The Stethoscope

Quarterly newsletter of the Erie County Medical Society

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A Note from Your President…

A Hidden Danger

Clostridium difficile infection (CDI) has the highest population base incidence of healthcare associated infections in United States. CDI has recently surpassed methicillin-resistant staphylococcal aureus (MRSA) as the most common healthcare associated infection. Clostridium difficile (CD) is a gram-positive, spore forming, toxin secreting obligate anaerobic bacillus. The spores are transmitted via the fecal oral route. The transference of CD spores by contact with the hands of contaminated healthcare personnel, appear to be the most predominant means of spread of this infection. The Infectious Disease Society of America (IDSA) defined CDI as "the presence of diarrhea or evidence of megacolon or severe ileus and either a positive laboratory diagnostic test result or evidence of pseudomembranes demonstrated by endoscopy or histopathology". There is a rising concern about the emergence of highly virulent strains. The strains have been associated with increased morbidity and mortality.

In order to diagnose and treat CDI, one needs to have a high index of suspicion in any patient with diarrhea. There also appears to be a high incidence of CDI in individuals older than 65 years old. The incubation period is unknown. The most important modifiable risk factor is exposure to antibiotic agents. The implicated antibiotics are third generation Cephalosporins, Fluoroquinolones, Carbapenems, and Clindamycin. These appear to have the greatest risk. The risk of CDI is present during antibiotic treatment and can occur up to 3 months after antibiotic course has been completed. The highest risk appears to be during the first 4 weeks after antibiotic exposure.

IDSA guidelines clearly delineate recommendations for minimizing risk of transmitting CDI. The most important of these for healthcare workers is to consistently hand wash with soap and water upon any contact with feces or fecal contaminated objects. Use of gloves is mandatory and using soap on water or alcohol-based hand hygiene prior to and after blood use is necessary. Those with Clostridium difficile infection should be isolated until at least 48 hours after the diarrhea has resolved.

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There is a continuum of treatment for CDI based on severity and recurrence. Current IDSA guidelines define severe Clostridium difficile infection using laboratory values of leukocytosis greater than 15,000and serum creatinine greater than 1.5 mg/dL. These criteria are still not validated and become problematic with patients who have renal insufficiency or hematologic malignancies.

In conclusion, I would like to stress the importance of handwashing with soap and water, despite the use of alcohol-based hand sanitizers both before and after patient contact.

The Myths and Realities of Medication Assisted-Treatment for Opioid Use Disorder

"May I never see in the patient anything but a fellow creature in pain."
- Oath of Maimonides

By Timothy D. Pelkowski, MD

Maimonides was born at Cordova, Spain, in 1135. He was a famous physician known for his scholarly philosophical comments. One of the writings he is best known for is the Oath of Maimonides. His famous quote from that oath above is a reminder to all physicians to commonly view our patients as those suffering and in need. This is regardless of what the reason for that suffering is. This seems an especially apt reminder for those patients that are treated for opioid use disorder (OUD). Many have preconceived notions regarding patients with OUD. Physicians need to be there for those with this illness. We need to remember that these patients include our family members and colleagues and individuals across all socioeconomic divides. Regardless of our medical specialty we are all at least tangentially involved in caring for patients with OUD.

We are all familiar with the horrendous epidemiology surrounding OUD. These statistics are seen on a daily basis nationally and in our own community. More than 49,000 Americans died from opioid overdoses in 2017. This translates to about 130 lives per day in the U.S. Currently 2.1 million Americans have OUD. The tragedy is that less than one fifth of those with an OUD receive treatment for this addiction. The current treatment for this disorder in the U.S. is fragmented and challenging to navigate even in the best of times, let alone when actively trying to overcome an addiction.

There are currently three medications approved by the U.S. Food and Drug Administration for the use of OUD. These include buprenorphine, methadone, and naltrexone. Unfortunately, there is a stigma associated with the use of this medication assisted-treatment (MAT). Methadone can be obtained only through regulated treatment programs when used for MAT purposes. Naltrexone requires complete abstinence before treatment can begin. Buprenorphine represents the treatment with the greatest opportunity to become intertwined with routine medical care. It was approved from the U.S. Food and Drug Administration in 2002 for the treatment of OUD. Embedding this particular treatment within primary care can help the patient receive treatment for other concomitant medical problems. It is imperative that we make it easier for patients to obtain buprenorphine than it is to obtain heroin and fentanyl. MAT can help manage this chronic disorder just as diabetic medications can manage hyperglycemia

and antivirals can manage HIV. Helping a patient escape the cycle of addiction can be life saving for the patient and rewarding for the physician.

There have been a number of myths cited specifically around the use of buprenorphine and these have been outlined in the literature (Wakeman, 2018). The first is that buprenorphine is more dangerous than other chronic disease medications. In actuality this medicine is no more complex than any of the other medications we use on a daily basis. Especially when compared to insulin regimens and anticoagulant use. Some truly basic training can readily remediate this issue. The second myth is that the use of buprenorphine is simply a "replacement" addiction. Taking a prescribed medication to manage a chronic illness is not the same as an addiction with its coexisting negative impact on the patient's life. The next myth is that detoxification for OUD is effective. The evidence points to MAT as being superior. The fourth myth is that prescribing this medication is burdensome. With minimal education and processes this can be a medication that is easy to work with. The FDA has approved a generic version of buprenorphine that has the potential to make this more widely available and even easier to prescribe. On October 12, 2018, Pennsylvania announced that all major commercial insurers are eliminating prior authorization for MAT. This is another step that will remove barriers in treatment. A final myth is that simply reducing opioid prescribing will reduce opioid deaths. Frequently in this situation those abusing opioids will shift to the illicit drug market with all of its concomitant risks.

As buprenorphine treatment has been slowly increasing in the United States there has been a change in its use in practice (Martin, 2018). Whereas it was once thought this medication could only be initiated in a medical setting there is expanding use of beginning this medication in the patient's home. Although concomitant treatment with buprenorphine and benzodiazepines needs to be evaluated closely it is no longer an absolute contraindication to be on both agents. A patient who experiences relapse while on buprenorphine does not necessitate the absolute discontinuation of this agent. At one time behavioral treatment was felt to be an absolute requirement while on buprenorphine. New evidence suggests it should be provided only if the patient desires. Finally, there is an awareness that some individuals may need long-term treatment rather than focusing on a termination date for MAT. All of these changes in the use of buprenorphine could allow for improved access to this treatment. The underlying goal of all of this is to reduce the deaths associated with OUD.

Although MAT is available in the Erie community it needs to become more robust if it is to have a significant effect on the health of our community. The Erie County Medical Society prompts a call to all physicians to become knowledgeable regarding the use of MAT for the management of patients with OUD. This can even be as simple as knowing were patients can go for assistance. See the resources noted below for more information. We need to remember the quote from Maimonides and to look at patients with OUD as in pain and offering them our nonjudgmental support along with effective, evidence based, treatment.

Resources:

- *National Institute on Drug Abuse* *www.drugabuse.gov*
- *Erie County Office of Drug and Alcohol Abuse* *www.eriecountypa.gov*

References:

- *Hawk K, D'Onofrio G. Time to Change the Way We Approach Opioid Use Disorder: A Challenge to the Status Quo. Ann Intern Med. 2018 Nov 6;169(9):652-653.*
- *Martin SA, Chiodo LM, Bosse JD, Wilson A. The Next Stage of Buprenorphine Care for Opioid Use Disorder. Ann Intern Med. 2018 Nov 6;169(9):628-635.*
- *Saloner B, Stoller KB, Alexander GC. Moving Addiction Care to the Mainstream -Improving the Quality of Buprenorphine Treatment. N Engl J Med. 2018 Jul 5;379(1):4-6.*
- *Wakeman SE, Barnett ML. Primary Care and the Opioid-Overdose Crisis -Buprenorphine Myths and Realities. N Engl J Med. 2018 Jul 5;379(1):1-4.*

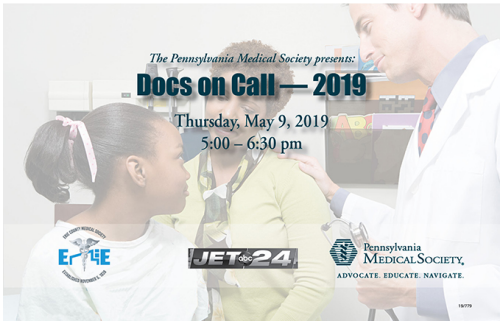
Upcoming Events

Save the date for the 10th Annual Health Expo on October 12, 2019!

Do you want to get involved this year? Have your practice become a Sponsor or host a Screening/Registration table!

Screening/Registration Tables: $50 Early Bird Rate/$70 Regular Rate
Silver Sponsorship: $1,200. Includes 2 tables.
Gold Sponsorship: $2,000. Includes 4 tables and discounted advertising in 4 issues of The Stethoscope.

Exhibitor and Sponsorship information and registration will be distributed soon.



Volunteers Needed

The Pennsylvania Medical Society and Erie County Medical Society are looking for volunteers to bring health care guidance to JET-24 viewers during the annual Docs on Call event on May 9 from 5:00pm - 6:30pm. If you can help, submit your interest to ECMS staff at https://form.jotform.com/PAMEDSSMS/ecms-docs-on-call

Questions? Contact us at eriecms@Pamedsoc.org or 814-866-6820.

2017-2018 Year-End Legislative Session Report

Introduction

The Pennsylvania General Assembly concluded its regular session, passing more than 80 pieces of legislation in the final days of the two-year session. In total, 3,953 bills were introduced and considered by the legislature in 2017 and 2018. Only 246 bills — approximately 6 percent — were passed and signed into law.

At last count, the Pennsylvania Medical Society (PAMED) staff actively tracked 259 bills that were introduced during the 2017-2018 session that affect physicians, from proposals that would directly impact the practice of medicine to those that more generally relate to the provision of health care in our state. Below is a review of what PAMED accomplished this session, what we hope to build on in the coming year, and a summary of some of the significant initiatives advanced this session.

Legislation

Practice Advocacy Issues – Scope of Practice

PAMED dedicated a substantial amount of time and resources this session to the successful defeat of legislation that would allow Certified Registered Nurse Practitioners (CRNPs) to practice independently of physicians in Pennsylvania without the safety net of a collaborative agreement. Legislation was introduced in both chambers — House Bill (HB) 100 in the House of Representatives and Senate Bill (SB) 25 in the Senate — to eliminate the current requirement for CRNPs to collaborate with physicians in order to diagnose, treat, and prescribe drugs to patients. In the end, neither HB 100 nor SB 25 were brought up for consideration in the House of Representatives this session.

Two bills — SB 895 and SB 896 — were introduced in the Senate that would have changed the patient record review process, the composition of the State Board of Medicine and State Board of Osteopathic Medicine, and the supervisory/written agreement between physician assistants and physicians. PAMED went on record to oppose both bills by relaying our position both verbally and in written form to key senators. Neither of the bills were brought up for a committee vote and did not see any action beyond introduction of the bills.

PAMED also supported the Pennsylvania Association of Ophthalmology (PAO) in opposition of SB 668, which would have allowed optometrists to perform ocular surgery, treat systemic diseases, and order imaging tests. SB 668 saw passage in the Senate late in the legislative session but did not move in the House of Representatives.

Through our educational efforts and the advocacy of physicians who answered our call for grassroots action, all scope of practice bills were defeated. PAMED will continue to strongly oppose scope of practice expansion legislation and support the preservation of physician-led, team-based care for all patients in Pennsylvania. It is within the framework of education and clinical training that health care professionals are prepared to deliver safe, quality care. The rigorous education and supervised training physicians receive ensures that they are well-equipped to independently provide complex differential diagnosis, develop a treatment plan that addresses multiple organ systems, and order and interpret tests within the context of a patient's overall health condition.

Practice Advocacy Issues – Credentialing and ASC Tax

HB 125, introduced by Rep. Matt Baker and supported by PAMED, would have standardized the credentialing process for health care practitioners in the Commonwealth. All health insurers licensed to do business in the Commonwealth would be required to accept the CAQH credentialing application or other nationally recognized form designated by the Pennsylvania Insurance Department. The bill would have required health insurers to issue a credentialing determination within 45 days after receiving a complete credentialing application. While HB 125 passed the House of Representatives (190-0), it did not get out of committee in the Senate.

Originally included in the Governor's budget was a three percent tax on Ambulatory Surgery Center (ASC) Net Patient Revenue. PAMED supported several specialty societies and their efforts to oppose the assessment. The tax was not included in the final state budget.

Public Health Advocacy Issues – Opioids

While dozens of bills were introduced this session to address the opioid epidemic and heroin abuse facing the state, a handful of bills were identified as priorities by both the Governor and legislative leaders and ultimately received action before the end of the year.

Thanks to the strong lobbying efforts of PAMED's government relations team, we were successful in adding several exceptions to HB 353, which sought an e-prescribing mandate for Schedule II-V controlled substances. Emergency situations, temporary technological malfunctions, lack of access to the Internet/EHR system, and direct administration by a physician were listed as exceptions.

Act 96 was signed by the Governor on Oct. 4, 2018. Any physician, pharmacy, or health care facility that does not meet one of the exceptions in Act 96 but is unable to timely comply with the electronic prescribing requirements may petition the Department of Health for an exemption from the requirements based upon economic hardship, technical limitations, or exceptional circumstances. The Department is required to adopt rules establishing the form and specific information that must be included in a request for an exemption. The exemption may not exceed one year from the date of approval but may be renewed annually upon request and approval. The Department, in its discretion, may establish additional exemptions through the regulatory process.

Act 96 does not take effect until Oct. 24, 2019. As the law just was enacted on Oct. 24, 2018, the Department has not released its rules establishing the form and specific information that must be included in a request for an exemption. Once the Department does so, PAMED will provide this information to its members. Members can also access PAMED's informational *Quick Consult* at www.pamedsoc.org/QuickConsult. *It is recommended that physicians not wait until next fall to begin preparing for this e-prescribing requirement. Physicians who may be seeking a hardship exemption are encouraged to continue to plan for the e-prescribing requirement, as that requirement must be implemented unless an exception applies, or the Department grants a hardship exemption.*

Another bill, SB 655, would have created an Advisory Council within the Department of Health that could have mandated that physicians follow guidelines, such as the current voluntary guidelines, when prescribing opioids. PAMED opposes legislation that would force physicians to practice "cookie-cutter" medicine. PAMED was at the Capitol in Harrisburg on Sept. 25, 2018, visiting the offices of House Health Committee members to talk about why cookie-cutter approaches don't work well in medicine. It was a chance to deliver our message in a unique way – with sugar cookies and caduceus cookie cutters. We urged House members to oppose SB 655 and instead focus on a more immediate need in this crisis: increasing funding and access for those who need treatment for an opioid use disorder. This legislation was passed unanimously in the Senate but was never voted on in the House of Representatives.

Of particular concern was HB 1987, which would have limited the use of fentanyl to surgery within a health care facility or to a hospice patient. PAMED and The Hospital and Healthsystem Association of Pennsylvania (HAP) wrote a joint opposition letter expressing concern over appropriate use of the drug in clinical settings and preventing patients from receiving appropriate care. Through our concerted lobbying efforts, HB 1987 was successfully amended to include "chronic pain not associated with cancer" and therefore, our position moved to neutral. It is also important to note that HB 1987 was voted on favorably within the House of Representatives, but it saw no action within the Senate Health and Human Services Committee or on the Senate floor.

Thanks to strong lobbying efforts, PAMED was able to advocate for bills that do not infringe on physicians' ability to address the individual needs of their patients. PAMED worked closely with legislative leaders and staff to ensure that what ultimately was signed into law was clinically sound and in the best interest of patient care.

Public Health Advocacy Issues – Lyme Disease and Sunscreen in Schools

HB 174, introduced by Rep. Matt Baker, would have required insurance coverage for Lyme disease and related tick-borne diseases as prescribed by a patient's health care practitioner, regardless of if the treatment plan includes short-term or long-term antibiotic treatment. Similar legislation was introduced in the Senate (SB 100) by Sen. Stewart Greenleaf. Both bills never made it out of the Senate Banking and Insurance Committee.

HB 2301, introduced by Rep. Rosemary Brown, would have established that a licensing board require a licensee complete at least two hours of continuing education in the assessment, diagnosis, and treatment options for Lyme disease and other related tick-borne diseases as a portion of the total continuing education required for license renewal. The bill was introduced in April 2018 and saw no movement in the House or Senate.

The issue of Lyme disease continues to evolve in the state legislature as lawmakers try to respond to constituent concerns about treatment protocols for treating the disease and for insurance coverage. PAMED expects to see additional legislation introduced related to Lyme and other tick-borne diseases in the next session.

PAMED supported the Pennsylvania Academy of Dermatology regarding legislation (HB 1228) that allows school students to have sunscreen at school in order to apply and reapply as needed for recess, field trips, sporting events, and other extracurricular activities. The governor signed Act 105 into law on Oct. 24, 2018, and the earliest effective date is Dec. 23, 2018.

Physicians help build healthy communities in every corner of Pennsylvania. Combining legislative advocacy efforts with PAMED's "Building Healthy Communities" – a project that provides an outlet for physician members to educate the public on relevant public health topics – we believe that PAMED is a commonsense resource for lawmakers as they work to address public health issues. Learn more about "Building Healthy Communities" at www.pamedsoc.org/HealthyCommunities.

Patient Advocacy Issues – Telemedicine, POLST, and Patient Test Results

Two bills – SB 780 and HB 1648 – would have established a statutory definition for telemedicine, mandated that telemedicine services be reimbursed, and prohibited "audio only" services (video available if requested by the patient or provider). This

legislation had the potential to bring health care to the most vulnerable populations such as those who reside in remote areas of the commonwealth, urban communities that lack reliable or affordable transportation, and for patients with significant mobility challenges that present a barrier to in-person consultations with physicians. PAMED strongly believed that passage of SB 780 would help improve access to care across the state. In June 2018, SB 780 was favorably voted on in the Senate and passed 49-0. Coming right off the heels of the Senate vote, retiring House Professional Licensure Committee Chairman, Rep. Mark Mustio, toured facilities over the summer to witness telemedicine technology firsthand. A public hearing was held on Sept. 12, 2018. Momentum for this critical legislation looked positive. However, 26 amendments were added to the bill in September and October and they ultimately slowed the legislation to a grinding halt. While this bill was not signed into law, it did pass a chamber for the first time since introduction.

The Pennsylvania Senate passed legislation 47-1 that would have created a legal framework for Pennsylvania Orders for Life Sustaining Treatment (POLST) directives and ensured that a patient's wishes for end-of-life care followed the patient across health care settings. PAMED strongly supported SB 623 and is part of a multi-year, collaborative effort of nearly 30 health care and patient advocacy organizations, with the goal of easing the difficult clinical decisions patients and their family members encounter when end-of-life circumstances present themselves. While this bill did not make it through the House of Representatives, it did pass a chamber for the first time since its initial introduction more than five years ago.

HB 1884, introduced by Rep. Marguerite Quinn, requires an entity performing a diagnostic imaging service, in addition to sending the results to the ordering physician, to directly notify the patient or the patient's designee that the results of the test were sent to the ordering physician when there is a significant abnormality and that follow-up with the ordering physician is recommended. Act 112 was signed into law by the governor on Oct. 24, 2018. PAMED is reaching out to the Department of Health to seek clarification on several issues, including the requirements of Act 112, who is subject to Act 112, and how the Department will be implementing the law.

Act 112 takes effect on Dec. 23, 2018. PAMED will provide updates to its members as we obtain them from the Department. In the interim, it is recommended for physicians and facilities to start discussions on developing policies on implementing Act 112 and to speak to their in-house legal counsel, malpractice carrier, or other applicable legal counsel for further guidance. Members can also access PAMED's informational Quick Consult at www.pamedsoc.org/QuickConsult.

At PAMED, we believe that while business outcomes are important, patient outcomes are more paramount. As we look toward the 2019-2020 legislative session, we will continue to shine a light on patients and giving them the tools they need to ease health care related burdens while also safeguarding against administrative red tape for physicians.

PAMPAC Update

PAMPAC is the political arm and the muscle of PAMED. One of the largest bipartisan political action committees in the state, it is made up of members of PAMED and its Alliance who are interested in making a positive contribution to the medical profession through the political process. PAMPAC supports pro-medicine candidates, as well as provides interested members with advice on organizing local fundraising events for legislative candidates and advises members interested in seeking public office. If you're not a current PAMPAC member, learn more and join 500+ of your colleagues in adding your voice at https://www.pamedsoc.org/laws-advocacy/PAMPAC.

A Look Ahead

PAMED's Board of Trustees approved the following issues as equal priorities for 2019:

- Scope of Practice
- Prior Authorization
- Maintenance of Certification
- Narrow Networks/Any Willing Provider and Out-of-Network Billing
- Physician Wellness

To stay up to date on PAMED's advocacy and legislative priorities, visit https://www.pamedsoc.org/laws-advocacy/topics.

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2018 – 2019
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