic viability and death rates? In fact, this is the core question being asked in an intense debate among our political – and business – elites. The ideological right and much of the business community are making a case for an early resumption of economic activity lest the "country will die;" the left and most health care experts are calling for tighter controls on economic and personal exchanges lest "more people will die." We are facing the worst kind of trade-off.



Elie Azrak, MD, MHA, FACC, FSCAI, MSMA member since 2001, is a Cardiologist in St. Louis, Missouri. He is a Missouri Delegate to the American Medical Association.

While our health care system – mostly acute care hospitals, the recipients of the financial relief package under the CARES Act – is dealing with, or gearing up to deal with a surge in COVID-19 cases, public health experts are scrambling to use the meager, long-starved resources of the local and regional health departments, and the Centers for Disease Control (CDC) to "flatten the curve". This requires: 1) communicating – and enforcing – social distancing, the most effective measure of preventing transmission; 2) scaling up diagnostic testing for mass detection of cases; and 3) tracing, notifying and quarantining contacts of COVID-19 infected individuals (contact tracing).

The second and third measures also have proven effective when adopted early and scaled up in countries such as Germany, South Korea and Singapore. In South Korea, where lessons were learned from the 2003 SARS epidemic, legislative change to allow government access to medical records without warrants, the use of



big data to track cases and contacts through cell phone records and locations, and the widespread use of "push notification" messages to alert suspected contacts and monitor their compliance with quarantine were extremely effective.[4] Important to say, the social, cultural, and political nature of the U.S. is vastly different, and the notion of government intrusion into private health records is probably a non-starter!

Nonetheless, there needs to be an optimized avenue through which effective public health measures in the U.S. can be adopted in order to effect maximal protection of lives. This avenue can only be achieved through active engagement of political and public health leaders – hitherto natural foes that have resented each other. Public health leaders may have to step down from their perceived moral high horse, abandon the dictum of "primacy and purity" of scientific evidence, and understand nonscientific factors that help "move knowledge and research into policy and practice."[5]

Just as the public recognizes the importance of science and investments in public health,[6, 7] political leaders and elected officials will have to recognize science as relevant – even critical to policy success – and proactively seek alternative solutions from public health experts.[8] Only then can policy making became pertinent, both for the short timeframes that drive politics and the long timeframes which dominates public health science and interventions. Only then will we have laws which include provisions to save banks and Boeing (which may be necessary); only then will we also include provisions that ensure success of public health campaigns and future pandemic planning that will save lives both statistical and real.

References

1. Schwartz Karyn, Neuman Tricia. A Look at the $100 Billion for Hospitals in the CARES Act. Published on March 31, 2020. Accessed on March 31, 2020 at: kff.org.
2. Yan Victoria Y, Jamison Dean T, Summers Lawrence H. Pandemic risk: how large are the expected losses? Bulletin of the World Health Organization 2018; 96:129-134.
3. Kaiser Family Foundation. Trends in COVID-19 Coronavirus Cases & Deaths in the US. Source: kff.org (Coronavirus Tracker). Accessed April 9, 2020 at: kff.org
4. Dudden Alexis, and Marks Andrew. South Korea took rapid, intrusive measures against Covid-19 – and they worked. The Guardian. Friday March 20,2020. Accessed April 10, 2020 at: theguardian.com.
5. Greer Scott L, Bekker Marleen, De Leeuw Evelyne, Wismar Matthias, Helderman Jan-Kees, Ribeiro Sofia, Stuckler David. Policy, Politics and Public Health. European Journal of Public Health. Vol. 27, Supplement 4, 2017. P 40-43.
6. Trust for America's Health. Poll: American Public Supports Investment in Prevention as Part of Health Care Reform. Published at: tfah.org. November 2009. Accessed April 5, 2020.
7. Research America. Americans' views on science and 2016 elections. Published at: http://www.researchamerica.org. September 2015. Accessed April 5, 2020.
8. Hunter Edward L. Politics and Public Health—Engaging the Third Rail. J Public Health Management Practice, 2016, 22(5), 436–441.

MM

TRI-STATE OCCUPATIONAL MEDICINE

Physicians Needed for Outpatient Exams/ No Treatments

Tri-State Occupational Medicine, Inc. (TSOM) is looking for physicians to perform disability evaluations in their MO offices. Part-time opportunities. No treatment is recommended or performed. No insurance forms. No follow up. No call, no weekends and no emergencies. Preferred specialties – rehab med, emergency med, internal med or family med. Training and all administrative needs including scheduling, transcription, assisting, and billing are provided. Must have a current MO medical license.

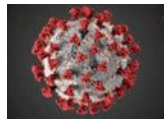
Contact: Susan Gladys
susang@tsom.com
866-929-8766 / 866-712-5202 (fax).



Letters to the Editor

Submissions reflect readers' opinions and may be edited for length. Use in subject line: "For Publication"

Email
- drjhagan3@gmail.com
- lfleenor@msma.org



PERSPECTIVE

State of Missouri Supported by Four Essential Pillars for COVID-19 Response

by Randall W. Williams, MD

Missouri was one of the first states to have the Battelle Critical Care Decontamination System which can decontaminate as many as 80,000 N95 face masks per day so they can be safely reused.

The first COVID-19 patient was diagnosed in the State of Washington on January 21, 2020, and we stood up our DHSS Public Heath Incident Response Team on January 27.

From day one, we adopted the admonition from Mark Twain: the secret to getting ahead is getting started. May 6 marked 100 days in which we have met daily, except for a very few days on weekends, and on those weekends we have still worked to meet time-sensitive challenges around the state.

As I told the Senate and the House in March, I have always felt we were prepared to ride out a storm because of the faith I had in a whole government approach that aligns all of state government with our providers, hospitals, and local public health departments. I felt then and have had my faith affirmed that we would all rise up to meet whatever came our way.

We have a saying in public health that relationships are everything, and everything else is derivative. I have always thought public health at its best is a force multiplier that aligns and coordinates resources at a time of crisis while providing calm, cool, and collected leadership.



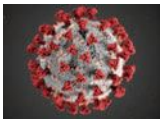
Randall W. Williams, MD, FACOG, MSMA member since 2017, is the Director of the Department of Health and Senior Services in Jefferson City, and an Obstetrician and Gynecologist.

There is another old saying in public health that "a crisis is no time to be making introductions," and we have worked very hard over the last three and a half years to engage with our external partners at the local level.

Communication is vital. Governor Parson has led the way as he has met weekly for the past nine weeks with the Missouri Hospital Association, a group of infectious disease physicians, mayors, clergy, sheriffs, and county commissioners. The daily press briefings he gives have become a staple, and they have provided the opportunity to explain the data and science behind policy decisions that almost always result in divided opinions.

Missouri is a diverse state and it is necessary to collect data when making life and death decisions. But clinicians understand that at the end of the day, one must treat the patient and not the chart, and that is where experience and expertise make a big difference. Many of you have walked into a patient's room and had someone say, "I am so glad you are here." I found while practicing for over 30 years that what that meant was they were in pain or anxious and they were glad someone with the experience and expertise had arrived to help them. I know the Governor, as a former sheriff, and I, as a former clinician, have relied on our training and experiences handling emergencies during this situation.

After being in Washington with my fellow state health directors and others from the U.S. Department of Health and Human Services and the White House during the last week of February, I decided the best recommendation going forward was to stress testing and access to mobile test sample collection sites (more than 150 mobile sites are now in Missouri). I want to extend my appreciation to the clinicians, hospitals, laboratories. and local health departments that



made that happen in parallel with social distancing requirements.

On April 12, one week after Missouri hit its peak number of cases while we were testing symptomatic patients almost exclusively, I calculated the per capita rate of testing and we were 15th out of 37 states with populations over 1.5 million, and 2nd among our 8 contiguous states, including Illinois.

We met with the White House the week of May 4, and while our testing rates fluctuate as we have fewer symptomatic people, we are still in the top tier for testing capacity in the country with 16 commercial and academic labs along with our State Public Health Laboratory. We currently have the capacity to do more than 8,000 tests per day in Missouri. By partnering with a commercial lab, we were recently able to get 3,000 tests with sampling kits in 12 hours when we applied our "box in" strategy to a processing plant in St. Joseph in late April. We tested asymptomatic employees and about 15% received positive results (consistent with CDC's reporting of 19 states' experiences).

We are now at a R0 of 1 with this outbreak, and fortunately never had to engage a crisis care plan in Missouri, even in the St. Louis region where half of our cases have occurred. Our positive cases continue to trend downward, as do our hospitalizations and ventilator utilization. We have been helped by an early diminution in flu cases this year, so we now move out of the acute phase and into a recovery phase. We understand the importance of continued social distancing and the ability to quickly respond to outbreaks in vulnerable populations such as long-term care and other congregate living facilities, meatpacking plants, and first responders and clinicians.

As we move forward, the four essential pillars of the state's "Show Me Strong Recovery" plan include:

1. Expand testing capacity and volume in the state.
2. Expand reserves of PPE by opening public and private supply chains.
3. Continue to monitor and, if necessary, expand hospital and health care system capacity.
4. Improve ability to predict potential outbreaks using Missouri's public health data.

Expanding testing capacity and volume in the state gives us the capability to "box in" outbreaks and do monitoring and surveillance, including antibody testing. The State Public Health Laboratory will soon receive DiaSorin instrumentation which can do 175 tests per hour and is one of the serological tests approved by FDA.

The state is expanding reserves of personal protective equipment by opening public and private supply chains. Missouri was one of the first states to have the Battelle Critical Care Decontamination System which can decontaminate as many as 80,000 N95 face masks per day so they can be safely reused.

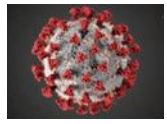
The third pillar guides us to monitor, and if necessary, expand hospital and health care system capacity. This includes isolation and alternate care facilities for those who cannot self-quarantine at home. Missouri has also purchased 225 ventilators to supplement the 123 we have available if needed regionally or statewide.

The fourth pillar calls us to improve our ability to predict potential outbreaks using statewide public health data.

I am particularly fond of President Harry Truman, and one of my favorite quotes from him summarizes the actions of so many Missourians over the last few months, "I have tried to give it everything that was in me." We join you in mourning with all who lost loved ones and hope we can continue to learn and advance so that we can decrease the number who are affected and become ill in the future.

In closing, I can't state it any better than the Governor who recently said, "Because Missouri took aggressive actions to combat COVID-19 from the start, we are in a good place with each of these pillars, and we are confident we are ready to move forward into the recovery process. I want to encourage all Missourians to make wise decisions, love your neighbors, and support each other in every way you can." **MM**

MSMA has coordinated a series of COVID-19 conference calls between MSMA physicians and Randall Williams, MD, Director of the Missouri Department of Health and Senior Services. Visit www.msma.org/covid19-conf-calls for latest conference call schedule.



School of Medicine
University of Missouri Health

Patient-Doctor Telemedicine: Virtual Care in the Era of COVID-19 and Beyond

by Steven Zweig, MD, MSPH

Virtual visits will likely remain in place after this pandemic is over. We will need to be mindful of their advantages and disadvantages going forward.

This issue of *Missouri Medicine* includes updates on the use of telehealth techniques from experts. The use of telehealth to support long distance care and education has increased substantially.[1] Telemedicine use for behavioral/psychiatric care has been common. It has also been used increasingly to support emergency services, intensive care or stroke, particularly in rural environments.

Project ECHO started as a strategy to disseminate knowledge about the treatment of Hepatitis C in New Mexico,[2] but has now, as described in this issue, has become a broad-based educational strategy with 24 unique programs supported by the Missouri Telehealth Network. This spring those of us who knew nothing about telemedicine – as well as our patients – had to quickly learn the makeshift strategies that would enable nonemergent health care to continue.

Our first experience with virtual visits was a special clinic to evaluate patients with respiratory complaints (who could have COVID-19) that enabled them to reassure the patient who clearly did not and to triage patients to either the emergency department if very sick or MU Health Care's drive-through testing center if they were not. This strategy also kept potentially contagious patients our of the clinics and physically isolated from others. The strategy used for health care surge control is called "forward triaging" which enables protections for patient, provider, and community from exposure.[3]

In the pre-COVID era, routine home-based patient-doctor telemedicine care was limited due to lack of reimbursement. Not surprisingly capitated systems like Kaiser Health have been the earliest adopters where 52% of the more than 100 million patients visits in 2018 were virtual ones.[4] The COVID-19 pandemic created changes nearly overnight. Now patient and physicians were striving to reduce in-person visits for public health reasons.

In a period of two weeks, MU physicians primary care and subspecialty physicians went from none to over 4,000 virtual outpatient visits per week on a secure platform. This allowed us to take care of all of the other problems



Steven Zweig, MD, MSPH, MSMA member since 2019, is Dean of the University of Missouri - Columbia School of Medicine. He practices family, geriatric, and hospice and palliative medicine.

our patients had in spite of the pandemic. We did our best to not defer patients who would otherwise be stacked on to future schedules, miss the opportunity to have needed evaluations or refills, or worst of all become sicker from their acute or chronic illness requiring avoidable visits to emergency or hospital admissions.

The rule changes by Centers for Medicare and Medicaid (CMS) to pay for virtual visits between physician and patient helped to enable this innovation. Physicians can follow the same documentation guidelines used for in-person visits and get paid the same rate for virtual visits incorporating both audio and visual capabilities. Unfortunately, many of our patients could not operate the ZOOM platform, did not have a computer or smart phone, or did not have sufficient internet resources to enable a connection. Whereas follow-up visits by phone were equally important, reimbursement for these visits was at first much less. Not surprisingly those patients most vulnerable due to poor social resources were likely to suffer once again by even more limitations in access. Even before the COVID-19 pandemic, Missouri was among the most supportive states for telehealth reimbursement for professional services. [5]

Also, some important outpatient care does not lend itself to virtual visits. Virtual ophthalmology visits, for example, are much more difficult especially if an instrument assisted examination is required. Even in the primary care setting, we brought in patients who could not be care for virtually, such as those requiring a hands-on physical exam (e.g. abdominal pain) or a procedure (e.g. ingrown toenail excision). We felt comfortable doing this because of our comprehensive strategy to keep sick people out of the clinic (video assessment and drive through testing, keeping sick staff at home, preventing visitors, and screening all who enter the clinic with questions and temperature) knowing that we could make it safe for both our staff and our patients needing to be seen.

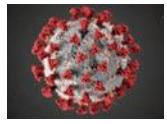
Virtual visits will likely remain in place after this pandemic is over. We will need to be mindful of their advantages and disadvantages going forward. While audio-visual care is likely more effective than audio only or asynchronous email consultations, there are limitations with the quality of the transmission, the stilted social interactions, potential for missing nonverbal cues, and the loss of "healing touch."[6] This also has implications for medical education. These past weeks students and residents have been included as third parties in the virtual visit. We will need to determine curricula that best prepare them for this change in practice.

All in all, the innovations that have come from catastrophe will help provide greater access for our patients, particularly those who are old or disabled, those with limited transportation ability, people in rural communities who need distant subspecialized care, behavioral health visits that may have been limited by stigma, and even working patients who are more likely to attend visits if they can minimize lost time from work. Elements of chronic disease care that emphasize how to help the person stay well in their home environment might be best accomplished in that environment, even virtually. How we can best provide that care and when it is a "better" substitute for in-person care will be an ongoing dynamic between physicians, patients, and probably payers in the future.

References

1. Health Resources Services Administration. Telehealth Programs. https://www.hrsa.gov/rural-health/telehealth. Accessed May 3, 2020.
2. University of New Mexico. Project ECHO. https://echo.unm.edu/. Accessed May 2, 2020.
3. Hollander JE, Carr BG. Virtually perfect? Telemedicine for Covid-19. N Engl J Med 2020;382:1679-1681. Duffy S, Lee TH. In-person health care as Option B. N Engl J Med 2018:378:2: 104-106.
4. Duffy S, Lee TH. In-person health care as Option B. N Engl J Med 2018:378:2: 104-106.
5. Lactman NM, Acosta JN, Levine SJ. Fifty state survey of telehealth commercial payer statutes. https://www.foley.com/-/media/files/insights/health-care-law-today/19mc21487-50state-survey-of-telehealth-commercial.pdf. Accessed May 3, 2020.
6. Wooliscroft JO. Innovation in response to the COVID-19 pandemic crisis. Academic Medicine 2020

MM



Missouri Rapid Rural Population Health Response to the COVID-19 Pandemic

by Kathleen Quinn, PhD, Jennifer L. Eldridge Houser, PhD & Julie M. Kapp, PhD

With the extensive reach and community-level resources MU Extension provides, our knowledgeable, caring faculty and staff were quickly able to gear up to meet these unprecedented demands, especially in rural Missouri.

The COVID-19 Pandemic

On March 11, 2020, the World Health Organization declared the novel coronavirus outbreak a pandemic. The coronavirus disease COVID-19, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is reportedly mild to moderate in approximately 80% of those diagnosed, severe in approximately 15%, and critical/fatal in approximately 5%.[1] It is mainly transmissible through respiratory droplets in the air and those that land on surfaces. COVID-19 is more transmissible than the seasonal flu, with the former having a reported[2] median basic reproduction number (the number of new cases transmitted by a single case) of 2.79 and the latter[3] of 1.28. Particularly concerning is the case-fatality rate (the proportion of deaths from COVID-19 among those diagnosed) reported to range from 2.3% in China to 7.2% in Italy.[4] As of May 18, 2020, there are a reported confirmed 4,748,356 cases of COVID-19 globally, with 1,491,547 cases in the U.S.[5]



Kathleen Quinn, PhD, (left), is the Associate Dean for Rural Health in the School of Medicine and with University Extension; Jennifer L. Eldridge Houser, PhD, is a County Engagement Specialist in Nutrition and Health Education in University Extension; and Julie M. Kapp, PhD, is with the School of Medicine and Population Health Sciences, Precision Health Initiative; all are at University of Missouri - Columbia, Columbia, Missouri.

Impact on Rural Missouri

On March 13, 2020, the Governor of Missouri declared a state of emergency. Missouri includes 115 counties or county equivalents (114 counties plus the City of St. Louis, referred to here as 115 "counties"). As of May 18, 2020, Missouri reported 10,789 cases and 594 deaths, impacting 88.7% of the 115 counties.[6] The population distribution of confirmed cases includes 3.4% ages <20; 12.9% ages 20-29; 13.5% ages 30-39; 15.2% ages 40-49; 17.7% ages 50-59; 15.6% ages 60-69; 9.9% ages 70-79; and 11.7% ages 80 and older.[6]

Missouri has the potential to mitigate the transmission and impact of COVID-19. Compounding the problem for the 99 of 115 counties (86%) that are rural is that 55 of those rural counties (56%) are without a hospital,[7] and only 71% of rural Missourians have access to broadband internet,[7] making even telehealth options challenging. COVID-19 places at highest risk for severe disease or death those over 60 years of age, those with underlying health conditions, such as hypertension, diabetes, cardiovascular disease, chronic respiratory disease, and cancer.[1] In 2019, Missouri ranked 40th out of the 50 states in cardiovascular deaths per 100,000; 33rd in the percent of the population uninsured, and 29th in the percent of the population with diabetes.[8]

Population Health Response

While the Missouri department of health is busy with surveillance, testing, and communication; and existing healthcare systems are busy providing

healthcare, there are 429 faculty and staff delivering programming through the University of Missouri (MU) Extension, which reaches into every county. These faculty deliver programming in four main areas: 1) agriculture and environment, 2) youth and family, 3) business and community, and 4) health and safety. They also engage with Missourians to extend MU knowledge and resources through collaboration with researchers and community leaders.



Because 99 of Missouri's 115 counties (86%) are rural, and 55 of those rural counties (56%) are without a hospital, MU Extension directed county-specific community coordination and advocation groups to track and share individual and community needs, including healthcare and food delivery to homebound individuals.

MU Extension's land grant mission is to improve lives, communities, and economies by producing relevant, reliable, and responsive educational strategies throughout Missouri. In late 2016 and early 2017, MU Extension gathered input from more than 1,000 Missourians on key challenges facing their communities through townhalls and qualitative-quantitative data collection. The emergent themes were named the "Three Grand Challenges:" 1) economic opportunity, 2) educational access and workforce preparedness, and 3) health and well-being. This re-imagining of the mission allowed MU Extension to focus efforts on being responsive to the most pressing needs of Missourians. Because of MU Extension's long history in each county and refinement of its responsive approach, MU Extension was uniquely positioned to provide innovative population health solutions to the COVID-19 pandemic as community educators, coordinators, and advocates. A sample of our efforts are described below.

1. Development and dissemination of COVID-19 educational materials, including handouts,[9] and a COVID-19 resources website.[10] The website was launched March 16, 2020. As of May 18, it has received 9,504 page views. The resources have resulted in 462 media placements for a total reach of 96,084,081.

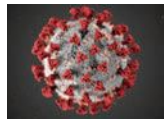
2. Development and dissemination of resources for MU Extension faculty on how to transition teaching and learning to online formats.[11] This page was launched March 13, 2020. As of May 18, it has received 6,054 page views.

3. Development and implementation of online programming for Missouri citizens, where broadband is available. Examples include:

(a) 4-H specialists statewide developed and implemented nine-week programming for Missouri youth via Zoom on science-based topics with hands-on lessons for kids to easily replicate at home, and an opportunity for kids to post videos to a forum showcasing their activities.

(b) Missouri Small Business Development Center created business resources for COVID-19, to include a step-by-step guide on how to respond to business disruption and how to manage their workforce.

4. In cooperation with other professionals in the University of Missouri System, development and dissemination of key resources for Missouri healthcare professionals to protect, diagnose and treat patients with COVID-19, as well as safeguard their communities.



5. County-specific community coordination and advocation.

(a) Two Extension county engagement specialists created Madison County Food Helpers Facebook group to track and share individual and community needs; schedule volunteers to collect and deliver food to homebound individuals and the local food pantry, and staff the food pantry according to CDC guidelines. Madison county reported a population of 12,088 in 2019.[12]

(b) Efforts by two County Engagement Specialists in nutrition and health education in Knox County (2019 population estimate: 3,959[12]). One author (EH) describes her involvement as follows:

"I went around last week checking in with essential businesses (pharmacy, grocery store, physician, farm equipment repair, feed store, banks) asking them about adjustments they have made and plan to make considering the impact that the coronavirus may have on their business. I asked them if employees were cross-trained so that more than one person could do every job, if a key employee were to become ill. I suggested a six-foot spacing if at all possible between employees and customers. I asked about employees who were high risk (older and/or with chronic health conditions) and plans to protect them specifically. I gave each business my card, personal cell phone number, recommendations from the CDC regarding policies, cleaning techniques, and other advice on how to continue business during this pandemic.

I suggested that the grocery store consider expanding their delivery business. They asked me to call their corporate headquarters as they were not planning on doing this, nor did they consider their highest risk employees and how to protect them. I called the corporate headquarters and emailed information to them from the CDC and offered to help the store in my county find volunteers to deliver groceries. Less than a week later the grocery store called and asked me to put together a team of volunteers for both shopping and delivery. I have done that and am currently trying to get the store to prioritize younger volunteers as they are at the least risk [for severe symptoms]. And I am trying to recruit younger volunteers to do this work, as the normal network of community volunteers is older.

I also went to the sole healthcare provider in the county to ask her what I could do to help her. She asked for a packet of information to give to patients that she asked to self-quarantine, that included all the delivery numbers in town, the rules of self-quarantine, and how to care for themselves. My office manager and student assistant assisted me in making 50 copy packets that were delivered to her within 48 hours."

To date, Madison county reports three cases and Knox county reports zero cases.

The University of Missouri Extension's innovative rural population health efforts to address COVID-19 prevention, mitigation, and containment have come to be known as "Show-Me Resilience."

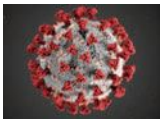
Conclusion

States must rely on their land grant universities as vital partners in the effort to contain the present and future epidemics or pandemics. With the extensive reach and community-level resources MU Extension provides, our knowledgeable, caring faculty and staff were quickly able to gear up to meet these unprecedented demands, especially in rural Missouri. The silver lining: these innovative practices will make us more effective as we move past this challenge and on to those that inevitably will arise in the future.

References

1. World Health Organization. Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19) 2020.
2. Liu Y, Gayle AA, Wilder-Smith A, Rocklov J. The reproductive number of COVID-19 is higher compared to SARS coronavirus. J Travel Med. 2020;27(2).
3. Biggerstaff M, Cauchemez S, Reed C, Gambhir M, Finelli L. Estimates of the reproduction number for seasonal, pandemic, and zoonotic influenza: a systematic review of the literature. BMC Infect Dis. 2014;14:480.
4. Onder G, Rezza G, Brusaferro S. Case-Fatality Rate and Characteristics of Patients Dying in Relation to COVID-19 in Italy. JAMA. 2020.
5. Johns Hopkins University & Medicine Coronavirus Resource Center. Coronavirus COVID-19 Global Cases by the Center for Systems Science and Engineering (CSSE). https://coronavirus.jhu.edu/map.html. Published 2020. Accessed May 18, 2020.
6. Missouri Department of Health & Senior Services. COVID-19 Outbreak. https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus/results.php. Published 2020. Accessed May 18, 2020.
7. Missouri Department of Health and Senior Services Offices of Rural Health and Primary Care. Health in Rural Missouri. Biennial Report 2018-2019.
8. United Health Foundation. America's Health Rankings Annual Report 2019. 2019.
9. University of Missouri Extension. What You Should Know About the Coronavirus. 2020.
10. University of Missouri Extension. COVID-19 resources. https://extension2.missouri.edu/covid-19-resources-public. Published 2020. Accessed March 26, 2020.
11. MU Extension Way. MU Extension COVID-19 Resources for Faculty and Staff. https://muextensionway.missouri.edu/covid-19-resources?dm_t=0,0,0,0,0. Published 2020. Accessed March 26, 2020.
12. United States Census Bureau. QuickFacts.

MM



PERSPECTIVE

COVID-19 Response in Mid-Missouri

by Christopher Sampson, MD, Amy Zguta, MD & Albert Hsu, MD

COVID-19 has manifested as twin public health and economic crises. In mid-Missouri, after shelter-in-place orders during the first wave, social and physical distancing appears to have worked well so far. The risks associated with reopening remain uncertain, but we have had the opportunity to learn best practices from other communities and health systems.

To date, approximately 10% of symptomatic (since early March) and also preoperative (since late April) patients statewide have tested positive for COVID-19. In Boone County, that number is reportedly closer to 2-3%.[1,2] The good news is that the first wave of COVID-19 was less severe in mid-Missouri than we had feared; the bad news is that we remain quite vulnerable to future waves of infection coming from either coast. Amid the tragedy, we have also been inspired by the innovations of our local community.

MU Emergency Department Response and Experience

Emergency Departments (ED) have seen plummeting patient volumes, both nationally and in mid-Missouri. When comparing to the pre-COVID admission rate, the University of Missouri (MU) EDs saw a 43% drop in overall ED volume in April 2020 compared to 2019 (Figure 1). The initial approach to the COVID-19 pandemic at the MU EDs was multi-faceted and encompassed three main areas: safety, clinical care, and education.

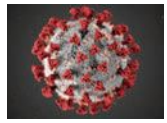
For emergency medicine (EM) physicians, the response is a natural outgrowth of our training. EM physicians are trained to be flexible and think "outside the box" in order to rapidly adapt to new situations. Learning from our Italian colleagues, we quickly divided our ED into two main areas: a "clean" and a "dirty" section. Patients were screened prior to physical entry into the ED for fevers and respiratory symptoms. Those who screened positive for these symptoms were separately admitted to the "dirty" side, in an effort to cohort possible COVID+ patients. Initially, the ED entrance was a tent; over time, this was upgraded to a shipping container-type building for our screening staff. This upgrade was necessary after accounting for staff needs of heating, air conditioning, and protection from the elements.

In another effort to keep potentially infectious patients away from the ED, we initiated telemedicine visits across the system for general health as well as for COVID screening. A remote drive-through COVID testing center was opened, and the timing was coordinated with similar efforts at Boone Hospital Center. Patients were given the option of a virtual screening visit, or to come to the drive-through site, and to be questioned using a nursing protocol. At our peak, over 200 patients were utilizing drive-through testing daily.

If one word were to describe our ED response to this pandemic, it would be "innovation." We converted our decontamination room to use as a COVID code room. Having an entrance to the outside prevented the critical concern of having a possibly infectious patient from passing through a clean ED. We outfitted that room to the same standard as one of our resuscitation rooms. Another benefit to the use of this room was that it was equipped for negative pressure. One of our faculty, Adam Beckett, MD, and his Global First Responder colleagues, also designed a portable airway protection device to help keep his ED and EMS colleagues safe when performing high risk procedures like intubation. We have also been inspired by community efforts to #HackThePandemic, from a local high school student who 3D-printed face shields for distribution,[3] to the collaborations between



Christopher Sampson, MD, is an Emergency Physician at the University of Missouri-Columbia; Amy Zguta, MD, MSMA member since 2012, is a private practice Ophthalmologist; Albert Hsu, MD, MSMA member since 2017, (left), is an Ob/Gyn and Reproductive Endocrinologist at the University of Missouri - Columbia.



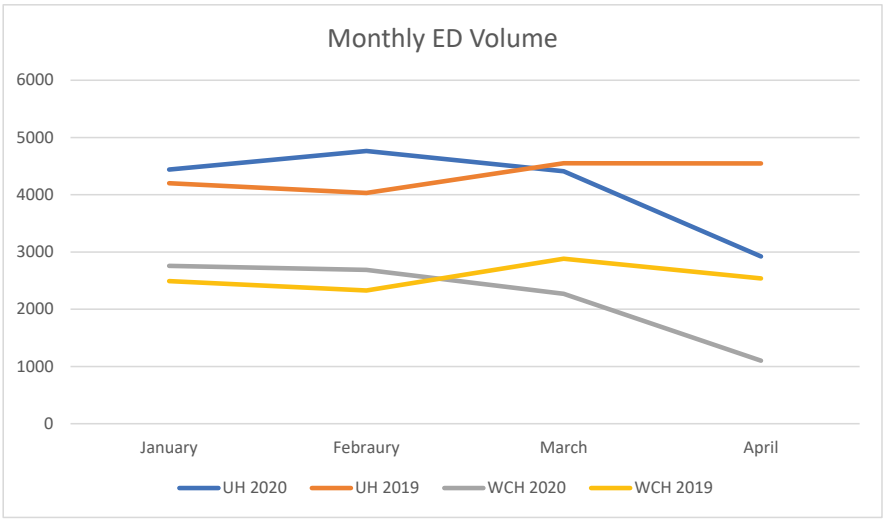


Figure 1. Monthly ED volume at University Hospital and Women & Children's Hospital.

the Columbia STEM alliance and the MU College of Engineering, and across the University of Missouri campus, where a MU Textile and Apparel Management student innovated a way to use a laser cutter to cut 10,000 pieces of cloth daily, to address the shortage of masks.[4]

Personal protective equipment (PPE) has been a national concern as well as at our facility. Thankfully, we have never reached the point of inadequate PPE, but cleaning and reusing N-95 masks is definitely the new normal. Our institution also implemented UVC for decontamination.[5] Who would have ever thought that a recommendation to use bandanas as face coverings would be featured on the CDC website? We also learned the side effects of long-term mask usage, previously used for only limited patient encounters, that we now wear for 8-12 hour shifts. Painful noses and facial abrasions were some of the new problems that our frontline healthcare workers have encountered.

The patient and family experience has also changed greatly. In conjunction with increased COVID-19 case numbers, stricter visitor rules were implemented. For most patients, this meant being in the ED without loved ones or advocates. Creative solutions such as video conferencing were used to help connect patients with their families. Perhaps the hardest times were with critically ill or dying patients. To not be able to spend your final moments with your family takes an emotional toll not just on families, but also on staff who sometimes feel that they have had to take on the role of supportive family members amid this pandemic. We certainly worry about burnout and compassion fatigue among all our caregivers.

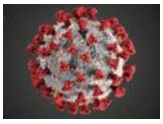
Despite everything, morale has remained high in the ED over the past few months. Community support has been amazing, from uplifting messages to the meals provided for frontline workers. Hopefully, what we have learned in this first wave will enable us to work more safely and efficiently in future spikes.

Boone County Medical Society (BCMS) COVID-19 Outreach

Although there is undeniable tragedy that comes with a pandemic, there are also opportunities. This pandemic has highlighted the cracks in the structure of our health care delivery systems, economy, and social welfare systems. Now more than ever, there is a role for organized medicine to provide a voice for our physicians on the frontlines, as well as to connect our physician community and provide timely and helpful information.

Given that data on COVID-19 has been limited, preliminary, and rapidly evolving, our Boone County Medical Society (BCMS) began hosting weekly webinars on COVID-19 on March 24, 2020. These webinars have been an important source of information for all our community physicians, and we opened up attendance to members and nonmembers alike, as well as to residents, fellows, and medical students throughout Missouri. It has also provided a forum to ask questions of our local experts.[1,2,5]

We have had speakers from our state and local health departments as well as leaders and physicians from all three major local hospital systems. It has been reassuring and heartening to know that leaders from all three local hospital systems are meeting weekly to strategize and to craft consistent and organized messaging and local responses. Especially in light of recent reports of conflict between state and local health departments in other states, it is comforting to see and hear our state and local health departments working closely together. Early, consistent and cohesive communication is critically important during this global crisis.



Almost every week, we have had a speaker representing the public health perspective, represented by Ashley Millham, MD, Medical Director of Boone County Public Health & Human Services and Randall Williams, MD, Director of the Missouri Department of Health & Senior Services. We have had an infectious disease physician speaker on most weeks, in which Christian Rojas-Moreno, MD, and Taylor Nelson, MD, have shared the latest research and their invaluable clinical experience at the University of Missouri. Christopher Sampson, MD, and Jonathan Heidt, MD, have contributed their experiences from the ED at MU. Outside of our MU system, we have also had speakers from the other two major health systems in our community: Robin Blount, MD, Chief Medical Officer (CMO) of Boone Hospital, and Lana Zerrer, MD, CMO of Truman VA Hospital.

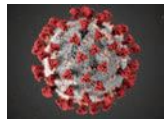
We are heartened to learn that we continue to have significant PCR testing capabilities here in mid-Missouri;[1,2] testing in Boone County has been bolstered (both in volume and rapid turn-around times) in part because GeneTrait has a local lab facility in Columbia, MO. Our public health officials have a systematic and thoughtful strategy for identifying and containing outbreaks at long-term care facilities. We have learned of the challenges facing our private hospitals and academic and private physician practice practices. We are impressed with the preparedness and innovation at the VA, where they did not suffer as many concerns over PPE shortages due to a federal mandate for pandemic preparedness; they are also making regular contact with each of the 40,000 veterans in their catchment area, which is an important and large undertaking.

The cancellations of schools, churches, and sports; the physical distancing; and the economic stressors associated with COVID-19 have also raised concern about physician wellness and worsened physician burnout during this pandemic, so we invited Steven Keithahn, MD Chief Wellness Officer at MU HealthCare and Craig Rooney, PhD, Program Director of the Office of Clinician Well-Being at MU School of Medicine to discuss physician autonomy, increased moral injury, and the defining point between burnout and depression. Dr. Keithahn also emphasized the importance of organized medicine in harnessing and amplifying our collective physician voices. To represent organized medicine, Jeff Howell, JD and Heidi Geisbuhler from the Missouri State Medical Association (MSMA) have also been regular speakers at our webinars, taking time out of their busy days to give us the latest updates[2,6] on state legislative action in Jefferson City. We were dismayed that the PDMP still did not pass this spring, but we are encouraged by many of the public health and medicine-friendly measures that did.[6]

These webinars have also been very helpful for disseminating best practices and for a clinical discussion of the early evidence. For example, clinical experience with convalescent plasma; toclizumab; and hydroxycholoroquine +/- azithromycin; and remdesivir were reviewed in our webinars.[1,2] We also had a wonderful discussion about how antibody testing is helpful for prevalence testing (from the public-health perspective) but currently useless (despite being overly-marketed) to demonstrate durable immunity.[7,8] This has empowered our physicians to better educate their patients and colleagues, and also provided an opportunity to discuss public health measures, like mask-wearing. While masks may have a role in source control, we are cognizant that not everyone can or even should wear a mask in public.[1,9] Some reasons to not wear a mask include:

- Concerns that mask-wearing may breed complacency in the wearer (such that wearers may want to attend a parade, rock concert, or Mardi Gras celebration), as masks are complementary to physical distancing and staying 6 feet apart;
- Possible risks to the wearer if the cloth mask gets wet or soiled;
- Possible risks to the wearer if the inside of the cloth mask gets dirty or contaminated;
- If the wearer gets severely claustrophobic or anxious, has significant breathing difficulties, or otherwise cannot wear a mask safely (which, in turn, should be further evaluated as a concerning medical condition).[1,]

Finally, Boone County Medical Society leadership (together with Debra Howenstine, MD) has served as a source of mentors and advisors for an inspiring medical student and MPH student volunteer response to COVID-19. This spring, the rising fourth-year medical students have an unbelievable set of stressors. These stressors include removal from inpatient experiences in their recent clinical clerkships (in accordance with national AAMC guidance), a national cancellation of all upcoming "away" rotations, a national conversion of their upcoming fall interview season to an all-virtual format, and a lack of transparency and information about abrupt cancellations of high-stakes NBME



exams. Indeed, in some cases, students have shown up at testing sites to take Step 1 or Step 2, only to find their Prometric testing center closed![10]

Despite these colossal sources of stress and anxiety, a student leadership team at MU (including MS1 Ben VanAmberg, MS3 Eric Grisham, MS3 Natalie Miller, MS3 Zeke Kapusciak, MS3 Lucy Sheahan, MS3 Elizabeth Modde, MS3 Shelly D'Alessandro, MS3 Ramya Ramadas, and new graduates Abbi Berry, MD and Colbey Ricklefs, MD) has been organizing grocery delivery to individuals quarantined for COVID-19, sharing positive stories via social media, and raising funds for several local organizations (including our food bank, homeless shelters, and soup kitchens). Students have also been involved in outreach and advocacy. Under the leadership of Abbi Berry and MS2 Cynthia Tang, students have created a "COVID infographic" based on CDC guidance, translated it into 14 languages, and distributed it among community partners. Led by MS3 Nikki Kagan, MS3 Taylor Ross and new graduate Calli Morris, MD, a student group also successfully lobbied our Governor for the "Stay Home" order in March, and lobbied against proposed measures to strip local Public Health Agencies of enforcement authority. With MS2 Patricia DeCastro and MS3 Clarence Chu, another student team is writing letters to senior citizens at nursing homes, to help brighten their days amid the social isolation of this pandemic.

Under the leadership of new graduate Toby Bradford, MD yet another student team wrote, directed, and produced five episodes of "Love is Viral," a spoof of the "Love is Blind" Netflix show, about dating during COVID-19.[11] These videos were designed to target 16-25 year-olds with messaging about the importance of social distancing and stay-home orders. [11] Medical students have also written articles about how a small craft distillery shifted production from spirits and cocktails to hand sanitizer,[12] and about how one local homeless shelter and community resource had readjusted to "stay home" orders when community members have unstable housing.[13]

Summary

COVID-19 has been a tremendous ongoing global tragedy. Amid ever-evolving public health guidelines, COVID-19 places physicians and other health care providers in a climate of anxiety, uncertainty, feelings of helplessness, and worries about the future. For those who see things as "black-and-white" and may have previously been overly dependent on guidelines and algorithms, this may be a particularly difficult time. The need for social and physical distancing, and the rapid and massive expansion of telemedicine, is revolutionizing healthcare. In learning to live with uncertainty, we should learn that with every plan, we must be flexible, prepared to absorb new information, and ready to change direction with very little notice. Moving forward, our community is closer together than it was, pre-COVID. After all, we're all in this together, and nobody is on the "side" of coronavirus. This is also a fine time to get involved in your local and state medical societies, to stay informed, to voice your concerns, and to advocate for our patients and profession. Together, we are stronger.

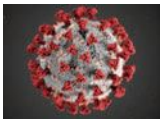
Acknowledgment

We appreciate the invaluable efforts of Sarah Luebbert, Gordon Casey, and Alan Hillard, MD, in making our BCMS webinars possible.

References

1. Boone County Medical Society (BCMS) COVID resources and BCMS webinars at <https://www.boonecountymedicalsociety.org/covid-19-resources.html>
2. Missouri State Medical Association conference calls with Dr. Randall Williams <https://www.msma.org/covid19-conf-calls.html>
3. "High School Student 3D Prints face shields amidst PPE shortage." April 2, 2020 at <https://krcgtv.com/news/local/high-school-student-3d-prints-face-sheilds-amidst-ppe-shortage> versus https://engineering.missouri.edu/2020/05/mu-partners-with-community-to-produce-face-shields/
4. "Cutting Cloth to Curb COVID: How one MU student lends her textile talents to fighting the COVID pandemic." April 21, 2020. at <https://medium.com/@courageincovid/cutting-cloth-to-curb-covid-85597e330ced>
5. "N95 decon" at <https://www.n95decon.org/uvc>
6. Missouri State Medical Association legislative "big wins" at <https://www.msma.org/big-wins.html>
7. NYS DOH (4/22/20) "Dear Colleague" letter to physicians, about antibody tests being marketed inappropriately, as antibody testing does *not* indicate durable immunity, at <https://www1.nyc.gov/assets/doh/downloads/pdf/han/alert/2020/covid-19-status-of-serologic-testing.pdf>
8. Yale statement (4/22/20) on serology testing at <https://bit.ly/YaleSerology>
9. 2019-nCoV – What We Know So Far About … Wearing Masks in Public at <https://www.publichealthontario.ca/-/media/documents/ncov/covid-wwksf/what-we-know-public-masks-apr-7-2020.pdf?la=en>
10. Step 1 scramble: Test-center closures leave medical students in limbo. May 8, 2020. at <https://www.ama-assn.org/residents-students/usmle/step-1-scramble-test-center-closures-leave-medical-students-limbo>
11 "'Love is Viral': MU medical students bring social distancing to Instagram" at <https://www.columbiamissourian.com/news/covid19/love-is-viral-mu-medical-students-bring-social-distancing-to-instagram/article_54766882-791c-11ea-af46-5b6094a8e73f.html>
12. "From Crafting Spirits to Crafting Hand Sanitizer." April 30,2020. at <https://medium.com/@courageincovid/from-crafting-spirits-to-crafting-hand-sanitizer-cc92abf6140b>
13. "'Staying Home' While Homeless." April 29, 2020. at <https://medium.com/@courageincovid/staying-home-while-homeless-55c76aa648b9>

MM



SCIENTIFIC

Laboratory Tests for COVID-19: A Review of Peer-Reviewed Publications and Implications for Clinical Use

by Daniel Shyu, James Dorroh, Caleb Holtmeyer, Detlef Ritter, MD, Anandhi Upendran, PhD, Raghuraman Kannan, PhD, Dima Dandachi, MD, Christian Rojas-Moreno, MD, Stevan P. Whitt, MD & Hariharan Regunath, MD



Daniel Shyu, James Dorroh, and Caleb Holtmeyer, are in the Department of Medicine. Detlef Ritter, MD, is in the Department of Pathology and Anatomical Sciences. Anandhi Upendran, PhD, is in the Department of Medical Pharmacology and Physiology and at the University of Missouri Institute of Clinical And Translational Science (MU-iCATS). Raghuraman Kannan, PhD, is in both the Departments of Radiology and Bioengineering. Dima Dandachi, MD, and Christian Rojas-Moreno, MD, are in the Department of Medicine – Division of Infectious Diseases. Stevan P. Whitt, MD, and Hariharan Regunath, MD, MSMA member since 2019 and *Missouri Medicine* Editorial Board Member for Infectious Disease, (above), are in the Divisions of Infectious Diseases, Pulmonary, Critical Care and Environmental Medicine. All are at the University of Missouri - Columbia, Columbia, Missouri.

Reverse-transcriptase polymerase chain reaction is now widely available in most health care settings, but it cannot differentiate between infectious and non-infectious viral shedding during recovery.

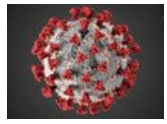
Abstract

Diagnostic tests for the coronavirus infection 2019 (COVID-19) are critical for prompt diagnosis, treatment and isolation to break the cycle of transmission. A positive real-time reverse-transcriptase polymerase chain reaction (RT-PCR), in conjunction with clinical and epidemiologic data, is the current standard for diagnosis, but several challenges still exist. Serological assays help to understand epidemiology better and to evaluate vaccine responses but they are unreliable for diagnosis in the acute phase of illness or assuming protective immunity. Serology is gaining attention, mainly because of convalescent plasma gaining importance as treatment for clinically worsening COVID-19 patients. We provide a narrative review of peer-reviewed research studies on RT-PCR, serology and antigen immune-assays for COVID-19, briefly describe their lab methods and discuss their limitations for clinical practice.

Introduction

There has been a lack of guidance for practicing physicians in interpreting published evidence and limitations of emerging lab tests for coronavirus disease 2019 (COVID-19). Current diagnosis requires a combination of symptoms/signs of respiratory infection and a positive reverse-transcriptase polymerase chain reaction (RT-PCR) for severe acute respiratory syndrome coronavirus-2(SARS-CoV-2).[1-4] The Chinese Centers for Disease Control and Prevention (China CDC) first submitted the SARS-CoV-2 genome to Global Initiative on Sharing All Influenza Data. The CDC in United States (U.S.) then obtained emergency use authorization (EUA) from the Food and Drug Administration(FDA) for the first RT-PCR.[5,6] Tests were limited to the CDC, but later extended to other agencies and Clinical Laboratory Improvement Amendments (CLIA) certified labs for rapid diagnosis to interrupt the transmission cycle via quick isolation.[7,8] With increasing EUAs, careful considerations are necessary to interpret test results.[9]

RT-PCR detects viral ribonucleic acid (RNA) using flourogenic primers/probes and thermal cycling steps (Figure 1).



It is sensitive, safe and cost-effective than viral culture methods, but not without limitations.[8,10,11] Serology has also gained attention based on certain advantages i.e. estimation of sero-prevalence, asymptomatic infections, contact tracing and vaccine effectiveness. In SARS, serology was reliable for diagnosis based on a negative test during the acute illness followed by a positive serology in convalescent samples, or a four-fold rise from acute to convalescent titers, tested in parallel.[12-17] Lateral flow immunoassay (LFIA), chemi-luminescence immunoassay or the traditional enzyme linked immunosorbent assay (ELISA) are common methods, that rely on IgG/IgM's affinity to recombinant spike (S) and nucleocapsid (N) proteins for SARS-CoV-2, and are point of care (POC) tests with a quick turnaround time (Figure 2), but certain disadvantages also exist.[16]

To assist the practicing physician in understanding COVID-19 lab tests in relevance to their schema, limitations, and statistical considerations for clinical practice, we performed a narrative review of research assays in COVID-19. Because other reviews have discussed the commercial assays with EUAs (available at link: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations,) we did not include them in our review.[18] The Infectious Diseases Society of America (IDSA) has also issued a guidance document on RT-PCR recently.[19]

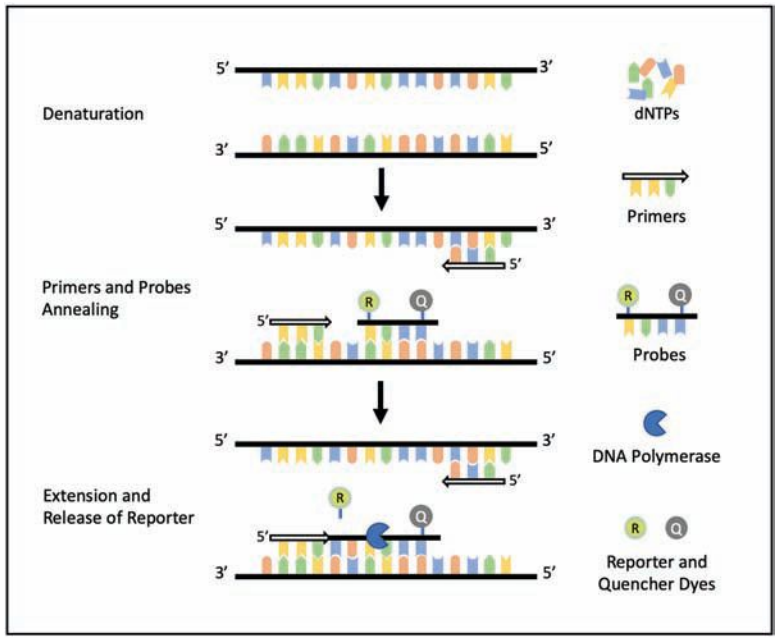


Figure 1. Steps of a single thermal cycle of RT-PCR
To detect the presence of RNA, samples are combined with the primer/probe sets, reverse-transcriptase (RT), DNA polymerase, buffer, and deoxy-nucleoside triphosphates (dNTPs). This mixture then undergoes an initial annealing phase where the first strand of complimentary DNA (cDNA) is formed at the target sequence. Thermal cycling starts with denaturation to separate the strands, followed by annealing of specific primers and probes to each strand. Probes containing reporter (R) and quencher (Q) dyes are designed to anneal to parts of the target genetic sequence between the primers. In the next step, polymerase extends the primer (extension phase) towards the probe and releases R generating a visible fluorescence. This thermal cycle repeats to amplify the genetic material with every cycle. A cycle threshold defined as the number of cycles to attain a certain fluorescence, is often used as a determination of positivity. It is important that both the primers and probes should be designed to be both specific and sensitive by identifying highly conserved regions unique to the COVID-19.
Abbreviations: RT-PCR – reverse transcriptase polymerase chain reaction, dsDNA – double stranded deoxyribonucleic acid, PCR – polymerase chain reaction

Methods

In order to avoid pre-prints (non-peer reviewed), we searched PubMed only using the following search terms with no restriction on start time, till April 15, 2020. Search terms were "PCR" and either "COVID-19" or "SARS CoV-2," and combinations of "serology" and "COVID-19," "IgM"and"COVID-19," and "IgG"and"COVID-19." Individual studies were manually screened and included only human original research studies that reported test characteristics, methodology, performance, sample type and statistical outcomes. We individually reviewed every study separately for RT-PCR and serology and the information was tabulated.

Results

Fourteen studies reported RT-PCR research assays and seven studies reported serological assays for COVID-19. There were currently no original research studies on antigen immunoassays for COVID-19.

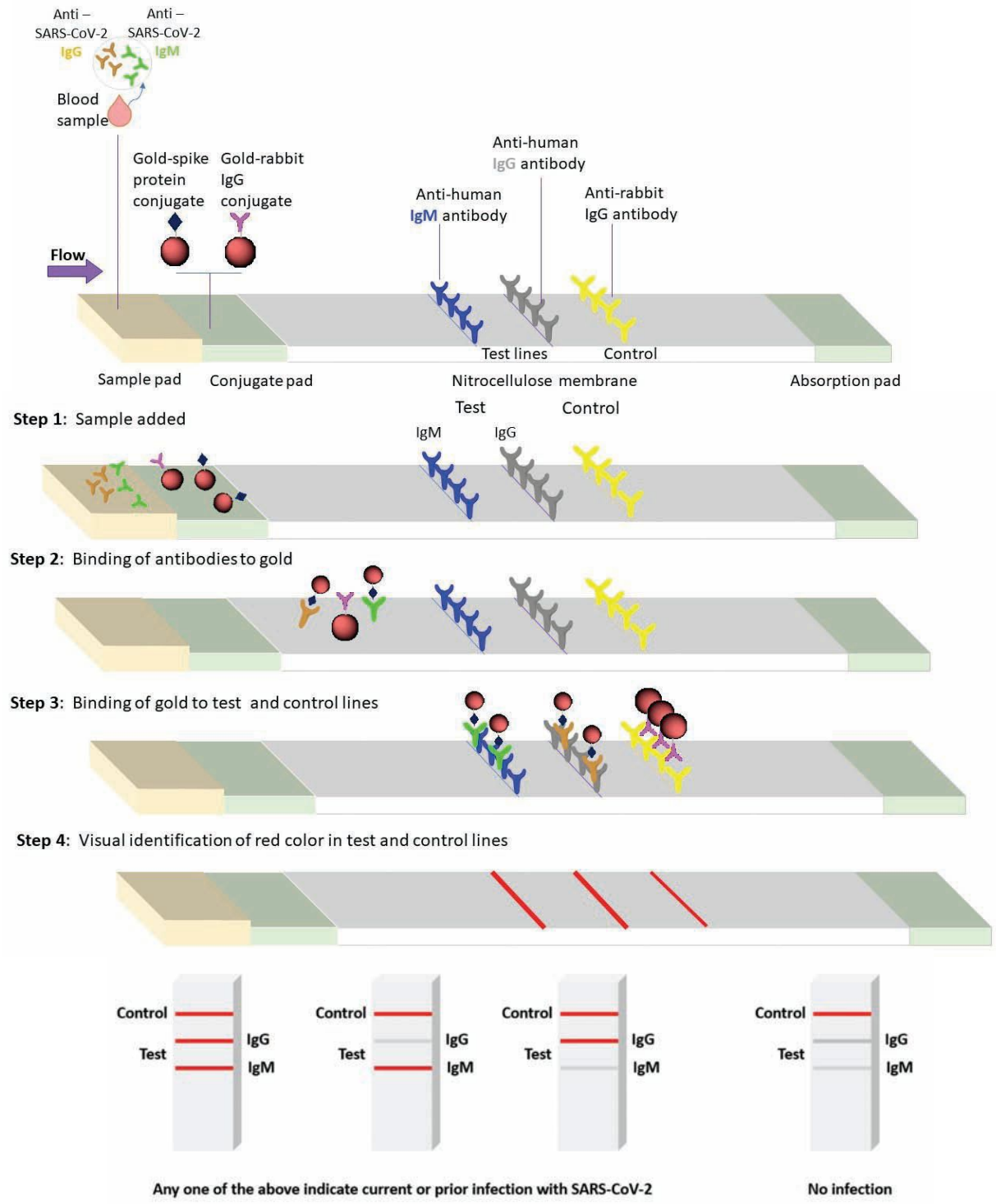
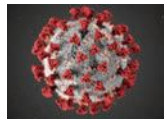


Figure 2: A schematic illustration of lateral flow immune-assay (LFIA) principle for antibody (IgG and IgM) testing for COVID-19. The LFIA uses a nitrocellulose membrane embedded with anti-human IgG, anti-human IgM and anti-rabbit IgG in designated spots for test and control, respectively. The sample for LFIA will use a finger-stick, single-use patient blood, which is drop-casted in the sample pad containing recombinant peptides of SARS CoV-2 conjugated with gold nanoparticle (AuNP; "red color indicator") and rabbit IgG gold conjugates as a control. If patient's blood has anti – SARS CoV-2 IgM or IgG antibodies, it will bind to the viral peptide-gold conjugate in sample pad, and capillary action drives the antigen-antibody complex and the control to the test and control spots respectively. A red color formation in the test spot is an indication of the presence of anti-SARS CoV-2 antibody (IgG or IgM - positive).



RT-PCR

Table 1 summarizes the peer-reviewed publications on RT-CPR, listed per publication date, and enumerates necessary test details that impact interpretation.

Most Sensitive and Specific Primers and Probes

The first robust RT-PCR for COVID-19 was developed in January 2020 in Germany by Corman et al.[20] Their primers and probes targeted the highly specific RNA-dependent RNA polymerase (RdRp) and envelope (E) genes of SARS CoV-2 and did not cross-react with other respiratory viruses or bacteria. The E-gene was first performed, followed by the RdRp-gene assay that differentiated SARS CoV-2 from SARS CoV. Follow-up studies further optimized the process to minimize hands-on time.[21,22] Chu et al. developed a sequential quantitative real-time RT-PCR that identified two different regions – open reading frame 1b (ORF1b) and nucleocapsid (N) of the SARS CoV-2 genomes, but as these are highly conserved sequences among Sarbecovirus, specificity was compromised by cross-reactivity[23]. SARS CoV-2's open reading frame 1ab (ORF1ab) and N genes were also targeted by Wang et al.[24] Another approach taken by Chan et al. utilized primers and probes designed for RdRp/helicase (Hel), S and N genes.[25,26] These novel real-time RT-PCR assays, which contained 7-9 nucleotide differences from human SARS-CoV, were found to be more sensitive than the RdRp-gene assay, while also not cross-reacting with other human-pathogenic coronaviruses and respiratory pathogens. More recently, Nalla et al. compared the primers and probes developed by Corman et al. with the N1, N2, and N3 sets developed by the CDC.[27,28] While all sets continued to be highly specific, the CDC N2 and Corman et al.'s E-gene sets were the most sensitive. In addition to the academic development of primer/probe sets for diagnosis of COVID-19, several EUA-granted commercial products have been developed.[29] As of March 15, 2020, the CDC's protocol for EUA assays contain N1 and N2 only excluding the N3 detection.

Performance of Different Specimen Types

As more primers and probe sets became available, a variety of specimens were tested. Among all specimens, lower respiratory tract specimens continue to have the highest sensitivity, followed by upper respiratory tract (naso- or oro-pharynx).[30] One study found that sets designed by Chan et al. were able to detect SARS CoV-2 in the saliva of 11/12 patients.[31] Other researchers have also tested sputum, blood, and feces using the ORF1ab and N gene primers/probes.[32] Despite several case reports of SARS CoV-2 detection in feces and blood, these specimens have lowest number of viral particles.

Chest Imaging and RT PCR

CT of chest has been reported to have a similar sensitivity to PCR and reported as a screening tool when RT-PCR is falsely negative.[33-35] A few early studies, where a high number of negative RT-PCR tests on those who satisfied clinical criteria for COVID-19 pneumonia and abnormal CT chest, projected the idea that radiological findings may be used as a surrogate. In one retrospective study, only 40%(241/610) with abnormal CT findings tested positive by RT-PCR, but 18 had a positive RT-PCR after two consecutive negative results.[36] Xiao et al. also found 15/70 patients testing positive after two previous consecutive negative results.[37] Ai et al. showed that from 1014 patients undergoing both chest CT and RT-PCR with throat swab sample, 21 who had positive RT-PCR results had a normal initial chest CT, but 308 with negative RT-PCR had chest CT images suggestive of COVID-19.[33]

Serology

Table 2 summarizes peer-reviewed research publications on serology research assays for diagnosis of COVID-19. One of the first large studies used lateral flow immunoassay (LFIA) to qualitatively detect IgM and IgG antibodies to the S protein of SARS-CoV-2 with a high sensitivity and specificity at various points of patient stays.[38] All of the finger-stick blood and venous blood serum and plasma, were sensitive to detect IgG and IgM. Reported turnaround time of 15 minutes combined with simple design enables POC testing. Currently, several commercial agencies are developing accurate and sensitive LFIAs for point of care diagnostics of SARS-

Table 1. Studies on RT-PCR Research Assays

Date, author, sample size	Time of collection from onset/hospitalization	Genes, Samples, Statistical Parameters /performance	Limitations
01/23/20, Corman et al, 310 samples[20]	N/A	Genes: E and RdRp, Specificity 100%.	Primers for RNA identical to 2019-nCoV target sequence & lack of testing with SARS-CoV-2.
02/12/20 To et al, 12 patients[31]	Median 2 days from hospitalization (range 0-7 days).	Sensitivity: 11/12 (91.7%). Specificity: 33/33 (100%)	Easier sampling. Limitations include limited sample size.
02/19/20, Fang et al, 51 patients[34]	3 ± 3 days for both chest CT and RT-PCR.	Sensitivities: Chest CT (50/51, 98%) Initial RT-PCR (36/51, 71%).	Study limited by lack of information on laboratory procedure and positive controls
02/26/20, Ai et al, 1014 patients[33]	Median interval between chest CT and initial RT-PCR was 1 day (range 0-7 days).	21/601 RT-PCR positive & not chest CT. 308/413 had positive chest CT & negative RT-PCR. 59% positive rate of RT-PCR. Chest CT sensitivity = 97%, specificity = 25%, accuracy = 68%, PPV = 65%, NPV = 83%.	
03/04/20, Chan et al, 273 specimens[25]	0-18 days - respiratory specimens, 4-15 days for other specimens.	Sensitivity: 85% with samples from respiratory tract, 11.1% from non-respiratory tract.	Primers had 7-9 nucleotide differences with SARS-CoV
03/05/20, Konrad et al, 669 respiratory samples[21]	Not reported.	SARS-CoV E gene assay was more sensitive than the two RdRp gene assays; however, the E gene assay showed unspecified signals at late cycles.	Lack of information on procedure and positive controls.
03/05/20, Pfefferle et al, 88 samples[22]	N/A	Specificity: 88/88 (100%) Sensitivity: LOD of 275.72 copies/process at 95% detection probability	Unable to validate the performance of the assay using clinical SARS-CoV-2 positive samples
03/07/20, Liu et al, 4880 patients[30]	Not reported.	Sensitivities and specificities not reported..	Validity of test results was not assessed.
03/11/20, Wang et al, 1070 specimens[32]	Pharyngeal swabs on 1-3 days after hospitalization. Variable time for other specimens.	Sensitivities: BAL (14/15; 93%), sputum (75/104; 72%), nasal (5/8; 63%), bronchoscope brush biopsy (6/13; 46%), pharyngeal (126/398; 32%), feces (44/153; 29%), blood (3/307; 1%), urine (0/72, 0%).	Insufficient data to analyze correlation between symptoms or disease course and test results. Small sample size for some specimen types.
03/25/20, Long et al, 204 patients[35]	Study group = 2.6 ± 1.7 days, control group = 3.2 ± 1.6 days.	Sensitivities: Chest CT (35/36, 97.2%), initial RT-PCR (30/36, 83.3%).	RT-PCR only performed in patients with fever due to limited test kit supplies. Small sample size.
03/26/20, Li et al. 610 patients[36]	Initial RT-PCR done prior to admission. Repeated 1-2 days if negative or weakly positive.	Not reported	Study limited by lack of detailed patient information or RT-PCR protocol.
03/30/20, CDC, 2071 respiratory specimens[28]	Not reported.	Specificity: 60/60 for both assays. 49/2071 respiratory specimens tested positive.	Study limited by positive controls.
04/08/20, Nalla et al. 300 specimens[27]	Not reported.	100% specific. Sensitivity: CDC N2 and Corman E-gene: 10/10 and able to reliably detect samples with only 6 genomic equivalents of viral RNA.	Limited sample size
04/09/20, Xiao et al. 70 patients[37]	Symptoms to nucleic acid conversion, median (IQR): Consecutive false-negative patients = 36 (28-40), all other patients = 21 (18-26).	15/70 (21.4%) positive on RT-PCR after two consecutive negative results.	Study does not mention details about the commercial detection kit.

Abbreviations: RT- PCR – reverse transcriptase polymerase chain reaction, RNA – ribonucleic acid, CDC – Centers for Diseases Control and Prevention, LOD – Limit of detection, CT-computed tomography, COVID – coronavirus disease, N-nucleocapsid, RdRp – RNA dependent RNA polymerase, E- envelope, BAL – broncho-alveolar lavage, SARS-CoV-2 - severe acute respiratory syndrome coronavirus-2, N/A – Not available.

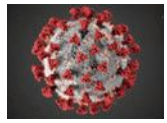


Table 2. Studies on SARS CoV-2 Serology Research Assays

Date/author/ study type	Method, sample type/ number	Time from onset to test	Statistical parameters	Limitations
02/17/20 Zhang et al. Case series[45]	ELISA kits developed using SARSr-CoV Rp3 NP as the antigen.	Day 10 of treatment	1st day of sampling: IgM and IgG titers were relatively low or undetectable 5th day of sampling: increase in both IgM and IgG seen in nearly all patients	No data after day 5. No data listed for specificity of ELISA kits.
02/27/20 Li et al. Diagnostic Accuracy Cross-sectional study[38]	LFIA - IgM and IgG antibodies to recombinant antigen that is the receptor binding domain of SARS-CoV-2 Spike Protein.	Day 8 to day 33 after onset	Sensitivity: IgG + IgM: 88.66%; IgG: 70.53%; IgM: 82.62% Specificity: IgG + IgM: 116/128 (90.63%); IgG: 126/128 (91.41%); IgM: 117/128 (91.41%)	This test cannot confirm virus presence or provide quantitative information. Day of sample collection was inconsistent from patient to patient
03/19/20 Haveri et al. Case series[43]	Serum on days 4, 9, 10, and 20 from onset of symptoms. IgM and IgG antibodies against SARS-CoV-2 were analyzed using IFA	Day 3 to day 23 after onset	Day 4: antibodies were undetectable. Day 9: IgG titer: 80; IgM titer: 80. Day 20: IgG: 1,280; IgM titer: 320	This study was able to track IgM and IgG temporally up to day 23 d.p.o. Sample collection was inconsistent from patient to patient. No specificity data noted.
03/21/20 Guo et al. Diagnostic Accuracy Comparative Study[42]	208 samples from 140 cases cases. Indirect ELISA for IgM, IgA, and IgG. 135 samples from adults with respiratory tract infections & 150 healthy adults were controls	1-7 days post-symptom onset (41 samples), 8-14 days (84 samples), 14+ days (83 samples)	**IgM**: Sensitivity: 90.4%; Specificity: 100% **IgG**: Sensitivity: 77.9%; Specificity: 100% **IgA**: Sensitivity: 93.3%; Specificity: 100%	Cross-sectional sample of specimens was used to determine the kinetics of antibodies; however, each patient has different kinetics for the development of antibodies.
03/28/20 Zhao et al. Diagnostic Accuracy Comparative Study[40]	173 patients, serial samples to a total of 535 samples. ELISA IgM, and IgG. for receptor binding domain of the Spike protein,	1-39 days after onset. Groups : 1-7 days (94 patients), 8-14 (135 patients), 15-39 (90 patients)	**Ab**: Sensitivity:93.1% Specificity: 99.1% **IgM**: Sensitivity: 82.7%; Specificity: 98.6% **IgG**: Sensitivity: 64.7%; Specificity: 99%	Sensitivities varied depending on which day after onset samples were collected. Patients were selected based on positive RT-PCR, potentially missing atypical patients with lower respiratory viral load
03/30/20 Cassaniti et al. Diagnostic Accuracy Cross-sectional study[41]	110 subjects, VivaDiag COVID-19 IgM/IgG Rapid LFIA.	Positive control collected at median 7 days (IQR 4-11).	**COVID-19:** Sensitivity of combined IgM and IgG: 63.3% were positive; 16.7% were weakly positive; 16.7% were negative, 1/30 was positive for IgM, negative for IgG **50 patients evaluated in ED** Sensitivity: 18.4%; Specificity: 91.7%.	Advantage of study is that patients enrolled from the ED provided a relatively consistent time frame of symptom onset. Limitation of the study is that there is no temporal data to follow.
03/30/20 Liu et al. Diagnostic Accuracy Case-Control study[44]	214 patients, 100 healthy controls. The recombinant nucleocapsid (rN) protein-based ELISA IgM or IgG.	Samples divided into 1-5 (22), 6-10 (38), 11-15 (54), 16-20 (55), 21-30 (32), 31-35 (6), and >35 (7) days post disease onset	**rN-based ELISA** Sensitivity: 80.4%; Specificity: 100% **rS-based ELISA** Sensitivity:82.2%; Specificity: 100%	Temporal data available, showing that IgM and/or IgG of SARS-CoV-2 might be positive at 11-15 d.p.o. Decreased positive rate of IgM was observed at > 35 d.p.o. A limitation is that samples were not collected from these patients after discharge.

Abbreviations: ELISA – enzyme-linked immunosorbent assay, IFA – immunofluorescence assay, d.p.o – days post-disease onset, LFIA – lateral flow immunoassay, IgM-Immunoglobulin M, IgG-immunoglobulin G, IgA- immunoglobulin A, RT-PCR – reverse Transcriptase polymerase chain reaction, SARS-CoV-2 - severe acute respiratory syndrome coronavirus-2.

COV-2. Sona-Nanotech in collaboration with GE Healthcare Life sciences, utilizes S1 domain of the virus for detection and uses gold nanoparticles as the label. Another company, Pharmact, developed a 20-minute assay for detecting N, S1, and S2 domains of the protein.[39] This test also detects IgM and IgG antibodies present in the patient's blood. The company has validated the test kit by confirming the infection in patients by PCR analysis. The kit showed a higher sensitivity for IgM after four days and the IgG after 11 days after the onset of symptoms. Traditional laboratory-based ELISAs have also been used to quantify total antibodies, IgM, and IgG.[40-46] A strong IgG and IgM response in blood compartment was reported by Amanat et al.[47] Zhao et al. found that the seroconversion rate for total antibodies was 93.1% and high titers of Ab were found to be associated with more severe disease. However, 6.9% of patients remained seronegative, possibly due to lack of blood samples from lost follow-up.[40]

Timing of Serology Testing

Median seroconversion time for total antibody, IgM, and IgG were 11, 12, and 14 days respectively, observed in >98.8% of COVID-19 patients with a rapid increase after six days from symptom onset. The sensitivity for IgM and IgG increased significantly after two weeks of symptoms.[40] Guo et al. also found similar results in respect to seroconversion rate with high sensitivity and specificity.[42] Lou et al. observed that those with prolonged incubation period, seroconverted in 21 days versus shorter incubation periods, who seroconverted in 13 days.[46] Zhao et al. reported a median seroconversion time of 11-14 days, depending on the assay used.[40] Okba et al. also found in their limited longitudinal serum samples, that IgG seroconversion was reliably detected at two weeks from onset.[48] Lastly, To et al. compared serial viral loads with antibody levels against the SARS-CoV-2 internal nucleoprotein (NP) and surface spike protein receptor binding domain (RBD) using enzyme immunoassay.[49] They found that IgG levels correlated with virus neutralization titer and that for the patients with samples available 14 days or longer after symptom onset, both IgG and IgM were highly sensitive for both anti-NP and anti-RBD.

Discussion

Clinical and epidemiological factors are primary drivers of pretest probability, crucial for interpreting any test result. Variations in available resources [E.g. materials needed by lab and clinical personal collecting samples] also affect testing decisions and interpretations. Understanding test characteristics is vital for interpreting positive or negative results.[50]

Statistical Considerations for Interpreting Diagnostic Test Results

Sensitivity, a test characteristic, is the proportion of people with disease who will have a positive result, whereas positive predictive value provides the odds of actually having the disease (accuracy) from a positive result. Table 3 lists the general effect of sensitivity and specificity of any dichotomous (positive or negative) diagnostic test on outcomes, and is worthy of review.[51] The effect of disease prevalence over positive predictive value without any change in sensitivity and specificity of the diagnostic test is illustrated Table 4. A useful and detailed review of how to interpret a diagnostic result in clinical decision making is available from Armstrong et al.[52] Cheng et al. provide a very useful heat map in their review and classify test choices based on four uses: screening, diagnosis of symptomatic cases, diagnosis of asymptomatic shedding and epidemiologic surveillance.[53]

RT-PCR

While RT-PCR is the current gold standard for the laboratory diagnosis of COVID-19, potential pre-analytical (ineffective symptom screening, sampling errors, prolonged transportation time, sample contamination, etc.) and analytical errors (insufficient sample, non-validated tests, instrument malfunction, testing out of diagnostic window, viral RNA recombination, etc.) that compromise the results should be kept in mind.[53, 54] While a false positive result may result in wasteful use of health care and public health resources, a false negative could lead to failure of isolation and foster community spread.[54] If SARS CoV-2 RNA quantity is below the threshold of RT-PCR analytical sensitivity (very early symptomatic or post-symptomatic/recovery), then results will be reported as negative, emphasizing the importance of appropriate sample collection technique and

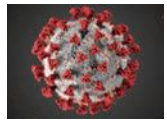


Table 3. Potential Outcomes of Screening Tests with Varying Levels of Sensitivity and Specificity [Reprinted with permission from © 2020 BioMed Central Ltd. Part of Springer Nature. 2012, BMC Research Notes; Vol 5, Iss 1; TGK Bentley et al. Implications of the impact of prevalence on test thresholds and outcomes: lessons from tuberculosis, p563]

Test characteristic	**High sensitivity**	**High specificity**
Impact on results	↑ True positives	↑ True negatives
Testing goal	Identify people with disease	Identify people without disease
Treatment goal	Treat disease Prevent future illness and, in the case of infection, possible disease spread	Avoid unnecessary treatment
Potential harms of opposite test characteristic	**Low sensitivity:**	**Low specificity:**
	↑ False negatives ↑ Potential future illness and suffering ↑ Potential future spread of disease (in the case of infection)	↑ False positives ↑ Bodily harms, toxicity, and financial costs of unnecessary treatment ↑ Social stigmatization ↓ confidence in screening program

Table 4. Effect of Prevalence on the Positive Predictive Value of Diagnostic Test

			Disease (gold standard)			
Dichotomous Diagnostic Test			Present	Absent	Total	
		+	a (True +)	b (False +)	a+b	PPV = a/(a+b)
		-	c (False -)	d (True -)	c+d	NPV = d/(c+d)
		Total	a+c	b+d		
			Sensitivity = a/(a+c)	Specificity = d/(b+d)		
Disease Prevalence = 1%*	Test	+	950	990	1940	PPV = 49%*
		-	50	98010	98060	NPV = 99.9%
		Total	1000	99000	100,000	
			Sensitivity = 95% *	Specificity = 99%*		
Disease Prevalence = 5%*	Test	+	4750	950	5700	PPV = 83.3%*
		-	250	94050	94300	NPV = 99.7%
		Total	5000	95000	100,000	
			Sensitivity = 95%*	Specificity = 99%*		

Abbreviations: PPV – positive predictive value, NPV – negative predictive value.
** Without any changes in sensitivity and specificity of the diagnostic test, the positive predictive value increased from 49% to 83.3% with an increase in prevalence of disease from 1% to 5%.*

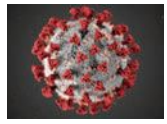
transport. The CDC has published clear guidelines for appropriate collection.[55] In contrast to SARS CoV infection (SARS 2002-2003) where RT-PCR sensitivity was low during the early symptomatic period, early shedding (pre- or early symptomatic phase of illness) of SARS CoV-2 virions is remarkable in COVID-19, accounting for its rapid spread in pandemic proportions.[56,57] Like other viral illnesses, the shedding of infectious SARS CoV-2 virions is also suspected to drop over time from onset of illness, but data is insufficient at this time.[49] Wolfel et al. evaluated SARS CoV-2 replication by assessing sub-genomic RNA (a marker of replication) from serial throat, sputum, blood, and fecal samples in nine mildly symptomatic COVID-19 patients.[56] They noticed early viral replication in throat and sputum samples that lasted for almost two weeks beyond the symptomatic period. Hence, RT-PCR from naso- or oro-pharyngeal samples will continue to remain as the reference standard for diagnosis during the acute phase of COVID-19.

CT chest should not be used as a stand-alone test for diagnosis of COVID-19, as it lacks specificity given that the typical changes (such as ground glass opacities) can also be found in a variety of other lung diseases/infections.[33] A CT chest should be considered for suspected pulmonary embolism, pneumothorax or another thoracic pathology, that will require it for further management.[58,59] CT chest in COVID-19, delays care for other non-COVID patients in dire need of it, as the disinfection process in most radiology units takes 1-2 hours.[59] Studies comparing CT chest with RT-PCR should be interpreted with caution due to differences in the RT-PCR research assays across the globe and the potential pre-analytical and analytical errors discussed above. If RT-PCR is negative and clinical suspicion for COVID-19 remains high, a repeat RT-PCR from an upper airway sample or from lower respiratory tract in intubated patients (higher positivity rates) with in-line suction may be considered.[33] The CDC's test-based strategy to release from isolation, was based on early studies that reported negative RT-PCRs in recovering patients. As a result of which, we now know that prolonged viral shedding is not uncommon, ranging from two to six weeks from onset.[60,61] Whether such persistent positivity by RT-PCR for prolonged periods imply continued infectious viral shedding remains to be determined.[56,57,62]

Serology

Considering the different antibodies that recovering patients may develop, it is important that serologic assays target those specific to the SARS CoV-2 structural proteins that differentiate it from the commonly circulating coronaviruses or SARS CoV. Despite the promising sensitivity and specificity for antibodies to N and S proteins of SARS CoV-2, human studies show wide variability (Table 2). With most studies suggesting seroconversion between days 11-14 after symptom onset, serology should not be considered for diagnosis during the acute phase of COVID-19.[44] Serology helps to determine an existing immune response in the host i.e. a surrogate of an immune response, but is not a concrete proof of protective immunity.[48,63] Humoral response is B cell mediated, which is only one arm of our protective immunity and may not last longer depending on the robustness of initial immune response.[64,65] In a phase 1 SARS CoV vaccine trial, T cell mediated responses (virus-specific memory cells) persisted for several years, while neutralizing antibodies only lasted for 1-2 years.[65,66] The most recent primer on serological assay from the IDSA, cautions about the high false positivity rates of serology tests when pre-test probability or prevalence of disease is <5%.[67]

In the absence of vaccines or proven effective treatment, the use of convalescent plasma (CP) from patients who recovered form COVID-19 is being explored as a treatment option.[68-70] CP has been used in the past for other infections, including the SARS and MERS epidemics.[71,72] In March 2020, the FDA supported the use of convalescent plasma to treat patients with severe or life-threatening COVID-19, under expanded access protocol.[73] Under Mayo Clinic's lead, as of April 26, 2020, 4,524 patients have been enrolled and 1,726 patients had received plasma across the U.S. However, the biggest challenge has been ensuring the availability of convalescent plasma.[74] Donors must have had a prior documented COVID-19 infection. COVID-19



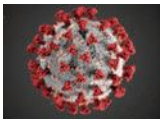
antibody testing can help widen the pool of plasma donors by determining a serologic evidence of prior infection.[75] The effectiveness of CP therapy depends on the neutralizing antibody titer exhibiting virus-killing function in donor plasma.[76] A defined titer of neutralizing antibodies has not been established and not all COVID-19 patients mount robust antibody response. Neutralization assays are not widely available and require biosafety level 3 facilities with skilled experts. Currently, the American Red Cross has a defined COVID-19 neutralizing antibody titer (e.g. > 1:80); however, it is not a needed criteria to refer a donor or transfuse plasma, because specimens are stored for testing later. ELISA and IFA, which are relatively easy and safe, have predicted neutralization activity, in MERS-CoV.[77] In one study, ELISA IgG predicted neutralization activity with >95% specificity at a cutoff optical density ratio of 1.6, suggesting it as a substitute in resource-limited situations.[78] With increasing COVID-19 prevalence, there is need for reliable serology assays to identify vaccine responses in trials and recovered patients who have detectable antibodies for therapeutic purposes i.e. donation of convalescent plasma as a potential treatment or for identification of past infection[18].

Antigen Immuno-Assays

On May 9, 2020 the U.S.FDA granted the first EUA for COVID-19 antigen test (Quidel Corporation) for use at the POC, which is only 80% sensitive compared to RT-PCR and 100% specific for detection of N protein of SARS CoV-2 from naso-pharyngeal and nasal swabs.[29] Antigen immuno-assays offer the potential for rapid, inexpensive, POC diagnosis of COVID-19.[53] Antigen tests are cheaper and simpler than RT-PCR and allow for early diagnosis. Antigen detection assays are available for adenovirus, respiratory syncytial virus (RSV), and influenza.[79] Well studied antigen assays for influenza and RSV have a high specificity.[80,81] They have also been developed for SARS-CoV and MERS-CoV.[82,83] The principal limitation is low sensitivity compared to RT-PCR.[80,81] Immuno-assays previously developed for the SARS-CoV and MERS-CoV coronaviruses may guide the development of similar tests for the novel SARS-CoV-2. Lau et al. utilized ELISA to detect SARS-CoV N protein using hyper-immune polyclonal antibodies. This assay demonstrated high specificity (≥96%) for nasopharyngeal, urine, and fecal specimens collected from patients without SARS, with respective sensitivities of 52%, 5%, and 55% from SARS-positive patients.[83] Chen and colleagues developed a capture ELISA using monoclonal antibodies specific to the MERS-CoV nucleo-capsid protein. This antigen detection assay demonstrated high specificity and sensitivity; yet, the study was limited by using only simulated MERS-CoV-positive specimens for determining sensitivity.[82] It is possible that antigen tests for SARS-CoV-2 may also be limited by poor sensitivity, particularly given the variability of viral shedding seen in COVID-19 patients.[53] Numerous other immune-assay test kits for COVID-19 diagnosis are under current development.[84]

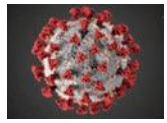
Conclusions and Future Perspectives

A combination of clinical, epidemiologic and laboratory considerations are essential for accurate diagnosis of emerging infections such as COVID-19. Community prevalence or disease activity plays an important role is choosing the laboratory test of choice and in interpretation of results. During the pandemic spread, RT-PCR being the most sensitive and specific test, it is the current laboratory standard for diagnosis during the acute phase of COVID-19. It is now widely available in most health care settings, but it cannot differentiate between infectious and non-infectious viral shedding during recovery. With increasing community spread, reliable serology testing is necessary for both epidemiologic and therapeutic reasons. Viral genomic recombination or acquired mutations, leading to phenotypic changes, could result in failure of these detection assays and pose threat to reliable interpretation of results.[85] Longitudinal studies are required to define a reliable test strategy.[64] Antigen based immuno-assays may have a role in the future for resource limited settings, but there are none available at this time.



References

1. Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet (London, England). 2020;395(10223):497-506.
2. Li Q, Guan X, Wu P, et al. Early Transmission Dynamics in Wuhan, China, of Novel Coronavirus-Infected Pneumonia. The New England journal of medicine. 2020;382(13):1199-1207.
3. Zhou P, Yang XL, Wang XG, et al. A pneumonia outbreak associated with a new coronavirus of probable bat origin. Nature. 2020;579(7798):270-273.
4. Corman VM, Landt O, Kaiser M, et al. Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. Euro Surveill. 2020;25(3):2000045.
5. Tan W, Zhao X, Ma X, et al. A novel coronavirus genome identified in a cluster of pneumonia cases—Wuhan, China 2019–2020. 2020;2(4):61-62.
6. Patel A, Jernigan DB, nCo VCDCRT. Initial Public Health Response and Interim Clinical Guidance for the 2019 Novel Coronavirus Outbreak - United States, December 31, 2019-February 4, 2020. MMWR Morb Mortal Wkly Rep. 2020;69(5):140-146.
7. Emergency Use Authorizations. 2020; https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations. Accessed 04/04/2020, 2020.
8. Caliendo AM, Gilbert DN, Ginocchio CC, et al. Better Tests, Better Care: Improved Diagnostics for Infectious Diseases. Clinical Infectious Diseases. 2013;57(suppl_3):S139-S170.
9. Petherick A. Developing antibody tests for SARS-CoV-2. The Lancet. 2020;395(10230):1101-1102.
10. Deepak S, Kottapalli K, Rakwal R, et al. Real-Time PCR: Revolutionizing Detection and Expression Analysis of Genes. Curr Genomics. 2007;8(4):234-251.
11. Valones MA, Guimaraes RL, Brandao LA, de Souza PR, de Albuquerque Tavares Carvalho A, Crovela S. Principles and applications of polymerase chain reaction in medical diagnostic fields: a review. Braz J Microbiol. 2009;40(1):1-11.
12. Patel R, Babady E, Theel ES, et al. Report from the American Society for Microbiology COVID-19 International Summit, 23 March 2020: Value of Diagnostic Testing for SARS-CoV-2/COVID-19. mBio. 2020;11(2).
13. President Donald J. Trump Is Ensuring States Have The Testing Capacity Needed To Safely Open Up America Again. 2020; https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-ensuring-states-testing-capacity-needed-safely-open-america/. Accessed 04/28/2020, 2020.
14. Coronavirus (COVID-19) Update: Serological Test Validation and Education Efforts. 2020; https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-test-validation-and-education-efforts. Accessed 04/28/2020, 2020.
15. Organization WH. WHO guidelines for the global surveillance of severe acute respiratory syndrome (SARS): updated recommendations, October 2004. Geneva: World Health Organization;2004.
16. Meyer B, Drosten C, Müller MA. Serological assays for emerging coronaviruses: challenges and pitfalls. Virus Res. 2014;194:175-183.
17. Pang J, Wang MX, Ang IYH, et al. Potential Rapid Diagnostics, Vaccine and Therapeutics for 2019 Novel Coronavirus (2019-nCoV): A Systematic Review. J Clin Med. 2020;9(3).
18. Cheng MP, Papenburg J, Desjardins M, et al. Diagnostic Testing for Severe Acute Respiratory Syndrome-Related Coronavirus-2: A Narrative Review. Ann Intern Med. 2020.
19. Hanson KE, Azar MM, Banerjee R, et al. Molecular testing for acute respiratory tract infections: clinical and diagnostic recommendations from the IDSA's Diagnostics Committee. Clinical Infectious Diseases. 2020.
20. Corman VM, Landt O, Kaiser M, et al. Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. Euro Surveill. 2020;25(3).
21. Konrad R, Eberle U, Dangel A, et al. Rapid establishment of laboratory diagnostics for the novel coronavirus SARS-CoV-2 in Bavaria, Germany, February 2020. Euro Surveill. 2020;25(9).
22. Pfefferle S, Reucher S, Norz D, Lutgehetmann M. Evaluation of a quantitative RT-PCR assay for the detection of the emerging coronavirus SARS-CoV-2 using a high throughput system. Euro Surveill. 2020;25(9).
23. Chu DKW, Pan Y, Cheng SMS, et al. Molecular Diagnosis of a Novel Coronavirus (2019-nCoV) Causing an Outbreak of Pneumonia. Clin Chem. 2020;66(4):549-555.
24. Wang D, Hu B, Hu C, et al. Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus-Infected Pneumonia in Wuhan, China. JAMA. 2020.
25. Chan JF, Yip CC, To KK, et al. Improved molecular diagnosis of COVID-19 by the novel, highly sensitive and specific COVID-19-RdRp/Hel real-time reverse transcription-polymerase chain reaction assay validated. J Clin Microbiol. 2020.
26. Chan JF, Yuan S, Kok KH, et al. A familial cluster of pneumonia associated with the 2019 novel coronavirus indicating person-to-person transmission: a study of a family cluster. Lancet (London, England). 2020;395(10223):514-523.
27. Nalla AK, Casto AM, Huang MW, et al. Comparative Performance of SARS-CoV-2 Detection Assays using Seven Different Primer/Probe Sets and One Assay Kit. J Clin Microbiol. 2020.
28. Centers for Disease Control and Prevention Division of Viral Diseases. CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. Revision: 03. In: FDA; 2020.
29. U.S. Food and Drug Administration. Emergency Use Authorizations. 2020; https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd. Accessed 04/14/2020.
30. Liu R, Han H, Liu F, et al. Positive rate of RT-PCR detection of SARS-CoV-2 infection in 4880 cases from one hospital in Wuhan, China, from Jan to Feb 2020. Clin Chim Acta. 2020;505:172-175.
31. To KK, Tsang OT, Chik-Yan Yip C, et al. Consistent detection of 2019 novel coronavirus in saliva. Clin Infect Dis. 2020.
32. Wang W, Xu Y, Gao R, et al. Detection of SARS-CoV-2 in Different Types of Clinical Specimens. JAMA. 2020.
33. Ai T, Yang Z, Hou H, et al. Correlation of Chest CT and RT-PCR Testing in Coronavirus Disease 2019 (COVID-19) in China: A Report of 1014 Cases. Radiology. 2020:200642.
34. Fang Y, Zhang H, Xie J, et al. Sensitivity of Chest CT for COVID-19: Comparison to RT-PCR. Radiology. 2020:200432.
35. Long C, Xu H, Shen Q, et al. Diagnosis of the Coronavirus disease (COVID-19): rRT-PCR or CT? Eur J Radiol. 2020;126:108961.
36. Li Y, Yao L, Li J, et al. Stability issues of RT-PCR testing of SARS-CoV-2 for hospitalized patients clinically diagnosed with COVID-19. J Med Virol. 2020.
37. Xiao AT, Tong YX, Zhang S. False-negative of RT-PCR and prolonged nucleic acid conversion in COVID-19: Rather than recurrence. J Med Virol. 2020.
38. Li Z, Yi Y, Luo X, et al. Development and Clinical Application of A Rapid IgM-IgG Combined Antibody Test for SARS-CoV-2 Infection Diagnosis. J Med Virol. 2020.
39. Sheridan C. Fast, portable tests come online to curb coronavirus pandemic. Nat Biotechnol. 2020.
40. Zhao J, Yuan Q, Wang H, et al. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. Clinical Infectious Diseases. 2020.
41. Cassaniti I, Novazzi F, Giardina F, et al. Performance of VivaDiag COVID-19 IgM/IgG Rapid Test is inadequate for diagnosis of COVID-19 in acute patients referring to emergency room department. J Med Virol. 2020.

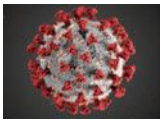


42. Guo L, Ren L, Yang S, et al. Profiling Early Humoral Response to Diagnose Novel Coronavirus Disease (COVID-19). Clinical Infectious Diseases. 2020.
43. Haveri A, Smura T, Kuivanen S, et al. Serological and molecular findings during SARS-CoV-2 infection: the first case study in Finland, January to February 2020. Euro Surveill. 2020;25(11).
44. Liu W, Liu L, Kou G, et al. Evaluation of Nucleocapsid and Spike Protein-based ELISAs for detecting antibodies against SARS-CoV-2. Journal of Clinical Microbiology. 2020:JCM.00461-00420.
45. Zhang W, Du RH, Li B, et al. Molecular and serological investigation of 2019-nCoV infected patients: implication of multiple shedding routes. Emerg Microbes Infect. 2020;9(1):386-389.
46. Lou B, Li T, Zheng S, et al. Serology characteristics of SARS-CoV-2 infection since the exposure and post symptoms onset. medRxiv. 2020:2020.2003.2023.20041707.
47. Amanat F, Stadlbauer D, Strohmeier S, et al. A serological assay to detect SARS-CoV-2 seroconversion in humans. medRxiv. 2020:2020.2003.2017.20037713.
48. Okba NMA, Muller MA, Li W, et al. Severe Acute Respiratory Syndrome Coronavirus 2-Specific Antibody Responses in Coronavirus Disease 2019 Patients. Emerg Infect Dis. 2020;26(7).
49. To KK, Tsang OT, Leung WS, et al. Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study. Lancet Infect Dis. 2020.
50. Patel R, Babady E, Theel ES, et al. Report from the American Society for Microbiology COVID-19 International Summit, 23 March 2020: Value of Diagnostic Testing for SARS–CoV-2/COVID-19. mBio. 2020;11(2):e00722-00720.
51. Bentley TGK, Catanzaro A, Ganiats TG. Implications of the impact of prevalence on test thresholds and outcomes: lessons from tuberculosis. BMC Res Notes. 2012;5:563-563.
52. Armstrong KA, Metlay JP. Annals Clinical Decision Making: Using a Diagnostic Test. Annals of Internal Medicine. 2020;172(9):604-609.
53. Tang YW, Schmitz JE, Persing DH, Stratton CW. The Laboratory Diagnosis of COVID-19 Infection: Current Issues and Challenges. J Clin Microbiol. 2020.
54. Lippi G, Simundic AM, Plebani M. Potential preanalytical and analytical vulnerabilities in the laboratory diagnosis of coronavirus disease 2019 (COVID-19). Clinical chemistry and laboratory medicine. 2020.
55. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19). 2020; https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html. Accessed 04/26/2020, 2020.
56. Wölfel R, Corman VM, Guggemos W, et al. Virological assessment of hospitalized patients with COVID-2019. Nature. 2020.
57. He X, Lau EHY, Wu P, et al. Temporal dynamics in viral shedding and transmissibility of COVID-19. Nature Medicine. 2020.
58. Hope MD, Raptis CA, Shah A, Hammer MM, Henry TS. A role for CT in COVID-19? What data really tell us so far. Lancet (London, England). 2020;395(10231):1189-1190.
59. Hope MD, Raptis CA, Henry TS. Chest Computed Tomography for Detection of Coronavirus Disease 2019 (COVID-19): Don't Rush the Science. Annals of Internal Medicine. 2020.
60. Zhou B, She J, Wang Y, Ma X. The duration of viral shedding of discharged patients with severe COVID-19. Clinical Infectious Diseases. 2020.
61. Zhou F, Yu T, Du R, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. 2020.
62. Atkinson B, Petersen E. SARS-CoV-2 shedding and infectivity. The Lancet. 2020.
63. Lin Q, Zhu L, Ni Z, Meng H, You L. Duration of serum neutralizing antibodies for SARS-CoV-2: Lessons from SARS-CoV infection. J Microbiol Immunol Infect. 2020.
64. Altmann DM, Douek DC, Boyton RJ. What policy makers need to know about COVID-19 protective immunity. The Lancet. 2020.
65. Channappanavar R, Zhao J, Perlman S. T cell-mediated immune response to respiratory coronaviruses. Immunologic Research. 2014;59(1):118-128.
66. Martin JE, Louder MK, Holman LA, et al. A SARS DNA vaccine induces neutralizing antibody and cellular immune responses in healthy adults in a Phase I clinical trial. Vaccine. 2008;26(50):6338-6343.
67. IDSA COVID-19 Antibody Testing Primer 2020; https://www.idsociety.org/globalassets/idsa/public-health/covid-19/idsa-covid-19-antibody-testing-primer.pdf. Accessed 04/20/2020, 2020.
68. Roback JD, Guarner J. Convalescent Plasma to Treat COVID-19: Possibilities and Challenges. JAMA. 2020.
69. Chen L, Xiong J, Bao L, Shi Y. Convalescent plasma as a potential therapy for COVID-19. Lancet Infect Dis. 2020;20(4):398-400.
70. Duan K, Liu B, Li C, et al. Effectiveness of convalescent plasma therapy in severe COVID-19 patients. Proc Natl Acad Sci U S A. 2020.
71. Mair-Jenkins J, Saavedra-Campos M, Baillie JK, et al. The effectiveness of convalescent plasma and hyperimmune immunoglobulin for the treatment of severe acute respiratory infections of viral etiology: a systematic review and exploratory meta-analysis. J Infect Dis. 2015;211(1):80-90.
72. Lai ST. Treatment of severe acute respiratory syndrome. Eur J Clin Microbiol Infect Dis. 2005;24(9):583-591.
73. Tanne JH. Covid-19: FDA approves use of convalescent plasma to treat critically ill patients. BMJ. 2020;368:m1256.
74. Arabi YM, Hajeer AH, Luke T, et al. Feasibility of Using Convalescent Plasma Immunotherapy for MERS-CoV Infection, Saudi Arabia. Emerg Infect Dis. 2016;22(9):1554-1561.
75. Zhao J, Yuan Q, Wang H, et al. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. Clin Infect Dis. 2020.
76. Franchini M, Marano G, Velati C, Pati I, Pupella S, Liumbruno GM. Operational protocol for donation of anti-COVID-19 convalescent plasma in Italy. Vox Sang. 2020.
77. Ko JH, Seok H, Cho SY, et al. Challenges of convalescent plasma infusion therapy in Middle East respiratory coronavirus infection: a single centre experience. Antivir Ther. 2018;23(7):617-622.
78. Ko JH, Müller MA, Seok H, et al. Suggested new breakpoints of anti-MERS-CoV antibody ELISA titers: performance analysis of serologic tests. Eur J Clin Microbiol Infect Dis. 2017;36(11):2179-2186.
79. Zhang N, Wang L, Deng X, et al. Recent advances in the detection of respiratory virus infection in humans. J Med Virol. 2020;92(4):408-417.
80. Chartrand C, Tremblay N, Renaud C, Papenburg J. Diagnostic Accuracy of Rapid Antigen Detection Tests for Respiratory Syncytial Virus Infection: Systematic Review and Meta-analysis. J Clin Microbiol. 2015;53(12):3738-3749.
81. Merckx J, Wali R, Schiller I, et al. Diagnostic Accuracy of Novel and Traditional Rapid Tests for Influenza Infection Compared With Reverse Transcriptase Polymerase Chain Reaction: A Systematic Review and Meta-analysis. Ann Intern Med. 2017;167(6):394-409.
82. Chen Y, Chan KH, Kang Y, et al. A sensitive and specific antigen detection assay for Middle East respiratory syndrome coronavirus. Emerg Microbes Infect. 2015;4(4):e26.
83. Lau SK, Woo PC, Wong BH, et al. Detection of severe acute respiratory syndrome (SARS) coronavirus nucleocapsid protein in sars patients by enzyme-linked immunosorbent assay. J Clin Microbiol. 2004;42(7):2884-2889.
84. SARS-CoV-2 diagnostic pipeline. 2020; https://www.finddx.org/covid-19/pipeline/?section=show-all#diag_tab. Accessed 4/19/20.
85. Yao H, Lu X, Chen Q, et al. Patient-derived mutations impact pathogenicity of SARS-CoV-2. In: medRxiv; 2020.

Disclosure

None reported.

MM



PERSPECTIVE

The Feds Act to Boost Competition in the Biosimilars Market

by Henry I. Miller, MD

Significant adoption of this class of drugs could save billions in healthcare costs.

Innovating new drug development is an expensive and uncertain business, typically taking 10-12 years and costing, on average, $2.55 billion to bring a new product to market. The risks are enormous, and deserve significant financial rewards; at the same time, it's undeniable that the costs of many new, complex drugs are high and possibly unsustainable. In the near future, one critical, emerging pricing issue will be how rapid is the uptake of a blockbuster class of drugs called "biosimilars," which can be thought of as generic versions of biologics, drugs that are complex biological molecules derived from living cells. Typical biologics include vaccines, gene therapy, blood and blood components, antitoxins, and allergenic products.

Importance of Generic or "Follow On," Versions of Brand-Name Drugs

Generic medicines are a critical element of Americans' health care. Since 1984, the marketing of generic versions of chemically synthesized "small molecule" drugs such as those used commonly to control diabetes, blood pressure, cholesterol, and pain, has been governed by legislation commonly known as the Hatch-Waxman Act. By allowing approval of generics through an abbreviated and less costly pathway than for innovator, or brand-name, drugs—a route that does not require new clinical trials but only a demonstration of "bioequivalence"—this legislation has balanced the need to preserve industry's incentive to innovate with the benefits of competition.

The result has been a robust and hugely important generic drug industry. More than four of every five drug prescriptions filled are for generic drugs, which saves consumers over $200 billion annually. The impact of newly available generic drugs is often rapid and impressive: when the first generic copy of a typical small-molecule drug reaches pharmacies, there is typically about a 30% drop in price, often reaching 80% as additional generic versions appear. Thus, brand-name drugs like Lipitor and Prilosec that were economic blockbusters while their patents were intact and they had the market to themselves have seen their market-share and revenues plummet once generics became available.

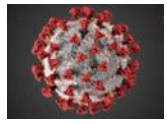
Biosimilars

When the pathway for generic drugs was established 30 years ago, the class of drugs called "biologics" was inconsequential compared to simpler small molecule drugs, but now they are common. Each year since 2010, they have represented the majority of new drugs that come onto the market, and they account for more than 20% of U.S. drug expenditures, with global sales topping $150 billion annually. In 2018, eight of the top 10 drugs by worldwide sales were biologics. Hoping to replicate for biologics the success of Hatch-Waxman, in 2009 Congress passed the Biologics Price Competition and Innovation Act (BPCIA), which was supposed to begin the process of creating a generic drug-like pathway for follow-on biologics, or "biosimilars." The objective was to stimulate the same sort of competition that lowers the price of small-molecule drugs after patents expire.

Passage of the BPCIA was accompanied by glowing predictions of cost savings. The Congressional Budget Office estimated that biosimilars would reduce total



Henry I. Miller, MD, a physician and molecular biologist, is a Senior Fellow at the Pacific Research Institute in San Francisco, California. He was the founding director of the FDA's Office of Biotechnology.



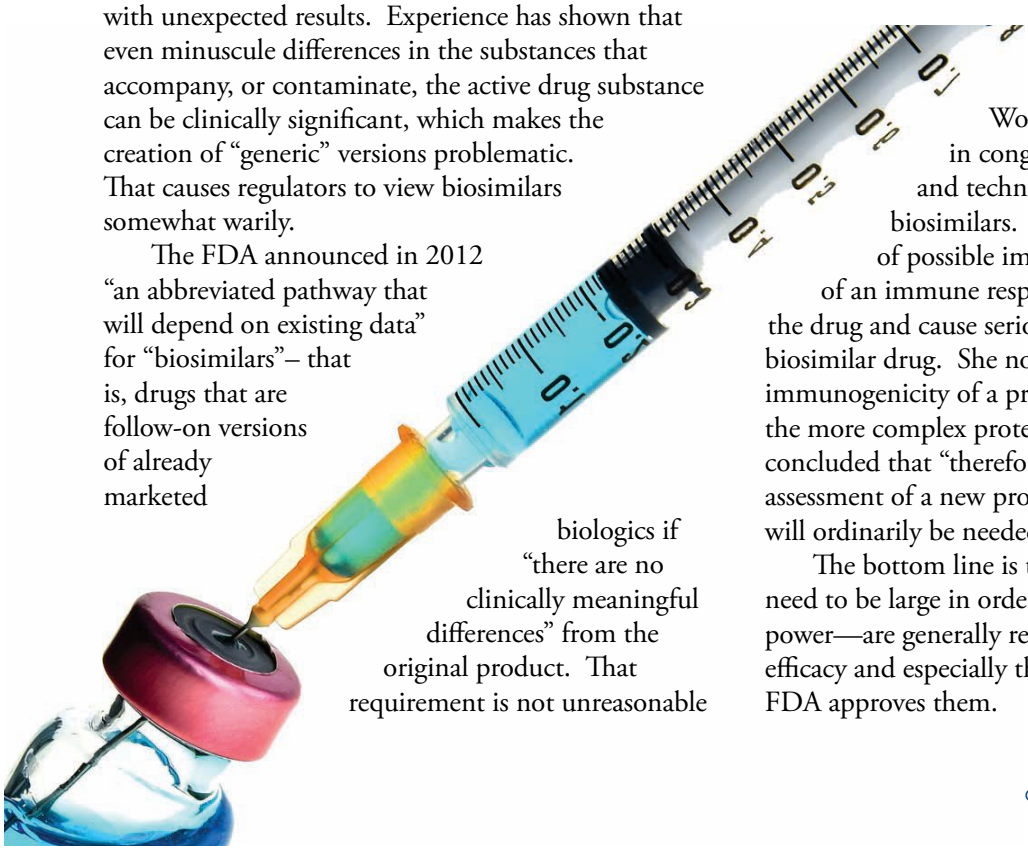
drug expenditures by $25 billion over 10 years; Steve Miller, MD, of Express Scripts, was far more bullish, estimating that cost savings could be a whopping $250 billion by 2024.

Looking primarily through a regulatory lens, I predicted five years ago that these predictions were far too optimistic. Indeed, the reality is likely to be far less rosy, thanks to several factors in addition to regulation – chemistry, patents, and a misinformation PR blitz by the competition.

Regulators Are Wary of Biosimilars

Scientific considerations make biosimilar replicas somewhat complicated. Biologics are generally made in living cells, which are usually bacteria, yeast or cultured mammalian cells that have been reprogrammed, or genetically engineered, to synthesize the drug by means of the insertion of new genetic material. The choice of cells and purification methods determines the nature and amount of contaminants in the final formulation. Nothing is ever 100% pure, but it's much easier to get closer to that goal with small molecules. For generic versions of small molecules, the manufacturer must only demonstrate "bioequivalence," the absence of significant differences from the original, or innovator, drug in its availability at the site of its action (for example, in the blood or GI tract). However, for biologics, protein folding, various kinds of enzymatic modifications and impurities inevitably introduce variation, sometimes with unexpected results. Experience has shown that even minuscule differences in the substances that accompany, or contaminate, the active drug substance can be clinically significant, which makes the creation of "generic" versions problematic. That causes regulators to view biosimilars somewhat warily.

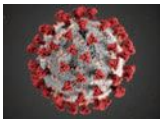
The FDA announced in 2012 "an abbreviated pathway that will depend on existing data" for "biosimilars"– that is, drugs that are follow-on versions of already marketed biologics if "there are no clinically meaningful differences" from the original product. That requirement is not unreasonable but it ensured that in spite of many predictions to the contrary, the availability of this new biosimilar pathway has neither significantly changed the drug development landscape nor put a significant dent in escalating medical costs.



An explanation of that requires some background. The FDA's involvement with biosimilars is not new; even before the 2012 policy was announced, over many years, regulators had already approved a small number of "follow-on biologics"—biosimilars by another name. This experience offers important insights into how regulators view biosimilars: Scientific considerations dictated that all of them required a substantial amount of laboratory and clinical testing—a far more elaborate, expensive process than has been required for small-molecule generics. There is no reason to think that the FDA's approach to such products has changed; quite the contrary, in fact, and this is reflected in the approval numbers. The first U.S. biosimilar was approved by the FDA in 2015, and as of January 15, only 26 had been approved. (This compared with 71 by the European Medicines Agency.)

Why the discrepancy? The FDA has long considered that even minor changes in the production of biological drugs—including even the same isolation and purification procedures applied at significantly larger scale than previously—yield a distinct, new drug that must undergo an independent demonstration of safety and efficacy. The head of FDA's drug center, Janet Woodcock, MD, has acknowledged in congressional testimony the scientific and technical challenges posed by biosimilars. She emphasized the importance of possible immunogenicity—the stimulation of an immune response (which can both inactivate the drug and cause serious side effects) -- by a biosimilar drug. She noted that "the ability to predict immunogenicity of a protein product, particularly the more complex proteins, is extremely limited," and concluded that "therefore, some degree of clinical assessment of a new product's immunogenic potential will ordinarily be needed."

The bottom line is that clinical trials—which may need to be large in order to achieve sufficient statistical power—are generally required to demonstrate the efficacy and especially the safety of biosimilars before FDA approves them.



Economic Obstacles to Biosimilars Usage

There are also various non-scientific, non-regulatory economic factors that create disincentives to the uptake of biosimilars once they are approved. Economist Wayne Winegarden explains two of them:

One of the more important obstructions is the current "buy-and-bill" reimbursement system that dis-incents lower-cost biosimilars. Under this system, providers purchase medicines and then, once the medicines have been administered to the patients, bill insurers for the costs of the medicine plus their mark-up. The provider mark-up is typically a percentage of the medicine's price. Since a biosimilar's price is less than a biologic's price, providers lose money when they prescribe a lower-priced biosimilar medicine instead of a higher-priced biologic medicine. These losses are not *de minimis* either. A 2017 study found that in the case of one medicine class, infliximab, broad adoption of the biosimilars could decrease providers' profits by as much as $100 million.

Next, insurance plans commonly include fail-first policies. Typically, the purpose of fail-first policies is to require patients to use lower-priced generic medicines first, then, only if the generic medicines fail to sufficiently help the patients, can a more expensive branded medicine be prescribed. As applied to biosimilars, however, fail-first policies work in reverse. In this case, the insurance clauses will only allow patients to use the less expensive biosimilars if they first failed on the more expensive biologics. Thus, as currently applied, fail-first policies bias the market against less expensive biosimilars, harming competition in the process.

Another factor inhibiting the uptake of biosimilars is patents, which protect market share and the pricing power of the brand-name biologics, most of which haven't been on the market long enough for their patents to expire, at which time competitors would be permitted to launch cheaper biosimilars. (For many brand-name biologics, the protection afforded by patents will soon expire, however.)

Finally, the uptake of biosimilars has been slowed by several strategies devised by the manufacturers of the brand-name biologics in order to retain market share. For example, they have inhibited the sales of biosimilars by gaming the rebate system: In order for a healthcare insurer to receive rebates that lower its cost per prescription for brand-name biologics, it is forced to agree to contracts that exclude biosimilars or, at least, provide the brand-name biologic with preferential placement on its drug formulary, which dictates how much patients pay at pharmacies.

Why would insurance companies enter into such arrangements? Possibly because biosimilars are viewed skeptically, as a result of a kind of whispering campaign about them, as described below.

Although the BPCIA states explicitly that a biosimilar must be highly similar to, have the same mechanism of action as, and have no clinically meaningful differences from the reference product, that has not deterred some makers of the more expensive brand-name products from raising theoretical concerns about the safety and efficacy of biosimilars. They claim that their goal is solely to inform and protect patients, but as H.L. Mencken said, "When someone says 'it's not about money', it's about money."

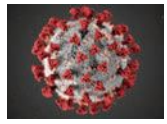
The Feds To the Rescue?

The FDA and Federal Trade Commission intend to ensure that the information about biosimilars is not inaccurate or misleading. In a joint statement on February 3, 2020, they announced a partnership aimed at supporting the adoption of biosimilars and interchangeable products by deterring what they called "anti-competitive business practices," such as communications that make a "false or misleading comparison between a reference product and a biosimilar in a manner that misrepresents the safety or efficacy of biosimilars, deceives consumers, or deters competition."

Also according to the statement, the FTC will use its authority to obtain and review patent settlement agreements between the manufacturers of reference (original) products and biosimilars, and will determine whether they include, among other things, anti-competitive reverse payments that curb or prevent the introduction of lower-priced drugs into the marketplace.

Conclusion

The bottom line is that biosimilars have great promise to moderate drug costs but face obstacles. Economist Wayne Winegarden estimates that small-molecule generic drugs "saved the U.S. health system $1.67 trillion between 2007 and 2016 alone," and his analysis indicates that with increasing market share of currently approved biosimilars, the savings could run well into the billions. At least in the short-term, the obstacles are imposing, however, and only time will tell whether biosimilars will realize their potential. **MM**



COVID-19: Has the Standard of Care Changed and Are Providers Immune from Liability?

by Lorinda Holloway, JD

The COVID-19 pandemic has had a rapid-fire impact on healthcare providers. And not just for those on the front lines. Providers have been and will continue facing a myriad of patient care challenges, financial hits to their business, and legal issues caused by COVID-19. The list of legal issues is long, but two pressing questions—particularly as states begin reopening and elective care resumes—are whether the standard of care has changed and whether providers have immunity from legal liability, particularly given how easily COVID-19 spreads and the limited availability of testing. Here's what Missouri providers need to know.

Has the standard of care in Missouri changed? No, but COVID-19 informs it and creates a need for thoughtful documentation. In the context of a medical negligence claim, negligence means "the failure to use that degree of skill and learning ordinarily used under the same or similar circumstances by members of defendant's profession."[1] That basic definition is not likely changing in Missouri because of COVID-19; however, COVID-19 is certainly relevant in assessing what a provider would ordinarily do or not do under similar circumstances, including decisions to delay elective care and to resume elective care.[2] In the final analysis, this means providers should stay in tune and meaningfully comply with the guidance published by the Center for Disease Control, their state licensing boards, and their state and local health authorities (and document these efforts) in order to demonstrate the reasonableness of their professional acts and omissions. When such guidance changes what an ordinary and reasonable provider would do or not do with regarding to a specific patient's care, the provider should document his or her rationale for doing so in the patient's record.

For instance, if a provider is in agreement that a patient's test or treatment can safely be delayed per an applicable stay-at-home order, or CDC or other guidance, the provider should document in the patient's record his or her rationale and any relevant clinical information and even medical literature in support of their decision. Such documentation will be important to the provider's defense, even if broad immunities are provided. Even when immunity is provided by law, it typically means the provider will have a defense on which to seek hopefully early dismissal. In other words, immunity alone does not typically stop a plaintiff from filing a lawsuit so providers want to be armed with contemporaneous documentation that demonstrates the reasonableness of their acts or omissions during this state of public health emergency.

Does federal law provide immunity to healthcare providers? Right now, in most circumstances, no. So far, federal law provides immunity in very limited circumstances. Specifically, the CARES Act protects only volunteer healthcare professionals. It is silent as to non-volunteer healthcare professionals, thus providing no wide-spread federal protection to employed or contracted professionals treating patients during the pandemic.[3] It is also silent as to and therefore does not immunize healthcare facilities. Another federal



Lorinda Holloway, JD, is a partner in the Austin, Texas, office of Husch Blackwell. She represents a full spectrum of health care providers in government investigations and in all manner of litigation, including medical malpractice.
Contact: lorinda.holloway@huschblackwell.com

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

statute provides some potential immunity for providers, but it, too, is very narrow. On March 10, 2020, the Secretary of Health and Human Services issued a Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) for certain medical products to be used against COVID-19. The PREP Act provides immunity for manufacturers, suppliers, and administrators of certain products and technologies used to combat COVID-19. However, there has been such confusion around the scope and application of the PREP Act that HHS recently issued an Advisory Opinion about it.[4]

Whether the federal government will enact broader immunity remains to be seen. Missouri's Attorney General has joined a 21-State coalition, urging Congress to enact COVID-19 liability protections, including protection for healthcare providers, that that help mitigate the threat of frivolous COVID-related lawsuits.[5] In the coalition's May 11, 2020 letter to Senate Majority Leader Mitch McConnell and others, the coalition explains that as attorneys general, they ensure their states have a legal and regulatory environment that protects consumers and allows the free enterprise system to thrive. The letter further explains that it is in keeping with this mission that they are calling on Congress to ensure that those businesses that have engaged in best practices and followed federal and state guidance for safe and appropriate operations as a result of this pandemic will be protected from baseless litigation. McConnell is certainly receptive, saying the next COVID-19 stimulus package would include liability protections, but this is a move strongly opposed by Democrats.

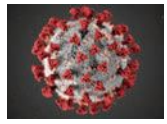
Regardless of what happens with the 21-State coalition's effort, it's clear that Health and Human Services sees liability protections as a job for the states to handle. Secretary of Health and Human Services Alex Azar recently sent a letter to all state governors, encouraging them to develop a list of liability protections for in-state and out-of-state physicians, telehealth services, and services consistent with expanded scopes of practice in order "to carry out a whole-America response to the COVID-19 pandemic."[6] Interestingly, the encouragement is focused only on limiting liability where regulations have been relaxed for purposes of addressing the pandemic and not on the idea of broader immunity. Presumably, some states will issue such protections, but nearly half the states have already taken more extensive action to protect those on the front line from liability. The protections vary considerably though.

Twenty-three States so far have enacted some level of immunity for first responders and healthcare workers, but they vary in scope, and Missouri is not yet among them. Governor Parson has issued a number of Executive Orders since declaring a state of emergency throughout the State of Missouri on March 13, 2020, including the relaxation of certain statutory and regulatory provisions related to telemedicine, allowing waiver of strict compliance with statutory or regulatory compliance where it would hinder the State's response to COVID-19, and easing licensing requirements to eliminate barriers to the provision of health care services.[7] But none of his Executive Orders extend immunity to healthcare providers responding to COVID-19 or aiding the response. The Missouri legislature, however, has been considering a number of bills toward the end of the current Session, all of which contained the following language:

Any health care provider who in good faith renders care or assistance, with or without compensation, in connection with the COVID-19 pandemic, including taking measures to coordinate, arrange for, respond to, provide, or address issues related to the delivery of health care services, shall not be liable for any civil damages for any acts or omissions that occur during a period where there is in effect an executive order issued by the governor of Missouri declaring that a state of emergency exists …."[8]

For many, the question would be whether the "in connection with the COVID-19 pandemic" language would be broad enough to immunize providers who are not on the front line but who have delayed or modified non-COVID-19 care because of the public health emergency and related guidance. This and other questions regarding legislation with an immunity provision for providers will have to wait for future legislative action.

Of the 23 States that have enacted some level of immunity for providers, few are as broad as the immunity provided in Louisiana, which appears tied only to the time frame of the state of emergency.[9] Many tend to be more specific to COVID-19 care or response efforts. For instance, Governor Kelly of Kansas tied immunity fairly directly to COVID-19 care,[10] specifically providing immunity for "making clinical and triage decisions and rendering assistance, testing, care or advice in the care of patients reasonably suspected or confirmed to be infected with COVID-19" through Executive Order 20-26.[11] The order does not provide liability protection for healthcare



providers delaying or deferring non-urgent care to non-COVID-19 patients during the declared emergency.

Governor Cuomo of New York, through Executive Order No. 202.10, granted more tailored immunity—immunity from civil and criminal liability to healthcare facilities and professionals for "any injury or death alleged to have been sustained directly as a result of an act or omission by such medical professional in the course of providing medical services in support of the State's response to the COVID-19 outbreak," unless the act or omission was caused by gross negligence or willful misconduct.[12] Governor Pritzker of Illinois took similar action through Executive Order No. 17, which granted healthcare facilities and professionals immunity from civil liability for any injury or death which occurs while the provider rendered health care services in response to COVID-19.[13] Like New York, the immunity does not extend to injuries caused by gross negligence or willful misconduct.

Governor Evers of Wisconsin recently signed into law the 2019 Wisconsin Act 185 with bipartisan support, enacting substantially similar protections as New York and Illinois, though referring to health services provided (or not provided) in good faith, or which are "substantially consistent" with public health emergency guidance (instead of referring specifically to COVID-19), absent reckless or wanton conduct or intentional misconduct.[14] This immunity is arguably broader than New York or Illinois' immunity provisions because it is not expressly limited to acts or omissions "in the course of providing medical services." In other words, perhaps it is broad enough to protect a provider sued for delaying an elective surgery, when that provider would have no protection otherwise in light of Wisconsin not issuing an order requiring the delay of elective surgeries.

In the end, even were immunity legislation to be enacted with provisions as broad as providers would like, providers should still comply with COVID-19 applicable guidance and document the rationale for their decisions, especially as elective care resumes.

As executive orders and stay-at-home orders begin lifting and practices start resuming elective care, it will be important to implement a safe process. There are several obvious but important steps to take to navigate the related liability risks: (1) check the CDC, local public health, and licensing board websites regularly for updates and implement and adjust infection control and other practices as necessary in order to comply; (2) consult applicable professional associations and the insurance carrier for guides to returning to practice; and (3) check with the insurance carrier to determine whether expanded coverage is necessary given the changes during COVID-19 (like expanded use of telehealth or bringing back retired practitioners) and whether the carrier is requiring reference to COVID-19 risks in informed consent forms.

And remember, the old risk management adage "if it isn't documented it wasn't done" applies. In other words, what seems unforgettable today—the considerable efforts providers are taking to provide safe care—will be easily overshadowed in the event of tragic outcomes. Therefore, providers should take the time to document their protocols and other actions taken to comply with applicable guidance. If a provider cannot meaningfully comply with the applicable guidelines then the provider should wait to resume elective care until compliance is manageable because no immunity provision that could potentially apply is likely to provide protection in that circumstance.

References

1. Mo. Approved Jury Instr. (Civil) 11.06.
2. In contrast, a few states like Alabama (through Governor Ivey) have literally changed the standard of care. Alabama has chosen to allow healthcare facilities which have invoked emergency operation plans in response to the pandemic to implement "alternative standards of care" plans, and those alternative standards of care are declared to be the state-approved standard of care in healthcare facilities to be executed by healthcare professionals and allied professions and occupations providing services in response to the outbreak. https://governor.alabama.gov/assets/2020/03/2020-03-13-Initial-COVID-19-SOE.pdf. This approach is unique and not common among the 23 states that have provided some level of immunity to healthcare providers in light of COVID-19.
3. https://www.congress.gov/bill/116th-congress/house-bill/748/text?loclr=bloglaw#toc-H16DA8E9326B14CE8B59468B2CC20C7FF
4. https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-april-14-2020.pdf
5. https://law.georgia.gov/press-releases/2020-05-12/georgia-leads-21-state-coalition-urging-congress-enact-covid-19-liability. The 21-State coalition is comprised of: Alabama, Alaska, Arkansas, Florida, Georgia, Idaho, Indiana, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Nebraska, North Dakota, Ohio, South Carolina, South Dakota, Tennessee, Texas, Utah, and West Virginia.
6. https://www.ncsbn.org/HHS_Secretary_Letter_to_States_Licensing_Waivers.pdf
7. https://www.sos.mo.gov/library/reference/orders/2020/eo10
8. The bills toward the end of the 2nd Regular Session of the 100th General Assembly of the Missouri Legislature were H.R. 2049, S.B. 580 and S.B. 662.
9. Governor Edwards of Louisiana, through Proclamation No. 25 JBE 2020, declared a public health emergency, which means under Louisiana State Legislature RS 29:771(B)(2)(c) that "[d]uring [the] state of public health emergency, any health care providers shall not be civilly liable for causing the death of, or, injury to, any person or damage to any property except in the event of gross negligence or willful misconduct." https://gov.louisiana.gov/assets/ExecutiveOrders/25-JBE-2020-Public-Health-Emergency-COVID-19.pdf. Remarkably, this immunity is not on its face limited to COVID-19-related care but rather it appears to operate as a blanket immunity for as long as there is a state of public health emergency.
10. https://www.healthcarelawinsights.com/2020/04/kansas-governor-issues-protections-for-health-practitioners-and-expands-health-workforce/
11. https://governor.kansas.gov/wp-content/uploads/2020/04/EO-20-26-Executed.pdf
12. https://www.governor.ny.gov/news/no-20210-continuing-temporary-suspension-and-modification-laws-relating-disaster-emergency
13. https://www2.illinois.gov/Pages/Executive-Orders/ExecutiveOrder2020-19.aspx
14. https://www.huschblackwell.com/newsandinsights/wisconsin-act-removes-barriers-to-providing-care-during-covid-19

MM

The Perilous Blessing of Opioids

by Travis N. Rieder, PhD

An injured bioethicist learned firsthand how desperately patients with severe pain need the relief of powerful drugs—and how little support they get to stop taking them.

On a beautiful Memorial Day weekend five years ago, I left my home in Germantown, Md., on one of my rare motorcycle trips, but I did not get very far. A few blocks from the townhouse where I lived with my partner and our baby girl, a young man drove his large white van directly into the side of my bike. My left foot was crushed, and I was tossed to the ground.

That day radically changed my life, and not just because of the injury itself. As a bioethicist at Johns Hopkins University, part of my job is to think about the moral quandaries raised by the practice of medicine. Unexpectedly becoming a trauma patient can be a particularly good way to uncover such issues. My own experience exposed a pair of linked challenges for patients like me and for our health care system: how to alleviate severe, debilitating pain while making sure that lives aren't destroyed by the opioids that remain, for now at least, an irreplaceable remedy.

I had five surgeries over the course of a month, at three different hospitals. There they gave me intravenous morphine, fentanyl, and hydromorphone. They sent me home with powerful oxycodone pills. The drugs were a godsend for getting through my ordeal, but I soon faced the results of being on high and escalating dosages for too long. I had formed a profound dependence. When my orthopedic trauma surgeon finally told me, two months after the accident, that it was time to get off the meds, I was caught completely off-guard.

That's when my trip through hell really began. Following the spectacularly bad advice of the plastic surgeon who prescribed my pills, I set out to wean myself from my medication over the course of four weeks. That is far too aggressive a taper. I later learned that a standard recommendation is to reduce the dosage by no more than 10% a week and to pause or slow the tapering as needed. But that information wasn't, and isn't, common knowledge among prescribers.

The aggressive schedule launched me into withdrawal, and I learned viscerally, firsthand, what the absence of opioids can do to someone whose brain has become accustomed to them. Those symptoms include increased sensitivity to the very pain that the opioids counteract, as well as extreme flu-like symptoms, insomnia, and crippling depression. I came to understand why people sometimes go back onto deadly dangerous drugs: because the alternative is such profound suffering that it makes you want to die.

I lived that lesson every moment of every day for four weeks, but I was incredibly fortunate. With the help of my family, I made it through the intense withdrawal and escaped the chemical hooks of the medication.

But no one in the health care system helped me through the weaning process—none of my prescribers, none of the pain-management doctors we consulted, nor any of the addiction medicine specialists we called. They all seemed to regard tapering as someone else's job, even though any patient on high enough doses of opioids for long enough will become physically dependent.



Travis N. Rieder, PhD, is the Assistant Director for Education Initiatives, Director of the Master of Bioethics degree program and Research Scholar at the Johns Hopkins Berman Institute of Bioethics.

Reprinted with permission from the *Wall Street Journal*.

This all might make it sound like opioids are too dangerous to be permitted. Combine my experience with the nearly 47,000 overdose deaths that involved an opioid in 2018 (the latest full year of data), and we might recoil from the drugs. But that peril is only half the story. Because for those weeks in the hospital and at home, nursing my mangled foot, the analgesic effects of opioids were all that made life worth living. Unmedicated pain was simply unbearable.

Opioids are not only dangerous; they also can be powerfully effective. Perhaps the greatest challenge about them today is to resist the urge to be simplistic or reactionary. America's current crisis of overuse has led some prescribers to avoid the drugs completely, and it has led politicians to occasionally consider ham-fisted policy solutions, like limiting the lengths or dosages of prescriptions regardless of any individual patient's needs. But when a medication has both risks and benefits, what we need isn't one-size-fits-all policies but nuance.

How do we get that? Though the picture is complicated, there are certainly some straightforward changes that we could make. For starters, clinicians need to reduce clearly inappropriate prescriptions. Moderate acute pain that can be effectively treated with acetaminophen and ibuprofen should not be treated with opioids, as has often happened in the past two decades for, say, routine pain from dental work or injury.

When opioids are appropriate—as in the case of severe acute pain—we need much better evidence-based guidelines for dosages, and we need doctors to follow them. Physicians have been aggressively prescribing opioids for decades without any data for guidance. The Michigan Opioid Prescribing Engagement Network (OPEN) is trying to rectify this situation, generating evidence and making recommendations regarding drugs and dosages for various surgeries. For instance, according to OPEN guidelines, while invasive, severely painful surgeries like a knee replacement could call for 50 tablets of 5mg oxycodone, a thyroidectomy should only yield a prescription for five of the pills. The battle now is to get clinicians across the country to use the guidelines, even if it means radically changing their practice.

Prescribing isn't the only relevant act when a patient is on opioid therapy. One of the most shocking features of my experience was that no one told me initially to worry about dependence or addiction, nor counseled me on what pain to expect or how to use the painkillers appropriately.

This kind of patient education is crucial. For other medical interventions we ask patients for their "informed consent," which is supposed to mean that they indicate their understanding and endorsement of a treatment plan. But none of my prescribers from three different hospitals thought that a similar level of understanding and consent was needed for the dangerous pain medications I was on.

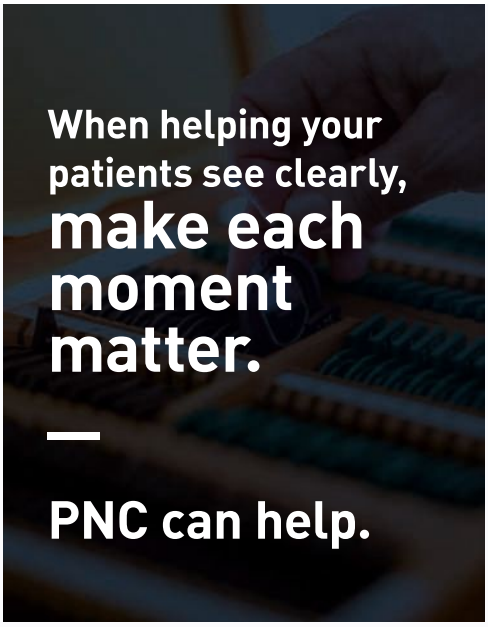
Doctors also must provide an exit strategy. In many instances, this would only require a plan for the number of days of use and a modest taper. But the longer a patient is exposed, the more complex the strategy may be. For every patient on opioid therapy, there must be a clinician who sees long-term management and tapering as their job. We cannot allow medical professionals to play hot potato with opioid patients, trying to toss them to someone else before the timer goes off.

Finally, physicians must compassionately engage with so-called "legacy" patients—those who, thanks to aggressive prescribing and overprescribing, have been on opioids for years or even decades. Taking the drugs away can send them into debilitating withdrawal, and the correct course of action isn't clear. The overdose crisis is no excuse to be callous about their suffering.

It would be nice if opioids were either just evil, dark magic, or (better) the simple solution to all of our pain problems. Then we would know what to do. But they're neither of those things.

A nuanced approach to opioids will be difficult. Extracting the benefits from them while avoiding the harms requires clinicians who know how to use them; a system that rewards clinicians who engage in thoughtful, attentive pain therapy; and a population of patients willing to do the hard work alongside clinicians. All of this will take time and effort. But people are suffering, being badly medicated and dying every day. Inaction isn't an option.

This essay is adapted from Dr. Rieder's new book, "In Pain: A Bioethicist's Personal Struggle with Opioids," published by Harper. It is reprinted with permission from The Wall Street Journal. **MM**









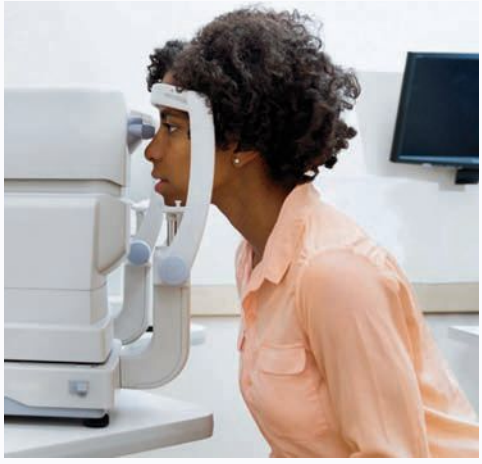


















We're making business banking easier.

At PNC, our team of dedicated Healthcare Business Bankers understands your business challenges and the important role that cash flow plays in your success. That's why we offer a range of solutions to help optimize management of your practice's revenue cycle and payables, so your business can run with less complexity and payments can be received promptly.

Learn more at pnc.com/hcprofessionals or by calling 877-566-1355

PNC BANK
Make today the day.®

©2020 The PNC Financial Services Group, Inc. All rights reserved. PNC Bank, National Association. **Member FDIC**

Correspondence

Public Reporting of COVID-19 Management

I initially was going to only discuss the discrepancies discovered regarding the escape of COVID-19 from Wuhan, China; the dismal failure of the COVID-19 models, e.g. Imperial College epidemiologist Neil Ferguson, who predicted two million casualties in the USA. These flawed 'models' triggered the lockdown of the whole country destroying the economy, producing 30+ millions of unemployed. To appreciate the serious effects on medical care in St. Louis and the region, see "Hospitals, a buffer for St. Louis in last recession, now share economic pain," from the *St. Louis Post-Dispatch*, May 24, 2020, by Annika Merrilees, and Jacob Barkerand. This COVID-19 lockdown produced policies, some irrational, that restrict the freedom of citizens, ignore the Constitution and the Bill of Rights.

This crisis quickly became political. Contradictory opinions were given daily by putative experts; disparate treatments were discussed by the media; divides along political ideologies became obvious. The COVID-19 Wuhan virus was a battlefield where politicians fought a war of blame.

I wish also to express my belief that what was reported as facts by newspapers, networks, internet sites, etc., were really just opinions. These media reports are too numerous to be referenced, and can be found in newspapers, cable TV, networks, etc. They are obvious to anyone that watches an hour of pandemic coverage.

What disturbed and worried me most was the use of medical science to achieve political goals. Contradictory "data," "studies," "opinions of scientists" were used to support political ideologies that went against common sense, such governors and health officials mandating admission of COVID-19 patients to state nursing homes, and leaving packed subways running. The sad part was the involvement of medical professionals in this political never-ending conflict.

These activities showed the transformation of good intentioned physicians and scientists into partisans interested in promoting political views from either side of the enormous political divide. This manipulation of facts and opposing opinions/recommendations may diminish the respect medicine has earned by centuries of selfless care of patients, our search for valid research for cures to save lives, heal, remove pain, bring smiles and happiness to patients.

It is harmful to abuse the faith that people have in the integrity of a profession based on science. Controversy has always existed in scientific research; the experimental method was the foundation that provided the tools to analyze reality. Claude Bernard reminded us, "We must alter theory to adapt it to nature, but not nature to adapt it to theory."

It is dangerous when a society stops trusting our profession, science, and true knowledge. The side taken by the professional is irrelevant, what counts is when people start suspecting the motives and the moral integrity of the experts. It is sad to see intelligent people trusted with carrying the flame of the noblest calling abandon the honorable tradition of our profession and become partisan political advocates.

We need to return to the roots of our profession. We need to work together having always present why we decided to devote our lives to serve our patients. Our calling is sacred, we have the great privilege to be able to heal, give hope, and sometimes cure. We need to distinguish between opinion and science.

J. C. Corvalan, MD
St. Louis, Missouri
MSMA member since 1976

COVID-19 Guidelines for Sports and Physical Activity

As the medical community continues to deal with the COVID-19 pandemic and its impact on our society, much of the effort has been spent on how to safely return to a "new normal." Sports and physical activity are a large part of society. Secondary to this, it is vital that we plan for the safety of each participant in multiple settings.

The St. Louis Sports Medicine COVID-19 Task Force, a collaboration between medical experts at BJC HealthCare, Mercy Health Systems, and SSM Health worked together to provide a set of recommendations for return to youth and high school sports in the St. Louis region.

The recommendations depend on each community meeting gating criteria as stated in the Center for Disease Control (CDC) and the White House

guidelines for Opening Up America Again. Once met, we recommend 4 phases as below. As each community works through the return to play phases, it is vital that the gating criteria is reviewed and met with each step. Obviously, different communities will be to progress faster than others.

Phases

- Phase 1: Groups of only 10 or less people should be at team workouts or practices. Social distancing should remain during these practices.
- Phase 2: Team practices can begin. They should be limited to one on one drills and individualized equipment. Social distancing should be in place for most of the practice.
- Phase 3: Full team practices and scrimmages can begin.
- Phase 4: Full competition can begin, but it should be limited to local and regional teams.

The recommendations include doing a COVID-19 symptom screen prior to any activity start for all athletes, coaches, and officials. This can include a temperature check but is not required. If there is a positive response, the person is isolated, sent home, and asked to seek further care. They are not allowed to return until they have a negative PCR test or a clearance letter from their medical provider. Social distancing during and between activities and hand hygiene is essential. We recommend no use of locker rooms or sharing of water bottles. Practices and games should be spaced out with no spectators at any practices. Face coverings should always be worn by parents, coaches, and officials. Equipment should be regularly disinfected as often as feasible.

To view the entire list of recommendations visit: https://www.mercy.net/newsroom/2020-05-19/st--louis-health-care-systems-collaborate-to-offer-guidance-for-/.

Our task force hopes these recommendations will be used to guide a safe, timely return to sports in Missouri.

Brian L. Mahaffey, MD, MSPH, FAAFP, CAQSM
Medical Director, Mercy Sports Medicine
Team Physician and Coordinator of Major League Medical Services, St. Louis Cardinals
MSMA member since 1999

March/April 2020: Special COVID-19 Issue

Congratulations on a very timely and information-packed issue! I know you two (John Hagan, MD, Editor, and Lizabeth Fleenor, Managaing Editor) did a lot of work, and you were very successful!

Charles Van Way, III, MD
Kansas City, Missouri
MSMA member since 1989

Editor's Note: Should We Have Seen This (COVID-19 Pandemic) Coming? Addendum, President George W. Bush Did in 2005 and Began Planning

At the end of my *Missouri Medicine* March/April 2020 editorial on COVID-19, I asked rhetorically if we should have seen the pandemic coming (page 80-81). I quoted Bill Gates' 2015 TED talk suggesting a pandemic was more likely than a nuclear war to cause millions of deaths in the next 10 years, and a 2007 scientific paper from Clinical Microbiology Review predicting the re-emergence of novel COVID viruses from China. A physician-researcher subscriber sent me this YouTube video in which President George W. Bush in 2005, during his address to the National Institutes of Health, predicted a future pandemic like COVID-19. View here: https://www.youtube.com/watch?v=uSDC5L7qYUc.

Then President Bush called for $7 billion from Congress and future administrations to prepare for the inevitable pandemic. Bush called for: 1) world-wide monitoring for virulent viruses and early outbreak warning; 2) A national pandemic plan for the U.S. to protect citizens by stockpiling of essential materials, rapid vaccine development and deployment; and 3)coordinated plans of local, state, and federal governments to deal with social, health, and economic exigencies caused by the pandemic. Bush predicted the need for social distancing, and said the effects of a pandemic could last "for a year or more." At that 2005 meeting, he announced a government website for information on pandemics at www.pandemicflu.gov (still up and running). Among the physicians and scientists attending (listening?) to President Bush was CDC head Anthony Fauci, MD.

It is worth your time to view the video. Odds are you will not see reference to President George W. Bush's prescient, but ignored, admonitions on the national media. I thank the physician contacting me for adding this insight. **MM**

Missouri Medicine in the News

The Journal announces changes in the Editorial Board.

Hariharan Regunath, MD, MSMA member since 2019, is the new Editorial Board Member for Infectious Disease. Dr. Regunath practices Critical Care Medicine, Infectious Diseases, and Pulmonary Disease at the University of Missouri - Columbia School of Medicine/ MU Health Care. He replaces Eden Esguerra, MD, whom the Journal thanks for her service on the Board since 2011. Dr. Esguerra has been honored with the *Missouri Medicine* Distinguished Service Award.

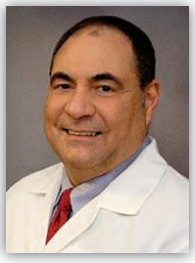


Evan Schwarz, MD, has been named the Editorial Board member for a new medical specialty: Toxicology & Addiction Medicine. Dr. Schwarz, MSMA member since 2014, is a board certified physician in Emergency, Toxicology, and Addiction Medicine at Washington University in St. Louis.



Missouri Medicine regretfully reports the death of internationally-known former Editorial Board member for Allergy and Immunology, Chitra Dinakar, MD.

The Journal would also like to thank the following MSMA Section leaders for serving on the 2019-2020 Editorial Board and welcome their 2020-2021 replacements: Medical Student Section: Calli Morris, BS (departing), Alex Shimony, BS (new); Resident & Fellow Section: Frances Mei Hardin, MD (continuing); Young Physicians Section: Fola Fasuyi, MD (departing), Marc Mendelsohn, MD (new); and Women Physicians Section Joanne Loethen, MD (continuing).



Keith Bonacquisti, MD, recently joined Lake Regional ENT and Audiology. MSMA is proud to have Dr. Bonacquisti, as one of our newest members.



Stuart Braverman, MD, of Sedalia, has been a steadfast supporter of MSMA since 1992. MSMA applauds Dr. Braverman's recognition by the University of Missouri School of Medicine as the recipient of the Rural Track - Distinguished Community Based Faculty Award.

Congratulations to Janet Dunn, MD, on joining St. Joseph Medical Center and helping expand their psychiatric services. MSMA appreciates your membership since 2006.



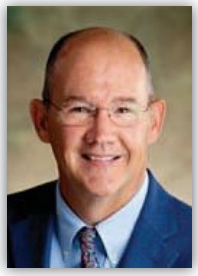


Congratulations to Patrick B. Harr, MD, MSMA member since 1976, on receiving the honorary Doctor of Humane Letters degree from Northwest Missouri State University. Dr. Harr is a valuable asset to his community and to MSMA.

Luke Small, MD, recently joined Saint Francis Healthcare System's Cape ENT Group and is also a new member to MSMA.



Jeffrey Tedrow, MD, is now providing family practice care at Katy Trail Community Health in Warsaw. Dr. Tedrow has been an MSMA member since 1983.



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

MM

Alliance Finally Takes a Virtual Bow

by Gill Waltman

This year's end-of-year Annual Meeting of the Alliance was decidedly non-traditional! When the MSMA made the decision to cancel the state convention in St. Louis because of the pandemic, the Alliance followed suit and cancelled its Annual Meeting too. Consideration was given to delaying a gathering for a month or two and combining the annual business meeting, the installation of officers, and the incoming president's executive board meeting into a one-day meeting in Columbia. In retrospect, that anticipated early May date was sadly far off the mark.

After further deliberation, it was decided to hold two separate virtual events; the annual business meeting and a combined Awards Ceremony and Installation of Officers.

The first of these was held on Thursday, April 30, via a Zoom conference with Gill Waltman still presiding as President, and Recording Secretary Sana Saleh acting as the Zoom host. There was an excellent attendance with the full board present. Sana had collected and collated annual reports from all the officers and committee chairs and created an electronic version for distribution prior to the meeting. The hard copy will be made available at a later date when the Alliance members can meet in person. Business conducted included approval of the minutes from the Winter Board Meeting held March 2 in Jefferson City, brief summaries from the president and president-elect, and financial reports from Treasurer Debora Snyder and Budget and Finance Chair Allene Wright.



Gillian Waltman is the Immediate Past President of the MSMA Alliance and Professor, Ophthalmology, Saint Louis University, St. Louis, Missouri.

Immediate Past President and Nominating Committee Chair Marsha Conant presented the slate of officers for 2020-2021, and this was voted on and accepted unanimously. Nominations were taken for members to serve on the 2020-2021 Governance Council. Five were nominated and members were asked to vote electronically for four of the five the following day, as an anonymous vote is hard to finesse on a Zoom conference. Those elected will serve on the committee with next year's Nominating Committee Chair Gill Waltman.

The Zoom conference ended with a poignant memorial ceremony conducted by Kathy Weigand in memory of those members or their family members lost in the past year. She also recognized two members' sons serving in the U.S. Airforce and welcomed several new grandchildren.

The following week on Friday, May 8, a second Zoom conference took place for members to 'attend' the Awards Ceremony and Installation of Officers. President Gill Waltman welcomed everyone and introduced special guests. The MSMA Alliance was delighted to welcome AMA Alliance President Mary Beth Ellison from Akron, Ohio. Allene Wright was introduced as the installing officer. Incoming president Diana Corzine introduced her siblings Glenn Hugi and Sherry Hugi, son Jason Corzine, and good friend Nancy Tanner Edwards, PhD, who was invited to give the invocation.

A brief farewell commentary was given by Gill as she completed her second term as MSMA Alliance president. She thanked her board members and committee chairs for their support and service. She talked about the successes and happier times of the past two years, including two great Fall Conferences with first-rate conference chairs Donna Corrado (Fulton 2018) and Sandra Murdock (Hannibal 2019), and two excellent Legislative Days (February 2019 and March 2020 with White Coat Day) organized by Kirk Doan. Kathy Weigand organized the successful British Invasion as the Foundation Fundraiser in Kansas City at the state convention in April 2019, but the plans that her committee had put in place for a James Bond-themed event this year were thwarted by the pandemic.





Next, Mary Beth Ellison addressed the members and gave an update on AMA Alliance activities. She discussed the final plans for the Annual Meeting in Chicago, where our very own Sue Ann Greco will be installed "virtually" as AMA Alliance President on Saturday, June 6. All the other in-person activities have been cancelled, but there are several virtual activities being planned. Although there is no charge for the virtual business meeting and installation, Mary Beth encouraged members to register online for the event.

Following Mary Beth's address, Awards Committee Chair Barbara Hover was introduced and presented the Jean Wankum "Spirit of the Alliance Award" to Past President Jana Wolfe from Greene County. Jana has a nursing background and has been involved as a volunteer in many organizations over the years. Barbara described how Jana has embraced many of the causes of these organizations, not least of which has been her local, state and national involvement in the Alliance.

MSMA liaison to the Alliance Liz Fleenor then presented the Jean E. Duensing Literary Award to deserving member Allene Wright from Buchanan County. Liz spoke of the role Jean Duensing had with the MSMA staff many years ago and described how the award was established. Liz said that Allene was recognized for her meticulous record keeping over the years and for being a "bulldog" when working on the details for our Annual Meetings.

The installation ceremony began with an introduction of Nancy Tanner Edwards, PhD. Nancy is a friend of several Buchanan County members, and spoke eloquently on the responsibilities of taking office and set a serious tone for the installation.

Installing officer Allene Wright gave a warm introduction and described Diana's background and talked of her long involvement in the Alliance.

Allene recognized the board members who had served on the board for the past year and then installed the 2020-2021 Alliance officers. Diana Corzine (President), Barbara Hover (President-Elect), Kelly O'Leary (VP Foundations), Angela Zylka (VP Health), Kirk Doan (VP Legislation), Jennifer Gast (VP Membership), Mary Catherine Heimburger (Recording Secretary), Debora Snyder (Treasurer). Those officers being installed raised their right hands to highlight their position on the Zoom screen and a photo was taken by Liz Fleenor. Diana was presented with flowers by her son Jason.

The ceremony continued with the virtual hand-off of the president's pin and gavel from Gill to Diana, and the presentation of a past president's pin to Gill from Marsha Conant. Diana then announced that donations exceeding $1,000 have been collected from members in Gill's honor for the St. Louis Society for the Blind and Visually Impaired.

A highlight of the ceremony was a delightful and very professional-looking video, complete with the soundtrack That's What Friends Are For, made by the Conants with highlights of Gill's two years as president.

Diana then gave her presidential address. She thanked Nancy for the invocation and Allene for her introduction. She acknowledged those who had mentored her leading up to this role, especially the six MSMA Alliance past presidents from Buchanan County – Eileen Dyer, Marsha Conant, Mary Shuman, Rhonda Wade, Kathy Weigand, and Allene Wright. She thanked Gill Waltman for her encouragement and advice throughout her two terms as President-Elect.

She talked about the strong traditions of the Alliance and the dedication and flexibility of its members and how our organization and its traditions have been challenged in recent times. She talked of her vision for the Alliance for this year and hoped to continue most of the fine community health programs we already have in place, depending on the social restrictions in the coming months. She still hopes to hold her Executive Board Meeting in person in Columbia at a future date.



Special presentations were made to Diana by Marsha Conant and Kathy Weigand representing Buchanan County. First was the Anna McGlothlan Award, named after the first Buchanan County Auxiliary president to become MSMAA president (1926-27) and then AMAA President (1931-32). It is in the form of a Pony Express rider because of St. Joseph's association with the starting point for the riders. Diana also received a congratulatory letter from James Reynolds, MD, President of Buchanan County Medical Society. **MM**

St. Louis Metropolitan Medical Society

Despite Challenges, St. Louis Physicians Rise to the Test

As 2020 marks both the beginning of a new decade and the 184th year of organized medicine in St. Louis, no one could have predicted the challenges that physicians would be facing during this arduous time, including COVID-19, prior authorizations, and bureaucratic healthcare systems. But one thing remains constant: the St. Louis Metropolitan Medical Society (SLMMS) continues to advance its mission "to support and inspire member physicians to achieve quality medicine though advocacy, communication and education." The Society is inspired to move forward by its vision and purpose, "physicians leading healthcare and building strong physician-patient relationships."

Challenges are met with strong leadership, and SLMMS has been fortunate to be guided by physicians who are committed to working to overcome them. In 2019, Ramona Behshad, MD, a SLUCare dermatologist, served as President of the Society, becoming its first female leader in over 20 years, and only the third in its long history. In her inaugural address, Dr. Behshad noted how it was both an exciting and challenging time for medicine. Exciting due to the advancements in treatment, pathology, and public health, but challenging because the patient-doctor relationship is threatened and weakening. "Despite all of the technology and science we bring to the bedside," she noted, "I believe our humanity, our caring, and our concern is the ultimate measure of success. Contrary to this, success is currently measured with metrics, computer systems, encounter numbers and satisfaction scores."

Dr. Behshad's term as SLMMS President was notable for helping to build understanding of the power of organized medicine, increasing participation and encouraging advocacy, particularly among younger physicians. She was named to the *St. Louis Business Journal's* 2019 "40 Under 40" class, an honor recognizing young professionals who are already making their mark on the St. Louis business community. Her objectives as president included engaging more medical students, providing mentorship, and combating burnout through community.

"Advocacy cannot be someone else's problem," she stated. "We need to be present to improve the system, and our local medical society is a great place to start. The successes of organized medicine prove that we are stronger together; when we are working in unity, there is no limit to what we can accomplish."





Left, 2020 SLMMS President - Jason Skyles, MD, MSMA member since 2011; right, 2019 SLMMS President - Ramon Behshad, MD, MSMA member since 2012.

Choosing Wisely

SLMMS has continued to build upon the momentum created from its 2018 physician-driven insurance survey, designed to capture physician assessment of insurance company performance. SLMMS leaders were invited to present the study findings to the boards of directors of both the St. Louis Area Business Health Coalition and the Midwest Health Initiative (MHI). The subsequent dialog led to a partnership with MHI to analyze Choosing Wisely opportunities in the St. Louis market. The objective of the project is to meaningfully improve adherence to recommended care and reduce low-value care in the region, through an engaged, multi-stakeholder approach using measurement, education, and aligned, coordinated interventions. SLMMS members have





2019 White Coat Rally
Top: SLMMS members - Edmond Cabbabe, MD, Inderjit Singh, MD, Samer Cabbabe, MD, and Toniya Singh, MD, with State Senator Jill Schupp.

Bottom: SLMMS members and medical students in the Capitol rotunda.

been working with MHI committee physicians to offer input and direction on shared opportunities identified by the program.

Issues Advocacy

SLMMS continues to use its collective voice on key issues that impact the practice of medicine. In recent months, the Society has tackled many issues, including air ambulance coverage, surprise billing, and barriers impacting prior authorization. SLMMS actively opposed the medical marijuana ballot issues in Missouri, given that risks to the patient supersede the lack of any extensive research studies demonstrating its health benefits. SLMMS members have brought forward resolutions at the state level addressing prior authorization for opioid use disorders, the healthcare needs of children of incarcerated parents, and ensuring affordable insulin. The Society has supported the continued development of St. Louis County's Prescription Drug Monitoring Program as it has been adopted more widespread across all of Missouri.

St. Louis Metropolitan Medicine

SLMMS continues to publish its bi-monthly member magazine *St. Louis Metropolitan Medicine*. Each issue addresses a specific theme, and the journal has provided a platform for discussions on the use of artificial intelligence in medicine; accountable care organization (ACO) collaboration and results; and emergency department use. The magazine also encourages regular commentary contributions from SLMMS members. In 2019, the magazine sponsored a survey on electronic health record utilization to reveal

areas where improvement is most needed. The majority of physicians responding felt the EHR system they use is better suited to enhancing billing and coding, and less inclined to improve patient care.

Continuing Education

The Medical Society sponsors or supports a number of physician continuing medical education programs. The annual Hippocrates Lecture tackled drug pricing transparency in 2018, giving members the opportunity to engage in conversation with a pharmacy benefits manager. In 2019, the lecture focused on Medicare for all, and a discussion with an advocate from physicians supporting a national health program. Through our relationship with the League of Healthcare Experts, recent programs have been presented on changes to tax laws and physician burnout.

Navigating Change

Radiologist Jason Skyles, MD, a fellowship-trained mammographer with West County Radiology group providing services to Mercy Hospital St. Louis, assumed the role of SLMMS President for 2020. At his installation, Dr. Skyles spoke on the accelerated rate of change in the practice of medicine. "It's an exciting time, but also a scary time," he said. "In the next 20 years we will likely see the implementation of technologies like genomic editing and the use of artificial intelligence. As physicians, we should be the ones leading the discussion on all issues related to medicine and helping to direct policy for the betterment of the medical profession, and ultimately for the benefit of our patients."

Dr. Skyles enumerated issues that physicians need to address, including fighting the anti-vaccination movement, protecting the role of physician in scope of practice discussions, tort reform, and working with insurance companies to improve access. "Organized medicine gives us the strong unified voice to tackle these things, and allows the local physician to get involved," he stated. "We need to ensure that physicians maintain an active role in helping to shape future policy."

SLMMS in the Community

SLMMS continues to connect with medical students and residents, with student liaisons from both Saint Louis University School of Medicine and Washington University School of Medicine participating on the SLMMS Council. Grants from the Society's charitable foundation, the St. Louis Society for Medical and Scientific Education (SLSMSE), have supported the innovation incubator programs (SlingHealth at Washington University and MedLaunch at Saint Louis University) at both schools. SLSMSE also supports other physician and community activities such as the Greater St. Louis Science Fair, World Food Day, the SLU Primary Care Symposium, the Missouri Physicians Health Program, and the SLMMS Alliance. The Alliance continues to play an integral part of fulfilling the SLMMS mission through community health education, charitable projects and legislative advocacy. Two St. Louis Alliance members are making their mark at the state and national levels as well, with Gillian Waltman finishing two years as the MSMA Alliance President, and Sue Ann Greco assuming the presidency of the AMA Alliance in June of 2020.

SLMMS is also proud of three physician members serving in visible leadership roles: Sam Page, MD, moved from chair of the St. Louis County Council to serving as St. Louis County Executive in 2019; Emily Doucette, MD, a current member of the SLMMS Council, was named acting co-director of the St. Louis County Department of Public Health in 2019; and George Hruza, MD, a SLMMS past president, was recently elected the 2020-2021 President of the Missouri State Medical Association.

Looking Forward

The practice of medicine has been disrupted this year by the COVID-19 pandemic. SLMMS has served as a conduit for providing information to its members and the St. Louis physician community, dedicating publication space to public health responses, summarizing the impact on physician practices, and creating an online resource page. COVID-19 has taught us some very tough lessons, and elevated concern for the health and well-being of medical professionals on the front lines of treatment. Dr. Skyles, SLMMS President, addressed members saying that "all of us can play an important role in education. Most of us are not infectious disease or public health experts, but as physicians our patients, friends and families look to us for guidance and assurance. In times of crisis such as now, we all need to not only come together, but to work smartly and efficiently for the benefit of all." **MM**

More Important Than Ever

Telehealth and Outreach in the Post COVID-19 World: The MU Show-Me ECHO Program as a National Model

by Karen Edison, MD

Missouri Telehealth Network
University of Missouri

Our Show-Me ECHO program is one of seven ECHO Super Hub sites in the U.S., and we are training other states and other countries to begin ECHO in their regions.

Show-Me ECHO (Extension for Community Healthcare Outcomes) is an innovative and practical solution to the lack of access to specialty healthcare in rural and underserved areas of Missouri. (See Appendix 1) describing the model in detail. It is the brainchild of Sanjeev Arora, MD, hepatologist at the University of New Mexico. In 2003, he realized patients were dying from the complications of untreated hepatitis C and committed himself to training a larger healthcare workforce prepared to treat these patients. About five years ago, R. Wayne Cooper, MD, then state representative from Camdenton, Missouri, learned about Project ECHO and made sure the leadership of the Missouri Telehealth Network (MTN) was aware of it. A group of state legislators and MTN leadership attended a Project ECHO conference in Albuquerque in 2013. We quickly realized that Project ECHO was needed in Missouri. Thankfully, with the help of Dr. Cooper and Missouri Representative Diane Franklin, our state's leaders agreed.

In this edition of *Missouri Medicine*, dedicated to Wayne Cooper, MD, you will learn about the Show-Me ECHO program, its growth, and the positive outcomes we are seeing: early indications of improvements in access to care, quality of care delivered, and early evidence that costs may be reduced in some diseases and geographic areas. You will also read about the perspectives of the Show-Me ECHO professional participants and the importance and promise of including the patient and patient caregivers' input and viewpoint. A thorough look at telehealth in Missouri is included, along with a discussion of the importance of creating health care learning collaboratives to encourage high quality patient outcomes.

The COVID-19 pandemic has made vividly clear the need for the availability of both telemedicine for safe patient care and the ECHO model for safe and effective continuing medical education. Because the Missouri Telehealth Network already had a highly effective team with experience and skill in creating and launching ECHOs, we were able to quickly assemble COVID-19 ECHO programs early in the unfolding coronavirus crisis. COVID-19 ECHO was created to provide timely education across the state to enable healthcare providers to make informed care decisions based on the latest pandemic evidence.

We have seen rapid growth of our ECHO programs over the past five years and are now



Karen E. Edison, MD, FAAD, MSMA member since 1991, Professor Emerita of Dermatology, Senior Medical Director, Show-Me ECHO/Missouri Telehealth Network, and Senior Medical Director, Missouri Center for Health Policy, University of Missouri Health Care.
Contact: edisonk@health.missouri.edu

reaching 93 of Missouri's 114 counties as well as the city of St. Louis. We envision continued growth and even better outcomes in the future as the program matures, we better understand how to assess patient outcomes in the various ECHOs, and we beneficially touch more lives in Missouri.

I have used telemedicine to care for rural and underserved dermatology patients throughout Missouri for the past 26 years. This has given me a unique perspective on the quality of care delivered. While rural Missouri has committed, high-quality healthcare professionals, in many areas there is a lack of specialty care for patients. This lack of access has serious consequences, including "unmet health needs, delays in receiving appropriate care, financial burdens, and preventable hospitalizations."[1]

Missouri has a loan repayment program called PRIMO (Primary Care Resource Initiative) designed to encourage primary care physicians (PCPs) to practice in underserved areas of Missouri, and this program has had some success. But, rural hospital closures (14 since 2014) have had a negative impact on access to care, putting a heavier burden on the remaining providers and clinics. Medical schools, especially the University of Missouri School of Medicine in Columbia, have promising educational programs that place students in underserved areas with the hope that some will stay. Thankfully, some do – but we struggle to place new doctors in rural Missouri where our current workforce is aging. In 2018, the average age of rural Missouri physicians was 60 years old, and 60% were over the age of 50.[2] As rural physicians are aging, care is shifting increasingly toward generalist advanced practice nurses and physician assistants, some with gaps in their training to care for the complex patients they see. Also, recommended best practice and evidence-based medicine is changing rapidly making it difficult for busy PCPs to keep up to date. Show-Me ECHO can be part of the answer for these challenges.

Missouri ranks 39th out of 50 states in recent health rankings. We do have high quality and committed health foundations, healthcare systems, academic health centers, and state health agencies; however, in the past two decades we have been unable to see a sustained improvement in the healthcare outcomes reflected in the rankings.[3]

In 2008, the Institution for Healthcare Improvement (IHI) released their "Triple Aim" framework to evaluate new innovations in health care: 1) improve the patient experience (quality and satisfaction); 2) improve population health outcomes; and 3) decrease the per capita cost for healthcare.[4] Nearly all the innovations in healthcare I have seen in my career have improved one aim, while making the others worse and some have arguably made all three worse. (The electronic health record comes to mind.) The ECHO model improves all of the Triple Aims, leading to increases in access to high quality care and better patient outcomes which decrease the per capita cost for healthcare. Also, with increasing recognition of the problem of physician burnout, many add the fourth aim of healthcare team well-being.[5] Show-Me ECHO helps in these areas as well. It is frequently cited by hub team members and primary care participants alike as one of the most enjoyable activities they do at work.

Missouri should be proud! Our Show-Me ECHO program is one of seven ECHO Super Hub sites in the U.S., and we are training other states and other countries to begin ECHO in their regions. I hope you will read this issue of *Missouri Medicine* cover to cover and plan to join one or more ECHOs in the future. Simply go to showmeecho.org to register and the Missouri Telehealth Network will take care of the rest.

References

1. U.S. Department of Health and Human Services, Healthy People 2020. Access to Healthcare Services. https://www.healthypeople.gov/2020/topics-objectives/topic/Access-to-Health-Services , Updated January 15, 2020. Accessed January 15, 2020.
2. Becker, M. Missouri Hospital Association. Primary Care Physicians — Missouri Workforce Update. https://www.mhanet.com/mhaimages/Special%20Reports/Primary%20Care%20Physician%20Status_0818.pdf Published August 2018. Accessed January 15, 2020.
3. America's Health Rankings United Health Foundation. 2018 Annual Report. https://www.americashealthrankings.org/learn/reports/2018-annual-report/findings-state-rankings Accessed January 15, 2020.
4. Berwick, D., Nolan, T., Whittington, J. The triple aim: care, health, and cost. Health Affairs 2008; 27(3):759-69.
5. Feeley, D. The Triple Aim or the Quadruple Aim? Four Points to Help Set Your Strategy. Institute for Healthcare Improvement. http://www.ihi.org/communities/blogs/the-triple-aim-or-the-quadruple-aim-four-points-to-help-set-your-strategy Published on November 28, 2017. Accessed on January 15, 2020.

MM

Embracing the Power of Show-Me ECHO Learning Communities to Transform Clinical Practice in Missouri

by Lea Brandt, PhD, Melissa Warne-Griggs, PhD, Kimberly Hoffman, PhD, Lori Popejoy, PhD & E. Rachel Mutrux, BA

Missouri Telehealth Network
University of Missouri

Show-Me ECHO acts as a catalyst to shift professional development, moving learning from learning in isolation about a complex medical problem to learning as part of a multidisciplinary team and learning how to provide comprehensive care for real patients.



Lea Brandt, PhD, OTD, MA, (above), is Associate Professional Practice Professor; Melissa Warne-Griggs, PhD, is an Administrative Consultant; Kimberly Hoffman, PhD, is Professor Emerita, Family and Community Medicine; Lori Popejoy, PhD, RN, FAAN, is Associate Professor, School of Nursing; and E. Rachel Mutrux, BA, is Senior Program Director, Missouri Telehealth Network, Director, Show-Me ECHO, State Director, Heartland Telehealth Resource Center; all are at the University of Missouri-Columbia, Columbia, Missouri.
Contact: brandtlc@health.missouri.edu

Abstract

Show-Me ECHO, a state-funded project, provides access to education within a community of learners in order to optimize healthcare for the citizens of Missouri. Through videoconferencing and case-based review, ECHO shifts professional development from learning about medical problems in isolation to experiential learning as part of a multidisciplinary team. The establishment of a statewide COVID-19 ECHO is allowing a rapid response to this novel, unprecedented, and unanticipated health care crisis. There are many ongoing opportunities for clinicians from across the state to join a Show-Me ECHO learning community as a means to elevate their practice and improve ability to respond amidst a constantly evolving health care environment.

Introduction

In a personal interview, Dr. Sanjeev Arora, a Hepatitis C specialist at the University of New Mexico, recalls a patient's story that inspired him to start the Extension for Community Healthcare Outcomes project (Project ECHO). The patient was a 43-year-old woman with Hepatitis C, who was a single mother of two after being widowed when her husband died in a car accident. There was an eight-month wait to see Dr. Arora, a Hepatitis C specialist located hundreds of miles from her home. Unfortunately, by the time the woman was able to get in to see Dr. Arora she had already developed cancer of the liver. The greatest tragedy of this story is that her illness was curable with early treatment. Because providers in her area lacked the evidenced based knowledge about how to treat Hepatitis C, she died a premature death, orphaning her two children.[1]

While every patient's story is unique, this type of situation occurs regularly across the US. Even though the US healthcare system is home to some of the most sophisticated treatments and medical technologies in the world, there are vast discrepancies in the quality of care to which patients have access depending on their geographic location and the knowledge of the providers within their communities.[2] In response to these types of barriers, the Institute of Medicine (IOM) published multiple blue-ribbon reports describing the essential features of quality care: health care that is safe, effective, patient-centered, timely, efficient and equitable. The IOM

Best Care at Lower Cost: The Path to Continuously Learning Health Care in America outlines a vision to catalyze effective, efficient high quality care in a system that continuously learns to become better.[3] Show-Me ECHO, a state-funded telehealth project created and operated by the Missouri Telehealth Network at the University of Missouri, addresses the IOM's six domains of quality care by offering opportunities for health care providers to participate in learning communities aimed at improving access, safety, and elevating the care provided to residents across the State of Missouri and beyond.

ECHO connects primary care providers with each other, with local resources, and with specialists through structured and formalized live-interactive video sessions. By linking rural and underserved populations with specialized expertise, Show-Me ECHO elevates care and promotes lifelong learning by providing clinicians access to the most current knowledge they need to effectively care for their patients. Existing literature demonstrates that the ECHO principles are congruent with other national calls for health care reform: 1) Macy Foundation's 2008 call to shift continuing medical education to focus on practice-based learning; 2) Institute of Medicine's (IOM) 2009 report describing the role of continuing education to achieve and maintain proficiency, and 3) Carnegie Foundation's 2010 description of the significant challenges, and needed changes in preparing physicians for the future.[4] The ECHO model resonates with salient features of Best Care at Lower Cost: The Path to Continuously Learning Health Care in America[3] including the need to: 1) generate and apply knowledge in real time, 2) engage patients, families and communities in the provision of care, 3) manage increasing clinical complexity, and 4) leverage opportunities from technology. The ability of the ECHO model to meet these needs was demonstrated in Show-Me ECHO's quick response to COVID-19 which helped providers to generate and apply knowledge in real time in order to meet the demand of ever-changing guidelines and knowledge.

Background

Show-Me ECHO began in 2014 after a Missouri team visited the University of New Mexico, home to Dr. Sanjeev Arora and Project ECHO. There they learned about the success of ECHO, a technology-enabled collaborative learning and capacity building model for Hepatitis C. The ECHO model "connects specialists with multiple other health care professionals through simultaneous interactive videoconferencing for the purpose of facilitating case-based learning, disseminating best practices and evaluating outcomes".[5] ECHO has been replicated across the United States and internationally to address a wide variety of disease conditions. Key features of ECHO programs include: 1) a hub and spoke organization where multidisciplinary content experts mentor participants through teleconferencing, 2) regular and recurring virtual meetings, 3) focused didactic presentations, and 4) case-based learning where participants select and present cases from their own practices.[5] ECHO offers an alternative to traditional continuing education as it situates learning within authentic professional practice and connects to workplace learning.[4, 6, 7] Show-Me ECHO connects Missouri primary care providers with each other and with specialists as well as other health care team members. Diverse perspectives are incorporated into ECHO, as the teams may include, among others, persons with lived experience, physicians, nurses, social workers, therapists, community members, counselors, chaplains, administrators, etc. These multidisciplinary participants collaborate in a case-based learning environment where discussions with, and mentoring from, content experts help equip providers with the knowledge and tools they need to give their patients the right care, in the right place, at the right time.

In recognition of its rigorous adherence to the key tenets of ECHO, the University of New Mexico's Project ECHO designated Missouri's Show-Me ECHO as a "Super Hub" training organization, one of only seven global sites. As a super-hub, Show-Me ECHO provides immersion training for new ECHO content expert panels and staff. What began as a partnership with the Missouri Primary Care Association (MPCA) to support one pilot chronic pain management ECHO in 2014 has grown into 22 Show-Me ECHOs with more in the planning stage (Appendix 1). Show-Me ECHOs are scheduled for 1-1.5 hours, and most occur year-round.

Table 1. Show-Me-ECHO Participants from Inception through December 2018

Show-Me-ECHO Project	# of Participants	# of Participants' Cases Presented	# of MO Counties
Autism	93	105	28
Asthma	164	145	34
Child Psychiatry	85	25	28
Community Health Worker	166	25	35
Dermatology	86	392	28
Hepatitis C	39	140	20
HIV	32	3	5
Multi-Tier System of Support	104	9	18
Opioid Use Disorder	116	22	25
Pain Management	101	41	36

Table 2. Pre-Post ECHO Participation Outcomes Data

ECHO	Medicaid Claims Data	Pre-Post ECHO Participation Outcomes
Pain Management	Opioid Prescribing Patterns Morphine Milligram Equivalents (MME)	19% decrease in MME*
Autism	Child Development Screenings	29% increase in screenings
Dermatology	Claims containing one or more specific dermatology diagnosis code	452% increase in coding specificity**

** 2 years post participation*
***by providers that attended more than one Dermatology ECHO*

Learning occurs through three routes: 1) short didactic presentations, 2) deidentified case presentation selected from the clinical practices of participants and 3) opportunities for practice and feedback among all participants as they consider the case.[4, 8] Content experts facilitate discussions and model the best approach in management of each case. Although Show-Me ECHO draws participants from across the United States and internationally, it focuses on the needs of Missourians.

ECHO creates a bridge between academic medical centers, other content experts, and multidisciplinary teams, and increases access to care in rural and underserved areas.[2] Show-Me ECHO recruits expert mentors from across the state, to ensure that these teams have the opportunity to work with specialists in the field. Nearly 300 participants from different health care organizations in 21 counties and three states have been represented on the expert hub teams from inception in 2014 thru December 2018. Additionally, Show-Me ECHO has touched 80 of Missouri's 114 counties plus the city of St. Louis. This geographic diversity is evidence that the University of Missouri recognizes and partners with experts located throughout the state who can best understand local resources, contacts, and realities for providing care in underserved areas. The number of learners engaged by Show-Me-ECHO, the number of Missouri counties participating, and the number of case-based learning opportunities are presented in Table 1.

Other articles in this series examine outcomes in more detail, however, Table 2. provides illustrative examples of the impact of Show-Me ECHO on patient care. It is important to note that patients benefit not only indirectly through the knowledge acquired by participating clinicians, but also directly. Patients whose case is presented during ECHO, directly benefit from the review by a community of learners, whose combined expertise exceeds the knowledge of any one provider.

Although ECHO models are now widespread, a February 2019 Report to Congress calls for strengthening the evidence base to help determine how best to expand use of the ECHO model.[5] One must understand the essential features of ECHO in order to successfully replicate this model. In this article, we draw from rich literature on adult learning, social cognition, situated learning, communities of practice and learning organizations to describe how and why the ECHO model enhances learning and transforms learning into improved patient outcomes. In addition, the article provides a reflection on how established ECHO learning communities were leveraged to generate and apply knowledge in real time during the COVID-19 pandemic.

Connecting Learning to Professional Practice

Lifelong learning is critical to high-quality medical practice. Because clinical information

is constantly growing, successful clinicians must persistently refresh medical knowledge and understand personal limitations related to knowledge acquisition and application. This requires a commitment to self-assessment and to identifying learning needs.[9] Reflection is a necessary skill for self-directed learning because the individual must be able to consider their own strengths and weaknesses in order to pursue learning. Traditional cognitive approaches to expertise often emphasize diagnostic ability and assume that expertise is an end-state of mastery of existing knowledge and technique. However, these assumptions of the cognitive model unnecessarily limit conceptions of expertise in medicine and elucidate the need to distinguish between "routine expertise and "adaptive expertise".[10] Routine expertise involves a set of habits used by the practitioner. Adaptive expertise, on the other hand, is flexible and involves combining old and new knowledge to generate different ways of thinking about a problem in order to achieve meaningful learning.[10] When practitioners engage in meaningful learning it fosters flexibility and a more comprehensive understanding of health in order to better meet the dynamic needs of patients, giving practitioners the tools necessary to incorporate context and alternative approaches into practice.

Adult learning theories tell us that adults prefer learning opportunities that draw upon their life experiences, are problem-centered, experiential, and focus on the "why" behind what they are learning.[11] Learning through doing is an important part of professional preparation and continuing education. Most innovations and changes in practice take place in the context of use, not formal education.[7] Instead of mastering proven procedures, much of professional learning occurs through activities that provide an opportunity to practice and problem solve in contextually relevant situations (i.e., experiential learning).

Theory is usually explicit in "book knowledge" and implicit in "action knowledge;" thus, people have a difficult time verbalizing knowledge gained through experience.[7] This does not imply this type of knowledge is unimportant but rather that it is difficult to articulate and explicitly teach. One way to address this is through the use of narrative. Narrative thinking (thinking through telling and interpreting stories) involves trying to understand experiences or patient cases.[12] Telling the narrative story of a person or patient turns knowledge into understanding by allowing for reflection and translation of the story to a clinical reality that is actionable information.[13, 14] Problem/patient-based learning is powerful because, it makes the knowledge more accessible and more likely to be used when caring for patients. In contrast to traditional classroom-based learning that seems disconnected from practice, problem or case-based learning is inextricably connected to patient encounters.[15]

Traditional classroom education falls short of meeting the needs of adult learners that have transitioned from formal education programs and into clinical practice. This can be attributed to Kegan's theory of adult development positing that adults use four lenses, instrumental, social, self-authoring, and self-transforming, to enable and constrain what they pay attention to in order to make sense of a given situation.[16] A person is not aware of using a particular lens until the lens becomes inadequate to address a situation. This disorienting case helps the person see the lens they were using. Kegan calls this a shift from subject to object because the lens then becomes something that the individual can perceive and investigate. These shifts reflect transformative learning. For transformative learning to occur, the learner must be able to recognize and critically examine the lens they are using. Through their participation in case-based learning, the clinicians can identify their lens, practice using new lens, reflect on their own knowledge/learning and are therefore better positioned to incorporate new learning into their professional practice. One can begin to see why participation in ECHO not only results in transformative learning, but also results in transformation of clinical practice.

Transformative Learning Through ECHO

ECHO offers an alternative to traditional clinical education and reaches providers where they practice. ECHO is transformative as it not only promotes knowledge acquisition and increases confidence to treat complex conditions; it creates

Table 3. Participant Quotes Related to Learning Principles of Learning Health Systems

Learning Principle	Corresponding Show-Me ECHO Participant Comments
Draw on wisdom of groups and value connections	There is a huge need for pediatric providers in rural settings to be better educated in identifying characteristic and to be able to screen in order to initiate therapies early. I participate because it is a support resource, links me to the professional who educate and guide me in the care of my patients. Learning from other professionals that I usually would not be able to connect with on a regular basis. There was a need for better care in my area and this was a great opportunity to connect with specialists and other providers to help provide that care.
Embrace sensemaking over decision making in dealing with the unexpected	When a case was presented and then talked out with everyone's ideas, I found that it helped me be more open minded. Case presentation review - I think I understand something till we talk about it in a particular patient scenario. The opportunity to get expert help is immeasurably important. Another way to connect to the asthma community to share ideas and troubleshoot difficult cases.
Bring diverse perspectives to complex challenges	To observe other CHWs styles or approaches to difficult cases. It is reassuring knowing others in this position may have the same struggles. Also, one can learn about resources they might not be aware of. I have a better understanding of the legal implications involving guardians, the legal system, and the medical field. Learn from other clinicians how they are working though hurdles of accessing and managing HCV treatment for their specific patient populations.
Animate people, provide direction, update regularly, and interact respectfully	The collegial atmosphere is very conducive to learning without feeling threatened or left out. There are no stupid questions and we don't have egos in this group. We help each other learn. Feels like a true team.
Appreciate the power and ubiquity of emergent change and the limitations of planned change	Made aware that there are occasions that seem to be the right thing to do may be in conflict with regulations. I enjoyed finding new resources and helping other CHWs that may have run out of ideas for helping a patient. Saw a need in my patients and those in my community-long wait times at specialty centers.
Concentrate on small wins and characterize challenges as mere problems	Passion to make a change in a rural health setting to offer a broader developmental screen to catch these children early for earlier intervention to improve the overall outcome. Brainstorming ideas with fellow peers regarding resources and patient care. The wait for referral to [Autism] Center was so long for my patients that I was excited to be able to facilitate quicker access to treatment for children in rural areas. Saw a need in my patients and those in my community-long wait times at specialty centers
*Representative quotes come from participants of the following ECHOs: Asthma, Autism, CHW, Derm, Ethics, Hep C, HIV, OUD, Pain.	

an opportunity for experiential learning so providers can use new knowledge to improve problem solving in order to meet the dynamic needs of patients.[6, 17-20] Current research on ECHO learning outcomes include acquisition of both book and experiential knowledge, improved self-efficacy, improved competency and enhanced clinical performance.[6, 8, 21] Learning outcomes are determined through various means, including quantitative assessment of knowledge acquisition as well as collection of qualitative data outlining the participant's ECHO experience. To understand the power of ECHO as a learning community, we must understand the salient features of ECHO that foster deep learning and the articulating learning outcomes that demonstrate a full understanding and retention of the content presented as well as ability to apply it to future practice. Potts describes six principles of learning health systems.[22] Table 3 illustrates quotes from Show-Me ECHO participants that are congruent with the identified learning principles.

This commentary by the community of learners cultivated through Show-Me ECHO, gives credence to how participation in ECHO creates a learning culture among participants. This draws on the wisdom of groups and values connections, embraces sense making over decision making in dealing with the unexpected, brings together diverse perspectives to complex challenges, provides opportunity to interact respectfully, appreciates the power and ubiquity of emergent change and finally allows participants to concentrate on small wins.[22] ECHO enhances learning, resulting in transformational outcomes that improve patient and community health.

ECHO uses real-time cases depicting the true complexity of health care practice environments. It creates a safe space, where diverse viewpoints are explored. ECHO promotes collaborative, individualized health care choices, drives the process of discovery, is embedded in community, accommodates learners at different stages in the learning process and is a natural outgrowth of clinical care of patients.[3] ECHO

participants engage in learning that not only transforms the clinician's practice, but in turn improves health outcomes of patients. The ECHO model is better able to teach complex, dynamic content reflective of clinical environments and the skills practitioners need to effectively treat patients, current and future; even in cases where future needs are unforeseen.

The COVID-19 pandemic has forever changed delivery of health care across the world. During the early stages of the spread, panic was rampant and misinformation pervasive. In collaboration with the Missouri Department of Health and Human Services and the Missouri Hospital Association, Missouri Telehealth Network (MTN) was able to leverage established Show-Me ECHO learning communities to connect people with diverse areas of expertise, who were willing to work collaboratively in order to address unexpected and complex challenges. The ECHO model was well suited to engage providers in learning how to protect, diagnose and treat patients with COVID-19 as well as support them in working to protect their communities. Starting up the ECHO quickly optimized Missouri's response and saved lives.

Conclusion

This review demonstrates how ECHO helps refresh knowledge and translate that knowledge into practice providing a foundation for replication across the highest-priority care issues for the State of Missouri. This goal is already being realized with the growth in ECHOs across the last 16 years and a steady increase in provider participation will help to maximize the impact. The COVID-19 ECHO exemplifies the power of learning communities to quickly disseminate information, facilitate agile decision making and to respond to urgent needs reflective of the pandemic. Show-Me ECHO acts as a catalyst to shift professional development moving learning from learning in isolation *about* a complex medical problem to learning as part of a multidisciplinary team and learning *how to* provide comprehensive care for real patients.[7] This in turn promotes real changes to clinical practice and improved patient outcomes.

References

1. Arora S. Dr Sanjeev Arora Explains the Origins of Project ECHO and Improving Access to Care. Youtube. Available online: https://www.youtube.com/watch?v=nw8Sx3aMLx8 2018.
2. Arora S, Thornton K, Komaromy M, et al. Demonopolizing medical knowledge. Acad Med. 2014;89(1):30-32.
3. Institute of Medicine . Board on Global H. Best Care at Lower Cost: The Path to Continuously Learning Health Care in America. In Smith M, Saunders R, Stuckhardt L, et al., (Eds). Washington, DC: The National Academies Press 2013:436.
4. Arora S, Kalishman SG, Thornton KA, et al. Project ECHO: A Telementoring Network Model for Continuing Professional Development. J Contin Educ Health Prof. 2017;37(4):239-244.
5. (ASPE) OotASfPaE. Current State of Technology-Enabled Collaborative Learning and Capacity Building Models. In Policy OoH, (Ed). REPORT TO CONGRESS 2019.
6. Mazurek MO, Brown R, Curran A, et al. ECHO Autism. Clin Pediatr (Phila). 2017;56(3):247-256.
7. Eraut M. Developing professional knowledge and competence: London ; Washington, D.C. : Falmer Press, 1994. 1994.
8. Arora S, Geppert CM, Kalishman S, et al. Academic health center management of chronic diseases through knowledge networks: Project ECHO. Acad Med. 2007;82(2):154-160.
9. Aronson L. Twelve tips for teaching reflection at all levels of medical education. Med Teach. 2011;33(3):200-205.
10. Mylopoulos M, Regehr G. Cognitive metaphors of expertise and knowledge: prospects and limitations for medical education. Med Educ. 2007;41(12):1159-1165.
11. Knowles M. The Adult Learner: A Neglected Species. Houston, TX: Gulf Publishing 1984.
12. Brunner J. Actual minds, possible worlds. Cambridge, MA: Harvard University Press 1986.
13. Astrom G, Norberg A, Hallberg IR, et al. Experienced and skilled nurses' narratives of situations where caring action made a difference to the patient. Sch Inq Nurs Pract. 1993;7(3):183-193; discussion 195-188.
14. Benner P, Tanner, C. & Chelsea, C. . Expertise in nursing practice: Caring, clinical judgment and ethics. New York: Springer 1996.
15. Wenger E. Communities of Practice: Learning, Meaning, and Identity. New York: Cambridge University Press 1998.
16. Lewin LO, McManamon A, Stein MTO, et al. Minding the Form That Transforms: Using Kegan's Model of Adult Development to Understand Personal and Professional Identity Formation in Medicine. Acad Med. 2019.
17. Arora S, Kalishman S, Thornton K, et al. Project ECHO (Project Extension for Community Healthcare Outcomes): A National and Global Model for Continuing Professional Development. J Contin Educ Health Prof. 2016;36 Suppl 1:S48-49.
18. Komaromy M, Bartlett J, Manis K, et al. Enhanced Primary Care Treatment of Behavioral Disorders With ECHO Case-Based Learning. Psychiatric services (Washington, DC). 2017;68(9):873-875.
19. Fisher E, Hasselberg M, Conwell Y, et al. Telementoring Primary Care Clinicians to Improve Geriatric Mental Health Care. Population health management. 2017.
20. Wood BR, Unruh KT, Martinez-Paz N, et al. Impact of a Telehealth Program That Delivers Remote Consultation and Longitudinal Mentorship to Community HIV Providers. Open forum infectious diseases. 2016;3(3):ofw123.
21. Sohl K, Mazurek MO, Brown R. ECHO Autism: Using Technology and Mentorship to Bridge Gaps, Increase Access to Care, and Bring Best Practice Autism Care to Primary Care. Clin Pediatr (Phila). 2017;56(6):509-511.
22. Potts J, Thompson R, Merchant R, et al. Learning: Contemplating the unexamined core of Learning Health Systems. Learning Health Systems. 2017;1(4).

Disclosure

None reported. **MM**

Building Regional Expertise: Perspectives from Show-Me ECHO Participants

by Melissa Warne-Griggs, PhD, Lea Brandt, PhD, Kimberly Hoffman, PhD, Tracy Greever-Rice, PhD & E. Rachel Mutrux, BA

Missouri Telehealth Network
University of Missouri

Participation in a community of clinicians committed to providing the best care possible has given interviewees the opportunity to become important regional resources for their patients and other providers.



Melissa Warne-Griggs, PhD, (above), is an Administrative Consultant; Lea Brandt, PhD, OTD, MA, is Associate Professional Practice Professor; Kimberly Hoffman, PhD, is Professor Emerita, Family and Community Medicine; and E. Rachel Mutrux, BA is Senior Program Director, Missouri Telehealth Network, Director, Show-Me ECHO, State Director, Heartland Telehealth Resource Center; All are at the University of Missouri-Columbia, Columbia, Missouri. Tracy Greever-Rice, PhD, is Director, Center for Health Policy, Assistant Research Professor, University of Missouri-Columbia, Columbia,

Abstract

This article highlights four primary care providers that practice in underserved areas in Missouri. Show-Me ECHO (Extension for Community Healthcare Outcomes) provides colleagues opportunities for consultation and Continuing Medical Education (CME) around particular conditions. Through their participation, these providers have 1) enhanced their comfort and skill in diagnosis and treatment, 2) become important regional resources for patients and other providers, and 3) improved access to specialty services in their community.

Introduction

This article highlights how participation in Show-Me ECHO (Extension for Community Healthcare Outcomes) enhanced comfort and skill in diagnosis and treatment for four primary care providers practicing in underserved areas in Missouri. It also explores how ECHO collaborations enhance access to specialty services and allow participants to become important regional resources for patients and other providers.

Providers of underserved populations can face isolation, excessive workloads and may lack access to consultation. The purpose of this article is to demonstrate how participation in Show-Me ECHO addresses these issues by providing colleagues, opportunities for consultation and Continuing Medical Education (CME).[1] ECHO participants demonstrate significant increases in their knowledge, improved attitudes, and confidence in clinical and nonclinical skills.[2] Further, they report increased self-efficacy which fosters behavioral change.[2-3]

Background

Show-Me ECHO is a state-funded telehealth project created and operated by the Missouri Telehealth Network at the University of Missouri. Begun in 2014, Show-Me ECHO is modeled after the University of New Mexico's Project ECHO which was originally created to educate providers about Hepatitis C. Key features of all ECHOs include: 1) a hub and spoke organization where multi-disciplinary content experts mentor participants through teleconferencing, 2) regular and recurring virtual meetings, 3) focused didactic presentations, and 4) case-based learning where participants select and present cases from their own practices.[4] There are opportunities for practice

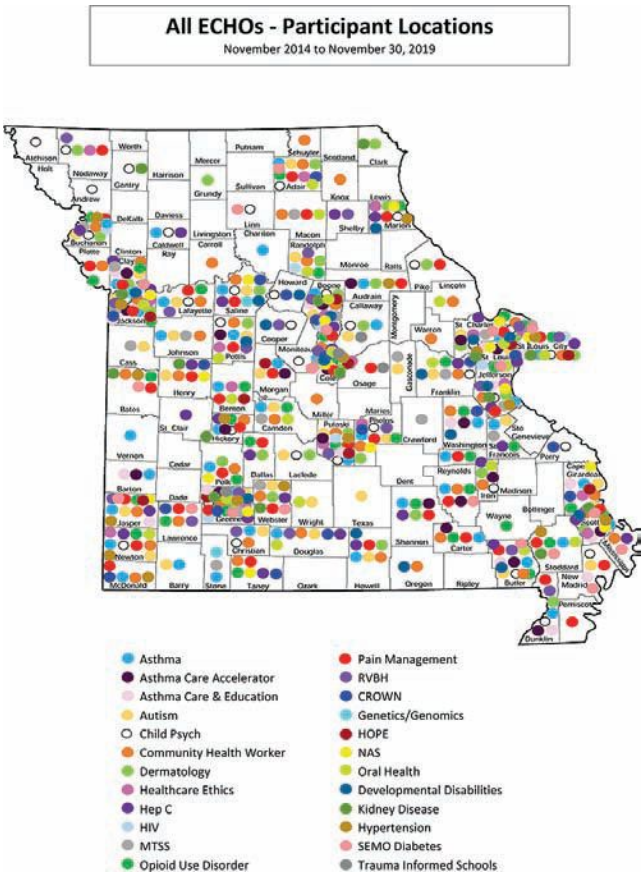


Figure 1. Participation in ECHO from 2014-2019

in diagnosis and treatment and feedback among all participants as they consider complex cases.[1,5]

Although Show-Me ECHO draws participants from across the United States and internationally, it focuses on the needs of Missourians. Expert mentors are recruited from across the state with twenty-one counties represented on expert hub teams from inception to date. This geographic diversity enhances learning because these experts understand local resources, local contacts, and local realities for providing care in underserved areas. Show-Me ECHO participants come from 89 counties (Figure 1).

Learning in ECHO

ECHO adheres to best practices in adult learning theory. Using informal discussions and guidance, ECHO offers the advantages of learning through authentic cases, focusing on the current needs of participants and building on participants' current knowledge.[6] ECHO situates learning within professional practice and connects to workplace learning thus enhancing the likelihood that newly acquired knowledge will change professional practice. [5,7-8]

Multidisciplinary teamwork is essential to the ECHO model.[9] Show-Me ECHO connects primary care providers with each other, with specialists, and with regional resources. Diverse perspectives aid the ECHO teams in arriving at "wise action" better than any one individual participant.[10] Discussions with, and mentoring from, content experts help equip primary care providers to give their patients the right care, in the right place, at the right time. Knowledge is no longer created top-down, but is made by the group, "by demonopolizing medical knowledge and creating collaborative practices between community-based clinicians and specialists, local primary care clinicians can become experts in a chronic condition and they can provide the best evidence-based treatments to many more patients."[9(p32)] This article highlights four health care providers experiences of learning within Show-Me ECHOs.

Interviews

ECHO hub leadership recommended the four providers that we interviewed. After a short introduction, excerpts from longer interviews provide insight into their considerable experience as members of the ECHO learning community.



Ning Haluck, MD, is a Pediatrician and Director of Pediatrics at Swope Health, which is a federally qualified health center in Kansas City, Missouri. She has been practicing medicine for four years. Dr. Haluck began participating in the Asthma ECHO when her boss suggested it.

"He showed me some information about Asthma Ready. I signed up mostly because my boss told me to, but as I did it and got to learn more about what ECHO was, as well as about asthma, I realized 'Wow, this is amazing.' I learned about asthma in training, but learning about it and then doing it is so different.

Having a community of experts who work with me is a great benefit of ECHO. I had been using (national asthma guidelines) through residency, but when I had

problems, I didn't really know what to do, (and) it took us a lot longer to access specialists. ECHO (gave me planned) access for one-hour per week. (When) I had a patient who was a little bit trickier, then I thought, 'I can just bring it up in the next session'. And, they were just so helpful. There were no stupid questions. So, I can take very nitty gritty, practical questions and they just had a treasure trove of answers.

Since participating in ECHO, I've started seeing myself more as a bridge in my community. Between my patients and the specialist information that they need because some of my patients either can't make it to the specialty clinics or don't want to because they've already established care with me and our clinic. So now even with other topics, not just asthma, I've found the courage and have the format to get information from a specialist in ways that I probably wouldn't have before. It can be pretty intimidating as a primary care provider who knows a little bit about a lot of things, to be able to go out to a specialist, ask my questions and not let fear or anything else get in the way.

Now, I have access to (experts) and share that access with my patients and with kids in my community. I am a pediatrician, but I'm also a mom. Everything that I'm learning at work, I am using at home with my family and with my friends' kids. So really, I'm learning that being a pediatrician is being an advocate and the best way to be an advocate is to have knowledge. And that knowledge currently is with the specialists. So, I'm just trying to disseminate it as best I can and ECHO is a great dissemination model. I was able to get my two nurse practitioners on board. And so now as a clinic, every kid with asthma, no matter who they see, even if asthma's not the reason why they come to our clinic, gets to have their asthma taken care of. ECHO taught me how to do it in a systematic way and in a way that pushed me towards continued improvement.

What I really love is the community. Now when I sign on to a meeting, I just wave at everybody. It's just all these people that I know are as dedicated as I am to providing excellent care for asthma. I've been able to make so many changes in the year I've been involved with ECHO without actually having to go anywhere other than work. It's so convenient!"



Bill Wright, MD, is a family medicine physician located in Houston, Missouri. He has been practicing medicine since 1980. Dr. Wright participates in three ECHOs related to autism. He began participating as his practice was shifting.

"I gave up obstetrics and started working in an office practice doing mostly pediatrics and some family medicine. It wasn't the same intensity that I had with obstetrics. I was kind of floundering around and one day I had this invitation from the Thompson Center about autism. I liked it the first week, so I attended the second session and it was really almost too much for me. (But) then I went back a third time, and I just fell in love with it. And so, I continued along (joining additional ECHOs), kind of getting immersed in the whole arts and science of autism.

I'd never seen anything like ECHO really. I haven't done much stuff online before. It was good teaching and then you actually got to work, on a case basis at least, and hear kind of what happened. The greatest part about it is having been able to work with the hub teams. I've got some good friends on the hub team now and that makes it just that much more powerful.

It's just a really good learning experience. A couple of the people that are involved nearby, I've gotten to know them and actually worked with a couple of them directly; and that's been nice to be able to do that. But I think it's a combination of learning: a little bit of didactic information, along with going through and studying the cases. It's really helpful as far as learning goes.

I've always practiced medicine with the idea that I need to be able to teach patients about what's going on with their health, whatever that may be. Whether it's having a baby or it's taking care of a child with pneumonia, or whatever it may be. I think that ECHO helped a lot both in the insight of what goes on with families that are dealing with this difficult diagnosis and their

children. I think it's been really helpful in allowing me to be hopefully a better clinician and a better teacher. I think it has.

My community benefits. This is a very rural area. And, because there are not any other providers nearby, that provide (autism services), I'm getting referrals from all over this area of the state really. So typically, I would say people are driving on average forty-five minutes to be seen here for the evaluation. One family I saw this morning drove for an hour and twenty minutes. Between Springfield and Columbia and somewhere down near the Cape, there are no behavior therapists available. I mean not certified behavior therapist. Hopefully soon we'll have someone in this area. So, for a therapy that is supposed to be happening several times every week, you can't travel a hundred miles every day to take your child to therapy, take him home and then turnaround go back. So that's a little frustrating. I've got dreams of having something like that happen; still just dreams as far as I can figure out.

I would tell others that are interested that the hub people in all three ECHOs that I've been in have been encouraging. They've been stimulating. They've been knowledgeable. It's been a pleasure to work with them. I think it's a great opportunity to learn more and to get some feedback and on what you're doing."



Hope Misterovich, DO, is a family medicine physician located in Springfield, Missouri. She has been practicing medicine since 1998. Dr. Misterovich began participating in the Dermatology ECHO in 2016.

"I guess it was four years ago now, our health system was really struggling with access to dermatology in particular. They approached me about starting a primary care skin care clinic as a way to offset some of the referrals that were kind of overwhelming the current dermatologist with our system. As we investigated it, we wanted to have some sort of backup or access to a higher level of knowledge if needed. So, we started participating before we ever started the primary care skin care clinic.

I utilize ECHO for a number of different resources. One is just for the education piece at the beginning of each session, I think that's valuable. They, at times, will make it simpler and at times make it more advanced. And I appreciate all levels that they explore when they present their didactic portion.

I like it all. I like the camaraderie. I like the collegial atmosphere. I've even gotten to know some of the participants that are in outlying communities. We have met at conferences and have gotten to know the other people that are participating. I enjoy it tremendously.

My patients benefit because I am able to say, 'I'm not sure what's going on here, but I'm gonna reach for my backup and get their thoughts and their opinions, and see if we can help you'. I tell patients, 'You know, we don't know what's going on. You're not responding to the treatment that would typically help this condition. I'd like to present your case at the ECHO'. I describe it as a situation where we present their case in an anonymous format with no charge to them. They have the benefit of getting several dermatologist opinions, and then I call them with the recommendations. Patients love it. They're thrilled that somebody has taken the time to listen to them and has taken their concerns seriously.

My community benefits as well. I've had other providers say, 'I'm referring you this patient. They're very complicated. You may want to present this patient to Derm ECHO'. So, they know that I'm kind of the point person, and look to me as a resource. They're from the surrounding community, so they're within the Springfield area, but they're in outlying areas as well: Monett, Aurora, and Branson.

I try to talk about Derm ECHO every chance I can when I talk to other providers. I'm happy to talk about the great resource. ECHO is really easy to do and so much fun. And, you get CME. It's a great opportunity to connect with other providers in the state and I've enjoyed every aspect of it."



Karyn Dean, NP, is a nurse practitioner located in Kennett and Hayti, Missouri. She has been practicing for about thirteen years. Karyn has participated in both the Asthma and the Child Psych ECHO. She began participating to help bring specialized care to her area.

"The nearest pediatric specialist is anywhere between an hour to three hours away for patients. So, by doing the ECHOs and learning the information from the experts, it allowed me to better practice and keep the patient in the local area as much as possible.

ECHO helped me become more of an expert and a resource to my colleagues within the clinics I work at and to the community. Patients can receive high quality care without having to leave their communities as often and travel long distances. Also, helping me to improve my practice gave me more confidence.

My favorite part of ECHO is getting to network with my fellow nurse practitioner and physician colleagues in the state and even beyond because there were some from Africa and other places that were on the ECHOs. (Also) just to have access to those experts, those specialists to consult with and pick their brains.

My asthma patients benefit because I know the guidelines quite a bit better off the top of my head, so I can better diagnose them and manage them. I learned to use different tools in evaluating patients and have actually gotten some of the physical tools to use in the clinic, and that allows me to more objectively evaluate the patients.

The Child Psych ECHO gave me access and knowledge of different screening tools, and the pharmacist on that ECHO was very helpful. He helped a lot with giving me knowledge about the different main drugs used for different mental health illnesses. It did give me exposure to some of those common psychological therapies because I really had no knowledge of that. In fact, the Child Psych ECHO prompted me to go ahead and become a pediatric mental health specialist through my certifying board.

I see my role in the community after going through the ECHOs as more of a center of excellence. (Patients) can know that they're getting the most current evaluation and management methods and that I now have contact people that I can turn to if I have questions in the future. Also, I've shared (information learned in ECHO) within the clinic (and) at the provider meetings (for the) five or six clinics within SEMO Health Network. I'm the only pediatric nurse practitioner and there's not a pediatrician in either clinic that I work at, so I serve as a general pediatric expert, too. So, they oftentimes will pick my brain.

It's an easy and very valuable way to get added education on disease processes and management and you get official CME credit. That's always a plus. We need that for our licensure. And, it gives a way to network with your colleagues and other experts in the field without having to really leave your hometown or (even) home sometimes!"

Conclusions

Similar to other ECHO participants, our interviewees were motivated to participate in ECHO to learn more about medical conditions, to increase collaboration with specialists, a desire to save patients time, and to obtain CME. [11] As these four dedicated clinicians have shown, Show-Me ECHO helped them meet their personal goals and benefitted their patients and larger community.

All of our interviewees really appreciate the access to specialists. Specialists on the hub team are able to answer practical questions and to help participants build up their own condition-specific knowledge. Beyond relationships with hub team specialist, interviewees value the relationships they have developed with other ECHO participants. Building a community of clinicians committed to providing the best possible care has given our interviewees more confidence in their own practice and the confidence to interact with specialists outside of the ECHO format.

Local access to specialized medical care can be especially helpful for patients with transportation issues or other limitations. The larger community benefits as ECHO participants become local

resources. All of our interviewees described taking information learned in ECHO back to their communities, and sharing their new knowledge with other healthcare providers.

If you would like to experience for yourself the benefits described by interviewees, please visit https://showmeecho.org/ for more information.

References

1. Arora S, Geppert CM, Kalishman S, Dion D, Pullara F, Bjeletich B, Simpson G, Alverson DC, Moore LB, Kuhl D, Scaletti JV. Academic health center management of chronic diseases through knowledge networks: Project ECHO. Academic Medicine. 2007;82:154-160.
2. Colleran K, Harding E, Kipp BJ, Zurawski A, MacMillan B, Jelinkova L, Kalishman S, Dion D, Som D, Arora S. Building capacity to reduce disparities in diabetes training community health workers using an integrated distance learning model. The Diabetes Educator. 2012; 38(3):386-96.
3. Furlan A, Zhao J, Voth J, Hassan S, Dubin R, Stinson JN, Jaglal S, Fabico R, Smith AJ, Taenzer P, Flannery JF. Evaluation of an innovative tele-education intervention in chronic pain management for primary care clinicians practicing in underserved areas. Journal of Telemedicine and Telecare. 2018; 0(0)1-9.
4. (ASPE) OotASfPaE. Current State of Technology-Enabled Collaborative Learning and Capacity Building Models. In Policy OoH, (Ed). REPORT TO CONGRESS 2019.
5. Arora S, Kalishman SG, Thornton KA, Komaromy MS, Katzman JG, Struminger BB, Rayburn WF, Bradford AM. Project ECHO: A telementoring network model for continuing professional development. Journal of Continuing Education in the Health Professions. 2017; 37:239–244.
6. Komaromy M, Bartlett J, Manis K, Arora S. Enhanced primary care treatment of behavioral disorders with ECHO case-based learning. Psychiatric Services. 2017; 68(9):873-5.
7. Mazurek MO, Brown R, Curran A, Sohl K. (2017). ECHO autism: A new model for training primary care providers in best-practice care for children with autism. Clinical pediatrics. 2017; 56(3), 247-256.
8. Eraut M. Developing professional knowledge and competence. London; Washington, D.C.: Falmer Press; 1994.
9. Arora S, Thornton K, Komaromy M, et al. Demonopolizing medical knowledge. Academic Medicine. 2014; 89:30–2.
10. Weick C. Educational organizations as loosely coupled systems. Administrative Science Quarterly. 1976; 21, 1-19.
11. Salgia RJ, Mullan PB, McCurdy H, et al. The educational impact of the specialty care access network-extension of community healthcare outcomes program. Telemedicine Journal and E-Health. 2014; 20:1004–8.

Disclosures

None reported. **MM**



Today – Do more of what you love

At Mercy Clinic, we span across four states with a team of more than 2,100 Mercy primary care and specialty care physicians, 600 advanced practitioners. Mercy was named one of the top five largest U.S. Health Systems in 2017 by Truven, an IBM Watson Health Company and we serve millions annually. Mercy includes 44 acute care and specialty (heart, children's, orthopedic and rehab) hospitals, more than 700 physician practices and outpatient facilities, more than 40,000 co-workers and more than 2,000 Mercy Clinic physician in Arkansas, Kansas, Missouri and Oklahoma. Mercy also has outreach ministries in Arkansas, Louisiana, Mississippi, and Texas.

To find out about Physician and Advanced Practitioners openings across the Mercy System please contact:

Sara McCleary, Director of Physician Recruitment
Sara.McCleary@mercy.net | 417-556-8963

Or go to **http://www.mercy.net/careers** to search for your specialty opportunities.

Mercy

List of Specialties:

- Anesthesiology
- Cardiology - Electrophysiology
- Cardiology - Interventional
- Cardiology - Non-Invasive
- Critical Care - Intensivist
- Dermatology
- Emergency Medicine
- Endocrinology
- Family Medicine
- Family Medicine - OB
- Gastroenterology
- General Surgery
- General Surgery - Breast Surgery
- Geriatric Medicine
- Gynecology - Urogynecology
- Hematology and Oncology
- Hospitalist
- Infectious Disease
- Internal Medicine
- Maternal-Fetal Medicine
- Med-Peds
- Neonatology
- Nephrology
- Neurological Surgery
- Neurology
- Neurology - Neuroimaging
- Obstetrics and Gynecology
- Obstetrics and Gynecology - OB Hospitalist
- Occupational Medicine
- Oncology - Gynecological
- Oncology - Surgical
- Ophthalmology
- Oral and Maxillofacial Surgery
- Orthopaedic Surgery
- Orthopaedic Surgery - Adult Reconstructive Surgery
- Orthopaedic Surgery - Hand Surgery
- Orthopaedic Surgery - Trauma
- Otolaryngology
- Pain Medicine
- Palliative Care
- Pediatrics
- Pediatrics - Emergency Medicine
- Pediatrics - Hospitalist
- Pediatrics - Ophthalmology
- Pediatrics - Surgery
- Pediatrics - Urgent Care
- Physical Medicine and Rehab
- Plastic Surgery
- Psychiatry
- Psychiatry - Child
- Pulmonary Disease
- Pulmonary Disease - Critical Care
- Radiation Oncology
- Radiology
- Rheumatology
- Sleep Medicine
- Telemedicine
- Trauma Surgery
- Urgent Care
- Urology
- Vascular Surgery

Telehealth and Telemedicine in Missouri

by Mirna Becevic, PhD, Lincoln R. Sheets, MD, Emmanuelle Wallach, MA, Anne McEowen, MS, Angie Bass, MHA, E. Rachel Mutrux, BA & Karen E. Edison, MD

Missouri Telehealth Network
University of Missouri

With increased use comes the need to design telehealth policies and procedures that ensure high quality of care and patient safety.



Mirna Becevic, PhD, (above), is Assistant Professor, Department of Dermatology, Lead Evaluator; Lincoln R. Sheets, MD, PhD, is Assistant Research Professor, Department of Health Management and Informatics, Associate Director of Data and Evaluation; Emmanuelle Wallach, MA, is Evaluation Coordinator; E. Rachel Mutrux, BA, is Senior Program Director and Director; Karen E. Edison, MD, FAAD, MSMA member since 1991, is Professor Emerita of Dermatology, Senior Medical Director; all are at the Show-Me ECHO/Missouri Telehealth Network, University of Missouri-Columbia School of Medicine, Columbia, Missouri. Anne McEowen, MS, is at Center for Health Policy, University of Missouri-Columbia, Columbia, Missouri. Angie Bass, MHA, is Chief Executive Officer, Missouri Health Connection, Columbia, Missouri.
Contact: becevicm@health.missouri.edu

Abstract

Missouri is a national leader in telemedicine, and the Missouri Telehealth Network has led operational, legal and regulatory, and research and evaluation efforts since 1994. Telehealth and telemedicine have the potential to increase access to and efficiency of healthcare delivery, improve quality, and improve patient outcomes. Coverage and reimbursement rules vary by regulator, and Missouri enjoys a broad statutory definition of telehealth coverage and reimbursement parity (no distinction between in-person and telehealth services).

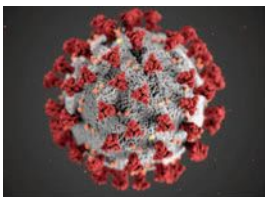
Introduction

Missourians face a growing demand for specialized health care and multiple impediments in accessing the health care they need. The state's elderly population is projected to increase to 1.2 million or 19.1 percent of the state's total by 2025. [1] More than 30 percent of Missouri's residents live in rural areas, which cover 97 percent of the state.[2] Rural Missouri has fewer physicians than in 2011, and rural Missouri physicians are two years closer to retirement on average than their urban Missouri counterparts.[3] With limited or no access to timely and quality care, rural Missourians are overall less healthy than their urban counterparts, with significantly higher death rates (867 per 100,000 rural Missourians versus 799 per 100,000 urban Missourians). [4]

Telemedicine and telehealth are readily available tools in the state's arsenal for overcoming obstacles to accessing health care. Their use can improve patient outcomes, primarily by reducing the transportation time and costs and increasing the access to physicians. This is especially true for rural patients needing access to specialized physicians. Physician efficiency may also be improved resulting in overall reduction in health care costs.[5] Early adopters in nearly all clinical specialties have had good results from telemedicine and telehealth, but many barriers to adoption remain. [6]

Telemedicine and Telehealth

Telemedicine and telehealth are often used interchangeably. Missouri law defines both as "the delivery of health care services by means of information and communication technologies which facilitate the assessment, diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care while such patient is at the originating site and the health care provider is at the distant site." [7] It is also useful to consider telemedicine strictly as the delivery of clinical care at a distance,[8] and use telehealth as an umbrella term that includes telemedicine but also includes education and training. "Telehealth



How COVID-19 Changed the Telehealth and Telemedicine Landscape

Due to an ongoing COVID-19 pandemic, the CMS has issued a number of new rules and waivers of federal requirements in order to expand the use of telehealth services.[1]

More than 80 additional telehealth services, including direct-to-consumer, emergency department, nursing facility visits, are now reimbursable. These policy changes allow patients to receive necessary care without putting self or others at risk.[1]

Some of the important changes include allowing out of state clinicians to provide services via telehealth as well as billing for non-enrolled providers.[2]

The Office of Civil Rights also announced that, due to the nationwide public health emergency, potential HIPAA penalties will be waived for providers using telehealth technologies to communicate with patients.[3]

This enforcement discretion also supports the use of commonly used communication applications, such as FaceTime and Skype, to be used for visits with patients for diagnostic and treatments purposes.[3]

These rules are expected to tighten as the pandemic wanes and physicians should move toward the use of secure platforms for telemedicine as soon as they can.

Table 1. CMS COVID-19 Telehealth Policy Update

- Phone and video visits allowed
- Out of state providers allowed
- Temporary billing for non-enrolled clinicians
- Rural requirement for Medicare reimbursement removed
- Expansion of hospice, nursing/assisted living facilities
- Tele-supervision of medical residents

The CMS recognizes the fluidity of the current healthcare crisis, and continues to update the reimbursement and billing policy to be implemented immediately across the country. Table 1 summarizes some of these policy updates as of April 24, 2020.

MO HealthNet now allows new patients to be seen via telelealth and waives patient co-pays during the pandemic.[4] It also allows providers who are quarantined or providing telehealth services from alternative hub locations to bill for those services.[4]

References

1. https://www.cms.gov/newsroom/fact-sheets/additional-backgroundsweeping-regulatory-changes-help-us-healthcare-system-address-covid-19-patient
2. https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf
3. https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html
4. https://dss.mo.gov/mhd/providers/pages/provtips.htm

technologies include video-conferencing, the Internet, asynchronous "store-and-forward" imaging, streaming media, and terrestrial and wireless communications."[9]

Missouri has been a leader in using telehealth to address the shortfall of physicians in rural areas. In early days, telehealth was primarily used to connect rural patients with specialty care. Today, the uses are myriad and include telehealth coverage of tele-ICU and emergency departments, telehealth into schools, hospital to hospital telehealth such as tele-stroke, remote monitoring of chronic diseases into the patient home for conditions such as congestive heart failure, and many more applications.

The Missouri Telehealth Network (MTN) was a pioneer in this field in the mid-1990s, receiving funding, through grants and contracts, from telecommunications companies early on, and then federal and state grants over the years. Since 1994,

MTN has served to provide specialty care services to rural and underserved Missourians in every corner of the state. Some of the most common specialties using telehealth have been psychiatry, dermatology, cardiology, neurology and subspecialty pediatrics. In 2013, over 40,000 patients received telehealth visits in Missouri,[10] and MTN increasingly provides specialty care through its robust "Show-Me ECHO" (Extension for Community Healthcare Outcomes) program.[11]

In the MO HealthNet program, the use of telehealth in Missouri doubled between 2012 and 2016.[10] Today, nearly every major health system in the state has adopted some form of telehealth. In addition, a recent MHA survey of rural hospitals indicated that more than half of participating hospitals use telehealth services, and over 80 percent of those retained patients within their communities because of the use telehealth.[10] Since 2001, MTN has been a telehealth resource center facilitating the adoption of telehealth throughout the state for both public and private partners. MTN, due to its experience is a trusted expert partner, with expertise in legal and regulatory telehealth, for state agencies designing telehealth policies and regulations. Missouri is now a state with few regulatory barriers to the adoption of telehealth. In 2018, Missouri House Bill Number 1617 was passed and signed into law, effectively allowing telehealth to be used for patients in most settings and by any licensed "health care provider," and stipulating only that the same standards of care apply as when that provider sees a patient in person. [12]

Telehealth Reimbursement

Medicare

Medicare reimbursement for telehealth services generally requires the use of live interactive video that "permits real-time communication" between the patient at an "originating" site and a physician at the "distant" site, except in Alaska and Hawaii where the use of asynchronous store-and-forward telehealth is also reimbursable.[13] Table 2 summarizes restrictions by payer in Missouri: Medicare has three new reimbursement codes for telehealth - technology-enabled virtual check-in, store-and-forward of pre-recorded information to determine whether a visit is needed, and inter-professional consultation over the Internet. In less than a year since these codes have been approved, low reimbursement rates have limited their adoption.

Table 2. Restrictions by Payer in Missouri for Telemedicine

Payer	Medicare	MO HealthNet (Missouri Medicaid)	Private Payer
Type of telehealth reimbursed	• Live-interactive • Technology-enabled virtual check-in • Store-and-forward to determine whether a visit is needed • Inter-professional consultation • Store-and-forward in AK & HI	• Live-interactive • Store-and-forward	Coverage and reimbursement parity: • Must allow tele-visits instead of in-person visits • Must pay similar amounts for in-person and tele-visits
Originating (patient) site	• Physician's offices • Hospitals and clinics	No restrictions	Varies by payer
Eligible practitioners	• Physicians • Nurse practitioners • Physician assistants • Certified registered nurse anesthetists • Clinical nurse specialists • Clinical social workers • Nurse midwifes • Psychologists • Registered dietitians or nutrition professionals	Any licensed physician or other health care practitioner registered with MO HealthNet	Varies by payer

Telehealth visits from these originating sites are reimbursable: physician's offices, rural health clinics, Critical Access Hospitals (CAH) and other hospitals, Federally Qualified Health Centers (FQHC), Skilled Nursing Facilities (SNF), Community Mental Health Centers (CMHC), mobile stroke units, renal dialysis facilities and hospital-based renal dialysis centers, and homes of beneficiaries with End-Stage Renal Disease (ESRD) who are getting home dialysis.[13] However, reimbursements are further limited to visits where the originating (patient) site is in a rural Health Professional Shortage Area (HPSA) in a rural census tract, or in a county outside a Metropolitan Statistical Area (MSA). This restriction leaves out many elderly patients from other areas, especially those in skilled nursing facilities, in-patient settings, or at home but unable to travel due to other barriers. Violating this rule is a common reason that telehealth services are found to be ineligible for Medicare reimbursement.[14]

Missouri Medicaid

In many ways, telehealth reimbursement from Missouri's Medicaid system (MO HealthNet) mirrors Medicare reimbursement policies. Telehealth care must follow the same licensure requirements and standards of care as in-person services, and can be reimbursed at the same rate. Prescriptions and other treatment can only be provided within a physician-patient relationship, which can be established via telehealth but must consist of an interview – an Internet or

telephone questionnaire is not enough. Parental authorization is also required for telehealth services to children.

MO HealthNet does have a few unique requirements for telehealth reimbursements. As for in-person visits, eligible physicians must reside in Missouri or one of the neighboring states in addition to being licensed to practice medicine in Missouri. Unlike Medicare, MO HealthNet eligible originating sites are not limited by geographic location and include both rural and metropolitan areas. Table 3 summarizes the relevant Missouri statutes as of 2019.

Table 3. Relevant Missouri Statutes for Telemedicine as of 2019

Senate Bill (SB)	Effective Year	Summary
SB716	2014	• Creates the Show-Me ECHO (Extension for Community Healthcare Outcomes) Program • Authorizes collaboration between Show-Me ECHO and the Missouri Department of Social Services
SB579	2016	• Physician-patient relationship required • Must consist of an interview – an Internet or telephone questionnaire is not enough • Must follow standards of care and evidence-based standards of practice • Prescriptions, controlled substance, and other treatment within the scope of practice based solely on a telephone evaluation ONLY IF a patient-physician relationship has previously been established
SB951	2018	• Services provided by licensed health care practitioners can also be provided via telehealth • **Licensure requirements and scope of practice are the same for telehealth vs. in-person** • Same reimbursement for telehealth as for in-person services • Same standard of care • May consider a fee for the originating site • No restriction on originating (patient) site • Subject to parental authorization, children may receive telehealth services in school
SB514	2019	• Improved Access to Treatment for Opioid Addictions Act (IOTOA) • Expands the ability of assistant physicians, physician assistants, and advanced practice registered nurses to help with opioid addiction treatment within the IOTOA program • In particular, a remote collaborating physician is still considered on-site (even though the collaboration is conducted via telecommunications)

Credentialing. Licensure and Liability

The originating site, which is the location of the patient, determines the jurisdiction of medical care and the state in which the physician must be licensed.[15.] States are responsible for regulating credentials and issuing licenses, and their rules vary considerably. [15] Since not all states have telehealth laws and regulations, if a complaint is received regarding a physician who is not licensed in the state where the patient is, then the regulatory board might impose "operating without a license" penalty provision.[15]

This is a potential barrier to expanding telehealth in Missouri. In theory, a Missouri patient could choose a telehealth physician from another state; but in practice, this is limited by the requirement for the physician to pay licensing fees and adhere to state-specific practice regulations in order to be licensed in Missouri. This may be discouraging to physicians[16] but helps to ensure accountability for high-quality care.

All this may become easier if Missouri joins the Interstate Medical Licensure Compact (IMLC), which offers an expedited pathway for licensure across state lines and currently includes 29 states, the District of Columbia, and the Territory of Guam.[17] It is not in effect in Missouri, but has been recommended by Missouri Governor Mike Parson and the Missouri Hospital Association.[18] One of the main advantages of the IMLC is its database of easy-to-share information between member states. However, in Missouri, data capture and implementation processes are not complete because the requirements for the state are complex and costly.[16]

Legal liability is a common concern for physicians starting telehealth, and it is likely that the number of malpractice suits will increase as telehealth becomes more widely used.[19] However, case law has been quite limited to date.[20] Physicians should consult with their malpractice insurers before starting a telehealth practice.

Restrictions

Telehealth has expanded from its original rural focus [21] to metropolitan areas, and has been shown to compare favorably to in-person consultations for a number of conditions including asthma,[22] chronic heart failure,[23] and opioid use disorder. [24, 25, 26] However, Medicare has not expanded its geographic restrictions, except for acute stroke, substance use disorders, and co-occurring mental health disorders. [27] Privacy concerns also lead many insurers, including Medicare, to limit the originating (patient) site to a health care location due to Health Information Portability and Accountability Act (HIPAA) restrictions.

The Ryan Haight Act [28] prohibits the prescription and dispensing of controlled substances via telecommunications nationwide, except in established and specifically defined physician-patient relationships. Missouri Senate Bill Number 579 specifies that telehealth prescriptions and treatment may only be delivered within an established patient-physician

relationship,[29] as regulated by the Missouri Board of Registration for the Healing Arts.[30]

Direct-To-Consumer Telemedicine

Direct-to-consumer (DTC) telemedicine refers to patient-initiated, on-demand health care with their own physician, another physician within the same practice, or, more commonly, a physician with whom the patient has no existing relationship. The latter is commonly offered by for-profit companies, with direct-pay options.[31] There are, however, issues with quality assurance, access to medical history, continuity of care, and follow-up care in the DTC model.

Studies have suggested that contrary to traditional telemedicine, where patients who connect with specialists under the guidance of their primary-care physician receive comparable care to what they would have experienced in-person, direct-to-consumer models suffer from a lack of quality care.[32, 33] For example, studies have shown that DTC telemedicine physicians are more likely than in-person physicians to prescribe antibiotics, less likely to order diagnostic testing, and that the proposed treatment is less likely to be guideline-concordant.[32, 34] This may be related to the fact that the success of DTC telemedicine is primarily dependent on 'user' ratings, and antibiotics-prescribing physicians were found to be more likely to receive a five-star rating from a parent when they prescribed antibiotics for their child's respiratory tract infection.[35]

Misuse and Abuse of Telehealth

As with any new technology, telehealth has the potential to be misused. Even with the best of intentions, prescribers may be more likely to over-treat minor complaints during telehealth visits than during in-person visits[36] and poor-quality telehealth care may put patients at risk.[33] Legitimate telehealth services also create new potential for erroneous reimbursement claims, many of which may result from unfamiliarity with reimbursement rules. In a 2018 audit of telehealth claims by the Deputy Inspector General of the Centers for Medicare and Medicaid Services (CMS), 31% of sampled claims were for services received at non-rural originating sites or were otherwise unallowable.[14]

Of course, the potential for erroneous or fraudulent telehealth is not limited to physicians; for example, thousands of online pharmacies illegally sell prescription medications, including controlled substances, without a prescription and often at exorbitant prices.[37] Telehealth technology is well suited to the delivery of some evidence-based complementary and alternative therapies such as yoga[38, 39] and mindfulness.[40] However, there is some evidence that it is also being used for alternative medical practices with less scientific support, such as homeopathy,[41, 42] and Scientology.[43] Arizona, one of a few U.S. states that allow licensed naturopathic doctors (ND) to write prescriptions, has permitted NDs to examine patients and prescribe medications by telehealth since 2014.[44] Using telehealth to expand the delivery of complementary and alternative medicine, like using it to increase access to standard evidence-based medical care, will have the unintended consequence of also increasing opportunities for misuse and fraud.

Rural Access and Connected Health

One of the key evidence-based strategies for addressing these challenges is the adoption of connected health systems, which have the potential to increase access to care, improve capacity of physicians to treat patients in rural and isolated areas, and support the needs of patients and their caregivers in their own communities.[45] "Connected health" is a conceptual model of care that encompasses wireless, digital, electronic, mobile, and telehealth technologies designed to enable proactive and efficient health care services.[45] The rapid increase in, and the upward trend of personal use of technological devices and mobile applications, are a driving force behind the connected health growth. The availability and convenience of mobile and connected health technologies are radically transforming and improving care delivery, not only by optimizing services through the use of disruptive innovation applications, but also by empowering patients to take a more active role in their health care.[46]

A leading example of connected health in Missouri, as described on https://missourihealthconnection.org website, is "the Missouri Health Connection (MHC), one of the largest health information exchanges (HIE) in the United States and the only secure, statewide,

private, non-profit HIE in Missouri."[47] MHC supports its participating health care stakeholders by providing an up-to-date, comprehensive, longitudinal health record including clinical and claims data.[47] MHC is a trusted "vendor agnostic" system that connects hundreds of disparate data sources including health care providers, regional, state and national HIEs, health plans, and accountable care organizations (ACO).[47] MHC makes comprehensive health records for more than 22+ million patients available to over 7,000 providers, hundreds of clinics, 14 of 28 community health centers in Missouri, more than 75 hospitals (including Missouri's four largest health systems), three payers, two ACOs, numerous long term care facilities, the Veterans Administration, and the Department of Defense.[47] MHC is the nationally identified Midwest HIE gateway in the CMS supported Patient Centered Data Home initiative, facilitating the exchange of clinical information across the country by connecting to more than 40 other HIEs and covering 92% of the United States population.[47]

In order for connected health to fill some of the gaps left by disappearing rural hospitals and retiring rural physicians, Missouri's 101 rural counties[48] will need the reliable broadband and cellular access already available in its 14 urban counties. Missouri has one of the lowest rates of broadband access in the United States,[49] but Missouri Governor Mike Parson and the Missouri Hospital Association have emphasized the importance of improving rural access to broadband internet in Missouri for improved health care, education, and agriculture.[50]

Conclusions

Missouri has used telehealth technologies for the past 25 years, but has seen a dramatic uptick in use for the past five to ten years. While live interactive health services, such as telepsychiatry and teleICU care, still make up the bulk of the telehealth activity, store-and-forward telehealth services, such as teledermatology, are growing, especially through the network of Veterans Health Affairs hospitals and community-based clinics in the state. And, as payment schema shift toward value-based payment, monitoring of chronic diseases are also increasingly common. [51] With increased use comes the need to design telehealth policies and procedures that ensure high quality of care and patient safety. Health care delivery is increasingly team-based, coordinated care where there is ample communication between the consultant and the primary care team. DTC telemedicine when the teleconsultant has no or limited access to the patient's allergies, medication list, or problem list, may present unique challenges to high quality care, especially for patients with multiple chronic diseases on multiple medications.

Health care is best when it can be delivered regionally, or even better, locally, and where the teleconsultant has a working knowledge of the culture, health resources, and infrastructure that surround the patient where they live. Telehealth policy is being supported and influenced by physicians and their professional organizations locally[18] and nationally. [52 53] Missouri has always moved forward, carefully but steadily, in embracing telehealth technology and should continue to put the patient in the center when designing policy around telehealth.

References

1. Who are Missouri's older adults. Available at: https://www.leadingagemissouri.org/page/MOOlderAdults. Accessed December 9, 2019.
2. Ten things to know about urban vs. rural. Available at: http://mcdc.missouri.edu/help/ten-things/urban-rural.html. Accessed December 9, 2019.
3. Missouri Hospital Association. Primary Care Physicians: Rural and Urban Disparities in Missouri. 2014. https://web.mhanet.com/Primary_Care_Physician_Rural_Urban_Disparities_0614.pdf. Accessed December 31, 2019.
4. DHSS Office of Primary Care and Rural Health. Health in Rural Missouri. Jefferson City 2016-2017.
5. Sherling D, Sherling M. The Promises and Pitfalls of Telemedicine. The American Journal of Accountable Care. 2017;5(2):24-26.
6. Bashshur RL, Shannon G, Krupinski EA, Grigsby J. Sustaining and Realizing the Promise of Telemedicine. Telemedicine and e-Health. 2013;19(5).
7. Revisor of Statutes - State of Missouri. Title XII PUBLIC HEALTH AND WELFARE. August 28, 2018. Available at: https://revisor.mo.gov/main/OneSection.aspx?section=191.1145&bid=35039&hl=. Accessed December 4, 2019.
8. American Academy of Family Physicians. What's the difference between telemedicine and telehealth?. 2019. Available at: https://www.aafp.org/media-center/kits/telemedicine-and-telehealth.html. Accessed December 20, 2019.
9. Telehealth Programs. August 2019. Available at: https://www.hrsa.gov/rural-health/telehealth/index.html. Accessed December 9, 2019.
10. Dillon D, Mikes J. The status of telemedicine in Missouri. Jefferson City 2017.
11. Curators of the University of Missouri System. Extending Specialty Care into Primary Care. 2017. Available at: https://showmeecho.org/. Accessed December 20, 2019.
12. Missouri 99th General Assembly, Second Regular Session. House Bill No. 1617. 2018. Available at: https://house.mo.gov/billtracking/bills181/hlrbillspdf/4389H.01I.pdf. Accessed December 20, 2019.

13. CMS. Telehealth services. January 2019. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/TelehealthSrvcsfctsht.pdf. Accessed December 9, 2019.
14. Jarmon GL. CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements. Washington, DC 2018.
15. Cason J, Brannon J. Telehealth regulatory and legal considerations: Frequently asked questions. Int J Telerehabil. 2011;3(2):15-18.
16. Wicklund E. Debating the pros and cons of licensure compacts for telehealth. March 16, 2018. https://mhealthintelligence.com/news/debating-the-pros-and-cons-of-licensure-compacts-for-telehealth. Accessed December 11, 2019.
17. Interstate Medical Licensure Compact (IMLC). The IMLC. 2019. Available at: https://imlcc.org/. Accessed December 9, 2019.
18. Gamm J. Missouri reimagines rural health care. News Tribune. December 2019.
19. Public Health Institute Center for Connected Health Policy. National Policy - Malpractice. 2019. Available at: https://www.cchpca.org/telehealth-policy/malpractice. Accessed December 20, 2019.
20. Elser W, Ackerman B. Is the Doctor In? Medical Malpractice Issues in the Age of Telemedicine. National Law Review. 2019.
21. Institute of Medicine (US) Committee on Evaluating Clinical Applications of Telemedicine; Field MJ, editor. 2. Evolution and Current Applications of Telemedicine. Telemedicine: A Guide to Assessing Telecommunications in Health Care. Washington DC: National Academies Press (US); 1996.
22. Portnoy JM, Waller M, De Lurgio S, Dinakar C. Telemedicine is as effective as in-person visits for patients with asthma. Annals of Allergy, Asthma, & Immunology. 2016;117(3):241-245.
23. Lin MH, Yuan WL, Huang TC, Zhang HF, Mai JT, Wang JF. Clinical Effectiveness of Telemedicine for Chronic Heart Failure: A Systematic Review and Meta-Analysis. Journal of Investigative Medicine. 2017;65(5):899-911.
24. Eibla JK, Gauthier G, Pellegrini D, et al. The Effectiveness of Telemedicine-Delivered Opioid Agonist Therapy in a Supervised Clinical Setting. Drug and Alcohol Dependence. 2017;176:133-138.
25. Weintraub E, Greenblatt AD, Chang J, Himelhoch S, Welsh C. Expanding access to buprenorphine treatment in rural areas with the use of telemedicine. The American Journal on Addicitons. 2017;27(8):612-617.
26. Zheng W, Nickasch M, Lander L, et al. Treatment Outcome Comparison Between Telepsychiatry and Face-to-face Buprenorphine Medication-assisted Treatment for Opioid Use Disorder: A 2-Year Retrospective Data Analysis. Journal of Addiciton Medicine. 2017;11(2):138-144.
27. Center for Medicare and Medicaid (CMS). Telehealth. 2019. Available at: https://www.medicare.gov/coverage/telehealth. Accessed December 6, 2019.
28. 110th Congress, 2nd session. H. R. 6353 - An Act to amend the Controlled Sustances Act to address online pharmacies. September 23, 2008. https://www.justice.gov/archive/olp/pdf/hr-6353-enrolled-bill.pdf. Accessed December 9, 2019.
29. Missouri Senate. SB 579. 2016. Available at: https://www.senate.mo.gov/16info/BTS_Web/Bill.aspx?SessionType=R&BillID=22246494. Accessed December 20, 2019.
30. Missouri Division of Professional Registration. Missouri Board of Registration for the Healing Arts. 2019. Available at: https://www.pr.mo.gov/healingarts.asp. Accessed January 2, 2020.
31. Elliott T, Shih J. Direct to consumer telemedicine. Current Allergy and Asthma Reports. 2019;19(1).
32. Uscher-Pines L, Mulcahy A, Cowling D, Hunter G, Burns R, Mehotra A. Access and quality of care in direct-to-consumer telemedicine. Telemedicine and e-Health. 2016;22(4).
33. Resneck Jr. JS, Abrouk M, Steuer M, et al. Choice, Transparency, Coordination, and Quality Among Direct-to-Consumer Telemedicine Websites and Apps Treating Skin Disease. JAMA Dermatology. 2016:768-775.
34. Ray KN, Shi Z, Gidengil CA, Poon SJ, Uscher-Pines L, Mehrotra A. Antibiotic Prescribing During Pediatric Direct-to-Consumer Telemedicine Visits. Pediatrics. 2019;143(5).
35. Foster CB, Martinez KA, Sabella C, Weaver GP, Rothberg MB. Patient Satisfaction and Antibiotic Prescribing for Respiratory Infections by Telemedicine. Pediatrics. 2019;144(3).
36. Mehrotra A, Paone S, Martich GD, Albert SM, Shevchik GJ. A Comparison of Care at E-visits and Physician Office Visits for Sinusitis and Urinary Tract Infection. JAMA Internal Medicine. 2013:72-74.
37. Pomerantz JM. Internet Prescriptions: Risky Business for Physicians and Patients Alike. Medscape News & Perspective. April 1, 2004. Available at: https://www.medscape.com/viewarticle/474975.
38. Schulz-Heik RJ, Meyer H, Mahoney L, et al. Results from a clinical yoga program for veterans: yoga via telehealth provides comparable satisfaction and health improvements to in-person yoga. BMC Complementary and Alternative Medicine. 2017:198-206.
39. Selman L, McDermott K, Donesky D, Citron T, Howie-Esquivel J. Appropriateness and acceptability of a Tele-Yoga intervention for people with heart failure and chronic obstructive pulmonary disease: qualitative findings from a controlled pilot study. BMC Complementary and Alternative Medicine. 2015:1-13.
40. Davis JM, Manley AR, Goldberg SB, Stankevitz KA, Smith SS. Mindfulness training for smokers via web-based video instruction with phone support: a prospective observational study. BMC Complementary and Alternative Medicine. 2015:95.
41. North American Society of Homeopaths. The Use of Telemedicine in Homeopathy Prescribing. North American Society of Homeopaths. June 3, 2019. Available at: https://homeopathy.org/the-use-of-telemedicine-in-homeopathy-prescribing/.
42. Gopalakrishnan V. Telemedicine in Homoeopathy -The need of the hour. Similima - Everything on Homeopathy. July 7, 2018. Available at: https://www.similima.com/telemedicine-in-homoeopathy-the-need-of-the-hour/.
43. D'Onfro J. These online volunteers fight fake reviews, ghost listings and other scams on Google Maps — and say the problem's getting worse. CNBC Top News. April 13, 2018. Available at: https://www.cnbc.com/2018/04/13/google-maps-spam-fighters.html.
44. Arizona State Senate. Senate Bill 1339. Phoenix, AZ 2014.
45. Caulfield B, Donnelly S. What is connected health and why will it change your practice? QJM An International Journal of Medicine. 2013;106(8):703-707.
46. Frist W. Connected health and the rise of the patient-consumer. HealthAffairs. 2014;33(2).
47. Missouri Health Connection. Missouri Health Connection. 2019. Available at: https://missourihealthconnection.org/. Accessed January 2, 2020.
48. Missouri Department of Health and Senior Services. Health in Rural Missouri. 2015. Missouri Department of Health and Senior Services. Accessed December 31, 2019.
49. BroadBandNow. US States With the Worst and Best Internet Coverage 2018. 2018. https://broadbandnow.com/report/us-states-internet-coverage-speed-2018/. Accessed December 31, 2019.
50. Shaw A. Crucial need for rural broadband creates inequities in Missouri. Columbia Missourian. December 2019.
51. Paré G, Jaana M, Sicotte C. Systematic Review of Home Telemonitoring for Chronic Diseases: The Evidence Base. Journal of the American Medical Informatics Association. 2007;14(3):269-277.
52. American Academy of Dermatology. Position Statement on Teledermatology. 2016. Available at: https://server.aad.org/Forms/Policies/Uploads/PS/PS-Teledermatology.pdf. Accessed December 20, 2019.
53. Daniel H, Sulmasy LS. Policy Recommendations to Guide the Use of Telemedicine in Primary Care Settings: An American College of Physicians Position Paper. Annals of Internal Medicine. 2015;163(10):787-789.

Disclosure

None reported. **MM**

Accelerating Care Through ECHO: Case Examples from the Field

by Mirna Becevic, PhD, Emmanuelle Wallach, MA, Lincoln R. Sheets, MD, Hope Misterovich, DO, Susan Norris, FNP-C, Evelyn Aboagye, MD, Jonathan A. Dyer, MD, Bruce R. Bacon, MD, Karen Edison, MD & Kristin Sohl, MD

Missouri Telehealth Network
University of Missouri

These patients' stories provide evidence of the increased care capacity that is the main goal of Show-Me ECHO.



Mirna Becevic, PhD, (above), is Assistant Professor, Department of Dermatology, Lead Evaluator; Lincoln R. Sheets, MD, PhD, is Assistant Research Professor, Department of Health Management and Informatics, Associate Director of Data and Evaluation; Emmanuelle Wallach, MA, is Evaluation Coordinator; Karen E. Edison, MD, FAAD, MSMA member since 1991, is Professor Emerita of Dermatology, Senior Medical Director; Kristin Sohl, MD, FAAP, is Associate Professor Department of Child Health, Executive Director, ECHO Autism Medical Director; all are at the Show-Me ECHO/ Missouri Telehealth Network, University of Missouri-Columbia School of Medicine, Columbia, Missouri. Hope Misterovich, DO, is with Cox Health, Springfield, Missouri. Susan Norris, FNP-C, is with Shannon County Family Clinic, Eminence, Missouri. Evelyn Aboagye, MD, MPH, FAAP, is with Mercy Clinic Rolla Pediatrics, Rolla, Missouri. Jonathan A. Dyer, MD, is Interim Chair Department of Dermatology, Professor of Dermatology, Director of Pediatric Dermatology and Child Health, University of Missouri-Columbia School of Medicine. Bruce R. Bacon, MD, is the James F. King MD Endowed Chair in Gastroenterology, Professor of Internal Medicine, Director of the Saint Louis University Liver Center, Saint Louis University, St. Louis, Missouri.
Contact: becevicm@health.missouri.edu

Abstract

In this article, we describe three life-changing patient cases demonstrating high-quality and timely care they received in their communities, thanks to the Show-Me ECHO project. Early autism diagnosis, a potentially deadly tumor manifesting as a benign-looking rash, a recalcitrant case of hepatitis C: rural and underserved Missourians now have access to state-of-the-art care through their local providers receiving interdisciplinary telementoring on evidence based practices.

Introduction

Early interventions for a toddler result in his increased independence and improved quality of life for the family; a woman obtains information that corrects a misdiagnosis and saves her life; and another receives services that cure a life-altering disease. At first glance these seem unrelated, however none of these individuals would have realized life-changing benefits if not for Show-Me ECHO.

Show-Me ECHO (Extension for Community Healthcare Outcomes) is a continuing education and telementoring project that leverages videoconferencing technology and adult learning theory to improve care for rural and underserved patients in Missouri. Founded as a replication of New Mexico's Project ECHO, Show-Me ECHO seeks to "move knowledge rather than patients."[1] ECHO invites primary care providers (PCPs) to attend regularly scheduled virtual learning sessions in a didactic and case-based format, where they gain expertise and confidence in treating their existing patients within their own community. ECHO sessions are strategically focused and organized to follow a tested model: a) amplification of scarce resources through leveraging virtual technology, b) best-practices: a multi-disciplinary hub team content experts provide short didactic presentations on best practice, c) case-based learning: PCPs present real-life but de-identified cases for guidance and mentoring, and d) data monitoring: process and outcomes data are collected and analyzed.

Hub-team specialists are trained facilitators who foster an inclusive and judgment-free environment, and cultivate a community of practice by working through cases with all members of the ECHO. This practice fosters development of regional experts as described in other articles in this series. Most providers join an ECHO because they have noticed a gap in their knowledge, or have identified

a health issue in their patient population that they feel ill-prepared to address, and many continue to participate for years.

ECHO increases the capacity of participating PCPs which, in turn, improves timely diagnosis and quality of patient care. Patients benefit in general by their providers' increased knowledge gained through ECHO. Some benefit directly by having their de-identified case discussed within the ECHO specialty hub team. Here they benefit from the combined wisdom of a large group of providers with differing perspectives and specialties. During case discussions, the hub team shares expertise, and participants contribute their knowledge of local resources and culture. The patient's PCP is available to answer questions. Care provided through the ECHO model is potentially superior to referral to specialists, because each specialist would only have access to a reductive snapshot of the patient's problems, and the PCP would need to integrate recommendations from different specialists.

We examine three patient cases that illustrate Show-Me ECHO's impact on improved patient outcomes in Missouri.

Methods

Three cases were selected from Show-Me ECHO archives for autism, dermatology, and hepatitis C. The PCPs presented the cases to help the individual patient and foster learning among all ECHO participants. Cases highlight disparate diseases, patient populations (children, inhabitants of rural areas, and older adults), and ECHO goals (empowering pediatricians to diagnose autism, educating PCPs to address complex skin problems, and bringing cure to patients who would not get treated otherwise).

We used: 1) transcripts of the recorded case presentations, 2) PCP submitted summaries of patient's demographics, medical history, and current complaint ("case forms") and 3) hub team case recommendation forms, highlighting the diagnosis and next steps. All cases were de-identified prior to presentation. The project was reviewed and acknowledged by the University of Missouri Institutional Review Board (IRB).

Results

Case 1: ECHO Autism

Autism Spectrum Disorder affects 1 in 59 children in the U.S. and is an early childhood neurodevelopmental disorder.[2,3] It can be reliably identified by age 24 months, however, age of diagnosis for the United States is four years seven months.[2,3] This delay significantly impacts outcomes as early intervention is critical for optimal improvement.[4,5,6] Missouri's Show-Me ECHO Autism is empowering primary care providers to diagnosis young children with obvious symptoms of autism.[5, 7]

A two-year nine-month-old boy is referred to a primary care clinic for autism evaluation by his First Steps support specialist who had convinced foster parents to seek care due to concerns for delayed speech, excessive emotional meltdowns, restrictive eating, and poor interaction with peers. Missouri First Steps is "an early intervention system that provides services to families with children, birth to three years of age, with disabilities or developmental delays."[8] With the support of ECHO Autism, a local pediatrician had been providing comprehensive Autism evaluation for four years and routinely received referrals from community agencies, local school districts, and other medical practices.

The pediatrician noted that the boy had been saying a few single words and was using sign language by nine months of age, but had regressed to no words or use of sign. He had multiple foster placements intermixed with biological parents as caregivers. At the time of presentation he was in emergency foster care with a relative who had consistently been in his life. His foster parents had noted the regression in his speech and changes in his behavior. The boy had a complete two-part Autism evaluation within four weeks.

He had considerable symptoms across diagnostic categories based on the Diagnostic and Statistical Manual of Mental Disorders (DSM) 5 parent interview. He did not respond to his name when called, had minimal to no engagement with caregivers and did not seek to engage others in activities or share emotions. He was noted to give forceful hugs and kisses. His play skills were limited and he showed minimal interest in peers. Additionally, he made no eye contact, vocalizations, or gestures to communicate his wants and needs. His preferred method was to place his hand on another person's and move it to the item he wanted. All of these behaviors are noted as significant for deficits in social communication, social pragmatics, and interaction with peers. He had restricted interests in his toy cars, which he liked to line up. He sorted

his objects in color and followed patterns when lining them. He exhibited repetitive hand flapping or running in circles. He liked to put his head on the floor, and showed extreme distress in changes in routine or transitions, which manifested as excessive crying, screaming, spitting, and putting fingers down his throat to gag himself. His insistence on sameness was highlighted in his restrictive eating pattern, limited to ramen noodles, spaghetti sauce and noodles, crackers or chips from a bag. He was obsessed with mirrors, water, and rocks. He liked to carry his sippy cup and blanket, and it was challenging for him to transition away from these items. Additionally, he visually inspected items like the floor and other objects.

His physical exam was negative for dysmorphic features. Consistent with foster parent reporting, he demonstrated very limited eye contact, difficulty with transitions, significant emotional distress, no words, hand flapping, running in circles, and gagging himself. With these restrictive repetitive behaviors and deficits in social communication, there was enough concern for Autism Spectrum Disorder (ASD) and further testing using Screening Tool for Autism in Toddlers and Young children (STAT). With foster parent consent, his First Step records were reviewed, which showed significant delays in communication and social-emotional development, and behavior concerns exhibited in the home setting. He had no formal hearing evaluation completed and no other testing for his developmental delays. He was also having staring spells, which both First Steps provider and foster parents had noted, concerning for a seizure. General developmental screening using Ages and Stages Questionnaire (ASQ) showed global developmental delay in the areas of social communication, fine motor skill development, social skills and problem solving. Modified Checklist for Autism in Toddlers-Revised (MCHAT-R) was at risk for autism. With ASD as a possible diagnosis for his behavior and delays, STAT testing was done showing significant risk for ASD. Given the complexity, the pediatrician presented the case at ECHO Autism, for further guidance and mentoring from the hub team.

Together with clinical history, records reviewed from First Steps, at risk STAT testing and other developmental tools such as MCHAT-R, ASQ, the boy met the criteria for ASD, which was confirmed at ECHO Autism. Autism resources, including Autism Speaks, were given to the foster parents. While awaiting testing, the patient was referred to audiology for hearing evaluation and blood tests for micronutrient deficiency completed. Neurology was consulted to rule out a seizure disorder with staring episodes; and later he was sent to genetics due to family history of ASD, his behaviors, and global developmental delays.

Together with clinical history, records reviewed from First Steps, at risk STAT testing and other developmental tools such as MCHAT-R, ASQ, the boy met the criteria for ASD, which was confirmed at ECHO Autism. His foster parents were relieved they were able to get the diagnosis in their community, and without travel. They received an information packet on ASD and tools to help with communication. He was enrolled in services and guidance for early childhood with local school system special education to begin at the age of three years. An Individual Education Plan (IEP) and Applied Behavior Analysis (ABA) therapy services were requested. Every four months follows up with the pediatrician were scheduled.

Case 2: Dermatology ECHO

Dermatomyositis (DM) is a complex skin condition characterized by an inflammatory skin rash, muscle inflammation, and the potential for involvement of other organs. DM can be difficult to diagnose due to variability in severity of clinical and histologic features.[9] Classic clinical features include muscle weakness, fever, fatigue, and gastrointestinal symptoms (reflux and diarrhea); which vary significantly from patient to patient.[9] With a prevalence of 1-9 per 100,000 patients, DM is rare and often misdiagnosed.[10,11] Delayed diagnosis of DM may cause significant damage to muscles and other organs, as well as a potential association with internal malignancy. Failure to diagnose DM can lead to prolonged patient suffering and poor patient outcomes, including significant morbidity and mortality.[11]

In 2018, a 66-year-old woman was referred to a Dermatology ECHO-participating PCP with a rash on her hands, upper arm, and lateral proximal thighs that had started a 1.5 months, after a trip out of state (Figures 1-3). The patient reported chronic lower extremity muscle weakness that she blamed on the statins she had taken for a short while in 2005. However, there were no concerns related to proximal muscle weakness, which the PCP confirmed by observing the patient during her visit.







Figures 1, 2, 3. A Patient Presented with These Rashes to a Dermatology ECHO-Participating PCP

A first provider made a working diagnosis of contact dermatitis and prescribed prednisone, after triamcinolone 0.1% cream proved ineffective. After 12 days on prednisone with no improvement, the patient was referred to a local primary care dermatology expert who had participated in Dermatology ECHO for four years, and the patient remained under her care until her issues were resolved. The appearance of the skin rash, including exam findings of ragged cuticles and dilated capillaries, suggested Dermatomyositis. The PCP performed a skin biopsy (Figure 1) which revealed changes consistent with lupus or Dermatomyositis,

Table 1 - Summary of Healthcare Visits for Case 2

Timeline of office visits	Diagnosis	Medication prescribed	Procedures performed/ordered	Results
t = -100 days *Routine surveillance*			Colonoscopy	Normal
			Mammogram	Normal
t = -21 days	66-year-old Caucasian female notices rash after travel out of state			
Initial *t* = 0 *Referring PCP*	Contact dermatitis	TAC 0.1% cream		
t = 30 days *Referring PCP*	?	Two-week course of oral prednisone	Biopsy of right upper extremity	Pathology consistent with superficial perivascular dermatitis with eosinophils, possible drug reaction but nonspecific.
t = 42 days *Local dermatology-expert PCP*	Dermatomyositis		Skin biopsy of right hand	Interface dermatitis: lupus or Dermatomyositis
			Various labs	- Mildly elevated aldolase (11.3) - Markedly elevated ANA levels (1:1,280, speckled pattern) - Normal CA-125 levels (12.8)
t = 49 days ***ECHO consult*** *by dermatology-expert PCP*	Dermatomyositis confirmed	Methotrexate or Imuran recommended	CT chest-abdomen-pelvis suggested every 6 to 12 months; baseline PFTs; proximal muscle testing	
t = 61 days *dermatology-expert PCP*	Shared ECHO recommendations with patient; referred to rheumatology			
Rheumatology	Amyotrophic Dermatomyositis	Initially plaquenil, but rash developed; then methotrexate with improvement in rash	Various labs	- Repeat aldolase normal at 4.5 - Low white blood count so methotrexate dosing limited to 15 mg weekly
			CT scan	Ovarian mass; possible endometriomas
			MRI of pelvis and pelvic ultrasound	Patient referred to gynecological oncology
Gynecological oncology			Serial imaging	
			Serial CA-125	- 11.9 at *t* = 115 - 16.4 at *t* = 235 - 46.6 at *t* = 325
t = 325 days *Surgery*			Hysterectomy with BSO	Pathology consistent with right ovary serous borderline tumor and left ovary clear cell borderline adeno-fibroma. Peritoneal cytology negative for malignancy.
Second ECHO consult: Resolution	Asymptomatic	No longer on MTX		

Both aldolase and antinuclear antibody panel (ANA) levels were elevated, but cancer antigen 125 (CA-125) levels were normal. A routine mammogram and colonoscopy performed three to four months prior were also normal (Table 1).

The Dermatology ECHO hub team focused mentoring discussion on: a) yearly evaluation for lung disease using appropriate pulmonary function tests, and b) screening for malignancy by repeat (6-12 month) computerized tomography (CT) scans of the chest, pelvis, and abdomen, for the first three years after diagnosis. Muscle strength evaluation was recommended to establish a baseline should her existing weakness progress. The diagnosis and recommendations were shared with the patient and the patient was referred to rheumatology for further treatment.

The PCP presented a follow-up case a year later. The CT scan showed ovarian cancer in both ovaries, which had been successfully treated by a hysterectomy nine months after the first case presentation. The rash and Dermatomyositis immediately resolved without need for further treatment. The Dermatology ECHO recommendation for continued CT monitoring resulted in timely treatment and may have saved this patient's life.

Case 3: Hepatitis C

Hepatitis C is a viral liver infection that becomes chronic in 70-85% of patients. [12] Untreated Hepatitis C may result in liver cirrhosis, liver cancer, and death.[6] Hepatitis C infection is often asymptomatic and many people are unaware of it. The virus spreads easily though contact with blood or body fluids and is a major public health concern. Estimates are about 3.5 million people are living with Hepatitis C virus (HCV) in the US.[13] Hepatitis C is curable with appropriate, timely treatment.[14] Studies show that newer medications yield sustained virologic response (SVR) rates in excess of 95% after eight to twelve weeks of treatment.[15] In 2017, a 61-year-old, woman presented to her PCP, a family nurse practitioner, for a well-woman exam with a complaint of fatigue. Routine HCV screening, as recommended by the CDC for baby boomers, yielded a diagnosis of hepatitis C. The route of transmission was believed to have been a 30-year-old tattoo.

Table 2 - Summary of Healthcare Visits for the Patient in Case 3

Timeline of office visits	Diagnosis	Meds.	Procedures	Results
t ≈ -30 years	Patient acquires a tattoo			
Initial *t* = 0	Hepatitis C Chronic Hepatitis B?		Hep B serology	- HBsAB negative - HBsAG negative - HBcAB IgM negative - HBcAB positive
			Hep C serology	- Genotype 1A - HCV viral load 1,243,483
			Other serology	- Hepatitis A negative serology - HIV negative
			Other labs	- WBC 7.9 - HGB 14.3 - Platelets 42.5 - INR 1.1 - Creatinine 0.74 - ALT (SGPT) 76 - AST (SGOT) 65 - Total bilirubin 0.6 - Albumin 4.1 - HCG negative - TSH 1.67 - Urine drug test negative - HGB A1c 6.6%
			Fibrosure	- METAVIR score of F3 (bridging fibrosis) - Abdominal ultrasound results not yet available (will be normal)
ECHO consult (*t*=1 mo)	Hepatitis C	Harvoni (8 weeks) recommended		
Follow-up with patient (*t* = 1 month)		Harvoni	Updated labs	- WBC 7.6 - Platelets 332 - INR 1.1
Follow-up with patient (*t* = 3 months)				- Negative Hep C RNA
t = 9 months	Hepatitis C relapse		Updated labs	- HGB 8.6 - Creatinine 0.84 - ALT (SGPT) 31 - AST (SGOT) 41 - Albumin 3.8 - HBcAB positive - HB-DNA negative - Total bilirubin 0.5 - HBsAB negative - HCV viral load 740,992 IU/mL
			Blood transfusion	Normalized HGB
ECHO follow-up (*t* = 9 months)		Vosevi recommended		
Follow-up with patient *t* = 13 months	Fibrosis cured	Vosevi (1 month in)	Updated labs	- HGB 7.6 - ALT 20 - AST 35
			Cancer screening	- Large abdominal mass palpable - CA-125 1,550

The patient had a medical history of diabetes, hypertension, anxiety, and depression, the latter two exacerbated by her Hepatitis C diagnosis. She reported smoking one pack of cigarettes per week and drinking one small glass of wine daily, and denied getting drunk or binge drinking. She also had a history of marijuana use. Smokers have increased risk of liver damage, and smoking has been shown to negatively impact hepatitis C anti-viral therapies.[16] During her initial visit, the PCP ordered Hepatitis B serology screen and suggested a Fibrosure test for liver damage (Table 2). Results showed a METAVIR score of F3 (bridging fibrosis). An abdominal ultrasound results were not available at the time. As of her initial visit, patient medications included losartan (50 mg daily), glimepiride (1 mg daily), cinnamon tablets (two 500 mg capsules daily), and acetaminophen, naproxen, or ibuprofen taken as needed.

The case was presented to the Hepatitis C ECHO in May, 2017. The PCP's main questions were: "Is eight weeks of Harvoni the optimal treatment choice for this patient? Does the patient have inactive Hepatitis B?" The PCP was assured of continual support in treating her patient until a cure of Hepatitis C was achieved. The team would come back to this patient's case two additional times before a cure was achieved, about 20 months later.

The first ECHO discussion focused on validating the provider's proposed course of treatment. While the hepatitis C hub team specialists suggested several medications to consider, they ultimately agreed with the proposed eight weeks of Harvoni.

While Hepatitis C RNA was negative at the end of treatment, it was positive again at her next visit, indicating relapse, although lab tests showed some improvement (Table 2). The PCP brought the case ECHO follow-up. A severe nosebleed necessitated a blood transfusion. An abdominal ultrasound indicated that the patient's liver was normal. The patient reported that she still smoked one pack of cigarettes a week but denied drinking or using marijuana. After discussion, the PCP was advised to treat with Vosevi, another Hepatitis C medication indicated for treatment following failure or relapse.

The patient committed to using Vosevi as a treatment and arrived for follow-up after her first month on the medication at which time the PCP palpated a large mass on abdominal exam. The PCP shared her concerns of ovarian cancer with the patient and recommended a CT scan, which revealed a tumor of about 13 centimeters. This PCP returned to ECHO with a concern of continuing treatment while the patient underwent surgery. At this point, the patient was in the normal range for ALT and AST (20 and 35 respectively) and liver inflammation was resolved. The PCP was encouraged to continue treatment despite the ovarian cancer surgery, and to make sure that the patient did not miss a dose.

The final follow up was presented ten months later, 23 months after the case was first discussed. The PCP reported the patient, having followed all treatment plans, had tested positive for a sustained virologic response (SVR) three months after the end of treatment, and had been declared cured. The entire ECHO team celebrated this victory with the PCP.

Discussion

These three cases highlight the profound effects that ECHO has on both providers and patients. Show-Me ECHO discusses approximately 400 cases annually. Because they have access to a learning community for education and support, providers gain the knowledge and confidence to treat complex patient cases that they might feel compelled to otherwise refer to far-away specialists. Patients gain the ability to access state-of-the-art care in a familiar, local, primary care setting.

In two of the cases, the patient went to see a particular primary care provider because of her expertise in their condition: both the pediatrician from Case 1 and the family practitioner from Case 2 have become known as the regional expert in Autism and Dermatology respectively. These patients' stories provide evidence of the increased care capacity that is the main goal of Show-Me ECHO. To review available ECHO topics please consult Appendix 1. We invite you to join an ECHO: observe, participate, and consider presenting a case of your own. We're excited for you to join our community of learners and start benefitting yourself, your patients, and your community.

References

1. University of New Mexico School of Medicine. Project ECHO. Available at echo.unm.edu Accessed October 2, 2019.
2. Centers for Disease Control and Prevention (CDC). Autism Spectrum Disorder (ASD). August 27, 2019. Available at: https://www.cdc.gov/ncbddd/autism/index.html. Accessed September 3, 2019.
3. Baio J WLCDea. Prevalence of Autism Spectrum Disorder Among Children Aged 8 Years — Autism and Developmental Disabilities Monitoring Network, 11 Sites, United States, 2014. MMWR Surveill Summ. 2018;67(SS-6):1-23.
4. Dawson G. Randomized, Controlled Trial of an Intervention for Toddlers With Autism: The Early Start Denver Model. Pediatrics. 2010;125(1):17-23.
5. The Autism and Developmental Disabilities Monitoring (ADDM) Network. A Snapshot of Autism Spectrum Disorder in Missouri. 2018. https://www.cdc.gov/ncbddd/autism/addm-community-report/missouri.html. Accessed September 3, 2019.
6. The Autism and Developmental Disabilities Monitoring (ADDM) Network. Spotlight On: Delay Between First Concern to Accessing Services. 2018. https://www.cdc.gov/ncbddd/autism/addm-community-report/delay-to-accessing-services.html. Accessed September 3, 2019.
7. Missouri Telehealth Network (MTN). Autism Specialist Support for Primary Care. 2019. Available at: https://showmeecho.org/clinics/autism/. Accessed September 3, 2019.
8. Missouri First Steps. 2010. Available at: https://www.mofirststeps.com/. Accessed December 3, 2019.
9. Thompson C, Piguet V, Choy E. The pathogenesis of dermatomyositis. British Journal of Dermatology. 2017;179(6)
10. Dermatomyositis. July 23, 2019. Available at: https://www.orpha.net/consor/cgi-bin/OC_Exp.php?Expert=221. Accessed July 24, 2019.
11. Harna B, Sharma P, Dutt Dwivedi D, Sabat D. Dermatomyositis a Diagnositic Delimma: An Interesting Case Series and review of literature. Journal of Clinical and Experimental Dermatology Research. 2017;8(5).
12. Centers for Disease Control and Prevention (CDC). Hepatitis C. June 13, 2019. https://www.cdc.gov/hepatitis/hcv/index.htm. Accessed September 3, 2019.
13. Edlin BR, Eckhardt BJ, Shu MA, Holmberg SD, Swan T. Toward a More Accurate Estimate of the Prevalence of Hepatitis C in the United States. Hepatology. 2015;62(5):1353–1363.
14. American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. 20129. Available at: https://www.hcvguidelines.org/. Accessed September 3, 2019.
15. Hepatitis Central. Medications to Treat Hepatitis C – A Timeline. 2019. Available at: https://www.hepatitiscentral.com/medications-to-treat-hepatitis-c-a-timeline/. Accessed September 3, 2019.
16. Zimmermann T, Hueppe D, Mauss S, et al. ffects of Smoking on Pegylated Interferon alpha 2a and First Generation Protease Inhibitor-based Antiviral Therapy in Naïve Patients Infected with Hepatitis C Virus Genotype 1. J Gastrointestin Liver Dis. 2014;25(1):15-24.

Disclosure

None reported. **MM**

Integrating the Lived Experience Conditions and Care in the ECHO Model

by Tracy Greever-Rice, PhD, Lea Brandt, PhD, Melissa Warne-Griggs, PhD & Kimberly Hoffman, PhD

Missouri Telehealth Network
University of Missouri

The Show Me ECHO 'lived experience' role is intended to lift up the patient perspective, foster engagement of patients and families and help address power imbalances.



Tracy Greever-Rice, PhD, is Director, Center for Health Policy, Assistant Research Professor, University of Missouri-Columbia, Columbia, Missouri. Lea Brandt, PhD, OTD, MA, is Associate Professional Practice Professor; Melissa Warne-Griggs, PhD, is an Administrative Consultant; Kimberly Hoffman, PhD, is Professor Emerita, Family and Community Medicine; all are at the University of Missouri-Columbia School of Medicine, Columbia.

Abstract

Show Me ECHO has introduced a 'lived experience' role by including patients and caregivers into some of its ECHO Hub Teams. Grounded in the patient-centered care model, this role provides insights into the lived experience of patients and caregivers experiencing chronic conditions. The goals are to improve patient outcomes, strengthen authentic communication and partnership between providers, patients, and patients' support systems, and to enhance local communities' ability to support its members dealing with chronic conditions.

Introduction

Alicia listened carefully to a team of health care providers as they discussed the behaviors of a 10-year-old boy with autism. The boy's primary care provider described his condition and behaviors, and the team puzzled together as to why the boy arrived at school each day without his shoes. Was this neglect? Did the team need to engage a child welfare representative or the school district? As a parent of a child with autism, Alicia had a different perspective, a lived experience perspective. Perhaps the boy was simply exercising his autonomy and getting rid of his discomfort with shoes by tossing them and his socks out of the school bus window.

Key to providing the right care in the right place at the right time is understanding what works for the patient and their family within their own community. Show Me ECHO (Extension for Community Healthcare Outcomes) has used this fundamental principle while providing education and mentoring to primary care providers who work with underserved populations. They have done this by including in their panel of experts (the Hub Team) a person or family member of a person with the condition being studied. In this lived-experience role, Alicia Curran shares insights, practical examples, potential unintended consequences, and strategies as ECHO teams discuss patients. This paper describes how a family member with lived experience was integrated into Show Me ECHO's Autism ECHO and highlights the benefits of incorporating the lived experience voice into ECHO.

Background

The Show Me ECHO model is based on the University of New Mexico's technology-enabled collaborative learning and capacity building model developed by Dr. Sanjeev Arora to address Hepatitis C in rural New Mexico.[1] Show Me ECHO utilizes a standard format to provide mentoring to participants which includes: 1) regularly scheduled sessions via teleconferencing technology, 2) focused didactic presentations by a member of the multi-disciplinary content expert team (Hub Team),

and 3) providers presenting patients from their own practice for consideration, advice, and mentoring from the Hub Team and other session participants.[2] Incorporating an individual with the condition being studied is not a standard part of the ECHO model. ECHO Autism piloted the lived experience role in 2015.[3,4] Now routine, Show Me ECHO Autism serves as a model for other ECHOs that are working to incorporate the lived experience of patients and caregivers. In order to illustrate the benefits of this role, we provide perspectives from Alicia Curran, other Hub team members, and from participants. This information was obtained through interviews and ECHO evaluation forms.

The Lived Experience Perspective Improves Patient-Centered Care

As a chronic condition impacting development in a pediatric population, autism treatments require close collaboration with caregivers. Parents of children with autism have emerged and matured as an engaged and activated community of advocates for the clinical and educational needs of their children. Programs and initiatives have been co-created that integrate the goals and work of parents and clinicians.

The Lived Experience Role Operationalized

Alicia Curran is an exemplar of this co-creation both for her own child, and many other children with autism. Alicia works for the University of Missouri as the ECHO Autism Director of Operations, Family Faculty for the Missouri Leadership Education in Neurodevelopmental and Related Disabilities (LEND) program.[5] Additionally, she is a Missouri ambassador for the CDC's Learn the Signs. Act Early program.[6] Although her experience as a parent of a child with autism is valuable, Alicia explains why her other work with autism related organizations is so helpful to ECHO learning:

"There are a couple of key components that are really important to this position being effective. First, your story is really important, but having access to many stories is even better. Meaning someone who is active in the 'lived experience' role and autism community is really important because they have interactions with multiple other families and are able to have a broader perspective, when sharing about the family dynamic." (Alicia Curran)

As a Hub team member, Ms. Curran contributes a unique form of expertise to the ECHO team. One way that Curran contributes the parent/caregiver perspective is during case discussions. Evidence of how the 'lived experience' role changes learning for ECHO participants is highlighted in Curran's description of an ECHO discussion:

"A physician said, 'A family had filled out an autism-specific screener (negatively), and right in front of me this kid is doing exactly that behavior, and I'm thinking, why are you lying about what's on that form?' When he got finished, I said, 'Hold on for a second, I want you to think about this a different way. Sometimes when a family is grieving, that totally blinds them. A family not reporting a behavior doesn't mean they're lying – they may be in denial, they may be grieving, or they may see the behavior as perfectly normal because that's all they know.'" (Alicia Curran)

As an ECHO Hub team member, Alicia also uses her expertise to present didactics that help providers support families and encourage effective coordination of care. The 'Supporting Families' didactic focuses on the socio-emotional impact of autism on individual family members, the child with autism, and on the family as a unit. [7] It explores issues like living with grief, ambiguity, and the ongoing adjustment to developmental change. It also identifies short and long-term stressors, and concludes with discussion of the productive tools, techniques, interventions and attitudes that clinicians and clinical practices might engage in supporting children with autism and their families.

Similarly, Curran's 'Coordination of Care' didactic identifies common clinical and non-clinical systems and supports that families with a child with autism may utilize.[8] She identifies: 1) the benefits and risks to families of these engagements, 2) strategies for coordination that maximize family and child wellbeing, and 3) gaps or overlaps that have the potential to increase stress on both children with autism as well as their family and caregivers.

Reactions to the Lived Experience Role

Other members of the ECHO Autism Hub Team also identify benefits of including the lived experience role in routine ECHO discussions:

"Having Alicia as part of the Hub Team definitely makes a difference. One of the things that sometimes happens, particularly for kids with disabilities and families of kids with disabilities, is health care providers find it difficult to deal with the issues and as somewhat of a defense mechanism the providers may sometimes take actions to de-personalize the patient and the family.

It is not intentional but may happen. Having Alicia there and contributing to the conversation, if depersonalizing ever starts it is quickly interrupted. Everyone's humanity is reinforced by having her present. She has significant and challenging real-life experiences and sharing those keeps [the team] patient centered and family centered. Alicia is a full member of the Hub team. She has tons of knowledge, and has also done a lot of professional work in this area. She brings both a professional perspective and personal expertise to the Hub Team." (Rachel Brown, Child Psychiatrist and Hub Team member)

Table 1. Representative Comments from ECHO Evaluations 2015-19

- "I appreciate the invaluable input from Alicia as a parent who has a child with autism. She has very good insight and helps us all think about his from both sides."
- "I think it was good to learn the parent perspective of the grieving process. Every day may be different in the cycle."
- "Having the parent perspective as part of the hub team brings all of the professional recommendations back to reality."
- "She reminds that my patients have families and I have a responsibility to them as well as to the patient. And she puts it all into perspective-that it's tough at time and sometimes sad and she does it without self-pity."
- "She is candid about the realities of raising a son that is significantly impacted by autism. The perspective and insight that a family member brings to clinic is not able to be replicated by any other team member."

ECHO session evaluations reflect the positive impact of the lived experience role on participants' learning. Table 1 provides illustrative comments showing the value of having multiple perspectives available in the ECHO learning environment.

One primary care physician and long-time ECHO Autism participant put it this way:

"It's a whole other viewpoint as far as what's going on and gives you a much-needed sense of what actually goes through the mind of someone who has a child that's on the spectrum, things that they deal with, concerns that they have. I think a lot of times as providers of care, we get so specialized and we get so concentrated on what we're doing, that a lot of times it's hard to empathize maybe with what patients are going through." (Dr. Bill Wright, participant)

Clearly, the lived-experience role adds to the expertise available in the ECHO team by: 1) advocating for the patient, 2) focusing on the 'whole person', 3) sharing examples of community-based resources and activities, and 4) identifying support systems for patients and families.

Discussion

Including the lived experience role is reflective of the patient-centered healthcare reform agenda that has emerged over the past few decades. Patient-centered health reforms seek to better engage both patients, and the public in defining and shaping the organization and delivery of health care. The Institute of Medicine (IOM) 2001 seminal work, conducted by the Committee on Quality of Health Care in American and Institute of Medicine, articulated six domains of health care quality: 1) safe, 2) effective, 3) patient-centered, 4) timely, 5) efficient, and 6) equitable. In the IOM model patient-centered care is characterized by "providing care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions."[9]

The benefits of patient engagement, well documented in the patient-centered reform literature, result from: 1) capitalizing on the expertise of patients and their networks, 2) allowing for more service choices for patients, 3) enhancing responsiveness to changing user needs, and 4) reducing cost and waste.[10, 11]

Meaningful patient engagement fosters involvement of patients and their families, integrated alongside health professionals, to improve health and healthcare services. However, health care providers, health professions educators, and continuing medical education have been challenged to meaningfully integrate the patient perspective into the initial and continued learning of health professionals in part due to power imbalances between patient, providers and policy makers.[10]

Current literature cautions about practices that nullify or minimize the 'lived experience' contribution. For example, tokenism or "making only a perfunctory or symbolic effort to do a particular thing, especially by recruiting a small number of people from underrepresented groups in order to give the appearance of sexual or racial equality within a workforce" is also

a potential risk to successfully integrating the lived experience role into health professions education.[12] Conversely, current literature also provides guidance on how to effectively and authentically engage patients. Successful strategies include: 1) ensuring clarity about the patient role as health team partner, 2) supporting shared and personalized decision making, 3) enhancing communication among care team partners, 4) having patients and team members each contribute information to guide care decision and then explore information to achieve mutual understanding, and 5) recognizing providers and patients as partners that both make vital contributions to produce good health and to improve quality of life for patients, caregivers and family.[11, 13, 14]

Current and Potential Contributions of the Lived Experience Role

Patient-centered approaches to care have been central to the ECHO model from its inception. Dr. Arora described the ECHO model as: "Community providers, particularly community-based health centers, provide coordinated, patient-centered care in facilities proximal to their patients," and "patients are likely to have greater trust in local providers, who tend to be culturally competent with respect to their specific communities. This may enhance patients' adherence to treatment and allow for greater direct contact with the clinician, including more frequent visits."[15]

Incorporating the 'lived experience' role into Show Me ECHO promotes a quality healthcare system that is "coproduced by patients, families, and healthcare professionals working interdependently to co-create and co-deliver care."[16] Show Me ECHO seeks to include the lived experience to support care plans that are culturally relevant for a given conditions and are better able to achieve the IOM's vision of patient-centered care.[11]

The Show Me ECHO 'lived experience' role is intended to lift up the patient perspective, foster engagement of patients and families and help address power imbalances. Building on the patient-centered care model, Show Me ECHO is incorporating the 'lived experience' role in more ECHOs. Beginning with the Opioid Use Disorder ECHO (2017) and the Rural Veterans Behavioral Health ECHO (2018), a person contributing a 'lived experience' perspective as a caregiver or in a dual role as a clinical provider with personal experience with the condition was included as part of the Show Me ECHO Hub Team. More recently, Show Me ECHO has integrated a 'lived experience' Hub team member into ECHOs addressing developmental disabilities (2019) and diabetes management (2019). Show Me ECHO's long-term strategy is to develop, study, and to continuously improve the 'lived experience' role into the ECHO model.

To join an ECHO and see the influence of the lived experience role first hand, go to showmeecho.org.

References

1. Arora S, Thornton K, Jenkusky SM, et al. Project ECHO: Linking university specialists with rural and prison-based clinicians to improve care for people with chronic hepatitis C in New Mexico. Public health reports (Washington, DC). 2007;122 Suppl 2:74-77.
2. Arora S, Kalishman S, Dion D, et al. Partnering urban academic medical centers and rural primary care clinicians to provide complex chronic disease care. Health affairs (Project Hope). 2011;30(6):1176-1184.
3. Sohl K, Mazurek MO, Brown R. ECHO Autism: Using technology and mentorship to bridge gaps, increase access to care, and bring best practice autism care to primary care. Clinical Pediatrics. 2017; 56(6), 509-511.
4. Mazurek MO, Brown R, Curran A, Sohl K. ECHO autism: A new model for training primary care providers in best-practice care for children with autism. Clinical Pediatrics. 2017; 56(3), 247-256.
5. Leadership in Education in Nurodevelopmental and Related Disabilities (LEND). Thompson Center for Autism & Neurodevelopmental Disorders University of Missouri website. https://thompsoncenter.missouri.edu/tips4kids/. Accessed January 7, 2020.
6. Centers for Disease Control and Prevention. Learn the Signs. Act Early. https://www.cdc.gov/ncbddd/actearly/index.html. Accessed January 7, 2020.
7. Curran A. ECHO Autism – Supporting Families [PowerPoint slides]. Provided by the author; 2018.
8. Curran, A. ECHO Autism – Coordination of Care [PowerPoint slides]. Provided by the author; 2018.
9. Institute of Medicine (IOM). Crossing the Quality Chasm: A New Health System for the 21st Century. Washington DC: National Academy Press: 2001.
10. Goodridge D, Isinger T, Rotter T. Patient family advisors' perspectives on engagement in health-care quality improvement initiatives: Power and partnership. Health Expectations. 2018 (21:1) 379-386. Wiley Online Library doi: 10.1111/hex.12633.
11. Batalden M, Batalden P, Margolis P, Seid M, Armstrong G, Opipari-Arrigan L, Hartun H. Co- production of health care services. BMJ Qual Saf. 2016;25:509-517.
12. Hahn DL, Hoffman AE, Felzien M, LeMaster J, Xu J, Fagan LJ. Tokenism in patient engagement. Family Practice. 2017; 34(3): 290–295. doi: https://doi.org/10.1093/fampra/cmw097.
13. Okun S, Schoenbaum S, Andrews D, Chidambaran P, Chollette V, Gruman J, Leal S, Lown B, Mitchell P, Parry C, Prins W, Ricciardi R, Simon M, Stock R, Strasser D, Webb CE, Wynia M, Henderson D. Patients and health care teams forging partnerships . Discussion Paper, Institute of Medicine. 2014. doi: https://doi.org/10.31478/201412f.
14. Hessenlink G, Johnson J, Batalden P, Carlson M, Geense W, Groenewoud S, Jones S, Roy B, Sanson C, Wolf J, Bard B, Wollersheim H. Reframing healthcare services through the lens of co-production (RheLaunCh): A study protocol for a mixed methods evaluation of mechanisms by which healthcare and social services impact the health and well-being of patients with COPD and CHF in the USA and The Netherlands. BMJ Open. 2017;7:e017292. doi:10.1136/bmjopen-2017-017292.
15. Arora, S. Is Project ECHO the telemedicine model that healthcare is missing? mHealthIntelligence. December 22, 2017. https://mhealthintelligence.com/features/is-project-echo-the-telemedicine-model-that-healthcare-is-missing. Accessed January 8, 2020.
16. Sabadosa KA, Batalden PB . The interdependent roles of patients, families and professionals in cystic fibrosis: a system for the co-production of healthcare and its improvement. BMJ Qual Saf. 2014;23:i90–i94. Doi: http://dx.doi.org/10.1136/bmjqs-2013-002782.

Disclosure

None reported.

MM

Assessing Impact of Show-Me ECHO on the Health of Missourians: Two Examples

by Mirna Becevic, PhD, Tracy Greever-Rice, PhD, Emmanuelle Wallach, MA, Lincoln R. Sheets, MD, Kara Braudis, MD, Benjamin Francisco, PhD, Kimberly Hoffman, PhD & Karen E. Edison, MD

Missouri Telehealth Network
University of Missouri

What started as a pilot in 2014 has grown into 22 Show-Me ECHO offerings providing multiple opportunities for Missouri providers.



Mirna Becevic, PhD, (above), is Assistant Professor, Department of Dermatology, Lead Evaluator; Emmanuelle Wallach, MA, is Evaluation Coordinator; Lincoln R. Sheets, MD, PhD, is Assistant Research Professor, Department of Health Management and Informatics, Associate Director of Data and Evaluation; Karen E. Edison, MD, FAAD, MSMA member since 1991, is Professor Emerita of Dermatology, Senior Medical Director; all are at the Show-Me ECHO/ Missouri Telehealth Network; Kimberly Hoffman, PhD, is Professor Emerita, Family and Community Medicine; Kara Braudis, MD, is Assistant Professor, Department of Dermatology; Benjamin Francisco, PNP, PhD, is Teaching Professor, Pulmonary Medicine, Program Director, Asthma Ready® Communities; all are at the University of Missouri-Columbia School of Medicine, Columbia. Tracy Greever-Rice, PhD, is Director, Center for Health Policy, Assistant Research Professor, University of Missouri-Columbia, Columbia, Missouri.
Contact: becevicm@health.missouri.edu

Abstract

Show Me ECHO is a model for interprofessional collaboration that utilizes telehealth technologies to share evidence-based medical knowledge to improve patient outcomes and minimize variation in care for underserved populations. To measure ECHO outcomes, Show Me ECHO develops both an evaluation of clinical outcomes for patients as well as assessing learner outcomes on the Kirkpatrick Typology of Evaluation. This paper describes evaluation models for Dermatology and Childhood Asthma ECHOs.

Introduction

In 2017, Missouri ranked as one of the unhealthiest states in the union: Health Rankings Report positioned Missouri 40th out of 50 states.[1-2] Lack of access to timely and quality care significantly contributes to this ranking.[1] Further, Missouri declined by 16 slots since 1990, which is one of the largest observed declines.[2] This report uses behaviors, community and environment, policy, and clinical care as determinants to evaluate health outcomes.[2] Missouri ranks in the bottom 31 to 40 states in premature, cancer, and drug deaths, and at the 43rd place in self-reported smoking rates (22 percent of adults in Missouri are smokers, compared to 17 percent nationally). [2]

Preventable hospitalizations, with estimated costs of over $30 billion annually, are one of the largest financial burdens on health care systems. [2] Average discharge per 1,000 Medicare enrollees is 49.4, however, Missouri has one of the highest numbers of preventable hospitalization of all states, 56.6 per 1,000 enrollees.[2] Studies show that lack of accessible and effective primary care services, as well as inadequate preventative and routine outpatient care, are key drivers of preventable hospitalizations. [2-3] Further, patients who live in physician shortage areas are 70% more likely to have preventable hospitalizations and poorer outcomes than patients with adequate access to healthcare services. [3-4]

The Missouri Telehealth Network (MTN) leads a Show-Me ECHO (Extension for Community Healthcare Outcomes) Project, with the primary goal of capacity building and telementoring for primary care providers (PCPs) practicing in rural and underserved areas in order to improve healthcare

Table 1. Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
• Active participant of Dermatology ECHO (registered with ECHO to present and discuss cases) • Primary care provider (MD, DO, PA, APRN, ACCN, FNP) • Licensed (if applicable), certified and practicing in Missouri	• Not signed up as participant of Dermatology ECHO • Medical specialist (dermatologist) • Dermatology ECHO hub team member • Student or resident • Not licensed/certified in Missouri and/or not practicing in Missouri

outcomes and reduce costs. Providers from isolated areas often have large patient panels, with complex and difficult to manage conditions. Management is further complicated by the geographic distance from specialists and large medical centers. Project ECHO bridges this gap and broadens access by utilizing telehealth technologies, case-based learning, and collaborative communities of practice.[5]

Project ECHO is an innovative model for interprofessional collaboration, which supports the diagnostic management team approach.[6] It utilizes telehealth technologies to share and democratize evidence-based medical knowledge and best practices with the aim of reducing variation in care. [6] Project ECHO literature demonstrate increased competence and improved practice of participating PCPs, as well as greater work satisfaction due to collaboration and networking with the ECHO specialty hub team. [6]

Since the first pilot in 2014, Show-Me ECHO has experienced significant and sustained growth and now supports 22 unique ECHOs with both medical and non-medical topics (Appendix 1). The number and diversity of ECHO programs uniquely positions Show-Me ECHO to explore different approaches to help us understand the impact of Show-Me ECHO on Missouri. We are committed to systematically collecting and analyzing data to understand the Show-Me ECHO programs' impact on the health of Missourians. This paper highlights two approaches: 1) the first demonstrates an increase in the number of dermatologic diagnoses and claims after participation in the Dermatology ECHO, and 2) the second shows improvement in asthma outcomes for patients in counties served by providers that participated in Asthma ECHO. By looking at chronic conditions and an acute, high mortality condition, we achieve a clearer understanding of one of Show-Me ECHOs goals, to have a positive impact on Missouri's underserved populations.

Dermatology Example

A recent Show-Me ECHO pilot study showed that providers participating in Dermatology ECHO on average see patients with skin conditions between 2.9 (pediatric) and 3.3 (adult) years before the primary care provider presented the patient's case in a Dermatology ECHO session. [7] However, almost half of the cases were incorrectly diagnosed, and in over 80 percent of adult and 70 percent of pediatric cases, the treatment was either modified or changed as recommended by the Dermatology ECHO hub team. [7] This earlier study showed that participation in Dermatology ECHO raised the diagnostic concordance of participating participants with the expert hub team from 49% at the beginning of participation to 69% after robust participation. [7- 8]

To build on the pilot work we explored the impact of continuous participation in Dermatology ECHO on participating providers' skin disease diagnostic management efforts. Available literature suggests that improved diagnostic ability of providers reduces medical errors and improves patient outcomes. [9]

Materials and Methods

We wished to better understand the impact of Dermatology ECHO on participating providers' diagnostic accuracy using Medicaid (MO HealthNet) claims data. Here, aggregate participation data and claims data provide an avenue to go beyond the current literature focused on comparing non-dermatologists and dermatologists. [10- 11] Our approach to combine ECHO participation and claims data allowed us to assess the influence of continuous telementoring on improvement in diagnostic accuracy.

Table 2. Dermatology Diagnoses Used in the Analysis

Most common dermatologic diagnoses	Less common, but important to recognize in primary care
• Acne vulgaris	• Brown recluse spider bite
• Pruritus	• Granuloma annulare
• Benign neoplasms	• Necrobiosis lipoidica diabeticorum
• Skin infections	• Pigmented purpura (capillaritis)
• Melanoma	• Bullous pemphigoid
• Warts/Molluscum	• Morphea/lichen sclerosis
• Psoriasis	• Alopecia areata
• Eczema/dermatitis	• Tinea versicolor
• Rosacea	• Neurodermatitis/lichen simplex chronicus
• Skin cancer	• Subacute lupus erythematosus

Participants

Participants were 47 clinicians who joined Dermatology ECHO sessions from November 2015 – June 2017. After applying our inclusion and exclusion criteria (Table 1), a total of 41 Dermatology ECHO participants' data were analyzed. Baseline data were collected for 12 months prior (November 2014 – October 2015) and 12 months after participating in Dermatology ECHO. All participants had unique start dates, and we adjusted the pre- and post-timeframe for each participant to include the relevant 12-month participation period.

Materials

We used online Show-Me ECHO registration data to collect the number of ECHO sessions, number of CME didactics, number of CME credits, and number of attendees in Dermatology ECHO. Through the University of Missouri (MU) MO HealthNet Data Project, we obtained de-identified claims data. We used a total of 20 dermatologic diagnoses (Table 2): ICD 9 codes were used for claims submitted prior to October 1, 2015, and ICD 10 codes were used for claims submitted after that date.

Results

Total attendance and Participation

Dermatology ECHO started in November 2015 and has had a total of 133 sessions to date (December 2019), and 234 individual participants. Individual participants included primary care physicians, advanced practice nurses, medical, nursing, and physician assistant students, medical residents, specialists as well as other learners interested in skin conditions – providers from other states, school nurses, educators, etc. Sessions are offered twice monthly, during a one-hour meeting. Each session consists of: 1) a 15 minute Continuing Medical Education approved didactic and, 2) a number of real-life case presentations and 3) discussions and mentoring from ECHO Hub Team members.

Over 414 CME credits have been awarded, and all participants attended an average of 10 sessions.

Claims with Dermatologic Diagnoses

The 47 providers included in this study diagnosed 50 patients with one of the 20 diagnoses included in this study 12 months prior to their participation in Dermatology ECHO (Table 3). We observed an increase of 584 percent, and a total of 342 patients diagnosed during the 12 months after participating in Dermatology ECHO. In addition, a total number of claims submitted prior to participation in Dermatology ECHO was 59. We observed a 666 percent increase, and a total of 452 claims submitted 12 months after joining Dermatology ECHO.

Table 3. Claims with Dermatologic Diagnosis

Pre- ECHO		Post-ECHO	
Number of patients with dermatologic diagnosis	Number of Mo HealthNet claims (total visits) with dermatologic diagnosis	Number of patients with dermatologic diagnosis	Number of Mo HealthNet claims (total visits) with dermatologic diagnosis
50	59	342	452

Dermatology Conclusion

Significant increases in the number of dermatologic diagnoses and claims during the post-ECHO period is suggestive of improved diagnostic accuracy of participating providers. Current literature shows that lack of adequate dermatological training for primacy care practitioners often results in low self-efficacy and knowledge of diagnosis and management of skin conditions. [12] Together with our earlier study on diagnostic concordance, this pilot study of diagnostic claims strongly suggests that the ECHO model is effective in increasing the diagnostic accuracy of participating providers.

Asthma Example

The childhood Asthma ECHO is an endeavor of the University of Missouri (MU) Asthma Ready Communities® (ARC) in collaboration with Show Me ECHO and the Missouri Asthma Prevention and Control Program (Missouri Department of Health and Senior Service and the Center for Disease Control and Prevention- MAPCP). MAPCP/ARC work to reduce childhood asthma burden in Missouri. The Show Me ECHO framework, through its use of telehealth technology, extends the reach of the MAPCP/ARC to patients and providers in Missouri's rural and other underserved areas. Established in 2015, the Asthma Show-Me ECHO meets weekly for four-week sessions that occur annually in January, February, May, June, September, and October. Similar to the Dermatology ECHO, Asthma ECHO includes Continuing Medical Education didactic sessions and providers' presentations of their patients for mentoring and discussion by the ECHO Hub Team and participants. Childhood Asthma ECHOs are grounded in well-validated standards of care and measurement of patient outcomes. Use of Medicaid administrative claims supports interesting opportunities to assess the effectiveness of specific elements of ECHO sessions for more than 50,000 Missouri children.

In 2018 the "Asthma Best Practices" study began to assess the impact of Asthma ECHO on provider adoption of best practices and subsequent changes in health outcomes for patient panels using a quality improvement model. The specific aim of this program is to reduce the rate of uncontrolled asthma for patients of participating pediatricians and family physicians. An asthma best practices item inventory survey was developed and completed by 55 participating Asthma ECHO providers. Results showed that only 33.6% of asthma best practices were described as routine in day-to-day asthma care by clinicians during the baseline year. After participation in the QI Asthma ECHO the number of best practices reported as routine doubled. These newly adopted best practices included standardized asthma education delivery, consistent coaching for better inhalation technique, routinely confirming ICS medication adherence, dispatching home and school preventative asthma services for high risk patients. Medicaid health service utilization analysis including change in patterns of dispensed asthma medications such as inhaled corticosteroids (ICS), short acting beta agonists (SABA), systemic oral steroids (SOS), acute care visits, and total costs of health care are compared from baseline year (2017) to impact year (2019) as well as randomized comparative provider panels in similar urban sites. Results are pending over the summer 2020.

Table 4. Asthma ECHO Outcomes

Outcome Measures	FY15	FY18
Number of Asthma Cases/DCN*	41,587	39,793
Rescue Drugs		
Number SOS**	31,360	26,847
SOS/DCN	0.85	- .75
Number SABA***	94,630	87,555
SABA/DCN	2.26	2.19
Maintenance Drugs		
Number ICS****	46,358	50,735
ICS/DCN	1.13	1.27
Rescue Visits		
Hospital Days	2,390	1,726
Hospital Days/DCN	0.06	0.04
Emergency Department Visits	8,138	6,638
Emergency Department Visits/DCN	0.14	0.17
Maintenance Visits		
Office Visits	17,562	21,741
Office Visits/DCN	0.46	0.55

* DCN = Document Control Number/Patient ID assigned by MO HealthNet
** SOS = Systemic Oral Steroids
*** SABA = Short-acting Bronchodilator Inhalers
**** ICS = Inhaled Corticosteroids

This article is the first phase of assessment on the impact of the Childhood Asthma ECHO model, describing outcomes for patients residing in counties of Asthma ECHO provider participants. The next phase is to identify the patient population of ECHO provider participants to assess changes in practice patterns and patient outcomes through a pre/post ECHO participation analysis.

Materials and Methods

Participants

From August 2015 and November 2019, 680 providers representing multiple health care professions participated in Show Me Asthma ECHOs. Providers participated in at least one of 144 sessions. During these sessions, 191 cases were reviewed. Of the 191 cases, 185 were new and six were follow up cases. During this time, 755.75 Continuing Medical Education units were awarded to 178 individuals. To consider the outcomes for patients, Medicaid patients from Missouri counties with providers that participated in ECHO were analyzed using MO HealthNet administrative claims data.

Materials

Asthma is a chronic condition with: 1) established diagnostic criteria 2) evidenced-based best practice guidelines for treatment, and 3) medications based on disease state. Evaluation criteria have been established as norms for understanding both the effectiveness and cost effectiveness of treatment. Asthma ECHO uses evaluation criteria from prior MU Childhood Asthma Initiative field projects that have been modified to address the use of telehealth technology. The indicators used to track patient outcomes are aligned with Center for Disease Control (CDC) HEDIS measures including hospitalizations, ER visits, and office visits as well as utilization of classes of maintenance and rescue drugs.

In state fiscal year 2018, MO HealthNet covered approximately 45% [13] of Missouri's child population, or about 620,000 children, which is typical of the past several years. The MO HealthNet population is particularly well aligned with the underserved geographies targeted by the Show Me ECHO program. Via MO HealthNet claims, the following outcomes were obtained for patients with a primary or secondary diagnosis of asthma: prescribing and pick-up patterns for systemic oral steroids (SOS),

short-acting bronchodilator inhalers (SABA), and inhaled corticosteroids (ICS), office visits, emergency department visits, days of hospitalization.

Data evaluation included Missouri state fiscal years 2015 – 2018 and Missouri counties from which ECHO participants practice. The MU Childhood Asthma ECHO evaluator determined the assignment of counties to the ECHO/Non-ECHO categories.

Results

Asthma Cases Reviewed by ECHO Provider Participant Counties

Asthma ECHO has served 680 providers in 29 Missouri counties during fiscal years 2015-2018. Approximately 40,000 cases of childhood asthma per year were identified by Missouri Department of Social Services, MO HealthNet Division, 'DCN' case number. 'Childhood' cases are defined as 18 years of age and younger.

Outcomes for Asthma Cases from ECHO Provider Participant Counties

Asthma management protocols seek to avoid exacerbations requiring 'rescue' interventions through appropriate maintenance medications and medical management. Table 4 illustrates data from ECHO provider participant counties. Between FY15 and FY18, the average number of hospital days and the average number of prescriptions for 'rescue' (SOS/SABA) medications both declined as anticipated. Additionally, ICS prescriptions on average have increased as desired, as have billable office visits. Conversely, the average number of emergency department visits ticked up slightly, though in the context of the positive outcomes realized in types of prescriptions used, the decrease in hospitalizations, and the increase in office visits, the increase in emergency department usage is likely explained by increased awareness of risk by ECHO participant providers, families, and patients.

Asthma Conclusion

A growing body of literature suggests that childhood asthma is most successfully managed through a multi-disciplinary approach.[14] The Missouri Asthma Prevention and Control Program, MU ARC® and Show Me Asthma ECHO are grounded in this approach, including clinicians and educators from multiple fields (such as physicians, advanced practice nurses, school nurses, and asthma educators) to educate and train community-based providers and family members in chronic disease management. This approach has produced the desired results of decreasing emergency department visits and hospitalizations.[15] Missouri.

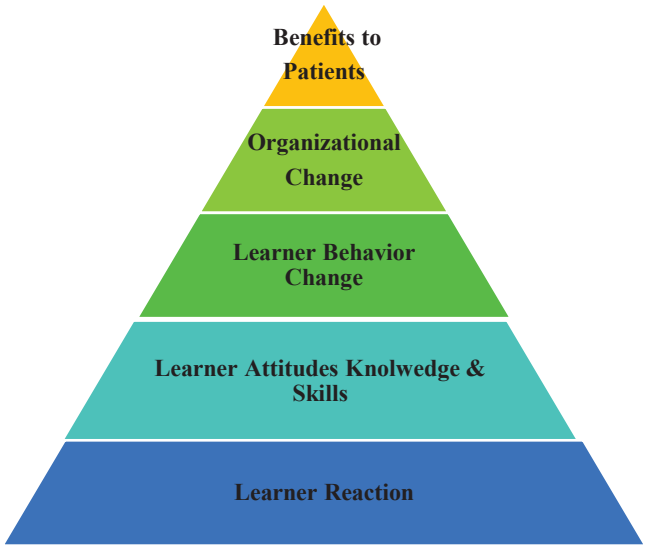


Figure 1. Kirkpatrick's Typology of Evaluation

Additional work is needed to specifically understand Asthma ECHO's selective impact. A county-based analysis to date shows positive changes, but does not assess the selective impact of either MAPCP/ARC or Show Me Asthma ECHO interventions. Next steps include identifying Asthma ECHO provider participants by cohort, intervention inputs, patterns of participation, and geography, as well as indications of adoption of best practices. Additionally, because it is possible to tie ECHO provider participants to their patients, there is opportunity to measure the influence of the ECHO model not just on individual providers but on their practice setting and local provider communities.

Discussion

A 2019 Health and Human Services Report to Congress describes widespread use of ECHO and ECHO-like programs consistently show positive effects. Further, the report concluded "existing empirical evidence for their impact on patient and provider outcomes remains modest". [16p3] Since inception Show-Me ECHO had 3,330 unique Missouri attendees across ECHOs, hosted 863 ECHO sessions and provided 21,215 instructional hours to participants[17] Beyond these substantial contributions to enhance the knowledge of Missouri providers, Show-Me ECHO is committed to systematically collecting and analyzing data that will help us to better understand how participation in Show-Me ECHO impacts the health of Missourians. Given the number and variety of Show-Me ECHOs, the team is uniquely positioned to explore different approaches that will help us understand what works for whom and under what conditions. The Dermatology and Asthma ECHO examples take different approaches but both illuminate the positive influence of ECHO on the health of Missourians. Assessing the effectiveness of ECHO models on health is a complex task, requiring both qualitative and quantitative approaches. Kirkpatrick's typology of evaluation is a helpful model to evaluate the effectiveness of educational programs and educational innovations.[18]

First modified to be applicable in business, the five levels range from satisfaction with the training program to return on investment and results for the business (Figure 1). Kirkpatrick's model has also been adapted for use in health education and continuing education programs. Here the hierarchical model moves from learner satisfaction with the educational program to demonstrated benefits to patients.[19- 20] As one moves toward the tip of the triangle gathering evidence becomes more challenging and requires more robust data collection. The first levels focus on learners while level four and above seek to analyze changes to organizations and improvements in patient outcomes. Show-Me ECHO's collaboration with the University of Missouri (MU) MO HealthNet Data Project assists Show-Me ECHO in accessing data needed to analyze impact on patients. Kirkpatrick's model is limited in that it aims to measure anticipated outcomes. It does not ask the questions more broadly, such as what outcomes (positive, negative, intended, unintended) did we observe and why did we achieve the outcomes?[21]

Since its inception, Show-Me ECHO has routinely collected data on learner reaction and learner perceptions' of learning consistent with Kirkpatrick's first levels. The 2018 Show-Me Project ECHO Evaluation Report is one example.[22] Data collected from Show-Me ECHO inception to summer 2019 indicate strong satisfaction with ECHO participation. Show-Me ECHO also collects self-efficacy survey data and these data are consistent with the literature on the four stages of competence. Here leaners move from: a) being unaware they lack proficiency to b) an awareness but not yet proficient, to c) able to use new knowledge and skills with effort and finally to d) performing the new skill is automatic.[23] Six-month post Show-Me ECHO participation surveys demonstrate decreased self-efficacy as compared to pre participation surveys. Importantly, this trend reverses with continued ECHO participation and respondents report improved self-efficacy over baseline data. Show-Me ECHO survey respondents recognize the impact participation in ECHO has on the care they provide to their patients. For example, of the 39 unique individuals participating in over 125 sessions of Dermatology ECHO Continuing Medical Education (CME) surveys, 99% of respondents agreed or strongly agreed with the statement "After attending the Dermatology ECHO, I am better able to care for patients in my practice with skin conditions". In the future, these self-reported data will be supplemented by analysis of changes in practice. However, the participant's self-reported responses suggest changes in behavior and help to inform Kirkpatrick's third level.

To ultimately change knowledge, behavior, and improve the health of Missourians, providers must be willing to participate. Show-Me ECHO has successfully improved provider participation and their knowledge of disease identification and management across Show-Me ECHOs. For example, 1,840 unique healthcare providers joined Show-Me ECHO by 2017, 250 patients were cured of hepatitis C, 60 melanomas diagnosed, and 100% of families in Missouri now live within 60 miles from an ECHO autism provider. [17]

Overall Conclusion

What started as a pilot in 2014 has grown into 22 Show-Me ECHO offerings (Appendix 1) providing multiple opportunities for Missouri providers to enhance their knowledge, to receive mentoring from specialists, and to "give their patients the right care, in the right place, at the right time."[23] With this growth comes a responsibility to assess the effectiveness of these programs and to collect evidence about the impact on patients and providers. The dermatology and asthma studies described here illustrate Show-Me ECHO's movement toward the higher levels of Kirkpatrick's model and toward a better understanding of the ECHO models impact on the health of Missourians. We invite you to join an ECHO and engage in our learning communities. To join visit www.showmeeho.org.

References

1. Crum B. Report: Missouri's health is getting worse. February 19, 2018. https://www.news-leader.com/story/news/local/ozarks/2018/02/19/missouri-less-healthy-than-most-other-states-and-getting-worse-heres-why/342235002/. Accessed January 8, 2020.
2. United Health Foundation. America's Health Rankings. 2017. https://www.americashealthrankings.org/learn/reports/2017-annual-report. Accessed January 8, 2020.
3. Nyweide D, Anthony D, Bynum J, et al. Continuity of care and the risk of preventable hospitalization in older adults. JAMA Internal Medicine. 2013;173(20):1879-1885.
4. Parchman M, Culler S. Preventable hospitalizations in primary care shortage areas: an analysis of vulnerable Medicare beneficiaries. Arch Fam Med. 1999;8(6):487-491.
5. Gondi S, Patel K. Improving rural health: how system-level innovation and policy reform can enhance health outcomes accross the United States. IEEE Pulse. 2016;7(6):8-12.
6. Katzman J, Comerci G, Boyle J, et al. Innovative telementoring for pain management: Project ECHO Pain. Journal of Continuing Education in the Health Profesisons. 2014;34(1):68-75.
7. Bridges C, Morris C, McElroy J, Quinn K, Dyer J, Becevic M. Utility of Dermatology Eextension for Community Healthcare Outcomes (ECHO) sessions in the adult and paediatric population. Journal of Telemedicine and Telecare. 2018:https://doi.org/10.1177%2F1357633X19874200.
8. Morris C, Becevic M, Edison K, Mutrux R, Shyu D. Dermatology ECHO: An evaluation of physician learning using a guided practice model. Paper presented at: American Telemedicine Association Annual Conference, 2018; Chicago, Il.
9. National Academies of Sciences, Engineering, and Medicine. 2015. Improving Diagnosis in Health Care. Washington, DC: The National Academies Press. https://doi.org/10.17226/21794.
10. Feldman S, Coates M, Fleischer A, Mellen B, Willford P. Comparing the Diagnostic Accuracy of Dermatologists and Nondermatologists. JAMA Dermatology. 2001.
11. Sellheyer K, Bergfeld W. A retrospective biopsy study of the clinical diagnostic accuracy of common skin diseases by different specialties compared with dermatology. JAAD. 2005:823-830.
12. Kownacki S. Skin diseases in primary care: what should GPs be doing? Br J Gen Pract. 2014;64(625):380-381.
13. Missouri Medicaid Basics. Missouri Foundation for Health. 2019. https://mffh.org/wp-content/uploads/2019/01/2018-Missouri-Medicaid-Basics-web.pdf. Accessed March 1, 2020.
14. Burke , Davis J, Evans S, Flower L, Tan A, Kurukulaaratchy RJ. A multidisciplinary team case management approach reduces the burden of frequent asthma admissions. ERJ Open Res. 2016;2(3).
15. Infectious Disease in Children. Healio. June 2014. Available at: https://www.healio.com/pediatrics/allergy-asthma-immunology/news/print/infectious-diseases-in-children/%7Bf72fff57-450b-4762-80d2-e4b7a20a06ad%7D/team-approach-improved-asthma-prevention-care. Accessed March 2020.
16. Current state of technology-enabled collaborative learning and capacity building models: U.S. Depart of Health and Human Service Report to Congress; 2019. https://aspe.hhs.gov/pdf-report/report-congress-current-state-technology-enabled-collaborative-learning-and-capacity-building-models. Accessed January 7, 2020.
17. Missouri Telehealth Network. Show-Me ECHO. Available at: https://showmeecho.org/wp-content/uploads/2020/03/2020LegislativeFlyerMap.pdf. Accessed April 1, 2020.
18. Kirkpatrick D, Kirkpatrick J. Evaluating training programs: The four levels. San Francisco, CA: Berrett-Koehler Publishers, Inc.; 2006.
19. Cox M, Cugg P, Brandt B, Reeves S, Zierler B. Measuring the impact of interprofessional education on collaborative practice and patient outcomes. Journal of interprofessional Care. 2016;30(1):1-3.
20. Fry A, Hemmer P. Program evaluation models and related theories: AMEE Guide No. 67. Medical Teacher. 2012;34(5):e288-e299.
21. Yardley S, Dornan T. Kirkpatrick's levels and education evidence. Medical Education. 2012;46(1):97-106.
22. Missouri Telehealth Network. Project ECHO Evaluation Report 2018. Show-Me ECHO. 2019. Available at: https://showmeecho.org/wp-content/uploads/2020/03/2020LegislativeFlyerMap.pdf. Accessed March 2020.
23. Cannon H, Feinstein A, Friesen D. Managing complexity: applying the conscious-competence model to experiental learning. Developments in Business Simulations and Experiental Learning. 2010;37:172-182

Disclosure

None reported. **MM**

Missouri Telehealth Network
University of Missouri

Appendix 1

SHOW-ME ECHO

- Uses videoconferencing to create learning collaboratives of primary care physicians and specialists.
- Uses the principals of adult learning theory: after a short didactic, case-based learning is employed.
- Primary care physicians (PCPs) can present their own patient cases to gain insights and recommendations on care delivery.
- Hub teaching teams include multi-disciplinary specialists from across the state.
- Primary care physicians participate using their tablet, laptop, or desktop.
- Most are twice monthly over lunch.
- No-cost CME is granted for participation.
- All ECHOs are shame-free, collegial, and fun and we all learn from each other.
- Show-Me ECHO offers ample support for PCPs that want to participate.
- Simply go to showmeecho.org to get started.

Show-Me ECHO Project	Expertise Available To Participants	Session Schedule	Time	To Learn More Contact
Autism	Developmental Pediatrician, Child Psychologist, Child/Adolescent Psychiatrist, Dietitian, Resource Coordinator, Health Literacy Expert, Parent Advocate/Educator	First and Third Wednesday of the Month, Year-Round	Noon-1 pm	Shelly Gooding: (573) 884-5935; goodings@health.missouri.edu
Asthma	Clinicians in Pediatrics, Allergy and Environmental Assessment, Health Literacy Expert, Nursing and Asthma Education Specialists	Each Tuesday in January, February, May, June, September, October.	Noon-1pm	Shelly Gooding: (573) 884-5935; goodings@health.missouri.edu
Child Psychiatry	Child Psychiatrist, Pharmacist, Psychologists, Social Worker, Developmental Pediatrician, Health Literacy Expert	Second and Fourth Fridays May-October and November-April	Noon-1pm	Lauren Dahm: (573) 882-8240; dahml@health.missouri.edu
Community Health Worker	Community Health Workers, Educators, Community Resource Specialists, Behavioral Health Specialist, Nurse Care Manager, Health Literacy Expert	First and Third Tuesdays of the month	2pm-3pm	Shelly Gooding: (573) 884-5935; goodings@health.missouri.edu
Dermatology	General Dermatologists, Pediatric Dermatologists, Dermatopathologist, Nurse Practitioner, Clinical Psychologist	First and Third Fridays and Second Wednesday Every Month	Noon-1pm	Lauren Dahm: (573) 882-8240; dahml@health.missouri.edu
Hepatitis C	Hepatologist Clinical Psychologist Nurse Resource Specialist, Pharmacist, Health Literacy Expert	First and Third Fridays of the Month, Year-Round	Noon-1pm	Beth Monson: (573) 884-3847; monsonb@health.misssouri.edu
HIV	Physician, Clinical Pharmacist, HIV Nurse, HIV Medical Case Management Expert, Treatment Adherence Expert, Behavioral Health Expert	Second and Fourth Thursday of the month Year-Round	Noon-1pm	Wendy Hough: (573)884-3048; houghw@health.missouri.edu
Opioid Use Disorder	Psychiatrist, Psychologist, Social worker, Addictionologist, Pharmacist, Health Literacy Expert	Second and Fourth Fridays, Year-Round	11:45-1pm	Beth Monson: (573) 884-3847; monsonb@health.misssouri.edu
Pain Management	Chronic Pain Management Specialist, Clinical Psychologist, Pharmacist, Physical Therapist, Social Worker, Sleep and Pain Specialist, Health Literacy Expert	Second and Fourth Thursday From January - June and September - December	Noon-1pm	Beth Monson: (573) 884-3847; monsonb@health.misssouri.edu
Maternal Health	OB-Gyn, Maternal-Fetal Medicine, Labor and Delivery Nurse, Neonatologist, Psychiatrist, Pharmacist, Social Worker	TBD	Noon-1pm	Wendy Hough: (573)884-3048; houghw@health.missouri.edu
Neonatal Abstinence Syndrome (NAS)	Neonatologist, Pediatrician, Neonatal Outreach Educator, Lactation Consultant, Pharmacist, Social Worker	First and Third Thursday of the month Year-Round	Noon-1pm	Lauren Dahm: (573) 882-8240; dahml@health.missouri.edu
Oral Health	Dentist, Periodontist, Endodontist, Dental Hygienist, Pathologist, Pediatric Dentist, Oral Surgeon, Pharmacist	Second Wednesday of the Month	Noon-1pm	Wendy Hough: (573)884-3048; houghw@health.missouri.edu
Diabetes	Endocrinologist, Primary Care Physician, Behavioral Health Specialist, Nephrologist, Pharmacist, Community Health Worker, Diabetes Educator, Dietician	First and Third Tuesday of the month Year-Round	Noon-1pm	Beth Monson: (573) 884-3847; monsonb@health.misssouri.edu
Kidney Disease	Nephrologist, Social Worker, Dietician, Pharmacist, Diabetes Educator, Transplant Nurse, Patient Advocate	First and Third Thursday of the month Year-Round	Noon-1pm	Shelly Gooding: (573) 884-5935; goodings@health.missouri.edu
Developmental Disabilities	Behavior Analyst, Psychiatrist, Patient Advocate, Caseworker, Pharmacist	Second and Fourth Thursday of the month Year-Round	Noon-1pm	Lauren Dahm: (573) 882-8240; dahml@health.missouri.edu
Hypertension	Cardiologist, Internist, Nephrologist, Psychologist, Exercise Kinesiologist, Pharmacist, Dietician, Social Worker	Second and Fourth Monday of the month Year-Round	Noon-1pm	Wendy Hough: (573)884-3048; houghw@health.missouri.edu
Trauma Informed Schools	Principal, Program Training, School Counselor, Social Worker, District Administrator	First and Third Tuesday of the Month Year-Round	1:30-2:30pm	Wendy Hough: (573)884-3048; houghw@health.missouri.edu
Autism: Behavior Solutions	Behavior Analyst, Pediatric Psychologist, Child Life Specialist, Child Neurologist, Parent Advocate	First and Third Monday of the Month Year-Round	11:45am-1pm	Lauren Dahm: (573) 882-8240; dahml@health.missouri.edu
Head Start	MO Head Start Director, Developmental Disabilities Expert, Child Psychologist, Trauma Informed Care Specialist, Early Head Start Director, Developmental Pediatrician, School Administrator, DHSS System Expert, Parent Advocate	Third Wednesday of the Month Year-Round	11am-Noon	Wendy Hough: (573)884-3048; houghw@health.missouri.edu
Certified Peer Specialist	Mental Health Manager, Credentialing and Training Expert, Peer Support Training Specialist, Recovery Specialist, Homeless and Probation Specialist, Trauma Informed Care Specialist, Director of Transitional Operations	First and Third Wednesday of the Month Year-Round	11am-Noon	Beth Monson: (573) 884-3847; monsonb@health.misssouri.edu
COVID-19	Department of Health and Senior Services Director, Clinical Quality Improvement, Infectious Disease, Emergency Medicine, Health Ethics	Every Monday	Noon-1pm	Beth Monson: (573) 884-3847; monsonb@health.misssouri.edu
Telemedicine (General)	Telehealth Resource Center Directors, Telemedicine Manager, Program Manager, Medical Director, Telebehavioral Health	Every Tuesday	9am-10am	Lauren Dahm: (573) 882-8240; dahml@health.missouri.edu

MM

Part Two of Three-Part Series

Colorectal Surgery Review for Primary Care Providers

by Rakesh Hegde, MD, John M. Trombold, MD & José M. Dominguez, MD

Inflammatory and functional colorectal conditions are complex problems.



Rakesh Hegde, MD, (above), John M. Trombold, MD and José M. Dominguez, MD, MSMA member since 1996, are in the Department of Colon and Rectal Surgery, Ferrell-Duncan Clinic, CoxHealth, Springfield, Missouri.

Abstract

Colon and rectal disorders can be functional and inflammatory. This is the second paper of a three-part series[14] and will focus on the diagnosis and treatment of rectal prolapse, fecal incontinence and inflammatory bowel disease.

Rectal Prolapse

Rectal prolapse is a disorder of the pelvic floor that leads to severe dysfunction during defecation.[1] Patients complain of bleeding, mucous drainage, pelvic pressure, tenesmus, rectal bulge, constipation, and fecal incontinence. This may lead to isolation and depression due to these serious functional difficulties. Risk factors include advanced age, female gender, multi-parity, other pelvic organ prolapse, chronic bowel dysfunction including constipation, chronic straining, vaginal deliveries, chronic diarrhea, developmental delays, psychiatric comorbidities, cystic fibrosis, dementia and stroke.[1] Women are six times more likely to develop rectal prolapse than men. The peak incidence is in the seventh decade of life.

Diagnosis of rectal prolapse is through visual inspection with confirmation of a prolapsing rectum with circumferential rings. Severe hemorrhoidal prolapse may be misdiagnosed as rectal prolapse

The radial groves separating different hemorrhoid locations distinguish hemorrhoid prolapse from the circumferential "bee-hive" appearance of rectal prolapse.[1]

Straining on the commode during office evaluation usually confirms the diagnosis. Patients may provide their own pictures of the reported prolapse, which can be helpful with intermittent prolapse. Further workup of can include defacography (helps identify other pathology or internal prolapse), colonoscopy (to exclude other pathology and "clear" the proximal colon prior to repair), urodynamic and gynecologic evaluation (to assess for additional pelvic abnormalities), and barium enema (colonoscopy frequently incomplete due to redundant colon).[2]

Severity of disease ranges from early internal prolapse (only seen on defecography) and mucosal prolapse, which does not involve complete external intussusception of the rectum, to full-thickness rectal intussusception.

Rectal prolapse will not resolve with medical treatment. However, dietary manipulation, fiber supplementation, laxatives, intermittent manual reduction and pelvic floor physical therapy serve

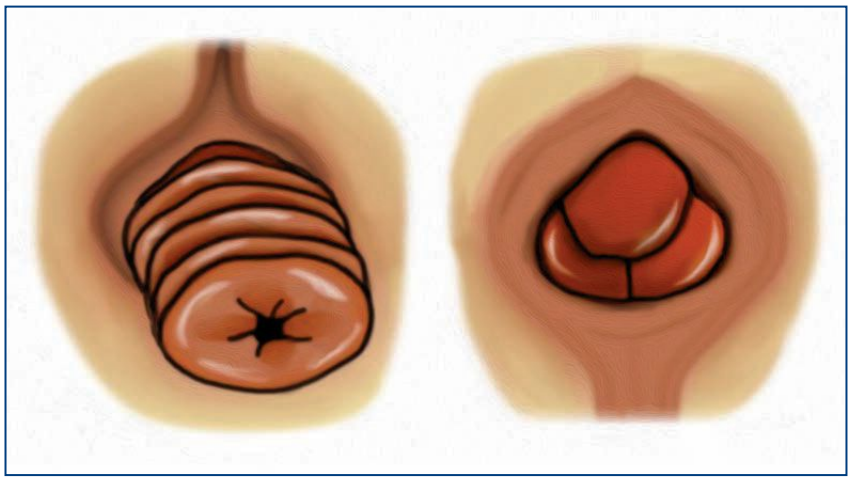


Figure 1. Rectal Prolapse. Concentric folds of rectal prolapse on left, radial folds of prolapsed hemorrhoids, right.

an adjunct role.

There are many named operations for the treatment of rectal prolapse. The basic surgical decision depends on an assessment of the patient's operative risk.[3] High-risk patients generally undergo a trans perineal operative approach, either a Delorme (usually for mucosal prolapse only) or Altmeier perineal proctectomy.[4] These operations can be done under spinal or general anesthesia. They carry low operative risk but a higher recurrence rate.

Low to moderate risk patients are candidates for trans-abdominal repairs. This involves fixation of the rectum to the sacrum with suture material or mesh. Sigmoid resection can be added, especially in patients with more significant constipation. The transabdominal operations can performed through an open, laparoscopic or robotic approach.[5] Bowel resection carries additional risks but recurrence does not change recurrence rates.

Fecal Incontinence

Fecal incontinence is defined in a consensus conference report in 2001 as recurrent uncontrolled passage of fecal material for at least one month, in an individual with a developmental age of at least 4 years. Incontinence to flatus may cause substantial impairment of quality of life is in the spectrum of disease. Incidence is reported between 1.4 to 18%[6]. Higher rates in nursing home residents, parous women, elderly, patients with neurologic and cognitive impairments.

Anal sphincter injury during vaginal delivery is a common cause of fecal incontinence. Pelvic nerve injury related to a traction injury may also contribute. Risk factors include forceps delivery, occipitoposterior position, previous anorectal surgery, prolonged labor and episiotomy/ lacerations.[7] Obstetrical injuries can be occult or under-reported.

A detailed history frequently elicits exacerbating factors such as gastrointestinal or neurologic disorders. Inspection of the perineum may show anal scarring or a patulous anus. Digital exam can help gauge splinter strength. The majority of patients will require colonoscopy to exclude associated colorectal disorders such as tumor or ileitis/colitis. Anorectal manometry (to quantify strength, tolerance to rectal stretch and anal reflexes), pudendal nerve testing (to assess for nerve injury/ function), anal sphincter ultrasound (to assess for injury) and defecography can be considered.[8]

Correcting loose or frequent stools resolves many incontinence episodes. Stool bulking agents and dietary manipulation can help with stool consistency. Antidiarrheal agents to decrease stool frequency and firm up the stool is necessary. Over the counter loperamide, in titrated doses aiming for one bowel movement daily or every other day, typically has excellent results. Fewer bowel movements with better control of solid stool will typically eliminate a need for a formal workup. Pelvic floor physical therapy can aid in strengthening the pelvic floor.

Operative intervention is reserved for life-style limiting incontinence refractory to non-operative measures and is not needed often. Overlapping sphincteroplasty, only an option if a sphincter defect is confirmed, is historically the procedure of choice but has fallen out of favor due to moderate rate of long-term recurrent incontinence and significant wound complications. However, it remains the procedure of choice for incontinence with concomitant rectovaginal fistula.[7] Sacral nerve stimulator implantation is a promising newer treatment option. It is expensive and requires device maintenance. Long-term data is lacking but is currently the procedure of choice for refractory incontinence. These advanced procedures are not indicated unless the patient is highly motivated

and has refractory incontinence despite an extensive trial of antidiarrheals and nonoperative intervention. Again, most patients will have good results with constipating medications and surgical intervention with implanted devices is not often a consideration.

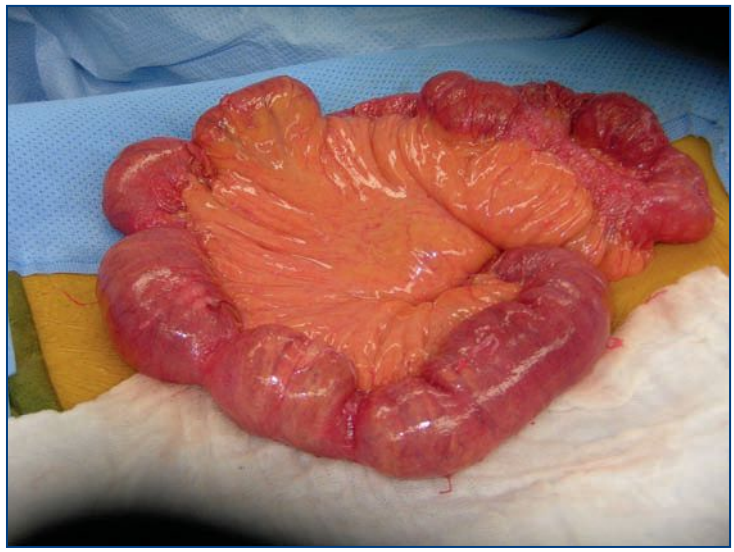


Figure 2. Crohn's Disease of Small Bowel with Stricture

Inflammatory Bowel Disease

Crohn's disease and ulcerative colitis are the two most common inflammatory bowel diseases (IBD). IBD is characterized by periods of symptomatic relapse and remission. The cause of IBD is believed to be a combination of environmental, genetic, microbiologic, and immunologic factors. The immune response causes varying degrees and locations of inflammation with resulting symptoms.[9] Medical treatment continues to improve with the introduction of biologic agents. Failure of medical management or concern for malignancy indicate benefit from surgical evaluation.

Crohn's Disease

Crohn's disease (CD) is a chronic inflammatory condition that can affect any area of the gastrointestinal tract from the mouth to the anus. The terminal ileum and colon are most commonly involved. The inflammation tends to be focal and transmural. Inflammation results in fistulae, perforation and strictures. Associated symptoms including pain, bleeding, obstruction, weight loss, diarrhea, and fever, among others. A multitude of extra-intestinal manifestations can affect the eyes, skin, mouth and joints.

Evaluation of CD frequently requires endoscopy with confirmatory histology, CT/MR enterography and laboratory analysis including hemogram and inflammatory markers such as CRP[9] and fecal calprotectin. The medical treatment include various combinations of anti-inflammatories such as sulfasalazine preparations or steroids (systemic or topical such as suppositories), immunomodulators such as methotrexate or azathioprine, and biologic agents such as Humira.[12]

It is important to remember that no operation can "cure" CD and surgical intervention is reserved for the medically refractory complications of CD. These include hemorrhage, intestinal obstruction, perforation, malignancy and fistula. There is increasing understanding regarding the risk of malignancy in CD. Risk is directly related to the severity and duration of the inflammation- regardless of location. Therefore, severely inflamed bowel must be regularly surveyed endoscopically.

Emergent surgical intervention is rarely indicated unless fulminant peritonitis exists. Concerning exam findings may be absent or blunted by steroid or biologic therapy. TPN should be considered peri-operatively for the severely catabolic patient. At operation, sites of refractory disease are resected.[10] Primary anastomosis or ostomy can created. Stricturoplasty can help preserve bowel length if addressing short foci of stricturing disease. Diffuse jejunoileal disease benefiting from stricturoplasty is rarely the case, with terminal ileocolic disease amenable only to resection being far more common. Intestinal stomas, temporary or permanent, are commonly used for distal colorectal disease or severe ileal disease when operating under austere circumstances like malnutrition. Crohn's colitis frequently requires total colectomy, but if the rectum and anus are healthy, an ileorectal anastomosis can provide good function without the need for an ileostomy. Perianal CD can lead to severe pain, fissures, fistulae and abscesses. Perirectal abscesses

require drainage. Fistulae are best treated initially with seton drainage.[9] Systemic CD medication can improve anorectal disease but the patient with severe fistulizing perianal disease may require fecal diversion due to persistent infections, inflammation, poor bowel control, and a refractory poor quality of life.

Ulcerative Colitis

Ulcerative colitis (UC) is a chronic inflammatory condition resulting in ulceration of the rectal and colonic mucosa. It starts in the distal most rectum and progresses proximally. Common symptoms in UC are bloody bowel movements, diarrhea, urgency and tenesmus. Similar to Crohn's, the etiology of UC is multifactorial.

Initial treatment of UC involves anti-inflammatories, sometimes including steroids, immunomodulators, and biologic agents.[11] Monitoring for the development of dysplasia requires periodic colonoscopy with biopsies. Progression to malignancy is possible and also depends on severity and duration of inflammation.

Medically refractory disease requires operation. Dysplasia and malignancy are also indications for surgery. Contrary to Crohn's, UC is cured with total proctocolectomy. Healthy patients without continence issues can be candidates for ileal-pouch anal anastomosis (IPAA or J-pouch) to prevent permanent ileostomy.

Increasingly, patients and gastroenterologists are delaying surgical evaluation due to the hope that more aggressive biologic therapy, which has its own risks and expense, will delay operation indefinitely. Unfortunately, these patients present for surgical evaluation in subtle extremis with profound malnutrition, severe colitis with occult sepsis, DVT, and a severely compromised immune system, which blunts their physical findings. They require up to three operations including upfront urgent subtotal colectomy and ileostomy.[13] Once normal physiology is restored, completion proctectomy is performed with either end ileostomy or J-pouch creation. Many J-pouch patients require protective ileostomy that will eventually require a "reversal" operation. Early surgical consultation, many times to merely to establish a relationship, should be strongly considered.

Conclusion

Inflammatory and functional colorectal conditions are complex problems. This requires specialized evaluation and treatment. A high degree of suspicion with prompt referral to colorectal surgery could achieve a desirable result.

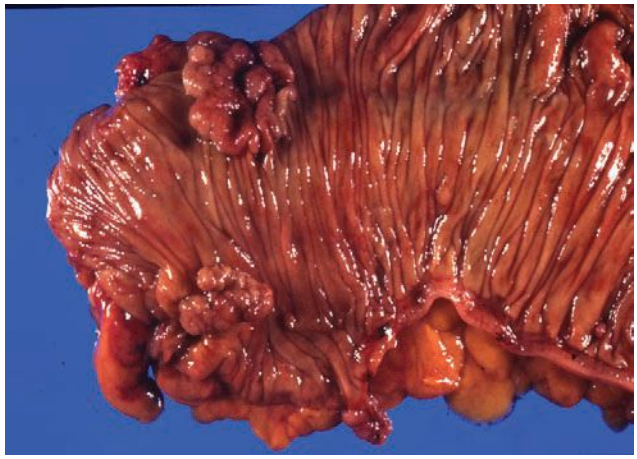


Figure 3. Ulcerative Colitis with Pseudo Polyps

References

1. Garret R. Carl Thiersch 1822-1895. Concerning prolapse of the rectum with special emphasis on the operation by Thiersch.Dis Colon Rectum. 1988; 31:154–155.
2. Delorme M. Edmond Delorme 1847–1929. On the treatment of total prolapse of the rectum by excision of the rectal mucous membranes or recto-colic. Dis Colon Rectum. 1985; 28:544–553.
3. Wells C. New operation for rectal prolapse. Proc R Soc Med. 1959; 52:602–603.
4.. Altemeier WA, Culbertson WR, Schowengerdt C, Hunt J. Nine- teen years' experience with the one-stage perineal repair of rectal prolapse. Ann Surg. 1971; 173:993–1006.
5. Frykman HM, Goldberg SM. The surgical treatment of rectal procidentia. Surg Gynecol Obstet. 1969; 129:1225–1230
6.Whitehead WE, Wald A, Norton NJ. Treatment options for fecal incontinence. Dis Colon Rectum 2001; 44:131–44.
6.Madoff RD, Parker S C, Varma MG, Lowry AC. Fecal incontinence in adults. Lancet 2004; 364:621–32.
7.Nelson R, Norton N, Cautley E, Furner S. Community- based prevalence of anal incontinence. JAMA 1995; 274:559–61.
8. Bharucha AE, Zinsmeister AR, Locke GR. Prevalence and burden of fecal incontinence: a population-based study in women. Gastroenterology 2005;12
9.Torres MI, Rios A. Current view of the immunopathogenesis in inflammatory bowel disease and its implications for therapy. World J Gastroenterol. 2008;14(13):1972–80.
10.Rutgeerts P, Van Assche G, Vermeire S. Review article: Infliximab therapy for inflammatory bowel disease – seven years on. Aliment Pharmacol Ther. 2006;23(4):451–63.
11. Schroder O, Blumenstein, Stein J. Combining infliximab with methotrexate for the induction and maintenance of remission in refractory Crohn's disease: a controlled pilot study. Eur J Gastroenterol Hepatol. 2006;18(1):11–6.
12. Sandborn WJ, Feagan BG, Stoinov S, et al. Certolizumab pegol for the treatment of Crohn's disease. N Engl J Med. 2007;357(3):228–38.
13 . Rutgeerts PJ, Mellili LE, Li J, Pollack PF. Adalimumab maintains improvement in IBDQ scores over 1 year following the initial attainment of remission in patients with moderately severely active Crohn's disease: results of the Classic II study. Gastroenterology. 2006;130: A479.
14. Hegde R, Trombold JM, Dominguez JM. Colorectal Surgery Review for Primary Care Providers. Missouri Medicine. 2020; 117:154-158

Disclosures

None reported. **MM**

Factors Associated with Adherence to Screening Guidelines for Diabetic Retinopathy Among Low-Income Metropolitan Patients

by Jessica Kuo, MD, James C. Liu, MD, Ella Gibson, P. Kumar Rao, MD, Todd P. Margolis, MD, PhD, Bradley Wilson, MA, Mae O. Gordon, PhD, Emily Fondahn, MD & Rithwick Rajagopal, MD, PhD

Adhering to diabetes eye screening recommendations continues to be a challenging task, particularly in a patient population that is socioeconomically disadvantaged.



Jessica Kuo, MD, James C. Liu, MD, Ella Gibson, P. Kumar Rao, MD, Todd P. Margolis, MD, PhD, Bradley Wilson, MA, Mae O. Gordon, PhD, Rithwick Rajagopal, MD, PhD, (above), are all in the John F. Hardesty Department of Ophthalmology and Visual Sciences; Emily Fondahn, MD, is in Department of Medicine; all are at Washington University School of Medicine, St. Louis, Missouri.

Abstract

In this retrospective analysis of patients with diabetes in an academic primary care clinic in St. Louis, attendance at ophthalmic screening appointments was recorded over a two-year observation window. Factors associated with adherence were analyzed by multivariable regression. Among 974 total patients included, only 330 (33.9%) were adherent within a two-year period. Multivariate analyses identified older age, female gender, primary language other than English, and attendance at ancillary diabetes clinic visits as factors associated with improved diabetic retinopathy screening adherence. Factors not associated with adherence included race and insurance status.

Introduction

Diabetic retinopathy is one of the leading causes of preventable new-onset vision loss in adults worldwide.[1] Because the disease is clinically silent until very late stages, it is estimated that up to 90% of vision loss may be prevented by regular screening examinations.[2] Guidelines issues by the American Academy of Ophthalmology (AAO) and the American Diabetes Association (ADA) recommend annual dilated eye examinations in adult patients with diabetes. Recently, these guidelines were amended such that if an initial retinal exam is normal, and glucose control is good, the interval between dilated retinal exams could be extended to two years.[3] Even so, only 50%-60% of patients with diabetes in the U.S. adhere to these recommended guidelines.[4-6] In populations with poor access to resources, which tend to be at greatest risk for vision loss from advanced stages of diabetic retinopathy (Figure 1), rates of eye examinations are even lower.[7-11] Patients cite multiple barriers preventing them from attending eye exams, including transportation difficulties, cost, and long wait times.[12-14] Better quantification and qualification of the prevailing factors associated with poor adherence is essential to implementing strategies to mitigate key barriers to retinal examination among patients with diabetes, and improve their rates of adherence to screening guidelines.

Referral to an eye care specialist for in-person retinal examination



Figure 1. High-risk Proliferative Diabetic Retinopathy. Although diabetes is a leading cause of impaired vision and blindness, regular screening examinations can prevent up to 90% of vision loss from advanced stages of disease as show in this patient with vitreous hemorrhage from proliferative diabetic retinopathy.

remains the standard for diabetic retinopathy screening in the U.S. Such practice patterns are currently in place at the Washington University School of Medicine-Barnes Jewish Hospital healthcare network, which serves as a "safety net" for many medically-vulnerable patients in the St. Louis City and County area. Rates of adherence to eye examinations have historically been low in this population, highlighting a need for improvement in health care delivery. In this retrospective study, we sought to 1) determine the rate of adherence to recommended eye screenings; and 2) identify factors associated with adherence to recommended eye care guidelines in a primary care medicine clinic serving predominantly high-risk, low-income patients with diabetes.

Patients, Methods, and Materials

Subjects

Consecutive patients with type 1 or type 2 diabetes mellitus over the age of 18 who completed a non-emergent appointment at the Primary Care Medicine Clinic (PCMC) at Barnes Jewish Hospital between July 2016 and March 2017 were included in the study. Participants were excluded if they lived outside of a 50-mile radius from the PCMC in order to exclude traveling distance as a factor contributing to adherence. Every patient with diabetes was encouraged to follow up with their previous ophthalmologist if established, or referred to the Washington University Eye Clinic for an annual diabetic eye exam in accordance with the screening recommendations delineated by the AAO and the ADA.

Patient data – including demographic information, insurance status (classified as either private, public [Medicaid or Medicare], or self-pay), pertinent laboratory values, and ancillary diabetes clinic visits (foot exams and diabetes education visits) – were extracted from the electronic medical record system and de-identified for analysis. Each patient record was manually reviewed to document instances of eye care clinic attendance within a two-year window, beginning one-year interval before and ending one-year after the reference visit at the PCMC. Patients who had at least one documented eye care visit within this two-year window were denoted adherent with annual eye screening.

Statistical Analyses

Descriptive statistics (mean, standard deviation and percent) were reported for demographics and laboratory data. Various factors were analyzed for their association with patient adherence using SAS 9.4 software (SAS Institute, Cary, NC). To adjust for confounding effects, variables with univariate logistic p-values <0.05 were entered simultaneously into a multivariable regression model. Factors with an adjusted p-value <0.05 were retained. Odds ratios were used to describe the relationship between factors and adherence.

Results

Patient Demographics

Included in this study were 981 unique adult patients with diabetes who visited PCMC during the specified time period. After excluding seven patients because their primary residence was greater than 50 miles from the PCMC, 974 patients were included in the final analysis. The study population was predominantly female (58.0%), African-American (76.6%), and with an average age of 56 years (Table 1). The majority of patients (70.6%) were covered by public insurance (Medicare or Medicaid).

Table 1: Patient Demographics with Chi-square Analysis

Demographics	Patients n = 974 (% of total)	Adherence† n = 330 (% adherent)	p-value	OR 95% CI††
Age				
Mean	56; SD = 13.8	58.4; SD = 13.6	**0.0022**§	**1.49 (1.12, 1.98)**§
Sex				
Male	409 (42)	118 (28.9)		
Female	565 (58)	212 (37.5)	**0.005**	**1.48 (1.13, 1.95)**
Race				
White	161 (16.5)	55 (34.2)		
Black or Afr Am	746 (76.6)	246 (33.0)	0.259	0.95 (0.66, 1.36)
Other†	65 (6.7)	28 (43.1)		1.46 (0.81, 2.63)
Unknown	2 (0.2)	1 (50.0)		
Insurance Type‡				
Public	688 (70.6)	248 (36.1)	**0.0208**	**1.73 (1.17, 2.57)**
Private	110 (11.3)	35 (31.8)		1.44 (0.84, 2.46)
Self-pay	159 (16.3)	39 (24.5)		
Unknown	17 (1.7)			
Primary Language				
English	904 (92.8)	296 (32.7)	**0.0079**	**0.52 (0.32, 0.84)**
Not English	70 (7.2)	34 (48.6)		
Ancillary Visits#				
No visit	860 (88.3)	271 (31.5)		
≥1 visit	114 (11.7)	59 (51.8)	**<0.0001**	**2.33 (1.57, 3.46)**

*Asian, Hispanic, and of Middle Eastern descent
†Adherence defined as at least one ophthalmology office visit within two-year time period. Percentages of each subgroup within a demographic recorded as adherent
†† CI calculated as odd ratio of adherence to nonadherence within subgroups, excluding the unknown values.
‡Public insurance included Medicare and Medicaid and Private included all PPO and HMO. N=17 patients excluded because insurance type listed as "miscellaneous" or "commercial."
§ p-value and OR from chi-square analysis reflects age per decade comparison between adherent and nonadherent groups
#Ancillary diabetes visits are calculated as the sum of diabetes education visits and foot care visits
Bolded = significant CI.

Predictors of Adherence by Univariate Chi-Square Analysis

Of the 974 patients included, 330 distinct patients were adherent with ophthalmic examination. Characteristics associated with higher adherence in univariate analysis included older age, female sex, public insurance, and attendance to at least one other diabetes care visits ($p<0.05$; Table 1). The odds of women being adherent were 1.48 the odds of men being adherent at the time of their visit to the primary care clinic. Patients with public insurance had 1.75 times the odds of those without insurance coverage to have a screening diabetes eye exam. However, there was no statistically significant difference between adherence rates in patients with private insurance versus any other insurance subgroup. Patients who attended at least one associated diabetes care visit (foot care visit or diabetes education visit) had about 2.3 times the odds of having attended a screening eye exam as those who did not (OR 2.33 [95% CI, 1.57-3.46]). Unexpectedly, English speakers were about half as likely as non-English speakers to complete recommended retinal screening.

Predictors of Adherence by Multivariable Analysis

Factors including insurance type, age per decade, female gender, attendance at ancillary diabetes visits, and primary language other than English were entered into the multivariable analysis. Insurance type was no longer a significant factor after adjusting for the effects of age (aOR 1.17 [95% CI, 1.06-1.29]), female sex (aOR 1.48 [95% CI, 1.11-1.96]), ancillary diabetes education visits (aOR 2.41 [95% CI, 1.61-3.61]), and primary language (aOR 0.55 [95% CI, 0.33-0.91]). All remaining variables were significantly associated with increased adherence with diabetes eye exams (Table 2). The Hosmer-Lemeshow Goodness-of-Fit test demonstrated good fit in our multivariable model ($p=0.75$).

Race was not noted to be a significant predictor of adherence under univariate analysis and was therefore excluded from multivariate analysis. Similarly, factors such as last serum glycated hemoglobin index (HbA1c) values and last LDL values did not demonstrate a statistically significant difference between the adherent

Table 2: Multivariate logistic regression

Predictor	Univariate p-value	Adjusted p-value	p-value; excluding insurance	aOR 95% CI*
Insurance	0.0208	0.0931	--	--
Age per decade	0.0022	0.01	0.002	**1.17 (1.06, 1.29)**
Sex (Female vs Male)	0.0049	0.0132	0.007	**1.48 (1.11, 1.96)**
≥1 Ancillary Visit	<0.0001	<0.0001	<0.0001	**2.41 (1.61, 3.61)**
Primary Language (English vs Not English)	0.0079	0.0088	0.0189	**0.55 (0.33, 0.91)**

*aOR = adjusted odds ratios calculated from multivariable regression after excluding insurance type.
Bolded = significant CI.

and non-adherent groups (HbA1c: n=313 7.93% ± 1.78 SD vs. n=570 7.95% ± 2.15 SD, respectively; OR 0.996 [95% CI, 0.93-1.07]; LDL: n=279 94.28 mg/dL ± 42.8 SD vs n=468 99.46 mg/dL ± 42.5 SD, respectively; OR 0.997 [95% CI, 0.994-1.00]).

Discussion

Adhering to diabetes eye screening recommendations continues to be a challenging task, particularly in a patient population that is socioeconomically disadvantaged. We sought to highlight this difficulty by quantifying the rate of adherence within a primary care clinic serving low-income urban patients. Previous papers have cited adherence rates in the 50-60% range for patients with diabetes, but populations in these studies tended to contain more affluent and education patients.[6, 9] Our study demonstrates a far smaller rate of 33.9% adherence, comparable to recent studies based on similar demographic population of predominantly low-income African-American patients with diabetes.[4, 8, 10]

We chose to utilize a two-year window based on recent evidence that promotes screening diabetes eye examinations every two years, instead of annually.[15] By allowing a two-year window to fulfill the screening diabetes eye examination, we may have overestimated the true adherence rate in our population. When evaluating adherence during the one-year interval following the reference PCP visit, we found that only 18.7% of patients with diabetes fulfilled their recommended screening eye examination. Sub-analysis of this group showed that patients who demonstrated adherence in the past were more than three times as likely to be adherent in the one-year following the reference PCP visit (39.9% vs. 11.5%). These findings highlight the difficulty of changing patterns of nonadherence but suggest that measures to increase adherence to even one eye care visit may produce durable adherent behavior.

Additionally, we found that in our cohort of patients, older age, female gender, attendance at diabetes-related care visits were all associated with greater adherence to diabetic retinopathy screening. In our multivariate logistic regression for adherence, female patients were 1.48 times as likely to be adherent with screening. Likewise, older individuals were more likely to comply with recommended screening eye exams, with our model showing that each additional decade of life increased odds of adherence by 17%.

Among the factors identified in this study linked to increased adherence to annual retinal screening examinations, attendance to ancillary diabetes care visits (diabetes education sessions and foot care visits) was the strongest predictor (OR 2.41). One explanation for these findings is that eye care, education, and foot care visits all have similar barriers preventing patients from attending them. Those able and/or willing to overcome those barriers in one setting are self-selecting to comply with screening guidelines. However, an alternate explanation is that increasing patient self-awareness through educational measures may have the largest impact in determining future adherence to health screening recommendations. In support of the latter view, the beneficial effects of educational programs on multiple aspects of diabetes care, including weight loss, glycemic control, self-monitoring, and adherence to health screening (including retinopathy surveillance) are well-established.[16-20] Furthermore, attendance at diabetes education sessions has previously correlated with increased rates of adherence to screening recommendations.[21-23] One of the health systems with the highest rates of diabetic retinopathy screening adherence – the Veteran's Health Network, which



Figure 2. Non-mydriatic Retinal Photography as a Point-of-Care Service. To improve screening rates among patients with diabetes, ophthalmic photography can be performed in physicians' office and clinics by easily-trained technicians using retina cameras not requiring drops to dilate pupil.

consistently reports 90% adherence rates for annual dilated retinal examination – utilizes a multipronged educational approach to ensure that patients with diabetes are meeting several metrics of appropriate diabetes care, such as glycated hemoglobin goals, foot examinations, setting blood pressure goals and receiving retinal examinations.[24]

In other study populations, African-American race, younger age, male sex, and lower household income are associated with lower adherence.[4, 8, 25, 26] We found no such association with race or income, likely because our population was predominantly poor, African-American (76.6%), and supported by publicly-funded healthcare (70.6%). Our findings are similar to a recent analysis of factors associated with retinopathy screening adherence in a population with comparable demographics.[8] Unexpectedly, English speakers were nearly two times less likely than non-English speakers to complete recommended retinal screening. Though language barriers and difficulty obtaining interpreter services are potential obstacles to health care access and diabetic retinopathy screening, these factors may have been mitigated in our study population by the provision of these services free of charge through Barnes Jewish Hospital. The interpreter available at PCMC may also serve as a healthcare advocate who can help the patient navigate the referral system.

A major limitation in our retrospective review was the inability to account for screening eye examinations that occurred outside the Barnes Jewish Washington University network. In our study design, patients who underwent eye examination outside of our healthcare network would have been incorrectly categorized as noncompliant, resulting in a falsely-low observed adherence rate. However, based on prior referral patterns within our tertiary care center, shared electronic medical record systems, and identical insurance provider policies, nearly all patients receiving primary care at PCMC also receive ophthalmic care within the Washington University healthcare network, suggesting the number of outside screening exams to be minimal. Furthermore, the utilization of a two-year window to allow for adherence was meant to compensate for any underestimation from non-recorded eye examinations elsewhere.

The results of our study suggest that certain patient characteristics – male gender, younger age, private insurance policy holders or self-pay patients, patients who do not attend other diabetes clinic visits – may correlate with lower adherence with recommended diabetes eye examinations. This knowledge may be helpful in identifying more at-risk patients who may need additional counseling in order to motivate them to adhere to recommended screening eye exams. The results of this analysis highlight the complex network of influences that affect patient adherence as well as the difficulty in overcoming the numerous barriers that patients face in adhering to recommended health care exams. Many of those barriers may be circumvented if screening is conducted during the primary care encounter as a point-of-service test, instead of during a separate clinic visit. These tests could be provided during wait times, or other similar periods of currently underutilized clinic time. In a study of healthcare claims data of Medicaid patients, completion rates of diabetic retinopathy screening examinations were more likely when a non-mydriatic retina camera was available in the primary care setting.[27] Automated image analysis coupled to non-mydriatic fundus photography may provide this

opportunity, allowing for quick, affordable, and accurate automated screening as a point of care test (Figure 2). Furthermore, point-of-care retinal testing introduces an opportunity for individualized patient education, tailored to severity of retinal disease. Based on our findings, such educational interventions may be most effective in improving retinal surveillance in our healthcare network and in other networks serving low-income patients. Finally, our results suggest that implementation of services to help patients navigate along various facets of medical landscapes, in addition to improving education and point-of-care services, could improve retinopathy screening and perhaps other aspects of comprehensive diabetes care.

Conclusion

Low screening rates for diabetic retinopathy in this low-income urban population were associated with younger age, male gender, and lack of attendance at other ancillary health screens or diabetes education sessions. Our findings suggest that efforts to improve diabetes education could have the largest impact to improve adherence rate to retinopathy screening in this population, and other patient populations with similar characteristics. In light of recent efforts to incorporate point-of-care services such as non-mydriatic retinal photography in primary care clinics, our results argue that integrating diabetes education and medical advocacy into such systems would be valuable.

Epilogue: COVID-19 Pandemic

Society and medicine now faces an unprecedented and ongoing crisis caused by the severe acute respiratory syndrome-coronavirus-2 (SARS-CoV2), a pathogen that has claimed over 200,000 lives at the time of this writing. The pandemic caused by SARS-CoV2 highlights an imperative need for a paradigm shift in practice patterns across medical specialties. Such a dire need is now at the forefront of discussion because of the immediate health threat posed by a novel pathogen, but the concerns for preventing nosocomial or iatrogenic transmission of diseases are long-standing.

Hospital and health care visits have always posed potential dangers for contagion (e.g. MRSA, hospital-acquired pneumonia, viral infections), especially among vulnerable and indigent populations. Such concerns for preventing transmissible disease add to other needs for paradigm shifts in medicine – including increase access to medical care in populations that typically lack resources, as discussed above and as highlighted by the results of our study. Therefore, changes in medical practice that permit remote provision of care, when appropriate, or those that allow for fewer physical patient encounters could be of great help.

One such shift, embraced by many of our colleagues in light of the SARS-CoV2 pandemic, involves the use of telemedicine. Though telemedicine has inherent limitations in fields such as ophthalmology that rely heavily on physical examination, technical advances in imaging could provide innovative solutions. As an example, the development of facile and reliable non-mydriatic cameras, capable of being operated by unskilled or non-ophthalmic personnel, would allow retinal imaging in patients across a wide variety of settings such as primary-care offices or remote-screening centers. Digital transfer of the images captured by such cameras to reading centers, physicians-on-call, or even artificial intelligence platforms would allow for rapid access to care, and could increase such access to much larger patient populations. Pre-screening in this manner could also allow care providers to identify high-risk patients who require physical care, thereby minimizing the spread of contagious disease among other low-risk individuals.

The SARS-CoV2 pandemic has upended life and society, but perhaps a silver lining to such disaster is that people across sectors are pioneering ways to solve the various new problems we now face. Some of these novel solutions might mitigate other long-standing problems, just as telemedicine might do for improving poor access to care among those suffering from common diseases that were pandemic long-before SARS-CoV2, such as diabetes.

Acknowledgments

This work is supported by NIH/NEI EY025269 (R.R.), a Career Development Award (R.R.) from Research to Prevent Blindness (NY), the Horncrest Foundation (R.R), and an unrestricted grant and to the Department of Ophthalmology and Visual Sciences at Washington University from Research to Prevent Blindness (NY).

References

1. Global Data on Visual Impairments; 2010. http://www.who.int/blindness/publications/globaldata/en/. Accessed 3/14/2014.
2. Early photocoagulation for diabetic retinopathy. ETDRS report number 9. Early Treatment Diabetic Retinopathy Study Research Group. Ophthalmology. 1991;98: 766-785.
3. American Diabetes A. 10. Microvascular Complications and Foot Care: Standards of Medical Care in Diabetes-2018. Diabetes care. 2018;41: S105-S118.
4. Maclennan PA, McGwin G, Jr., Heckemeyer C, et al. Eye care use among a high-risk diabetic population seen in a public hospital's clinics. JAMA ophthalmology. 2014;132: 162-167.
5. Perez CM, Febo-Vazquez I, Guzman M, Ortiz AP, Suarez E. Are adults diagnosed with diabetes achieving the American Diabetes Association clinical practice recommendations? Puerto Rico health sciences journal. 2012;31: 18-23.
6. Saaddine JB, Engelgau MM, Beckles GL, Gregg EW, Thompson TJ, Narayan KM. A diabetes report card for the United States: quality of care in the 1990s. Annals of internal medicine. 2002;136: 565-574.
7. Eppley SE, Mansberger SL, Ramanathan S, Lowry EA. Characteristics Associated with Adherence to Annual Dilated Eye Examinations among US Patients with Diagnosed Diabetes. Ophthalmology. 2019.
8. Keenum Z, McGwin G, Jr., Witherspoon CD, Haller JA, Clark ME, Owsley C. Patients' Adherence to Recommended Follow-up Eye Care After Diabetic Retinopathy Screening in a Publicly Funded County Clinic and Factors Associated With Follow-up Eye Care Use. JAMA ophthalmology. 2016;134: 1221-1228.
9. Moreton RBR, Stratton IM, Chave SJ, Lipinski H, Scanlon PH. Factors determining uptake of diabetic retinopathy screening in Oxfordshire. Diabetic medicine : a journal of the British Diabetic Association. 2017;34: 993-999.
10. Tran EMT, Bhattacharya J, Pershing S. Self-reported Receipt of Dilated Fundus Examinations Among Patients With Diabetes: Medicare Expenditure Panel Survey, 2002-2013. American journal of ophthalmology. 2017;179: 18-24.
11. Lu Y, Serpas L, Genter P, Mehranbod C, Campa D, Ipp E. Disparities in Diabetic Retinopathy Screening Rates Within Minority Populations: Differences in Reported Screening Rates Among African American and Hispanic Patients. Diabetes care. 2016;39: e31-32.
12. Hartnett ME, Key IJ, Loyacano NM, Horswell RL, Desalvo KB. Perceived barriers to diabetic eye care: qualitative study of patients and physicians. Archives of ophthalmology. 2005;123: 387-391.
13. Lu Y, Serpas L, Genter P, Anderson B, Campa D, Ipp E. Divergent Perceptions of Barriers to Diabetic Retinopathy Screening Among Patients and Care Providers, Los Angeles, California, 2014-2015. Preventing chronic disease. 2016;13: E140.
14. Walker EA, Basch CE, Howard CJ, Zybert PA, Kromholz WN, Shamoon H. Incentives and barriers to retinopathy screening among African-Americans with diabetes. Journal of diabetes and its complications. 1997;11: 298-306.
15. Modjtahedi BS, Theophanous C, Chiu S, Luong TQ, Nguyen N, Fong DS. Two-Year Incidence of Retinal Intervention in Patients With Minimal or No Diabetic Retinopathy on Telemedicine Screening. JAMA ophthalmology. 2019;137: 445-448.
16. Basch CE, Walker EA, Howard CJ, Shamoon H, Zybert P. The effect of health education on the rate of ophthalmic examinations among African Americans with diabetes mellitus. American journal of public health. 1999;89: 1878-1882.
17. Ismail K, Winkley K, Rabe-Hesketh S. Systematic review and meta-analysis of randomised controlled trials of psychological interventions to improve glycaemic control in patients with type 2 diabetes. Lancet. 2004;363: 1589-1597.
18. Javitt JC. Preventing blindness in Americans: the need for eye health education. Survey of ophthalmology. 1995;40: 41-44.
19. Murray CM, Shah BR. Diabetes self-management education improves medication utilization and retinopathy screening in the elderly. Primary care diabetes. 2016;10: 179-185.
20. Norris SL, Engelgau MM, Narayan KM. Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. Diabetes care. 2001;24: 561-587.
21. Paksin-Hall A, Dent ML, Dong F, Ablah E. Factors contributing to diabetes patients not receiving annual dilated eye examinations. Ophthalmic epidemiology. 2013;20: 281-287.
22. Schoenfeld ER, Greene JM, Wu SY, Leske MC. Patterns of adherence to diabetes vision care guidelines: baseline findings from the Diabetic Retinopathy Awareness Program. Ophthalmology. 2001;108: 563-571.
23. Zhang X, Williams DE, Beckles GL, et al. Diabetic retinopathy, dilated eye examination, and eye care education among African Americans, 1997 and 2004. Journal of the National Medical Association. 2009;101: 1015-1021.
24. Cavallerano AA, Conlin PR. Teleretinal imaging to screen for diabetic retinopathy in the Veterans Health Administration. Journal of diabetes science and technology. 2008;2: 33-39.
25. Shi Q, Zhao Y, Fonseca V, Krousel-Wood M, Shi L. Racial disparity of eye examinations among the U.S. working-age population with diabetes: 2002-2009. Diabetes care. 2014;37: 1321-1328.
26. Wang SY, Andrews CA, Gardner TW, Wood M, Singer K, Stein JD. Ophthalmic Screening Patterns Among Youths With Diabetes Enrolled in a Large US Managed Care Network. JAMA ophthalmology. 2017;135: 432-438.
27. Hatef E, Vanderver BG, Fagan P, Albert M, Alexander M. Annual diabetic eye examinations in a managed care Medicaid population. The American journal of managed care. 2015;21: e297-302.

Disclosure

None reported.

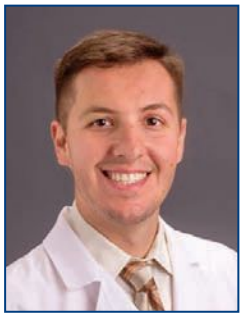
MM

Patient Perception of Vaping in the Midst of the Electronic Cigarette and Vaping Product Associated Lung Injury (EVALI) Epidemic

by Tarang Patel, MD, Ethan Karle, DO, Tamar Gubeladze, MD, Genevieve Pentecost, MS4 & Armin Krvavac, MD



Although the younger respondents and e-cigarette users continue to view these products as safe, the overall consensus among respondents remains that they are unsafe, require additional regulation, and should not be recommended as a smoking cessation aid.



Tarang Patel, MD, Ethan Karle, DO, Tamar Gubeladze, MD, Genevieve Pentecost, MS4, are all with the Department of Medicine; and Armin Krvavac, MD, (above), in the Division of Pulmonary, Critical Care, and Environmental Medicine, Department of Medicine; all are at the University of Missouri-Columbia School of Medicine, Columbia, Missouri.

Abstract

Purpose of Study

EVALI has reached epidemic proportions. With the increasing prevalence, new information has come to light regarding the safety of electronic cigarettes. We investigate the impact of the recent EVALI epidemic on patient perception surrounding vaping.

Methods

An anonymous survey was developed to evaluate patient perception regarding vaping. The survey was administered to adult patients at various clinics at University of Missouri. A total of 287 survey responses were analyzed.

Results

In all, 81.5% of respondents reported that e-cigarettes are unsafe, 73.2% did not feel that the absence of THC oils or vitamin E acetate made e-cigarettes safer, and 55.1% felt that e-cigarettes are less safe than traditional cigarettes. A majority (76%) felt that e-cigarettes/ vaping products should be more regulated and pose a public health concern. Most surprising, 67.6% of participants answered that they knew somebody who was negatively affected by EVALI.

Conclusion

The survey responses suggest that the current EVALI epidemic is changing the public's perception and the narrative surrounding safety of e-cigarettes and vaping products.

Introduction

Electronic cigarettes (e-cigarettes) were introduced into the marketplace in 2003.[1] Since then the e-cigarette has undergone many iterations, evolving into hundreds of brands, designs, and flavors.[1,2] It is now well established that e-cigarette use (vaping) can cause a myriad of lung injury patterns, including but not limited to acute eosinophilic pneumonia, diffuse alveolar hemorrhage, organizing pneumonia, hypersensitivity pneumonitis, and lipoid pneumonia.[3-5] Collectively these patterns of lung injury are referred to as electronic cigarette or vaping product associated lung injury (EVALI).[3] As of January 2020, there have been over 2,600 reported cases of EVALI requiring hospitalization.[6]

Despite the reported health risks and widespread media coverage regarding EVALI, e-cigarette popularity and use have increased significantly in the past

five years amongst people of all ages. Most concerning is the incidence of e-cigarette use among the youth, which has more than doubled from 2017 to 2019.[7,8] Several factors have contributed to the widespread use and adoption of e-cigarettes by the youth. These include the introduction of newer, sleeker, easily hidden vaping devices, unrestricted marketing techniques, and creation of flavors that are targeted to be appealing to a younger demographic.[9,10]

In our review of the current literature, there has been no assessment of public perceptions surrounding e-cigarette use since the emergence of the EVALI epidemic. We set out to investigate various patient populations' understanding and perception surrounding vaping. A survey was developed to elucidate the reason vaping continues to remain popular despite the emergence of significant health risks over the past six months. Hypothesizing that perception regarding the safety of e-cigarettes, the necessity for e-cigarette regulation, and their role in smoking cessation would vary significantly based on age and prior e-cigarette use.

Materials and Methods

An anonymous survey was developed to evaluate perception regarding e-cigarettes and vaping among various patient populations. The aim of our study was to develop a concise survey tool that could provide demographic data, unbiased insight into opinions surrounding e-cigarettes, and perception surrounding the use of e-cigarettes as a smoking cessation tool.

The survey tool was comprised of 15 multiple choice questions. The first five questions captured demographic data (age group, gender, education, familiarity with vaping products, and history of vaping product use). The subsequent six questions used a Likert scale to evaluate the participant's perception surrounding the safety and need for regulation of e-cigarette/vaping products. The survey tool concluded with a final four set of yes/no questions which assessed experience with vaping and opinions regarding the role of e-cigarettes as a smoking cessation tool.

Approval was obtained from the University of Missouri Institutional Review Board (IRB); the survey tool was created using Qualtrics™, and underwent validation using Collingridge's survey validation method. This included establishment of face validation with the use of a combination of eight board certified Internal Medicine physicians and board certified Pulmonary and Critical Care Medicine physicians. After undergoing face validation, the survey tool was pilot tested with 30 participants (10% of the anticipated sample population) at the internal medicine clinic site. The collected pilot data was reviewed to assess proper understanding of the survey questions by the pilot test group. Pilot data was not used in the final analysis.

After validation, the survey was administered to adults (age > 18 years). Prior to survey administration, study participants were notified that the survey was completely anonymous, voluntary, and no incentive would be provided for participation. Administration of the survey occurred over the course of two weeks between 1/27/2020 and 2/7/2020. During this time, the survey was administered by the study group for three one-half days at each clinic location. Three separate clinic locations (general internal medicine clinic, medicine specialty clinic, and student health clinic) were chosen for the purposes of achieving a broad range of study participants. Subjects were given the option of taking the survey on their mobile device via use of a QR code or by filling out a printed (pen and paper) version of the same survey questions. At the conclusion of data collection, statistical analysis was performed using Fisher's exact test.

Results

A total of 308 participants were asked to complete the survey, of which 296 completed the survey. Nine surveys were excluded from the analysis as they were incomplete. A total of 287 completed surveys were used for the final analysis. The basic demographic data of the study participants is outlined in Table 1. Those surveyed were asked to quantify their familiarity with e-cigarettes and whether they had used e-cigarettes/vaping products. Among respondents, 26.5% (76/287) reported being very familiar, 53.7% (154/287) somewhat familiar, and 19.9% (57/287) unfamiliar with vaping products. In regard to prior e-cigarettes/vaping product use, 4.5% (13/287) endorsed daily use, 30% (89/287) endorsed prior use, and 64.5% (185/287) reported no prior use.

Additionally, a Likert scale was used to gauge public perception of e-cigarette/vaping products. A majority, 81.5% (234/287) of respondents disagreed with the statement that e-cigarettes/vaping products are safe. Furthermore, 73.2% (210/287) did not feel that the absence of tetrahydrocannabinol (THC) oils or vitamin E acetate made e-cigarettes safer. This closely resembled the group's opinion on the safety of post-purchase modifications (modding) of e-cigarettes with 85.4%

Table 1. Patient Demographics

Patient Demographics (n=287)			
Q1: What age group do you fall in?	18-35	35-50	>50
	n=147	n=39	n=101
	51.2%	13.6%	35.2%
Q2: What gender do you identify as?	Male	Female	Other
	n=102	n=184	n=1
	35.6%	64.1%	0.3%
Q3: What is your highest level of education?	High school/GED	Undergraduate	Graduate
	n=141	n=81	n=65
	49.1%	28.2%	22.6%
Q4: How familiar are you with electronic cigarettes/vaping products?	Very familiar	Somewhat	Unfamiliar
	n=76	n=154	n=57
	26.5%	53.7%	19.9%
Q5: Have you used electronic cigarettes/vaping products?	Use daily	Used previously	Never used
	n=13	n=89	n=185
	4.5%	30.0%	64.5%

that e-cigarettes/vaping products pose a public health concern and should be more regulated (Figure 1).

The final set of questions in the survey study were a series of yes/no questions to evaluate provider screening of e-cigarette use in the ambulatory setting, to assess perception related to the use of e-cigarettes to assist with smoking cessation, and to quantify the scope of the EVALI epidemic in the mid-Missouri region. Surprisingly, 56.8% (163/287) of respondents reported no screening by their providers

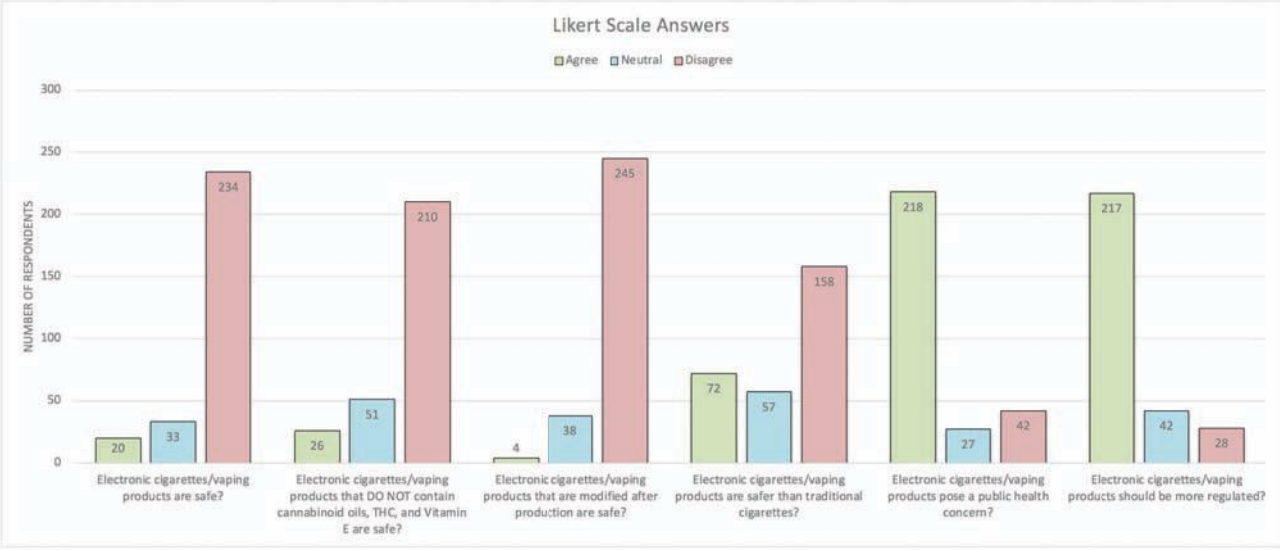


Figure 1. Likert Scale Answers. Responses from participants to each Likert scale question.

(245/287) considering this to be an unsafe practice. The remaining three Likert scale-based questions were designed to assess the safety of e-cigarettes compared to traditional cigarettes and participants views on the necessity for further regulation of e-cigarettes. Here, 55.1% (158/287) felt that e-cigarettes were less safe when compared to traditional cigarettes. Whereas, 25.1% (72/287) felt that e-cigarettes were safer than traditional cigarettes, and 19.9% (57/287) were neutral on the issue. Although, the majority (76%) still felt regarding e-cigarette use. Furthermore, in regard to the role of e-cigarettes as a smoking cessation tool, only 10.1% (29/287) reported use of e-cigarettes to quit smoking, while 76.7% (220/287) recommended against the use of e-cigarettes as a smoking cessation aid. The scope of the EVALI epidemic was highlighted by the final question of the survey. Of the 287 participants, 194 (67.6%) answered that they knew somebody who was negatively affected by EVALI (Figure 2. Patient Perceptions).

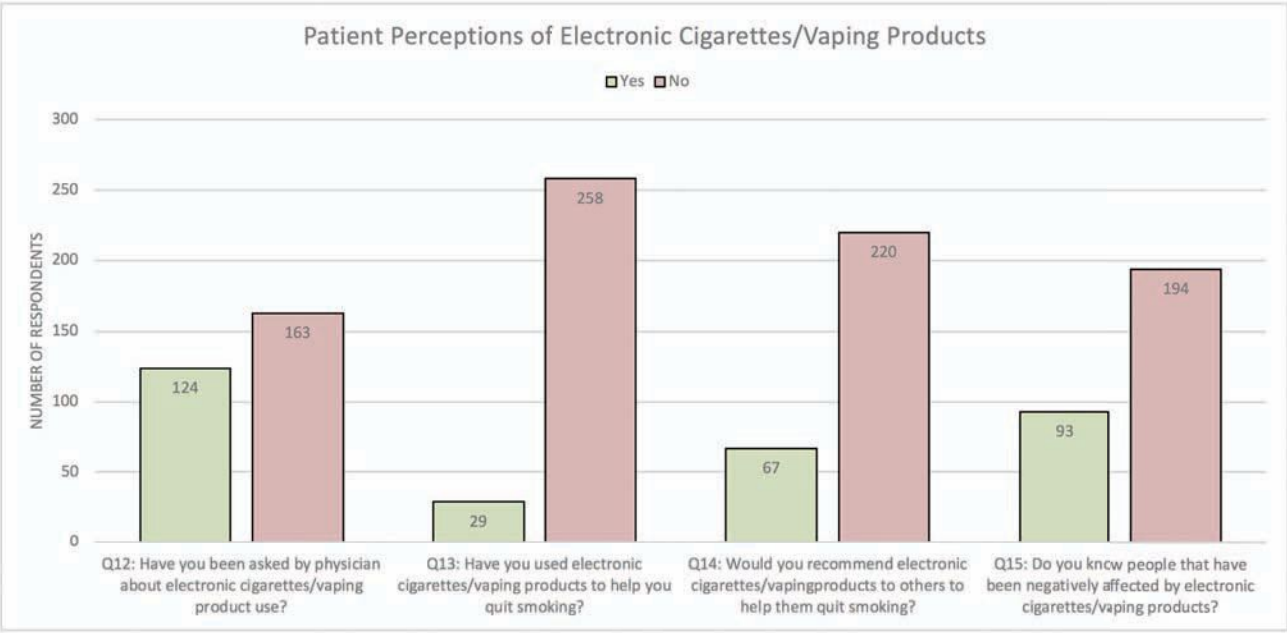


Figure 2. Patient Perceptions of Electronic Cigarettes/Vaping Products and responses from participants to each Yes/No question.

Discussion

To understand the mounting popularity of vaping, one needs to look no further than our youth. Since 2014, e-cigarettes have replaced traditional cigarettes and tobacco chew as the most commonly used forms of nicotine.[11] Even more concerning is that the prevalence of vaping among youth has more than doubled between 2017-2019.[7] There have been many proposed reasons behind this, many of which revolve around the targeted marketing of youth, the wide variety of flavors, and the ability to customize the device.[9] There also appears to be a discrepancy in respect to age and the safety of vaping. Analysis of our survey responses illustrated that those between the ages of 18-35 tend to view e-cigarettes as safer than traditional cigarettes when compared to the responses of those over the age of 50 ($p<0.001$). Furthermore, those over the age of 50 were more inclined to feel that e-cigarettes should be more tightly regulated versus their younger counterparts ($p<0.001$). This data indicates that age plays a significant role in regard to perception of vaping, which we suspect is one of the driving factors of the vaping epidemic.

The increasing popularity in the use of e-cigarettes among youth, and the general population, is alarming as it represents a major set-back in the decades long fight to curtail the use of tobacco products among Americans. It appears that e-cigarettes have captured popularity by propagating the unsubstantiated notion of a safer alternative to traditional cigarette products.[12,13] In the United States, electronic cigarettes were first introduced to the public as a safer alternative to traditional cigarettes in 2008.[9] However, studies evaluating e-cigarettes as a smoking cessation tool compared to FDA approved medications have been inconclusive at best.[14-17] Furthermore, the combination of nicotine replacement therapy with pharmacologic smoking cessation aids (varenicline or bupropion) may be superior to e-cigarettes in continued smoking abstinence.[18] Particularly as, many of those that used e-cigarettes as a smoking cessation tool subsequently maintain dependence on vaping products for more than a year after smoking cessation.[18,19] The findings of these studies call to question if e-cigarettes truly play any role in smoking cessation. In fact, only 10.1% (29/287) of respondents in our survey reported using e-cigarettes as a smoking cessation tool and 76.7% (220/287) recommended against the use of e-cigarettes as a smoking cessation aid.

Since the initial reports were published regarding EVALI, it was clear that THC containing e-cigarette products played a role in the propagation of EVALI. In an epidemiologic study of the initial 53 patients affected by EVALI, 80% were noted to have used THC oils when vaping.[3,20] THC oils and vitamin E acetate were not the only compounds implicated in EVALI, in fact

14% of the reported cases of EVALI were the result of e-cigarettes containing only nicotine.[6] These findings suggest that additional factors, unique to e-cigarettes, may also play a role in EVALI. One such factor is that the heat produced by e-cigarette vapor may results in direct thermal injury to the airways.[21] Additionally, e-cigarette cartridges contain propylene glycol and vegetable glycerin, both of which have been implicated in causing epithelial compromise and aberrant airway remodeling.[13,21-23] Within our survey participants, 67.6% (194/287) indicated that they know someone who has been negatively affected by EVALI. This unique subset felt strongly that e-cigarettes are not safe ($p=0.012$), pose a public health concern ($p=0.085$), and should be more closely regulated ($p=0.023$). Whereas, those who did not know someone affected by EVALI remained neutral. These findings echo the conclusions found in the literature, which note lower rates of EVALI in nations (United Kingdom) where e-cigarettes and vaping products are more strictly regulated.[22]

Survey responses were analyzed to assess if there were any significant differences in opinions regarding the role of THC oils and vitamin E acetate in the safety of e-cigarettes. It revealed significant differences in opinions regarding overall safety of e-cigarettes ($p<0.001$), the role of THC oils and vitamin E acetate on e-cigarette safety ($p=0.001$), and the safety of e-cigarettes compared to traditional cigarettes ($p<0.001$) between those who endorsed prior e-cigarette use versus those who had never used e-cigarettes. As a group, prior e-cigarettes users viewed e-cigarettes and THC oils or vitamin E acetate containing e-cigarettes as safer than traditional cigarettes. These results demonstrate that perceptions of e-cigarettes vary widely between prior users and those who have never used e-cigarettes. In fact, 75% of current and prior e-cigarette users responded that e-cigarettes are safe and 66.7% responded that they were safer than traditional cigarettes. These findings are in line with prior surveys of e-cigarette users that show >90% of respondents reporting e-cigarettes as safer than traditional cigarettes.[24] The results suggest that novel information regarding the role of THC oils, vitamin E acetate, and e-cigarette specific factors in EVALI are not significantly changing the perceptions surrounding e-cigarettes safety in current and prior users. Although the overall perception among survey respondents has clearly been impacted by the EVALI epidemic.

Despite our best efforts to distribute the survey to a large number of participants, we only received 287 complete responses. Additionally, our survey only evaluated participants at a single academic teaching hospital within the United States. This may limit the external validity of our findings outside of the mid-Missouri region. Although, the authors attempted to design the survey questions to succinctly assess perceptions surrounding EVALI and e-cigarettes more questions would have been helpful in providing additional insight. However, we feel that additional questions would have adversely impacted response rates by increasing complexity and time needed to complete the survey. Lastly, we cannot say with certainty that perceptions surrounding EVALI, e-cigarettes, and vaping products are directly the result of new information brought to light in the literature. This may be an area that warrants further evaluation in the future.

Conclusion

The responses clearly indicate a shift in opinion regarding the safety of e-cigarettes and vaping related products among patients. Although the younger respondents and e-cigarette users continue to view these products as safe, the overall consensus among respondents remains that they are unsafe, require additional regulation, and should not be recommended as a smoking cessation aid. It appears that increased media attention and public education have been contributing to a change in perception. Although our results show that knowing someone or being personally affected by EVALI has the most significant impact on perceptions.

While the long-term effect of EVALI is yet to be fully understood, it is clear that this national epidemic has led to a fundamental paradigm shift regarding the safety of electronic cigarettes. A plethora of international experts and national societies have provided input regarding proposed mechanisms of EVALI, calls for nationwide action to limit the sales and marketing of e-cigarettes, and to define the part e-cigarettes play in smoking cessation. It is the combination of widespread media coverage, multiple public service announcements, and the availability of new information regarding the significant health risks surrounding e-cigarettes which has molded public perception of vaping as a generally unsafe practice and to be in dire need for further regulation.

Epilogue

Patient understanding surrounding the dangers of vaping has become even more important during the COVID-19 pandemic caused by the novel coronavirus (SARS-CoV-2). Analysis of patients who have been infected by SARS-CoV-2 in China showed a case fatality rate of 6.3% in those with chronic respiratory illnesses compared to 2.3% amongst the overall infected group.[25] Moreover, prior studies have shown chronic smokers and those with substance abuse disorders have a worsened prognosis when infected with other strains of coronaviruses, specifically SARS-CoV-1 and Middle Eastern Respiratory Syndrome (MERS).[26] One proposed mechanism for the worsened outcomes in chronic smokers with SARS-CoV-1 and SARS-CoV-2 is that both of these coronavirus strains utilize angiotensin-converting enzyme 2 (ACE-2) receptors to gain cellular entry.[27,28] ACE-2 utilizing coronaviruses may have higher infectivity in chronic smokers as ACE-2 receptors are upregulated in the lungs in response to smoking.[29] It is plausible that a similar upregulation of ACE-2 receptors is seen among users of vaping products; a topic that would certainly merit more robust formal studies to establish a causal relationship.

While the role of vaping in regard to infectivity and outcomes with SARS-CoV-2 has not been specifically studied, some postulate that the aerosols generated by vaping nicotine, THC, or flavorings downregulate the lungs' immune response to infections making vaping use a potential risk factor for SARS-CoV-2 infection.[26,30,31] Furthermore, though it has not yet been established, we need to consider the possibility that vaping by patients already infected with SARS-CoV-2 could lead to aerosolization of the virus and act as a vector for transmission. While additional clinical trials will need to be conducted in order to assess the role of vaping in SARS-CoV-2, it is reassuring that public perception towards vaping is changing. Although we have made significant progress over the past year, the need for continued patient education regarding the health hazards of vaping and further regulation of vaping related products remains of outmost importance in light of the current COVID-19 pandemic.

References

1. Bhatnagar A, Whitsel LP, Ribisl KM, et al. Electronic cigarettes: a policy statement from the American Heart Association. Circulation. 2014;130(16):1418-1436.
2. Zhu SH, Sun JY, Bonnevie E, et al. Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation. Tob Control. 2014;23 Suppl 3(suppl 3):iii3-9.
3. Christiani DC. Vaping-Induced Acute Lung Injury. N Engl J Med. 2020;382(10):960-962.
4. Salzman GA, Alqawasma M, Asad H. Vaping Associated Lung Injury (EVALI): An Explosive United States Epidemic. Mo Med. 2019;116(6):492-496.
5. Wilhite R, Patel T, Karle E, Shankar S, Krvavac A. Diffuse Alveolar Hemorrhage: An Uncommon Manifestation of Vaping-associated Lung Injury. Cureus. 2019;11(12):e6519.
6. Krishnasamy VP. Update: Characteristics of a Nationwide Outbreak of E-cigarette, or Vaping, Product Use–Associated Lung Injury—United States, August 2019–January 2020. MMWR Morbidity and Mortality Weekly Report. 2020;69.
7. Miech R, Johnston L, O'Malley PM, Bachman JG, Patrick ME. Trends in Adolescent Vaping, 2017-2019. N Engl J Med. 2019;381(15):1490-1491.
8. Wang TW, Gentzke AS, Creamer MR, et al. Tobacco product use and associated factors among middle and high school students—United States, 2019. MMWR Surveillance Summaries. 2019;68(12):1.
9. Dinakar C, O'Connor GT. The health effects of electronic cigarettes. New England Journal of Medicine. 2016;375(14):1372-1381.
10. Jones K, Salzman GA. The Vaping Epidemic in Adolescents. Mo Med. 2020;117(1):56-58.
11. Gentzke AS, Creamer M, Cullen KA, et al. Vital signs: tobacco product use among middle and high school students—United States, 2011–2018. Morbidity and Mortality Weekly Report. 2019;68(6):157.
12. Fairchild AL, Bayer R, Colgrove J. The renormalization of smoking? E-cigarettes and the tobacco "endgame". N Engl J Med. 2014;370(4):293-295.
13. Hswen Y, Brownstein JS. Real-Time Digital Surveillance of Vaping-Induced Pulmonary Disease. N Engl J Med. 2019;381(18):1778-1780.
14. Bullen C, Howe C, Laugesen M, et al. Electronic cigarettes for smoking cessation: a randomised controlled trial. The Lancet. 2013;382(9905):1629-1637.
15. Bullen C, McRobbie H, Thornley S, Glover M, Lin R, Laugesen M. Effect of an electronic nicotine delivery device (e cigarette) on desire to smoke and withdrawal, user preferences and nicotine delivery: randomised cross-over trial. Tob Control. 2010;19(2):98-103.
16. Caponnetto P, Campagna D, Cibella F, et al. EffiCiency and Safety of an eLectronic cigAreTte (ECLAT) as tobacco cigarettes substitute: a prospective 12-month randomized control design study. PloS one. 2013;8(6).
17. Halpern SD, Harhay MO, Saulsgiver K, Brophy C, Troxel AB, Volpp KG. A Pragmatic Trial of E-Cigarettes, Incentives, and Drugs for Smoking Cessation. N Engl J Med. 2018;378(24):2302-2310.
18. Bhatnagar A, Payne TJ, Robertson RM. Is there a role for electronic cigarettes in tobacco cessation? Journal of the American Heart Association. 2019;8(12):e012742.
19. Hajek P, Phillips-Waller A, Przulj D, et al. A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy. N Engl J Med. 2019;380(7):629-637.
20. Layden JE, Ghinai I, Pray I, et al. Pulmonary illness related to e-cigarette use in Illinois and Wisconsin—preliminary report. New England journal of medicine. 2019.
21. Mukhopadhyay S, Mehrad M, Dammert P, et al. Lung Biopsy Findings in Severe Pulmonary Illness Associated With E-Cigarette Use (Vaping) A Report of Eight Cases. American Journal of Clinical Pathology. 2020;153(1):30-39.
22. Kalininskiy A, Bach CT, Nacca NE, et al. E-cigarette, or vaping, product use associated lung injury (EVALI): case series and diagnostic approach. The Lancet Respiratory Medicine. 2019;7(12):1017-1026.
23. Triantafyllou GA, Tiberio PJ, Zou RH, et al. Vaping-associated Acute Lung Injury: A Case Series. Am J Respir Crit Care Med. 2019;200(11):1430-1431.
24. Foulds J, Veldheer S, Berg A. Electronic cigarettes (e-cigs): views of aficionados and clinical/public health perspectives. Int J Clin Pract. 2011;65(10):1037-1042.
25. Wu Z, McGoogan JM. Characteristics of and important lessons from the coronavirus disease 2019 (COVID-19) outbreak in China: summary of a report of 72 314 cases from the Chinese Center for Disease Control and Prevention. Jama. 2020.
26. Volkow ND. Collision of the COVID-19 and Addiction Epidemics. Ann Intern Med. 2020.
27. Li W, Moore MJ, Vasilieva N, et al. Angiotensin-converting enzyme 2 is a functional receptor for the SARS coronavirus. Nature. 2003;426(6965):450-454.
28. Hoffmann M, Kleine-Weber H, Schroeder S, et al. SARS-CoV-2 cell entry depends on ACE2 and TMPRSS2 and is blocked by a clinically proven protease inhibitor. Cell. 2020.
29. Brake SJ, Barnsley K, Lu W, McAlinden KD, Eapen MS, Sohal SS. Smoking upregulates angiotensin-converting enzyme-2 receptor: a potential adhesion site for novel coronavirus SARS-CoV-2 (Covid-19). In: Multidisciplinary Digital Publishing Institute; 2020.
30. Madison MC, Landers CT, Gu BH, et al. Electronic cigarettes disrupt lung lipid homeostasis and innate immunity independent of nicotine. J Clin Invest. 2019;129(10):4290-4304.
31. Harrill WC. Vaping during the COVID-19 pandemic: NOT GOOD!! Laryngoscope Investigative Otolaryngology. 2020.

Disclosure

None reported.

MM



OFFICIAL MINUTES & REPORTS

Resolutions and speeches will be reported in the July/August 2020 *Missouri Medicine*



Meet MSMA's 2020-2021 President

George J. Hruza, MD
St. Louis, Missouri

Contact: ghruza@gmail.com

George J. Hruza, MD, MBA, FAAD, FACMS, Diplomate of the American Board of Dermatology, from St. Louis, Missouri, will serve as President of the Missouri State Medical Association in 2020-2021. He was formally installed April 4, 2020, during MSMA's 162nd Annual Convention.

Dr. Hruza was born and raised in Prague, Czech Republic. In 1966, he escaped from the communist Czechoslovakia with his parents and older sister, initially to Sweden and ultimately to New York City where he learned English and graduated from Stuyvesant High school, a math and science focused school. He earned his Bachelor of Arts in Physics Summa Cum Laude and Phi Beta Kappa at New York University School of Arts and Science in 1978. From there he attended New York University School of Medicine to earn his MD in 1982 at the top of his class and joined Alpha Omega Alpha medical honor society.

Dr. Hruza did his internal medicine internship at New York Hospital-Cornell University, Sloan Kettering Memorial Hospital and Hospital for Special Surgery in New York City taking care of some of the earliest patients with AIDS, the cause of which was unknown at the time. He became very interested in the visual and hands-on aspects of dermatology and received his dermatology training at New York University Medical Center, Bellevue Hospital, and Manhattan Veterans Administration Hospital getting a broad exposure to all dermatologic conditions including infrequently seen conditions such as leprosy, cutaneous T-cell lymphoma, and blistering disorders.

His physics background led to an interest in the use of lasers in dermatology that were in their infancy in 1986. He was one of the first laser surgery fellows at the Wellman Laboratory at Massachusetts General Hospital-Harvard University under the tutelage of Dr. R. Rox Anderson, the inventor of the theory of selective photothermolysis and inventor/developer of most laser and energy-based applications in dermatology and several other specialties.

Dr. Hruza's interest in skin cancer led to his going to University of Wisconsin-Madison to do a fellowship in Mohs micrographic surgery for the treatment of challenging skin cancers under the tutelage of Dr. Fred Mohs, the inventor of the technique and Drs. Snow and Larson. After completion of his fellowship he was recruited to run the dermatologic surgery section at Washington University School of Medicine in St. Louis where he rose to the position of Associate Professor of internal medicine (dermatology), otolaryngology and surgery (plastic surgery).

Dr. Hruza found that the business aspects of practice were growing more complex and important. With that in mind, he obtained an MBA from Washington University and shortly thereafter, went into solo private practice focusing on skin cancer treatment and laser and energy-based dermatologic procedures moving into a state of the art medical building with a certified ambulatory surgery center he built with his dermatology partner in Chesterfield, Missouri, 10 years ago. With the accelerating consolidation in healthcare by insurers, hospitals, labs, and physician practices Dr. Hruza partnered with United Skin Specialists three years ago.

Dr. Hruza has trained 21 Mohs micrographic surgery fellows, and continues to teach dermatology

residents as an adjunct professor of dermatology at Saint Louis University and rotating fellows from University of Missouri-Columbia, and Saint Louis University at his Laser and Dermatologic Surgery Center in Chesterfield, Missouri.

Dr. Hruza has had a career-long interest in laser and energy-based technology and has contributed more than 150 publications to the medical literature including four textbooks on laser surgery and has lectured on laser and dermatologic surgery on five continents. He also serves on four dermatology journal editorial boards and as assistant editor of Dermatologic Surgery and formerly as assistant editor of the Journal of American Academy of Dermatology and section editor of the Archives of Dermatology. He has been the editor of the dermatologic surgery section of Bologna Dermatology, the main dermatology textbook, for the last three editions.

The rapid encroachment on the practice of medicine and the doctor-patient relationship by insurers, regulators, and legislators and healthcare entity administrators has led Dr. Hruza to become very involved with organized medicine throughout his career having served on the Association of Academic Dermatologic Surgeons, American Academy of Dermatology (AAD), American College of Mohs Surgery, AAAHC and American Society for Dermatologic Surgery (ASDS) Boards of Directors, and the Missouri State Medical Association (MSMA) and St. Louis Metropolitan Medical Society Council, as Treasurer of the American Society for Laser Medicine and Surgery (ASLMS) and MSMA, and as President of ASDS, ASLMS and St. Louis Metropolitan Medical Society. He currently serves as the 2019-20 President of the American Academy of Dermatology.

When not traveling on behalf of organized medicine or on innumerable conference calls, Dr. Hruza is a passionate snow skier going to British Columbia every year with his wife, Carrie, to go helicopter skiing. Closer to home, they love to go on long distance bicycle rides, hikes, and to practice yoga. With his daughter Stephanie, he enjoys scuba-diving in the Caribbean. The whole family, Carrie, Stephanie, Paul, Hope and Rose, love traveling together far and wide.

As Missouri State Medical Association President, Dr. Hruza will continue to advocate for our patients, strengthening the doctor-patient relationship, and keep the physician central in the delivery of healthcare. **MM**

Credentials & Appointments

The 162nd Annual Convention of the Missouri State Medical Association was held via conference call on Saturday morning, April 4, 2020, at 8:00 a.m. The convention, scheduled to have been held April 3-5, 2020, at the Renaissance St. Louis Airport Hotel, was cancelled due to concerns over the COVID-19 pandemic. Sam Page, MD, St. Louis, Missouri, presided as Speaker of the House of Delegates. Parliamentarian was Jo-Ellyn Ryall, MD, St. Louis.

The Committee on Credentials reported that 10 Officers, 23 Councilors, and 111 Delegates were credentialed for the House of Delegates.

This report and the minutes of the 161st Annual Convention as published in the May/June 2019 issue of Missouri Medicine were approved.

The MSMA Nominating Committee members were: Organized Medical Staff Section – James Conant, MD, St. Joseph, Chair; 1st District – Tom Weigand, MD, St. Joseph; 2nd District – Sandra Ahlum, MD, Hannibal; 3rd District – Edmond Cabbabe, MD, St. Louis; 4th District – Keith Ratcliff, MD, Washington; 5th District – Alan Hillard, MD, Columbia; 6th District – Amanda Turner, MD, Nevada; 7th District – Michael O'Dell, MD, Kansas City; 8th District – Brian Curtis, MD, Joplin; 9th District – David Barbe, MD, Mountain Grove; 10th District – Gordon Jones, MD, Sikeston; International Medical Graduate Section – Louis DelCampo, MD, Springfield; Young Physician Section – Sarah Florio, MD, Lee's Summit; Women Physicians Section – Lauren Umstattd, MD, Columbia; Resident and Fellow Section – Jared Lammert, MD, Columbia; Medical Student Section – Alex Shimony, Washington University. **MM**

MSMA Elects Leadership: 2020-2021

MSMA Officers

President
George Hruza, MD, Chesterfield

President Elect
Alexander Hover, MD, Ozark

Secretary
Brian Biggers, MD, Springfield

Treasurer
David Pohl, MD, St. Louis

1st Vice President
Laurin Council, MD, St. Louis

Honorary Vice President
David Chalk, MD, Washington

Honorary Vice President
Ted Groshong, MD, Columbia

Immediate Past President
James DiRenna, Jr., DO, Kansas City

Speaker
Sam Page, MD, St. Louis

Vice Speaker
Timothy Swearengin, DO, Springfield

Councilors

Chair, MSMA Council
George Hubbell, MD, Lake Ozark (5th District)

Vice Chair, MSMA Council
Lancer Gates, DO, Kansas City (7th District)

1st District
Robert Corder, MD, St. Joseph

2nd District
John Memken, MD, Hannibal

3rd District
Elie Azrak, MD, St. Louis
Robert Brennan, MD, St. Louis
Inderjit Singh, MD, St. Louis
Christopher Swingle, DO, St. Louis

4th District
Kevin Weikart, MD, Lake St. Louis

5th District
Lisa Thomas, MD, Columbia

6th District
David Kuhlmann, MD, Sedalia

7th District
Betty Drees, MD, Kansas City
Michael O'Dell, MD, Kansas City

8th District
Matthew Stinson, MD, Lee's Summit
Ellen Nichols, MD, Joplin

9th District
Lirong Zhu, MD, Clayton

10th District
Sharon Wallace, MD, Cape Girardeau

Organized Medical Staff Section
Peggy Barjenbruch, MD, Mexico

International Medical Graduate Section
Sri Kolli, MD, Fenton

Young Physician Section
Sarah Florio, MD, Lee's Summit

Women Physicians Section
Joanne Loethen, MD, Kansas City

Resident & Fellow Section
Jared Lammert, MD, Columbia

Medical Student Section
Priya Jain, UMKC

Vice Councilors

1st District
Robert T. Weigand, MD, St. Joseph

2nd District
Sandra Ahlum, MD, Hannibal

3rd District
Ramona Behshad, MD, St. Louis

4th District
Keith Ratcliff, MD, Washington

5th District
Amy Zguta, MD, Columbia

6th District
Amanda Turner, MD, Nevada

7th District
Fariha Shafi, MD, Kansas City

8th District
Tim Swearengin, DO, Springfield

9th District
David Barbe, MD, Mountain Grove

10th District
Douglas Wallace, MD, Cape Girardeau

Organized Medical Staff Section
Hossein Behniaye, MD, Hannibal

International Medical Graduate Section
Louis DelCampo, MD, Springfield

Young Physician Section
Sara Hawatmeh, MD, St. Louis

Women Physicians Section
Frances Mei Hardin, MD, Columbia

Resident & Fellow Section
Brette Harding, MD, Columbia

Medical Student Section
Sree Lanka, UMKC

AMA Delegates & Alternate Delegates*

Elie Azrak, MD, St. Louis
Edmond Cabbabe, MD, St. Louis
James Conant, MD, St. Joseph
Joseph Corrado, MD, Mexico
Warren Lovinger, MD, Nevada
Charles Van Way, III, MD, Kansas City

*Peggy Barjenbruch, MD, Mexico
*Betty Drees, MD, Kansas City
*Alexander Hover, MD, Ozark
*Ravi Johar, MD, Chesterfield
*Joanne Loethen, MD, Kansas City
*Samantha Lund, St. Louis

AMA Past President
David Barbe, MD, Mountain Grove

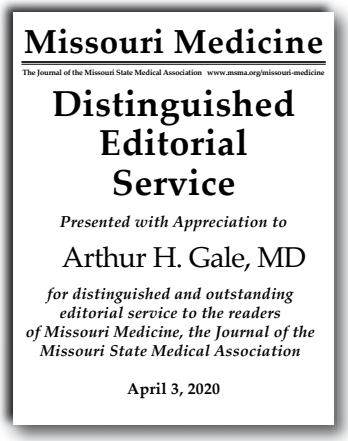
AMA Regional Student Delegate
Manna Varghese, UMKC

Alliance

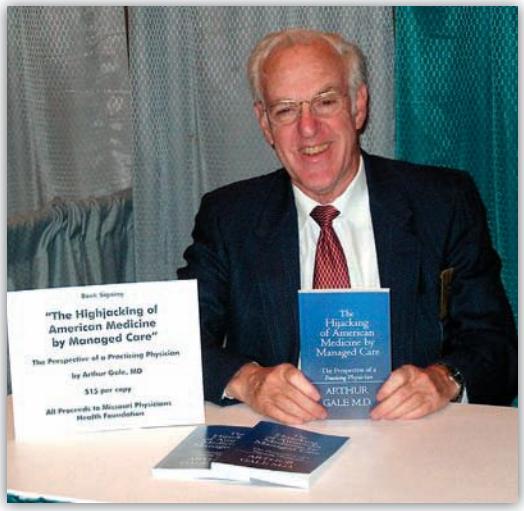
President
Diana Corzine, St. Joseph

President Elect
Barbara Hover, Ozark

Arthur Gale Receives Distinguished Editorial Service Award



Over the last 20 years one of our greatest assets and most prolific writers at *Missouri Medicine* has been Arthur H. Gale, MD, of St. Louis. The award "presented" to him on April 3 is the highest honor the Journal can bestow: the Distinguished Editorial Service Award. Dr. Gale has had a brilliant career in internal medicine and has been extremely generous in teaching and mentoring students and residents. He is a long-time member of MSMA and was first chosen to the *Missouri Medicine* editorial board in October 1991 for his exceptional skills and reputation in Internal Medicine.



Arthur H. Gale, MD, MSMA member since 1976, is a *Missouri Medicine* Contributing Editor and published author. Above, at past MSMA Annual Conventions, funds raised from the sale of his books were donated to the Missouri Physicians Health Foundation. He is now a retired Internist in St. Louis. He would have received the *Missouri Medicine* Distinguished Editorial Service Award at the 2020 Annual Convention in St. Louis, April 3, but it was cancelled due to the COVID-19 Pandemic. Congratulations Dr. Gale!

Dr. Gale is an accomplished writer and has expertise on a wide range of medical, social, and political matters. He was soon promoted to Contributing Editor. During my tenure as Editor, Dr. Gale has authored more manuscripts and articles than any other physician. His articles are often requested for reprint in other state journals. He has written several thoughtful books. Dr. Gale has served a skilled and talented peer-reviewer, and by his editing and emending of submitted works has greatly raised the quality of our content. He has been a trusted advisor to me on many matters of considerable importance for *Missouri Medicine*. Thank you so much, Art. I regret that we were not able to give this to you in person at the Annual Convention.

I ask you all to join in congratulating Arthur Gale, MD, for a brilliant and distinguished career. He is the epitome of the compassionate, accomplished, and articulate physician.

John C. Hagan III, MD, Editor, *Missouri Medicine, The Journal of the Missouri State Medical Association* **MM**

Summary of Council Actions: 2019-2020

Meeting of April 7, 2019 – Kansas City

James DiRenna, DO, Gladstone, President, presided. George Hruza, MD, St. Louis, was elected President Elect. Alexander Hover, MD Springfield, was elected Chair, George Hubbell, MD, was elected Vice Chair. Brian Biggers, MD, Springfield, was elected Secretary. David Pohl, MD, St. Louis, was elected Treasurer.

Meeting of July 14, 2019 – Osage Beach

During the July 2019 Council Meeting in Osage Beach, Missouri, MSMA voted to support a campaign for the November 2020 ballot initiative regarding Medicaid expansion. Currently, a proposed statute and a proposed Constitutional amendment, both with the same language, have been filed with the Secretary of State. MSMA support would be given to whichever option emerges as viable. The Council also approved supporting Missouri Hospital Association's subcontract with Iowa Healthcare Collaborative for the CMS Clinician Quality Improvement Collaboration.

Advocacy

The Council heard a review of legislative issues, including prior authorization reform, medication-assisted treatment, APRN, Physical Therapy, and other

scope of practice issues, as well as public health issues such as homelessness and anti-vaccination.

Two resolutions were referred to the Committee on Legislative Affairs. Discussion on Resolution 1 regarding Chronic Traumatic Encephalopathy was tabled until October so staff can gather more information; Resolution 7 - Supporting Environmental Health Legislation, was adopted:

RESOLVED, that the Missouri State Medical Association support legislation that addresses the harm presented by environmental pollution, and seeks to improve air and water quality as it affects the health of Missouri patients.

Other actions from the Annual Convention resolutions can be found at www.msma.org/resolution-actions.

Participation in the 2019 Physician of the Day program was very much appreciated; the sign-up form and available dates for 2020 are now on the website. Physicians may also agree to have a student shadow them. MSMA encourages volunteers to bring along a non-member colleague to the Capitol. White Coat Day for 2020 will be held on March 3. A sign-up form is also on the website.

MSMA has hosted several advocacy events, one in St. Louis and one in Kansas City, co-sponsored by St. Louis Metropolitan Medical Society and Kansas Medical Society. MSMA staff is happy to bring an advocacy event to you at your local medical society, medical staff, or at your home. MSMA can arrange to have your local state representative stop by. Contact MSMA for more information.

In addition to the weekly legislative updates that are provided during the legislative session, MSMA will now provide updates on the second and fourth Thursdays of the months outside of session. Please share this information with non-members.

A new communication tool, Phone2Action, will allow members to send a one-time text to sign up to be linked with their legislators, and will receive notifications when important issues are being addressed. They will then be able to provide input directly to their elected officials.

SHINE

There are changes in the ownership of KAMMCO Healthcare Solutions (KHS). KAMMCO is the professional liability insurance company sponsored by Kansas Medical Society. The insurance company has divested, and has sold KHS to Kansas Health Information Network, a 501c(3). The contractual relationships with KHS are unchanged, although they now have a new parent company. Department of Social Services budget includes $1 million, and SHINE (Show-Me Health Information Network) hopes to leverage that for the federal 90% match. It has already received $83,000 as the share of the Physicians Foundation grant, and hopes to use those funds to defray some of the up-front connection costs. The SHINE HIE connection fee is about $3,500, and EHR connection costs to HIEs are between $3,000 and $20,000.

CME

Identified topics for the 2020 Annual Convention, based on evaluation summaries and practice gaps, include state and national advocacy efforts, science of medical marijuana, e-cigarettes and vaping, and medicine/artificial intelligence. An ad hoc committee, chaired by Betty Drees, MD, will study the MSMA Annual Convention to find ways to streamline the programming, identify savings, increase efficiency, and find alternative means that maintain its purpose of governance, education, and camaraderie.

Missouri Physicians Health Program

Lisa Thomas, MD, Medical Director for MPHP, praised the success rate of the program. The rate of return to successful practice is high because the MPHP program is longer and more comprehensive than other programs of similar nature.

AMA Report

Edmond Cabbabe, MD, reported that the AMA delegation, including Drs. Jim DiRenna and George Hruza, as well as the student and resident representatives, attended the AMA Annual Meeting in Chicago in June. Dr. Cabbabe has completed his second year on the Council of Long-Range Planning and Development and encouraged application to the AMA Community Health Grants through the AMA Foundation. David Barbe, MD, has completed his leadership role with the AMA, and as Past President he will have a seat in the House of Delegates. He is now in line to be President-Elect of the World Medical Association. MSMA presented a resolution at the AMA meeting regarding the care of children of incarcerated parents. It was combined with a similar resolution, and was adopted.

Alliance

Gill Waltman reported that she and Diana Corzine have been installed for a second term in their roles as

President and President-Elect. The Alliance executive board met on May 29, with Fall Conference scheduled for October, Winter Board Meeting and Day at the Legislature to be held in conjunction with White Coat Day, and the Annual Meeting planned for April 3. The AMA Alliance Annual Meeting was held in Chicago in June, and Missouri had the largest representation. The AMA Alliance will be adding "vaping" to the list of issues to be addressed through their programs. The SLMMS Alliance received the 2019 AMA Alliance Health Awareness Promotion Award for its opioid awareness program at Loyola Academy in St. Louis.

Announcements

Council Chair Alexander Hover, MD, welcomed new Council members: Christopher Swingle, DO, District 3 Councilor; Michael Weaver, MD, First Vice President; Samantha Lund, AMA Student Delegate from Washington University; and Priya Jain, Medical Student Section Vice Councilor from UMKC. Councilor Advisors were appointed: David Kuhlmann, MD – Commission on Medical Economics; Peggy Barjenbruch, MD – Commission on Continuing Education; George Hubbell, MD – Commission on Public Affairs; Lisa Thomas, MD – Physicians Health Committee.

Councilor District Reports (Selected)

District 1

Robert Corder, MD, reported that Buchanan County Medical Society is focusing on issues that affect the health of the community, specifically human trafficking and the opioid epidemic. Dr. Corder participates in the Missouri ECHO program, which offers teleconference CME for free during the semi-monthly Opioid Use Disorder program offered by ECHO.

District 3

Christopher Swingle, DO, reported the 17th Annual Hippocrates Lecture will take place on September 17 at Spazio's Westport in St. Louis. More information is available on the SLMMS website.

District 6

Warren Lovinger, MD, reported that Nevada Regional Medical Center, which is owned by the community, has been very close to being liquidated several times. The Sole Community Hospital program, along with a half-cent sales tax, will help NRMC to meet its required bond payments.

District 7

Lancer Gates, DO, announced that Marc Taormina, MD, has been appointed by Governor Parson to serve on the Missouri Board of Healing Arts. The Kansas City Medical Society Annual Meeting will be on Sept. 26. The guest speaker is Vanila Singh, MD, the Chief Medical Officer for the office of the Assistant Secretary of Health for the U.S. Dept. of Health and Human Services.

District 8

Matthew Stinson, MD, reported that Greene County Medical Society has been involved in the Tobacco 21 measure locally, and hopes that the measure will pass. Brian Curtis, MD, reported that the Joplin Medical School is in its third year; there should be nearly 120 students coming into the two hospitals, Freeman and Mercy, next year.

Organized Medical Staff Section

Peggy Barjenbruch, MD, reported that approximately 100 physicians attended the AMA OMSS in June in Chicago. Out of 12 business items, three prompted robust discussion: accountable care organizations, restrictive covenants, and limitations on physician access to hospital services based on case and monetary volumetrics. The section sent six resolutions to the House of Delegates, including one on ergonomic injuries.

Medical Student Section

Scott Berndt encouraged members to reach out to students to attend their meetings. He thanked the Council for its help with the resolution that the MSS put forth and got passed at the AMA Annual Meeting regarding care of children of incarcerated parents. MU is working on a Homeless Connect project. UMKC is continuing to work on advocacy and getting students signed up to vote. Washington University recently hosted a Pints and Policy event. KCUMB and SLU both have upcoming meetings.

Meeting of October 13, 2019 – Jefferson City

Demonstrating the value of membership through its upcoming advocacy efforts, MSMA announced its top priorities for medicine at the October Meeting in Jefferson City: making the credentialing process less of a headache, curbing vapor product usage by minors, and fighting the anti-vaccination movement.

Advocacy

Working on those three issues and many more begins with the 2020 legislative session on Wednesday, January 8. MSMA has held numerous statewide meetings to increase communication and advocacy this summer and fall, and has been meeting with lobbyists, discussing both old and new issues and anticipating an interesting year for public health. The October Legislative Report highlighted the importance of building relationships with elected officials before the legislative session convenes. Identify your state legislators and make contact with them. Phone2Action is a new tool to connect members to MSMA's legislative text alert network. Visit www.msma.org/action to sign up.

An FAQ flyer on medical marijuana is being developed by MSMA, and physicians are encouraged to submit any questions they or their patients have to Jeff Howell at jhowell@msma.org so that those issues can be incorporated.

The Missouri Health Insurance Innovation Task Force has been established to look into a Section 1332 waiver in the ACA and will put in legislation to launch a re-insurance program similar to what other states have done. MSMA member Rep. Jonathan Patterson, MD, is on the committee.

Five MSMA members on the state's Opioid Prescriber Advisory Committee give MSMA great input into Medicaid opioid policies. An effort to expand the 12-month drawback period for HMO payments to physicians was turned back in the Governor's Medicaid Fraud Task Force.

The Council discussed the possibility of creating a Missouri Healthcare Collaborative to jointly pursue shared interests, as Iowa and Kansas hospital and medical associations have done.

Events to sign up for:

Physician of the Day program www.msma.org/physician-of-the-day

March 3, 2020 - White Coat Day www.msma.org/white-coat-day

Annual Convention/CME

Programming is underway for the 162nd Annual Convention, April 3-5, 2020, Renaissance St. Louis Airport Hotel, reported Peggy Barjenbruch, MD. She said the CME Commission accredited Hannibal Regional Hospital for four years, and approved progress reports for North Kansas City and Lake Regional. The MSMA annual maintenance fee will increase due to an ACCME fee increase, and beginning in 2021, providers will pay the maintenance fee directly to the ACCME.

An ad hoc committee on the Annual Convention is reviewing possibilities for cost savings and ways to increase attendance among younger physicians. Other improvements include changes to the exhibit hall, CME, and registration fees. By 2022, the delegate handbook will be only available via MSMA's website.

SHINE

SHINE is continuing with its existing policies and structures, and is working with MO HealthNet to determine how to distribute $10 million in federal matching funds, which are intended to assist clinics with connection fees to HIEs; these fees remain the largest challenge to signing up. SHINE is now owned by the Kansas Health Information Network, rather than KAMMCO.

MSMA Insurance Agency

Ronnie Staggs, Director, discussed the current market analysis, which showed that for the first time in many years, insurance companies are filing for rate increases across the board. Progress continues on the Association Health Plan. It was delayed due to a new ACA format allowing individual states to make more decisions on what they will allow for groups under 50.

Services Update

MSMA will continue administration services in 2020 for Boone County Medical Society, and the Missouri organizations of the American College of OB-GYN, American College of Emergency Physicians, and American College of Physicians.

Missouri Physicians Health

Lisa Thomas, MD, Medical Director for the Missouri Physicians Health Program, reported that educational presentations will continue in 2020, and asked all physicians to support their physicians' health program in their respective hospitals and practice settings. She reviewed the participation figures, which are mostly internal medicine and family practice physicians. Dr. Thomas also announced her candidacy for State Representative of House District 124 comprised of portions of Camden and Miller counties. She is a resident of Lake Ozark and has been involved in MSMA leadership since 2005. She is currently MSMA's District 5 Councilor.

Actions and Recommendations

Resolution actions of the 2019 House of Delegates were approved and can be found at www.msma.org/resolution-actions.

Constitution and Bylaws

Two areas of the MSMA Constitution and Bylaws are to be updated through resolutions introduced at the January 2020 Council Meeting. First, the Women Physicians Section, established in April 2019, is crafting bylaws to amend MSMA's Constitution and Bylaws. Secondly, the bylaws that address the allocation of councilor positions based on membership will be updated to keep the allocations unchanged.

Councilor District Reports (selected)

District 2

Councilor John Memken, MD, Hannibal, reported that Patricia Herner, MD, presented the American College of Surgeons "Stop the Bleed" program at a recent society meeting.

District 3

Councilor Inderjit Singh, MD, St. Louis, reported the annual Hippocrates lecture topic was "Healthcare in Crisis," presented by Dr. Ed Weisbart in September. Following the lecture, participants discussed the pros and cons of a "Medicare for All" single-payer program. The partnership with the Midwest Health Initiative (MHI) and the St. Louis Business Health Coalition (BHC) continues to provide physician input for the Choosing Wisely initiative. A sub-group of four SLMMS physician members have joined with physicians from the MHI board to analyze areas of high cost and potential waste reduction in healthcare. Using payer-provided data, the physicians are identifying opportunities in the St. Louis market and will publish findings in 2020.

District 4

Councilor Kevin Weikart, MD, St. Charles, reported that St. Charles Lincoln County Medical Society will be awarding $7,500 for their medical student scholarship.

District 5

Councilor George Hubbell, MD, Lake Ozark, reported that Boone Hospital in Columbia will no longer be a subsidiary of BJC, but instead will be managed by itself as a county hospital, led by long-time MSMA member Jerry Kennett, MD. The University of Missouri is in the process of buying out SSM-St. Mary's in Jefferson City and Mexico. MU is expanding its family practice residency to include Bothwell Hospital in Sedalia. Amy Zguta, MD, Columbia, will become the District 5 Vice Councilor, due to the relocation of Clark Andelin, MD, Mexico. Boone County Medical Society held two events: a residency forum for directors and third-year medical students and an educational forum on medical marijuana.

District 6

Vice Councilor Amanda Turner, MD, Nevada, expressed her appreciation for Dr. Lovinger's efforts to effect the passing of a sales tax to keep the Nevada, Mo., hospital from closing. Dr. Turner thanked MSMA for its presentation on advocacy and communication at the West Central Society's meeting in August.

District 8

Vice Councilor Brian Curtis, MD, Joplin, reported the medical school in Joplin is now in its third year, so the original students are now in their third-year rotations.

District 9

Vice Councilor Omofolarin Fasuyi, MD, Rolla, thanked MSMA for its advocacy presentation and expressed his appreciation for the opportunity to serve on the MSMA Council as he will be moving to Georgia to continue his practice.

District 10

Councilor Sharon Wallace, MD, Cape Girardeau, has reached out to St. Francis Medical Center to address credentialing and contracting issues. St. Francis, along with Southeast Hospital, is the ACO for 16,000 people.

Sections

Medical Student Priya Jain, UMKC, encouraged members to reach out to the medical schools and be involved in their meetings. Mizzou and Washington U have had Pints and Policy meetings. KCU and UMKC had a combined meeting in which the AMA government relations staff addressed the students.

The Council accepted Jared Lammert, MD, to fill a vacancy for the Resident and Fellows Section Vice Councilor position, and accepted Joanne Loethen, MD, as Councilor, and Frances Mei Hardin, MD, as Vice Councilor, for the Women Physicians Section. Dr. Loethen reported the WPS has held two organizational meetings to create vision and goals.

AMA Report

Elie Azrak, MD, reported the AMA delegation is preparing for the 2019 AMA Interim meeting in San Diego, November 15-19. Resolutions and reports are on the website and can be viewed and commented upon ahead of the meeting. Dr. Loethen is running for an open delegate seat in the AMA Resident and Fellows Section, and Dr. Azrak has submitted his name for appointment to an open seat on the AMPAC board. The delegation chair, Edmond Cabbabe, MD, continues to serve on the AMA's Council for Long-Range Planning and Development.

Dr. Cabbabe reminded members that the AMA has many monetary awards. There is also the annual grant from the Missouri Honor Fund for a free, physician-led clinic. Go to the AMA Foundation website to nominate or apply.

Missouri for many years was part of the four-state Heart of America caucus at the AMA. Oklahoma and Arkansas decided to join the Southeast Caucus. Missouri remains aligned with Kansas.

Alliance

Diana Corzine, MSMAA President-elect, encouraged participation in the Alliance's Holiday Sharing card campaign. The deadline to contribute is November 22. She announced the Foundation Fundraiser, the "Alliance Celebrates 50 Years of James Bond," is scheduled for Friday, April 3.

Meeting of January 11, 2020 – Jefferson City

The MSMA Council met via conference call for its January 11, 2020, Meeting due to inclement weather. Below are the highlights.

Advocacy

Ravi Johar, MD, reported that MSMA staff have read 1,500 bills and are following 400 bills that affect healthcare. He encouraged members to sign up for Physician of the Day, and to consider allowing a medical student to shadow. White Coat Day at the Capitol will be March 3, 2020. Phone2Action is a good tool for physicians to connect with legislators. Currently, there are 120 physicians signed up.

The Council approved that Resolution #1, which addresses the issue of tackle football below high school age, not be adopted. Members were also updated on the E/M coding revision and Texas v. Azar challenge to the ACA.

Other updates included marketing efforts, membership outreach, Medicaid expansion, and a healthcare collaboration with Missouri Hospital Association.

James DiRenna, Jr., DO, MSMA President, reported on his travels throughout the state, as well as other states. He encouraged members to keep in touch with their legislators. MSMA's Annual Legislative Award be presented to Representative Robert Ross and Senator Bill White. The MSMA Constitution and Bylaws will be changed to reflect the addition of the Women Physicians Section, which was added at the 2019 Annual Convention.

Annual Convention and CME

The Actions and Resolutions from the 2019 Annual Convention can be found online at msma.org/annual-convention. Peggy Barjenbruch, MD, outlined general session topics for the upcoming Annual Convention including Vaping, Science of CBD, Stop the Bleed, Artificial Intelligence, and Missouri Medicaid. The report also reviewed recent accreditation decisions. Betty Drees, MD, reported on the restructuring of the Annual Convention. A proposal will be presented at the July MSMA Council meeting.

MSMA Insurance Agency

George Hubbell, MD, reported that the agency continues to meet member needs, urged them to utilize the agency for any insurance coverage, and encourage their colleagues to do likewise. The Council also discussed the status of MPM-PPIA/ Physician Standard Insurance Company.

Physicians Health Program

Bill Woods, MD, offered the report as Chair of the Physicians Health Committee. Due to the resignation of Executive Director Bob Bondurant as of December 31, 2019, Acting Executive Director Mary Fahey has been named Bob's replacement. The organization chart has been changed so that the Physicians Health Committee will oversee the operations of the MPHP; the finances will be overseen by the MSMA EVP, both will report to the Physicians Health Foundation board.

Dr. Woods outlined the Safe Haven system

that is used in some states, which would allow those seeking voluntary help from MPHP from reporting this to the Board of Healing Arts, as long as they are actively involved in the program. MPHP staff will research the issue and come up with recommendations to be presented at the next Council and the Physicians Health Foundation board.

Membership

Joseph Corrado, MD, reported that the Committee had met on January 7 via conference call. He reviewed current membership numbers, the results of the Councilor-signed recruitment letters, recent advocacy events, and other marketing strategies. Staff will be connecting with hospital Chief Medical Officers. He encouraged everyone to sign up for the Advocacy App Phone2Action.

Publications

The Council gave its approval of Missouri Medicine's 52-member Editorial Board to serve in 2020. The Editorial Board provides peer-review and submits articles to the Journal.

Alliance

Gill Waltman reported on the fall conference in Hannibal in October. She thanked all who contributed to the 2019 Alliance Holiday Sharing Card, which raised over $3,200. Sue Ann Greco, St. Louis, will be installed as AMA Alliance President next June.

AMA Report

Elie Azrak, MD, reported that the delegation represented Missouri at the AMA interim meeting in San Diego in November. A resolution put forth at the 2018 MSMA Annual Convention resulted in a change in AMA policy, which addressed the inclusion of health system science subjects in medical curricula and LCME accreditation. AMA members are encouraged to read and comment on resolutions, which can be accessed online.

Councilor District Reports – Selected

District 3

I.J. Singh, MD, reported that the St. Louis Metropolitan Medical Society will install Jason Skyles, MD, as the 2020 SLMMS President. Four physicians were presented with awards, including Sam Page, MD, who received the Schlueter Award and Bill Huffaker, MD, who received the President's Award. Dr. Singh also offered an update on the Choosing Wisely program.

District 5

Lisa Thomas, MD, reported that the Boone County Medical Society had a successful residency forum in October. They will be offering a second session on financial, legal and insurance issues for medical students and residents. BCMS held its annual installation of officers and gala on February 1. The BCMS Alliance has been reorganized under the direction of Mary Katherine Heimburger and Donna Corrado, and will be renamed as Central Missouri Medical Alliance. The BCMS board approved a contribution to the MPHP in 2019.

District 8

Matt Stinson, MD, reported that the Greene County Medical Society held a medical marijuana discussion led by Lyndall Fraker of DHSS. Kayce Morton, DO, will be taking over the GCMS presidency. Dr. Hover expressed his appreciation for the social and recruiting events hosted by the Alliance.

District 9

Lirong Zhu, MD, reported that David Barbe, MD, had been named the President-Elect of the World Medical Association. She stated that new members had joined at Mercy Clinic-Rolla and Phelps Health, and they anticipate more new members in the coming months. They are seeking to fill the vacancy of Vice Councilor-District 9.

Women Physicians Section

Joanne Loethen, MD, reported that they have had three conference call meetings since inception of the new section. They will have an information mixer on Friday, April 3, in St. Louis during the Annual Convention. They are looking at having networking events across the state in 2020.

Medical Student Section

Scott Berndt reported that two legislative bills are proceeding in support of the resolution that the MSMA Council passed at AC 2019 regarding adverse events suffered by children of incarcerated parents, which was sponsored by the MSS. **MM**

Reports of the Delegate Handbook: 2019-2020

Secretary

The Missouri State Medical Association had 3,450 members as of December 2019. This was a net loss of 281 members from our membership of 3,731 as of December 2018. Following is a breakdown according to classification.

Year	Students	Residents	Active	Honor	Total
2018	835	112	2,381	403	3,731
2019	740	115	2,226	369	3,450

The number of member deaths reported during 2019 totaled 17.

The Committee on Nominations, which is appointed by the President, from the House of Delegates, must submit nominations for the following offices:

Three Vice Presidents to fill the expired terms of Michael Weaver, MD, Kansas City; Sandra Ahlum, MD, Hannibal; and Rebecca Hierholzer, MD, Leawood, KS.

Speaker and Vice Speaker to fill the expired terms of Sam Page, MD, Creve Coeur, and Tim Swearengin, DO, Springfield.

Two Delegates and five Alternate Delegates to the AMA to fill the vacancies created by the expiration at the conclusion of the 2020 Annual Convention of the terms of Delegates: Edmond Cabbabe, MD, St. Louis; Warren Lovinger, Jr., MD, Nevada; and Alternate Delegates: Ravi Johar, MD, Chesterfield; Michael O'Dell, MD, Kansas City; George Hruza, MD, Chesterfield; Joseph Corrado, MD, Mexico; and Samantha Lund, St. Louis (one-year term). The new two-year terms will begin at the conclusion of the 2020 MSMA Annual Convention and end at the conclusion of the 2022 MSMA Annual Convention.

The terms of the following Councilors will expire in 2020: 3rd District – Elie Azrak, MD, St. Louis; Chris Swingle, DO, St. Louis; 5th District – George Hubbell, MD, Lake Ozark; Lisa Thomas, MD, Lake Ozark; Lancer Gates, DO, Kansas City; Marc Taormina, MD, Kansas City; 8th District – Matthew Stinson, MD, Springfield; 9th District – Lirong Zhu, MD, Rolla; Organized Medical Staff Section – Peggy Barjenbruch, MD, Mexico; International Medical Graduate Section – Sri Kolli, MD, Fenton; Women Physicians Section – Joanne Loethen, MD, Prairie Village, KS; Resident and Fellow Section – Daniel Young, MD, St. Louis; Medical Student Section – Scott Berndt, Kansas City.

Alliance

The 2019-2020 Alliance year began in April during the MSMA convention in Kansas City when the Alliance officers were installed. Millie Bever, Kansas City, installed Gill Waltman, who was re-installed as president, and Diana Corzine as president-elect, both for second terms. Also installed were Vice presidents Kelly O'Leary (Health), Kirk Doan (Legislation), Jennifer Gast (Membership), Sana Saleh (Recording Secretary) and Debora Snyder (Treasurer.)

Looking through Rose-Colored Glasses was the theme selected by Mrs. Waltman as a carry-on from her Look on the Bright Side Monty Python-inspired theme from the previous year. This was an optimistic approach to reflect changes in the world around us with many natural disasters, economic problems, the political climate, and health-related issues including the opioid crisis and now the new electronic cigarette or vaping epidemic affecting our youth. Burnout wears down the medical profession from all sides with the need to defend medicine and patients from public opinion, invasive hospital and insurance influences, and scope-of-practice usurpers.

Mrs. Waltman presided over an Alliance Executive Board Meeting on May 29 in Columbia. Additional officers were appointed to the board and all members presented their plans for the year. The dates and venue for Fall Conference in Hannibal was circulated and plans for Day at the Legislature to be combined with the MSMA White Coat Day on March 3 were discussed.

At the AMA Alliance Annual Meeting in Chicago in June 2019, MSMA Alliance Past President Sue Ann Greco was sworn in for a second term as the national AMA Alliance Board Secretary. Missouri had excellent representation at the meeting. Due to the resignation of the AMA Alliance President Elect, Sue Ann will

be installed as the AMA Alliance President at the annual meeting in Chicago in June 2020. The installation will take place on Tuesday morning at the Hyatt Centric Magnificent Mile Hotel. Sue Ann is only the 6th Missourian to be installed as AMA Alliance President. The Missouri contingent will be honoring her with a suitable celebration event and those MSMA members who will be in Chicago are invited to attend in support.

The Alliance Fall Conference was held October 29-30 in Hannibal. Sandra Murdock, conference coordinator set the venue at the Holiday Inn Express opposite the Medical Center. The program on Tuesday afternoon included invited speakers from the Hannibal Clinic recommended by Sandra Ahlum, MD. Eric Meidl, MD, an internist specializing in obesity working closely with the bariatric surgical team, spoke on the current management of obesity and discussed the pros and cons of various weight loss therapies and current trends, including intermittent fasting. Patricia Hirner, MD, a general surgeon, presented the American College of Surgeons' new initiative called Stop the Bleed. This was a hands-on course aimed at the general public on how to stop hemorrhage at a trauma site, such as a road traffic accident or a shooting. Michael Bukstein, MD, a vascular surgeon at the Hannibal Clinic, assisted in the demonstration which included the correct methods of applying compression to a bleeding wound, packing the wound with clean cloth or hemostatic gauze, and the use of tourniquets. Dr. Hirner recommended that everyone carry a trauma kit with these contents (can be purchased online) in the glove compartment of their vehicles.

The Tuesday evening event was held at the Hannibal Country Club courtesy of members Sherry and Michael Bukstein. Henry H. Sweets, III, the Curator and Executive Director of the Mark Twain Boyhood Home and Museum spoke to the group on Medicine and Pharmacy in the time of Mark Twain.

The Alliance Board meeting continued on Wednesday morning. Pertinent board issues discussed were the transfer of the Alliance Scholarship funds to the MSMF which will handle future distribution to the Missouri medical schools. Kathy Weigand announced that the (also British) theme for the Friday night Foundations event would revolve around James Bond.

In December, the Alliance Holiday Sharing Card was published with donor names in Show Me Alliance News, Missouri Medicine, and on the MSMA website. Proceeds from donations amounted to more than $3,300 to benefit the MSM and AMA Foundations. Thanks to all who participated. The Alliance hosted many charity and fundraising events over the holidays to provide support for local food banks, a mobile food drive, shelters, school programs and local charities.

This year, the Alliance has moved its traditional Winter Board meeting and Day at the Legislature to coincide with the MSMA White Coat Rally to be held on Tuesday March 3 in Jefferson City. Legislative Vice President Kirk Doan has arranged for members to stay in a Holiday Inn & Suites and coordinated his efforts on behalf of the Alliance with the staff at MSMA. Alliance members will attend the winter board meeting the previous day and meet for dinner the night before for a briefing by the MSMA lobbyists.

The MSMA Alliance Annual Meeting will be held in conjunction with the MSMA convention in St. Louis April 2-4. For the business sessions, there were two topics of interest: the St. Louis Society for the Blind and Visually Impaired – an extraordinary organization that gives many opportunities to teach skills to individuals to empower them at home and at work; and the neurophysiologic, neuroanatomic, and neurocognitive changes from vaping on the teenage brain, which will be heard as part of MSMA's General Session on vaping by Washington University Associate Professor of Psychiatry Donald Bohnenkamp, MD.

The Alliance Foundation Fundraiser Dinner will be held on Friday April 3 at the Renaissance Airport Hotel. Kathy Weigand chose The British Invasion last year in keeping with Mrs. Waltman's heritage and this year the theme is The Alliance Celebrates James Bond- 007.

Current Alliance Issues: Pertinent issues and challenges discussed at board meetings this year continue to include maintaining membership numbers and identifying current members to take on leadership positions. The Nominating Committee did a good job finding some new faces to join the leadership. The Alliance worked hard

to increase membership, round up former members and recruit new ones. The former Boone County Medical Association Alliance is in the process of being resurrected and will take on a new name of Central Missouri Alliance.

Continuing Medical Education

The Commission reviewed and approved the following accreditation actions:

- Institute for International Medicine-Kansas City, MO
- Mercy Hospital St. Louis-St. Louis, MO
- Hannibal Regional Hospital-Hannibal, MO
- St. Louis STD/HIV Prevention Training Center-St. Louis, MO
- Missouri Baptist Medical Center-St. Louis, MO
- Mercy Hospital Springfield-Springfield, MO

The following entities submitted Progress Reports that were approved by the Commission:

- North Kansas City Hospital-Kansas City, MO
- Lake Regional Health System-Osage Beach, MO
- Cape Girardeau County Area Medical Society-Cape Girardeau, MO

The Commission planned and approved the 2019 Annual Convention CME Program approved for 10.00 hours of AMA PRA Category 1 CreditsTM. Additionally, the program was approved for 7.5 American Board of Internal Medicine Maintenance of Certification Points.

Following the Annual Convention, attendees were able to participate in an online survey that measured outcomes based on questions designed by the Commission.

In 2019, SSM St. Mary's Hospital of Jefferson City chose to not seek reaccreditation as an accredited provider. The Missouri State Medical Association currently accredits twenty-three entities statewide. MSMA staff conducted a spring and fall new staff training at MSMA headquarters.

The Missouri State Medical Association and Kansas Medical Society hosted a provider training in Lenexa, KS. Staff from the ACCME and the AMA provided attendees with an update of information as it related to the updated commendation criteria and the revisions to the AMA PRA handbook. Benita Stennis, MSMA staff, attended the state medical society meeting sponsored by the ACCME April 29-May 2, 2019 in Chicago, ACCME's Annual Conference where attendees discussed issues and trends relevant to CME. Benita Stennis, MSMA staff, also attended the 2019 ACCME State Medical Societies Meeting in Chicago, IL December 11-12, 2019. Additionally, staff participated in the ACCME's monthly noon conference calls.

Executive Vice President Report

You should be proud that your Missouri State Medical Association is widely recognized as the voice of medicine in Missouri. Be it the Missouri General Assembly, the state government departments and divisions, the business community, the insurance industry, hospitals, advocacy groups, or the media, MSMA is considered the leading advocate for your profession and your patients. Following is just a sample of the many things your MSMA did for you in 2019.

State Advocacy Activities

Your MSMA lobbyist team enjoyed a very good year in the state Capitol in 2019. They are quick to credit you and your MSMA colleagues with much of that success, not only for your active involvement in the political process, but also for the respect you command in your community. MSMA is involved in more legislative issues (>400) than any other organization in the state; everything from prior authorization to medication assisted treatment (MAT) to scope of practice and PDMP. Your two lobbyists are among the first to arrive at the Capitol and among the last to leave – every day. Their diligence and effectiveness are unsurpassed. Rather than overwhelm you with details here, I'll refer you to our Legislative Report, which members receive weekly during the legislative session and twice monthly August through December. If you are not reading this publication, you're missing out. If you are reading it, please reach out to your local senator and representative to ensure they know which issues matter to you. Your personal contact amplifies your lobbyists' efforts. MSMA initiated local advocacy outreach in 2019 with 29 meetings in various parts of the state. This is designed to promote a better understanding of issues impacting members and non-members. Your lobbyist team received great input and will expand this activity in 2020.

Federal Activities

MSMA's advocacy work is not limited to Missouri's borders. We are involved in a wide range of federal government issues, year in and year out, both alone and with other organizations within the house of medicine. We lobbied federal authorities on such issues as opioids, surprise billing, and drug prices last year. Those efforts weren't limited to letters, e-mails, and telephone calls to Washington, DC. Your MSMA leadership and staff traveled to Capitol Hill to lobby in person in the halls of Congress.

Other Notable Activities

Despite having the resources and numbers of a medium-sized state medical association, your MSMA is one of the most diverse and active state organizations in the nation. Here are just a few of the activities undertaken on your behalf over the last year.

Your President and MSMA staff attended a number of local component society meetings across the state in addition to the aforementioned advocacy meetings. Your medical association staff and leadership are available to all parts of the state, no matter how large or small.

MSMA boasts an outstanding group of member physicians who, twice a year, give the better part of a week to represent you and your patients in the AMA House of Delegates. It is significant and sometimes thankless work, but this is a valuable service they perform. Please thank them.

In addition to its regular duties, your MSMA staff also provides top-rate administrative services for one local medical society, several statewide medical specialty societies, and serves on or maintains liaison with many external governmental and private-sector committees, task forces, boards and commissions.

Membership Services and Benefits

Your MSMA staff and leadership are constantly striving to bring even more value to your membership. One constant priority is to improve communications with our members and respond more quickly to answer questions and resolve issues. In recent years, MSMA has increased its email communications to provide additional content without increased costs. The website and social media are two additional areas of electronic communication which receive frequent updates.

Missouri Medicine, MSMA's outstanding scientific journal, is included with your membership. It has won seven prestigious Ranly Awards, and is published in digital format in addition to the print copy you receive. The journal's scientific content is accessible in the renowned PubMed database, and it enjoys a unique partnership with MedHelp, the world's largest online health community, joining such other notable partners as Johns Hopkins, the Cleveland Clinic, and Cornell University. You can find current and archived electronic editions on our website.

Progress Notes, our monthly newsletter (free to members), is full of timely news items, tips, and information. We began a monthly e-Progress Notes in 2018 to provide more specifics about your medical association's activities in the capital city.

MSMA also offers you free CME credits at the Annual Convention, and numerous other opportunities to earn CME through our statewide CME recognition program. MSMA accredits 23 entities to offer CME, many of which participate in joint providerships across the state. Yet another membership benefit.

We know everyone struggles with providing health insurance for employees. Your Association staff and the staff of the MSMA Insurance Agency invested significant hours in 2019 working with other state medical associations in researching an Association Health Plan (AHP). This AHP will harness the combined numbers of many state medical associations on behalf of MSMA member physicians. We expect this Association Health Plan to be an important member and employee benefit. Ask Agency staff for additional information.

I would ask you to also be mindful of other direct benefits your MSMA membership offers. For example, we are partners with Moneta, an outstanding financial services firm that provides MSMA members with expert financial planning and investment services. SHINE is a health information exchange (HIE) which facilitates electronic medical records software sharing clinical information with other EMRs in addition to providing assistance with Medicare MIPS compliance. We also have a relationship with the Resolve Physician Agency,

which offers a wide range of career services, including job placement, contract review and negotiation, practice evaluation, benefits analysis, debt management, and a lot more, all at a discount to MSMA members. We are partnered with the CCPA Purchasing Partners to give you access to up-front discounts on a variety of medical and office supplies, including some vaccines. We have an exclusive arrangement with DocbookMD, which offers you a secure, HIPAA-compliant tool to send messages, patient information, images, and more to your MSMA colleagues through an application on your smart phone or other hand-held device (free to MSMA members). Medical Waste Services offers MSMA members significant savings on medical and biohazard waste removal and treatment services. Other partners include Officite, a medical practice website development and internet marketing provider and MedJet Assist, a medical transport service. All of these offer MSMA members a nice discount on their services. Other great offers include the Missouri Drug Card, coding and billing resources, and Go Next for your travel arrangements, all with special rates and savings for MSMA members. When put to good use, these benefits save MSMA members far more than the cost of membership dues.

MSMA's Affiliate Organizations

Your Missouri State Medical Foundation has loaned more than $11.8 million to Missouri medical students since its inception more than fifty years ago. The Foundation board made the decision in 2017 to cease its loan program due to the significant number of private lenders already in the market. The focus is now on scholarships for Missouri medical school students. The Foundation is currently funding ten $4,000 MSMA Scholarships at each of the six Missouri medical schools ($240,000 in total). The Foundation also offers $5,000 in matching funds to component medical societies to create their own medical student scholarship funds.

Your Missouri Physicians Health Program is widely considered one of the most successful of its kind in the nation. Last year, the program served 94 medical students, residents, and practicing physicians who were dealing with chemical, emotional, or behavioral issues. You can assist your colleagues by asking your hospital medical staff and administration to contribute funds to assist this exceptional and vitally important program.

Your Missouri Medical Political Action Committee is one of the most respected and effective PACs in the state. In the last election cycle, MMPAC contributed close to $120,000 to support physician-friendly candidates across the state. Membership begins at the $100 Sustaining Member level, but you can demonstrate your political savvy by upgrading to Silver ($250), Gold ($500), or Diamond ($1,000) level. Your participation is essential to our political effectiveness.

Your MSMA Insurance Agency was formed by MSMA and is directed by physicians to serve you and your practice. This independent insurance agency is a trusted source for all lines of insurance and provides financial support for MSMA. Please visit with the Agency's staff during the Convention.

The MSMA Alliance has dedicated and enthusiastic physician spouses who work tirelessly to promote health education and support health-related charitable activities, all toward improving the health and welfare of all Missourians. And they are a force to be reckoned with when they march on the Capitol every year to advance medicine's legislative causes.

The Center for Patient Safety is a private, not-for-profit organization originally founded by MSMA, the Missouri Hospital Association, and Primaris. It is dedicated to being the leader in providing solutions and resources to reduce medical errors and improve patient safety, and was among the very first organizations in the nation to win federal designation as a Patient Safety Organization. We are very proud of the Center's work.

Your Organization

It is nearly impossible to list all of the duties and services MSMA provides for the physicians of Missouri. The advocacy and representation, the publications, the CME, the Foundation, the

MSMA Insurance Agency, the Physicians Health Program, the Alliance, and your AMA Delegation all create an organization deeply rooted in service to its members and the patients they serve. The MSMA is YOUR organization, and your officers and staff welcome your thoughts on how best to serve you and your fellow members. Feel free to seek them out – at this convention or at any time – and share your ideas.

Staff

On behalf of the staff and the entire MSMA membership, I want to express gratitude for your officers, councilors, committee members, and other leaders who give so much of their time and resources for the betterment of the Association, the profession, and patient care in Missouri.

I also want to express my appreciation for allowing me to work with talented and dedicated MSMA employees whose creativity and diligence are unmatched anywhere. Liz Fleenor, the Director of Communications, is the Managing Editor of your award-winning *Missouri Medicine* and *Progress Notes*, designs all the MSMA pamphlets and logos you see, and oversees MSMA's website. Benita Stennis, the Director of Scientific Affairs, does all of our meeting planning – including the Annual Convention – and also directs CME credentialing and programming. Jeff Howell is General Counsel and Director of Governmental Relations. In addition to handling legal affairs, he heads your extremely effective lobbying team and writes the Legislative Report. Heidi Geisbuhler is your Director of Legislative Affairs and contributes to Progress Notes and the Legislative Report. Haley Wansing, the Director of Membership, works tirelessly to maintain and grow the membership base, and travels widely to liaison with the local societies, residents, and students. Stephen Foutes, your Director of Marketing, has boosted our social media presence, travels the state to personally interact with local societies and staffs Boone County Medical Society. Sarah Luebbert, the Director of Specialty Society Services, staffs ACP, ACOG, and MO ACEP and staffs internal and external committees. Cheri Martin, the Office Manager, keeps the office running like a well-oiled machine, day in and day out. She also manages MMPAC's day-to-day activities. Kelli Clemens, the Finance Manager, is new to our staff and keeps the books and controls cash inflow and outflow. Cassie Williams, the Membership Data Manager, tends to our complicated member database and coordinates all the membership billing and mailing for MSMA, and most of our local component societies. Carol Meyer, the Administrative Assistant, is an invaluable team member who helps a great deal with CME and convention details.

And finally, please allow me to thank you, the physicians of Missouri, for the opportunity to serve you in this outstanding organization.

Membership

The 2019 MSMA membership year closed with 2,226 active members, 115 residents, 740 students and 369 retired members. 173 physicians joined as new members in 2019. In addition to traditional recruiting methods, MSMA has had a positive response to MSMA Councilors sending hand-signed letters to non-members. Peer-to-peer outreach is very beneficial to maintaining and growing membership.

MSMA initiated 29 advocacy updates by MSMA lobbyists in 2019 at component society meetings, medical resident and student events, specialty groups and hospital leadership. MSMA will host similar meetings after the 2020 legislative session concludes, as well as district meetings and meetings with hospital CMOs.

All physicians, not just MSMA members, are encouraged to sign up for legislative text alerts through MSMA's Phone2Action program. Physicians communicating directly with legislators is very persuasive. Text MOMEDICAL to 52886 for enrollment.

MSMA has launched an awareness-building campaign, aimed at non-members and lapsed members. Phase 1 has emailed non-member Missouri physicians to introduce/re-introduce them to MSMA through a four-part series focused on vaccinations.

On social media, Facebook was the most

successful platform for connecting with physicians in 2019. MSMA placed ads and promoted posts on Facebook reaching more than 44,000 people.

On MSMA's other social media channels:

Impressions on Twitter increased 19%;

MSMA shared 111 posts on Instagram and added more than 30 new followers;

Twenty-two videos were posted to YouTube and Facebook, generating more than 18,000 video views across the two platforms.

We encourage all members to follow us on social media and to share our posts with member and non-member colleagues.

Missouri Physicians Health Foundation

This has been a busy year as indicated by the number of referrals and the numerous Missouri physicians that were assisted. The MPHP provides a variety of services. This includes consultation, intervention, referral for treatment, monitoring and advocacy. The consultive service is especially active. Hospital administrators, physicians, colleagues and family members call the Program Coordinator or Clinical Coordinator to make a referral, discuss a potential referral or brainstorm about the necessity of making a referral. Information is often requested about how to identify problems, what services are available and how to handle issues of impairment should they occur. Many hours are required to meet their needs. The MPHP provides a safe and knowledgeable venue for any question or concern about physician health.

Missouri State Medical Foundation

The Foundation made more than 3,000 medical school student loans over 50 years, totaling almost $12 million. The loan program has been closed and the Foundation funds the MSMA Scholarships awarded over the past 15 years.

In 2019, the Foundation awarded $4,000 MSMA Scholarships to ten Missouri medical students at each of the six medical schools.

Last year, 60 Missouri medical school students received $240,000 in MSMA Scholarships. This gives us a cumulative scholarship total of $1.2m awarded to Missouri natives who are attending a Missouri medical school.

The Foundation has also matched funding up to $5,000 for local medical societies and the MSMA Alliance which have initiated their own scholarship funds.

The MSMA Alliance has been an important partner to the Foundation through generous fund-raising activities. The Alliance closed their scholarship fund in 2019 and donated the entire $74,000+ to the Foundation.

MSMA Insurance Agency

Your MSMA Insurance Agency is an independent insurance agency that offers professional insurance consultation to all Missouri physicians. The Agency offers policies primarily for professional liability and health, but also covers workers compensation, business office coverage, disability, and life.

Agency staff have been exploring with other state medical associations the formation of an Association Health Plan. Due to a highly regulated environment this has moved very slowly, but it remains a worthwhile pursuit.

The board is supportive of the Agency and encourages all MSMA members to contact the Agency for a competitive health insurance or professional liability insurance bid.

Commission on Medical Economics

The MSMA Medical Economics Commission addressed MSMA Resolution #5 (2018) which was referred to the MSMA Council by the House of Delegates. The commission submitted a motion to the MSMA Council that was approved at the July 2018 meeting:

Motion: the MSMA work with the Missouri Pharmacy Association (MPA) to identify measures to promote speedy and safe communication between physicians and pharmacies in the State of Missouri, including, but not limited to, seeking to have a physician access number placed very early in the automated queues of as many pharmacies as possible.

MSMA staff has developed a workgroup with the MPA staff to identify ways to work together toward a better communication system for both groups of medical professionals.

Committee on Publications

Volume Number 116 of *Missouri Medicine* showcased national authors and featured state of the art scientific articles. This volume published four issues featuring "theme" articles and two issues featuring a variety of scientific topics and micro-series. It contained 508 pages and 52 scientific articles.

The Journal received a satisfactory number of unsolicited articles; acceptance rate is about 75%. We continue to have an outstanding publication queue of high-quality papers. Papers published this past year were reprinted in two state medical Journals. Our theme issues are fully subscribed through November/December 2021. Two first literature reports appeared this past year in our Journal.

"The Science of Near-Death Experiences" (University of Missouri Press 2017) continues to do extremely well in sales, is now available as an audiobook, and was the Fall 2019 cover featured article by Proto the magazine of Massachusetts General Hospital.

In September 2018 *Missouri Medicine* announced that after a thorough review, PubMed, the indexing service of the National Library of Medicine (NLM), would continue to index our Journal. PubMed has indexed *Missouri Medicine* since 1966. After a separate review, PubMed Central, a free full-text archive of biomedical and life sciences journal literature at the NLM/NIH also approved *Missouri Medicine* for inclusion. *Missouri Medicine* has now completed the upload of all previous (digital-only) issues dating from 2010. These new and updated services are critical to our Journal to remain one of the foremost state medical journals in the United States, and to be certain all content is available at all world data bases and literature electronic literature searches. In January 2020, modifications were made to the masthead page for greater clarity.

Our thanks to the Contributing Editors and Publications Committee for their good work: Drs. David Fleming, Art Gale, William Reynolds, Charles Van Way, III, Justin Albani, Jeffrey G. Copeland, Betty Drees and Jessica Bauerle. Added experts in 2019 to the Editorial Board are: Stephanie L. Graff, MD, FACP, Hematology/Oncology; Michael S. Clarke, MD, Military Medicine; Laine M. Young-Walker, MD, Psychiatry; Gary A. Salzman, MD, Pulmonary Medicine; Patricia I. Dickson, MD, Genetics and Genomic Medicine; and Jacqueline L. Reiss, MD, Allergy and Immunology. We wish Kan N. Huang, MD, Gary S. Gottesman, MD, and Susan Berdy, MD, the best for the future and thank them for their service on the Editorial Board. A new board position for Women Physicians Section was created and now Chaired by Joanne Loethen, MD. Elizabeth J. Plogsted James, MD, a former *Missouri Medicine* Editorial Board member for Neonatology, passed away January 2, 2019, at her home in Columbia, Missouri. The founder of MU's neonatal-perinatal medicine program, she served as medical director of the neonatal intensive care unit for 36 years until her retirement.

Missouri Medicine would like to publicly thank the following non-Editorial Board experts who have done peer-review of submitted manuscripts in 2019: Angel Baldan, PhD, Doug Bogart, MD, Stephen Braddock, MD, J. Patrick Brooks, MD, Sophia M. Chung, MD, Joel Eissenberg, PhD, Muhammad Ishaq Farhan, MD, Sean Gratton, MD, Richard Hellman, MD, Charles M. Lederer, MD, Lenard Politte, MD, and Stephen Reintjes, Jr., MD.

Missouri Medicine provides reprinted papers for several prestigious medical specialty magazines and journals, and also selectively reprints articles from the medical component societies in Missouri and from national publications appropriate for our audience.

The Publication Committee Chair and Editor, John C. Hagan, III, MD, and Managing Editor, Lizabeth Fleenor, appreciate the many contributions of the MSMA, Alliance members, and others who have contributed to *Missouri*

Medicine. The Committee appreciates the Association's continued support of the Journal. By any objective criteria *Missouri Medicine* is among the top three state medical society journals in the United States.

Sections - Young Physician Section

MSMA's YPS elected its governing council members for 2020. They are:

Chair – Marc Mendelsohn, MD, assistant professor of Emergency Medicine at Washington University School of Medicine.

Vice-chair – Kunj Patel, MD, director of oncology at Encompass/Barnes Jewish Rehabilitation Hospitals.

Secretary – Sara Hawatmeh, MD, internal medicine specialist in private practice at Sam Hawatmeh, MD PC, in St. Louis.

Treasurer – Ramona Behshad, MD, dermatologist and Mohs surgery specialist at SLU Care and assistant professor of Dermatology at Saint Louis University.

Daniel Lovinger, MD, an internal medicine specialist at University Hospital in Columbia, was selected to serve as the section's Alternate Delegate to the MSMA House of Delegates for Annual Convention.

Sarah Florio, MD, an internal medicine specialist at St. Luke's Health System in Lee's Summit, will serve as the section's Delegate for 2020, having been voted to the position at the 2019 MSMA Annual Convention.

Sections - Resident & Fellow Section

The Resident and Fellow Section (RFS) primary objectives are increasing MSMA awareness among non-member colleagues, increasing RFS membership, and implementing strategies and events for ongoing membership recruitment. The RFS continues to network and collaborate with the Medical Student Section (MSS) and Young Physician's Section (YPS), both at local institutions and at national meetings.

RFS members continue to participate in the Resident Ambassador Program, Physician of the Day opportunities in Jefferson City, and the MSMA White Coat Rally. New membership enrollment and advertisement for these opportunities has targeted new fellows and residents (interns), many of whom have recently moved to Missouri.

The RFS governing council meets quarterly with representation at the AMA Annual and Interim meetings, as well as the MSMA annual meeting.

Please contact Frances Mei Hardin, MD, at hardinf@health.missouri.edu with any thoughts, questions, or concerns regarding the MSMA RFS.

Sections - Medical Student Section

The Medical Student Section had a productive year statewide. Individual medical schools hosted a wide variety of events throughout the year including events that focused on advocating for our patients. Medical school chapters hosted naloxone workshops where students learned more about the opioid epidemic and were trained to teach their patients about the importance of recognizing the signs of opioid overdose and how to obtain and administer naloxone. Other medical schools hosted our MSMA lobbyists to learn more about important issues affecting our patients in Missouri.

Students participated in resolution writing workshops to learn how to write resolutions, effectively support them, and enact change through policy. Additionally, many students represented our Missouri medical schools at the AMA Annual and Interim meetings, where they authored and passed resolutions at both the MSS and AMA HOD on trauma-informed care, incorporating gun violence education into medical school curricula, and addressing the healthcare needs of children with incarcerated parents.

The Medical Student Section Board implemented a new quarterly newsletter for all medical student members with updates from each medical school about events they have hosted or projects they have been working on, information about upcoming MSMA and AMA programs, recaps about important policies passed at MSMA and AMA meetings, and information about bills affecting healthcare in the Missouri legislature. **MM**

Missouri State Medical Association

Statement of Financial Position
December 31, 2019

ASSETS

	2019	2018
CURRENT ASSETS:		
Cash and Cash Equivalents	$ 877,639	$ 810,040
Short-Term Investments	5,941,573	9,588,792
Interest Receivable	74,157	47,913
Accounts Receivable	4,250	-
Prepaid Expenses	13,870	11,062
Total Current Assets	6,911,489	10,457,807
FIXED ASSETS:		
Land	83,000	83,000
Building and Improvements	605,078	605,078
Furniture and Equipment	291,052	274,184
Less: Accumulated Depreciation	(852,868)	(850,101)
Total Net Fixed Assets	126,262	112,161
OTHER ASSETS:		
Note Receivable - MSMA Ins. Agency	199,610	209,610
Investment in Subsidiary - MSMA Ins. Agency	2,800	(22,295)
Investment in Association Health Plan	5,000	-
Long-Term Investments	8,820,220	2,639,020
Total Other Assets	9,027,630	2,826,335
TOTAL ASSETS	$ 16,065,381	$ 13,396,303

LIABILITIES AND NET ASSETS

	2019	2018
CURRENT LIABILITIES:		
Accounts Payable and Accrued Expenses	$ 18,505	$ 17,735
Accrued Vacation	56,564	59,831
Funds Held for Others	59,533	18,977
Contract Liabilities - Subscriptions and Conference Income Received in Advance	36,934	34,442
Contract Liabilities - Dues Received in Advance	612,578	606,310
Total Current Liabilities	784,114	737,295
NON-CURRENT LIABILITIES:		
Deferred Compensation Agreement	506,490	484,863
Pension Benefit Liability	3,081,923	3,292,770
Total Non-Current Liabilities	3,588,413	3,777,633
Total Liabilities	4,372,527	4,514,928
NET ASSETS:		
Without Donor Restrictions	11,692,854	8,881,375
Total Net Assets	11,692,854	8,881,375
TOTAL LIABILITIES AND NET ASSETS	$ 16,065,381	$ 13,396,303

Missouri State Medical Foundation

Statement of Financial Position
December 31, 2019

ASSETS

	2019	2018
CURRENT ASSETS:		
Cash	$ 432,080	$ 596,483
Investments	4,583,340	3,480,006
Notes Receivable - Current	256,954	273,230
Accrued Interest	54,153	69,223
Total Current Assets	5,326,527	4,418,942
EQUIPMENT:		
Office Equipment	1,091	1,091
Software	10,692	10,692
Less: Accumulated Depreciation	(11,783)	(11,710)
Total Net Fixed Assets	-	73
NON-CURRENT ASSETS:		
Investments	1,174,119	1,073,553
Notes Receivable - Long Term	853,818	1,093,917
Allowance for Doubtful Accounts	(218,880)	(218,880)
Notes Receivable - Long Term (Net)	634,938	875,037
Total Non-Current Assets	1,809,057	1,948,590
TOTAL ASSETS	7,135,584	6,367,605

LIABILITIES AND NET ASSETS

LIABILITIES:		
Excise Tax Payable	231	-
Funds Held for Others	155,693	208,891
TOTAL LIABILITIES	155,924	208,891
NET ASSETS:		
Without Donor Restriction	6,979,660	6,158,714
TOTAL LIABILITIES AND NET ASSETS	$ 7,135,584	$ 6,367,605

Missouri Physicians Health Program

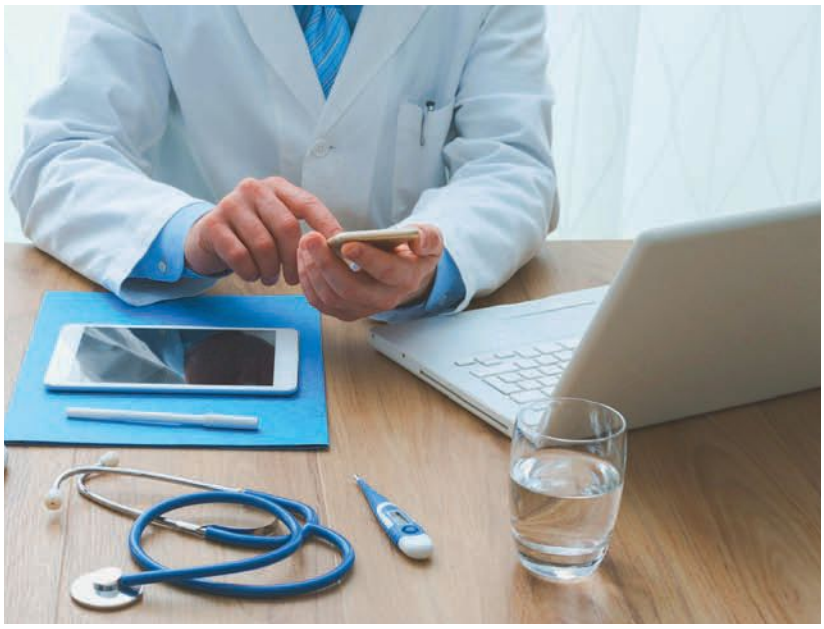
Statement of Financial Position
December 31, 2019

ASSETS

	2019	2018
CURRENT ASSETS:		
Cash and Cash Equivalents		
Cash - Checking	$ 289,004	$ 62,624
Cash - McIntosh Fund	92,668	77,045
Mutual Funds - McIntosh Fund	33,583	12,639
Certficates of Deposit	-	240,000
Accounts Receivable	144,775	154,709
Allowance for Doubtful Accounts	(34,040)	(34,071)
Accrued Interest	-	36
Total Current Assets	525,990	512,982
NON-CURRENT ASSETS:		
Investments - McIntosh Fund	6,729	12,006
Property and Equipment		
Office Furniture and Equipment	43,210	43,370
Less: Accumulated Depreciation	(38,996)	(37,267)
Net Property and Equipment	4,214	6,103
Total Non-Current Assets	10,943	18,109
TOTAL ASSETS	$ 536,933	$ 531,091

LIABILITIES AND NET ASSETS

CURRENT LIABILITIES:		
Accounts Payable	$ 2,891	$ 5,472
Accrued Payroll Tax	319	166
Accured Vacation	31,393	31,324
Total Current Liabilities	34,603	36,962
NET ASSETS:		
Without donor restrictions	502,330	494,129
Total Liabilities and Net Assets	$ 536,933	$ 531,091





Physician Advocacy

24 / 7 / 365

MSMA is your state government specialist with two full-time employees addressing physician issues all day, every day. Communication with state government is our specialty.

INVITE US TO HOST A VIRTUAL MEETING WITH YOUR PHYSICIAN COMMUNITY: PRACTICE, PEERS, OR MEDICAL SOCIETY.

Email: Jhowell@msma.org

MSMA
Missouri State Medical Association



Children's
HOSPITAL & MEDICAL CENTER
OMAHA

When one number connects you to the region's best pediatric specialists, **Anything can be.**

1.855.850.KIDS (5437) is your 24-hour link to pediatric specialists for physician-to-physician consults, referrals, admissions and transport.

Education • Research • Advocacy • Care



Coverage for Affluent Homes

Experience the peace of mind that comes from working
with an insurance professional who understands your unique needs.

MSMA Insurance cares for physicians and
covers their personal and professional needs.

Contact Ronnie Staggs | 866-676-2467 | www.msma.biz | rstaggs@msma.biz

MSMA
Missouri State Medical Association
Insurance

