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OPIOID USE AND ABUSE

Changing practices to address the public health crisis

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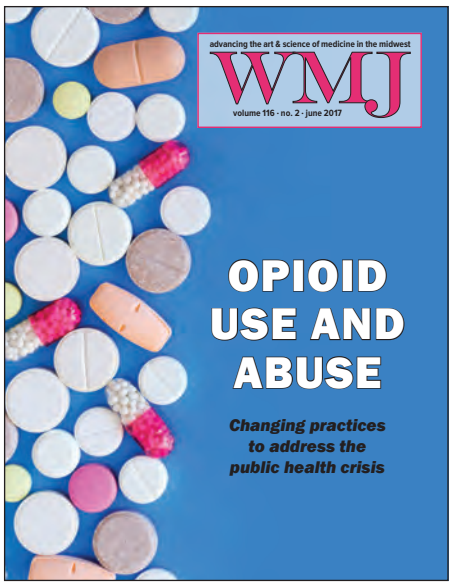

COVER THEME
Opioid Use and Abuse: Changing practices to address the public health crisis

Opioid abuse is a major concern in the United States. From 1999 to 2015, more than 183,000 people in the United States died of opioid-related overdose, and in 2013 alone, an estimated 1.9 million people abused or were dependent on prescription opioid medication. In this issue of *WMJ*, authors explore ways to address the problem as it connects to the practice of medicine.

Cover design by Stefanie Klett

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CASE REPORTS

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How Physicians Can Save 56 Hours Per Year

To the Editor:

Modern health care delivery, especially in primary care, has become increasingly complex. As the system has migrated from paper records to electronic health records (EHR), many benefits and unintended consequences have been noted. While adoption of the EHR has led to better organization of huge amounts of data, it also has resulted in a significant number of new tasks that add little, if any value to the clinician-patient encounter.

Primary care clinicians perform a significant number of tasks and processes within the context of a typical patient encounter. These include accessing the patient's chart securely, placing orders, reviewing data, reviewing health maintenance recommendation status, documentation of the visit, and coding/billing for the visit. It is currently estimated that primary care clinicians spend as much as 75% of their time related to a patient visit doing non—face-to-face tasks.[1] These activities often are considered low or no value to the encounter by clinicians and have led to a dramatic increase in physician burnout and frustration, as well as patient, staff, and clinician dissatisfaction. But fixing these problems often seems overwhelming to organizations.

One way to address inefficiencies in the processes is to apply industrial and systems engineering approaches by documenting current workflow processes in a primary care clinician's day. Using a "new eyes" approach, once the processes are documented and analyzed, wasteful (low or no value) steps can be identified using LEAN methods and either eliminated or made more efficient. In prioritizing projects, one can choose either complex, multistep processes and reduce the number of steps or choose less complex, fewer-step processes and reduce the number of times the process needs to be performed.

SSM Health Dean Medical Group, based in Madison, Wisconsin, performed a pilot focusing on reducing the number of double validation sign-ins a clinician must perform each day to access a patient's chart. The pilot involved implementing Single Sign-On/"tap and go" technology for clinicians at a primary care site as well as pain management and neurosurgery clinics.

Before the pilot, clinicians at SSM Health Dean Medical Group had to log in with a username and a password any time they accessed a patient's chart. The password must be changed every 90 days for security reasons. On average, primary care clinicians log in 81 times per day, taking 7 to 12 seconds per login. Approximately 24 times per day, clinicians "misfire" or type the entry incorrectly, requiring that they repeat the sign-in process. As might be expected, there are more misfires in the days and weeks following a change in password.

SSM Health worked with Imprivata to implement technology allowing the clinician or staff to sign in with double verification at the beginning of each half-day session, instead of each time they accessed the patient's chart. After the initial double verification sign-in, the clinician or staff taps their ID badge on a reader next to any computer in the department. The new procedure takes 1 to 2 seconds to perform. Thus, the number of manual sign-ins with the new technology has decreased from 125 sign-ins to 2 per full day.

Once implemented, the results of the pilots were dramatic. Using 10 seconds as the average sign-in time, going from 125 sign-ins per day to two resulted in a time savings for the average clinician of 17 minutes per day, which is 76.5 minutes per week (assuming 4.5 days of in clinic time per week), and 56 hours per year (assuming 44 weeks worked per year). Again, this savings is per person.

Following the pilot, SSM Health recommended spreading the technology across the 4 states where it provides services. Once completely implemented, it is anticipated that the increase in physician satisfaction will be significant.

In summary, SSM Health Dean Medical Group piloted a new workflow using Single Sign-On/"tap and go" technology that resulted in huge projected time savings for physicians and staff, as well as improved satisfaction. This represents an obvious win-win situation.

—Philip A. Bain, MD, Madison, Wis

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Wisconsin Medical Society

Practical Psychology

Editor's Note: The following editorial was published in WMJ*, July, 1967; Volume 66, No. 7, p. 283.*

The Milwaukee Journal recently pointed its editorial finger at the consistently negative attitude of organized medicine first toward the establishment of Medicare and now toward its expansion. The newspaper noted that Medicare is here to stay and that it will probably be expanded despite the opposition of the American Medical Association. "It would be better," concluded the Journal, "if expansion came with medicine's cooperation and support."

Contrary to the predictions of spokesmen for the AMA and the anticipation of many doctors, the establishment of Medicare has not meant the end of free enterprise in the practice of medicine. It has not significantly interfered with the relationship between doctor and patient, and it apparently has eased the burden of health care costs for many elderly people. Social Security costs have increased for the entire population and the volume of paperwork imposed on doctors has risen precipitously but, on balance, Medicare probably must be assessed as a positive value.

What Medicare might have been without the consistent opposition of organized medicine is hard to say. Unquestionably the opposition served to limit excesses that might have been written into the bill; the moderate, non-disruptive character of the present program derives from the creative democratic process that produces something less than the proponents wanted to have and something more than the opponents wanted to permit.

Opposition is not useless when it is realistic and constructive. Unfortunately, the medical profession has a reputation in some quarters for blind, mindless opposition for the sake of opposition. As the Milwaukee Journal suggests, organized medicine has an important role in the planning of future health care programs. The programs are going to come about anyway, and it would be better for the representatives of medicine to approach their problem positively. It is psychologically smarter to take a position of approval *with amendments* rather than simple opposition. To work to curb excesses, to limit extremes, to modify and control is not to compromise principle. It is, instead, to participate, and by participating, to act in a responsible, socially valuable manner.

—D.N. Goldstein, MD, Kenosha, Editorial Director

An Epidemic, a Scourge, or a Plague

John J. Frey, III, MD, Medical Editor

Ebola and Zika viruses are infectious diseases that spread and reached numbers that fit comfortably into the strict World Health Organization and Centers for Disease Control and Prevention definitions of epidemic. HIV has been there for almost 40 years. There undoubtedly will be more of these types of epidemics as zoonoses are out there lurking and climate changes have the potential to unleash many more national and international epidemics.[1]

However, calling the dramatic increases in the prevalence of type 2 diabetes, obesity, and other other chronic diseases "epidemics" has the potential to shift attention for addressing these increases away from human behavior and society toward medical or surgical solutions. Medicalizing a societal problem ignores all the "upstream" issues that helped bring it into being. Referring to the large increase in opioid overdoses and related deaths as an epidemic calls attention to the problem, but the term doesn't help physicians and mental health professionals, the pharmaceutical industry, hospitals and health systems, families, and societal forces—all of which have been complicit in creating the current situation over the past 50 years. An emphasis on medicalization and cure can cause people to pay less attention to root causes, which is where the hard work has to be done.

Opioid overuse is a problem that must be addressed in a deliberate, evidence-driven, compassionate way. Physicians have to own what we helped create but need help from every level of our communities to change the direction of the problem. This issue of the *WMJ* contains several articles that address the problem of opiate overuse as it connects to the practice of medicine.

Prince and Seiden offer suggestions in their commentary[2] that range from becoming more consistent about the monitoring and prescribing of opioids in clinical practice to policy about public education, harm reduction, and the expansion of treatment and mental health over incarceration. Most of what they recommend in the clinical realm have been or are being implemented in the large health systems that dominate the state of Wisconsin and most electronic health records are set up to remind clinicians of what they suggest. However, their list of recommendations summarizes very well the areas that must be used as part of the prevention and treatment of opioid-addicted patients.

Opioid overuse is a problem that must be addressed in a deliberate, evidence-driven, compassionate way. Physicians have to own what we helped create but need help from every level of our communities to change the direction of the problem.

The use of emergency departments (ED) and urgent care centers for pain and pain control creates challenges for opioid management. Often ED and urgent care, particularly in smaller hospitals and freestanding centers, may not have access to patient records in a way that would let them make clinical plans consistent with the case managers and primary care clinicians who manage most of opioid prescribing. Hernandez-Meier[3] and colleagues carried out a study of the use of the state's electronic Prescription Drug Monitoring Program (PDMP) by ED physicians. Although the use of the enhanced PDMP became mandatory April 1, 65% of physicians queried used the program during the study period and virtually everyone found it useful and changed their prescribing as a result. Barriers of time and documentation made the use of the PDMP difficult, but fortunately it is not a big gap between pre- and post-mandatory use.

Office management, particularly in pain clinics, needs to move away from individual management of opioid use to a registry and population management process that captures all patients in a practice and uses a registry and team process to improve care. Koschak and colleagues describe a quality improvement process that should be a model for pain clinics.[4] The authors offer some examples of data sheets and team care that assure that patients are monitored and receive best-practice care.

Looking at everyone in a practice to find patterns is essential to practicing successfully in the 21st Century.

And finally, occupational medicine is another important place where medical care, pain management, and functional assessment are managed. Vasudevan offers a perspective from employee health that is similar to the other examples in this issue and represents a fortunate coalescence of management that, if used, will at least begin to make consistent care of pain and opioid prescribing across systems in communities.[5]

Genomics, genetics, and human behavior

Someone once asked how family doctors keep up with all the new developments emanating from basic and clinical research and my answer is that we can't. The challenge is to be able to determine which new direction in basic research is likely to translate into important progress that should be applied widely to populations. Genetics and genomics are 2 areas that hold great promise but may not be thought currently of as a part of everyday practice. So it is no surprise that McCauley and colleagues found in a survey of Wisconsin physicians that adult generalists were less likely to know about genetics, genetic testing, and use it in their practices than specialty clinicians.[6] There was also a split in the group by age, with younger physicians—who undoubtedly had genetics as a larger part of their training—more inclined to do testing.

A hospital-based case control study from a large Midwest health system looked at the relatively unusual syndrome of heparin-induced thrombocytopenia and found a high level of comorbidity with a number of known autoimmune disorders.[7] These findings should be kept in mind whenever a patient with an existing autoimmune disorder requires anticoagulation, or a patient who develops the syndrome should be investigated for an autoimmune disorder. Further research about this syndrome no doubt will involve genetic studies.

Programs to increase hand washing by staff as an indicator process have been used as ways to change the culture of a medical system or hospital. A study from the Veterans Affairs System by Bittner and colleagues randomized patients in intensive care units and medical-surgical wards and studied their and their family members' willingness to remind physicians to wash their hands as they entered the room.[8] Despite most patients saying they were willing to remind their physicians, and despite information outside of each room on hand washing, mentioning hand washing to physicians was unusual in great part because patients in hospitals are often too ill to engage. It well may not be helpful to depend on patients and families as part of a reminder system.

Saporta and colleagues report a very unfortunate and thankfully rare complication of cardiac ablation treatment.[9] The patient developed an atrioesophageal fistula that seeded her brain and led, through a complex series of clinical complications, to her death. No procedure, no matter how frequently done, is without possible consequences.

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The National Opioid Epidemic: Local, State, and National Responses

Joel M. Prince, MD; William B. Seiden, MD, FACP

After falls, the leading cause of accidental death in 2013 among all Wisconsin residents was drug overdoses. That year, prescription opioids such as oxycodone, hydrocodone, and methadone were involved in 45% of these overdoses.[1] Nationally, overdoses are the number one cause of unintentional injury deaths among 25 to 65 year olds.[2]

Prescription opioids were developed to treat the pain associated with terminal conditions like cancer, end-of-life pain, and severe acute pain following surgery. In the 1990s, the concept of pain as the "fifth vital sign" was developed by the Veterans Affair Hospital System with the thought that pain was undertreated. The American Pain Society quickly adopted and propagated this view, resulting in professional and consumer groups advocating for increased use of opioids for management of chronic, nonterminal pain. Coincidently, in 1996, Purdue Pharmaceuticals released OxyContin, an extended release form of oxycodone, that was touted in an aggressive marketing campaign as having less abuse potential than short-acting opioids. In 2000, the Joint Commission for Accreditation of Hospital Organizations' Ambulatory Care Division launched a campaign in partnership with Purdue Pharmaceuticals advocating patients' right to effective pain assessment, thus perpetuating the treatment of pain as a vital sign. The addiction and abuse potential soon became clear as this original OxyContin could be chewed, crushed, snorted, or injected, producing a high similar to heroin. This is of concern because 1 in 4 patients prescribed prescription painkillers will transition to long-term use.[3] In the United States, the number of prescriptions written for opioids increased by 300% between 1991 and 2009.[4] In 2007, Purdue Pharmaceuticals pleaded guilty to misleading marketing regarding the abuse and addiction potential of OxyContin, resulting in a $634.5 million fine.[5]

Evidence supporting the efficacy of long-term opioid use over nonopioid therapy for chronic pain treatment is poor outside of the setting of end-of-life care and must be weighed carefully against the substantial risks.[6] Studies suggest that opioids for chronic pain actually may increase pain and decrease functional status by potentiating pain perception.[7] Chronic opioid therapy is associated with an increased risk of myocardial infarction; heart failure; respiratory depression; opioid-associated androgen deficiency; osteoporosis; fractures secondary to increased falls; immunosuppression; opiate-induced hyperalgesia, addiction, and misuse; fatal and nonfatal overdose; and all-cause mortality.[8] Risk for overdose clearly increases in a dose-response manner with markedly greater risk at doses of 90 or more morphine milligram equivalents (MME) per day.[6]

Prior to initiating opioids, other pharmacologic options should be considered. Nonopioid pharmacologic options include acetaminophen, NSAIDs, Cox-2 inhibitors, duloxetine (particularly for chronic pain related to fibromyalgia or coincident with depression), gabapentin (particularly for neuropathic pain), other antidepressants, eg, tricyclics and topical analgesics.[9] Nonpharmacologic modalities include physical therapy, massage, manipulation, physical activity and weight loss, cognitive behavioral therapy, and treatment of comorbid mental illness.[9]

The 2016 Centers for Disease Control and Prevention (CDC) Guideline[6] is consistent with contemporary review papers along with platforms from the American Medical Association (AMA), American College of Physicians (ACP), and the Wisconsin Medical Society. We strongly support the CDC guideline: providing direction for clinicians, recommendations for health systems and legislatures, and awareness of the issues nationally. The guideline provides practicing clinicians a structure for safe prescribing of opioids and guidance with patient discussions. (See Box 1.)

We also strongly support and advocate for the dissemination of the 2016 Wisconsin Medical Examining Board (MEB) Opioid Prescribing Guideline.[10] This guideline closely follows the CDC guideline for evidence-based best practices and adds specific recommendations to indications, dosing, follow-up, discontinuing opioids with specific tapering regimens, and assessing risk and mitigating harms of opioid use. (See Box 2.)

Additionally, we applaud the Food and Drug Administration (FDA) for its proactive response to prescription opioid abuse.[11] The FDA supports development of abuse-deterrent formulations of opioids, expanding availability of lifesaving reversal agents like naloxone and prioritizing approval of nonopioids for pain. Manufacturers of long-acting opioids are now required to have stricter labeling, post-market safety and outcomes research, and funding of voluntary continuing medical education for prescribers referred to as Risk Evaluation and Mitigation Strategy (REMS).

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Box 1. Summary of Centers for Disease Control and Prevention Guideline

1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Opioid therapy should be considered only if the expected benefits in both pain and functional improvement are anticipated to outweigh risks to the patient. Additionally, if opioids are used, they should be combined with nonpharmacologic therapy.
2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals which include both pain control and functional improvement.
3. Clinicians should discuss with patients known risks and realistic benefits of opioid therapy.
4. When starting opioid therapy, clinicians should prescribe immediate-release opioids instead of extended-release opioids. Methadone is not the first choice for a long-acting opioid and should be only used by clinicians with special expertise.
5. When opioids are started, clinicians should use the lowest effective dosage. Clinicians should carefully assess individual risks/benefits when considering dosages of 50 morphine milligram equivalents (MME) or more per day, and must carefully justify a decision to prescribe 90 MME or more per day.
6. For acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and in no greater quantity than the expected length of severe pain requiring opioids, a duration of 3 days in most cases while more than 7 days will rarely be needed.
7. Benefits and harms of opioid therapy should be reviewed with patients within 1 to 4 weeks of starting therapy or escalating dose, and at least every 3 months thereafter.
8. Clinicians should incorporate strategies to mitigate opioid risk into the management plan, including offering naloxone when factors are present that increase risk for opioid overdose. Providers should avoid prescribing opioids to patients with moderate to severe sleep apnea due to increased risk for overdose. Other patient populations requiring closer monitoring include patients with renal or hepatic impairment, over age 65, with mental health conditions, and with a history of substance abuse. Additionally, caution should be exercised in patients with a history of prior nonfatal overdose. Secure storage is essential to help prevent diversion or overdose risk posed to household members, particularly children and young adults.
9. Clinicians should review prescription drug monitoring programs at the initiation of opiate therapy and at least every 3 months thereafter to determine if high drug dosages, dangerous combinations of prescriptions, or multiple prescribers place the patient at increased risk.
10. Clinicians should consider using urine drug testing at initiation of opioid therapy and at least annually thereafter.
11. Clinicians should avoid concurrent benzodiazepine use whenever possible due to increased risk for overdose.
12. Clinicians should monitor patients for opioid use disorder, such as addiction or dependence, and offer or arrange for evidence-based treatment. This may include medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies.

Adapted from 2016 CDC Guideline.[6]

To help limit the substantial risks of addiction, overdose, and death from chronic opioid therapy, we advocate for the following measures and also make special note of measures already addressed in Wisconsin.

1. ***Required use of Wisconsin's enhanced Prescription Drug Monitoring Program (ePDMP) by prescribing clinicians.*** As of April 2017, Wisconsin state law requires prescribers to review the ePDMP before prescribing any controlled substance for greater than a 3-day supply.[10] Prescribers will require education on the optimal use of the state ePDMP (offered by the Wisconsin Medical Society as one of its opioid prescribing webinars).[12] We advocate for the development of a national prescription drug monitoring program to track cross border and interstate prescriptions in an effort to avoid multiple providers/pharmacies, high opioid dosages, and dangerous combinations such as concomitant benzodiazepine use.
2. ***Mandatory physician-patient narcotic contracts with initiation of long-term opioids.*** The contracts should outline appropriate behavior, refill protocols including warnings for early or lost refills, agreement to limit refills to a single clinician and a single pharmacy, and warnings against using medications not prescribed or illicit drugs. Consequences for contract violations should be clearly outlined. Although this recommendation is not evidence-based, both the CDC and the Wisconsin MEB urge the use of narcotic contracts to detail and document the risks for adverse effects and to outline required patient behaviors to limit these risks.
3. ***Periodic urine drug screens, at least once a year, also should be mandatory and used to identify situations of drug divergence and abuse.*** This also may be beneficial in early identification of patients who are at risk of polypharmacy overdose. Additionally, we encourage the development of urine drug screen standardization at the national level.
4. ***Prescriber education about the appropriate use and risks of opioid therapy is much needed as most US clinicians have not received such formal training.*** The Drug Enforcement Administration Office of Diversion Control should mandate opioid education programs in order to renew licenses for those clinicians prescribing scheduled drugs. More than 60 US medical schools, including the University of Wisconsin School of Medicine and Public Health, now require education consistent with the 2016 CDC Guideline.[13] The American Medical Association and other national organizations have developed online self-education programs for the safe prescribing of opioids. The Wisconsin MEB now requires that all DEA licensees complete an approved 2-hour course on its guideline from the course's approval date through the calendar year of 2017 and again during 2018-2019.[14] A Wisconsin Medical Society opioid prescribing webinar satisfies this requirement.
5. ***Medical systems, health plans, and insurers should play an increased role by closely monitoring opiate prescriptions for possible abuse, misuse, and unsafe prescribing practices.*** Organizations should develop and mandate medical informatics systems to promote safe prescribing. Ideally, local health care systems should be proactive about identifying additional targeted educational opportunities for practitioners prescribing outside standard parameters as outlined by new guidelines. We also call for prescription plans to end financial incentives for 90-day supplies of opioids, as this practice significantly increases the risk for overdose and is not conducive to tapering.[15]

Box 2. Summary of Wisconsin Medical Examining Board Opioid Prescribing Guideline

1. Assess pain to see if intensity matches causative factors and if the pain can be addressed with nonopioid therapy.
2. Start with the lowest possible effective dosage of immediate-release opioids for the shortest possible duration and the fewest number of pills. In most cases, less than 3 days and rarely more than 5 days are needed.
3. Attempt to identify the cause of pain; opioids should not be prescribed unless the underlying medical condition would reasonably be expected to cause pain severe enough to warrant opioid treatment.
4. Opioids should not be the first choice for treatment. Evidence for opioids in acute pain is weak and for chronic pain evidence is poor. There is no high-quality evidence to support the efficacy of opioids longer than 6 months in duration. Despite this fact, it is acceptable, although not preferable, to continue patients on chronic opioid therapy started prior to the Guideline release if they have not shown evidence of aberrant behavior.
5. Patients should not receive opioids from multiple providers/pharmacies.
6. Providers should avoid the use of intravenous or intramuscular opioids for exacerbations of chronic non-cancer pain in acute care settings.
7. Providers are encouraged to review the prescription Drug Monitoring Program (PDMP) prior to prescribing. After April 2017, review of the PDMP will be mandatory for prescribing opioids for greater than 3 days duration.
8. Pain from acute trauma or chronic inflammation can often be managed with non-opioids prior to surgery. Surgery outcomes are improved without opioids prior to surgery, ie, less surgical complications and improved patient satisfaction.
9. Avoid coprescribing benzodiazepines as the combination triples the already high annual mortality rates from overdose.
10. Oxycodone use is discouraged due to increased abuse and addiction potential compared to other opioids.
11. Patients presenting for chronic pain treatment, in addition to targeted history and physical exam, should be evaluated for conditions which may affect therapy such as:
    - Coexisting illnesses, ie, respiratory disease, sleep apnea, renal insufficiency.
    - Personal or family history of substance abuse.
    - History of psychiatric disorders associated with opioid abuse, eg, bipolar, attention deficit hyperactivity disorder, borderline personality disorder, uncontrolled depression.
12. Prior to starting opioids, objective symptomatic and functional goals should be established, with a plan for discontinuation if not met.
13. Risk/benefit ratio should be assessed continually. If evidence of increased risk develops, opioids should be weaned or discontinued with treatment for withdrawal. Components of ongoing risk assessment include review of the PDMP, periodic urine drug testing, periodic pill counts, and violations of the opioid agreement.
14. All patients on chronic opioid therapy should have informed consent agreements, which should detail specifically possible significant adverse effects including addiction, overdose, and death. The agreement also should outline required patient behaviors to ensure that they remain safe.
15. Initial dose titration should start with short-acting opioids.
16. Opioids should be prescribed in the lowest effective dose for the shortest possible duration. Caution should be noted for dosages above 50 MME and, given no evidence to support dosages over 90 MMEs along with dramatically increased risks for overdose and death, appropriate justification for use should be carefully documented in the chart.
17. The use of methadone is not encouraged unless the prescriber has extensive training or experience in its use. Methadone has variable metabolism, multiple drug interactions, and can have a potent effect on prolonging the QTc, increasing the risk for fatal arrhythmias.
18. Prescribing of opioids is strongly discouraged for patients abusing illicit drugs, as these patients are at extremely high risk for abuse, overdose, and death.
19. During initial opioid titration, patients should be re-evaluated every 1 to 4 weeks and during chronic therapy, at least every 3 months.
20. Practitioners should consider co-prescribing naloxone for patients at high risk for overdose as evidenced by aberrant behaviors, dosages over 50 MME per day, clinical depression, and history of overdose, which alone is a relative contraindication to chronic opioid therapy. Family members can be prescribed naloxone for use with the patient.
21. All prescribing practitioners are expected to provide care for potential complications of the treatments they provide, including opioid use disorder, by either directly providing medication-assisted treatment or referral to an addiction treatment center that is willing to accept the patient.
22. Discontinuing Opioid Therapy: Consider tapering or discontinuing if circumstances warrant.
    If lack of efficacy is determined, opioid weaning can be performed by tapering the MED by 10% weekly and then discontinued when tapered to 5mg to 10mg MED.
    - If evidence of increased risk develops, opioid weaning can be performed by tapering the MED by 25% weekly and then discontinued when tapered to 5 mg to 10mg MED.
    - If evidence of imminent danger (addiction, overdose) or diversion, opioids should be discontinued immediately and the patient should be treated for withdrawal. Exceptions requiring slower taper include patients with unstable angina and pregnant patients, as withdrawal may precipitate angina and preterm labor, respectively.
    - Prescription of clonidine 0.2mg by mouth (po) twice a day or tizanidine 2mg po 3 times a day can be provided to patients complaining of opioid withdrawal related symptoms.

Adapted from the 2016 Wisconsin Medical Examining Board Opioid Prescribing Guideline. [14]

6. ***Targeted public education and awareness of the many potential harms of opioid treatment should be strengthened for high-risk groups, teenagers, and parents of teenagers.*** A recent CDC survey found that 1 in 5 high school students had taken a prescription drug without a prescription. Community outreach is necessary to curb the epidemic by education and cultural change. In fiscal year 2015, the CDC committed $20 million to launch safe opioid prescribing programs in 16 states. The AMA, ACP, and many other national organizations have developed public education and physician education campaigns. At the state level, in 2016 the Wisconsin Attorney General launched a campaign called "A Dose of Reality" to educate the public regarding the dangers of prescription painkiller misuse.

7. ***When opioid prescriptions are justified, care must be taken to ensure that prescriptions are not diverted, intentionally or otherwise.*** According to the National Survey on Drug Use and Health, over 67.6% of people who reported nonmedical use of prescription drugs obtained their supplies from friends or relatives.[16] Patients must be educated regarding the importance of locking up prescriptions

and making sure they are not being diverted by theft or by family members.[12] Prescribers must be educated to prescribe the lowest effective dose of short-acting opioids for a period no greater than that which would be expected for the severity of pain: "3 days or less will often be sufficient; more than 7 days will rarely be needed."[6]

8. ***Legislation for closer monitoring and tighter regulation of opiate prescribing, both at the state and federal level, is essential.*** Tighter oversight by regulatory agencies like the DEA could make clinicians, health care systems, and insurance carriers more accountable for prescribing patterns. In 2016, the AMA organized a task force to reduce opioid abuse and is working at the federal and state levels to address the prescription drug abuse and diversion crisis. In addition, the Wisconsin Legislature has passed 17 bills known as the Heroin, Opioid Prevention and Education (HOPE) Agenda aimed at prevention and treatment of the growing heroin and prescription drug epidemic.
9. ***Harm reduction strategies should be implemented at the local, state, and national levels.*** Practitioners should consider prescribing naloxone for patients at higher risk for overdose and those on opioid doses over 50 MMEs/day as recommended by the MEB Guideline. Furthermore, in August 2016, Wisconsin passed the first of the HOPE bills, which provides standing orders for pharmacies to dispense naloxone, without a prescription, to any person in a position to assist an individual at risk for opioid-related drug overdose. Many local police departments and pharmacies nationally are installing safe medication disposal units, providing a necessary outlet to properly dispose of unused medication.[13]
10. ***Lastly, and perhaps most importantly, increased availability, access, funding, and support for behavioral health, substance abuse, and addiction services is paramount.*** Prescribers should be able to provide medication-assisted treatment or refer patients to local addiction treatment centers.[10] Yet, sadly, affordable and timely access to treatment centers is one of the biggest barriers to long-term success in combating the opioid epidemic. Local, state, and federal resources should be allocated to lifesaving, quality addiction treatment centers and improved access to behavioral health clinicians to treat mental illness comorbidities and support healthy decisions. Complementary, psychological, and multidisciplinary therapies also are effective for chronic pain, but often cost is a barrier for patients.[6] In response, a federal task force was created in March 2016 to implement federal parity protections intended to ensure that health plans' coverage of mental health and substance abuse disorder benefits are comparable to coverage of medical and surgical benefits.[13] At the state level, guaranteed coverage also could be driven by requiring all insurers—including public options—to cover the costs of substance abuse treatment, including medication-assisted treatment, multidisciplinary treatment teams, mental health services, and recovery support.[17]

Advancing the understanding of the prescription drug epidemic through ongoing education and community outreach needs to occur at the office, health system, state, and national levels. We are very encouraged by physician education at the office level, new opiate prescribing policies, and electronic databases at the health system level; new legislation (HOPE Agenda bills), new prescribing guidelines (the MEB Opioid Prescribing Guideline), prescriber education (the Wisconsin Medical Society opioid prescribing webinars), and public education (Dose of Reality) at the state level; new federal funding to support expanding access to treatment along with parity protections, the CDC 2016 opioid prescribing guideline, and national organization involvement in public and physician education at the national level. The wheels of change have been set in motion, but success will require a cultural sea change.

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Opioid Use for Treatment of Chronic Pain: An Overview and Treatment Guideline for Injured Workers

Sridhar V. Vasudevan, MD, for The Health Care Advisory Committee of the Wisconsin Worker's Compensation Division, Department of Workforce Development

Opioid misuse and abuse leading to deaths is an urgent problem facing the American public, and prescription of opioids by physicians is one of several reasons attributed to the sudden escalation of this crisis. To address the issue, the Centers for Disease Control and Prevention (CDC) issued its Guideline for Prescribing Opioids for Chronic Pain in March 2016. Prior to that, however, the members of the Wisconsin Worker's Compensation Health Care Provider Advisory Committee (HCPAC) raised concerns regarding excessive prescribing of opioids for patients injured at work who are covered by the Wisconsin Worker's Compensation System.

This commentary describes the complexity and challenges of pain management, especially chronic pain, and the Committee's development of *Chronic Opioid Clinical Management Guidelines for Wisconsin Worker's Compensation Patient Care*.

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Challenges of Managing Individuals With Chronic Pain

Acute pain that accompanies an injury, illness, or surgical procedure usually resolves with appropriate treatment—or without treatment—in 6 to 8 weeks. Chronic pain, however, generally serves no biological purpose, persists beyond its healing period for the condition, and leads to significant functional decline.[1] It frequently is described as "pain that occurs on at least half the days for 6 months or more,[2] and the prevalence of people experiencing chronic pain in the United States is estimated at nearly 11.2% of the adult population.[3]

Since the early 1960s, chronic pain has been recognized as a biopsychosocial problem, which led to the development of multidisciplinary pain management programs. But despite copious research on the effectiveness of programs that use multimodal treatment for chronic pain, and the dearth of evidence for single modality approaches such as opioids, injection/interventional procedures, and surgery, over the past 2 decades there has been a decline in these programs in the United States (while at the same time such programs are developing in other parts of the world).[1]

Individuals with chronic pain frequently demonstrate several "Ds": *Dramatic* verbal and nonverbal pain behaviors, *Disuse* of body parts with pain, *Deconditioning*, eg, generalized disability that exceeds the degree of identifiable objective medical findings, *Depression*, and *Drug* misuse/abuse, especially with excessive use and dependence on opioids.[1]

Both natural and synthetic opioids can be a very effective part of pain management. They are the first-line drugs for many patients with post-operative and post-injury pain—with evidence supporting short-term efficacy of opioids in randomized clinical trials lasting primarily 12 weeks or less. However, opioid use also presents serious risks and there is minimal evidence-based research to support their effectiveness in treating chronic pain.[4,5]

Meanwhile, primary care clinicians report that they find managing patients with chronic pain to be stressful. They have concerns about opioid pain medication misuse, patient addiction, and insufficient training in prescribing opioids,[6,7] which has helped fuel the development of numerous educational programs and various guidelines related to the use of opioids.

Prescription Opioid Abuse

Opioid abuse is currently a major concern in the United States. In 2013 alone, an estimated 1.9 million people abused or were dependent on prescription opioid medication.[7] And from 1999 to 2015, more than 183,000 people in the United States died of opioid-related overdose.[8] The number of deaths from "opioid abuse disorder" is estimated to be higher than the number of deaths from motor vehicle accidents.[10]

As awareness of this growing problem has increased, numerous medical organizations, governmental agencies and state and federal policymakers sought ways to address it.

For example, in 2015 the American Medical Association (AMA) created a "Task Force to

Box 1. Worker's Compensation Advisory Council, Health Care Provider Advisory Committee Members

Mary Jo Capodice, DO, MPH, Sheboygan, Wis	Jeff Lyne, DC, Sun Prairie, Wis
Theodore Gertel, MD, Mequon, Wis	BJ Dernbach, Chair, Madison, Wis
Amanda Gilliland, Madison, Wis	Jim Nelson, Fort Atkinson, Wis
Richard J. Goldberg, MD, Skokie, Ill	Barb Janusiak, RN, West Allis, Wis
Jennifer Seidl, St. Francis, Wis	Peter Schubbe, DC, Appleton, Wis
Maja Jurisic, MD, Brookfield, Wis	Ron H. Stark, MD, Brookfield, Wis
Stephen Klos, MD, Whitefish Bay, Wis	Sri Vasudevan, MD, Belgium, Wis

Reduce Opioid Abuse," whose objectives are to increase physicians' use of effective Prescription Drug Monitoring Programs; enhance physicians' education on effective, evidence-based prescribing; reduce the stigma of pain and promote comprehensive assessment and treatment; reduce the stigma of substance use disorder and enhance access to treatment; and expand access to naloxone in the community and through co-prescribing.[11]

In addition, many organizations have attempted to address this problem by developing guidelines for treating chronic pain, including the CDC, which in 2015 released its "Guidelines for Prescribing Opioids for Chronic Pain-United States."[12] It is detailed, comprehensive, and practical and serves as an important resource for clinicians prescribing opioids.

At the state level, Wisconsin has been recognized as a national leader in its efforts to reverse this problem. Since 2013 the state legislature has enacted 17 bills as part of the Heroin, Opioid Prevention and Education agenda.[13] In 2016, the Wisconsin Medical Examining Board released its Opioid Prescribing Guideline,[14] based on the CDC Guideline, and made education on the guideline mandatory for all physicians with a US Drug Enforcement Administration number to prescribe controlled substances.

Prior to the publication of either of these guidelines, however, the Wisconsin Division of Worker's Compensation released *Chronic Opioid Clinical Management Guidelines for Wisconsin Worker's Compensation Patient Care.*[15]

Wisconsin Worker's Compensation Background and Guideline

The original Wisconsin Worker's Compensation (WC) Act was adopted on May 3, 1911, making Wisconsin the first state in the country to enact a constitutionally acceptable worker's compensation program. Administered by the Wisconsin Division of Worker's Compensation, the program is designed to ensure that injured workers receive required benefits from insurers or self-insured employers; encourage rehabilitation and reemployment for injured workers; and promote the reduction of work-related injuries, illnesses, and deaths. Most Wisconsin employers are required by law to have worker's compensation insurance and nearly all workers in Wisconsin are covered.[16]

The Worker's Compensation Advisory Council (WCAC) was created to advise the Department of Workforce Development and legislature on policy matters concerning the development and administration of the worker's compensation law. Comprised of representatives from Labor and Management, the WCAC submits recommendations for law changes to the legislature each session and reports its views on any pending WC bill to the proper legislative committee.

The Health Care Provider Advisory Committee (HCPAC) assists the WCAC in these efforts by establishing treatment guidelines used by the Worker's Compensation Division. (See Box.) Comprised of physicians and other health care professionals, the committee meets regularly several times a year to address concerns regarding the appropriate evaluation and treatment of injured workers and makes recommendations to the WCAC.

In 2012, there were 23,579 claims stemming from workplace injury filed with the Wisconsin Workman's Compensation Division. The leading cause of injury was strain due to lifting, pushing, and pulling (45%); followed by falls and slips (23%).[17]

Also in 2012, the HPAC began to recognize opioid prescription abuse and misuse among injured workers as a growing concern. Over the next 2 years, the committee reviewed existing research and guidelines, which eventually led to the development by consensus of *Chronic Opioid Clinical Management Guidelines for Wisconsin Worker's Compensation Patient Care*. To help ensure injured workers in Wisconsin receive prescription of opioids in a safe and effective manner, the guideline states, "For any worker's compensation patient who will need opioid treatment for a period of more than 90 days, the treating physician should follow these guidelines and/or consider referral to a pain management specialist."[15]

The full guideline is available on the Worker's Compensation Division's Website at https://dwd.wisconsin.gov/wc/medical/pdf/CHRONIC%20OPIOID%20CLINICAL%20MANAGEMENT%20GUIDELINES%20.pdf and addresses the following:

1. Adequately evaluating the pain generator.
2. Presenting non-opioid options to the patient.
3. Patient criteria for long-term opioid therapy.
4. Required documentation and management on initial and subsequent visits for patients on, or starting, chronic opioids.
5. Opioid dosing and guidelines.
6. Alternative pain medications to opioids.
7. Addiction, pseudo-addiction, and aberrant behaviors definitions.
8. Tapering and discontinuing opioids.
9. When subspecialty consultation should be considered.

The HCPAC members voted unanimously to adopt this guideline in October 2014 and it has been available through the WC website to physicians and other health care professionals who treat injured workers since then.

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The Use of a Statewide Prescription Drug Monitoring Program by Emergency Department Physicians

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ABSTRACT

Background: Little is known about how emergency physicians have used Wisconsin's Prescription Drug Monitoring Program (PDMP).

Objective: To characterize emergency physician knowledge and utilization of the program and how it modifies practice.

Methods: Online survey data were collected 1 year after program implementation. Descriptive statistics were generated and qualitative responses were grouped by content.

Results: Of the 63 respondents, 64.1% had used the program. Lack of a DEA number and knowledge about how to sign up were the most common barriers to registration. Over 97% of program users found it useful for confirming suspicion of drug abuse and 90% wrote fewer prescriptions after program implementation. Time constraints and the difficult log-in process were common barriers to use. More users than nonusers stated that their workplace was supportive of program use.

Conclusions: Although barriers exist, PDMP utilization appears useful to emergency physicians and associated with modifications to patient management.

INTRODUCTION

In 2014, unintentional poisoning was the leading cause of injury deaths in the United States,[1] approximately 56.% of which were related to prescription drugs.[2] After falls, drug overdose was the leading cause of Wisconsin injury deaths in 2013 and has surpassed motor vehicle traffic deaths since 2008.[3] Multidisciplinary efforts are needed to address this epidemic at national, state, and local levels.

States have responded to increases in prescription drug misuse and overdoses by implementing prescription drug monitoring programs, also known as PDMPs, which are statewide databases that collect information on scheduled and other selected drugs that have been dispensed.[4] These programs serve several purposes, including to identify and prevent drug abuse and diversion and to identify and treat patients abusing or dependent on prescription drugs.[4] Currently, 49 states either have operational programs or are in the process of implementing one.[5] In 2013, Wisconsin implemented a fully operational PDMP.[6] Dispensers and prescribers, their delegates, and other approved individuals[4] have access to the database.

Most prescription drug monitoring programs became operational in the last decade[6] and more evaluation on barriers and facilitators to program utilization, and how these programs affect clinical practice is needed. It is important to note that effective April 1, 2017, Wisconsin 2015 Act 266 requires physicians and other prescribers to review a patient's records from the ePDMP before issuing a prescription order for a controlled substance, with limited exceptions.[7] However, this study sought to examine how Wisconsin emergency physicians used the PDMP prior to the mandate. To that end, we sought to examine how emergency physicians use the Wisconsin program. These physicians are in a unique position as they care for patients—many with whom they have no prior physician-patient relationship—who present with acute and chronic pain complaints. This study aimed to determine what emergency department physicians know about the Wisconsin PDMP, their opinions of the program, and how it affects their clinical decision-making.

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METHODS

Study Population

This cross-sectional observational study was approved by the Human Research Protection Program at the Medical College of Wisconsin. Eligible participants included those members of the Wisconsin Chapter of the American College of Emergency Physicians who were on the organization's electronic contact list at the time of survey dissemination (N=386). Electronic study invitations and a survey link were disseminated to members on behalf of the researchers. Monetary incentives were not provided.

Prescription Drug Monitoring Program Questionnaire

The authors developed a deidentified questionnaire with 36 items. Initial questions identified respondents who had utilized the Wisconsin program during an emergency department shift. Those who were unaware of the program (n=2), aware but not registered (n=15), and registered but had not utilized it (n=5) were skipped out of subsequent questions related to program utilization. The 41 remaining respondents answered questions related to why, when, and how often they accessed the system. They also were asked about ease of use and impact on prescribing behaviors. Finally, all 63 respondents were asked about demographics, usefulness of the program, their past behaviors when they suspected patients were abusing prescription medication, and how the program had been promoted at their workplace. A final open response question provided opportunity for additional comments about the program.

Data Preparation

Continuous age was recoded into 10-year categories. A dummy variable was created to differentiate respondents on whether they had ever used the program during a shift. Skip patterns and minimal missing data resulted in varying response rates across questions. Content analysis was used to group qualitative comments and describe them with frequency counts and text quotations.

Data Analysis

Staff utilized STATA and results are descriptive in nature without hypothesis testing. Population estimates of Wisconsin emergency physicians from a Wisconsin Medical Society administrative database (N=459) were used to determine the "representativeness" of the study sample. A Chi-square goodness of fit test with Yate's correction for continuity and 2-tailed 1-sample Student's t-tests were used to compare the distributions of gender, age, and years of practice of responders and emergency physicians in the population database (expected proportions of .209 for females and .791 for males; continuous age [μ=50.2, σ=10.3] and years in practice [μ=22.45, σ=10.3]).

RESULTS

Sample Characteristics

Surveys were completed by 63 respondents for a response rate of 16.3%. Respondents practiced in 28 Wisconsin counties, with Milwaukee and Dane counties being most represented (27.0% and 19.0% respectively). Table 1 provides respondent demographics and practice characteristics.

Table 1. Emergency Physician Respondent Demographics and Characteristics

Demographics/Characteristics	Total (n=63) No. (%)	Program Users (n=41) No. (%)
Mean age (years) *(SD)*	42.7 (11.7)	44.4 (10.8)
Mean years in practice *(SD)*	15.2 (11.6)	16.3 (10.9)
Age groups		
26-35	23 (36.5)	10 (24.4)
36-45	14 (22.2)	14 (34.1)
46-55	10 (15.9)	7 (17.1)
56-67	11 (17.5)	8 (19.5)
Sex=male	45 (71.4)	31 (75.6)
Race		
African American	1 (1.7)	0 (0)
White	56 (93.3)	39 (95.1)
Hispanic/Latino	1 (1.7)	1 (2.4)
Asian/Pacific Islander	1 (1.7)	0 (0)
Other	1 (1.7)	0 (0)
Practice setting		
Urban	22 (34.9)	12 (29.3)
Suburban	23 (36.5)	15 (36.6)
Small town	15 (23.8)	13 (31.7)
Rural	2 (3.2)	1 (2.4)
Level of training		
Attending physician	53 (84.1)	38 (92.7)
Resident	10 (15.9)	3 (7.3)
Certification status		
Board certified in emergency medicine	47 (74.6)	36 (87.8)
Eligible for emergency medicine certification	7 (11.1)	4 (9.8)
No certification	8 (12.7)	2 (4.9)
Certified in non-emergency medicine specialties	5 (8)	2 (4.9)
Had used a program in another state	18 (28.6)	30 (73.2)
Work in an Emergency Department with a pain management protocol/ pathway	39 (61.9)	26 (63.4)

No significant difference between gender proportions in our study and the population database were found $\chi^2(1)=1.81$, P=.179). There were significant differences in age t(62)= -4.74, P <.0001 and years in practice t(62)= -2.81, P <.01. Emergency physicians in the population database overall were older and had been practicing longer than our sample.

Wisconsin PDMP Awareness, Registration and Utilization

Of the 61 respondents who had heard of the Wisconsin PDMP, 24.6% were not registered. Main reported reasons for not being registered are presented in Table 2. Of the 46 registered respondents, 89.1% had used it during an emergency department shift.

Barriers and Facilitators to Wisconsin PDMP Use

Table 2 describes barriers for initiating program registration and

Table 2. Responses From the Survey Assessing Utilization, Perceived Usefulness, and Effect on Patient Management and Prescribing of the Wisconsin Prescription Drug Monitoring Program

Variable	Total (N=63)	Program Users (N=41)	Program Nonusers (N=22)
Barriers for initiating program registration (n=15)[a]			
Don't know how			6 (40.0)
No Drug Enforcement Administration Number			5 (30.0)
Too difficult			3 (20.0)
No time			3 (20.0)
Tried and declined			1 (6.7)
Won't use			1 (6.7)
Barriers for ED use in registered, nonuser respondents (n=5)[a]			
Too busy to log on			2 (40)
Forgot password or ID			2 (40.0)
Don't think about using it			1 (20.0)
Haven't needed it			1 (20.0)
Difficult log in process			1 (20.0)
Supportive workplace initiatives[a]			
Supportive of your use of the program?	39 (61.9)	30 (73.2)	9 (40.9)
Employee education and awareness	26 (41.3)	16 (39.0)	10 (45.5)
Included program in policies related to care of patients with substance issues	8 (12.7)	6 (14.6)	2 (9.1)
Distributed promotional materials	6 (9.5)	4 (9.8)	2 (9.1)
Peer support system for use	5 (7.9)	4 (9.8)	1 (4.5)
Supervisor training program	0	-	-
A printout of patients' program report at triage would encourage use	51 (81.0)	33 (80.5)	18 (81.8)
Extremely or moderately useful for patient management in the ED	59 (93.7)	39 (95.1)	20 (90.9)
Past responses to patient suspicious medication use behavior[a]			
Screened for drug use	22 (34.9)	17 (41.5)	5 (22.7)
Referred a patient to substance abuse treatment	21 (33.3)	18 (43.9)	3 (13.6)
Completed or revisited pain/ treatment agreement	21 (33.3)	11 (26.8)	10 (45.5)
Counseled on overdose risk factors, symptom recognition and response	35 (55.6)	24 (58.5)	11 (50.0)
Contacted patients' primary care physician	37 (58.7)	26 (63.4)	11 (50.0)
Referred to another provider	10 (15.9)	7 (17.1)	3 (13.6)
Conducted a urine screen	20 (31.7)	13 (31.7)	7 (31.8)
Informed law enforcement	3 (4.8)	3 (7.3)	0
Contacted patients' pharmacy	18 (28.6)	12 (29.3)	6 (27.3)
Nothing or ignored	7 (11.1)	2 (4.9)	5 (22.7)

[a]Respondents were able to choose all that applied.

Abbreviation: ED, emergency department.

use. Most of the 23 open-ended responses referenced utilization barriers, including that the system was too cumbersome (43.5%) and it takes too much time to use (21.7%). These sentiments were described in the following comments: "The biggest challenge is the multiple pages that one has to go through to get to the info needed. Would be nice to have a link that takes you directly to the site or have a printout available at triage…" and "You have a valuable tool that no one is using because it requires a separate login and times out. Emergency physicians don't have the time to do this..." Four respondents expressed high regard for the system and three expressed interest in interstate sharing of data with neighboring states.

As seen in Table 2, many respondents' work environments had engaged in supportive activities related to the program and most felt that a printout of a patient's PDMP report at triage would encourage their use of the system's information.

Perceived Usefulness, Utilization, and Influences on Clinical Behaviors

As shown in Tables 2 and 3, most respondents reported that the information in the Wisconsin PDMP was useful. Table 3 shows that respondents utilized the program for various reasons and used various criteria for determining which patients to look up. Nearly all users reported that the information sometimes or often changed their management of a patient and over 70% reported writing fewer prescriptions for some medications since implementation of the program.

Past Responses to Suspicious Medication Use Behavior

As shown in Table 2, in general, more user than nonuser respondents had ever taken some selected actions upon finding suspicious, "drug-seeking" medication use by a patient.

DISCUSSION

Overall, respondents found the program useful and users reported

changing their management of patients after viewing program information. Users also changed prescribing behaviors after the program was implemented. In other studies, prescribers reported both increasing and decreasing prescription writing after accessing a prescription drug monitoring program.[8-11] Only 1 respondent in this study reported increased prescription writing. Of note is that we asked users about prescribing since Wisconsin program implementation, not specifically for after viewing information in the program. Program presence alone could contribute some influence on prescribing behavior, even outside of utilization. Future surveys in the state should ask how actual program utilization has affected prescribing behaviors, particularly since the mandate requiring prescribers to check the PDMP went into effect.

Similar to Green and colleagues,[12] we found that in general, more users than nonusers had ever engaged in selected proactive responses when they suspected suspicious medication use. The Wisconsin PDMP may increase identification of suspicious medication use or physician willingness to engage in the selected responses. It could also be that physicians with certain experiences or personal attributes are more likely to utilize programs voluntarily.

Our results indicate that more program users than nonusers reported workplace support for its use. Like Perrone and colleagues,[9] this study found lack of time to be a barrier to use. The complex login process and user interface also were barriers. Of note is that an updated version of the PDMP–the Enhanced Prescription Drug Monitoring Program (ePDMP)–was launched in January of 2017 to address some of these barriers. Future studies that collect data from prescribers after the mandate and launch of the ePDMP could provide important feedback on how these program and policy changes impact attitudes and behaviors, especially in comparison to our data which was collected before these changes went into effect. The Wisconsin program allows prescribers to designate delegates to check the system on their behalf, and over 80% of this study's respondents said that having a printout of a PDMP report at triage would encourage their use of the information. Clinical environments could consider actively supporting program use, as well as system-level changes to facilitate the identification of delegates and efficient incorporation of the program into clinical workflows.[13]

Table 3. Affirmative Responses From the Survey Assessing Utilization, Perceived Usefulness and Effect on Patient Management and Prescribing of the Wisconsin Prescription Drug Monitoring Program (PDMP)

Variable	Total (%) N=41
How often respondents used the PDMP	
Once a week or less	12 (29.3)
2 to 4 times a week	13 (31.7)
5 or more times a week	16 (39.0)
Ease of use of the PDMP	
Somewhat or very easy to use	20 (48.8)
Somewhat or very difficult to use	15 (36.6)
Why emergency physicians use the Wisconsin PMDP[a]	
Identify Rx drug abuse	41 (100)
Confirm a patient's story	33 (80.5)
Identify a patient's provider	17 (41.5)
View a patient's current medications	15 (36.6)
Identify a patient's pharmacy	13 (31.7)
View own prescribing history	5 (12.3)
Avoid drug interactions	3 (7.3)
How respondents determine which patients to look up in the Wisconsin PDMP[a]	
Certain complaints	39 (95.1)
Patients with a history of frequent visits to the ED	38 (92.8)
Clinical intuition	37 (90.2)
Patient requests paid medications	35 (85.4)
Multiple allergies to non-narcotic pain meds	34 (82.9)
Lack of response to pain medications in the ED	14 (34.1)
All patients currently on controlled substances	6 (14.6)
All patients before prescribe a controlled substance	3 (7.3)
Useful as confirmation of clinical suspicion of drug abuse or misuse	40 (97.6)
Wisconsin PDMP sometimes or often changed patient management	37 (90.3)
Wrote more prescriptions than before the PDMP was implemented[b]	1 (2.4)
Wrote fewer prescriptions than before the PDMP was implemented[ac]	29 (70.7)
Opioids in general	26 (63.4)
Benzodiazepines	10 (24.4)
Schedule II opioids	5 (12.2)
Schedule III opioids	4 (9.8)
Tramadol	2 (4.9)

[a] Respondents were able to choose all that applied.

[b] The respondent reported writing more nonscheduled opioids.

[c] No respondents reported writing fewer prescriptions for Schedule IV opioids, barbiturates, stimulants, or antidepressants.

Our study had several limitations. We sent a reminder to complete the survey but experienced low response rates commonly reported with physician samples.[12,14] Low response rates have raised concerns about nonresponse bias or the likelihood that nonresponding physicians will be systematically different from the population under study.[14] This concern is supported by research showing modest differences between responders and nonresponders and between early and late respondents on demographic and/or practice-related characteristics.[14]

Respondents were emergency physicians who were members of a local professional association and our results cannot be generalized to all Wisconsin prescribers. Our sample was significantly younger and had fewer years of clinical experience compared to emergency physicians in Wisconsin. Future studies should survey

broader, representative samples of prescribers and within other specialties. Finally, our results are observational in nature and results should be viewed as tentative until statistical analyses are performed on a larger, more representative sample.

CONCLUSION

Respondents reported that the Wisconsin Prescription Drug Monitoring Program has value for clinical care. It is currently one of the most accessible ways for prescribers to identify patients at risk of prescription abuse and overdose and to counsel and refer patients who abuse or are dependent on controlled substances. At the same time, it may allow prescribers to more accurately treat those who are in legitimate need of prescription medications. Our results indicate that respondents found the system useful and that it influenced patient management, perhaps leading to improved prescribing stewardship. System modifications may make it more user-friendly and responsive to the needs of clinical environments. The effect of this system on clinical practice should continue to be monitored in order to maximize efficiency, usefulness, and ability to serve its purpose.

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Genetics and Genomics in Clinical Practice: The Views of Wisconsin Physicians

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ABSTRACT

Introduction: Decreasing costs and increased availability of genetic testing and genome sequencing mean many physicians will consider using these services over the next few years. Despite this promising future, some argue the present roadmap for translating genetics and genomics into routine clinical practice is unclear.

Objective: We conducted a pilot study to explore Wisconsin physicians' views, practices and educational desires regarding genetic and genomic testing.

Methods: Our study consists of an Internet survey (n=155) conducted in August and September 2015 and follow-up phone interviews with a portion of survey participants. Physicians of all specialties were invited to participate. Variables measured include physicians' general knowledge and experience regarding genetic and genomic testing, attitudes and perceptions toward these tests, testing intentions, and educational desires. Sociodemographic variables included gender, age, and medical specialty.

Results: In our exploratory survey of Wisconsin physicians, adult primary care providers (PCPs) lagged behind other providers in terms of familiarity and experience with genetic and genomic testing. PCPs in our sample were less likely than other physicians to feel their training in genetics and genomics is adequate. Physicians younger than 50 were more likely than older colleagues to feel their training is adequate.

Conclusions: Our exploratory study suggests a gap in physician education and understanding regarding genomic testing, which is fast becoming part of personalized medical care. Future studies with larger samples should examine ways for physicians to close this gap, with special focus on the needs of PCPs.

INTRODUCTION

Decreasing costs and increased availability of genetic testing and genome sequencing mean many physicians will consider using these tools over the next few years, with some projecting that sequencing will become fully integrated into standard medical care within 10 years.[1-5] The clinical utility of sequencing is recognized for certain diseases and in an increasing number of medical specialties,[5-6] with genetic and genomic medicine offering the promise of improved diagnostics and treatments – and patients asking physicians about the applicability of these technologies for their own care.[1,6-9] However, some experts caution the roadmap for translating genetics and genomics into routine clinical practice is unclear.[5]

Many physicians are hesitant to deepen their involvement with genetic and genomic technologies because of lack of knowledge, concerns over cost and reimbursement, and questions about clinical utility.[1,5,6,10-14] Adoption may be especially difficult for adult primary care providers (PCPs),[15] older physicians,[4] rural practitioners,[16] and specialists concerned about interpreting findings that fall outside their areas of expertise.[1] Despite these concerns, only a handful of studies have attempted to assess US physicians' experiences with genetic and genomic testing.[1,9,11,17-19] With these issues in mind, we designed a pilot survey of Wisconsin physicians exploring knowledge, experience, and attitudes regarding genetic and genomic testing, plans for using these tests in clinical practice, and perceived training needs. Respondents also were invited to participate in semistructured interviews to share additional answers and new insights. To date, there have been no similar studies that queried physicians of all medical specialties across an entire state.

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Table 1. Characteristics of the Sample

Distribution of Respondents by Key Sociodemographic Characteristics	Respondents N=155	
	n	%
Gender		
Male	89	57.4
Female	66	42.6
Age		
Under 30	5	3.2
30-39	22	14.2
40-49	32	20.6
50-59	45	29.0
60-69	41	26.5
70 or over	10	6.5
Race/Ethnicity		
White	130	83.9
Asian	12	7.8
Black/African-American	3	1.9
Hispanic/Latino	1	0.6
Did not answer/missing	9	5.8
Medical Specialty		
Adult primary care	67	43.2
Psychiatry	17	11.0
Pediatrics	10	6.4
Ob/Gyn	9	5.8
Surgery	8	5.2
Other	44	28.4

METHODS

The first part of this study consisted of an Internet survey in August and September 2015. (*Appendix "A" available at http://www.wisconsinmedicalsociety.org/_WMS/publications/wmj/pdf/116/2/McCauley__AppendixA.pdf*) E-mail invitations were sent to 12,564 Wisconsin physicians using a Wisconsin Medical Society mailing list. At the end of the survey, respondents were invited to participate in semistructured interviews. *(Appendix "B" available at http://www.wisconsinmedicalsociety.org/_WMS/publications/wmj/pdf/116/2/McCauley__AppendixB.pdf)* The study was developed by a multidisciplinary team with expertise in genetics and genomics, bioethics, law, biostatistics, and health communication. The Institutional Review Board at the Medical College of Wisconsin determined this study was exempt from oversight (PRO00024582) and formal consent from survey and interview participants was not necessary.

Data Collection and Analysis

Respondents provided sociodemographic information and medical practice characteristics via self-administered Internet questionnaires. Substantive parts of the survey used questions from previously published surveys.[8,16-19] Key *dependent variables* included questions on knowledge, training, and practice challenges phrased as dichotomous (yes/no) questions or as Likert-scale items that were transformed into yes/no responses. Physicians were asked about perceived benefits and learning needs, and to indicate their concerns about genetic and genomic testing from a list of 13 items. Those interested in training chose their desired modalities from a list of 12 items. *Independent variables* included age, medical specialty, and gender. While age was originally measured in 6 ranges, we chose to dichotomize physician responses into 2 categories: "younger than 50" and "50 or older." Owing to the modest size of our sample, we reduced all specialties into 6 categories: Adult Primary Care (family medicine, internal medicine, geriatrics), Psychiatry, Pediatrics, Ob/Gyn, Surgery (general surgery, neurosurgery, other surgery), and "Other." For heuristic purposes, we further reduced the data by categorizing physician specialties as either "Adult Primary Care" or "Other" specialty.

Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 22.0.[20] Our sample size precluded the possibility of using inferential statistics; thus, we ran crosstabular analyses to identify associations between all dependent and independent variables. Physicians who agreed to participate in semistructured interviews were asked 12 questions that paralleled the structure of the survey in order to provide detailed examples of physician views. Interview times varied, with an average duration of 18 minutes. Transcripts were analyzed with a 3-stage qualitative analysis process.[21] During structural coding, the principal analyst coded textual elements in each transcript corresponding with answers to the substantive questions in our interview schedule. This was enhanced by the use of QSR NVivo 10, an ethnographic data management software program. [22] This stage was followed by immersion/crystallization,[23] which involves immersing deeply in key portions of coded data and then backing away at regular intervals for reflection and second-level theme formation. The lead author performed these analytical procedures and generated NVivo output reports for cross-checking by 2 other coders. All authors reviewed the results of these processes and contributed to the summary of qualitative findings. In this study, we adhered to best practices for conducting and presenting mixed-methods research.[24]

RESULTS

Sample Characteristics

One hundred fifty-five physicians completed our online survey; their key sociodemographic and practice characteristics are reported in Table 1. More than half were men, yet the percentage of women in the sample is greater than contemporary estimates for Wisconsin physicians.[25-27] The modal age range for physicians in our sample was 50 to 59 years (29%), compared to 45 to 54 years (23%-29%) in 2 recent statewide population-based samples.[25-26] In terms of medical specialty, we slightly oversampled with respect to adult PCPs and psychiatrists. Regarding race and ethnicity, the white/nonwhite ratio in our sample is similar to that of physicians statewide.[25-27] Finally, our survey respondents were distributed evenly across urban, suburban, and rural practice settings, representing an oversampling of physicians from suburban

and rural settings. Nineteen physicians participated in semistructured interviews; they included 10 women and 9 men with a mean age of 53. Most interview participants were white, with 14 coming from urban or suburban practice settings. Six were psychiatrists, five were PCPs, and the remainder represented other specialties.

General Knowledge and Experience

Our survey results suggest physician specialty and age may be the primary drivers of key outcome variables (See Table 2). The size of our survey sample prevented us from making detailed comparisons between physicians from many specialties and subspecialties, however, PCPs in our sample were much less likely than other physicians to say they are familiar with genetic and genomic testing. In contrast, two-thirds of ob/gyn specialists and more than one-third of psychiatrists said they are familiar. PCPs in our sample were also less likely to feel adequately informed about the availability and clinical utility of these tests, while more than half of responding pediatricians said they are adequately informed. Younger physicians were more likely than colleagues 50 or older to have received formal training in genetic/genomic medicine. Finally, about 30% of physicians with practices in urban or suburban settings felt adequately informed about availability and clinical use, compared to 14% in rural settings.

The physicians interviewed generally spoke about the limited use of genetics and genomics in their own practices. However, some spoke about the promise of pharmacogenomics for fine-tuning psychiatric medications. (See Table 3 for a summary of other interview results.) While respondents said many patients are not yet asking about genetic and genomic tests, some physicians reported a heightened sense of interest in oncology applications. For example, a 44-year-old female breast surgical oncologist in suburban practice said:

> *"I see a fair amount of breast cancer patients, as well as patients who come seeking medical attention in terms of risk assessment and strategies for risk reduction for breast cancer. So, if they fit the NCCN guidelines to consider genetic testing or counseling, then that gets offered in my office."*

Some physicians said patients are asking about implications of genetic/genomic tests for prenatal concerns or as an extension of family medical history. Finally, most said the ability to use genetic and genomic testing is at least an important *consideration* in their practices, with special emphasis on select patients. Among physicians who said genetic and genomic testing is not currently important in their practice, some said testing may become important in time.

Table 2. Summary of Selected Survey Results

	Respondents	
	n	%
General Knowledge and Experience Regarding Genetic and Genomic Testing		
I am familiar with genetic/genomic testing		
Adult Primary Care Physicians	6	9.0
All Other Physicians	23	26.1
≥ 50 years old	19	19.8
Under 50	10	16.9
I have had some type of formal training in genetic/genomic medicine.		
Adult primary care physicians	18	26.9
All other physicians	30	34.1
≥ 50 years old	25	26.0
Under 50	23	39.0
I feel adequately informed about the availability and clinical applications of genetic/genomic testing		
Adult primary care physicians	8	11.9
All other physicians	30	34.1
≥ 50 years old	21	21.9
Under 50	17	28.8
Attitudes Toward Genetic Testing and Genome Sequencing		
I have sufficient knowledge to counsel patients about genetic risk for disease		
Adult primary care physicians	16	23.9
All other physicians	29	33.0
≥ 50 years old	24	25.0
Under 50	21	35.6
Testing Intentions		
I anticipate ordering/recommending a genetic/genomic test within the next 6 months		
Adult primary care physicians	29	43.3
All other physicians	44	50.0
≥ 50 years old	42	43.8
Under 50	31	52.5
Educational Desires		
I feel that my professional training in genetics/genomics is adequate		
Adult primary care physicians	2	3.0
All other physicians	19	21.6
≥ 50 years old	10	10.4
Under 50	II	18.6
I would be interested in further professional education in genetics/genomics		
Adult primary care physicians	54	80.6
All other physicians	69	78.4
≥ 50 years old	79	82.3
Under 50	44	74.6

Note: For brevity, results that pertain to specific specialties and other physician characteristics have been omitted.

Attitudes Toward Genetic Testing and Genome Sequencing

Between one-half and two-thirds of physicians in our survey sample said there are now sufficient benefits to warrant *genetic* testing for determining cancer type, prognosis, and/or targeted treatment; diagnosis of Mendelian or rare diseases; reproduction and family planning; and identifying genetic risk factors for adult-onset complex diseases. Nearly 55% said there are now sufficient benefits to warrant *genomic* testing for determining cancer type, prognosis, and/or targeted treatment. Most respondents said it is important for them to learn about a variety of new advances in genetic testing, with emphasis on determining drug and dose compatibility for a patient, and diagnosing and identifying genetic risk factors for adult-onset complex diseases. A slightly smaller major-

Table 3. Summary of Other Representative Interview Results

	Themes	Examples
General Knowledge and Experience	Limited exposure	"I don't have much experience; internists don't get much genetics/genomics training."
	What patients ask	"My patients ask about the risk of breast, ovarian or primary peritoneal cancer."
	Importance of genetic/genomic medicine	"Testing is important for certain patients regarding cardiac conditions or cancer."
Attitudes Toward Genetic Testing and Genome Sequencing	Personalized medicine is promising	"I'm interested in screening patients because my family faces certain genetic risks."
	Costs and benefits: clinical utility	"Let's get the right test to the right patients and explain the consequences."
	Concern over incidental findings	"If you test willy-nilly, you'll get noise. And noise leads to poor treatment."
Testing Intentions	Timely results for a reasonable price	"I'd like good and quick results to help patients better metabolize pain meds."
	A premium on tests that come with clear guidance	"Parents of children with birth defects need sound guidance about future pregnancies."
	Insurance companies sometimes put up harriers	"It's tough for me to order when insurance won't pay for tests or genetic counseling."
Educational Desires	General enthusiasm to learn more	"We have huge potential for impacting patients' lives by learning their genetic quirks."
	Self-directed online courses are best	"I don't have much time. But in the past, I did a ton of online CME during night shifts."
	Despite interest, there is precious little time to learn	"How much time does it take to become minimally proficient with this kind of testing?"

ity of respondents said it is important for them to learn about the same advances in *genomic* testing. Regarding testing concerns, about 70% of physicians worried that patients may interpret test results incorrectly. A smaller number were concerned that test results could lead to discrimination by insurers or that the validity or accuracy of results is questionable. Twenty-four percent of PCPs said they had sufficient knowledge to counsel patients about genetic disease risk, while one-third of all other physicians felt similarly (Table 2). Only about 20% of respondents said they had sufficient time in their practices to counsel patients about genetic risk for disease.

Most physicians interviewed found the prospect of personalized medicine promising, while some found it to be complex, citing a need to know which tests are applicable to their patients and may help to improve patient outcomes. Many called for the development of more contextual information about genetic testing and genome sequencing – actionable, evidence-based guidance formatted into easy-to-use decision aids. A fair number of physicians voiced concerns about insurance coverage and overall affordability. Others, especially psychiatrists, said the practice of pharmacogenomics holds great promise for patients who fail to respond to early medication trials.

Interviewees raised a variety of concerns regarding the clinical utility of genetic and genomic testing, including affordability and access, discrimination by insurers, and the possibility patients will misinterpret test results. Some of the most interesting comments concerned the handling of incidental findings, including this one by a 54-year-old male hematology and oncology specialist in urban practice.

> *"[Depending on the] particular panels of genes, you certainly get a lot of information that you are not sure what to do with. We find out mutations in all kinds of genes that, right now, aren't actionable, given [that] the quality of the data and understanding what they mean is not so clear. In that setting you can develop a bias of over-treatment based on perceived risk that may not necessarily be well vetted from a research standpoint."*

One psychiatrist also noted some patients learn things about themselves they did not want to know, prompting the need for psychoanalytic investigation into fears about illnesses they might develop later in life.

Testing Intentions

About 43% of PCPs in our survey anticipated ordering genetic or genomic tests within the next 6 months (Table 2), while roughly 60% to 75% of ob/gyn specialists, surgeons, pediatricians and psychiatrists said they would. Almost 44% of respondents said genetic and genomic tests are not applicable in their practice, while nearly 28% said they do not have enough knowledge about these tests.

Equal numbers of interview respondents said their level of ordering likely would stay the same in the near future or would increase if tests are shown to be efficient and cost effective. Most expressed a desire for clear guidance regarding the scientific reliability and clinical applicability of these tests. Others wanted timely and relevant results that suggest concrete solutions, including a 45-year-old female family physician in a rural practice who pondered the results of genomic testing aimed at uncovering causes and treatments regarding her own disease:

> *"You know, there may not always be a simple solution, but there are some things where there's clinical applicability and relatively simple nutritional solutions to get around these little SNPs. So, I really think this will be the wave of the future."*

Participants also spoke about several barriers to ordering genetic/genomic tests including high cost, insurance coverage, physicians' own lack of knowledge and experience, and the time commitment involved with ordering, interpreting, and counseling patients.

Educational Desires

Nearly three-quarters of survey respondents said their professional genetics/genomics training is inadequate, with PCPs being much more likely to feel this way. Physicians younger than 50 were more likely than older colleagues to feel their training is adequate (Table 2). Nearly 80% of respondents said they would be interested in further education in genetics/genomics; 88% of physicians from rural practices felt this way, compared to 75% of physicians in urban or suburban settings. More than 70% of respondents said they would be willing to devote time to continuing medical education (CME), with more than 60% preferring to receive additional training through self-directed online courses and 53% through in-person CME. Respondents also stated preferences for education via professional meetings (45.2%), journal publications (38.7%), and grand rounds or other in-house seminars (38.7%).

Most physicians we interviewed expressed unqualified enthusiasm for further education about genetic testing and genome sequencing. Some respondents, including younger physicians, noted the lack of genetics training during medical school. One 34-year-old male family physician practicing in a rural practice setting said:

> *"There was the requisite preclinical course on genetics, which was essentially a unit within the larger course on biochemistry. That was, frankly, a fairly cursory review compared to the deeper dive into genetics I had as an undergrad. This was very basic stuff; it did not get into things like whole genome sequencing. It really talked a lot more about specific case presentations of genetic disorder as opposed to some of the testing that would go along with it. So, more 'Here's what it looks like' [and] less about 'Here's how to find it.'*

Other participants spoke of PCPs' need for more in-depth training. Respondents also listed a few barriers to additional training, mainly regarding the lack of time physicians have within the context of a busy clinical practice. Some spoke of a lack of motivation to engage in such training given competing CME, and others acknowledged a lack of basic understanding or awareness regarding genetic/genomic testing on their part and amongst their colleagues. Finally, some respondents lamented the paucity of basic educational programs that would enable physicians who are not genetic specialists to become proficient enough to utilize certain tests in their own practice.

DISCUSSION

This exploratory study summarizes the views of a small sample of Wisconsin physicians about genetic and genomic testing, with an emphasis on general knowledge and experiences, attitudes toward testing, testing intentions, and educational needs. Consistent with current literature,[1,9,11,17,18] our study found that while physicians increasingly see the value of these tests, relatively few have significant experience with them or feel prepared to use them. Perhaps the most significant finding is that adult PCPs lagged behind other physicians in each of these areas and were less likely to feel their training in genetics/genomics is adequate. There are many potential explanations for these findings; regardless, this knowledge gap amongst PCPs is important to address for several reasons. For example, given the sheer volume of patients seen, PCPs likely serve a greater number and variety of people who may benefit from genetic/genomic testing than other specialists. Also, PCPs have been proposed as potential surrogates for genetic counselors, who are too few in number relative to the demand for their services.

Our study also suggests that younger physicians are more likely than older colleagues to report having formal training in genetics/genomics, and to feel their training is adequate. This finding should be interpreted with caution since self-reported genetic and genomic knowledge does not always correlate with the level of knowledge that physicians actually possess. Future studies could utilize exams evaluating participants' genetics/genomics knowledge and compare the results with self-reported knowledge. Furthermore, confidence in genetic/genomic competency must be tempered by the fact that the rapid pace of new developments in these areas may quickly render anyone's present knowledge obsolete. Thus, medical educators should continue to refine genetics/genomics curricula in medical school and residency training, and develop effective CME to help practicing physicians stay up-to-date on technologies applicable for their patients. Finally, survey respondents who practice in rural settings were about half as likely as physicians from urban/suburban settings to feel adequately informed about genetic/genomic medicine. Fortunately, these physicians recognize their knowledge deficits and were more likely to express interest in further education. This may be especially important in states like Wisconsin, where barriers associated with cost and lengthier wait times for testing and results may prevent patients in rural areas from realizing the full benefits of genetic/genomic technologies.[16]

This study is not without limitations. First, the sample size is small. However, we can make statements with confidence about key questions that pertain to differences between physicians from 2 age groups and 2 specialty categories of "Adult Primary Care" and "Other." Though our sample consists of 155 physicians from a variety of specialties, the number of physicians from many specialties was too small to deliver sufficient power for the use of inferential statistics. Finally, our sample may be biased toward physicians with a preexisting interest in genetics/genomics. Despite these shortcomings, our study offers an early look at the differences between primary care and other specialist physicians in Wisconsin regarding several key questions that pertain to their experience with this rapidly advancing field. Future studies with larger state-

wide samples might use our survey and interview questions to tease out additional details.

Many foresee rapid advances in genetic testing and genome sequencing over the next decade, with inevitable implementation into clinical practice. Our study adds to a small but growing body of literature documenting the growing pains of genetic and genomic medicine. Now is the time to ensure that knowledge about these technologies—and their importance to personalized medicine—is shared widely among physicians. To further deploy these technologies for optimal health outcomes at the population level, medical educators need to move the use of genetics/genomics beyond the realm of early-adopting physicians and into the hands of those who serve more diverse populations, including groups that are now underserved by our health care system.[5]

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Implementing Population Medicine in a Pain Management Practice

Barbara Koschak, DNP; David A. Bryce, MD; J. Timothy Harrington, MD

ABSTRACT

Purpose: To document and improve the quality of our chronic pain management using population management methods.

Methods: An analytic registry was developed, and all new patients were enrolled for 12 months. Patient demographics, standardized pain and function measures, and treatments were recorded. Usual care was provided. The registry was used to organize care and analyze management and outcomes.

Results: Of 454 total patients, only 154 (34%) completed a 6-month cycle of care. High no-show rates were documented for follow-up appointments for several reasons. The majority of 6-month completers showed improved pain levels.

Discussion: This quality improvement project identified assessment and care gaps and led to improvements. An ongoing need to improve measures of pain and function was documented.

INTRODUCTION

Managing chronic pain and its underlying causes presents a continuing challenge to health systems, clinicians, patients, and health planners in the United States.[1] Diagnoses and treatments for similar patients vary greatly by individual physician and across specialties. Opioid dependency is but one highly visible problem associated with current approaches to pain management. In fact, the fragmented and variable care processes, high costs, and suboptimal outcomes of chronic pain management differ little from those of most chronic diseases.[2]

Population medicine utilizes a disease registry to identify all patients within a population and to then guide care teams to provide and document necessary care on time. This approach changes the focus of care from one patient at a time to the population as a whole, with individual patient's care provided within this broader context. It allows practices to identify and close care gaps that cannot otherwise be appreciated or addressed. In general, population medicine is proving more effective than traditional approaches for managing chronic diseases.[3]

We have implemented population medicine methods within our pain management practice in an effort to improve our care and patient outcomes. This report describes our quality improvement project and initial results.

METHODS

Participants

An interventional pain physician (DAB) and a nurse practitioner (BK) conducted this project in a community-based pain management practice at 3 clinic sites in south central Wisconsin. A physician consultant (JTH) provided quality improvement and population medicine coaching. Our processes were developed to support best clinical practices and high clinical utility, and usual treatments were provided.

Procedure

We began by defining a set of standard disease and treatment data that we intended to collect routinely at baseline and each follow-up patient assessment. A data collection sheet was developed to capture this information (Figure 1). Treatments reported were those provided since the last assessment. The Patient Pain and Provider Global Scores (PGS) were reported on 0-10 segmented

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CME available. See page 78 for more information.

Figure 1. Data Collection Sheet

Date	Name	Date of Birth	Registry Number

Parameters		Treatments	
	Patient derived		***Medications***
VAS- current rating		Opioids	
VAS- maximum rating		Neuroleptics	
Oswestry score		Non steroidals	
	Provider derived	Local anesthetics	
Opioid risk score		Antidepressants	
MEDD		Mood stabilizers	
Practitioner Global Score			***Interventional***
	Cycle of Care - 6 months	Diagnostic	
Initial visit		Therapeutic	
One		Neuromodulation	
Two		Radiofrequency	
Three			***Psychology Evaluation***
		Cognitive therapy	
		Group therapy	
		Individual therapy	
			Therapy
		Physical therapy	
		Occupational therapy	

Standardized pain, function, and global measures and current treatments are collected at each patient assessment visit, generally at baseline, 6, 12, and 24 weeks.

Abbreviations: VAS, visual analogue scales; MEDD, Morphine Equivalent Daily Dose.

visual analogue scales (VAS) with 0 to .99 = Controlled, 1 to 3.9 = Low, 4 to 6.9 = Moderate, and 7 to 10 = High levels of pain and disability.[4] Opioid use was calculated as morphine equivalent daily dose (MEDD) from a standard conversion table, and the Oswestry Disability Index was calculated from a patient-generated questionnaire and segmented into low, moderate, and high levels.[5,6] The PGS was used to capture the clinician's overall impression based on patient history, other objective patient-derived measures, and examination findings. A PGS has been used widely in clinical trials and for documenting the activity of other chronic diseases[7] but, to our knowledge, not to capture the provider's overall impression in pain management.

We then determined the intervals at which we wished to follow patients after baseline evaluation and initiation of medical or procedural treatments, recognizing that these would vary in some cases. We assumed that our cycle of care was generally 6 months in duration and that assessments would be performed at 6 weeks, 12 weeks, and 24 weeks.

We next developed a disease population registry in an Excel database, backed up and protected on our practice's HIPAA-compliant information technology platform. We enrolled each new patient with their identifying information, referral source, date of consultation, and International Classification of Diseases, Ninth Revision (ICD-9) diagnoses. Each patient's clinical data were entered at baseline and at each follow-up assessment. Our analytic registry format is shown in Figure 2.

A nurse practitioner (BK) managed the registry. Data from collection sheets were entered real-time or batched and then entered separately as time permitted. The registry spreadsheet was sorted regularly by encounter dates to identify overdue patients and to analyze other data as indicated in Results. Encounters for each patient were also documented in our electronic medical record (EMR), including scanned data collection sheets.

We did not obtain Institutional Review Board oversight since quality improvement projects are generally exempt, as their purpose is to improve care delivery processes and not to perform research or deviate from usual treatments.[8,9]

RESULTS

The study population included all new patients seen for initial evaluation during a 12-month interval beginning on January 2, 2014 (N = 520). These patients were referred either by community primary (84%) and specialty (15.5%) physicians or were self-referred (0.5%). Patients were 54% male and 46% female and ranged from 20 to 89 years (median = 57). Sixty-six patients with more than 1 pain problem at enrollment were excluded from this analysis, leaving a total of 454. Initial ICD-9 codes included spine disorders (68%), other musculoskeletal conditions (18%), neuropathies (10%), and a variety of other diagnoses (3.5%).

Only 154 (34%) of these 454 enrollees had both baseline and 6-month assessments. An additional 146 (32%) did not keep their first scheduled follow-up appointment with major reasons being lack of insurance coverage and patient decisions to decline recommended care. The remaining 154 (34%) completed specialty pain management in less than 6 months. They were returned to their referring physician for medication management, referred to other specialists, continued in rehabilitation, and/or had resolved their pain problem. Many of this latter cohort did not have a discharge visit and assessment.

A variety of interventional procedures were performed on 170

Figure 2. Example Pain Population Registry

Patient	Physician	DOB	ICD-9	Baseline Date	Pain VAS	Oswestry	MEDD	PGS	6-week Date	Pain VAS	Oswestry	MEDD	PGS	12-week Date	Pain VAS	Oswestry	MEDD	PGS	24-week Date	Pain VAS	Oswestry	MEDD	PGS

This spreadsheet provides a template for entering a standardized patient data set and the analytic functions to sort and study the enrolled population.

Abbreviations: VAS, visual analogue scales; MEDD, Morphine Equivalent Daily Dose; PGS, Provided Global Scores.

(37%) of the 454 patients, and on 110 (71%) of the 154 6-month completers. Outcomes documented for the 6-month completers included reduced patient pain in 66 of 124 patients (53%) with moderate and high baseline pain scores. The MEDD, Oswestry, and PGS measures were unchanged in the majority of 6-month completers. The majority of baseline patient pain and PGS levels (58%) were concordant, and discordance was most frequent in patients with moderate baseline pain scores. We are unable to evaluate the effectiveness of individual treatments or the relationship of follow-up compliance to outcomes because of the relatively small patient numbers, lack of standardized treatment protocols for specific underlying disorders, the use of multiple treatments in some patients, and the lack of a clinical trial design.

Baseline opioid use was analyzed (N=454). No opioid use was reported by 200 patients (44%), 1-120 MEDDs was reported by 212 (47%), and greater than 120 MEDDs was reported by 42 (9%). No correlation was found between opioid use at enrollment and loss to follow up after initial evaluation.

DISCUSSION

Population medicine using disease registries and multidisciplinary care teams is an emerging alternative to traditional care of chronic diseases that has improved practice performance and outcomes.[3] Our experience suggests that this is also feasible and valuable in pain management practice. We hope that other pain specialists will consider adopting this alternative approach to traditional care processes.

We were unable to identify any other examples of population medicine approaches in pain specialty practices through a literature review and the authors' communications with other specialists. In addition, we are not aware of more comprehensive care coordination programs for chronic pain populations in health systems. One of us (JTH) has published the methods and results of an interdisciplinary system-level improvement project for low back pain management that utilized a similar population medicine approach.[10] This experience is what initially motivated the current project, and spine disorders represented 68% of our patients in this study.

A simple disease registry and standardized disease activity measures are essential for managing care reliably at the population level.[2] Enrolling all new patients provides a fully representative cohort for analyzing the managed population and the care provided. Electronic medical records generally do not provide the analytic registry functions needed for population medicine.

Pain measures are subjective by their nature. We adopted a standard measures set and intended frequencies of assessments to determine whether this would improve our documentation of patients' status and their improvement during treatment. Completing this assessment as intended proved difficult for the majority of patients who either did not return for follow-up care or did not have a discharge visit after completing pain management. The results in those who did complete a 6-month care cycle emphasize the continuing challenge for improving measurement in chronic pain populations.

Population medicine is allowing us to see patterns and care gaps that we had not recognized before, including the numbers of patients who were lost to follow-up, and why. We now define new patients' interest in interventional pain management and insurance eligibility before scheduling follow-up visits. We also have initiated follow-up calls to "no-shows" and encouraged a discharge visit for all patients completing pain management to document their status and plan for further care.

We also have developed a better-defined team care approach. Our nurse practitioner is our registry manager, coordinates patient encounters and assessments, contacts overdue patients, and provides medical follow-up care and education. The physician focuses on new patient evaluations, problem solving, and procedures. The team collaborates in care planning for those patients with high pain and high PGS metrics. The physician is able to see more new patients in a timely manner.

Many of the patients referred to our interventional pain management practice were using opioid analgesics prior to their initial visit; however, loss to follow-up did not correlate with baseline opioid use, as we had expected. Our care includes efforts to reduce opiate use through education, drug contracting, and alternative treatments. Our baseline and 6-month MEDD results suggest a need to increase these efforts.

The major study limitation is the short duration of follow-up within the specialty practice cycle of care for this complex chronic pain patient population. By the end of this 1-year study, we were substantially modifying our practice processes to address our care gaps and creating new cycles of improvement. These iterative process changes precluded a longer study duration and larger patient cohort.

In conclusion, this population medicine project has improved our interventional pain management practice. We hope our experiences will encourage others to adopt population medicine approaches and standardized measures of patients' status and outcomes, not only in pain management practices, but also within other specialties and broader health systems. Documenting and improving care and outcomes for chronic disease populations are critical to increasing the value of care and overcoming barriers to payment for effective services.

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Hand Hygiene Among Health Care Workers: Is Educating Patients and Families a Feasible Way to Increase Rates?

Marvin J. Bittner, MD; Jared M. Routh, MD; Matthew D. Folchert, MD; Nicholas E. Woessner; Sean J. Kennedy, BS; Chase C. Parks, BS

ABSTRACT

Background: The Centers for Disease Control and Prevention has recommended teaching patients to remind health care workers to disinfect their hands. However, cognitive impairment among patients may hamper such efforts.

Methods: The St. Louis University Mental Status (SLUMS) Examination was administered to randomly selected inpatients at the Omaha VA Medical Center in Omaha, Nebraska. We asked patients and their families about attitudes toward reminding health care workers to disinfect their hands: willingness, feeling comfortable, and feeling responsible.

Results: Of 143 patients, 94 completed SLUMS; 9 had normal mental status and appropriate attitudes. Overall, 16 encounters involved patients or family who were well-suited for giving reminders.

Conclusion: Programs to encourage hospitalized adults to remind staff to perform hand hygiene may encounter barriers related to cognitive impairment and attitudes.

BACKGROUND

Despite the value of hand hygiene in infection prevention, study after study has demonstrated disappointing compliance.[1] This is a concern in many hospitals at a time when infection prevention is particularly important because of nosocomial infections, increasing resistance to antimicrobials, and a paucity of new antimicrobial agents. One approach to improving compliance with hand hygiene is to teach patients to remind health care workers to perform hand hygiene. The concept of patient reminders has gained support from the World Health Organization and the Centers for Disease Control and Prevention, whose hand hygiene guideline asks infection prevention programs to "encourage patients and their families to remind health care workers (HCWs) to decontaminate their hands."[2]

Some literature[3] shows increased hand hygiene compliance by educating patients or their families to give reminders. However, recent trends raise questions about the viability of this approach. Trends toward shorter length of stay have left the remaining hospital population weighted toward sicker patients who may be less able to provide hand hygiene reminders and more vulnerable to infection. We suspected that our patients might be so sick that cognitive impairment would be widespread, and a program to promote hand hygiene reminders would be futile. Therefore, we evaluated our patients for cognitive impairment.

Aside from cognitive impairment, others have identified additional barriers to hand hygiene reminders. The literature raises several issues including whether patients are willing to ask nurses, physicians, and other health care workers if they washed their hands or if they would wash their hands,[4-5] and if patients think it is their responsibility.[6] Therefore, we evaluated our patients for the presence of these attitudinal barriers. In addition, we asked families about their interest in providing hand hygiene reminders because even if patients could not give hand hygiene reminders, their families might do so.

METHODS

In this cross-sectional study, we approached 120 adults hospitalized in medical-surgical units and 23 in intensive care beds at the

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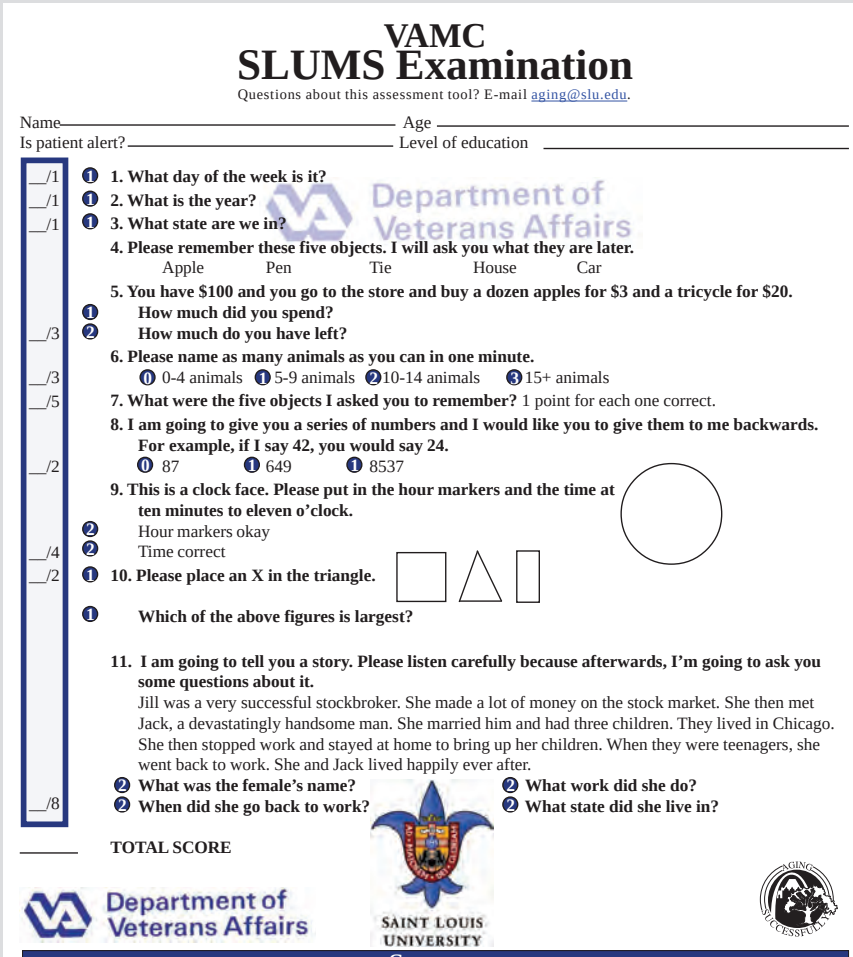
Figure. St. Louis University Mental Status Examination



VAMC
SLUMS Examination

Questions about this assessment tool? E-mail aging@slu.edu.

Name _____ Age _____
Is patient alert? _____ Level of education _____

__/1 1. What day of the week is it?
__/1 2. What is the year?
__/1 3. What state are we in?

4. Please remember these five objects. I will ask you what they are later.
Apple Pen Tie House Car

5. You have $100 and you go to the store and buy a dozen apples for $3 and a tricycle for $20.
How much did you spend?
__/3 How much do you have left?

6. Please name as many animals as you can in one minute.
__/3 0 0-4 animals 1 5-9 animals 2 10-14 animals 3 15+ animals

__/5 7. What were the five objects I asked you to remember? 1 point for each one correct.

8. I am going to give you a series of numbers and I would like you to give them to me backwards. For example, if I say 42, you would say 24.
__/2 0 87 1 649 1 8537

9. This is a clock face. Please put in the hour markers and the time at ten minutes to eleven o'clock.
2 Hour markers okay
__/4 2 Time correct

__/2 1 10. Please place an X in the triangle.

1 Which of the above figures is largest?

11. I am going to tell you a story. Please listen carefully because afterwards, I'm going to ask you some questions about it.
Jill was a very successful stockbroker. She made a lot of money on the stock market. She then met Jack, a devastatingly handsome man. She married him and had three children. They lived in Chicago. She then stopped work and stayed at home to bring up her children. When they were teenagers, she went back to work. She and Jack lived happily ever after.

2 What was the female's name?
2 When did she go back to work?
2 What work did she do?
2 What state did she live in?
__/8

_____ TOTAL SCORE

Department of Veterans Affairs

SAINT LOUIS UNIVERSITY

Scoring

High School Education		Less than High School Education
27-30	Normal	25-30
21-26	MNCD*	20-24
1-20	Dementia	1-19

* Mild Neurocognitive Disorder

SH Tariq, N Tumosa, JT Chibnall, HM Perry III, and JE Morley. The Saint Louis University Mental Status (SLUMS) Examination for Detecting Mild Cognitive Impairment and Dementia is more sensitive than the Mini-Mental Status Examination (MMSE) - A pilot study. J am Geriatri Psych (in press).

Source: http://medschool.slu.edu/agingsuccessfully/pdfsurveys/slumsexam_05.pdf

VA Medical Center in Omaha, Nebraska. Patients were selected randomly from a list of bed locations. We prepared a sequential list of bed locations ordered by nursing unit, then room number, then (for 2-bed rooms) bed number. Next, we used an Excel random number generator to prepare a sequence of random numbers and assigned the first bed location to the first random number, the second bed location to the second random number, etc. We then sorted the bed locations by their corresponding random numbers, which gave us a list of bed locations in random order. To avoid bias in patient selection, our first patient visit was to the first bed on our list of locations in random order, our second visit to the second bed location, and so on.

Evaluations included the St. Louis University Mental Status Exam (SLUMS)[7] (Figure) and were performed on weekdays from 8 AM to 10 AM and 2 PM to 4 PM for 4 weeks. One author performed all of the evaluations, which occasionally were observed by another author. We used SLUMS results to categorize patients. The SLUMS scoring range for those with at least a high school education is 1-20 for dementia, 21-26 for mild neurocognitive disorder (MNCD), and 27-30 for normal status. For those with less than a high school education, the scoring is 1-19 for dementia, 20-24 for mild neurocognitive disorder, and 25-30 for normal status.

To evaluate the attitudinal barriers to giving hand hygiene reminders, we asked patients the following questions, based on several studies:[4-6] "Would you be willing to ask your health care worker if he or she washed his or her hands?"; "Would you be comfortable asking your health care worker if he or she washed his or her hands?"; and "Do you think it is your responsibility to ask your health care worker if he or she washed his or her hands?" If family members were present, we asked them similar questions about their own attititudes toward giving reminders.

In addition, we made 2 observations regarding the hospital's program for encouraging patients to remind staff to wash hands. This program was confined to 2 interventions: signs in patient rooms with a message that it's okay to ask workers if they've cleaned their hands and similar signs near the elevators. We noted if any such posters were evident in the patient rooms.

We also noted whether, in view of signs encouraging patients to ask workers about cleaning hands, we ourselves were asked if we had cleaned our hands. The program does not involve any instruction in hand-washing techniques or methods of approaching health care workers to ask about cleaning hands, nor did we provide any such instruction.

The data collection sheet contained these elements: heading (date, room number, patient number, patient name), observation on entering room (patient present or not), response of patient to initial greeting (responsive, responsive but unintelligible speech, non-responsive), age, sex, initial assessment (able, asleep, sedated, intubated, lacking motor skills needed for mental status examination, questionable mental status, does not speak English,

other), factors related to risk of infection (intravenous device, urine collection device, endotracheal tube, chest tube, other device), and SLUMS score. The remainder of the sheet had a series of yes-no questions directed to the patient and to the family (if applicable) that evaluated the attitudinal barriers to giving hand hygiene reminders described above.

Approval was obtained from the Institutional Review Board to conduct this study with waiver of informed consent.

RESULTS

Among the 143 patients enrolled, 84% of the patients were white and 96% non-Hispanic. Of the 23 intensive care unit (ICU) patients, 95.7% were men, mean age was 69.3, with a standard deviation (SD) of 8.1. Of the 120 patients outside the ICU, 95.8% were men, mean age was 66.2, and SD 13.3.

Only 94 (65.7%) patients were willing and able to complete the SLUMS test; 20 had normal mental status. Of those 20 patients, 9 indicated that they were willing to give reminders, were comfortable giving reminders, and felt it their responsibility to do so.

Of the 94 patients who completed the SLUMS test, 21.3% were classified normal, 35.1% MNCD, and 43.6% dementia. For the normal classification, the median SLUMS was 28, mean was 28.1, and SD 1.0. For MNCD, the median was 24, mean was 23.6, and SD 1.9. For dementia, the median was 15, mean 14.8, and SD 3.7. For all those who completed SLUMS, the median was 21, mean 20.7, and SD 6.1.

One hundred seven patients answered questions about their attitudes toward giving reminders; 66% said they were willing to give reminders, 30% said they weren't, and 4% said they didn't know. For the question about being comfortable giving reminders, 54% said "yes," 43% said "no," and 3% said they didn't know. For the question regarding their responsibility to give reminders, 39% said "yes," 58% said "no," and the rest gave other answers, such as "yes and no" and "don't know."

Family members were present for 28 (19.6%) patients. Of those families present, 25 answered questions about their attitudes toward giving reminders and 8 (32%) indicated they were inclined to do so. Taking into account both patients who were well-suited to give reminders and families who were inclined to give reminders, a total of 16 (11.2%) were expected to remind health care workers to perform hand hygiene.

Two of our incidental observations are noteworthy because they are consistent with the findings of our mental status evaluation and our questions about attitudes toward giving hand hygiene reminders. First, among the 143 patients, 21 failed to respond to an initial greeting and were unable to complete the SLUMS exam. Second, of 122 rooms with responsive patients, 105 had signs with the message, "Patients & Visitors: It's okay to ask health care providers if they have cleaned their hands." Signs near elevators echo this message. Nonetheless, we were never reminded to practice hand hygiene by patients or their families.

DISCUSSION

For a patient to remind staff to perform hand hygiene, a patient must have adequate cognitive capability and an attitude consistent with an inclination to give reminders. Such patients comprised only 6.3% of our population. Taking into account both patient and family suitability to provide reminders, reminders could be expected in only 11.2% of encounters.

Our results suggest that approximately 1 patient in 15 may remind staff to perform hand hygiene. Some authors speculate that such reminders, albeit infrequent, would have a meaningful impact.[4] However, the value of infrequent reminders remains a matter of speculation.

Among our patients who completed SLUMS, dementia was more prevalent than in the pilot study describing SLUMS[7] (44% vs 12%). MNCD was also more common in our patients (35% vs 26%), and our patients were less likely to be classified normal (21% vs 62%). This is plausible since the pilot study involved 702 individuals seen for routine clinic visits in the Geriatric Research Education and Clinical Center clinics in St. Louis, Missouri; our patients were in ICU or acute medical-surgical beds.

Additional support for the plausibility of our findings comes from the failure of a passive approach to promoting hand hygiene reminders in our hospital. Despite signs promoting reminders, no one reminded us to clean our hands when we entered the rooms. Concerns about inability of patients to provide hand hygiene reminders are complemented by concerns about social barriers. Indeed, a recent controlled trial[8] evaluating patient reminders found no clinically significant increase in hand hygiene. This intervention may have been stymied by patient attitudes—rather than cognitive impairment—inasmuch as it focused on lucid patients and excluded wards "inappropriate" for patient participation such as the ICU, where patient reminders would face barriers.

Some literature,[9] including a report from a rehabilitation unit, has indeed supported efforts to teach patients to remind staff to perform hand hygiene. However, studies of this sort are burdened by limitations: small sample sizes, less reliable data due to self-reporting, investigation with short follow up, and research limited to an affluent area. Additionally, these studies have not focused on the barrier of cognitive impairment.

Others have looked at hand hygiene reminders; however, we were unable to locate a study that, like ours, examined the entire set of factors necessary for a patient to give reminders: intact mental status, willingness to give reminders, comfort in doing so, and feeling responsible. Also, there was a paucity of reports

that—as in this paper—used systematic, random patient sampling at varied times during admission. Another special feature of this study was evaluation of the potential for family involvement, which assessed an additional issue affecting the success of a reminder program.

This study has some limitations. Our method of assessing mental status—the SLUMS examination—is not widely used; however, our patient population (veterans in the Midwest) resembles the population in which SLUMS was developed. Also, SLUMS Question 11 has face validity for assessing a patient's ability to participate in a reminder program. It is a story that is read to the patient, who is asked questions about it. A reminder program requires a patient to listen to instructions, comprehend them, and apply what has been learned. Although one could speculate that patients with mild neurocognitive disorder could give reminders, this doesn't seem likely considering the cognitive demands of a reminder program. There may be concern that SLUMS has not been validated as a measure of ability to participate in a hand hygiene reminders program. However, we saw that 34.3% of patients did not even complete SLUMS. Is it reasonable to expect patients like that to listen to an explanation of a reminders program, understand it, remember the instructions, and recall them when reminders are needed?

Furthermore, a growing body of literature has recognized the value of SLUMS. SLUMS was devised by researchers who recognized that the widely used Mini-Mental Status Examination (MMSE) had value in identifying dementia yet was unsuitable for identifying mild neurocognitive disorder. Their seminal paper[7] deriving and validating SLUMS studied 702 patients whom clinicians classified, using standard criteria, as dementia, mild neurocognitive disorder, or normal. SLUMS was indeed thought by the authors to be superior to MMSE in identifying mild neurocognitive disorder and comparable in identifying dementia. The authors presented receiver operating curves supporting these conclusions, and they presented detailed data on sensitivity and specificity for SLUMS and MMSE for the detection of both dementia and mild neurocognitive disorder for 2 groups of patients: those with high school education and those with less than high school education. This resulted in scoring recommendations that were modified somewhat for the current version of SLUMS:

> "The scores for mild neurocognitive disorder and dementia for patients with less than high school education are 23.5 and 19.5, respectively. These cutoffs yield sensitivity/specificity values of 0.92/0.81 and 1.0 /0.98, respectively. The cutoff scores for mild neurocognitive disorder and dementia for patients with high school education or higher are 25.5 and 21.5, respectively. Sensitivity/specificity values for these cutoffs are 0.95/0.76 and 0.98/1.0, respectively."

Additional scholarly work evaluated SLUMS scores over time[10,11] and in different cultures.[12,13] SLUMS also has been the object of study in an explicitly nonveteran population,[14] in comparison with other instruments,[15] and as a predictor of decline.[16]

Our results may have limited generalizability. Our study was confined to adults in medical-surgical units and an ICU. However, such patients are typical of many US hospitals. In addition, our work may not be generalizable to populations of non-English speaking or culturally diverse patients. We suspect that language and cultural barriers would further challenge a patient empowerment program.

CONCLUSION

"Promote patient reminders" is an intervention that may be appropriate in some settings. The concept of tailoring hand hygiene improvement strategies to specific settings found support in a Joint Commission study.[17] This study of several hospitals sought to find the specific reasons for poor hand hygiene compliance in each setting. The authors encountered a variety of reasons for noncompliance. The study obtained substantial improvements in compliance, not by imposing a "one-size-fits-all" intervention, but rather by tailoring the intervention in each hospital to the specific reasons for noncompliance at each site. Interventions varied and included improving disinfectant dispenser placement, providing a space for workers to leave items they were carrying, and a commitment by leadership to glove use.

In a site with adult medical-surgical units resembling ours, however, the intervention of teaching patients to give hand hygiene reminders faces formidable barriers of cognitive impairment, exacerbated by patient and family attitudes.

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Atrioesophageal Fistula: A Rare Complication of Radiofrequency Ablation

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ABSTRACT

A 75-year-old woman was admitted with fever, chills, altered mentation, and right-sided weakness. A month earlier, she had undergone catheter radiofrequency ablation for treatment of chronic atrial fibrillation. A magnetic resonance imaging scan of her brain revealed septic emboli with multiple bilateral cerebral and cerebellar infarcts, as well as extensive bilateral leptomeningeal enhancement. Blood cultures were positive for *Streptococcus mitis, Rothia mucilaginosa, Streptococcus pneumonia*, and *Candida albicans*, which suggested a connection between gastrointestinal and cardiovascular systems. A chest computed tomography scan with contrast showed a curvilinear low attenuation structure communicating between the esophagus and the left pulmonary vein—an atrioesophageal fistula. Ten days after admission, the patient died from multiple cerebral septic emboli secondary to atrioesophageal fistula following radiofrequency ablation.

INTRODUCTION

A rare complication of radiofrequency ablation is atrioesophageal fistula,[1] which typically manifests as a new onset of neurological symptoms or as systemic polymicrobial infection and/or gastrointestinal bleeding. Fatal events usually are caused by polymicrobial sepsis and cerebral air embolism.[2] We report the case of a 75-year-old woman who died from multiple cerebral septic emboli secondary to atrioesophageal fistula following radiofrequency ablasion for chronic symptomatic atrial fibrilation.

CASE REPORT

A 75-year-old woman came to our emergency department for evaluation of altered mentation and possible stroke with right-sided weakness. She had a 10-year history of symptomatic paroxysmal atrial fibrillation despite medical therapy with sotalol, amiodarone, dronederone, and dofetilide. Five weeks earlier, while wintering in Arizona, she had seen her electrophysiologist, who recommended radiofrequency ablation of the left atria and pulmonary veins. She underwent the procedure, during which the electrophysiologist noted difficulty locating the right inferior pulmonary veins due to her anatomy. The procedure was further complicated by recurrent episodes of ventricular tachycardia and atrial fibrillation that required multiple cardioversions. Following the procedure, she was believed to be stable.

Ten days later she returned with episodic dizziness associated with blurred vision. A computed tomography (CT) scan of the brain was negative for any acute pathology. She was subsequently seen in neurology, where she was started on steroids and referred for vestibular therapy, owing to symptoms consistent with vestibular neuritis.

Approximately 3 weeks later she returned to the emergency department for evaluation of altered mentation and possible stroke with right-sided weakness. She had a fever of 38.3°C, chills, and leukocytosis (white blood cell count of 16 440/μL [16.44×10^9/L] with 20% bands).

An initial head CT scan was performed and indicated no acute hemorrhage or mass. Subsequently, a magnetic resonance imaging (MRI) scan of her brain was obtained (Figure 1), the results of which were concerning for septic emboli with multiple bilateral cerebral and cerebellar infarcts, as well as extensive bilateral leptomeningeal enhancement. Blood samples were collected for culture, and the patient was started on broad spectrum antibiotics.

Within a few hours of admission, the patient developed a new left-sided hemiparesis. Results of a repeat head CT scan were negative for acute hemorrhage. A transthoracic echocardiogram was performed to investigate for possible infective endocarditis, but no vegetations were apparent on the valves. Further evaluation for infective endocarditis with transesophageal echocardiogram indicated no gross thrombus or vegetation.

The patient's neurological status continued to fluctuate. Lumbar puncture was performed after several days of withholding rivaroxaban. Cerebrospinal fluid analysis indicated inflammatory changes

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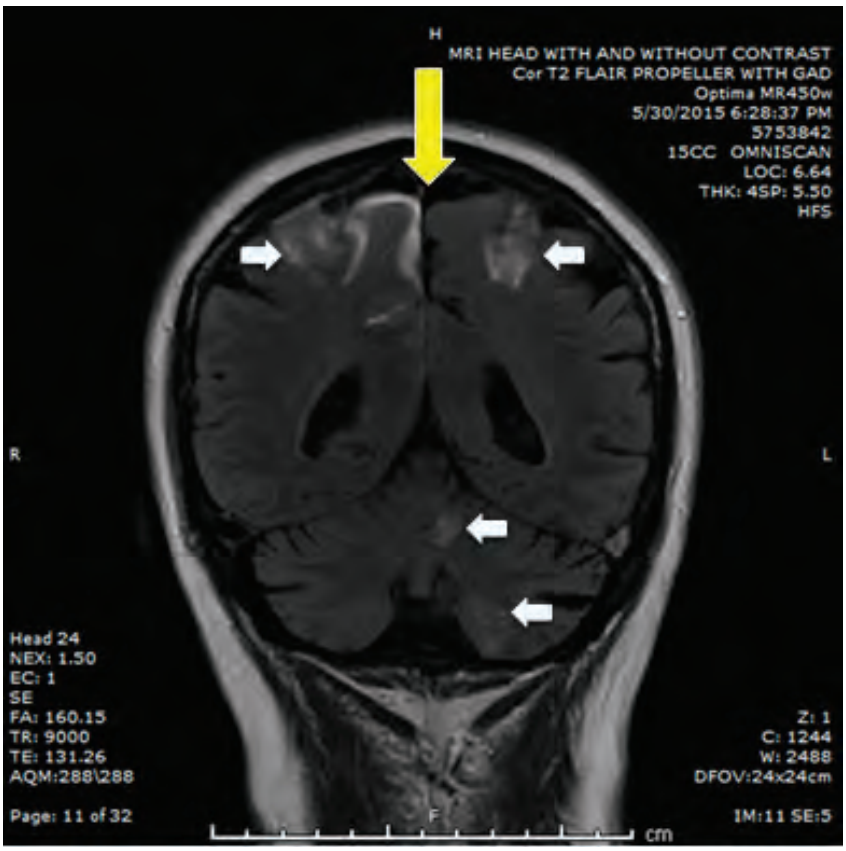
with no evidence of bacterial infection.

Initial blood cultures were positive for *Streptococcus mitis*, *Rothia mucilaginosa*, *Streptococcus pneumonia*, and *Candida albicans*. The polymicrobial nature of her infection suggested a connection between gastrointestinal and cardiovascular systems, but a CT scan of the abdomen and pelvis showed no obvious abdominal pathology to account for the positive blood cultures. A chest CT scan with contrast was obtained (Figure 2), which indicated a curvilinear low attenuation structure communicating between the esophagus and the left pulmonary vein. Our patient's clinical condition and imaging studies led to an atrioesophageal fistula diagnosis, a complication of her cardiac radiofrequency ablation. Approaches to therapy were discussed with the family, who chose comfort care in the setting of her rapidly declining neurological status. The patient died on the 10th day of her hospital admission.

Figure 1. Magnetic Resonance Imaging (MRI) Scan of the Brain.



MRI of the brain (T2 Flair images with gadolinium enhancement) demonstrates multiple cerebral infarcts (white arrows) and leptomeningeal enhancement (yellow arrow).

DISCUSSION

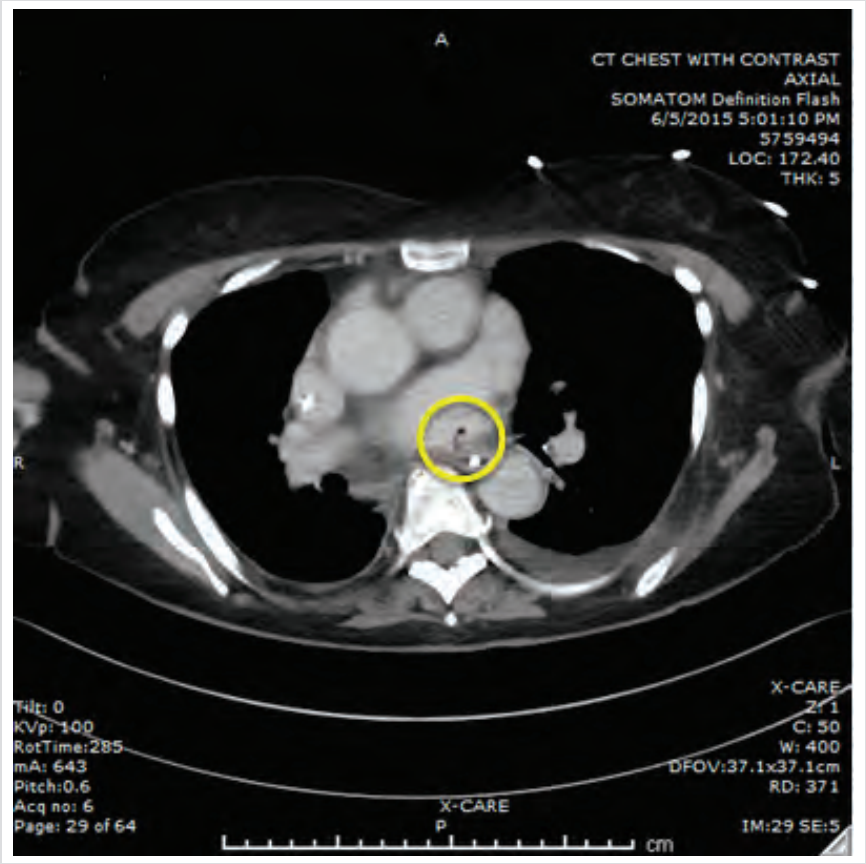
Cardiac radiofrequency ablation is associated with serious adverse effects, such as pericardial effusion/tamponade, hemo/pneumothorax, diaphragmatic paralysis, valve damage, sepsis, abscess or endocarditis, atrial flutter/tachycardia, stroke, pulmonary vein stenosis, arteriovenous fistula, atrioesophageal fistula, and, sometimes, death.[3,4] Although the rate of atrioesophageal fistula after recent radiofrequency ablation is less than 1%, its fatality rate is greater than 70%, either secondary to neurological causes, such as air embolism, or to polymicrobial sepsis.[1] Early signs and symptoms typically include neurological symptoms, such as altered mental status, seizures, hemiparesis, and stroke. Other symptoms may include fever, lethargy, weakness, chest pain, dysphagia, hematemesis, or melena.[5] Symptoms can manifest anywhere from 2 to 6 weeks after radiofrequency ablation.

Both anatomical and procedural factors have been suggested as causes of fistula development after radiofrequency ablation. The proximity of the esophagus to the left atrium is the most important factor responsible for the pathogenesis of esophageal mucosal injury during catheter ablation. Patients with left atrial dilatation have thinner fat pads and a larger contact area between the esophagus and the left atrium.[6] Extremely small patients also have been posited to be at greater risk.[7] Of the possible procedural factors, thermal injury is believed to be the most likely, and the risk is thought to increase as temperature and duration increase.[8] General anesthesia, too, has been suggested as a possible cause of esophageal injury because it limits the usual motility of the esophagus.[9]

The delayed presentation of atrioesophageal fistula after ablation suggests that mechanical perforation of the atrial wall during ablation is unlikely to be responsible for its development. Thermal injury is thought to affect the microvasculature of esophageal tissue, leading to ischemic necrosis of the mucosal layers. The progression of esophageal ulceration to atrioesophageal fistula formation has been associated with gastric hypomotility, esophagitis, and resultant acid reflux from vagal plexus injury.[6,10]

Progressive enlargement of atrioesophageal fistula can be promoted in two ways. One mechanism involves the relative higher intra-atrial pressure compared to esophageal pressure, which could cause a significant amount of blood to pass through the fistula, leading to gastrointestinal bleeding. The other mechanism involves increased esophageal pressure. Esophageal peristalsis can increase esophageal pressure to 10 times greater than intra-atrial pressure, leading to introduction of air in the cardiovascular system causing air emboli and polymicrobial sepsis.[1,11] Performing invasive diagnostic procedure such as upper endoscopy and transesophageal echocardiogram, or even placing a nasogastric feeding tube, can promote esophageal peristalsis and, hence, enlargement of atrioesophageal fistula.

Figure 2. Computed Tomography (CT) Scan of the Chest With Contrast



CT scan of the chest with contrast shows curvilinear low attenuation communication between the esophagus and the left pulmonary vein (center of yellow circle).

A CT scan of the chest seems to safely provide necessary clinical and anatomical information. Surgical repair is the definitive treatment and improves chance of survival. Muscle flap or pericardial patch is used to separate the esophagus and the atrium. However, the general and neurological condition of the patient guides treatment because surgical repair involves many risks.[3]

A few successful cases of nonsurgical treatment with esophageal stenting and pericardiocentesis have been reported. In these cases, the thermal injuries were small, and a scar was formed.[12] However, stenting is known to have an increased risk for air embolus.[2,3] Regardless of surgical intervention, early administration of antibiotics and supporting the patient's nutritional status via total parenteral nutrition were paramount in all cases.[13] Aggressive prophylactic treatment with a proton pump inhibitor is theorized to reduce the risk for atrioesophageal fistula formation, but evidence is lacking. For the neurological sequelae, early use of hyperbaric oxygen has been described, but no specific data validate its effectiveness.[14]

CONCLUSION

Having high suspicion is probably the most important factor in early recognition of atrioesophageal fistula and avoiding interventions that have the potential to worsen the fistula and, in turn, increase mortality. Early administration of antibiotics and nutritional support improves outcomes. In patients with favorable general and neurological status, however, surgical intervention is the definitive and most commonly used approach to correct atrioesophageal fistula.

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A Case of Atypical Synovitis-Acne-Pustulosis-Hyperostosis-Osteitis (SAPHO) Syndrome Presenting With Osteomyelitis of the Clavicle

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ABSTRACT

Synovitis-acne-pustulosis-hyperostosis-osteitis (SAPHO) syndrome is considered after exclusion of infection and arthritis; however, microbial infection may be present in osteoarticular lesions of these patients. Chronic osteomyelitis and associated bacterial infection were detected in a recurrent osteoarticular lesion in an adolescent patient with a history of clavicle pain, who complained of recurrent swelling in the left clavicle. Most pediatric case reports of SAPHO syndrome describe patients with associated skin conditions. This case report describes a patient diagnosed with SAPHO syndrome with no associated skin condition. Although SAPHO syndrome is characterized by dermatological and osteological symptoms, this acronym describes a collection of recurring symptoms. Complete patient medical history and thorough testing, including radiology and biopsy, are critical for prompt diagnosis and treatment of this condition, particularly in pediatric patients with persistent skeletal pain.

INTRODUCTION

Although one-third to one-half of cases with symptoms of osteomyelitis are culture negative, a variety of microbes have been isolated in culture positive cases.[1,2] *Staphylococcus aureus* (*S aureus)* has been identified as a major cause of acute hematogenous osteomyelitis (AHOM) in children.[1] The incidence of osteomyelitis in the United States is increasing with the emergence of community-acquired Methicillin-resistant *S aureus* (CA-MRSA).[3] We present a case of chronic osteomyelitis associated with *Propionibacterium acnes (P acnes)* as an atypical presentation of synovitis-acne-pustulosis-hyperostosis-osteitis (SAPHO) syndrome in an adolescent patient.

CASE REPORT

A 14-year-old female presented with swelling of her left clavicle. She had been seen several years prior with complaints of pain in the left clavicle after an accidental fall. The initial radiograph at the time of injury indicated a fracture in the medial left clavicle. Three months later, she presented at pediatrician's office due to worsening pain, and follow-up radiography revealed marked homogeneous cortical thickening of the proximal two-thirds of the clavicle. Laboratory evaluation was unremarkable except for elevation in erythrocyte sedimentation rate (ESR) at 34 mm/hr (reference range 0-14 mm/hr). Magnetic radiographic imaging (MRI) revealed an expansile mass around the medial half of the clavicle. After MRI findings, patient was referred to orthopedic specialist. She had an open biopsy of the left clavicle, which revealed a healing fracture with sterile aerobic and anaerobic bacterial cultures, but DNA sequencing was not performed. The patient apparently recovered from this injury, but had persistent swelling in the area with minimal pain. This persisted unchanged, but did not interfere with daily activities.

Four years after the initial injury, the patient described increased pain at the site of the previous fracture but reported no new injury. She continued to reside on the same central Wisconsin farm where she lived 4 years earlier, and actively cared for her family's livestock. She reported no travel or known exposure to blastomycosis other than living in an endemic region. She denied any tobacco, alcohol, or substance use, or sexual activity. With the exception of an elevated ESR at 25 mm/hr, the laboratory evaluation was again normal. Physical examination was notable only for swelling over the head of the left clavicle and mild comedonal acne. MRI was repeated and revealed a possible Brodie's abscess within the medial one-third of the left clavicular shaft with a thin sinus tract communicating with the skin surface, suggestive of chronic osteomyelitis of the clavicle. A biopsy for culture was obtained from the left clavicle, and the patient subsequently underwent debridement surgery for the chronic osteomyelitis. Anaerobic culture of the biopsy specimens grew *P acnes*. Histopathology was performed and revealed fragments of acute and chronic inflammatory granulation tissue with giant cells extending to underlying bone. A peripherally

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inserted central catheter (PICC) was placed to facilitate delivery of ceftriaxone. After improvement, the patient was switched to a 1-year course of doxycycline after 2 weeks of parenteral antibiotic treatment. Her pain and swelling improved, and she currently is taking nonsteroidal anti-inflammatory drugs. She reported resurgence of her comedomal acne after going off the doxycyline.

DISCUSSION

SAPHO syndrome is a cluster of cutaneous and osteoarticular manifestations, originally described in 1967 in a patient with osteomyelitis of the clavicle, which consists of symptoms of palmoplantar pustulosis, nodular cystic acne, and osteoarticular involvement.[4] Bony lesions are characterized by sclerosis and hyperostosis with or without synovitis. The association with sterile osteomyelitis has been frequently reported, but low levels of microbial infection, particularly with *P acnes*, may be present in some cases.[5-7] Although symptoms frequently are seen together, there are reports of skeletal involvement separated temporally from cutaneous manifestations, sometimes by years.[5] With the exception of a 2015 retrospective patient study by Kaiser and colleagues,[8] most pediatric and adolescent case reports of SAPHO describe patients with associated skin conditions.[8-11] Benhamou et al[12] devised a commonly used set of clinical criteria for SAPHO that consist of 4 inclusion criteria:[13] (1) osteoarticular manifestations in acne conglobata, acne fulminans, or hidradenitis suppurative; (2) osteoarticular manifestations in palmoplantar pustulosis; (3) hyperostosis (of the anterior chest wall, limbs, or spine) with or without dermatosis; (4) chronic recurrent multifocal osteomyelitis involving the axial or peripheral skeleton with or without dermatosis. The presence of only 1 of the 4 inclusion criteria is sufficient to arrive at a diagnosis of SAPHO syndrome.[14] Overall, biopsy results and radiographic features are the most critical components necessary for correct diagnosis of this condition. Our patient met the inclusion criteria but lacked the severe cutaneous manifestation, which therefore qualifies her for a diagnosis of atypical SAPHO syndrome. The anatomic location, organism recovered, and response to nonsteroidal anti-inflammatory drugs also supports the diagnosis of SAPHO syndrome.

In contrast, chronic osteomyelitis typically is characterized by chronic infection with devitalized bone, and often arises as a result of unrecognized or undertreated aerobic bacterial or fungal osteomyelitis. Chronic osteomyelitis lacks cutaneous findings. Anatomic location will mirror that of acute osteomyelitis, with long bones, hands, and feet being the primary locations in children. Acute vertebral osteomyelitis is also high risk for progressing to chronic osteomyelitis. Chronic osteomyelitis of the clavicle is uncommon.

CONCLUSION

Our case demonstrates that SAPHO syndrome should be considered in cases where inflammatory bone lesions fail to heal or recur, and highlights the importance of anaerobic cultures when obtaining biopsies of bone for culture, as presence of *P acnes* can suggest the diagnosis. The association of SAPHO syndrome with sterile osteomyelitis has been reported frequently. Whereas the index patient[4] met the Benhamou criteria[12] for SAPHO syndrome, our patient lacked the cutaneous manifestation of this condition and, therefore, was diagnosed with an atypical presentation of SAPHO syndrome. In our case, bone culture results and radiographic features of the infected clavicle were vital to confirming the diagnosis of SAPHO syndrome. In the primary care setting, skeletal pain that worsens or fails to improve despite conservative measures may suggest a diagnosis of SAPHO or other inflammatory bone disease, and should prompt radiographs. Inflammatory or hyperostotic lesions could suggest the diagnosis. Familiarity with this condition will aid clinicians in early diagnosis and appropriate treatment selection for resolution of the underlying infectious processes in pediatric patients with persistent skeletal pain of indeterminate origin.

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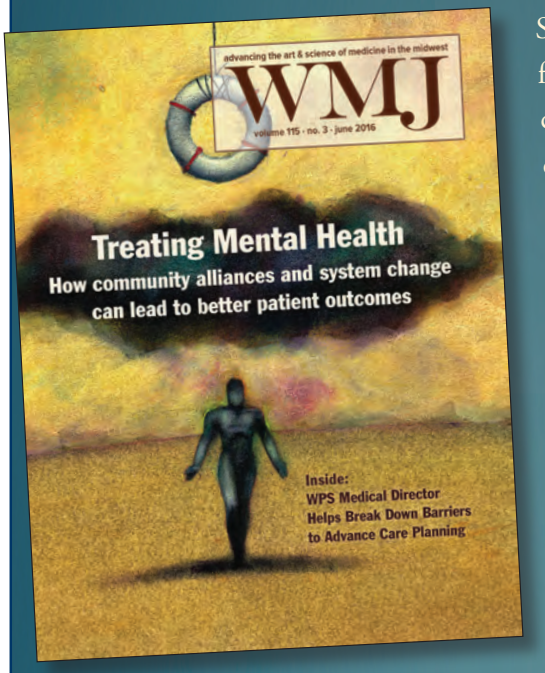

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As an approved Portfolio Program Sponsor, the Wisconsin Medical Society has been approved by the ABMS Portfolio Program to approve QI Efforts for MOC Part IV through Oct. 1, 2017.

Wisconsin Medical Society

George "Chip" Morris, MD

Working to Address the Opioid Crisis

George "Chip" Morris, MD, FAAN

It's no secret that the opioid crisis represents a serious threat to the health of Wisconsin citizens and the rest of the nation. From our exam rooms and emergency departments to every form of media, we're seeing the impact the misuse, abuse, and diversion of opioids is having on our patients and our communities every day. That's why, in 2015, the Wisconsin Medical Society (Society) convened an Opioid Task Force, which is committed to reducing and preventing opioid abuse, misuse, and diversion. The Society seeks to influence state and national legislation, while providing education on best practices and guidelines for physicians and patients.

Through the task force, the Society has focused its efforts in three key areas—legislation, physician education, and public awareness—with safe and effective pain management as its overarching goal.

Legislation

Perhaps some of our most visible and successful advocacy efforts have been related to the Heroin, Opioid Prevention and Education (HOPE) Agenda. Spearheaded by Wisconsin State Assembly Representative John Nygren, the HOPE Agenda is a series of bills introduced during the past 3 legislative bienniums that target heroin and prescription drug abuse. They have received overwhelming bipartisan support and, to date, 17 bills have become laws addressing a number of issues, including streamlining the use of the enhanced Prescription Drug Monitoring Program (ePDMP) to alert prescribers to the presence of potential abusers, expanding use of naloxone to prevent overdose and death, and increasing funding for treatment alternatives and diversion programs.[1]

Physician Education

It's essential that physicians and other clinicians have access to timely, relevant education in pain management. Members of the task force and other Society members who specialize in addiction and pain management have responded by creating nearly a dozen online courses approved for CME that address topics including the Wisconsin Medical Examining Board Opioid Prescribing Guideline, using the ePDMP, legal requirements for opioid prescribing, identifying opioid abuse risk in patients with chronic pain, interacting with drug-seeking patients, and more. In addition, the Society has developed an opioid performance improvement activity that addresses responsible opioid prescribing and supports the implementation and use of the ePDMP. Physicians who successfully complete the activity earn *AMA PRA Category 1 Credit*™ and satisfy Maintenance of Certification Part IV requirements. But more importantly than the credit, physicians are able to analyze their own prescribing patterns, set and implement goals, and make adjustments to improve their practice.

Public Awareness

Possibly most challenging is changing our culture and community response to pain. In addition to publishing editorials, disseminating public service announcements, and promoting "Drug Take-Back Days," the Society partnered with Wisconsin Attorney General Brad Schimel to help develop and promote "Dose of Reality," a statewide multimedia campaign launched in 2015 that aims to increase awareness and provide information to the public about the dangers of misusing prescription pain medicines.

Although we certainly can't take all the credit, as a state our efforts are paying off. During the fourth quarter of 2015, the total number of monitored drug prescriptions dispensed was 2,675,609. In comparison, during the same time period in 2016, that number was 2,461,013—a reduction of nearly 8%.[2]

This crisis doesn't mean physicians should never prescribe opioids. Effective pain care uses the most appropriate choice, weighing the risk and benefits, and not losing sight of the patient's quality of life. Our approach to managing pain must be a shared responsibility between the patient and physician. Patients should come to expect physician efforts to start with the low-risk approach of rest and non-narcotic treatments, including non-steroidal medications. Patients and physicians must agree that more risky medications such as opioids should be provided in limited quantities due to their addictive potential. Managing disease-related pain that has progressed beyond disease-based care, such as in cancer diagnoses, or other destructive conditions, has evidence-based approaches. The patient-physician partnership must follow these approaches with the risks in mind.

The Wisconsin Medical Society Opioid Task Force remains active and aggressive in these efforts, and we will not rest until pain management is a nuanced, successful process.

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Doctor Morris is a neurologist/epileptologist in MIlwaukee, Wisconsin. He is chair of the Wisconsin Medical Society's Opioid Task Force.

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A message from Wisconsin Department of Justice, Brad Schimel, Attorney General, and the Wisconsin Department of Health Services

Wisconsin Department of Health Services

Joseph E. Kerschner, MD

Transforming Medical Education

Joseph E. Kerschner, MD

Ensuring access to quality educational institutions has a significant role in shaping society's development. With regard to medical education, this societal value takes on an additional layer of importance because the learning imparted to those selected to become the next generation of physicians not only impacts their own personal life, but also every patient whom they treat throughout their careers.

Medicine has long been an extremely competitive and highly sought-after profession. As such, there are very many worthy applicants for each available seat in medical school. Those of us entrusted to lead our nation's medical schools place a great deal of thought into how we arrive at our selection processes for these coveted seats. However, there has been too little study of the processes and outcomes of these selections, or investigation into how we might better incorporate attributes such as character and compassion – which most would suggest are qualities of an "ideal" physician.

The manner in which we teach learners in medicine continues to change. It has evolved from apprenticeships and volumes of rote learning to problem-based learning and competency-based assessment. Medical knowledge is growing exponentially. In 1950, the doubling time of medical knowledge was 50 years; in 1980, 7 years; in 2010, 3.5 years. And it is projected to be 73 days by 2020.[1] Thus, physicians must be lifelong learners and incorporate new technologies to ensure provision of state-of-the-art care. Developing best practices and efficient methodologies and assessments of success in these areas also requires a great deal more study and disciplined investigation to guide the medical community toward progress.

This changing landscape, the need for a greater understanding across the continuum of medical education – from premedical studies to physicians in practice – and an even greater need for innovative new directions in medical education was the inspiration behind the recent creation of the Robert D. and Patricia E. Kern Institute for the Transformation of Medical Education (Kern Institute) at the Medical College of Wisconsin (MCW). The Kern Institute is supported by an exceptionally generous gift of $37.9 million – the largest individual noncorporate gift ever given to MCW – by the Kern Family and the Kern Family Foundation. In addition, Steve and Shelagh Roell (he is president of MCW's Board of Trustees) provided a generous gift to establish the Steven and Shelagh Roell Endowed Chair of the Kern Institute for the Transformation of Medical Education.

The Kern Institute will redefine medical education through the development of the Triple Aim for Medical Education, which will integrate core characteristics of physicians including character, caring, and competence. This Triple Aim will build on 4 pillars: faculty, students, curriculum, and culture and systems change. The Triple Aim for Medical Education parallels and complements the Triple Aim for Health Care – better care, better value, better health – and will allow the development of a new standard for medical education.

A unique aspect of the Kern Institute is its collaborative framework, as it will work closely with a National Transformation Network (NTN) to achieve this innovative progress in medical education. In addition to MCW, the NTN comprises the Geisel School of Medicine at Dartmouth, Mayo Clinic School of Medicine, University of California San Francisco School of Medicine, University of Texas at Austin Dell Medical School, University of Wisconsin School of Medicine and Public Health, and Vanderbilt University School of Medicine. Many founding members of the NTN have been working together since 2013. Recently, the collaboration learned that its manuscript on Advancing the Science of Health Care Delivery has been accepted for publication in *HealthCare*.

We look forward to the critical work of the Kern Institute and the National Transformation Network to bring together the strengths of our respective medical schools to identify and propel educational innovations into practice in Wisconsin and beyond.

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Joseph E. Kerschner, MD, is Dean, School of Medicine and Executive Vice President, Medical College of Wisconsin, Milwaukee, Wis.

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Understanding the Medicare Quality Payment Program

Christopher Becker, CPHIMS, CPHIT; Jay A. Gold, MD, JD, MPH

The Medicare Access and CHIP Reauthorization Act (MACRA) legislation introduced a new value-based reimbursement system that will affect Medicare reimbursement amounts beginning in 2019. The strategic goals of this program include improving beneficiary outcomes, maximizing participation, enhancing clinician experience, increasing adoption of advanced Alternative Payment Models (APMs), improving data and information sharing, and ensuring operational excellence in program implementation.

This new system, called the Quality Payment Program (QPP), repeals the sustainable growth rate (SGR) formula and is made up of 2 participation tracks—the Merit-Based Incentive Payment System (MIPS) and APMs. According to the Centers for Medicare & Medicaid Services (CMS), only about 10% of clinicians will qualify in 2017 under the advanced APM. By 2018, that number is expected to increase to 25%.

For clinicians who bill services under the Medicare Physician Fee Schedule (Part B), understanding the requirements and payment changes under MACRA are very important since payment adjustments that occur in 2019 will be based on action and performance starting January 1, 2017.

MIPS is a Medicare value-based payment system combining 3 Medicare programs (Physician Quality Reporting System [PQRS], Value-based Modifier [VM] and the Medicare Electronic Health Records Incentive Program) that were sunset at the end of 2016. The new system will evaluate the performance of all MIPS-eligible clinicians (ECs) or eligible groups across 4 performance categories to determine payment adjustments that will be applied in future years: Quality, Cost, Advancing Care Information, and Improvement Activities.

The first MIPS performance year is January 1, 2017 through December 31, 2017, and payment adjustments accrued from that performance year will be applied to Medicare Part B reimbursements beginning on January 1, 2019. In response to feedback from stakeholders and health care providers, CMS has designated the 2017 performance year as a transition year, with reduced requirements that are hoped will encourage broad successful participation by MIPS ECs.

For 2017, clinicians are eligible to participate in MIPS if they bill more than $30,000 to Medicare and provide care to more than 100 Medicare patients per year, and are one of the following provider types:

- Physician
- Physician Assistant
- Nurse Practitioner
- Clinical Nurse Specialist
- Certified Registered Nurse Anesthetist

In 2017, there are 3 exemptions from MIPS for clinicians who otherwise meet the eligibility requirements:

- First-year Medicare Part B participants
- Clinicians billing Medicare Part B less than $30,000 in allowed charges and/or providing care for fewer than 100 Part B patients in 1 year
- Providers sufficiently participating in an advanced APM

Excluded from MIPS payment adjustments are payments from Medicare Part A, Medicare Advantage Part C, Medicare Part D, Federally Qualified Health Center (FQHC), or Rural Health Clinic facility payments billed under all-inclusive payment methodologies, and Critical Access Hospital (CAH) Method I facility payments.

The other path available to clinicians to engage in the QPP is to participate in an advanced APM. An APM is a payment approach that provides added incentive payments for high-quality and cost-efficient care. The primary purpose of APMs is to move clinicians away from fee-for-service payment mechanisms to pay-for-value/value-based payment programs. Value, driven by the quality of care in relation to its cost, is measured and rewarded in APMs implementing value-based payment principles. APMs can apply to a specific clinical condition, a care episode, or a population. Advanced APMs are a subset of APMs and let practices earn more for taking on some risk related to their patients' outcomes. Clinicians may earn a 5% incentive payment by going further in improving patient care and taking on risk through an advanced APM.

CMS will provide a list of care models each year that qualify for advanced APM incentive payments. In 2017, the following models are advanced APMs:

- Comprehensive ESRD [End Stage Renal

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Authors are with MetaStar. Jay A. Gold, MD, JD, MPH, is senior vice president and chief medical officer; Christopher Becker, CPHIMS, CPHIT, is a project specialist. This material was prepared by the Lake Superior Quality Innovation Network, under contract with the Centers for Medicare and Medicaid Services (CMS), an agency of the US Department of Health and Human Services. The materials do not necessarily reflect CMS policy. 11SOW-WI-D1-17-56 041417

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- Comprehensive Care for Joint Replacement (CJR) Payment Model (Track 1- CEHRT)
- Vermont Medicare Accountable Care Organization (ACO) Initiative (as part of the Vermont All-Payer ACO Model)

Technical assistance for the QPP is available to practices with 16 or more ECs through the Lake Superior Quality Innovation Network (Lake Superior QIN), which includes Michigan and Minnesota in addition to Wisconsin. MetaStar represents Wisconsin in the Lake Superior QIN and provides technical assistance for clinicians in Wisconsin.

For practices with 15 or fewer ECs, assistance is available through the QPP Resource Center. For direct assistance with the QPP Resource Center, Wisconsin ECs should contact MetaStar. The QPP Resource Center, funded by CMS, is collaborating among 10 key partners across Michigan, Ohio, Indiana, Illinois, Kentucky, Wisconsin, and Minnesota.

The QPP Resource Center is tasked with helping more than 35,000 clinicians prepare for and participate in the QPP. If you have a small practice (15 or fewer clinicians), are in a rural area, a Health Professional Shortage Area (HPSA), or a medically underserved area, the QPP Resource Center is authorized to provide assistance to you.

If you are interested in exploring assistance with the QPP, regardless of practice size, e-mail MetaStar at qpp@metastar.com. As part of the Lake Superior QIN and the QPP Resource Center, MetaStar provides a one-stop-shop approach for questions about the QPP.

More information about the program can also be found at https://qpp.cms.gov/. For resources and assistance visit www.lsqin.org/qpp or https://qppresourcecenter.com.

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