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All material for publication, including advertisements, must reach the Society office no later than the 5th (business) day of the month preceding the date of issue, e.g. December 5 for the January/February issue. Thank you.

The Human Microbiome

By: Vincente Redondo, MD

THIS IS A RELATIVELY NEW CONCEPT THAT GENERALLY HAS NOT BEEN RECOGNIZED TO EXIST UNTIL THE LATE 1990S.

We define the microbiome as the genetic material of all microbes - bacteria, fungi, protozoa, viruses - that live inside or on the human body.

The number of genes in all the microbes that live in our microbiome is 200 times the number of genes in the human genome. There are 3.3 million non-redundant genes in our intestinal flora.

It has been recognized for a long time that the intestinal microbes have certain physiological capacities such as helping us digest food, vitamin production particularly vitamin K, protecting us from pathogenic bacteria as it is the case in relation to C. difficile infection and other enteric infections.

Recently, it has been discovered that a number of diseases are associated with dysfunction of the microbiome. For example the development of type 1 diabetes mellitus is associated with less diverse intestinal flora. Inflammatory bowel disease is characterized by inappropriate inflammation and that usually related to environmental and genetic risk factors. A study in pediatric patients that were treatment naïve showed that the microbiome of Crohn's disease patients had increased abundance of certain types of bacteria such as Enterobacteriaceae. Using a microbiome-disease association, a microbial dysbiosis index has been formulated that showed strong positive correlation with clinical disease activity and negative correlation with species richness. In addition, comparisons of microbiome of Crohn's disease patients with and without antibiotic exposure revealed that antibiotic use accentuates the microbial dysbiosis associated with Crohn's disease.

Regarding cardiovascular disease, it has been postulated that changes in the microbiome can produce pro atherosclerotic metabolites that could certainly contribute to cardiovascular disease.

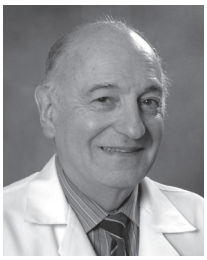
Nonpathogenic clostridia are capable of inducing colonic treg (anti-inflammatory regulatory T cells). This finding has great potential for the understanding and management of multiple inflammatory disorders.

There has also been suggestion of microbiome-gut-brain axis. Specifically there was a report that probiotic rich fermented milk product resulted in alterations in brain activity in response to visual emotional stimuli as measured by functional magnetic resonance images, as compared to intake of the control product.

Lastly there is great interest in the role of butyrate in the development of colon cancer. It turns out that microbes liberate short chain fatty acids form indigestible dietary fibers, and one of those fatty acids is butyrate. Its role nevertheless is not straightforward and it has to be combined with certain genetic abnormalities such as tumor suppression gene mutation (APC) and mismatch repair gene (MSH2) deficiency.

Clearly this research is in its infancy and we do not know much about the implications of changes in the microbiome and its interaction with our bodies, but certainly one can see a great potential in the future for understanding and treatment of a wide range of pathologies, particularly those related with derangements of immune mechanism and inflammatory disorders.

MSMS BOARD OF DIRECTORS TACKLES ADMINISTRATIVE BURDENS, SUBSTANCE USE, AND PRICE SETTING AT MEETING



By: Adrian J. Christie, MD; Paul Bozyk, MD; Donald R. Peven, MD;

During the mid-summer meeting of the Michigan State Medical Society (MSMS) Board of Directors, the Board discussed the latest information in regards to Health Can't Wait, a coalition of patients, physicians, and health care providers dedicated to putting Michigan patients first and ending delays in patients' access to health care. Below are some additional highlights from the July 12, 2019 meeting:

Michigan Department of Licensing and Regulatory Affairs Presentation. Haley Winans, Senior Analyst, and Amber Daniels, Department Analyst, provided a timely summary on the Michigan Automated Prescription System. They reviewed statistics on prescription numbers as well as the patient and provider reports. MSMS Board members expressed concerns on how MAPS analytics is being used to initiate investigations. As the speakers were not able to address all of the questions associated with these valid concerns, MSMS has requested a meeting with appropriate leadership at the Michigan Department of Licensing and Regulatory Affairs (LARA), including the Director of LARA on this and other licensing matters.

CMS Region V Meeting. In May, the Centers for Medicare and Medicaid Services (CMS) hosted the Region V annual in-person meeting in Chicago. The meeting provided MSMS the opportunity to network and learn more about upcoming CMS programs and policies. MSMS continues to stress the need for more alignment and simplification among federal, state, and commercial payer quality initiatives, as well as the importance of physician input during the design, decision-making, and roll-out of new initiatives.

Blue Cross Blue Shield of Michigan Update. MSMS attended the BCBSM Professional Provider Relations Advisory Committee (PPRAC) quarterly meeting earlier this month. This is a Board level committee which included presentations on utilization management, provider delivered care management, pharmacy strategy, and their new risk-based contract product. Of note, Marc D. Keshishian, MD, BCBSM Vice President and BCN Senior Vice President and Chief Medical Officer, presented on utilization management programs in BCBSM and BCN. When prompted, Doctor Keshishian stated that BCBSM/BCN intends to implement gold carding for all prior authorizations. This represents a change in BCBSM policy. MSMS will continue to follow-up on criteria and implementation dates.

Annual Scientific Meeting. The 154th Annual Scientific Meeting (ASM) is schedule for Wednesday, October 23 through Saturday, October 26, 2019, at the Sheraton Detroit Novi in Novi. Watch http://MSMS.org/ASM for more information.

Marijuana Policy Action Agenda. The MSMS Board of Directors adopted the following action agenda to help prioritize MSMS regulatory and legislative advocacy regarding adult use marijuana:

- MSMS advocates that any labeling of marijuana products include warnings that make clear the content, potency, as well as the known safety and health risks, based on the best available scientific evidence.
- MSMS advocates for prohibiting the use of marijuana in public places.
- MSMS advocates for funding of more research to determine the consequences of long-term marijuana use, especially among youth, adolescents, pregnant women, and women who are breastfeeding. Research should:

- Be conducted pursuant to valid research protocols, including properly controlled clinical studies of adequate size and duration;
- Explore how legalization impacts existing and emerging mental health and substance use issues facing communities; and
- Be vetted by independent evaluators with backgrounds in the health
- MSMS supports sanctions on sellers for misrepresenting health benefits of marijuana.
- MSMS supports dedicating a substantial portion of tax revenue from marijuana sales toward public health purposes, including substance use prevention and treatment program, marijuana-use

educational campaigns, and public service announcements, rigorous research on the health effects of marijuana and public health surveillance efforts.

- MSMS advocates for funding for ongoing surveillance to determine the impact of marijuana legalization and commercialization on public health and safety (e.g., emergency department visits and hospitalizations, impaired driving rates, traffic fatalities and injuries, unintentional exposures, crimes related to use/intoxication, impact on high-risk populations, etc.
- MSMS encourages the adoption of legal and regulatory tools to monitor and stem illegal activity related to marijuana.

House Bills 4459 and 4460 -- Legislation to address surprise, out-of-network bills. The Board voted to oppose HBs 4459-4460. The discussion focused on the problems with price setting as HB 4459 and the merits of the New York model were raised. Staff shared that they are working in close collaboration with the Michigan Health and Hospital Association and other physician specialty groups to form a united front to offer alternative language. Part of the strategy will include requesting that the state wait until Congress acts, which could be as soon as December.

House Bills 4607-4608, Lyme Disease Legislation. Introduced by Representative Karen Whitsett (D-9), the bills would require that physicians and providers order certain tests and provide written materials specific to Lyme disease; and that the Department of Health and Human Services develop a standardized procedure for the "diagnosis and treatment of Lyme disease." The Committee discussed amending the recommendation to include opposition to House Bill 4603, which would codify an already existing requirement to report Lyme disease to the state within 24 hours, imposing a civil fine when a physician fails to do so. The Board voted to oppose HBs 4607-4608.

Electronic Prescribing of All Prescriptions Update. MSMS updated the Board on the legislative developments related to the mandate to electronically prescribe all prescriptions, including controlled substances. It was shared that the Senate Health Policy committee recently approved substitutes to the bill with a 9-0 vote and that the House Health Policy committee had yet to take a vote. MSMS continues to work with leadership in the Senate, as well as House staff to adopt changes to the bills that align the state with the federal requirements and tie implementation to when the federal government actually imposes its requirement under Medicare Part D.

REFORMING PRIOR AUTHORIZATION: MSMS'S EFFORTS FEATURED AT AMA ROUNDTABLE

On August 1, MSMS Director of State and Federal Government Relations, Christin Nohner, participated on a panel during the American Medical Association's State Advocacy Roundtable. The Roundtable, which AMA hosts every summer, brings together more than 100 government relations experts from around the country and not only includes state medical societies but various national specialty societies and other partners in advocacy.

Ms. Nohner shared MSMS's efforts related to the Health Can't Wait campaign, touching on the catalyst for the effort; a deep dive into the process of building the campaign and what MSMS has learned thus far on the road to reforming prior authorization and other utilization management tools employed by payers. Ms. Nohner discussed the positive benefits reaped from partnering with other physician, provider, and patient groups, and working collaboratively toward a common goal. She also shared the rigorous and time-intensive effort that went into building the coalition and drafting the legislation to ensure that all players are on the same page. Acknowledging that many challenges lay ahead and there will be more lessons to learn, Ms. Nohner emphasized the importance of focusing first and foremost on the meticulous laying of groundwork in order to set the effort up for success.

Health Can't Wait Campaign. Making the prior authorization reforms a reality requires a multi-pronged approach that entails leveraging a broad coalition, legislative advocacy, and a strategic and comprehensive approach to earned media.

If you'd like to learn more about the Health Can't Wait campaign and/or share your stories, please contact Ms. Nohner cnohner@msms.org or Kevin McFatridge kmcfatridge@msms.org, MSMS Senior Director of Marketing and Public Relations. In order to make these reforms a reality, your support is required.

MSMS JOINS AMA AND OTHER LEADING MEDICAL ORGANIZATIONS IN FIGHT FOR TRANSGENDER AMERICANS

The Michigan State Medical Society (MSMS) in collaboration with the American Medical Association (AMA) and 14 additional medical, mental health, nursing and other health care organizations filed a joint friend-of-the-court brief urging the Supreme Court of the United States to rule in favor of protecting transgender individuals from

employment discrimination to ensure their physical and mental health.

The brief was submitted in the cases of Bostock v. Clayton County, Georgia, Altitude Express Inc. v. Zarda and R.G. & G.R. Harris Funeral Homes Inc. v. Equal Employment Opportunity Commission, which consider whether Title VII of the Civil Rights Act of 1964 protections against discrimination on the basis of "sex" include sexual orientation and gender identity.

The AMA-led brief cites more than four dozen studies and papers demonstrating the consensus among health care professionals regarding: what it means to be transgender; the protocols for the treatment of gender dysphoria, which include living in accordance with one's gender identity in all aspects of life; and the predictable harms discrimination poses to the health and well-being of transgender individuals.

The brief, intended to inform the high court, maintains that

"being transgender implies no impairment in a person's judgment, stability, or general social or vocational capabilities."

Despite this medical consensus, there is evidence of widespread employment discrimination against transgender people that exacerbates gender dysphoria, frustrates medical treatment, and impedes access to health care when such discrimination results in a person losing income or health insurance.

Many transgender individuals are diagnosed with gender dysphoria, a condition that is characterized by clinically-significant distress and anxiety resulting from the incongruence between an individual's gender identity and birth-assigned sex. Medical treatments are effective in alleviating gender dysphoria. But according to the brief, "employment discrimination against transgender people frustrates the treatment of gender dysphoria by preventing transgender individuals from living openly in accordance with their true gender identity and impeding access to needed medical care."

Employment discrimination also reinforces the stigma faced by transgender people. The stressful environment created by stigmatization causes negative health outcomes and produces significant health disparities between transgender and cisgender individuals. In contrast, as noted in the brief, "living in congruence with one's gender identity promotes well-being. Unsurprisingly, policies prohibiting employment discrimination lead to positive health outcomes in the transgender community."

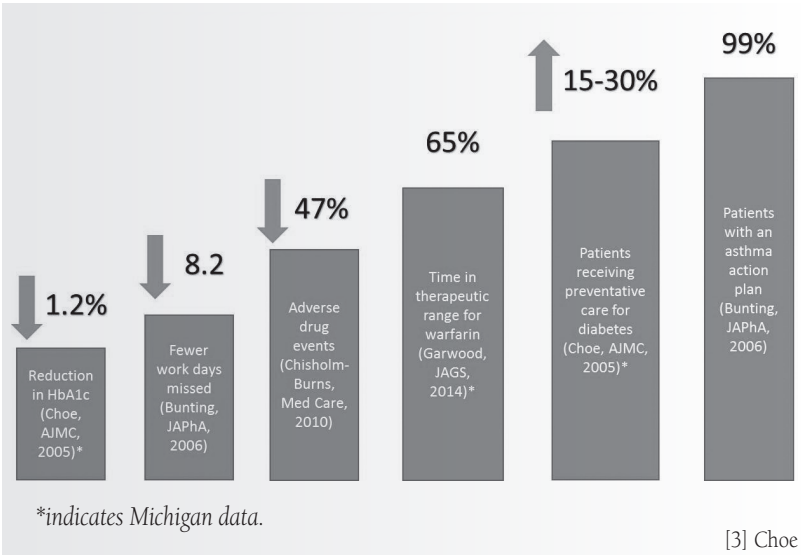
The Litigation Center of the AMA and State Medical Societies, a legal action coalition consisting of the AMA and medical societies from each state plus the District of Columbia, joined the brief. Other organizations that joined the AMA in the brief include the: AGLP: Association of LGBTQ Psychiatrists; American College of Physicians; American Nurses Association; American Public Health Association; Association of Medical School Pediatric Department Chairs; Endocrine Society; GLMA: Health Professionals Advancing LGBTQ Equality; Lesbian, Bisexual, Gay, and Transgender Physician Assistant Caucus; Medical Association of Georgia; Mental Health America; Michigan State Medical Society; National Council for Behavioral Health; Pediatric Endocrine Society; Society for Physician Assistants in Pediatrics; and World Professional Association for Transgender Health.

ROLE OF COLLABORATIVE PRACTICE AGREEMENTS IN TEAM-BASED CARE

The burden of chronic diseases ranks as one of the leading causes of morbidity and mortality in the U.S. and yet it is steadily increasing. Approximately 71 percent of the U.S. total healthcare spending is associated with care for individuals with more than one chronic condition. It is reported that, among Medicare fee-for-service beneficiaries, those with multiple chronic conditions account for 93 percent of total Medicare spending.[1] Thus, to meet the demand, improve public health and decrease cost, health care is shifting towards a multidisciplinary, team-based care approach.

Pharmacists are uniquely positioned to play a role in the healthcare delivery system through the utilization of collaborative practice agreements (CPAs). CPAs are formal practice agreements between pharmacists and physicians that expand clinical responsibilities of pharmacists.[2] Michigan law allows pharmacists to enter into CPAs under physician delegation which allows Michigan pharmacists to support patient care and engage with providers at the highest level of licensure.[3] CPAs identify the patient population and diseases that are covered under the CPA. This specification may include single or multiple disease states such as hypertension, asthma, COPD, diabetes, etc., or age restrictions, just to name a few. Once the patient population has been identified, the CPA will then outline patient care activities that pharmacists can provide under specified situations and conditions. Practitioners can determine the interventions that pharmacists are authorized to make, which may include initiating, modifying, discontinuing or monitoring drug therapy. Other examples of delegated responsibilities include obtaining labs such as ordering A1C levels for a diabetic patient, adjusting antihypertensive therapy as necessary, performing follow-up calls post-patient discharge, vaccine administration and dispensing naloxone.[2] Note that Michigan does not have a statute that restricts or provides guidance regarding CPAs between physicians and pharmacists. The restriction is based on the agreement and the scope that the delegating physician authorizes. Given that pharmacists are ideally suited to improve medication use, adherence and outcomes, CPAs benefit not only the patient, but health care overall.

Patients receive a multitude of benefits from CPA practices. Research consistently shows that patients who engage with pharmacist-provided clinical services are more likely to meet their health outcome goals and to be on guideline-directed preventative therapies. This downstream allows patients to live healthier lives, which ultimately decreases hospital readmission rates and prevents issues that result from uncontrolled chronic conditions. These results are especially significant for the most vulnerable patients with an increased disease burden who are offered pharmacist services. Most commonly, these services have been studied as part of the management of diabetes and asthma. Importantly, patients report increased satisfaction with their overall health care when a pharmacist is part of the clinical team.[4-6] Figure 1 displays clinical outcome data following pharmacist interventions and CPA.



**indicates Michigan data.*

CPAs also display cost-saving within the healthcare system. Touchette and colleagues reviewed studies on the economic impact of clinical pharmacy services and found that the benefit to cost ratio varied from 1.05:1 up to 25.95:1.[7] A survey of hospitals in Illinois, Indiana and Michigan completed by Thomas and colleagues showed that hospital administrators believe that pharmacist drug therapy management contributes to the strategic vision of the hospital.[8] These outcomes provide benefits for both the pharmacist and the health-system by allowing for a broader impact of healthcare services.

With health care shifting to an outcomes-based model, patient benefits also end up benefiting the overall health-system. Bunting and colleagues demonstrated a direct cost decrease of $725 per patient per year with their asthma medication management services.[4] This offers a significant opportunity for health-systems to retain valuable medical dollars by reducing the number of re-hospitalizations. In their diabetes management clinic, Anaya and colleagues similarly demonstrated a significant mean cost savings of hospitalizations and emergency department admissions of nearly $1,800.[9] These cost savings add up and are significant for health-systems to maximize their capitated reimbursement.

Developing CPAs requires trust and open communication between the two parties. As trust between the providers is being established, it is important to identify the roles of both the pharmacist and practitioner during this time to better understand each other's skills and competence. This is made possible through frequent interaction, which is highly encouraged to further strengthen the pharmacist-practitioner relationship. Once a relationship has been established, the CPA can be created based on the agreed upon guidelines between the two parties.

CPAs illustrate practice relationships between pharmacists and prescribers and integrate pharmacists into the team-based care model. It allows pharmacists to screen for qualifying patients and provide treatment based on standards identified within the protocol or procedure.

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[9] Anaya JP, et al. Evaluation of Pharmacist-managed Diabetes Mellitus under a Collaborative Drug Therapy Agreement. Am J Health-Syst Pharm 2008; 65:1841-1845.

Enrollment Requirement for Prescribers

PROGRAMS AFFECTED: MEDICAID, HEALTHY MICHIGAN PLAN, CHILDREN'S SPECIAL HEALTH CARE SERVICES (CSHCS), MATERNITY OUTPATIENT MEDICAL SERVICES (MOMS).

THIS MESSAGE COMES TO YOU FROM THE MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES MEDICAL SERVICES ADMINISTRATION:

The purpose of this message is to enforce federal Medicaid enrollment requirements that apply to providers who prescribe drugs to Medicaid beneficiaries. These requirements are outlined in Section 6401 of the Patient Protection and Affordable Care Act and Section 5005(b)(2) of the 21st Century Cures Act. The purpose of these requirements is to protect Medicaid beneficiaries by strengthening program integrity and care quality.

Effective October 1, 2019, providers who prescribe drugs to Medicaid beneficiaries must be actively enrolled in the Community Health Automated Medicaid Processing System (CHAMPS) - the state's online Medicaid enrollment system. The Michigan Department of Health and Human Services (MDHHS) will prohibit payment for prescription drug claims written by a prescriber who is not enrolled in CHAMPS.

For Prescribers

Claims for drugs prescribed by a provider who is not enrolled in CHAMPS will be denied. This applies to all providers who prescribe drugs, including medical residents. In order to avoid interruptions in beneficiary drug therapy, prescribers are encouraged to enroll in CHAMPS as soon as possible. For information about the provider enrollment process and how to get started, visit www.michigan.gov/MedicaidProviders >> Provider Enrollment. Providers who have questions about the enrollment process or require assistance may contact MDHHS Provider Support at 800-292-2550.

For Pharmacies

Since July 1, 2018, Medicaid Fee-for-Service (FFS) and Medicaid Health Plans have posted the following informational edit on pharmacy claims for drugs written by a prescriber who is not enrolled in CHAMPS:

NCPDP Code 889: PRESCRIBER NOT ENROLLED IN STATE MEDICAID PROGRAM

Starting October 1, 2019, subsequent claims with this edit will be denied.

There may be certain emergency circumstances where a beneficiary must receive their prescription medication. In those instances, the pharmacy may override the edit using either of the following Submission Clarification Codes in NCPDP field 420-DK when applicable:

- 13 - Payer-Recognized Emergency/ Disaster Assistance Request
- 55 - Prescriber Enrollment in State Medicaid Program has been validated

When the above codes are not applicable, a pharmacy or prescriber may initiate an override request by contacting the healthcare payer's Pharmacy Help Desk. For overrides on Medicaid FFS claims, call 888-411-6343. For Medicaid Health Plan contact information, visit www.michigan.gov/MCOpharmacy.

Manual Maintenance

Retain this bulletin until the information is incorporated into the Michigan Medicaid Provider Manual.

Questions

Any questions regarding this bulletin should be directed to Provider Inquiry, Department of Health and Human Services, P.O. Box 30731, Lansing, Michigan 48909-8231, or e-mailed to ProviderSupport@michigan.gov. When you submit an e-mail, be sure to include your name, affiliation, NPI number, and phone number so you may be contacted if necessary. Providers may phone toll-free 1-800-292-2550.

Henry Ford Macomb Hospital

CHRISTOPHER MILBACK, MD NAMED CHIEF MEDICAL OFFICER OF HENRY FORD MACOMB HOSPITAL

New Leader Also Serves as CMO of Henry Ford Health System's North Market, Northeast Region

Henry Ford Health System has announced a new chief medical officer for Henry Ford Macomb Hospital in Clinton Township. Christopher Milback, MD, MBA, FAAFP, joined the system on June 10. He will also serve as chief medical officer for the Northeast Region of the system's North Market. He replaces Dr. Joanna Pease, who retired in May.

In this role, Dr. Milback will provide executive leadership for physician services for Henry Ford Macomb Hospital and the Northeast Region. He will act as a champion for enhancing quality of care, ensuring comprehensive health care delivery and patient safety and providing an exceptional care experience in the hospital and region.

Dr. Milback most recently served as medical director of the Colleague Health Plan & Population Health for Trinity Health in Livonia, Mich. where he provided clinical leadership and oversight of care management, population health, quality, patient safety and utilization initiatives of the Colleague Benefit Plan, covering approximately 155,000 lives across the country.

Before his time at Trinity, Dr. Milback worked in a variety of leadership roles at Health Plus of Michigan in Flint and Beaumont Health.

Board certified in family medicine, Dr. Milback earned his medical degree from Upstate Medical University in Syracuse, New York and an MBA in health care management from Oakland University. He is currently president of the Oakland County Medical Society, a member of the Board of Directors of the Oakland County Medical Society and a member of the American Academy of Family Physicians. He also has experience as an associate clinical professor at both Oakland University and Wayne State University.

FIRST TAVR PROCEDURE PERFORMED AT HENRY FORD MACOMB HOSPITAL

Alternative to Open-heart Valve Replacement Now Offered

Doctors performed the first two catheter-based replacements of an aortic heart valve recently at Henry Ford Macomb Hospital, part of a continued expansion of the nationally recognized transcatheter aortic valve replacement (TAVR) program of Henry Ford Health System.

"This minimally invasive, revolutionary procedure to replace a defective heart valve without open-heart surgery brings new hope for people with advanced heart disease," said interventional cardiologist Samer Kazziha, MD, Chief of Cardiovascular Services for Henry Ford Macomb Hospital.

TAVR was an excellent option for both Christine Gilbert, an 87-year-old woman from Mt. Clemens, and Carole Wesner, an 82-year-old Shelby Township resident. Both women were diagnosed with aortic stenosis and underwent the TAVR procedure on August 7. Both patients were released from the hospital on August 8 and are recovering comfortably at home.

"TAVR is easier on the patient, allows for quicker recovery and, ultimately, can improve the patient's quality of life," said Raed Alnajjar, MD, Henry Ford Macomb Hospital's Director of Cardiothoracic Surgery Services. "We're pleased to now offer this option close to home for our patients in Macomb County and surrounding areas."

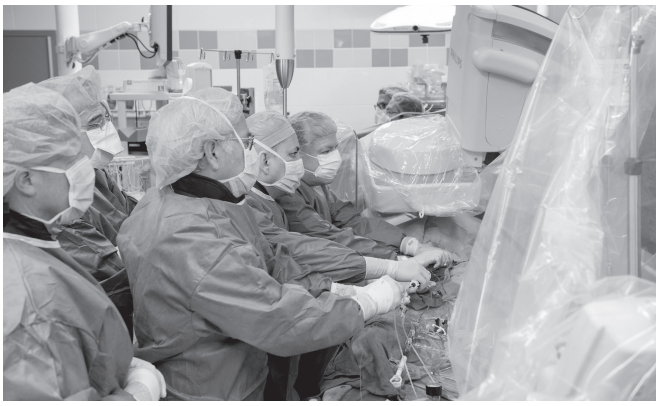
Ms. Gilbert has come a long way since she first visited an urgent care in May, for what she thought was indigestion. An EKG showed that she was having a heart attack and she had a stent put in that day, followed by balloon valvuloplasty in June.

"My shortness of breath is gone, I feel less tired and I'm able to climb stairs without feeling winded," said Ms. Gilbert, a retired MISD bus driver, just one day after the TAVR procedure. She is

SHARE YOUR NEWSWORTHY ITEMS

Have you or a MCMS colleague been elected to a position (specialty society, hospital, community based program, etc.) or honored for your volunteer service within the community or abroad? Let us know.

We would like to recognize MCMS members in the "Member News" section of the Medicus. Contact Heidi Leach at mcms@msms.org or macombcms@gmail.com with newsworthy information. *Publication is subject to availability of space and the discretion of the Editor.*



anxious to get back to quilting, treasure hunting at garage sales, tending her flower garden and walking her dog.

Ms. Wesner said she also noticed immediate improvement after her procedure at Henry Ford Macomb Hospital, and she hopes to resume yoga, walking and meeting up with her friends for breakfast soon.

"I had an easier time walking this morning and I don't get the 'fluttery' feeling in my chest that I did before the procedure," she said about 24 hours after her TAVR. "It has been really awesome. Every single person is so caring, professional and gifted."

Home to pioneering cardiologist William O'Neill, MD, who performed the first TAVR in the United States in 2005, the Henry Ford Center for Structural Heart Disease has performed more than 1500 TAVR procedures since 2012. The expansion into Macomb County follows the opening of the Center's TAVR program at Henry Ford Allegiance Hospital in Jackson, Michigan, in June. Specially trained, multi-disciplinary teams that include expert anesthesiologists, cardiac imaging specialists and support staff have been training for months to prepare.

Dr. O'Neill, Henry Ford Health System's Director of Structural Heart Disease, led the 2-hour procedures at Macomb with Dr. Alnajjar, as well as interventional cardiologists Dr. Kazziha and Subhi Sbahi, MD for Ms. Gilbert's TAVR and interventional cardiologists Natesh Lingam, MD and Luay Sayed, MD for Ms. Wesner's TAVR. Merajuddin Khan, MD, led the anesthesiology team for both procedures.

TAVR may be offered as an option for patients whose advanced age, frailty or degree of heart damage makes open-heart surgery particularly challenging. Using thin catheters, the cardiologists access the heart through the femoral artery in the groin region, threading the collapsed valve up through the tubing. Once properly positioned, a balloon expands the valve, pushing back the native valve and lodging the new device in place. Patients typically notice improved symptoms shortly after TAVR and can be released as soon as the next day.

"We're pleased to offer TAVR at Henry Ford Macomb Hospital after seeing so many patients feel so much better after their TAVRs at Henry Ford Hospital in Detroit," said Dr. O'Neill. "We've also treated many people with TAVR who have been turned away elsewhere - with fantastic results."

TAVR is one more option added to the advanced, specialized cardiology care offered at Henry Ford Macomb Hospital. The Henry Ford Center for Structural Heart Disease program at Macomb also offers balloon valvuloplasty, where a balloon is used to loosen buildup on stiff heart valves. Henry Ford Macomb cardiologists also perform the patent foramen ovale (PFO) closure procedure to close a small flap that failed to seal after birth between the two upper chambers of the heart.

To make an appointment or learn more about TAVR or other cardiology procedures available at Henry Ford Macomb Hospital, visit HenryFord.com/StructuralHeart.

(from left): Natesh Lingam, MD; Raed Alnajjar, MD; Samer Kazziha, MD; William O'Neill, MD and Subhi Sbahi, MD.

NEWLY-DONATED TECHNOLOGY SAVES WOMAN WHOSE HEART STOPPED AT HENRY FORD MACOMB HOSPITAL

Survivor Meets Family Who Gave ECMO on Behalf of Dad/Grandfather

A newly-donated portable heart-lung support system is credited as the crucial component in saving the life of a 49-year old patient recently at Henry Ford Macomb Hospital.

Michelle Rachuk of Waterford was visiting her parents in Chesterfield Township March 9 when a series of medical events starting with flu symptoms eventually led to her heart stopping.

Ultimately, doctors at Henry Ford Macomb used an ECMO (Extracorporeal membrane oxygenation) device to save Michelle's life. This vital piece of technology takes over the function of the heart and lungs when the heart has stopped or during open surgery. The device oxygenates the blood and pumps it back into the body -- providing time for the organs to rest and heal.

Today, Michelle met the Bedi family of Northville, who donated the ECMO machine in memory of their late father, Raj Bedi, who received exceptional care at Henry Ford Macomb Hospital.

"I'm so grateful that the Bedi family made this generous donation," Michelle said. "I hope it saves many more lives."

The small, portable system, not typically available at many hospitals, brings technology to the bedside that traditionally is only available in an operating room. The all-in-one heart-lung support system can be rapidly deployed in the fields of emergency medicine, cardiology and cardiac surgery to restore and stabilize a patient's cardiopulmonary functions, giving physicians valuable time to save the patient's life.

"It is certain that without this device, she would not have survived," said cardiothoracic surgeon Raed Alnajjar, MD, whose quick thinking led to Michelle being the first patient treated with ECMO at Henry Ford Macomb Hospital. "At the beginning, I didn't think Michelle was going to make it, but with the help of the ECMO machine, we were able to save her life."

Henry Ford Health System is a referral center for advanced therapies, including ECMO. Adept at using ECMO since 2012 as temporary mechanical support at Henry Ford Hospital, system doctors treated 73 patients in 2018 and expect to help more than 100 patients this year. After being stabilized in Macomb, Michelle was transferred to Henry Ford Hospital and cared for by nurses and other medical staff specially trained in ECMO support.

Her death-defying odyssey began with a positive flu and pneumonia test at an urgent care near her parents' home. Her blood glucose numbers were also very high, so Michelle, who is diabetic, was sent to the emergency department at Henry Ford Macomb Hospital.

After developing chest pains, it was determined that Michelle needed a cardiac catherization to stent a clogged "widow maker" artery. Once in the cardiac catheterization lab, interventional cardiologist Majid M. Al-Zagoum, MD placed a stent in her occluded artery. Although the stent successfully opened the blockage, Rachuk declined rapidly.

When the blood flow was re-established in the artery, her heart stopped beating. Dr. Al-Zagoum performed CPR for almost an hour, desperately trying to revive her as her body went into cardiogenic shock. But her heart did not respond.

Dr. Raed Alnajjar, Dr. Majid Al-Zagoum and patient Michelle Rachuk met Vik Bedi and Aditi Bagchi (wife of Ajay Bedi). A photo of Raj Bedi is displayed at left. The ECMO machine was donated in his honor.

Thinking quickly, Dr. Alnajjar mobilized his team to the cath lab with a new piece of equipment that had arrived only days earlier. Within five minutes, they had Michelle hooked up to the ECMO technology.

After her transfer to Henry Ford Hospital, she regained consciousness later that evening. Dr. Alnajjar was shocked to see her responsive so soon and called Dr. Al-Zagoum to share the good news. After slowly weaning off the ECMO machine over the course of a week, she was transferred back to Henry Ford Macomb Hospital for inpatient rehabilitation.

Not all hospitals have ECMO machines. Vikram and Ajay Bedi felt moved to carry on their father, Raj's, legacy by purchasing the ECMO machine to help patients at Henry Ford Macomb Hospital.

"Our father always taught us the importance of giving back to our community," son Vikram Bedi said. "Henry Ford Macomb Hospital means a lot to our family, because of my father's coronary artery bypass using the da Vinci robot there years earlier."

In recognition of the donation, one of the hospital's new operating rooms has been named in honor of Raj and Swaraj Bedi.

HENRY FORD MACOMB HOSPITAL STROKE CENTER EARNS QUALITY AWARDS

Henry Ford Macomb Hospital earned an American Heart Association/ American Stroke Association Get With The Guidelines™ Gold Plus recognition, which recognizes the hospital's commitment to ensuring stroke patients receive the most effective treatment according to nationally-recognized, research-based guidelines.

The hospital earned the awards by meeting specific quality achievement measures for stroke care at a set level for a designated period. These measures include evaluation of the proper use of medications and other stroke treatments aligned with the most up-to-date, evidence-based guidelines, with the goal of speeding recovery and reducing death and disability for stroke patients.

The Gold Plus Quality award is an advanced level of recognition that acknowledges the hospital's consistent compliance with Quality Measures embedded within the Patient Management Tool®.

The Target Stroke Honor Roll Elite Plus award recognizes the hospital for the speed at which eligible patients are treated with IV thrombolytic therapy, with 50 percent or more of patients receiving this treatment within 45 minutes.

While advancements in stroke care have led to better outcomes for patients in recent years, stroke remains the leading cause of disability among U.S. citizens, and the fifth leading cause of death in the country. Every 40 seconds on average, an American will have a stroke, meaning approximately 795,000 Americans have a new or recurrent stroke annually.

To learn more or request an appointment with a Henry Ford stroke specialist, please visit www.henryford.com/stroke.

Ascension Macomb-Oakland Hospital

ASCENSION ST. JOHN HOSPITAL ANNOUNCES NEW PULMONARY FELLOWSHIP PROGRAM

New Patient Tower Now Open at Ascension Macomb-Oakland Hospital, Warren

The $50 million addition to Ascension Macomb-Oakland Hospital in Warren is now completed and patients are finding the spacious and patient-friendly care units to be a comfortable healing environment. The hospital has grown "up." The expansion added three floors to the existing east patient tower, and completely renovated an additional existing floor.

The expansion enables the hospital to better serve the community with improved technology, private and more family-friendly patient rooms, and a more comfortable patient experience.

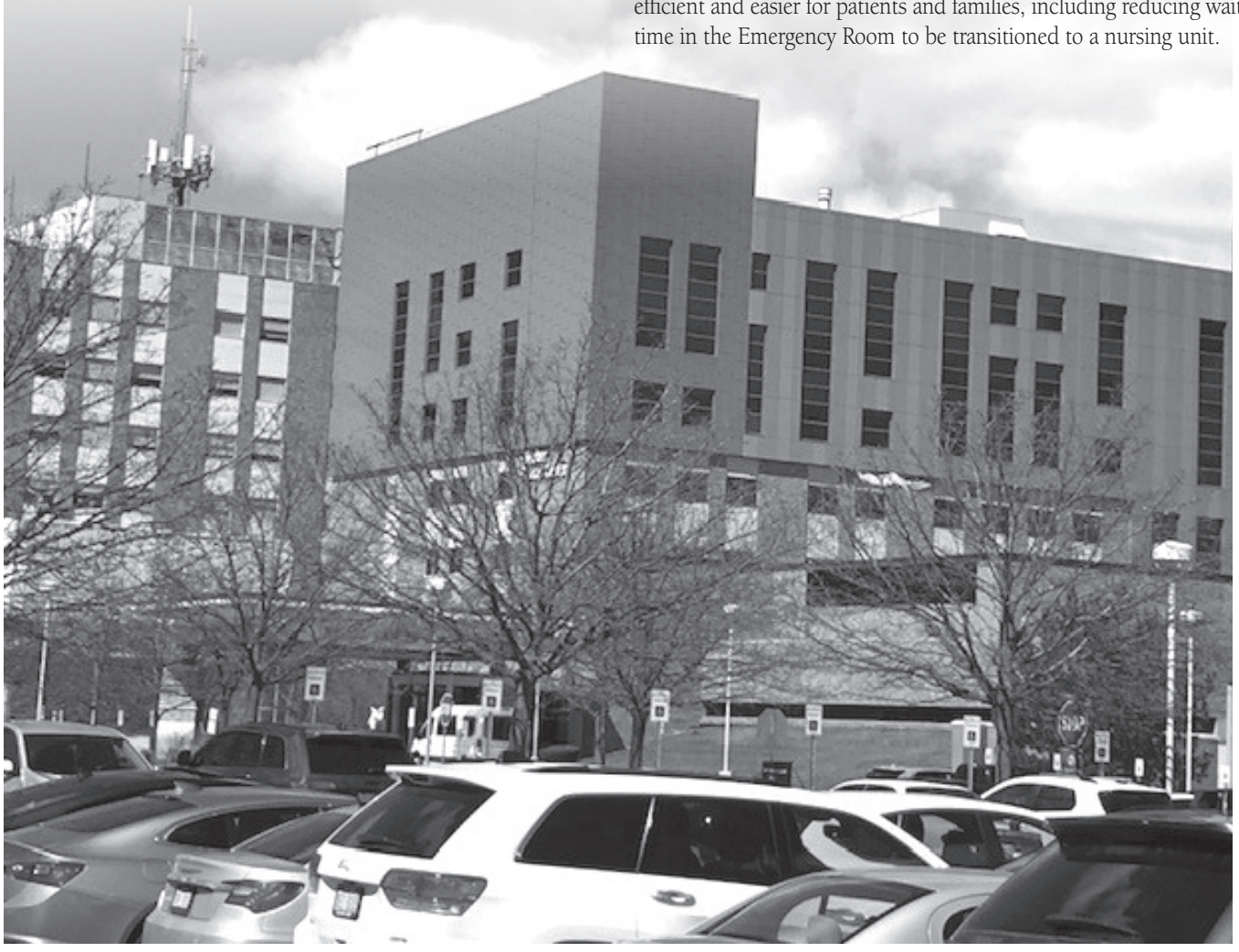
The project increases the number of private rooms to 220, more than half the patient rooms in the facility. Total number of inpatient beds at the campus is 375.

Private, spacious patient rooms provide comfortable furniture for loved ones who need to stay with the patient for extended periods of time; and ample room for several visitors without disturbing other patients.

All new state-of-the-art patient telemetry has been installed throughout the new space, as well as in all existing rooms at the hospital. Built in and convenient bedside charting gives nurses more time to be with patients in one-on-one interaction. The technology also creates an immediate interface with the patient's electronic medical record. New staff cell phone communication technology allows constant, easy to access communication among caregivers for immediate response to patient needs and changes, without unnecessary disturbance to patients.

The four newly renovated or constructed floors opened in phase during the summer, following a VIP Open House and ribbon cutting June 21 with Ascension Michigan leaders, community guests, Warren Mayor Jim Fouts and Macomb County Executive Mark Hackel.

The increase in number of patient beds, as well as the addition of private patient rooms, will make the entire patient experience more efficient and easier for patients and families, including reducing wait time in the Emergency Room to be transitioned to a nursing unit.



UPCOMING EVENTS

OCTOBER 22 - 26 MSMS Annual Scientific Meeting, at the Sheraton Detroit in Novi. For more information visit www.msms.org/eo

NOVEMBER 1 MSMS conference "A Day of Board of Medicine Renewal Requirements". Earn the new mandated Michigan Board of Medicine CME all in one day. Holiday Inn in Ann Arbor, 9 am - 2:45 pm. Credits: 5 AMA/PRA Category 1 Credits, cost $195 for MSMS members ($275 for non-members). For more information or to register visit www.msms.org/eo

NOVEMBER 2 MSMS 23rd Annual Conference on Bioethics, at the Holiday Inn in Ann Arbor, 9 am - 4 pm. For more information or to register visit www.msms.org/eo

ON-DEMAND WEBINARS MSMS has a catalog of on-demand webinars available, allowing you to watch and learn at your convenience. Check out the available series in the following categories: Practice Transformation, Clinical, Leadership, HIT, and Billing and Coding. Visit http://MSMS.org/OnDemandWebinars

Some of the Free On Demand Webinars offered:

* Health Care Providers' Role in Screening and Counseling for Interpersonal and Domestic Violence: Dilemmas and Opportunities
* In Search of Joy in Practice: Innovations in Patient Centered Care
* Legalities and Practicalities of HIT - Cyber Security: Issues and Liability Coverage
* Legalities and Practicalities of HIT - Engaging Patients on Their Own Turf: Using Websites and Social Media
* Opioid Town Hall
* Sexual Misconduct - Prevention & Reporting
* Tips and Tricks on Working Rejections
* Update on Chronic Fatigue Syndrome Part 1: Clinical Diagnostic Criteria for Chronic Fatigue Syndrome/CFS now called Myalgic Encephalomyelitis or ME/CFS
* Update on Chronic Fatigue Syndrome Part 2: Uniting Compassion, Attention and Innovation to treat ME/CFS

Watch for emails and fliers with the details of upcoming events.

Does the MCMS have your email address? If not, send it to us at macombcms@gmail.com or call 877-264-6592 so that we can keep you informed!

Change of Address? Let us know! Call 877-264-6592 or Email us macombcms@gmail.com any changes.

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Medical Records of Retired Physicians

Patients looking for their medical records from retired physicians frequently contact the MCMS. If you are retired or will be retiring shortly, please contact the MCMS at 877-264-6592 or email macombcms@gmail.com and let us know how patients can retrieve their records. If the records have been destroyed, please inform us of that also so we can note our database accordingly. Thank you!

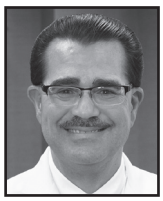
New Members

JEFFREY J. CARROLL, DO
Orthopedic Surgery - Board Certified

Medical School: MI State University College of Osteopathic Medicine, 1998. Post Graduate Education: McLaren Macomb (Mt. Clemens Regional) Hospital, completed 2003. Hospital Affiliation: Troy Beaumont, Grosse Pointe Beaumont, McLaren Macomb. Currently practicing at Movement Orthopedics, 43475 Dalcoma Dr., Ste.160, Clinton Township, MI 48038, ph. 586-436-3785, fx. 586-273-0109, website www.movementortho.com

SUSSAN J. SALAS, MD
Neurological Surgery

Medical School: Rutgers New Jersey Medical School, 2007. Post Graduate Education: Thomas Jefferson University Hospital, PA, completed in 2015; Hofstra Northwell School of Medicine, NY, completed in 2016. Hospital Affiliations: Henry Ford Macomb, Henry Ford Hospital. Currently practicing at Henry Ford Macomb Medical Pavilion, 16151 19 Mile Rd., Clinton Township, MI 48038, ph. 800-436-7936.



MARK A. ZAINEA, MD
Cardiovascular Disease - Board Certified & Interventional Cardiology - Board Certified

Medical School: Wayne State University School of Medicine, 1987. Post Graduate Education: Bon Secours Hospital, St. John Hospital and Medical Center, Providence Hospital. Hospital Affiliations: Ascension Macomb-Oakland, Ascension St. John Hospital, Ascension River District, Henry Ford Macomb Hospital, McLaren Macomb. Currently practicing at Cardiology Associates of MI, 50505 Schoenherr Road, Suite 320, Shelby Township, MI 48315, ph. 586-580-3062, fx. 586-580-3143, website www.cardofmich.com

Smile! The Doctor Is on Camera: The Pros and Cons of Recording Office Visits and Procedures

By: Rich Cahill, Vice President and Associate General Counsel for The Doctors Company

"DOCTOR, CAN I RECORD OUR CONVERSATION TODAY?"

Have you ever heard that question from a patient or a patient's family member? Or have you ever been worried a patient might record the visit without asking permission? As smartphones have become ubiquitous, giving patients a video and audio recorder that's always at hand, the question of whether or not these devices should be allowed in the clinic or hospital setting is becoming increasingly more common.

A high-profile case involved a patient who accidentally recorded his colonoscopy, capturing derogatory remarks from the anesthesiologist while he was under anesthesia. The patient sued for malpractice and was awarded $500,000.[1] While this case is extreme, it has raised the importance of addressing the issue in each practice and hospital.

Patients: To Record or Not to Record?

The issue of allowing patients to record their appointments requires balancing potential privacy and liability risks with the potential benefits of improved patient recollection of instructions and treatment adherence. Patient pamphlets and other educational materials handed out at office visits are often lost or forgotten, and patients forget or remember inaccurately a significant portion of information shared at doctor visits. Patients who have a better and more complete understanding of their condition and the treatment plan are more likely to be actively engaged and involved in their healthcare.

Despite these potential benefits, it's typically not the best course to allow patients to record the appointment. The recording devices could be disruptive and could be potentially intimidating to physicians and staff. In addition, these recordings - unlike the electronic health record - can be altered or manipulated to create an inaccurate portrayal of what actually occurred. These recordings can also easily be streamed or posted online, raising the issue of patient and staff privacy and HIPAA compliance. In addition, recording the visit may inhibit the flow of information between the doctor and patient. Patients may be less likely to be open about sensitive health issues because of the fear that the recording might be listened to by an outside party.

If a patient records a visit without the doctor's permission, that can result in a loss of trust, which is the basis of a strong physician-patient relationship. Only about a dozen states nationwide prohibit electronic recordings done without the explicit consent of all participants in the encounter. It is important to know the specific laws concerning recordings in the jurisdiction where you practice. Regardless, it is recommended that patients be advised unequivocally that digital recordings by handheld devices such as smartphones are prohibited on the premises in order to protect the privacy of other patients and staff in compliance with federal and state privacy laws.

Post this notice clearly on your practice website, in the conditions of treatment signed by the patient at the outset of the relationship, and as office signage near the reception window. Suspected violations should be handled immediately. If this policy is violated, meet with the patient in a confidential setting to discuss the issue and reiterate the office policy. Depending on the circumstances and the status of the patient's current episode of care, advise the patient that further violations may result in termination of the physician-patient relationship.

If patients ask to record the visit, encourage them instead to take notes or to have a trusted family member or friend join them for the office visit to help take notes, remember information, and ask questions. Doctors can also encourage patients to be engaged in the conversation with "Ask Me 3," a program that promotes clear communication through these three main questions:

1. What is my main problem?
2. What do I need to do?
3. Why is it important for me to do this?

Doctors should also ask patients to repeat back the information shared, and then correct any misunderstandings.

Important Policies for Recording Surgical Procedures

Practices and surgical centers also must decide whether they should video-record clinic visits or operative procedures. Office practices may want to record patient encounters to document when the informed consent occurred. Surgical centers may want to record

The guidelines suggested here are not rules, do not constitute legal advice, and do not ensure a successful outcome. The ultimate decision regarding the appropriateness of any treatment must be made by each healthcare provider in light of all circumstances prevailing in the individual situation and in accordance with the laws of the jurisdiction in which the care is rendered.

surgeries for educational purposes.

It is important to note that this additional documentation will become a part of the record and can be subsequently accessed by government agencies responsible for healthcare oversight, such as state medical boards, the Centers for Medicare and Medicaid Services, and the Office of the Inspector General for the United States Department of Health & Human Services, among others. Law enforcement will also be able to secure a copy with a search warrant or other court order. A patient may also obtain the recording with a valid HIPAA-compliant authorization.

If a medical group or healthcare facility is considering doing audio or video recordings, it is recommended that several factors be considered and implemented:

1. The practice or facility should create a written protocol detailing under what circumstances a digital recording - whether audio, video, or both - may be done.
2. The policy should also indicate how the digital recording will be stored, where it will be retained and by whom, and for how long it will be kept.
3. Any such protocol should reference the manner in which the digital document will be destroyed, consistent with federal and state privacy laws.
4. Patients should be advised in advance that a digital recording is being considered. The patient should sign a written release that explains the reasons for the recording. As with all consent forms, the signed authorization should be placed in the chart as part of the permanent record.
5. The practice or facility should put a procedure in place to ensure that the policies are being followed and that a responsible administrator conducts a periodic review to ensure the effectiveness of the protocols. Adopting and following these procedures helps to protect the practice or facility in the event of a subsequent inquiry as to the validity and completeness of the patient's chart.

References

1. Video in the Exam Room: Should You Allow Patients to Record Visits? Medical Economics. September 22, 2015. http://www.medicaleconomics.com/medical-economics/news/video-exam-room-should-you-allow-patients-record-visits . Accessed April 24, 2018.

Editor's Note: Under Michigan law, any participant in a conversation may record the conversation, and it is not considered to be "eavesdropping" under the plain language of MCL 750.539a (2) because, by very definition, a participant to a private conversation who records the same is not considered to be "eavesdropping" because the conversation is not the "discourse of others" under the statute. See Michigan case law Sullivan v. Gray, 117 Mich App 476, 481, 324 N.W. 2d 58 (1982); Lewis v. LeGrow, 258 Mich App 175, 185, 670 NW 2d 675 (2003). As the Michigan Court of Appeals in LeGrow recently reaffirmed, "a participant in a private conversation may record it without 'eavesdropping' because the conversation is not the 'discourse of others'" under the statute.

4 WAYS TO COUNTERACT MEDICAL MISINFORMATION

The recent spate of measles outbreaks in the U.S., the highest since 1994, might be the most evident example of the growing virulence of medical misinformation. It's a call to action for the medical community, from clinical and research physicians to educators and regulators, to clarify proven science and distinguish it from conspiracy theories. Two physician experts identify steps to take and explain how to coordinate them between public health's many stakeholders.

The AMA Code of Medical Ethics provides additional guidance on being a public personality, including opinion 8.12, "Ethical Physician Conduct in the Media," to help doctors fulfill their ethical obligations to patients, the public and the medical profession, as well as understand how their conduct can affect their colleagues and institutions.

A Viewpoint essay published in JAMA features analysis by Paul W. Armstrong, MD, of the Canadian VIGOUR Centre and the Division of Cardiology at University of Alberta, and David Naylor, MD, PhD, of the medicine department at University of Toronto. They outlined the roles that members of the health care, education and journalism communities can play in exposing, debunking and preventing medical misinformation.

Quackery is not a new phenomenon, of course, but it has gained unprecedented amplitude in recent years through digital media, the authors noted. Self-proclaimed experts, Twitter-savvy celebrities and digital scammers all have direct lines to the public, often with no editorial oversight.

"Nearly anyone can say almost anything and be taken seriously at least by some consumers," the authors wrote. "With billions of individuals online every day, health misinformation can spread at a rapid pace. Worse, exciting falsehoods apparently spread faster than boring truths on social media."

Research isn't enough

Medical journals are in a unique position to solicit and publish research on medical misinformation and coordinate topics to focus the public's attention and inform medical education, yet counteracting false claims requires an across-the-board response, Drs. Armstrong and Naylor wrote.

They noted four steps, below, that should be taken and how different health care and societal stakeholders can pitch in.

Limit dissemination. Medical journals are not the only agents responsible for preventing bad information from taking root in public discourse. Physicians also can identify the purveyors of misinformation, while regulators and social media executives can limit the extent to which these sources can get their messages out. Editors across traditional and new media, meanwhile, can help by not legitimizing falsehoods in the name of balanced reporting.

Create immunity through science literacy. The work of medical journals can be complemented by primary and secondary school educators' teaching students the scientific method, including why and how it works, as well as critical-thinking skills. Likewise, colleges and universities can work to ensure every graduate is versed in common cognitive errors and logical fallacies regarding qualitative and quantitative data.

Inoculate and educate. Physicians, faculty and health care organizations, along with public health agencies and communications experts, can all promote a general understanding of medical science and use their media outlets to lay bare common misconceptions.

Debunk myths and discredit purveyors. Here too, the larger journalism community, health professionals and medical researchers can provide direct rebuttals and cite the provenance of misinformation, revealing purveyors' credentials, or lack thereof, and pulling back the curtain on conflicts of interest.

INSIDE MAYO CLINIC'S 5-STEP PROCESS FOR HANDLING BIASED PATIENTS

Incidents of patient bias towards physicians and other health professionals are all too common, from subtle nonverbal actions to outright verbal attacks. Yet many health care organizations still lack policies, mechanisms and cultures to address them. Mayo Clinic recently developed a model for its staff to deal with racism, sexism, ageism and other types of patient misconduct while preserving patients' rights and safety.

The AMA Code of Medical Ethics provides additional guidance on dealing with inappropriate conduct, such as opinion 1.2.2, "Disruptive Behavior by Patients," to help physicians establish and maintain mutual respect with patients.

Following are highlights from an article

in the AMA Journal of Ethics™ (@JournalofEthics) by Rahma M. Warsame, MD, assistant professor of medicine and diversity chair in the Division of Hematology at Mayo Clinic, and Sharonne N. Hayes, MD, professor of cardiovascular medicine and founder of the Women's Heart Clinic at Mayo, highlighting their employer's policies and procedures related to patient and visitor conduct.

"How health care organizations balance providing appropriate and necessary care to patients with maintaining a supportive, respectful work environment for staff can be a litmus test of organizational culture and leadership," the authors wrote, noting that ignoring patient bias or taking a default patient-first approach can harm employee morale and open up organizations to legal liability. "Patients have a right to refuse care, but this right does not outweigh employees' right to be free of discrimination."

Mayo Clinic convened a working group to develop its patient and visitor conduct policy after a growing number of reports that its patients had requested physicians with or without specific personal attributes. In addition, an organization wide assessment found that inappropriate behavior by patients and visitors disproportionately affected workers and students of color.

"Staff and learners reported feeling demoralized, marginalized, unsupported by their supervisory staff and without recourse due to the lack of policy guidance or a formal reporting mechanism to address bias incidents," the authors wrote.

Creating a culture of responsibility

Mayo's "SAFER model" was developed to address instances in which patients request care team members with characteristics unrelated to care, as well as when patients or visitors behave in a discriminatory, harassing or demeaning manner towards staff.

The Mayo SAFER model recommends the following responses:

Step in when you observe behavior that does not align with Mayo Clinic values.

Address (the inappropriate) behavior with the patient or visitor.

Focus on Mayo Clinic values (such as respect and healing).

Explain Mayo's expectations and set boundaries with patients and visitors.

Report the incident to your supervisor and document the event using the patient misconduct form.

The model is reinforced by a decision tree for responding to inappropriate behavior and navigating requests based on care team members' personal attributes, and an online reporting system documents inappropriate requests and episodes of misconduct.

Mayo also has a dedicated website with supportive resources - including videos, answers to frequently asked questions and tips for de-escalation - and training is available to all staff in distinguishing a patient's needs from a patient's preferences. Meanwhile, the working group remains in place to monitor the frequency and severity of bias incidents and assess adherence to the process.

In addition, Mayo revised its patient-responsibility policy preamble to state, "We won't grant requests for care team members based on race, religion, ethnicity, gender, sexual orientation, gender identity, language, disability status, age or any other personal attribute."

This policy does allow for several exceptions, such as when patients have had prior trauma, when they have cultural needs that inform their requests or if failing to accommodate the request would compromise the patient's health.

WEARABLES, THE FDA AND PATIENT ADVICE: WHAT PHYSICIANS SHOULD KNOW

The Food and Drug Administration (FDA) has basic rules for regulating wearable devices and other digital health tools, but those rules may change as rapid innovation continues and the agency creates new pathways to ensure the safety and efficacy of new consumer-facing products. AMA experts outlined this and other need-to-know facts for physicians counseling patients who are increasingly looking to the wearable as a health tool.

Attorney Shannon Curtis, AMA assistant director for federal affairs, said during a recent education session that there are three important things for physicians to keep in mind when counseling patients about wearables or mobile health (mHealth) apps.

Be aware of an app or device's regulatory status before recommending it to patients. "You want to be mindful of what's being approved and what's not, and be aware that, a year from now, we can have a very different set of rules," said Curtis, pictured here.

Alert patients to data privacy issues. "Help patients understand that their data might not just stay with their wearable or their physicians, and they need to know where their data is going. These apps and wearables are big data mines for companies

that make them."

Help patients understand the information they receive. "A patient may tell you, 'My watch told me I'm having a heart attack, what do I do?'" Curtis said. Also, physicians should be ready to answer the questions and for the volume of questions that will come with the new technology, especially direct-to-consumer genetic tests.

On FDA regulation, the rule - for now, at least - is clear: Any device that is "intended for use in the diagnosis of disease of other conditions, or in the cure, mitigation, treatment, or prevention of disease" requires FDA approval, Curtis said. This goes for devices meant for humans and animals, as the FDA regulates both.

The scrutiny a new product receives is stratified by three levels of risk with products such as syringes and gauze at the first level and devices such as pacemakers in the third.

Wearable devices - mostly in the form of watches, bracelets, vests or glasses - are not regulated if they are intended for general wellness uses, which include maintaining or encouraging a general state of health or activity, or reducing the risk or impact of chronic disease. If a device that performs these same tasks is implanted rather than worn, then the FDA will regulate it, Curtis said.

mHealth apps are regulatorily treated in a similar fashion. Apps that purport to do the following get a light touch:

- Help users self-manage diseases or conditions without offering specific treatment suggestions.
- Provide information related to conditions and treatment.
- Organize and track patient health information.
- Automate physician tasks.

If, however, an app is making specific recommendations or a diagnosis, the FDA is going to take a look at it, Curtis said.

"It's probably going to change a lot more in the not-so-distant future, just because the innovation in this space is so quick," she added. "It's a new area for the FDA and it requires a lot of staff with very new expertise. Innovation is coming fast and furious."

There already has been some splintering to this approach. Last September, the FDA approved functions on the Apple Watch 4 that produce an electrocardiogram to detect the presence of atrial fibrillation (AF) and to analyze the wearer's pulse rate to identify irregular heart rhythms suggestive of AF and notify the user.

"This does not mean Apple Watch as a whole is FDA approved," Curtis explained. "It's only those functions. The FDA is not looking at anything else the Apple Watch does."

"Wild, wild West"

AMA research has found that physician enthusiasm for technology "is directly tied to a solution's ability to help them take better care of patients," said Meg Barron, AMA digital health strategy vice president. Curtis and Barron co-presented the education session at the 2019 AMA Annual Meeting.

"It can feel like the wild, wild West right now," Barron said. But one of the ways the AMA is helping is by leading Xcertia, a multistakeholder organization developing industry-vetted guidelines focused on improving the quality, safety and effectiveness of mHealth apps' ability to improve care.

Learn more about the AMA's digital leadership efforts by visiting https://www.ama-assn.org/practice-management/digital.

AMA KEEPS UP FIGHT TO PROTECT PHYSICIANS' FREEDOM OF SPEECH

What's the news: The AMA continues to fight back against a Trump administration physician gag rule after an appellate court ruling lifted a lower court's injunction blocking implementation of the regulation.

Why it matters to patients and physicians: The decision by a 9th U.S. Circuit Court of Appeals three-judge motion panel allows new rules to take effect, threatening physicians' freedom of speech. The AMA has called the rules unprecedented government interference in the patient-physician relationship.

The regulation affects the Title X family planning program, which ensures that every person has access to basic, preventive reproductive health care such as birth control, cancer screenings, and sexually transmitted-infection testing and treatment regardless of economic or insurance status.

The regulation imposes restrictions on physicians' ability to counsel their patients in the Title X program about the full range of family planning options, including referrals for abortion.

The lawsuit was filed in Oregon and led by the AMA, Planned Parenthood and its local affiliates, and the Oregon

Medical Association. The case was later consolidated with other lawsuits that include 20 states, the District of Columbia and individual health professionals.

The appellate ruling overturns an earlier decision by U.S. District Judge Michael McShane in Portland, Oregon, who agreed with the AMA position and wrote a strongly worded decision condemning what the administration was trying to do.

"This is madness," McShane wrote. "At the heart of this rule is the arrogant assumption that government is better suited to direct the health care of women than their medical providers."

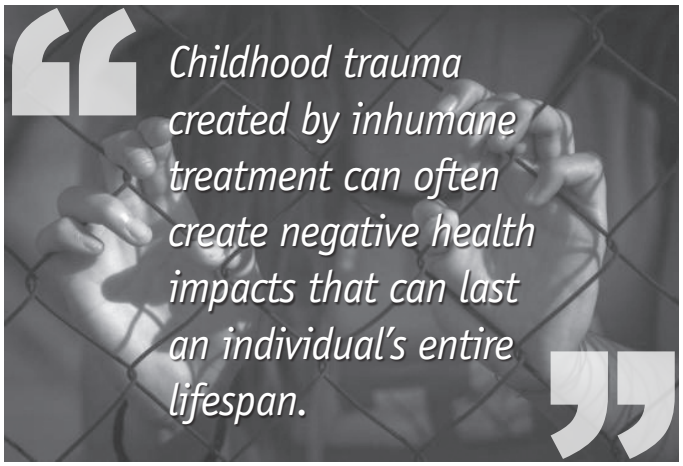
What's next: The ruling was issued by three judges randomly selected out of the 9th District's 29 presiding judges to decide the case. The AMA and Planned Parenthood filed a motion for emergency reconsideration en banc by a larger panel of judges.

Similar motions were also filed by the states of California, Oregon and Washington and other plaintiff organizations active in the case. The 4th Circuit U.S. Court of Appeals is hearing a separate case involving Title X services in Maryland.

The AMA has more resources on the changes to the Title X program, the lawsuit and the fight to protect physicians' freedom of speech. Visit https://www.ama-assn.org/delivering-care/physician-patient-relationship.

CONGRESS TOLD IMPACT OF IMMIGRANT CHILDREN'S TRAUMA MAY BE LIFELONG

What's the news: AMA urges Congress and the Trump administration to work with medical and mental health experts to ensure that the health of families and children seeking refuge in the U.S. is protected throughout the immigration process.



This recommendation was made in a statement delivered to the U.S. House Oversight and Reform Committee in advance of its hearings, "Kids in Cages: Inhumane Treatment at the Border" and "The Trump Administration's Child Separation Policy: Substantiated Allegations of Mistreatment."

Why it matters to patients and physicians: The ill health effects caused by the traumatizing conditions experienced by children in Customs and Border Protection (CBP) custody can last a lifetime.

"Families seeking refuge in the U.S. already endure emotional and physical stress, which is only exacerbated when they are separated from one another or held in family detention facilities during the pendency of their immigration proceedings," AMA Executive Vice President and CEO James L. Madara, MD, wrote in a letter to committee leaders. "It is well known that childhood trauma and adverse childhood experiences created by inhumane treatment often create negative health impacts that can last an individual's entire lifespan."

The statement also states how traumatizing conditions such as insufficient food and water, extreme temperatures and constant light exposure "are simply not appropriate places for children or for pregnant women."

This is not a new position of the AMA. The statement issued to the committee reflects policies adopted by the AMA House of Delegates at the 2017 and 2018 AMA Annual Meetings. The policies oppose the separation of parents from their children and support humane treatment of all undocumented children.

In September the administration released a proposed rule expanding the long-term detention of migrating families. Consistent with these policies, the AMA opposed the proposal and has demanded oversight of detention facilities.

What's next: The AMA and several medical specialty societies are strongly supporting H.R. 3239, the "Humanitarian Standards for Individuals in Customs and Border Protection Custody Act," as a necessary first step to ensure adequate health care, food and water, sanitation and shelter for individuals in CBP custody.

The AMA also urges Congress and the administration to make it a priority to support families and protect the well-being of children within those families throughout the immigration process.

GOVERNMENT EHR PROPOSALS THREATEN PATIENT PRIVACY

Two federal agencies have proposed rules pertaining to health information technology that will have a significant impact on the exchange, access and use of all health care data. While there are elements in both that deserve support, there are also several problems - particularly when it comes to patient privacy.

As proposed, the rules would shift the paradigm from permitting data sharing to requiring that data be shared, including with third parties who would be under no obligation to keep the information private.

"The proposed rules are complicated, intertwined and may result in a patient's information being shared with third parties in a way that patient didn't foresee or want," said AMA Immediate Past President Barbara L. McAneny, MD, an oncologist in private practice in Albuquerque, New Mexico.

The AMA is committed to making technology an asset in the delivery of health care, not a burden.

One proposal comes from the Office of the National Coordinator for Health IT (ONC) and covers the agency's potential new health IT certification requirements, as well as the information-blocking provisions from the 21st Century Cures Act.

The other proposal, which comes from the Centers for Medicare & Medicaid Services (CMS), seeks to spur health IT interoperability and promote a patient's access to the information their health plan has about them, including claims information.

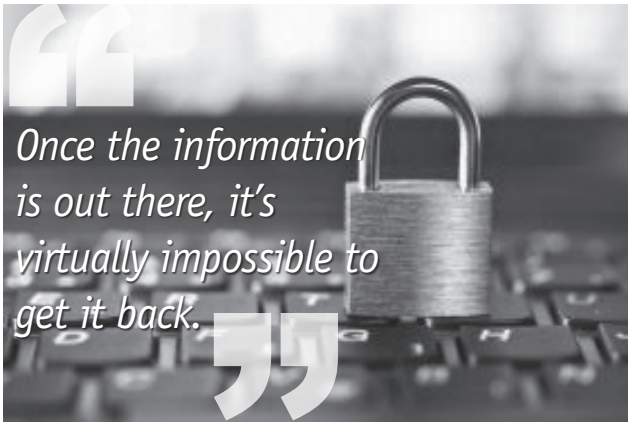
Turning patient data into a commodity

While these proposals include laudable goals, they could result in patient data being sold, marketed or traded. The AMA is calling for controls to be instituted that establish transparency as to how health information is being used, who is using it, and how to prevent the profiteering of patients' data.

"Once the information is out there, it's virtually impossible to get it back," Dr. McAneny said. "The technological capability to implement these controls exists. If ONC doesn't implement controls, it is making a policy decision to not prioritize privacy."

ONC's proposals give software applications and their developers protections and benefits equal to those enjoyed by patients. The AMA cautions that smartphone apps share sensitive health information with third parties, often without an individual's knowledge. Much of this information can end up in the hands of data brokers or be used for advertising and marketing.

Most patients will not be aware of who has access to the information, how and why they received it, and how it is being used. For example, an app may collect or use information for its own purposes, such as an insurer using health information to limit or exclude coverage for certain services, or may sell information to clients such as to an employer.



Data being used in this way may ultimately erode patients' privacy and their willingness to disclose information to their physicians, noted AMA Executive Vice President and CEO James L. Madara, MD, in a letter to National Coordinator Don Rucker, MD.

Opening a gate to negative consequences

Similarly, in a letter to CMS Administrator Seema Verma, Dr. Madara notes that "the AMA appreciates many of CMS' proposals," but has several concerns related to patient privacy, payer-to-to payer exchange of clinical data, and "unfettered" payer access to data contained in EHRs.

"Historically, payers have only had access to clinical information when necessary for payment," Dr. Madara's letter states. "Physicians have acted as 'gatekeepers' to determine what information is necessary for each individual to be covered and for the physician to be paid." Payers could use CMS and ONC's proposals to demand patients' medical information and circumvent a physician's clinical decision-making.

Physicians take data stewardship very seriously. Removing physicians' ability to safeguard patient data could have "negative downstream consequences for patients and physicians," that would delay needed care, Dr. Madara writes.

To prevent this, payers should attest that the clinical data they exchange with another health plan cannot be used as a basis to deny or delay coverage, increase rates, or implement step therapy. This attestation should be posted on the company's website and displayed in coverage documents.

CMS also should restrict payers from conditioning physician participation in a plan based on whether a doctor will grant the payer electronic access to the practice's EHR.

Final rules are expected in the late fall. The AMA has recommended that ONC first release a document that clarifies questions that have been raised regarding the proposed rule. That would give the agency flexibility to finalize certain aspects of the rule while still refining others.

Ask Our Lawyer: Physicians and Self-Regulation

By: Daniel J. Schulte, MSMS Legal Counsel

QUESTION:

I have always believed that self-regulation was an important characteristic of any profession. I realize that self-regulation is a part of the medical profession. This includes the voluntary reporting of our own illegal or unethical conduct and that of our fellow physicians. However, the methods and availability of reporting mechanisms are not well known. Can you advise us of the ways to report illegal and unethical conduct?

ANSWER:

What follows is a list of some of the more common mechanisms used by physicians in the self-regulation of the profession. The list is not meant to be complete, instead it sets forth the most common methods of reporting illegal or unethical conduct.

1 Michigan's Public Health Code – MCL 333.16222(1) requires that a physician having knowledge of another licensed health professional's violation of the public health code or having committed and act or omission that could be grounds for discipline has a duty to make a report to the Michigan Department of Licensing and Regulatory Affairs ("LARA"). The allegation packet and other information to do so is available on LARA's website: https://www.michigan.gov/documents/lara/BPL-LAD-100_523225_7.pdf . The duty to report includes knowledge of any of the grounds for discipline listed in MCL 333.16221 which includes a variety of personal disqualifications (incompetence, substance abuse, a mental or physical inability to practice in a safe manner, conviction of certain felonies and misdemeanors, adverse licensure actions in other jurisdictions, etc.), the commission of prohibited acts (various forms of fraud, false and misleading advertising, etc.), unprofessional conduct, violations of laws applicable to the health professions, etc.

This duty to report is subject to only one exception. A physician who learns that another health professional has committed an act requiring reporting as a result of providing physician services to that health professional is prohibited from making disclosure of information learned in the course of that physician-patient relationship.

2 MSMS Judicial Commission – Section 7 of the MSMS Bylaws and the rules and procedures of the MSMS Judicial Commission establish a mechanism for the reporting, investigation and potential discipline of members who violate the Principals of Medical Ethics of the American Medical Association, engage in unprofessional or dishonest conduct as proscribed by Michigan's Public Health Code, commit a felony or violate or disregard the MSMS Bylaws, principals, rules or regulations of MSMS, the Judicial Commission or the American Medical Association. Section 7.30 of the MSMS Bylaws limits the Judicial Commission's authority to: (1) reprimanding a member; (2) suspending or expelling a member; or (3) for a grievous offense making a recommendation to the Board of Medicine to revoke the member's license. The Judicial Commission does not have jurisdiction over non-members (and will mediate a grievance against a non-member only if he/she voluntarily agrees to participate).

3 OIG's Self Disclosure Protocol – Physicians may self-report to the U.S. Department of Health and Human Services Office of Inspector General ("OIG") violations of federal laws for which civil monetary penalties may be imposed. These include violations of the Medicare and Medicaid laws/regulations and the fraud and abuse laws (e.g. the anti-kickback statute, False Claims Act, etc.) other than the Stark Law (see below for Stark Law self-reporting) violations using the OIG's Self-Disclosure Protocol. Further information and forms are available at: https://oig.hhs.gov/compliance/self-disclosure-info/protocol.asp .

4 Stark Law Self-Reporting - A similar self-referral disclosure protocol is available for violations of the Stark Law's prohibition on physician self-referral. Information on this self-reporting mechanism is available at: https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/self_referral_disclosure_protocol.html.

5 Medical Staff Bylaws – If you are on a hospital or other medical staff you should carefully review the medical staff bylaws and any applicable policies and procedures. These documents frequently contain requirements for both self-reporting your violations of rules and policies of the medical staff and may also require your disclosures of the violations of others on the medical staff.

September/October 2019
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Health Department

Macomb County Health Department

Reportable Diseases Summary

Diseases Reported in Macomb County Residents*

Cumulative total for previous years; year-to-date total for July, 2019

	2019	2018	2017	2016	2015
AMEBIASIS	0	0	0	1	0
BLASTOMYCOSIS	0	0	0	1	0
BOTULISM (FOODBORNE)	0	0	0	0	0
BOTULISM (INFANT)	0	0	0	0	0
BRUCELLOSIS	0	0	0	0	0
CAMPYLOBACTER	89	138	120	96	79
CHICKENPOX	43	41	31	33	32
CHLAMYDIA	1,923	3,586	3,598	3,185	2,736
COCCIDIOIDOMYCOSIS	1	4	2	2	2
CREUTZFELDT JAKOB	0	2	2	2	2
CRYPTOCOCCOSIS	1	4	1	1	1
CRYPTOSPORIDIOSIS	3	12	6	10	1
CYCLOSPORIASIS	0	1	12	2	0
DENGUE FEVER	0	0	0	1	1
DIPHTHERIA	0	0	0	0	0
EHRLICHIOSIS	0	0	0	3	0
ENCEPHALITIS PRIMARY	1	2	4	1	2
ENC POST OTHER	3	2	1	1	1
FLU-LIKE DISEASE	13,639	23,444	28,172	21,747	27,943
GIARDIASIS	12	9	20	23	17
GONORRHEA	616	1,093	946	801	522
GRANULOMA INGUINALE	0	0	0	0	0
GUILLAIN-BARRE SYN.	8	10	9	10	4
H. FLU INVASIVE DISEASE	9	11	21	14	11
HEMOLYTIC UREMIC SYN.	0	0	0	0	0
HEPATITIS A	2	33	201	9	5
HEPATITIS B (ACUTE)	0	5	5	9	6
HEP B (CHRONIC)	59	102	108	110	125
HEPATITIS C (ACUTE)	16	31	49	31	16
HEP C (CHRONIC)	342	857	898	931	673
HEPATITIS D	0	1	0	0	0
HEPATITIS E	0	1	0	0	0
HISTOPLASMOSIS	1	3	0	5	5
HIV^	28	75	69	57	64
INFLUENZA	4,024	7,570	4,136	2,164	1,143
KAWASAKI SYNDROME	2	3	5	5	10

	2019	2018	2017	2016	2015
LEGIONELLOSIS	19	102	56	34	25
LISTERIOSIS	0	3	3	1	1
LYME DISEASE	2	8	5	3	5
MALARIA	0	2	2	2	2
MEASLES	0	0	1	0	0
MENINGITIS VIRAL	27	61	44	43	60
MENINGITIS BACTERIAL/BACTEREMIA *(EXCLUDING N. MENINGITIDIS)*	3	18	11	9	10
MENINGOCOCCAL DISEASE	0	0	0	1	1
MUMPS	1	2	3	2	0
PERTUSSIS	11	48	81	37	35
POLIO	0	0	0	0	0
PSITTACOSIS	0	0	0	0	0
Q FEVER	0	0	0	0	0
RABIES ANIMAL	1	4	2	1	1
RABIES HUMAN	0	0	0	0	0
REYE SYNDROME	0	0	0	0	0
ROCKY MNTN SPOTTED FVR	0	2	0	1	0
RUBELLA	0	0	0	0	0
SALMONELLOSIS	20	82	75	78	82
SHIGELLOSIS	11	10	46	50	22
STEC**	8	24	10	7	9
STREP DIS, INV, GRP A	23	47	32	31	27
STREP PNEUMO, INV + DR	45	54	45	55	52
SYPHILIS	51	145	84	79	108
SYPHILIS CONGENITAL	0	3	1	0	2
TETANUS	0	0	0	0	0
TOXIC SHOCK SYNDROME	1	1	0	0	1
TUBERCULOSIS	2	5	10	11	6
TULAREMIA	0	0	0	0	0
TYPHOID FEVER	2	0	0	0	1
VIBRIOSIS	0	2	0	1	0
VISA	0	2	1	0	0
WEST NILE VIRUS	0	11	7	2	4
YELLOW FEVER	0	0	0	0	0
ZIKA	0	0	0	4	0

*Includes both Probable and Confirmed case reports.

**Shiga-toxin producing Escherichia coli per MDHHS; combo of E. coli & Shiga Toxin 1 or 2.

15-Aug-19

^ Previously reported as "AIDS"