THE JOURNAL OF THE MINNESOTA MEDICAL ASSOCIATION

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NOVEMBER/DECEMBER 2014

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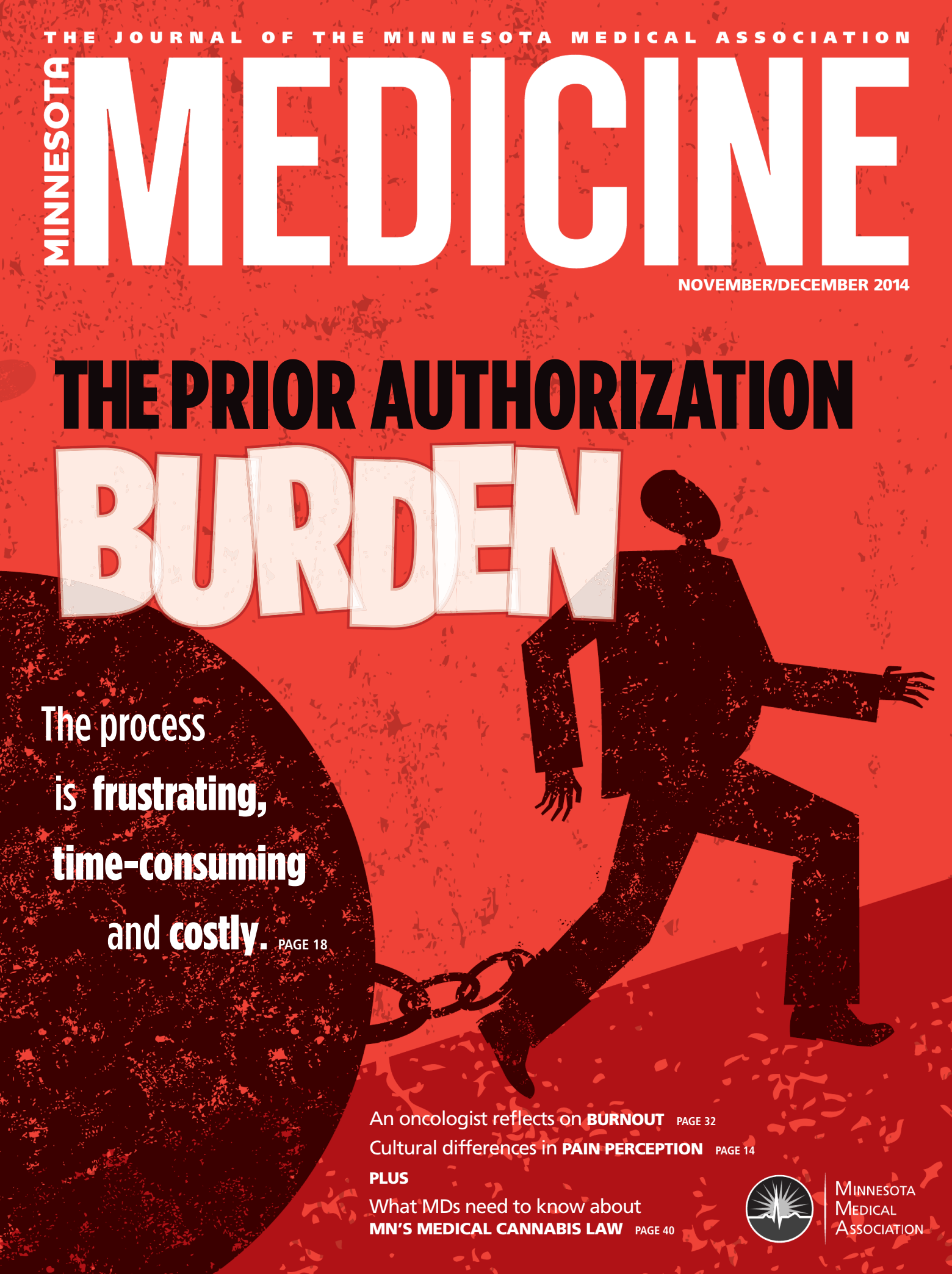

The process is **frustrating, time-consuming** and **costly.** PAGE 18

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PLUS

What MDs need to know about **MN'S MEDICAL CANNABIS LAW** PAGE 40

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PHOTO BY SCOTT WALKER

Charles R. Meyer, M.D., Editor in Chief

The certainty of uncertainty

Learning to act without ironclad assurance is perhaps the cardinal lesson in the art of medicine.

I glance at the clock—1:55 a.m.—as I roll over to answer the phone. The call is the third of the night from the ICU, and I have hit my three-call wall. I know the rest of the night will be a tug-of-war between the siren of sleep and the whirl of concern about my ICU patient. Will I be able to get her potassium down? Will her kidneys start working? Will we get her blood pressure above 90 systolic? The clinical goblins prevail, and I drag myself to the office in the morning dreaming of dreaming.

Rare, precious and forever sought, sleep is the platinum of a physician's life. From Day 1 of medical school to the final days of practice, it is the scarce commodity that none of us seem to get enough of. Medical practice harbors so many disrupters of solid sleep. Long work hours can leave you revved up, replaying the day even after your head hits the pillow. Nights on call, particularly if you cover a hospital practice, can contain more rude awakenings than nights with a 2-month old in the next room. After darkness falls, worry about the status and future of medical practice itself can spin troublesome tales of new threats to income and independence. The practice of medicine can be a veritable rogue alarm clock, going off at random times and messing with sleep.

Perhaps sleep lies at the core of the attraction of employment for physicians. For most physicians employed by large groups, call is infrequent and involves only outpatient problems. There are no concerns about hiring or firing employees or running a practice. And hours are usually defined and limited. The lifestyle seems better and the sleep promises to be sounder.

Yet practicing medicine is never without insomnia-provoking concerns, and this month we explore some of those insomnogenic goblins. Frustrations with the electronic health record can rankle. Irritations with insurance companies' intrusions into daily practice can gall. The looming threat of malpractice can frighten. The daily grind of sometimes difficult patients can nag.

The common thread for all of these is uncertainty. Uncertainty is the constant companion for practicing physicians, hovering in the shadows of every day. Medical training teaches us where the pituitary gland is and how to treat pneumonia, but mostly we have to teach ourselves how to deal with uncertainty. Diagnoses are rarely textbook. Patient response to treatment is variable. The patient you just sent out of the clinic with a prescription could end up in the emergency room, spawning questions about what you did wrong. Learning to act without ironclad assurance is perhaps the cardinal lesson in the art of medicine, and learning from your actions and mis-actions to build some certainty into your uncertainty is at the heart of continuing medical education and of staying functional in the practice of medicine.

My practice has changed. It's been two years since I've fielded a call from the ICU, but somehow I do still find something to roil my brain at 1:55 a.m. Uncertainty in medical practice will never disappear and the end of sleepless nights will always be a dream.

Charles Meyer can be reached at charles.073@gmail.com.

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Worth the money?

I read with interest Dr. David Walcher's commentary in the September issue of *Minnesota Medicine* ("A shift in focus," p. 41). I have spent a lifetime in businesses large, small and my own. The good doctor's comments are right, but the driving issues can be expanded upon. There are two major components behind high medical costs: the board compensation committee and the concept of "pay for talent."

We all expect that the most talented people will lead our companies, a simple axiom. In truth, CEO selection is flawed by the thought that the more we pay our CEO, the more the direct reports to the CEO will be paid. So we are driven to select the candidate with the highest salary demands, as we think doing so will increase our own salary. But here's how it works: Compensation committees are subsets of boards of directors. Directors' pay is most often determined by the CEO. The CEO identifies a board he or she can work with, and the board members' pay is set following the recommendations of the CEO and the compensation committee.

The results of this system are clear: The top executives are paid at a rate that is, in some instances, more than 800 times that of other managers. Using Dr. Walcher's calculation methodology, top-paid CEOs are earning more than $40,000 per hour. (The highest-paid medical industry executive in 2012 had a total annual compensation package in excess of $148 million not including termination and travel benefits. When challenged over his high pay, he insisted he was "darn well worth it.") Are they worth it? Denial and hubris may disorient the recipient reality, but ethics and common sense would emphatically say no, they are not worth that much.

The never-ending spiral of increasing executive pay, aside from being self-serving, is unhindered because of the mandate that medical benefits be a condition of employment. There are those who say that a free market will solve the problem of increasing health care costs. They say, end "medical" as a *pro forma* benefit and watch prices tumble. They say, make patients have "skin in the game" so that they live a healthy lifestyle. But it is simply absurd to suggest that individuals are responsible for the medical consequences of assault, car accidents, workplace contaminate exposure, etc.

Finally, a word about potential solutions. Practically, no solution to the problem of high health care costs is achievable without rethinking the role of insurance in medicine. The imperative to redefine our national priorities in this area is stymied by the immense amount of political money spent on maintaining the status quo. Sure, the insurance industry employs many thousands of people. Redeploying the population whose job it is to make medical care expensive would not be easy, nor would it be politically palatable. But frankly, I think that if politicians had the ethics of most doctors, reform would be accomplished in minutes.

The mandate of universal health care is unavoidable. The role of a private insurance industry, whether for-profit or not-for-profit, is unmaintainable. The concept of profiting from illness or sickness is way too Faustian. The medical judgments of high-minded physicians, not insurance clerks or single-vision HMO executives, ultimately need to prevail if we are ever to have both more effective outcomes and lower costs.

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Physicians' biennial CHECK-UP

Every two years, The Physicians Foundation attempts to find out what the country's doctors are thinking about their profession. This year, 44 percent described their feelings about medicine as positive, an increase from 32 percent in 2012. Younger physicians, female physicians, employed physicians and primary care physicians were more positive about the current medical practice environment than older physicians, male physicians, medical specialists and physicians who owned practices. The 2014 Survey of America's Physicians was emailed to 650,000 individuals. About 20,000 completed it (3.3% were from Minnesota).

Here are some other highlights:

On workload

81 PERCENT of physicians describe themselves as either overextended or at full capacity, up from 75 percent in 2012. Only 19 percent have time to see more patients.

44 PERCENT plan to take steps to reduce patient access such as cutting back on the number of patients seen, retire, work part time or close their practice.

72 PERCENT believe there is a physician shortage.

On practice setting

35 PERCENT of physicians describe themselves as owning an independent practice, down from 49 percent in 2012.

53 PERCENT describe themselves as being employed by a hospital or medical group, up from 44 percent.

17 PERCENT say they are in solo practice, down from 25 percent.

On medicine as a profession

29 PERCENT of respondents say they would not choose medicine if they had to do it over, a decrease from 35 percent two years earlier.

50 PERCENT say they would recommend medicine as a career to their children, an increase from 42 percent.

On health care reform

46 PERCENT of physicians give the Affordable Care Act a grade of D or F, while 25 percent give it an A or B, and 29 percent would give it a C.

85 PERCENT have adopted an electronic medical record (EMR) system, up from 69 percent in 2012. However, 46 percent indicate the EMR has decreased their efficiency, while only 24 percent say it has improved their efficiency.

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ON EBOLA WATCH

A conversation with Minnesota's top disease-trackers

INTERVIEW BY CARMEN PEOTA

When the country's first case of Ebola appeared in Dallas in October, experts at the Minnesota Department of Health were surprised—not because the virus had finally made its way to the United States but because it showed up in Texas first.

"If you'd asked us weeks ago, 'Where's the first case going to be?' a betting man would have said it would be here in Minnesota because we have such a large Liberian population," says Rich Danila, Ph.D., deputy state epidemiologist. Currently, an estimated 25,000 Liberians reside in Minnesota, and most of them live in the northwestern quadrant of the Twin Cities metro area.

Ruth Lynfield, M.D.

Rich Danila, Ph.D.

Danila and others in the Minnesota Department of Health's epidemiology unit had watched as Ebola virus disease wreaked havoc in western Africa. By July, they realized the state needed to gear up, just in case. By the end of September, when the World Health Organization was reporting nearly 3,500 cases and more than 2,000 deaths in Liberia alone, they expected that someone flying from Liberia to Minnesota would be the first to bring Ebola to the United States.

I asked Danila and State Epidemiologist Ruth Lynfield, M.D., who take the lead during disease outbreaks in Minnesota, whether they thought the state was prepared for Ebola. Early in October, they thought we were. By the end of the month, after two nurses had contracted the virus, they said Department of Health staff were learning from the experiences in Texas, as well as in Atlanta and Omaha, and they were redoubling their efforts to ensure that Minnesota health care providers had the information and resources they needed to face Ebola.

Q: *What have you been doing to get the state ready?*

LYNFIELD: We have been giving a lot of presentations and providing information to health care providers, public health staff, laboratorians, health care facilities and the general public on preparing for Ebola. We have been keeping up with evolving issues and new guidelines, and we have been adapting our approach to incorporate new information as it comes out, posting it on our website.

We also have been working closely with and providing information to the Liberians who live in Minnesota who, understandably, have a lot of questions and concerns about Ebola.

Q: *What are you telling physicians and other health care providers?*

LYNFIELD: That the really key question to ask patients up front is this: "Have you traveled in the past 21 days, and, if so, where?"

DANILA: Travel is so important in this world we live in. You could have been anywhere in the world two days ago and arrive here with a disease we normally wouldn't have thought about 25 years ago.

Q: *What are you telling hospitals?*

DANILA: There's a very good checklist for hospitals to go through to make sure they're prepared for their first case of Ebola. It goes through the infection-control issues, the screening of patients, medical and laboratory issues, and communications. Also, we are emphasizing the importance of training staff on how to use the recommended personal protective equipment—specifically, how to put it on and take it off safely.

Q: *Are physicians who work with people from Minnesota's Liberian community especially concerned?*

DANILA: We've received many calls. We've done grand rounds at North Memorial, which sees many people from Minnesota's Liberian community and talked to physicians at North. They recognize they are the physicians most likely to encounter an Ebola case. About 10 weeks ago, we were getting a lot of calls from nursing homes about Liberians returning to work after visiting family in Liberia. I think a couple months ago we had more Liberians flying back and forth than we do now.

Q: *Would an Ebola case be handled differently in Minnesota than it was in Texas?*

DANILA: We hope with all the preparation we've done that we would have picked up on it the first time the patient went into the emergency department and not the second time. But you never know. It depends on what the patient tells you and what you know.

Q: *If a case occurred here tomorrow, what would happen?*

LYNFIELD: We expect that we would get a call from the physicians who are evaluating the patient. We'd go through how the patient is presenting, review clinical findings and what specifically the exposures were. If we think the patient does meet the criteria for testing for Ebola, we would facilitate testing. We would also review infection control and prevention guidelines with the health care providers.

DANILA: Minnesota's public health lab is one of only about a dozen labs in the country, outside of the CDC, that can test for Ebola infection. The results would be back in six to eight hours.

LYNFIELD: The testing we would do in Minnesota would need to be confirmed by the CDC. If we think the patient may have Ebola, we would recommend that the person be isolated, and that the appropriate infection control procedures be used while tests are pending. It is important to know that during the first three days of symptoms, the PCR test may not be positive. So a follow-up test may be needed in someone presenting early in the course of their infection.

Q: *Will only certain hospitals and certain physicians be handling Ebola patients here?*

DANILA: Any hospital, clinic or urgent care must be prepared to identify a potential case because someone could present anywhere for care. Because patients infected with Ebola can become critically ill and may lose five to 10 liters of body fluids per day, it is becoming clear that these patients need special care in a facility that not only can provide critical care but also has a team that is proficient in the necessary infection control. What we have learned from the experience in Texas is that the health care providers taking care of these patients need to be very comfortable using the recommended personal protective equipment.

LYNFIELD: The mainstay of treatment is supportive care and meticulous infection control, although investigational therapies have been tried in some cases. The CDC has offered to help when a case is identified, including putting clinicians in touch with others who have experience in taking care of Ebola patients and sending a team to help. We would help facilitate this. However, infection control is key and health care providers need training and practice. All that said, discussion is occurring to identify facilities that will care for Ebola patients. Those facilities will have dedicated teams that are proficient in Ebola infection control and in clinical management.

Q: *How should physicians protect themselves?*

LYNFIELD: The CDC carefully reviewed the situation in Dallas and updated its guidance on personal protective equipment. Health care workers need respiratory protection with a PAPR or N95 respirator because infectious aerosols can be generated during the care of these patients. Also, they must wear an impermeable gown, two pairs of gloves, boot covers and an apron.

Anyone taking care of Ebola patients must have repeated training and demonstrate competency in infection control practices and procedures; no skin should be exposed (there should be full body

RESOURCES FOR PHYSICIANS

- Minnesota Department of Health Information on Ebola: www.health.state.mn.us/divs/idepc/diseases/vhf/index.html
- Guidance on Personal Protective Equipment to be Used by Health Care Workers during Management of Patients with Ebola Virus Disease in U.S. Hospitals: www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html
- Algorithm for Evaluation of the Returned Traveler for Ebola: www.cdc.gov/vhf/ebola/pdf/ebola-algorithm.pdf
- Checklist for Patients Being Evaluated for Ebola Virus Disease: www.cdc.gov/vhf/ebola/pdf/checklist-patients-evaluated-us-evd.pdf

CONTACT THE HEALTH DEPARTMENT

State Epidemiology Program staff are available 'round the clock, seven days a week. Call 651-201-5414.

coverage); an onsite manager should oversee the safe care of Ebola patients and a trained observer must supervise each step in the donning and doffing of protective equipment. Also, according to the new guidance, there should be a designated area for donning and doffing.

Q: *What worries you most right now?*

DANILA: One of the current problems we're having is with clinical laboratories not wanting to do routine clinical tests on patients who might have Ebola. Patients returning from West Africa may have a number of conditions, and it is important to sort out the exposure and clinical history. We would not want someone with malaria, typhoid or other conditions to be missed. We are concerned that clinical tests on a known patient won't be done because of the laboratories' concerns.

LYNFIELD: Another worry is that the media coverage about Ebola is leading people in the United States to amplify the risk. We've already seen negative consequences such as school closings because of misunderstanding about transmission of Ebola and fear. The best thing we can do to control Ebola in this country is to control it at the source, which is in Africa. This outbreak is having enormous consequences for the involved countries that will have a long-term impact. We need to do everything we can to help them.

Q: *What do physicians need to know about Ebola that they might not?*

LYNFIELD: Ebola is a really scary disease, and we never expected to encounter it in the United States. However, we have excellent tools at our disposal. Several medical centers are already experienced in treating Ebola patients safely, and they are sharing their procedures and approaches. The CDC is continuing to review, assess and refine their recommendations on Ebola.

Despite the occurrence of a few cases in the United States, we need to remember that conditions here are very different than conditions in Africa. We will not have an uncontrolled outbreak. Good, factual information is available, and we encourage physicians to become familiar with it. Also, we encourage physicians to call us if they have questions, and when they are evaluating someone who may have Ebola. Our staff is available 24/7. **MM**

Carmen Peota is an editor of *Minnesota Medicine*.

DIAGNOSIS AND MANAGEMENT OF PATIENTS WITH SUSPECTED EBOLA VIRUS DISEASE

- Assess the patient for fever (subjective or ≥100.4°F/38.0°C)
- Determine whether the patient has symptoms compatible with Ebola virus disease such as headache, weakness, muscle pain, vomiting, diarrhea, abdominal pain or hemorrhage
- Assess whether the patient has a potential exposure from traveling to a country with widespread Ebola transmission or having contact with an Ebola patient in the 21 days before illness onset
- Suspect Ebola if fever or compatible Ebola symptoms and an exposure are present
- Consult with the Minnesota Department of Health about diagnostic EVD RT-PCR testing (651-201-5414)
- Consider, test for and treat (when appropriate) other possible infectious causes of symptoms (eg, malaria, bacterial infections)
- Provide aggressive supportive care including aggressive IV fluid resuscitation, if warranted
- Assess for electrolyte abnormalities and replete
- Evaluate for evidence of bleeding and assess hematologic and coagulation parameters
- Provide symptomatic management of fever, nausea, vomiting, diarrhea and abdominal pain
- Consult the health department about other treatment options

Source: CDC

Perceptions of **pain**

Cultural differences add to the challenge of treating patients' pain.

BY SUZY FRISCH

When a patient presents with pain, physicians take part in a delicate dance as they attempt to assess the source and severity of the sensation and determine the best course of action. They want to alleviate suffering but don't want to prescribe a drug that could be abused. When the patient's culture or home country is different than the physician's, the dance becomes much more complicated. There may be language barriers and differences in how people describe pain, how they self-treat and what they want from their physician.

Keith M. Swetz, M.D., sees it all the time at Mayo Clinic. An associate professor of medicine at Mayo Medical School and a palliative medicine specialist, Swetz treats people from many different backgrounds who are dealing with pain. And over the years, he has noticed there are cultural variations in how his patients describe what they feel. He's learned that in some cultures, suffering is meant to be endured and that it's common to minimize it. In others, people may be highly dramatic, making sure that medical professionals understand their pain and symptoms. "It's hard to know if someone is markedly over-reporting what their pain is—even if that is their culturally appropriate response—versus someone who is very stoic and minimizes their pain and suffering, when indeed their symptoms far exceed what they are reporting," he says.

Cultural issues come into play in other ways as well. When caring for Somali patients at the end of life, Swetz has seen conflict between those who want medication to ease their pain and their family members who want to make sure their loved one is conscious and able to converse and pray before they die. "You have to frame the conversation for the patient accounting for their own culture and past experience, and sometimes that's hard to do," he says.

As Minnesota's population continues to become more diverse, physicians in every corner of the state are seeing people from a variety of backgrounds—a trend that only will continue. The Minnesota State Demographic Center indicates that one in every 14 people in Minnesota is foreign-born and projects that nonwhites and Latinos will comprise 13 percent of the population by 2015 and 25 percent by 2035. Minnesota already has the country's largest population of Somali and Liberian residents and the second-largest population of Hmong residents, following Cali-

fornia. More recently, the state has become home to refugees from Myanmar, Iraq and Bhutan.

Understanding patients' cultural backgrounds is critical, notes an Institute of Medicine report, "Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care." According to its authors, failing to support and foster culturally competent health care can lead to increased costs for the individual and society because of more hospitalizations and complications. And with fears of opioid abuse unabating, it's never been more important to factor in culture when assessing and managing a patient with pain.

Talk it out

Family physician Kara Pacala, M.D., sees patients from many ethnic groups and cultural backgrounds at the University of Minnesota Smiley's Family Medicine Clinic in Minneapolis—with East African patients making up a large portion of her caseload. Many of her patients have experienced the trauma of war, living in refugee camps or being separated from close family members. She aims to learn their personal stories and pair that information with what she learns from the medical history and physical exam to better understand the source of their pain. She also considers cultural factors. She has learned, for example, that patients from East Africa tend to describe pain in terms of temperature; that is, a sore area feels hot or burns. Combining that information with other diagnostic methods, Pacala attempts to get at the root of her patients' pain. That way, she's not treating emotional or somatic pain in the same way she would that caused by an ulcer or migraine.

"We learned to look for red flags—things that compel me to say that this headache the patient is experiencing might indicate something serious like a tumor. Or this is the headache of a woman who hasn't had a decent night's sleep in months or years," Pacala says. "I'm learning to hear in between, based on an understanding of culture and the stories of the patient. That makes a difference in the diagnosis and how you treat so that you can treat appropriately."

Jennifer Hines, M.D., also knows cultural factors need to be considered when assessing pain. An internist at Health Partners' Midway Clinic in St. Paul, which serves a significant number of Hmong, African and Hispanic patients (she also worked at a free hospital in Phnom Penh, Cambodia, for six years), she knows that many Asian patients—especially older ones—are reluctant to communicate with physicians. They have abiding reverence for doctors, who are considered to be in the highest profession, and many don't want to be disrespectful by bothering them with their troubles. So they understate their pain. Hines works hard to earn their trust and let them know that it isn't disrespectful to tell her if they're experiencing pain.

With her elderly Somali patients, she knows she has to tease out information. For example, she finds that many don't understand the numerical scale used to describe the intensity of pain. So Hines gathers information by asking the patient to describe what's happening at home. "I might have a conversation with the patient about her week and what she is able to do. How many hours did she sleep?" She uses the answers, along with observations on how active and communicative the patient is, to help her determine indirectly how much pain the patient is experiencing.

Elena Polukhin, M.D., a physical medicine and rehabilitation physician at Rehabilitation Consultants in Bloomington, says she often relies on interpreters to understand her patients' concerns. A native of Russia, Polukhin sees patients from Eastern Europe and Africa as well as the United States, many of whom have both chronic pain and chemical dependency issues. And while she would struggle to do her job without interpreters, she knows they sometimes bring their own opinions into the exam room.

Once when Polukhin was talking to a Bosnian patient struggling with alcoholism—a big taboo in the mainly Muslim country—about injectable naltrexone, which blocks the effects of narcotics and alcohol, the interpreter who was translating became judgmental. "We were explaining

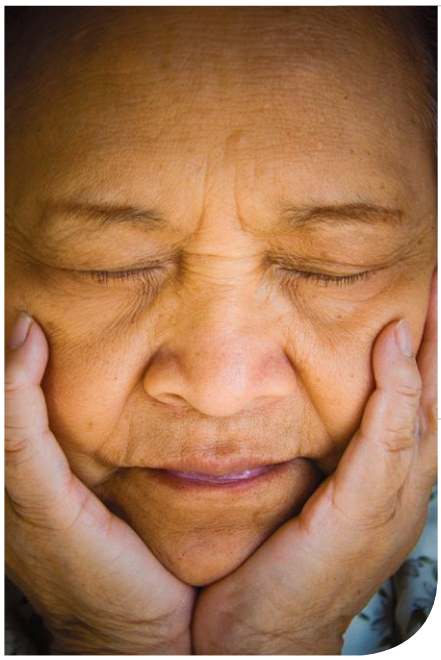

Elena Polukhin, M.D.


Keith Swetz, M.D.


Kara Pacala, M.D.

how it would be used, and the interpreter was very upset with the patient," she says. "The interpreter later told me that people like [the alcoholic patient] are garbage and deserve to die." Polukhin has since cultivated a select group of interpreters with whom she regularly works in order to avoid such unexpected responses.

Pacala also has had challenges when working with interpreters. For example, when she asked a Somali patient if he was depressed, the interpreter translated the question to, "Are you crazy?"—leaving the patient shocked and appalled. The problem: There was no word for "depressed" in the patient's language. Pacala has learned instead to ask patients if they are sad, if they have a poor appetite and whether they are sleeping well.



> "You have to frame the conversation for the patient accounting for their own culture and past experience, and sometimes that's hard to do."
>
> – Keith Swetz, M.D.

Culture and therapy choice

Physicians who treat patients in pain note that culture can serve as a guide when it comes to selecting appropriate treatments. In her practice, Hines finds it's rare for Asian patients to take opioids because of their tendency to endure or live with pain. Pacala says she has learned that many of her East African patients associate going to the doctor with receiving treatment of some sort. You have an illness, therefore you get medication. That doesn't necessarily mean those patients are seeking narcotics, she says. "But they think, 'If you are sick enough to go to the doctor, you are sick enough to be given treatment.' We're learning to work with that and understand that."

Many physicians treating pain patients use a combination of medication and complementary and other therapies—acupuncture, healing touch, chiropractic treatment, heat and ice. Whether a patient is open to a certain treatment may, in part, be influenced by their culture and background. Many of Pacala's East African patients, for example, are willing to trying massage and physical therapy, as long as the provider is of the same sex. They also will try heat, ice and topical medications when Pacala suggests them. Patients from other cultures aren't so interested. Polukhin knows that her Russian Orthodox patients, for example, are not fans of acupuncture, noting that they "think needles are from the devil." Her Hmong and Vietnamese patients, though, are willing to try acupuncture and healing touch. Polukhin also suggests nutritional supplements such as glucosamine microlactin as natural pain killers and finds that her American Indian and Muslim patients especially favor that kind of treatment.

Many of Hines' Asian patients use traditional pain-relief methods such as cupping, foot massage or topical medications. When those don't provide enough relief, they turn to her to find out what Western medicine can offer. So as she sees patients from other cultures, she always inquires about treatments they have already tried. If she knows she will be seeing a patient from a culture with which she is less familiar, she might ask an interpreter about which treatments are commonly used, so she can ask the patient informed questions.

Trust and understanding

With any patient claiming to be in pain, physicians have to be both wary about potential abuse and sensitive to culture and background. They need to watch out for red flags such as patients who doctor shop, ask for specific narcotics, frequently lose medications or repeatedly ask for early refills, Swetz says. Yet at the same time, clinicians have to be attuned to their patients' needs and preferences and their perceptions of pain and its treatment.

Pacala admits treating patients with pain can be tricky. "But it always comes back to the relationship you can form with the patient or family," she says. "Try to establish trust and give the message that you're trying to help and hope they understand the process. It's complicated for everyone." **MM**

Suzy Frisch is a Twin Cities freelance writer.

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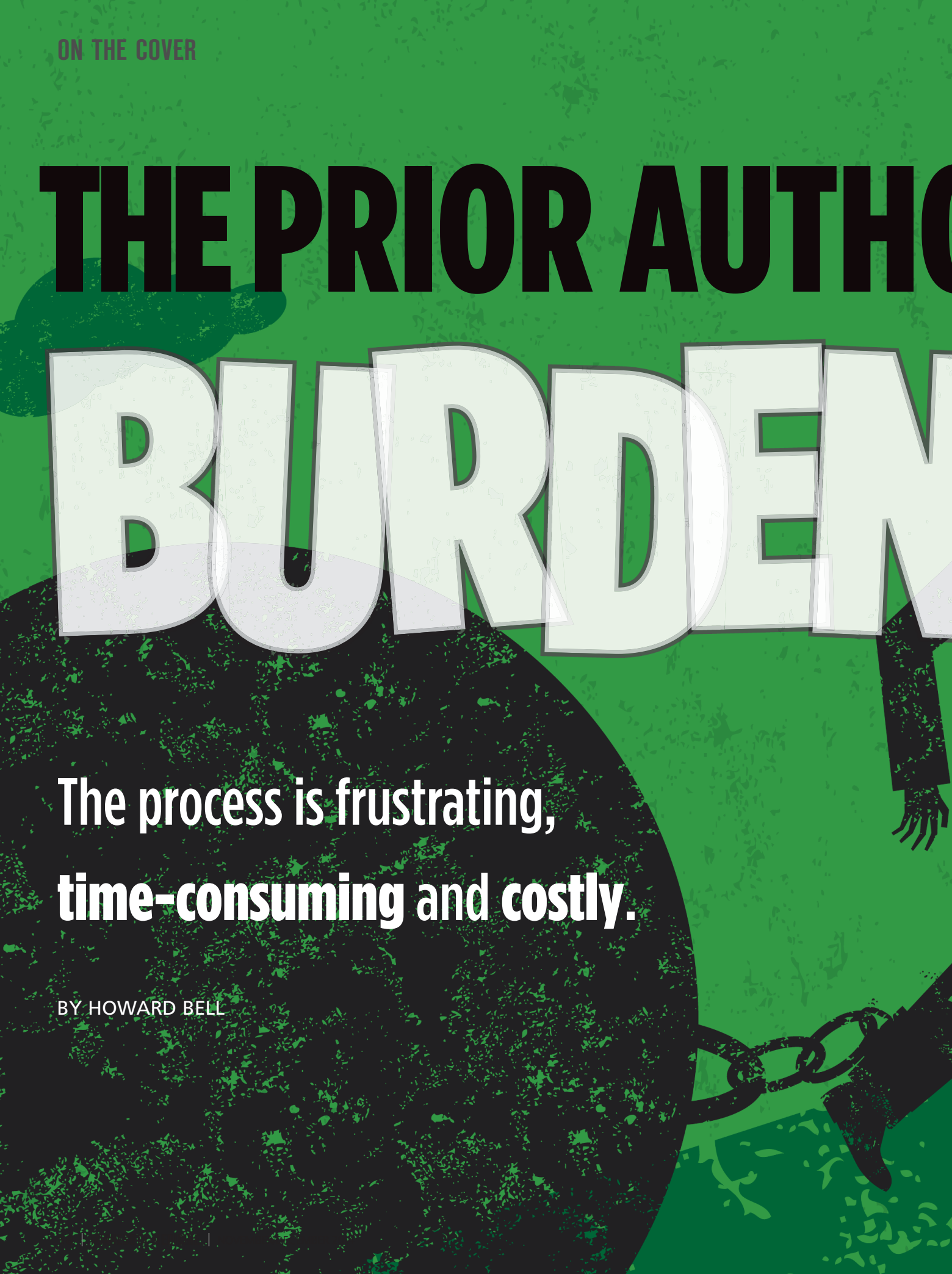

The process is frustrating, **time-consuming** and **costly**.

BY HOWARD BELL

ORIZATION

Moose Lake family physician Randy Rice, M.D., recalls the frustration he experienced when he tried to get a routine refill for a patient's rescue inhaler. He initially prescribed Ventolin, which the patient had been using for years, and was told that even though it had been a drug of choice on the health plan's formulary, it now required prior authorization (PA). "But they wouldn't tell me what the preferred drug was," he says.

Thus began the guessing game. Rice wrote a second prescription for Proventil, which was denied, then a third for ProAir, which was also denied. He then submitted a PA request for ProAir. Late on a Friday, he found out the request had been denied. He was told to choose a different drug, but the insurer still didn't tell him which one would be covered. "The patient, who has severe asthma, went home that weekend without his rescue inhaler and could have ended up in the ER or hospital," Rice says. On Monday, he learned that he needed to prescribe Xopenex, a newer, more expensive medicine that wasn't even on most formularies. "We shouldn't have to play this guessing game," he says.

Prior authorization is that extra step health plans require before they decide if they will pay for certain prescriptions. To physicians, PA is a time-consuming, costly task that takes them away from patients.

Nationwide, primary care physicians spend an average of 2.8 hours per week on PA and other formulary interactions, according to a survey of two-thirds of all practicing physicians in the United States. The investigators, who published their findings in *Health Affairs* in 2009, found nursing staff spent 16.9 hours per week

and clerical staff 5.6 hours per week on such tasks. Converting time into dollars, they calculated the average primary care practice spent $64,859 annually per physician on PA, nearly one-third the amount they paid for salary and benefits for the average primary care physician.

Rice says he personally spends about three hours a week on PA and that his nurses and other clinic staff spend about 10 to 15 hours on it. "My time spent on PA has gone up exponentially in the past few years. It's become vastly overused. No matter how well I follow best-practice lowest-cost guidelines, I still need to do PA, and I even have to do annual repeat PAs for drugs they've already approved." In what he calls the "ultimate absurdity," Rice says he once even had to fill out a PA form in order to get permission to fill out another PA form.

GOOD INTENTION IN NEED OF A FIX

Prior authorization has been part of medical practice in Minnesota since the advent of managed care formularies in the 1980s. But physicians say it is now required more often and for more drugs than it used to be. There are a number of reasons for that: More health care dollars get spent on drugs now because there are more drugs for more conditions. Biologics such as Enbrel and Humira and personalized drugs made possible by advances in pharmacogenomics can cost tens of thousands of dollars per month. In addition, the advent of Medicare Part D drug coverage in 2003 increased prescribing.

Health plans say they use PA to protect patient safety and reduce drug costs, encourage use of less-expensive generics, limit off-label uses of drugs, quell demand for newer and more-expensive drugs that are advertised directly to patients, and limit access to specialty drugs that only certain physicians have the expertise to prescribe. All of these are laudable reasons for PA. But for physicians, the recurring paperwork, phone calls, faxes and bureaucratic battles that it brings feel like an unnecessary burden.

Frustration over PA led the Minnesota Medical Association last year to search for ways to reduce the inconvenience. Staff have been interviewing health plan medical directors to learn more about their PA processes and talking with pharmacists, representatives from the state's Medicaid

ELECTRONIC PRIOR AUTHORIZATION

The National Council for Prescription Drug Programs is in the process of implementing nationwide standards for electronic prior authorization (PA) transmittal.

This will allow providers to transmit information requested for PA to a pharmacy benefits manager using e-prescribing networks such as SureScripts.

"Electronic PA will reduce missing or illegible information often found in paper-based faxes," says Kevin Burns, spokesperson for the Academy of Managed Care Pharmacy. "Turnaround time for PA responses would be reduced because of the built-in logic of the question sets." For example, one of the first questions might ask for a diagnosis code, which might eliminate the need for further questions.

Electronic PA will first be used for prescriptions paid for by Medicare Part D. Eventually it's expected to be adopted by all private and public health plans. Minnesota is already poised to accelerate adoption. Under current state law, all drug PA must be submitted electronically by January 2016. —H.B.

program and clinic office staff about its effect on cost and practice. And they've encouraged physicians to share their PA stories through an online tool on the MMA's website. The hope is that they'll have a plan for reducing the burden associated with prescription drug PA by January.

"We're not trying to eliminate drug prior authorization," says MMA Policy Director Janet Silversmith. "We just want to add some sanity to the process. As it's practiced now, we believe drug prior authorization is an onerous, inefficient process that sometimes harms patients."

HOW PA WORKS—AND DOESN'T

Prior authorization generally takes three forms in Minnesota, says MMA staffer Barbara Daiker, R.N, Ph.D. Health plans may require physicians to show that a patient has a clinical need for a particular medication before that medication will be authorized for coverage. They may require clinicians to show that one or more other drugs were tried first—and failed to work—before giving approval for the desired drug. They also may cap the amount of a drug that can be prescribed in a given time, so a physician who wants to prescribe beyond that must get permission to do so.

The health plans pay pharmacy benefit managers (PBMs) such as Express Scripts, CVS Caremark, Medical Impact and Prime Therapeutics to handle approvals, denials and most appeals for them. State law stipulates that initial decisions must be communicated to the physician and patient within 10 business days.

Many requests get approved almost instantly and automatically. And most eventually get approved, says George Schoephoerster, M.D., a geriatrician who has met with several Minnesota health plan medical directors to learn more about the PA process on behalf of the MMA. During those discussions, Schoephoerster learned that one plan denied 20 percent of requests in 2012. Such reviews delay care, he points out.

Not knowing which drugs are on each health plan's formulary and which ones require PA is one of the biggest frustrations for physicians. Rice's experience with inhalers is a case in point. Lists change often, and each health plan's may be different; in fact, each product offered by an insurer may have its own unique list.

"Every health plan has its own forms, questions and procedures for the same drugs, and very different lists of which drugs require PA," says Monica McKinnon, R.N., nurse manager for the Center for Reproductive Medicine in Minneapolis. She estimates her clinic staff spend 10 to 15 hours per week on drug PA. Another source of irritation is when the health plan says one thing and the PBM says another. For example, McKinnon has been told by a PBM to submit a PA request for certain drugs and after doing so received a letter from the health plan saying PA wasn't needed.

"We spend a lot of time on the phone on hold, taking away time that should be spent with our patients," she says. "And when we finally get through, they give us yet another number to call." Sometimes,

before McKinnon is allowed to talk to a real person, she has to navigate an automated phone tree. "When you finish that and finally get to talk to a real person, they ask you the same questions you just spent a lot of time answering."

Usually, McKinnon says, the person on the other end of the line has little or no medical knowledge about fertility medications and codes. That's true even when you appeal a PA denial, according to Randy Saliares, M.D., a gastroenterologist with CentraCare in St. Cloud, who along with Rice has been part of the MMA workgroup looking into the problems with PA. "For the appeal stage, I've learned to ask right away to speak with a specialist in my field. I've had cases where I ask again and again and never do get to talk to that specialist."

When Saliares suspects a drug may require PA, he sometimes sends a request to the pharmacy along with the prescription, in hopes his patient gets the medication quicker. But that doesn't always happen. "I've been told I can't submit the prior authorization request because it [the prescription] hasn't been denied yet—even though it's going to be denied and everybody knows it. If one drug gets denied and I call the plan or the PBM to find out which drug is O.K. to prescribe without prior authorization, they say they can't tell me until I try to get the drug I want."

A LOOK INSIDE A PUBLIC PAYER'S PROCESS

Because Medical Assistance (MA) is a public health plan, its prior authorization (PA) process is relatively transparent. Last year, fee-for-service MA approved 26,000 PA requests and paid for more than 3.4 million prescriptions, according to Sara Drake, R.Ph., pharmacy program manager for the Minnesota Department of Human Services, which administers MA. "More than 99 percent of prescriptions paid for by MA did not require a provider or pharmacy to submit a PA request," Drake says. "Often, prescribers can avoid PA on the front end by choosing to prescribe the preferred drug on our formulary," she says. That information is on the department's website or may be accessed through SureScripts. A drug may be on the PA list if it is more expensive than a similar one or if it has significant safety issues or abuse potential.

About 50 percent of PA requests to MA are denied. "That might sound high," Drake says. "But many of these denials are for drugs that never should have been submitted to us in the first place because federal law doesn't allow us to cover them for any purpose, Viagra being a good example."

Federal law requires the Department of Human Services to make a determination on the PA request within 24 hours of receiving it. They are required to notify the pharmacy through secure email or fax, and generate a letter to the patient within 24 hours after making the determination. The department isn't required to notify physicians but does so as a courtesy.

Prescribers can submit a PA request to MA by using MA's PA form or Minnesota's Uniform PA Form or by submitting the request electronically through the CoverMyMeds.com website.

Like private health plans, the state negotiates with drug makers to get lower prices for people on MA. But it also gets guaranteed minimum rebates that drug manufacturers must pay as a condition of being covered by the federal-state Medicaid program. When rebates and discounts are added up, it's not unusual for MA to pay 80 percent less than the manufacturer's list price for drugs that have been around for several years. —H.B.

Checking with the pharmacy isn't necessarily a solution, as the pharmacies don't always know which drugs may or may not get approved. "That's not their fault," Saliares says. "Some plans don't have a look-up feature for pharmacists to access on their computers."

Daiker says even when physicians have access to a plan's formulary, it can be difficult to find a particular drug on the list because health plans classify drugs differently. For example, Ambien might be listed on one formulary as an antipsychotic and on another as a sleeping aid. "It's unnecessarily complicated," she says.

Classification isn't the only concern. For example, the definition of "failure" in the case of step therapy may not be spelled out or may be different depending on the plan or the insurance products offered by a plan, according to Daiker, who has studied the language used by the health plans. "How many courses of a medicine do you need to try? Over what period of time—six weeks? A year? Is an allergic reaction considered failure? Sometimes it just doesn't say," she says.

Sifting through patient records to document why previously tried drugs failed is time-consuming, so it's especially annoying when the process must be repeated. Rice recalls a patient he put on the more expensive Benicar for hypertension because he couldn't tolerate lisinopril or other angiotensin receptor blockers. After

> "Every health plan has its own **forms**, **questions** and **procedures** for **the same drugs**."
>
> —MONICA MCKINNON, R.N.

the patient had been on the drug for a year, the PBM requested a new form be filled out detailing all prior failures before they would re-approve the medication they'd already approved. "PBMs should have that information in their records," Rice says. "Making physicians look up all that failure documentation again and resubmit it delays medications and costs my staff and me a lot of time and money without improving the patient's care."

CARE-DRIVEN OR COST-DRIVEN?

Health plans say quality of care is the reason for PA. Many physicians, Rice included, think it has less to do with quality and more to do with money. "A PBM's profit equals what the health plans pay them minus the cost of the drugs the PBMs pay for through submitted claims," he says. "So they have a vested interest in denying or at least delaying drug prescriptions. If they can delay by even three days approval of a one-month prescription, that's 10 percent of the drug cost they've saved for that month."

Daiker, who has compared the formularies of six Minnesota health plans, also is skeptical that quality is the primary motive for health plans. "There is extreme inconsistency across plans about which drugs are on their PA lists," she says. Of the 1,036 different medications she found that required PA, only six were on the PA lists of all the health plans. When she looked at which drugs were on five of six PA lists, it was only 26 more. Which prompts the question: If quality of care is the main reason for PA, why don't they have similar lists? "There's no evidence to refute that it's a financial model," Daiker says.

The heart of the PA issue, according to Rice, is that drug costs are divorced from other health care costs because they're carved out and managed by the PBMs. "If a patient doesn't get their meds in a timely fashion and ends up in the hospital, it'll cost the health plan, but it won't cost the PBM, which is looking at its own bottom line," he says. "I believe most PA decisions are purely about what saves the health plan or the PBM money in the short term, rather than what provides the best care for patients or what saves on the overall cost of care in the long run."

> "I believe most PA decisions are purely about **what saves the health plan or the PBM money**."
>
> – RANDY RICE, M.D.

The MMA's Silversmith says drug companies dislike PA as much as physicians do. "They work to stay off prior authorization lists by offering discounts to PBMs," she says. For that reason, one health plan might pay a very different price for a drug than another plan, according to Sara Drake, R.Ph., pharmacy program manager for Minnesota's Medical Assistance program. "When there are multiple similarly safe and effective drugs in a class, drug makers offer discounts to compete for placement on the PBM's formulary," she says.

First-line drugs of choice not requiring PA give the best discounts. That explains why there might be six hypertension drugs on a formulary, Rice says, "all generic and all costing within a few dollars of each other, yet every year the first-choice drug changes. It also explains why formulary lists often don't jive with what unbiased sources such as the *Medical Letter* recommend as most cost-effective."

SEARCHING FOR SOLUTIONS

In meetings with health plans, MMA staff have expressed physicians' frustrations and worked to gather information about the inner workings of the PA process in order to come up with recommendations for how to make it easier and quicker.

"They were willing to talk about their PA process," Schoephoerster says, "but it took a lot of asking and effort to get the most basic information about approval and denial rates."

Silversmith says she's been somewhat frustrated with their response. "Some say we don't see that there's a problem. Others say, we know there's a problem and prior authorization costs us money, too, but what are we supposed to do about it?"

The MMA's workgroup is tossing around ideas for how to make PA less burdensome. There's been some discussion about a standardized statewide formulary to reduce the extreme variability in how plans treat the same drug when it comes to PA. "As it is now," Rice says, "which medicine to pick to avoid PA is a moving target." But Drake doesn't see that happening because health plans and PBMs would no longer be able to use their national leverage to negotiate prices. "For better or worse, these discounts and rebates keep costs down for the whole health care system," she says.

Some think it would be a good idea if health plans at least deleted drugs from their formularies only once per year. Currently, they can make changes as often as they want. "This would minimize frequent switches often caused by price changes negotiated with drug makers," Saliares points out.

Others would like to see staff at PBMs and health plans who handle PA requests have medical knowledge. "Some are minimally trained and follow a prompt sheet, or only look for the magic key words you may or may not have included in your request," Saliares says. "Appeals, in particular, should always and from the beginning be reviewed by an appropriate medical specialist. And if you ask to speak to a specialist in your field regarding an appeal, they should honor that request."

Minnesota law requires that appeals be reviewed by physicians licensed in the state. But, according to anecdotal information submitted to the MMA workgroup, many believe that although an appeal must be signed off on by the medical director of a Minnesota health plan, the actual appeal reviews are done by people in other states under contract with the health plans or PBMs. "These outside reviewers have a financial incentive to deny or delay appeals," Saliares says.

The workgroup has not ruled out proposing legislation requiring health plans to comply with a standardized approach to PA, as 15 other states have done. Among states that have passed PA legislation, most have focused on requiring use of short, standardized PA request forms. Some stipulate how quickly a plan or PBM must respond to a PA request. For step therapy, some say failure need occur only once.

Legislation could require health plans to spell out which drugs must be tried first, for how long and what it means for a drug to fail. "It's simply telling the physician up front what they need to know so they're not prescribing blind," Daiker says.

Minnesota already has its Uniform Form for Prescription Drug Prior Authorization Requests. All plans accept this form, but Silversmith says clinics aren't using it. That's partly because it's not mandated and because clinics are waiting for the federal government to come out with its electronic transaction standard (see "Electronic Prior Authorization," p. 20).

Silversmith says that before the MMA workgroup makes its recommendations, it's trying to shed light on the "upstream end of the PA process." Why does a drug get put on a plan's PA list in the first place? Why do the drugs on these lists change so often? Why are the PA rules so unclear? Why are the PA lists and processes so different for each health plan? Why isn't the whole process easier?

Rice sums it up, saying, "If we had evidence-based formularies that were similar across health plans, and not changing with every new price deal, I suspect most physicians would have little trouble with prior authorization." Until then, PA will remain a costly, time-consuming burden. **MM**

Howard Bell is a medical writer and frequent contributor to *Minnesota Medicine*.

A fateful winter's night

Sometimes doing the right thing is the hardest thing.

BY ABBY GARDNER, M.D.

The art of the practice of medicine is to be learned only by experience; 'tis not an inheritance; it cannot be revealed. Learn to see, learn to hear, learn to feel, learn to smell, and know that by practice alone can you become expert.

—Sir William Osler

I was nearing the end of the first general internal medicine rotation of my intern year. I finished most of my duties at the hospital for the day and walked down what felt like the never-ending hallway of the medicine floor to Hazel's room. Hazel was a spunky 89-year-old with Alzheimer's dementia who had been brought to our hospital several weeks earlier. She had been found near a bus stop in the middle of a frigid night. Since then, she had been staying here awaiting a safe discharge plan.

When I got to her room, the EMS crew was busy loading her onto a stretcher to take her by ambulance to her new home, a nursing facility. She was very pleasant. She had dressed and put on her pearl earrings as if she were going on a social outing. Her handbag was at her side. She was clearly unaware of what was happening but happy to oblige nonetheless. As she was wheeled out the door, I breathed a quick sigh of relief, thankful that things had gone so smoothly.

Then I turned my attention to the room across the hall—a room that housed another of my patients, Hazel's daughter Alice. The two had been brought in together on that fateful winter's night.

Alice couldn't leave the hospital because she was being committed and was waiting for her own nursing home placement. It had become clear to me that it was unsafe for Alice and her mother to live on their own. Neuropsychiatry, PT and OT agreed. Family members reported Alice locking herself and her mother in or out of the house after losing the keys, or forgetting to pay bills.

Even so, the decision to pursue commitment had been agonizing. But it was the only way to keep Alice safe. She was newly diagnosed with dementia and because of her short-term memory loss didn't remember our conversations. She certainly couldn't remember why she was in the hospital. When told she needed to move to a more supportive living environment, she would immediately rattle off her qualifications as a caregiver and tell us why she should continue to live independently. There was no doubt in her mind that she was capable of caring for herself and her mother. In fact, as far as she was concerned, she was only in the hospital to care for her mother. Occasionally, she would put on her clothes and state that she was ready to go home. Other times, she would wear a hospital gown all day, but never without her elegant beaded hat.

Every day that I walked into Alice's room, I introduced myself to her and she did the same for me. Every day, we started over. It almost felt like we were rehearsing for a play. Some days, I took the time to explain why she was there, other days I just said hello and made small talk. It was exhausting to start the conversation over again only to have it end in frustration, anger and disappointment. If Hazel was in the room with her, she would make remarks under her breath, obviously disgusted with what I had said.

I wanted Alice to see my side, to understand that she was there because I cared about her and not because I was trying to ruin her life or hurt her. But I also knew that what was about to happen would not help my case. I thought about how I would feel if I were in her shoes. I tried to prepare myself for her reaction, which I knew would be heartbreaking. Right on cue, she walked out of her room, smiling and greeting the nurses. When she reached the doorway of her mother's room, she stopped short. Her body language was clear—she was shocked, and worry covered her face.

She frantically began asking where her mother was. The nurses and attending physician calmly explained that she'd been taken to a nursing home. This only angered Alice. After several minutes of her usual monologue about how she could care for her mother, she lost it and started sobbing. She walked over to the empty hospital bed, now a stark plastic mattress without linens or any evidence of its prior inhabitant, and placed her hands on it, as if touching it made her mother's absence more real. Her head hung low, and her whole body shook with the force of her anguish.

"Why are you breaking up my family?" she asked.

That's when I lost it. I couldn't hold it in; the tears began to well up in my eyes threatening to give me away. I didn't feel like a doctor, I felt like a bully. As I walked away wiping my tears, I began to feel sick. I tried to suppress the feeling of guilt but couldn't help but wonder if there was some truth to what she had said.

The image of Alice crying over her mother's bed haunted me that night. The next morning, I dreaded having to face her. I walked into her room during my rounds and introduced myself. She seemed genuinely pleased to meet me, which only added to my shame. We talked for a few minutes about the weather and her plans for the day. It gave me time to consider whether I should tell her what happened the day before. At some point, I realized that the only person I was protecting was myself.

I told her that her mother had been moved to a nursing home and that she was being held in the hospital because we felt it wasn't safe for her to go home. I told her we all hoped she could join her mother, that we were pursuing court support to make that happen and that she would not be able to return to her own home. I told her that I only wanted what was best for both her and her mother and that in my mind that would include them living in the same place. Understandably, she was very upset, and after yet another effort to highlight her qualifications, something changed. I think she was simply too exhausted to keep fighting.

Looking back, I wonder how I could have been so bold. How could I have told a woman much my senior what was best for her? Why had I felt my medical degree made me all-knowing, even able to decide where someone should live? I don't remember any formal lectures on that topic.

Alice agreed to be placed in a nursing home and eventually was able to join her mother at her facility, a place where the tragedy of dementia and memory loss could safely unravel. By all outward appearances, it seemed I had done my job adequately; both patients had a safe discharge. But if that was true, then why did I still feel I had done something wrong?

Even though this encounter required almost no clinical acumen, these ladies pushed me to my limits. They challenged my confidence and caused me to question my motives as a physician and reflect on what I could have done differently. For that I am thankful. Like most patients I encountered that year, those two helped shape the type of doctor that I will become. They taught me things that can't be learned in a classroom and reminded me that sometimes doing the right thing doesn't always make us feel good. **MM**

2014 **Writing Contest**
HONORABLE MENTION

Abby Gardner is an internal medicine resident at Hennepin County Medical Center in Minneapolis.

On what inspired this piece:

My attending suggested that I try writing about this experience. The emotional toll of caring for these patients weighed heavily on the members of the care team. Once I started, writing became a way to process what had happened and reflect on the work I have chosen as my career.

Leslie's story

When there is nothing more to be done, a physician offers compassion and wonders whether it was enough.

BY ANDREA WESTBY, M.D.

I frequently lose sleep over patients. I think it has something to do with my underlying anxiety and perfectionism. I think about difficult cases, replay less-than-ideal interactions and worry about a missed diagnosis or that I did something wrong. However, the case that gave me my most significant case of insomnia was one in which I was helpless as a physician and felt my patient's pain as if it were my own. Her sadness haunted my dreams for months.

I first met Leslie* in a time of crisis. She was 22 weeks pregnant. Her first two pregnancies had ended in late first trimester or early second trimester miscarriages, so I assumed she had spent the previous months planning and praying, thankful that she finally would have a baby. However, on the day I met her, she had come in twice because of pelvic pressure and cramping, and at her second visit, in the emergency room, an ultrasound revealed complete cervical dilation. The fetal head was already descending into the birth canal. Her obstetrician had been called, but he was away, and someone needed to give her the news, as well as deliver the child. I had been practicing medicine independently for only 12 months, but I knew that this would be one of the hardest things I would ever have to do.

Our rural hospital has 25 beds, four of which are labor and delivery suites, and we only on rare emergent occasions deliver patients before 36 weeks. The nurses on duty that evening continually questioned me: Shouldn't we transfer her somewhere else? Shouldn't she be seen by the neonatal specialists and perinatologists at our referral hospital? Wasn't there something else we should be doing?

Unfortunately for Leslie and her child, the answer was no. There wasn't anything to be done. Her perfectly formed baby boy was about to be born too soon, too early to live, and there wasn't anything I or anyone else could do to stop it.

I wasn't sure how much Leslie knew when I walked into the room. Dressed in a hospital gown, she was nestled into her bed with her husband sitting at her side. They looked up at me wide-eyed and hopeful. I sat down and placed my hand

(continued on page 31)

**name has been changed*

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Important Safety Information

Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Victoza® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as human relevance could not be ruled out by clinical or nonclinical studies. Victoza® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Based on the findings in rodents, monitoring with serum calcitonin or thyroid ultrasound was performed during clinical trials, but this may have increased the number of unnecessary thyroid surgeries. It is unknown whether monitoring with serum calcitonin or thyroid ultrasound will mitigate human risk of thyroid C-cell tumors. Patients should be counseled regarding the risk and symptoms of thyroid tumors.

Do not use in patients with a prior serious hypersensitivity reaction to Victoza® or to any of the product components.

Postmarketing reports, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed. Consider other antidiabetic therapies in patients with a history of pancreatitis.

When Victoza® is used with an insulin secretagogue (e.g. a sulfonylurea) or insulin serious hypoglycemia can occur. Consider lowering the dose of the insulin secretagogue or insulin to reduce the risk of hypoglycemia.

Renal impairment has been reported postmarketing, usually in association with nausea, vomiting, diarrhea, or dehydration which may sometimes require hemodialysis. Use caution when initiating or escalating doses of Victoza® in patients with renal impairment.

Serious hypersensitivity reactions (e.g. anaphylaxis and angioedema) have been reported during postmarketing use of Victoza®. If symptoms of hypersensitivity reactions occur, patients must stop taking Victoza® and seek medical advice promptly.

There have been no studies establishing conclusive evidence of macrovascular risk reduction with Victoza® or any other antidiabetic drug.

The most common adverse reactions, reported in ≥5% of patients treated with Victoza® and more commonly than in patients treated with placebo, are headache, nausea, diarrhea, dyspepsia, constipation and anti-liraglutide antibody formation. Immunogenicity-related events, including urticaria, were more common among Victoza®-treated patients (0.8%) than among comparator-treated patients (0.4%) in clinical trials.

Victoza® has not been studied in type 2 diabetes patients below 18 years of age and is not recommended for use in pediatric patients.

There is limited data in patients with renal or hepatic impairment.

In a 52-week monotherapy study (n=745) with a 52-week extension, the adverse reactions reported in ≥ 5% of patients treated with Victoza® 1.8 mg, Victoza® 1.2 mg, or glimepiride were constipation (11.8%, 8.4%, and 4.8%), diarrhea (19.5%, 17.5%, and 9.3%), flatulence (5.3%, 1.6%, and 2.0%), nausea (30.5%, 28.7%, and 8.5%), vomiting (10.2%, 13.1%, and 4.0%), fatigue (5.3%, 3.2%, and 3.6%), bronchitis (3.7%, 6.0%, and 4.4%), influenza (11.0%, 9.2%, and 8.5%), nasopharyngitis (6.5%, 9.2%, and 7.3%), sinusitis (7.3%, 8.4%, and 7.3%), upper respiratory tract infection (13.4%, 14.3%, and 8.9%), urinary tract infection (6.1%, 10.4%, and 5.2%), arthralgia (2.4%, 4.4%, and 6.0%), back pain (7.3%, 7.2%, and 6.9%), pain in extremity (6.1%, 3.6%, and 3.2%), dizziness (7.7%, 5.2%, and 5.2%), headache (7.3%, 11.2%, and 9.3%), depression (5.7%, 3.2%, and 2.0%), cough (5.7%, 2.0%, and 4.4%), and hypertension (4.5%, 5.6%, and 6.9%).

Please see brief summary of Prescribing Information on adjacent page.

1013-00018617-1 December 2013

Victoza® (liraglutide [rDNA origin] injection)
Rx Only
BRIEF SUMMARY. Please consult package insert for full prescribing information.

WARNING: RISK OF THYROID C-CELL TUMORS: Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Victoza® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as human relevance could not be ruled out by clinical or nonclinical studies. Victoza® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Based on the findings in rodents, monitoring with serum calcitonin or thyroid ultrasound was performed during clinical trials, but this may have increased the number of unnecessary thyroid surgeries. It is unknown whether monitoring with serum calcitonin or thyroid ultrasound will mitigate human risk of thyroid C-cell tumors. Patients should be counseled regarding the risk and symptoms of thyroid tumors *[see Contraindications and Warnings and Precautions]*.

INDICATIONS AND USAGE: Victoza® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Important Limitations of Use:** Because of the uncertain relevance of the rodent thyroid C-cell tumor findings to humans, prescribe Victoza® only to patients for whom the potential benefits are considered to outweigh the potential risk. Victoza® is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise. Based on spontaneous postmarketing reports, acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis has been observed in patients treated with Victoza®. Victoza® has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for pancreatitis while using Victoza®. Other antidiabetic therapies should be considered in patients with a history of pancreatitis. Victoza® is not a substitute for insulin. Victoza® should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings. The concurrent use of Victoza® and prandial insulin has not been studied.

CONTRAINDICATIONS: Do not use in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Do not use in patients with a prior serious hypersensitivity reaction to Victoza® or to any of the product components.

WARNINGS AND PRECAUTIONS: Risk of Thyroid C-cell Tumors: Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors (adenomas and/or carcinomas) at clinically relevant exposures in both genders of rats and mice. Malignant thyroid C-cell carcinomas were detected in rats and mice. A statistically significant increase in cancer was observed in rats receiving liraglutide at 8-times clinical exposure compared to controls. It is unknown whether Victoza® will cause thyroid C-cell tumors including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors could not be determined by clinical or nonclinical studies. In the clinical trials, there have been 6 reported cases of thyroid C-cell hyperplasia among Victoza®-treated patients and 2 cases in comparator-treated patients (1.3 vs. 1.0 cases per 1000 patient-years). One comparator-treated patient with MTC had pre-treatment serum calcitonin concentrations >1000 ng/L suggesting pre-existing disease. All of these cases were diagnosed after thyroidectomy, which was prompted by abnormal results on routine, protocol-specified measurements of serum calcitonin. Five of the six Victoza®-treated patients had elevated calcitonin concentrations at baseline and throughout the trial. One Victoza® and one non-Victoza®-treated patient developed elevated calcitonin concentrations while on treatment. Calcitonin, a biological marker of MTC, was measured throughout the clinical development program. The serum calcitonin assay used in the Victoza® clinical trials had a lower limit of quantification (LLOQ) of 0.7 ng/L and the upper limit of the reference range was 5.0 ng/L for women and 8.4 ng/L for men. At Weeks 26 and 52 in the clinical trials, adjusted mean serum calcitonin concentrations were higher in Victoza®-treated patients compared to placebo-treated patients but not compared to patients receiving active comparator. At these timepoints, the adjusted mean serum calcitonin values (~1.0 ng/L) were just above the LLOQ with between-group differences in adjusted mean serum calcitonin values of approximately 0.1 ng/L or less. Among patients with pre-treatment serum calcitonin below the upper limit of the reference range, shifts to above the upper limit of the reference range which persisted in subsequent measurements occurred most frequently among patients treated with Victoza® 1.8 mg/day. In trials with on-treatment serum calcitonin measurements out to 5-6 months, 1.9% of patients treated with Victoza® 1.8 mg/day developed new and persistent calcitonin elevations above the upper limit of the reference range compared to 0.8-1.1% of patients treated with control medication or the 0.6 and 1.2 mg doses of Victoza®. In trials with on-treatment serum calcitonin measurements out to 12 months, 1.3% of patients treated with Victoza® 1.8 mg/day had new and persistent elevations of calcitonin from below or within the reference range to above the upper limit of the reference range, compared to 0.6%, 0% and 1.0% of patients treated with Victoza® 1.2 mg, placebo and active control, respectively. Otherwise, Victoza® did not produce consistent dose-dependent or time-dependent increases in serum calcitonin. Patients with MTC usually have calcitonin values >50 ng/L. In Victoza® clinical trials, among patients with pre-treatment serum calcitonin <50 ng/L, one Victoza®-treated patient and no comparator-treated patients developed serum calcitonin >50 ng/L. The Victoza®-treated patient who developed serum calcitonin >50 ng/L had an elevated pre-treatment serum calcitonin of 10.7 ng/L that increased to 30.7 ng/L at Week 12 and 53.5 ng/L at the end of the 6-month trial. Follow-up serum calcitonin was 22.3 ng/L more than 2.5 years after the last dose of Victoza®. The largest increase in serum calcitonin in a comparator-treated patient was seen with glimepiride in a patient whose serum calcitonin increased from 19.3 ng/L at baseline to 44.8 ng/L at Week 65 and 38.1 ng/L at Week 104. Among patients who began with serum calcitonin <20 ng/L, calcitonin elevations to >20 ng/L occurred in 0.7% of Victoza®-treated patients, 0.3% of placebo-treated patients, and 0.5% of active-comparator-treated patients, with an incidence of 1.1% among patients treated with 1.8 mg/day of Victoza®. The clinical significance of these findings is unknown. Counsel patients regarding the risk for MTC and the symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea or persistent hoarseness). It is unknown whether monitoring with serum calcitonin or thyroid ultrasound will mitigate the potential risk of MTC, and such monitoring may increase the risk of unnecessary procedures, due to low test specificity for serum calcitonin and a high background incidence of thyroid disease. Patients with thyroid nodules noted on physical examination or neck imaging obtained for other reasons should be referred to an endocrinologist for further evaluation. Although routine monitoring of serum calcitonin is of uncertain value in patients treated with Victoza®, if serum calcitonin is measured and found to be elevated, the patient should be referred to an endocrinologist for further evaluation. **Pancreatitis: Based on spontaneous postmarketing reports, acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with Victoza®. After initiation of Victoza®, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, Victoza® should promptly be discontinued and appropriate management should be initiated. If pancreatitis is confirmed, Victoza® should not be restarted. Consider antidiabetic therapies other than Victoza® in patients with a history of pancreatitis.** In clinical trials of Victoza®, there have been 13 cases of pancreatitis among Victoza®-treated patients and 1 case in a comparator (glimepiride) treated patient (2.7 vs. 0.5 cases per 1000 patient-years). Nine of the 13 cases with Victoza® were reported as acute pancreatitis and four were reported as chronic pancreatitis. In one case in a Victoza®-treated patient, pancreatitis, with necrosis, was observed and led to death; however clinical causality could not be established. Some patients had other risk factors for pancreatitis, such as a history of cholelithiasis or alcohol abuse. **Use with Medications Known to Cause Hypoglycemia:** Patients receiving Victoza® in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogues) or insulin **Renal Impairment:** Victoza® has not been found to be directly nephrotoxic in animal studies or clinical trials. There have been postmarketing reports of acute renal failure and worsening of chronic renal failure, which may sometimes require hemodialysis in Victoza®-treated patients. Some of these events were reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Some of the reported events occurred in patients receiving one or more medications known to affect renal function or hydration status. Altered renal function has been reversed in many of the reported cases with supportive treatment and discontinuation of potentially causative agents, including Victoza®. Use caution when initiating or escalating doses of Victoza® in patients with renal impairment. **Hypersensitivity Reactions:** There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema) in patients treated with Victoza®. If a hypersensitivity reaction occurs, the patient should discontinue Victoza® and other suspect medications and promptly seek medical advice. Angioedema has also been reported with other GLP-1 receptor agonists. Use caution in a patient with a history of angioedema with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to angioedema with Victoza®. **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Victoza® or any other antidiabetic drug.

ADVERSE REACTIONS: Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety of Victoza® has been evaluated in 8 clinical trials: A double-blind 52-week monotherapy trial compared Victoza® 1.2 mg daily, Victoza® 1.8 mg daily, and glimepiride 8 mg daily; A double-blind 26 week add-on to metformin trial compared Victoza® 0.6 mg once-daily, Victoza® 1.2 mg once-daily, Victoza® 1.8 mg once-daily, placebo, and glimepiride 4 mg once-daily; A double-blind 26 week add-on to glimepiride trial compared Victoza® 0.6 mg daily, Victoza® 1.2 mg once-daily, Victoza® 1.8 mg once-daily, placebo, and rosiglitazone 4 mg once-daily; A 26 week add-on to metformin + glimepiride trial, compared double-blind Victoza® 1.8 mg once-daily, double-blind placebo, and open-label insulin glargine once-daily; A double-blind 26-week add-on to metformin + rosiglitazone trial compared Victoza® 1.2 mg once-daily, Victoza® 1.8 mg once-daily and placebo; An open-label 26-week add-on to metformin and/or sulfonylurea trial compared Victoza® 1.8 mg once-daily and exenatide 10 mcg twice-daily; An open-label 26-week add-on to metformin trial compared Victoza® 1.2 mg once-daily, Victoza® 1.8 mg once-daily, and sitagliptin 100 mg once-daily; An open-label 26-week trial compared insulin detemir as add-on to Victoza® 1.8 mg + metformin to continued treatment with Victoza® + metformin alone. *Withdrawals*: The incidence of withdrawal due to adverse events was 7.8% for Victoza®-treated patients and 3.4% for comparator-treated patients in the five double-blind controlled trials of 26 weeks duration or longer. This difference was driven by withdrawals due to gastrointestinal adverse reactions, which occurred in 5.0% of Victoza®-treated patients and 0.5% of comparator-treated patients. In these five trials, the most common adverse reactions leading to withdrawal for Victoza®-treated patients were nausea (2.8% versus 0% for comparator) and vomiting (1.5% versus 0.1% for comparator). Withdrawal due to gastrointestinal adverse events mainly occurred during the first 2-3 months of the trials. *Common adverse reactions:* Tables 1, 2, 3 and 4 summarize common adverse reactions (hypoglycemia is discussed separately) reported in seven of the eight controlled trials of 26 weeks duration or longer. Most of these adverse reactions were gastrointestinal in nature. In the five double-blind clinical trials of 26 weeks duration or longer, gastrointestinal adverse reactions were reported in 41% of Victoza®-treated patients and were dose-related. Gastrointestinal adverse reactions occurred in 17% of comparator-treated patients. Common adverse reactions that occurred at a higher incidence among Victoza®-treated patients included nausea, vomiting, diarrhea, dyspepsia and constipation. In the five double-blind and three open-label clinical trials of 26 weeks duration or longer, the percentage of patients who reported nausea declined over time. In the five double-blind trials approximately 13% of Victoza®-treated patients and 2% of comparator-treated patients reported nausea during the first 2 weeks of treatment. In the 26-week open-label trial comparing Victoza® to exenatide, both in combination with metformin and/or sulfonylurea, gastrointestinal adverse reactions were reported at a similar incidence in the Victoza® and exenatide treatment groups (Table 3). In the 26-week open-label trial comparing Victoza® 1.2 mg, Victoza® 1.8 mg and sitagliptin 100 mg, all in combination with metformin, gastrointestinal adverse reactions were reported at a higher incidence with Victoza® than sitagliptin (Table 4). In the remaining 26-week trial, all patients received Victoza® 1.8 mg + metformin during a 12-week run-in period. During the run-in period, 167 patients (17% of enrolled total) withdrew from the trial: 76 (46% of withdrawals) of these patients doing so because of gastrointestinal adverse reactions and 15 (9% of withdrawals) doing so due to other adverse events. Only those patients who completed the run-in period with inadequate glycemic control were randomized to 26 weeks of add-on therapy with insulin detemir or continued, unchanged treatment with Victoza® 1.8 mg + metformin. During this randomized 26-week period, diarrhea was the only adverse reaction reported in ≥5% of patients treated with Victoza® 1.8 mg + metformin + insulin detemir (11.7%) and greater than in patients treated with Victoza® 1.8 mg and metformin alone (6.9%).

Table 1: Adverse reactions reported in ≥5% of Victoza®-treated patients in a 52-week monotherapy trial

	All Victoza® N = 497	Glimepiride N = 248
Adverse Reaction	(%)	(%)
Nausea	28.4	8.5
Diarrhea	17.1	8.9
Vomiting	10.9	3.6
Constipation	9.9	4.8
Headache	9.1	9.3

Table 2: Adverse reactions reported in ≥5% of Victoza®-treated patients and occurring more frequently with Victoza® compared to placebo: 26-week combination therapy trials

Add-on to Metformin Trial			
	All Victoza® + Metformin N = 724	Placebo + Metformin N = 121	Glimepiride + Metformin N = 242
Adverse Reaction	(%)	(%)	(%)
Nausea	15.2	4.1	3.3
Diarrhea	10.9	4.1	3.7
Headache	9.0	6.6	9.5
Vomiting	6.5	0.8	0.4
Add-on to Glimepiride Trial			
	All Victoza® + Glimepiride N = 695	Placebo + Glimepiride N = 114	Rosiglitazone + Glimepiride N = 231
Adverse Reaction	(%)	(%)	(%)
Nausea	7.5	1.8	2.6
Diarrhea	7.2	1.8	2.2
Constipation	5.3	0.9	1.7
Dyspepsia	5.2	0.9	2.6
Add-on to Metformin + Glimepiride			
	Victoza® 1.8 + Metformin + Glimepiride N = 230	Placebo + Metformin + Glimepiride N = 114	Glargine + Metformin + Glimepiride N = 232
Adverse Reaction	(%)	(%)	(%)
Nausea	13.9	3.5	1.3
Diarrhea	10.0	5.3	1.3
Headache	9.6	7.9	5.6
Dyspepsia	6.5	0.9	1.7
Vomiting	6.5	3.5	0.4
Add-on to Metformin + Rosiglitazone			
	All Victoza® + Metformin + Rosiglitazone N = 355	Placebo + Metformin + Rosiglitazone N = 175	
Adverse Reaction	(%)	(%)	
Nausea	34.6	8.6	
Diarrhea	14.1	6.3	
Vomiting	12.4	2.9	
Headache	8.2	4.6	
Constipation	5.1	1.1	

Table 3: Adverse Reactions reported in ≥5% of Victoza®-treated patients in a 26-Week Open-Label Trial versus Exenatide

	Victoza® 1.8 mg once daily + metformin and/or sulfonylurea N = 235	**Exenatide 10 mcg twice daily + metformin and/or sulfonylurea** N = 232
Adverse Reaction	(%)	(%)
Nausea	25.5	28.0
Diarrhea	12.3	12.1
Headache	8.9	10.3
Dyspepsia	8.9	4.7
Vomiting	6.0	9.9
Constipation	5.1	2.6

Table 4: Adverse Reactions in ≥5% of Victoza®-treated patients in a 26-Week Open-Label Trial versus Sitagliptin

	All Victoza® + metformin N = 439	**Sitagliptin 100 mg/day + metformin** N = 219
Adverse Reaction	(%)	(%)
Nausea	23.9	4.6
Headache	10.3	10.0
Diarrhea	9.3	4.6
Vomiting	8.7	4.1

Immunogenicity: Consistent with the potentially immunogenic properties of protein and peptide pharmaceuticals, patients treated with Victoza® may develop anti-liraglutide antibodies. Approximately 50-70% of Victoza®-treated patients in the five double-blind clinical trials of 26 weeks duration or longer were tested for the presence of anti-liraglutide antibodies at the end of treatment. Low titers (concentrations not requiring dilution of serum) of anti-liraglutide antibodies were detected in 8.6% of these Victoza®-treated patients. Sampling was not performed uniformly across all patients in the clinical trials, and this may have resulted in an underestimate of the actual percentage of patients who developed antibodies. Cross-reacting anti-liraglutide antibodies to native glucagon-like peptide-1 (GLP-1) occurred in 6.9% of the Victoza®-treated patients in the double-blind 52-week monotherapy trial and in 4.8% of the Victoza®-treated patients in the double-blind 26-week add-on combination therapy trials. These cross-reacting antibodies were not tested for neutralizing effect against native GLP-1, and thus the potential for clinically significant neutralization of native GLP-1 was not assessed. Antibodies that had a neutralizing effect on liraglutide in an *in vitro* assay occurred in 2.3% of the Victoza®-treated patients in the double-blind 52-week monotherapy trial and in 1.0% of the Victoza®-treated patients in the double-blind 26-week add-on combination therapy trials. Among Victoza®-treated patients who developed anti-liraglutide antibodies, the most common category of adverse events was that of infections, which occurred among 40% of these patients compared to 36%, 34% and 35% of antibody-negative Victoza®-treated, placebo-treated and active-control-treated patients, respectively. The specific infections which occurred with greater frequency among Victoza®-treated antibody-positive patients were primarily nonserious upper respiratory tract infections, which occurred among 11% of Victoza®-treated antibody-positive patients; and among 7%, 7% and 5% of antibody-negative Victoza®-treated, placebo-treated and active-control-treated patients, respectively. Among Victoza®-treated antibody-negative patients, the most common category of adverse events was that of gastrointestinal events, which occurred in 43%, 18% and 19% of antibody-negative Victoza®-treated, placebo-treated and active-control-treated patients, respectively. Antibody formation was not associated with reduced efficacy of Victoza® when comparing mean HbA_{1c} of all antibody-positive and all antibody-negative patients. However, the 3 patients with the highest titers of anti-liraglutide antibodies had no reduction in HbA_{1c} with Victoza® treatment. In the five double-blind clinical trials of Victoza®, events from a composite of adverse events potentially related to immunogenicity (e.g. urticaria, angioedema) occurred among 0.8% of Victoza®-treated patients and among 0.4% of comparator-treated patients. Urticaria accounted for approximately one-half of the events in this composite for Victoza®-treated patients. Patients who developed anti-liraglutide antibodies were not more likely to develop events from the immunogenicity events composite than were patients who did not develop anti-liraglutide antibodies. *Injection site reactions:* Injection site reactions (e.g., injection site rash, erythema) were reported in approximately 2% of Victoza®-treated patients in the five double-blind clinical trials of at least 26 weeks duration. Less than 0.2% of Victoza®-treated patients discontinued due to injection site reactions. *Papillary thyroid carcinoma:* In clinical trials of Victoza®, there were 7 reported cases of papillary thyroid carcinoma in patients treated with Victoza® and 1 case in a comparator-treated patient (1.5 vs. 0.5 cases per 1000 patient-years). Most of these papillary thyroid carcinomas were <1 cm in greatest diameter and were diagnosed in surgical pathology specimens after thyroidectomy prompted by findings on protocol-specified screening with serum calcitonin or thyroid ultrasound. *Hypoglycemia* .In the eight clinical trials of at least 26 weeks duration, hypoglycemia requiring the assistance of another person for treatment occurred in 11 Victoza®-treated patients (2.3 cases per 1000 patient-years) and in two exenatide-treated patients. Of these 11 Victoza®-treated patients, six patients were concomitantly using metformin and a sulfonylurea, one was concomitantly using a sulfonylurea, two were concomitantly using metformin (blood glucose values were 65 and 94 mg/dL) and two were using Victoza® as monotherapy (one of these patients was undergoing an intravenous glucose tolerance test and the other was receiving insulin as treatment during a hospital stay). For these two patients on Victoza® monotherapy, the insulin treatment was the likely explanation for the hypoglycemia. In the 26-week open-label trial comparing Victoza® to sitagliptin, the incidence of hypoglycemic events defined as symptoms accompanied by a fingerstick glucose <56 mg/dL was comparable among the treatment groups (approximately 5%).

Table 5: Incidence (%) and Rate (episodes/patient year) of Hypoglycemia in the 52-Week Monotherapy Trial and in the 26-Week Combination Therapy Trials

	Victoza® Treatment	**Active Comparator**	**Placebo Comparator**
Monotherapy	**Victoza®** (N = 497)	**Glimepiride** (N = 248)	**None**
Patient not able to self-treat	0	0	—
Patient able to self-treat	9.7 (0.24)	25.0 (1.66)	—
Not classified	1.2 (0.03)	2.4 (0.04)	—
Add-on to Metformin	**Victoza® + Metformin** (N = 724)	**Glimepiride + Metformin** (N = 242)	**Placebo + Metformin** (N = 121)
Patient not able to self-treat	0.1 (0.001)	0	0
Patient able to self-treat	3.6 (0.05)	22.3 (0.87)	2.5 (0.06)
Add-on to Victoza® + Metformin	**Insulin detemir + Victoza® + Metformin** (N = 163)	**Continued Victoza® + Metformin alone** (N = 158*)	**None**
Patient not able to self-treat	0	0	—
Patient able to self-treat	9.2 (0.29)	1.3 (0.03)	—
Add-on to Glimepiride	**Victoza® + Glimepiride** (N = 695)	**Rosiglitazone + Glimepiride** (N = 231)	**Placebo + Glimepiride** (N = 114)
Patient not able to self-treat	0.1 (0.003)	0	0
Patient able to self-treat	7.5 (0.38)	4.3 (0.12)	2.6 (0.17)
Not classified	0.9 (0.05)	0.9 (0.02)	0
Add-on to Metformin + Rosiglitazone	**Victoza® + Metformin + Rosiglitazone** (N = 355)	**None**	**Placebo + Metformin + Rosiglitazone** (N = 175)
Patient not able to self-treat	0	—	0
Patient able to self-treat	7.9 (0.49)	—	4.6 (0.15)
Not classified	0.6 (0.01)	—	1.1 (0.03)
Add-on to Metformin + Glimepiride	**Victoza® + Metformin + Glimepiride** (N = 230)	**Insulin glargine + Metformin + Glimepiride** (N = 232)	**Placebo + Metformin + Glimepiride** (N = 114)
Patient not able to self-treat	2.2 (0.06)	0	0
Patient able to self-treat	27.4 (1.16)	28.9 (1.29)	16.7 (0.95)
Not classified	0	1.7 (0.04)	0

*One patient is an outlier and was excluded due to 25 hypoglycemic episodes that the patient was able to self-treat. This patient had a history of frequent hypoglycemia prior to the study.

In a pooled analysis of clinical trials, the incidence rate (per 1,000 patient-years) for malignant neoplasms (based on investigator-reported events, medical history, pathology reports, and surgical reports from both blinded and open-label study periods) was 10.9 for Victoza®, 6.3 for placebo, and 7.2 for active comparator. After excluding papillary thyroid carcinoma events *[see Adverse Reactions]*, no particular cancer cell type predominated. Seven malignant neoplasm events were reported beyond 1 year of exposure to study medication, six events among Victoza®-treated patients (4 colon, 1 prostate and 1 nasopharyngeal), no events with placebo and one event with active comparator (colon). Causality has not been established. **Laboratory Tests:** In the five clinical trials of at least 26 weeks duration, mildly elevated serum bilirubin concentrations (elevations to no more than twice the upper limit of the reference range) occurred in 4.0% of Victoza®-treated patients, 2.1% of placebo-treated patients and 3.5% of active-comparator-treated patients. This finding was not accompanied by abnormalities in other liver tests. The significance of this isolated finding is unknown. **Vital signs:** Victoza® did not have adverse effects on blood pressure. Mean increases from baseline in heart rate of 2 to 3 beats per minute have been observed with Victoza® compared to placebo. The long-term clinical effects of the increase in pulse rate have not been established. **Post-Marketing Experience:** The following additional adverse reactions have been reported during post-approval use of Victoza®. Because these events are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure: Dehydration resulting from nausea, vomiting and diarrhea; Increased serum creatinine, acute renal failure or worsening of chronic renal failure, sometimes requiring hemodialysis; Angioedema and anaphylactic reactions; Allergic reactions: rash and pruritus; Acute pancreatitis, hemorrhagic and necrotizing pancreatitis sometimes resulting in death.

OVERDOSAGE: Overdoses have been reported in clinical trials and post-marketing use of Victoza®. Effects have included severe nausea and severe vomiting. In the event of overdosage, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms.

More detailed information is available upon request.
For information about Victoza® contact: Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, NJ 08536, 1–877-484-2869
Date of Issue: April 16, 2013
Version: 6
Manufactured by: Novo Nordisk A/S, DK-2880 Bagsværd, Denmark
Victoza® is covered by US Patent Nos. 6,268,343, 6,458,924, 7,235,627, 8,114,833 and other patents pending. Victoza® Pen is covered by US Patent Nos. 6,004,297, RE 43,834, RE 41,956 and other patents pending.
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Leslie's story…

(continued from page 31)

on hers. I took a slow deep breath and told her that she would soon deliver and that her son would soon be born too soon to live. I asked if there was anyone she would like us to call. It took a few moments for my words to connect, and in that time, I held my breath.

After the situation became clear, she began sobbing. With gentle tear-filled eyes, she looked up at me and began imploring me to give her different news. "Isn't there anything else we can do to stop this?" she pleaded. "Isn't there any way that he can live? Please, please, do something."

As physicians, we are trained to heal, to help, to save. When the tools we have are not enough, the only ones that remain are those with which we are born and that make us human—compassion, empathy and caring.

I remained silent for a brief time, collecting my emotions, and responded with a soft "No, I am so very sorry."

With her permission, we called her pastor and her husband's priest, who arrived with a small bottle of holy water. And we waited. After what seemed like hours but actually was much less than that, her time came to deliver. A perfect little boy with paper-thin skin and eyes that would not open emerged from her body. He took his first and last breath while lying on her chest, which was heaving with cries. I closed my eyes, tears rolling down my face and waited for the placenta, while she and her husband said both hello and goodbye to their first son. The priest baptized the child, and we prayed together. My heart was heavy with helplessness.

As physicians, we are trained to heal, to help, to save. When the tools we have are not enough, the only ones that remain are those with which we were born and that make us human—compassion, empathy and caring. I have no way of knowing whether these things were enough for Leslie, as I have not seen her again, but they were all I had and everything I could give. **MM**

Andrea Westby is a family physician in Perham, Minnesota.

Reluctant reflections

An oncologist's take on how physician and patient burnout might be prevented

BY WILLIAM SHIMP, M.D.

I have never been a fan of dinner parties, galas or wine-tasting events, especially if word gets out I am a cancer specialist. Invariably, someone attempts to engage me in conversation about how depressing my work must be. Sometimes they are amazed that I can keep hanging in there amid such a steady diet of death and destruction. In response, I make no apology for my lot in life, and I do not try to explain what motivated me to make a career of cancer medicine in the first place. Usually, when people ask why I do what I do, I offer a few platitudes about what a privilege it is to bring solace to those who suffer, how it matters to provide comfort at the end of life and that it is possible to cure some of my patients. Then I act surprised to find that my wine glass is empty and excuse myself, hoping to regain anonymity and not be ambushed again.

But the unwelcome small talk with a stranger raises an important point. Some of my oncology colleagues do suffer from burnout and depression, and it is easy to see why.

Caring for cancer patients is hard work. Many of our "successes" often are seen as something other than that by friends and physician colleagues who do not understand what we do. Professional burnout is a stalker of oncologists everywhere, causing some to leave the field prematurely or, even worse, to disengage professionally and still stay on the job. After all, we are dealing with the saddest of circumstances, hoping for enough small victories along the way to sustain our zest for our profession.

We also witness another type of burnout that afflicts so many of our patients. They are fed up with an existence defined by doctor visits, IVs, scans and neuropathy. Because their life is not turning out the way they had planned, depression can become their constant companion. We are supposed to be tuned in to that, to inquire as to our patients' psychological and spiritual health, to listen with compassion, to prescribe antidepressants as needed and to ask for help from other colleagues when we are in over our heads.

Lurking among our patients is a subset that is potentially suicidal. Although one can argue suicide becomes a more understandable choice when one has a terminal condition, we still are prone to regard a patient's suicide—the ultimate expression of burnout with life—as a failure of our duty as physicians. We should have seen it coming. We should not have been so rushed that last day we saw them in the office. We should have spent less time talking about chemotherapy and more time asking about how they were doing and listening. The list of laments goes on and on.

Three of my patients have ended their ordeal with cancer by committing suicide. All were male, and all did so by gunshot. Each death rocked me to the core, caus-

ing me to ruminate on how I had missed the clues, how I hadn't asked the right questions and how I had let down those patients and their families. I found myself dealing with a witch's brew of loss, guilt and failure.

The first two patients were elderly loners, rather stoic and inscrutable, and new to my practice. Their suicides surprised me because their cancers were responding nicely to treatment (one had limited-stage small-cell lung cancer and the other non-Hodgkin lymphoma); I was optimistic they would do well for a time. Although they were mildly symptomatic from their chemotherapy, the men were having few symptoms from their disease. With hindsight, I see that their view of things was different from my own. I wonder if I hadn't stressed enough of the positives of their situations; did I come off as too negative? Since they asked few questions and didn't seem to demand much by way of communication, their office visits seemed easy. I worry that I scurried off too soon to see the next patient.

> We still are prone to regard a patient's suicide—the ultimate expression of burnout with life—as a failure of our duty as physicians.

Interestingly, their families were not surprised by their suicides. Concerned by my expressions of remorse, they told me I was not to blame and that I should not take it personally: "They were going to do what they were going to do. You couldn't have stopped them. Even psychiatrists lose some patients to suicide." The message was clear: Their suicidal personality traits had been in place long before their cancer. Remarkably, these families seemed to be more focused on ministering to me than to themselves. And so, immersed in my busy and demanding practice, I found the simple passage of time my best ally in making peace with what had happened.

The third suicide was more difficult, however. I had known this patient for many years. His chronic lymphocytic leukemia was under good control with periodic treatment with chlorambucil and prednisone. Most of his office visits were routine, consisting of an inquiry about symptoms, a blood count and lymph node palpation. I would describe him as quiet and at times taciturn, but always pleasant and at no time showing signs of depression. His adult daughter accompanied him to most of his office visits. Sometimes she did his talking for him. Although I can't be sure, perhaps this dynamic prevented me from appreciating his reaction to his disease, and from knowing the depth of his despair.

One evening he simply walked outdoors and shot himself with his deer rifle. Along with the rest of his family, we in the clinic were shocked by this act seemingly so at odds with his personality and his good quality of life. Unfortunately, he lingered for a few days in the intensive care unit before he died. During that time, his family and I were able to grieve over what had happened. We consoled each other by saying something had been lurking beneath the surface—something none of us had seen. But I have never been able to get over thinking I had to have missed an important clue. Most of all, I wished I had gotten to know him better.

None of these patients fit the conventional definition of "end stage," where the debate rages about physician-assisted suicide. Each would have lived for months to years with ongoing therapy. With symptom palliation and prolonged survival being the goal, we were well on our way to accomplishing that. I felt they had been cheated out of a longer and a reasonably comfortable life, and I had been cheated out of a chance to be a better doctor. The days I learned of their deaths were some of the most mind-numbing of my oncology career.

Friends and colleagues offer consolation by underscoring the difficult task of living with cancer. "If I were in their situation," they say, "I might have done the same thing." Some muse that I probably have prevented more suicides than I'll ever know, and that three is a surprisingly low number of such deaths. Others propose that the cancers may have been only a part of the reason for the suicides.

In reply, sometimes I have to parse a nuance distinguishing incurable-but-treatable cancer from end-stage disease. I explain that my patients were in the former category, not the latter, and that is why their deaths seemed particularly harsh. Nobody likes painful surprises, and in these cases, death came sooner—and from a different direction—than I expected. This reality makes it particularly difficult for me to find much consolation.

In talking with other physicians who have had similar experiences, I find that remorse is a common response. From there, it seems easy to gravitate to a place where some degree of self-flagellation becomes inevitable. But there has to be some learning in there somewhere, something that helps us "bullet proof" ourselves and our patients against future tragedies.

There has to be something that helps us "bullet proof" ourselves and our patients against future tragedies.

Since these patients' suicides, I have tried to be more intentional about understanding the mental and spiritual state of my patients. I have worked to better integrate into my practice the strategies of palliative care specialists, for whom probing and conversations with patients and their families are central to their work. Sometimes this boils down to asking some difficult and uncomfortable questions in the exam room, causing everyone to squirm a bit. But I think it is worth it. Thankfully, a growing drumbeat in our oncology literature is making this point and encouraging us all to move in that direction.[1]

So, how am I to keep myself and my patients from burning out? Perhaps I can attend to my own burnout risk by attending to theirs because our risks are interconnected. Perhaps I can work to find greater satisfaction by entering their world more with words than with drugs. Approaching care with a more balanced mix of science and compassion, and being content with achievements smaller than chemotherapy success, may go a long way toward sustaining my satisfaction in my work. Being able to discourage lung cancer patients from opting for increasingly difficult and likely futile third- or fourth-line chemotherapy, as an example, might be a surrogate measure of how I understand and define the true nature of my job as an oncologist, and how I continue to feel good about what I do.

Given the time constraints in the clinic and hospital and the reality that talking with patients consumes more time than writing chemotherapy orders, the challenges are great. But direct conversation is the only way to get inside patients' heads and to truly understand where they are in their psychological adjustment to their illness. If there are surprises to be had, I would rather they erupt as unexpected admissions from confiding patients and not as another midnight call from the county coroner.

I think the guy at the cocktail party could have been coaxed to understand this as well as anyone, but it would have taken too long to explain, and mercifully my wine glass was empty. **MM**

William Shimp is a medical oncologist who has practiced in Minnesota for more than 30 years.

REFERENCE

1. Carlson RH. Helping prevent suicide in cancer patients – Those thinking of it won't tell unless you ask. Oncology Times. 2010;32(18):15-9.

A CONVERSATION WITH

New MMA President Donald Jacobs, M.D.

It makes perfect sense that Donald Jacobs, M.D., is a guitar player. After all, as a surgeon of 30-plus years, he knows a thing or two about using his hands. But guitar-playing (he is a member of a rock band called HC/MC made up of Hennepin County Medical Center employees) and scalpel-wielding will take a back seat over the next 12 months as Jacobs assumes the role of the MMA's 148th president.

In this new role, Jacobs will crisscross the state meeting with practices large and small to hear about their concerns and priorities.

Taking a leadership position is nothing new for Jacobs. Since 2012, he has been HCMC's chief of clinical operations. Prior to that, he served 12 years as chair and CEO of Hennepin Faculty Associates, before it merged with HCMC. He has also served as interim chief of HCMC's department of surgery and as director of both its surgical residency program and its medical student surgical site rotation.

In addition, Jacobs is an assistant professor in the department of surgery at the University of Minnesota. If that wasn't enough, he was a governor of the American College of Surgeons and a board member and past-president of the Association for Surgical Education.

Jacobs takes over as MMA president after serving several years on the board of trustees and, most recently, as chair of the MMA's new Policy Council. He is also a member of both the Twin Cities Medical Society and the AMA.

So how does Jacobs plan to juggle his presidential duties with his other obligations? He doesn't. Jacobs has decided it's time to retire from his day job. Effective January 1, 2015, he will focus on his MMA position almost full time.

PHOTO BY KATHRYN FORSS

Newly annointed president Jacobs (left) poses at the Annual Conference with outgoing president Cindy Firkins Smith, M.D., and Richard Dart, M.D., of the Wisconsin Medical Society.

We asked Jacobs about his plans for the coming year.

Jacobs chaired the first meeting of the MMA's Policy Council held in St. Paul in 2014.

What are your goals as MMA president for 2014?

I hope to meet with as many of Minnesota's physicians as possible to engage them in a discussion about what we can and should do collectively to improve our profession and our ability to serve the health care needs of our communities. Physicians must understand and believe that our collective voice can make a difference.

What do you think are the biggest issues facing health care today?

There are so many that I won't do justice to them with a short answer. But

I would say that across health care we are being crushed by unreasonable administrative burdens that limit our ability to provide care at a reasonable cost. Those costs hurt our businesses and the very people we serve. Transformative change will require flexibility and nimbleness that are not easily achieved within the current system's regulatory and payment structures.


Jacobs rocks out with his band, HC/MC, at the 2012 Annual Meeting.

How long have you been a member of the MMA and what have been some of the highlights?

I have been a member of the MMA and AMA on and off since I was a medical student representative to the AMA in 1973. I have participated steadily for the past 20 years and have been privileged to serve as a trustee and to work on special committees and task forces. Perhaps the highlight was getting to chair the Healthy Minnesota work that led to many of the reforms we have championed in Minnesota over the past six years. There is much left to do, but those efforts are great examples of the MMA's importance as

News Briefs

Prior authorization group begins its work

The MMA has convened a 12-member task force that is taking an in-depth look at the prior authorization practices of Minnesota health plans and the state's Medicaid program. The group began meeting in September.

The group will work to:

- understand the impact of prescription drug prior authorization on physicians and their practices
- understand the effect of prescription drug prior authorization practices on patients' timely access to appropriate medications
- identify and recommend to the MMA Board of Trustees specific strategies for modifying the practice of prescription drug prior authorization in a way that improves patient care and reduces administration burdens for medical practices.

Work group members represent a variety of specialties and include: Alfred Anderson, M.D. (pain medicine); Vernon Berglund, M.D. (rheumatology); David Dorn, M.D. (neurology); David Einzig, M.D. (child psychiatry); Dean Gesme, M.D. (oncology); John Hitt, M.D. (internal medicine); Glenn Nemec, M.D. (family medicine); Randy Rice, M.D. (family medicine); Randy Saliares, M.D. (gastroenterology); George Schoephoerster, M.D. (geriatric medicine); Philip Stoltenberg, M.D. (gastroenterology); and Linda Van Etta, M.D. (infectious diseases).

Member hired to lead medical cannabis research

In October, the Minnesota Department of Health named MMA member Tom Arneson, M.D., as its lead research authority on medical cannabis.

Arneson, an internal medicine specialist, will manage the state's medical cannabis patient registry and the program's ongoing research efforts, and will serve as the department's expert on the risks and benefits of medical cannabis, according the Minnesota Department of Health website.

A Mayo Medical School graduate, Arneson has been a researcher for the Department of Health, director of population health at Stratis Health and medical director for industry-sponsored research at the Chronic Disease Research Group.

Former MMA leader passes away

Long-time MMA leader Harold "Hal" Brunn passed away on September 23 at age 95. He worked with the MMA from 1951 to 1983.

"He used to say, frequently, that he worked with the most noble, caring individuals ever put on Earth and he was proud to be associated with them," says George Lohmer, MMA CFO, who

PHOTOS BY STEVE WEWERKA

a leader and a trusted voice in the efforts to improve health and health care in Minnesota.

How do you plan to recruit new members?
I believe the best strategy is to have honest conversations with as many physicians and groups as I can about what needs to be accomplished. I want to hear their concerns and priorities. In the long term, we need to build robust networks of communication to understand in an easy, effective and timely way the views and needs of our members.

How long has the band HC/MC been around?
I started the rock band with some Hennepin colleagues four and a half years ago. We continue to play for fundraisers and team-building events. It has helped us build community within our organization in a way that is fun and inclusive. I hope to continue to play with the band even as I retire from my day job. It is a welcome respite from our busy work schedules and a great team "sport."

Do you have a favorite guitar?
The guitar of my dreams is one I used to own but sold to a nun while in medical school for $250. It was a beautiful 1968 vintage Rickenbacker 12-string electric (think of the sound of the Byrds). It would cost me about $5,000 to buy it back now. But I'm thinking about it. Each instrument has a very unique sound.

worked with Brunn from the late '70s through Brunn's retirement.

After graduating from the University of Minnesota, Brunn joined the Navy and attended Midshipmen School at Notre Dame. During his tenure with the Navy, he served under Admiral Chester Nimitz in Pearl Harbor. After World War II, he attended the University of Minnesota Law School.

He joined the MMA in 1951 as a lobbyist/associate director. After four years in that role, he became executive vice president, a position he held for 28 years.

Advocacy All-Star program launched

As part of its renewed commitment to physician grassroots advocacy, the MMA has launched the Advocacy All-Star program.

The program was created to recognize physicians who understand the importance of grassroots advocacy and are personally invested in bringing their expertise and personal experience to the legislative process.

By becoming an Advocacy All-Star, a physician commits to supporting the association's advocacy efforts by responding to Action Alerts promptly, forming or strengthening relationships with their state legislators, making themselves available to lawmakers as resources, attending the MMA's annual Day at the Capitol event, and becoming a MEDPAC member.

"Medicine has become increasingly political, and every year the future of the profession becomes more dependent on the decisions made by Congress, our state Legislature, and other regulatory and administrative agencies," says Evelyn Clark, the MMA's manager of grassroots and political engagement. "Unless physicians develop their political and legislative skills as constituents, control of the profession's future will slowly slip out of medicine's grasp."

If you are interested in becoming an Advocacy All-Star or just want more information, contact Evelyn Clark (eclark@mnmed.org) or call 612-362-3739.

Foundation honors five members with award, scholarships

In September, the MMA Foundation (MMAF) presented its 2014 Medical Student Leadership Award to Rishi Kumar, M.D., M.B.A., M.H.A., and scholarships to four first-year University of Minnesota medical students.

Kumar is currently a resident at Hennepin County Medical Center. He has been part of the AMA's Medical Student Section at Mayo Clinic and authored a resolution to give students health insurance for the time between graduating from medical school and beginning residency. He is also a member of the Zumbro Valley

Medical Society executive board and chair of the MMA's Medical Student Section.

The Foundation scholarship recipients were Lee Morris from Sabin, Nicole Pothen from Faribault, Rachel Warnert from St. Joseph and Jason Weiderin from Park Rapids.

Working through the University of Minnesota Foundation, MMAF awards scholarships to medical students from medically underserved Minnesota communities. Scholarships are $5,000 per year for four years.

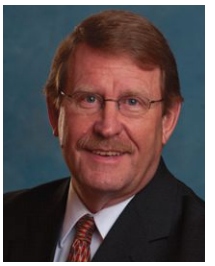
Twenty-three medical students have participated in the MMAF scholarship program. Two other MMAF scholars, Ryan Clark and Hannah Wangberg, will complete medical school at the University of Minnesota in the spring of 2015. All past recipients are in residency programs or are practicing medicine.

Save the date: Day at the Capitol is March 11, 2015

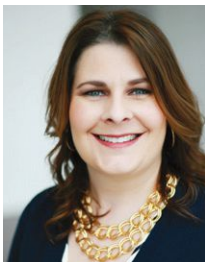
The MMA's annual event at which physicians meet face to face with their state senator and representative has been set for March 11. Watch *MMA News Now* for details.

PHOTO BY KATHRYN FORSS

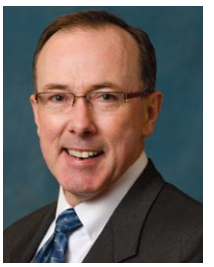
Day at the Capitol provides physicians direct access to lawmakers.



Terry Ruane



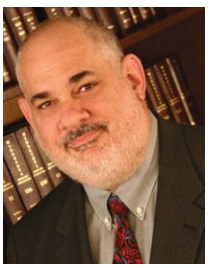
Kathleen Baumbach



Dennis Kelly

Janet Silversmith

Barbara Daiker



Robert Meiches, M.D.

MMA in Action

In October, **Terry Ruane**, director of membership, marketing and communications, and **Kathleen Baumbach**, manager of physician outreach, met with Mankato Clinic CEO Randy Farrow and CMO Julie Gerndt, M.D., to discuss the needs and concerns of their clinic and how the MMA can help.

Baumbach also met with Lori Bennett of Regions Hospital in St. Paul to discuss ways to engage medical residents working at Regions.

Dennis Kelly, MMA Foundation executive officer, hosted the Foundation's "Care Where It Counts" fundraiser at the University of Minnesota's McNamara Center in October and took part in a rural family medicine panel presentation for first-year medical students at the University of Minnesota Medical School, Duluth campus.

Janet Silversmith, MMA director of policy, attended the Centers for Medicare and Medicaid Services' Region V meeting in Chicago with representatives from other state medical associations in September. There, she discussed Medicare value-based payment reform, new Medicare demonstration projects for patients who are eligible for both Medicare and Medicaid, and physician training needs. She also presented a talk, "Affordable Care Act—Changes and Challenges for Physicians," at Allina's Cambridge Medical Center.

In September, Silversmith and **Barbara Daiker**, MMA manager of quality, met with Minnesota Department of Health staff to discuss recently passed legislation requiring the state to develop a plan for stratifying state quality measures by race, ethnicity, language, disability and other sociodemographic factors. The Health Department is looking to the MMA, the Minnesota Hospital Association and others for insight and expertise.

Members **Ken Kephart**, M.D., and **Phil Stoltenberg**, M.D., led a discussion with the physician leaders of Minnesota Gastroenterology, PA, in St. Paul on independent practice, physician well-being, burnout and recent achievements of the MMA and Twin Cities Medical Society (TCMS). They were joined by **Robert Meiches**, M.D., MMA CEO, **Sue Schettle**, TCMS CEO, and **Brian Strub**, MMA manager of physician outreach.

In mid-September, Strub and **Nancy Bauer** and **Andrea Farina** of TCMS met with student leaders from the University of Minnesota Medical School to discuss issues relevant to medical students. The MMA and TCMS will design educational programs based on this information.

VIEWPOINT

On solving problems and speaking up

Donald Jacobs, M.D.

A single twig breaks, but the bundle of twigs is strong. –Tecumseh, leader of the Shawnee tribe

I think of this quote when asked why I invest so much of my time in organized medicine. Physicians working alone have a tough climb when it comes to changing policy or improving public health; together, we can be resolute.

The MMA and our component medical societies provide a place where physicians can come together to figure out what none of us as individuals, practices or even large organizations can alone. Collectively, we are more creative and resourceful in our problem-solving than any of us might be individually.

And there are many problems to solve. First and foremost is the issue of how to support the goals of the Triple Aim—improving the patient experience, reducing costs and improving population health. Organized medicine—including the MMA and our component medical societies—must champion all that will help us achieve those aims.

One thing we, as physician leaders, need to be prepared to do now is help design and embrace new models of care that are relevant to our changing practices. This includes incorporating physician assistants and advanced practice nurses into our practices in new ways. Physician assistants and advanced practice nurses, working closely with physicians, have been critical to survival for many clinics, hospitals and health systems in our reimbursement-constrained environment. That certainly has been the case at Hennepin County Medical Center, where I work. We've been able to do this in a way that upholds our commitment to quality, safety and service. For example, we've used a team-based model and paired hospitalists with advanced practice nurses. This has allowed us to provide better care for the rapidly growing number of observation-status patients at a reduced cost. We need to embrace care partners of all types if they can be used in ways that help us achieve the Triple Aim.

What is the role for organized medicine in this? From my perch, I think it is to speak up. We have a powerful voice and we need to use it to advocate for enhancing the patient experience, reducing costs and improving population health. We need to advocate for the resources necessary to train and develop the new workforce, to advocate for sensible regulation and to push for payment models that are flexible and sustain viable business models.

Some of this advocacy needs to be done by individuals working within their organizations. But much of it needs to be done on a larger scale—by physicians working collectively to shape the environment within which their organizations function. Physicians today may feel they are a small part of massive health care systems. But as Tecumseh said, the bundle is stronger than the twig.

Collectively, we are more creative and resourceful in our problem-solving than any of us might be individually.

MDs and marijuana

What you need to know about Minnesota's medical cannabis law

BY KEVIN C. RIACH, J.D.

The Minnesota Legislature passed a law in 2014 legalizing the manufacture, sale and use of medical marijuana. Physicians, physician assistants and advance practice nurses are at the heart of the law, for without their participation, Minnesota's medical marijuana program cannot succeed. This article discusses the basics of the new law and explains the responsibilities of physicians as well as the risks arising from participation in Minnesota's medical cannabis program.

Qualifying Conditions

- Cancer
- Glaucoma
- AIDS
- Tourette's syndrome
- Amyotrophic lateral sclerosis (Lou Gehrig's disease)
- Epilepsy
- Crohn's disease
- Terminal illness with a life expectancy of less than one year where the patient is suffering from severe or chronic pain, nausea or wasting.

The law empowers the Department of Health to add new conditions to the list of those approved under the law, subject to veto by the Legislature. It also requires that the Commissioner of Health specifically consider adding intractable pain to the list before any other new conditions and to report to the Legislature on the reasons for doing so.

Source: Minn. Stat. §152.22, subd. 14

Minnesota's Medical Marijuana Program

Under the law, "health care practitioners," defined as physicians, physician assistants and advance practice nurses, will not prescribe medical marijuana or recommend the amount or dosage of medical marijuana for a patient. Instead, they will simply diagnose a patient with a qualifying condition (see box) and complete a certification form indicating the patient has such a condition. To obtain medical marijuana, the patient must apply to and register with the Minnesota Department of Health.[1]

The law authorizes consumption of medical cannabis in pill form or through a vaporizer, essentially an e-cigarette-type device that converts cannabis oil to vapor so a patient can inhale it. It specifically prohibits consumption of medical marijuana in raw plant form and the smoking of medical marijuana.[2] The Department of Health is currently evaluating whether the law would permit delivery of medical cannabis via nasal spray or through a topical cream.[3]

Registered caregivers are allowed under the law to assist registered patients incapable of obtaining or self-administering medical marijuana (eg, a child or severely disabled individual). These caregivers, unless they are a parent or legal guardian of a qualifying patient, must apply to and register with the Department of Health separately from the patient under their care.[4] A registered caregiver may provide support to only one patient under the law, thus foreclosing any problems with "caregivers for hire." Some have pointed out that this limit may pose issues for group homes, assisted living facilities or other facilities in which multiple patients may depend on the same caregiver(s) to obtain and administer their medical marijuana.

The State of Minnesota will license two manufacturers to produce the medical marijuana used in the state. Transport of marijuana across state lines will remain illegal and a focus of government prosecution. Thus, manufacturers must produce their medical cannabis within the state. The manufacturers must contract with independent laboratories to perform safety and quality testing on the medical marijuana they produce.[5]

The manufacturers will operate eight distribution sites around the state. Patients (or their registered caregivers) will only be able to obtain medical marijuana from one of those eight locations. A pharmacist must staff each distribution site; however, the Minnesota Department of Health recently stated in response to questions from potential manufacturers that it may be open to distribution via telemedicine or automatic dispensing.[5]

Pharmacists will consult with patients to determine the appropriate dosage and strain of medical marijuana for that patient, based on information about the efficacy of various strains of medical marijuana provided by the Department of Health's newly created Office of Medical Cannabis. The law requires the health department to publish a report "on the existing medical and scientific literature regarding the range of recommended dosages for each qualifying condition and the range of chemical compositions" by December 1, 2014. The department will update this report annually.[6] The law includes several protections for registered patients. First, it creates a presumption that a registered patient is lawfully using any medical marijuana he or she possesses. That presumption can

be rebutted by evidence that the patient used the marijuana recreationally. Second, the law prohibits housing or employment discrimination based on registered patients' use of medical marijuana. Finally, a person's status as a registered patient will have no effect on their custody or visitation rights.[7]

The law establishes a task force to consider the social and health effects of the use of medical marijuana. Task force members include representatives from law enforcement, legislators, patients, health care providers, substance abuse treatment providers and commissioners of several state agencies. The task force has been holding regular listening sessions to hear from stakeholders and the public and will report to the Legislature on what they learn. Among the specific areas on which the task force must report is "the impact [of the law] on the health care provider community."[8]

Physician Responsibilities under the Law

The law does not require physicians or other health care practitioners to certify patients or otherwise participate in the program. However, for those who do choose to participate, the law imposes several duties.

First, before providing a patient with the required certification, they must offer the patient "explanatory information" about the potential risks, benefits and side effects of using medical marijuana, including a disclosure that treatment with medical marijuana is experimental. The Department of Health will create the required information to be disclosed and make it available before the program begins operating on July 1, 2015. Health care practitioners are also required to notify certified patients and their caregivers about nonprofit patient-support groups and organizations.[9] The law does not specify whether these support groups relate to the patient's qualifying condition or marijuana use nor does it indicate whether the Department of Health will create a list of such organizations for providers to use.

In addition to this "explanatory information," the law requires that the physician or other health care practitioner provide patients with what is known as a Tennessen warning. A Tennessen warning informs individuals of the purpose and intended use of the requested data, as well as any known consequence of supplying the data, which in this context includes publication in aggregate form in connection with research to be performed by the Department of Health regarding the efficacy of medical marijuana.[10] The law does not clarify whether the health department will provide health care practitioners with a standardized Tennessen warning.

Second, the law requires that before certifying that a patient has a qualifying condition, a physician must "agree to continue treating the patient's qualifying medical condition and report medical findings to [the health department]."[11] Similarly, the law requires that patients "continue to receive regularly scheduled treatment" for their condition.[12] Finally, the law requires that health care practitioners "determine, on a yearly basis, if the patient continues to suffer from a qualifying medical condition and, if so, issue the patient a new certification of that diagnosis."[13]

Finally, once a patient is participating in the program, physicians and health care practitioners must provide the patient's health records to the Department of Health, which will establish a patient registry to "evaluate data on patient demographics, effective treatment options, clinical outcomes, and quality-of-life outcomes for the purpose of reporting on the benefits, risks and outcomes regarding patients with a qualifying medical condition engaged in the therapeutic use of medical cannabis."[14] Physician submission of patient health records will provide the Department of Health with the information it needs to accomplish these goals. It will conduct research on data from health records submitted to the registry program and submit reports on its research results to the Legislature and scientific journals. The Department of Health will work with physicians and other health care practitioners to prevent the unauthorized release of patient data.

The law's imposition of these responsibilities inspires many as-yet unanswered questions. For example, what should a physician do if his or her diagnosis of a qualifying condition changes before the annual required recertification? Can a physician ever refuse to treat a patient once that patient has begun participation in the medical marijuana program? What if the patient or his or her insurance company refuses to reimburse the physician? What if a patient refuses to commit to a treatment option recommended by the physician? Must the physician report this refusal to the health department?

The Department of Health clearly recognizes it will need the help of physicians to resolve these (and other) issues. It has issued draft rules for patients and providers, and it is soliciting comments on those proposed rules from the health care community. A working draft of the rules is available on the Office of Medical Cannabis' website for review and comment by interested parties.[15] These rules will undoubtedly change before they are finalized and published, however they suggest the ways in which the Office of Medical Cannabis intends to clarify some of the uncertain aspects of the law.

The draft rules list the steps a provider must take before certifying a patient as having a qualifying condition:

1. Conduct an in-person physical examination of the patient
2. Take a medical history of the patient, including a review of medical records from other treating physicians from the previous 12 months
3. Conduct relevant consultations about the qualifying condition
4. Diagnose the patient's current medical condition
5. Develop a treatment plan for the patient.

Under the draft rules, providers must confirm in their certification of a qualifying condition that they have completed these steps, have established a "practitioner-patient relationship," and have explained the potential risks and benefits of

medical marijuana use to the patient or his or her caregiver.[16]

The draft rules explain that the law's requirement that providers continue treating registered patients whom they certify means:

> . . . follow[ing] the patient clinically at appropriate intervals at the discretion of the provider to provide follow-up care and treatment to the patient for his or her qualifying medical condition including, but not limited to, physical examinations, to determine the health effects of cannabis for treating the patient's qualifying medical condition or the symptom of the qualifying medical condition for which the written certification was issued.[17]

They also clarify that providers must notify the Commissioner of Health within 14 calendar days of becoming aware of the death of a qualifying patient, or if a change in the status of a patient's qualifying condition affects the patient's eligibility for medical marijuana.[18] Finally, the draft rules explain what must be contained in the health records provided to the health department in connection with patient participation in the medical marijuana program.[19]

Physician Risks under the Law

Because marijuana remains classified as a Schedule I controlled substance, its manufacture, distribution and use are illegal under federal law. Minnesota's medical marijuana law provides that health care practitioners will not be subject to state criminal prosecution or discipline by the Board of Medical Practice for participating in the program.[20] However, the remote possibility still exists that a physician or provider could be subject to federal prosecution for his or her involvement.

Minnesota physicians can take some comfort from the way in which courts and the federal government have approached conflicts between state and federal laws on marijuana. In the past, the federal government was more aggressive in threatening to prosecute health care providers who promoted the use of medical marijuana. That posture began to change, however, after the California case *Conant v. Walters* made its way through the courts from 2000 to 2003.

Prior to *Conant*, the government had been threatening to investigate and prosecute California doctors who recommended medical marijuana to their patients as a treatment option. A group of physicians and patients filed a class-action lawsuit in federal court seeking to enjoin the government from undertaking such prosecutions.[21] The court sided with the doctors and enjoined the federal government from "(i) revoking a class-member physician's DEA registration merely because the doctor recommends medical marijuana to a patient based on a sincere medical judgment and (ii) from initiating any investigation solely on that ground."[21] The court explained that "this injunction applies whether or not the physician anticipates that the recommendation will, in turn, be used by the patient to obtain marijuana in violation of federal law."[21] The case was appealed to the Ninth Circuit Court of Appeals, which upheld the injunction, explaining that investigating and intimidating health care practitioners who lawfully recommended medical marijuana treatment "strike[s] at core First Amendment issues of doctors and patients."[22]

In the years after *Conant*, the Department of Justice issued several rounds of guidance to U.S. Attorneys, setting forth the circumstances in which it would be appropriate to prosecute an individual for marijuana possession or distribution in a state where medical marijuana is legal. Generally, the guidelines indicate that the federal government has no interest in prosecuting patients or caregivers acting in compliance with state medical marijuana laws. However, there are several federal prosecution priorities that may draw the scrutiny of the government and trigger federal prosecution even in a state where medical marijuana is legal. Those priorities include:

- Distribution to minors
- Influx of criminal enterprises, gangs and cartels
- Diversion of marijuana to other states
- Trafficking of other illegal drugs or other illegal activity
- Violence and the use of firearms
- Drugged driving and other adverse public health consequences
- Preventing the growing of marijuana on public lands
- Preventing marijuana possession or use on federal property.[23]

Health care practitioners and patients are unlikely to run afoul of those priorities, and thus the risk of criminal sanction is very low for doctors participating in the program. Not surprisingly, the few federal prosecutions arising from medical marijuana distribution have focused on dispensaries and growers that have through their business practices been implicated in one of the above.

The law does create several new criminal penalties for patients and providers. It provides that a person who "knowingly submits false records" or a false "certification of qualifying condition" to the Department of Health is guilty of a felony. Further, a health care practitioner who "knowingly refers" a patient to a caregiver, advertises as a manufacturer, or issues certifications of qualifying condition while holding a financial interest in a manufacturer is guilty of a misdemeanor.[24] Additionally, the Department of Health's draft rules state that a provider may not "offer a discount or any other thing of value to a qualifying patient who uses or agrees to use a particular designated caregiver, distribution facility, or cannabis product."[25] Finally, the draft rules state that providers may not "[d]irectly or indirectly benefit from a patient obtaining a written certification," however this prohibition would not bar a provider from "charging an appropriate fee for the patient visit."[26]

The bottom line is that, while participation in Minnesota's medical marijuana program is not without risk, the risk is comparatively low. Nonetheless, health care provider organizations would be wise to incorporate specific policies regarding medical marijuana into their compliance programs to minimize those risks.

(continued on page 45)

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When hybrid records cause harm

How to avoid putting yourself at risk when making the switch to an EHR

BY TRISH LUGTU, B.S., CPHIMS, CHP

In 2010, Jane Doe, age 68, visited her urologist because of a urinary tract infection (UTI), problems with incontinence and gross hematuria. The urologist ordered computed tomography urography (CTU). A few weeks later, the CTU was done. The urologist examined the scan and found no abnormalities. He wisely waited for the final word from the radiologist, who was also interpreting the CTU. The radiologist, however, did find a problem and noted it in the patient's medical record: "The uterus demonstrates central decreased attenuation raising the possibility of underlying neoplastic changes. Ultrasound is recommended for further evaluation."

This is when the trouble began. The health system had switched from a paper medical record system to an electronic health record (EHR) system on the very day the CTU was ordered. Three weeks later, when the scan was done, the radiologist dictated his interpretation directly into the EHR, unbeknownst to the urologist. The urologist, who expected to get a paper copy of the results, assumed no news was good news and simply treated Jane's UTI with ciprofloxacin. The urologist never saw the radiologist's note.

Jane returned several times with worsening symptoms. However, it wasn't until 18 months later that she finally received a correct diagnosis from a different physician. Based on her symptoms during a routine exam, her OB/GYN ordered a test for a cancer marker and a transvaginal ultrasound—the same test that the radiologist had recommended 18 months earlier. The OB/GYN found elevated levels of the cancer marker and identified a large

uterine mass through the ultrasound. The mass was then biopsied.

Jane was diagnosed with advanced uterine carcinoma and suffered through three rounds of chemotherapy, plus surgery to debulk the tumor. Her life expectancy was considerably decreased.

EHRs and patient safety

Since 2008, adoption of EHR systems has increased five-fold across the United States. Currently, 59 percent of hospitals have implemented a basic EHR, and an additional 34 percent have arranged for, but not yet implemented, a certified EHR.[1] Although lagging behind hospitals in their adoption rate, office-based practices also are rapidly implementing to EHRs. With the Centers for Medicare and Medicaid Services' EHR incentive programs for meaningful use progressing to Stage 2, hospitals and clinics that have not yet done so will have to switch to an EHR during the next few years.

It is hard to argue against the benefits of EHRs. They can help ensure patients obtain preventive care. They can help prevent medication errors. And they can assist with clinical decision making for management of patients with chronic conditions. EHRs also capture data that can be used in research and for improving population health.[2]

But the wave of rapid implementation has had an unintended consequence: During the transition from paper to electronic records, hybrid records are often unavoidable. If they are not managed well, patients can be harmed. Stories like Jane's are making their way into the patient-safety and malpractice literature.[3]

In one study of EHR-related malpractice claims by CRICO Strategies, problems with hybrid records and conversions were found in 16 percent of the claims with at least one EHR-related contributing factor. This was second only to "incorrect information," which was identified in 20 percent of claims.[4] In an analysis of MMIC's claims from 2010 to 2012, only 1.1 percent involved an EHR-related contributing factor. Although that may not seem like a significant number, it may not tell the whole story, as years can pass between the time an incident occurs and when a claim is made. In the EHR-related claims from 2010 to 2012, the incidents occurred as early as 2007—three years prior to the claim. Given this time lag, it is reasonable to predict an increase in EHR-related claims in the coming years and that some of those claims will be the result of having hybrid records.

Additionally, "hybrid records" are not exclusively a mix of paper and electronic records. They also can include information from nonintegrated electronic systems such as a practice management system, a lab information system, a picture archiving and communication system, or even a legacy EHR system. (Operating with these

disparate systems can cause hybrid records to persist indefinitely.)

Sources of information including transcribed documents, faxed documents and X-ray films also can contribute to the creation of hybrid records.

Jane's case illustrates one point at which problems can arise—during an initial EHR implementation. However, problems involving hybrid records can occur any time disparate systems are maintained.

How to avoid problems

You can do number of things to minimize the risks associated with hybrid records.

Know where and when to look for information.

When EHR modules are rolled out over time, medical records can become moving targets. And no formula for "going live" fits all practices. Some groups bring their EHR online one location at a time, others do so according to physicians' specialty or even their technical aptitude, still others use a combination of approaches. During transitions, knowing where to look for certain information is crucial to patient care and avoiding risk.

A helpful tool for tracking this during transitions is a simple and easily accessible spreadsheet on which you document shifts of information. At the very least, it should allow you to list the record type (eg, lab results, X-rays) and the system (eg, film, CD-ROM, EHR, picture archiving and communication system, lab information system). If groups of providers transition at different times, information about that should be noted as well. This becomes especially important when a physician sees a patient on behalf of a colleague. A useful example of a tracking tool can be found in the American Health Information Management Association's guide for the legal record.[5]

Think through how you notify staff about critical information.

With an EHR, incoming documents can easily be missed if they are not routed through a messaging inbox or logged in a task queue or other monitoring system. Make sure your staff understand the importance of filing and tasking test and lab results accurately, no matter where those results originate (from electronic interfaces with external organizations or manually scanned or filed documents). Help staff define the different levels of notifications for critical and noncritical results.

Look for open orders.

Make sure your staff can use your EHR to identify all modes for ordering tests, so they are able to create appropriate audit reports. Had such a process been in place, Jane Doe's adverse outcome would likely have been avoided.

Conclusion

To minimize the risk of problems associated with hybrid records, physicians must stay engaged throughout EHR implementation. They must be able to identify gaps in information related to patient care, define critical thresholds for notification and empower EHR support staff to create appropriate audit processes. MM

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MDs and marijuana

(continued from page 42)

Conclusion

Medical marijuana is here to stay in Minnesota. Although details about the state's new law and how it will be implemented are yet to be determined, in the future we will likely see increased access and more qualifying conditions, if the experience of other states is any indication. Regardless of the direction the law takes, physicians will be critical to its implementation and will play a valuable role in setting its course. MM

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Obstructive Sleep Apnea in Children

More than a Bad Night's Sleep

BY YOSEF WEXLER, M.D.

Obstructive sleep apnea (OSA) is being seen in an increasing number of children. Because OSA can have serious sequelae, physicians who treat children are encouraged to screen for snoring and for OSA, if it is suspected. This article presents the case of a 4-year-old boy who was found to have OSA prior to a dental surgery. It discusses the signs and symptoms of OSA and explains why OSA is not an insignificant diagnosis. It also describes treatment approaches and stresses the importance of follow up.

A 4-year-old boy comes to see you in the clinic for a preoperative exam. He is scheduled to have a sedated dental procedure in an outpatient surgery center in five days. His mother reports that he does not have pain with chewing or cold intolerance while drinking, and that he has been free of fever, local jaw swelling and acute illness. She also reports that he has always been healthy and has not had previous hospitalizations or surgeries. In fact, his mother reports that no one in the family has ever had surgery.

During your review-of-systems inquiry, you discover that the boy is a nightly snorer. His mother confirms that he gasps for breath intermittently throughout the night and that occasionally his breathing pauses. She believes that he still rests well because he does not seem overly tired during the day and no longer needs a nap. She reports that he never complains of headaches and that he does not seem to have exercise intolerance, as compared with his playmates. On physical exam, the boy is found to be 105 cm tall and weigh 22 kg. His body mass index (BMI) is calculated at 20 (>95%). His exam is remarkable for dental caries and 2-3+ tonsils but otherwise is normal.

Given the findings elucidated during the exam and review of systems, you should be concerned about obstructive sleep apnea (OSA) and consider delaying dental surgery until the child can be evaluated for OSA.

Background

Obstructive sleep apnea is defined as episodes of complete or partial upper-airway obstruction during sleep and is caused by increased resistance in the upper airway. It is estimated that OSA occurs in 1% to 3% of healthy, nonobese children[1] and perhaps in as many as one-quarter of obese children.[2] It occurs with greatest frequency in children between 2 years and 10 years of age, coinciding with the timing of maximum adenotonsillar lymphatic tissue growth.

Many factors can contribute to increased upper-airway resistance. Generally, etiologies fall into three nonmutually exclusive categories: 1) internal (space-occupying), 2) external (compressing problems) and 3) intrinsic (decreased tone). In healthy children, adenoid and tonsillar tissue are the most common cause of OSA. In obese children, external compression by adipose tissue can be the source of the problem.[3,4] It can be difficult to identify decreased tone, although it should be considered in a child with a neuromuscular condition. In a developmentally normal child, decreased tone is diagnosed after other causes are ruled out. The number of children whose OSA is caused by obesity has increased as childhood obesity rates have risen.[5]

Signs suggestive of OSA include a report of consistent snoring (minimum of three nights per week), night-time sweating, restless sleep, sleeping in unusual positions, parasomnias, mouth-breathing, morning headaches, secondary enuresis, excessive daytime sleepiness or hyperactivity mimicking attention-deficit hyperactivity disorder. Serious sequelae of OSA in children include failure to thrive, behavioral and cognitive problems, hypertension and myocardial reshaping.

Some have theorized that OSA is a proinflammatory condition contributing to insulin resistance and metabolic syndrome.[6] OSA alone, and more so in conjunction with obesity, can affect exercise tolerance.[7] Children with OSA are at increased risk for peri- and postoperative complications including atelectasis and

hypoxia, pneumonia and even respiratory failure.[8]

Clinical Care

The American Academy of Pediatrics recommends that primary care providers screen all children for snoring.[9] The physical examination of a child with suspected OSA should include assessment of BMI; craniofacial abnormalities; palate structure; tone, teeth and bite alignment; and, of course, tonsillar size. Poor nasal airflow can suggest adenoid hypertrophy or allergic rhinitis caused by nasal congestion.

If the findings are suggestive of OSA, a polysomnograph (PSG) should be obtained in order to determine if the child has OSA and, if so, assess its severity. Even if the main cause appears to be enlarged tonsils and adenoids, the PSG may be useful, as it can help elucidate the severity of the upper airway obstruction and help predict the outcome of a surgical intervention.[10] The information it provides also may help you temper the parents' expectations for complete resolution after surgery. It is important to follow up with children who have lower probability that surgery will completely resolve their sleep-disordered breathing.[11]

Weight loss is important for children who are obese and have OSA.[12] CPAP, which is the gold standard treatment for adults, has a role in pediatrics as well; however, compliance may be a problem.

Conclusion

In the case described, delaying dental surgery in order to complete an evaluation for OSA is certainly warranted. You might refer the child to a sleep medicine specialist for evaluation with a PSG and EKG. Given the patient's obesity and mild tonsillar hypertrophy, a referral to an otolaryngologist alone might illicit the internal etiology but fail to reveal any contributions from external compression or intrinsic decrease in tone. Adenotonsillectomy alone has an OSA curative range of 34% to 69%, depending on the severity.[10]

If dental surgery cannot be delayed and a comprehensive evaluation cannot be completed prior to surgery, the anesthesiologist must be made aware of your concerns of probable OSA in order to best determine a safe plan for your patient's recovery.

With our current childhood obesity rates, OSA is a growing concern. Those providing medical care to children need to be aware of its signs and symptoms and recognize that it may have consequences that go beyond a poor night's sleep. **MM**

Yosef Wexler recently completed his pediatrics residency at the University of Minnesota. He is currently completing a sleep medicine fellowship at Hennepin County Medical Center.

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2014 Minnesota Academy of Pediatrics Poster Competition Winners

Each year, the American Academy of Pediatrics encourages its state chapters to invite medical students and residents to take part in a scientific poster competition. Residents and students submitted posters for consideration at the Minnesota chapter's annual meeting in Minneapolis in June. Both of the state's pediatric training programs (the University of Minnesota's and Mayo Clinic's) were well-represented.

Posters were judged by practicing pediatricians, pediatricians from the state's academic medical centers, and the students' and residents' peers. "Poster Rounds" were conducted for the peer-judging process. Criteria used by judges included clinical relevance, originality, and written and visual presentation. A "People's Choice" award winner was also selected. Special thanks to Andrew Olson, M.D., from the University of Minnesota for coordinating the competition. Congratulations to all of the participants on their excellent work.

MEDICAL STUDENT CLINICAL VIGNETTE WINNER

Amantadine Toxicity in an Adolescent with End-Stage Renal Disease

BY MEGAN PETERSON AND CHRISTIAN HANNA, M.D., UNIVERSITY OF MINNESOTA

Amantadine is an antiviral drug used against influenza A and as a treatment for Parkinson's disease. Recently, it has been used for treatment of psychotropic-induced weight gain in children and adolescents. The drug's full mechanism of action is not entirely understood, but it is known to have dopaminergic, antimuscarinic and anti-NMDA-glutamatergic properties. Amantadine toxicity most often affects the cardiac and central nervous systems.

Presentation: Our patient is a 16-year-old female with bipolar disorder and subsequent end-stage renal disease (ESRD) secondary to lithium toxicity requiring chronic hemodialysis. Because of weight gain from the antipsychotics, she was prescribed amantadine. She presented with acute worsening of tremors, weakness, gait problems and vision loss, as well as acute hypoxia noted at dialysis the morning of admission. She had been admitted to the hospital with similar symptoms on two separate occasions during the previous month without a clear etiology of those symptoms. Her vision loss was attributed to corneal edema with an unknown cause.

During her admission, she was intubated and required respiratory support for two weeks as well as continuous renal replacement therapy. She also had new onset arrhythmia and seizure episodes during her stay in the intensive care unit. Her urine drug screen from admission was positive for amantadine.

A diagnosis of amantadine toxicity was made after eliciting further history from the patient's mother. The patient had been taking doses higher than recommended for ESRD patients for five months prior to presentation. Her symptoms gradually improved with supportive care and cessation of amantadine.

Conclusion: Our patient developed amantadine toxicity because she was prescribed much higher doses of the drug than recommended for patients with ESRD. Amantadine accumulates in patients with abnormal kidney function, and the amount of the drug removed by hemodialysis is small.

Reports have described effects of amantadine toxicity on the cardiac and central nervous systems. One report described an acute respiratory distress syndrome (ARDS)-type presentation in an adult with ESRD. Since we did not find any specific etiology for our patient's respiratory status, it is very likely that our report describes the first case of ARDS secondary to amantadine toxicity in children. It also may be the first case of amantadine toxicity in children with ESRD.

This case emphasizes the importance of drug dose adjustment in patients with renal impairment, in addition to good communication between the physicians and other health care providers involved in a patient's care. MM

MEDICAL STUDENT RESEARCH/QUALITY IMPROVEMENT WINNER

Reduction of Pediatric Head CT Rates in a Community ED: A Preliminary Report

BY THUY DUONG NGUYEN-TRAN AND JEFF LOUIE, M.D., UNIVERSITY OF MINNESOTA

Head injury is a common reason for emergency department (ED) visits, and a head CT (HCT) is frequently used to evaluate for traumatic brain injury. Unfortunately, there is no national benchmark data for pediatric HCT rates; studies have estimated rates to be between 5% and 70%. A 2012 study by Menoch et al. found the HCT rate was 29% for head injuries at two tertiary pediatric emergency departments. However, the rate of children who receive a HCT and require neurosurgical intervention is less than 1%. Thus, it raises concern that some children with head injury are exposed to unnecessary radiation, which could increase their risk for malignancy.

Objective: Our study's purpose was to determine the HCT rate in a pediatric population at a community ED and identify factors that could help reduce HCT rates while still maintaining provider comfort and patient safety. In 2009, a prospective study by Kuppermann et al. validated prediction rules that identified children at low risk of clinically important traumatic brain injuries (ciTBI) and would obviate the need for a HCT. These prediction rules included severity of injury and certain signs and symptoms such as loss of consciousness, palpable skull fracture and impaired mental status. These prediction rules were developed into a guideline for evaluating head injuries and discussed with providers at a community ED that also serves as a Level III trauma center.

Methods: Our retrospective study looked at patients from birth to 18 years of age who were evaluated in the ED in 2012 for a head injury or concussion or who had a HCT, focusing on HCT rates before and after provider education and application of Kuppermann's guidelines.

Results: The ED had a total volume of 28,072 visits, 5,727 of which involved patients younger than 18 years of age. Head injury or concussion comprised 5% of the pediatric visits. The overall HCT rate for pediatric patients was 42%. The guidelines were discussed with providers in July 2012, and there was an initial decrease in the HCT rate for three months (to an overall low of 25%), after which rates began to rise. Additionally, variables commonly not documented were GCS (66%), vomiting (20%) and severe headache (28%).

Conclusion: These data gave us a baseline for HCT rates and identified key factors that require improved documentation. Our next goal is to implement PDSA (Plan-Study-Do-Act) cycles after each educational intervention. Our educational bundles will include interventions to improve awareness and use of the guidelines such as standardized EMR templates for head injuries and pocket handouts. We hope to standardize the evaluation of pediatric head injuries and decrease the use of HCT while optimizing patient safety and provider comfort. MM

PEDIATRIC RESIDENT RESEARCH WINNER

Improving the Consistency of Screening for Syphilis and Human Immunodeficiency Virus in Expectant Mothers

BY LINDSEY YOCK, M.D., KRISTI BOLDT, M.D., WILLIAM CAREY, M.D., CHRISTOPHER COLBY, M.D., AND THOMAS BOYCE, M.D., MAYO CLINIC

Objective: We sought to standardize our approach to prenatal screening so that the maternal syphilis (VDRL) and human immunodeficiency virus (HIV) status of every expectant mother would be determined and documented during the second trimester, with postpartum testing of the mother or newborn if the initial screening were declined.

Methods: We convened a workgroup with representatives from the obstetrics, pediatrics, neonatal medicine, infectious diseases and legal departments. Members adhered to the DMAIC (define, measure, analyze, improve and control) framework of quality improvement. We measured our baseline performance and found that VDRL and HIV status were absent from 20% and 9% of maternal records, respectively, among 100 consecutive newborns admitted to our NICU. Using causal tree analysis, we identified critical barriers to screening and documentation of serologies. We then developed standardized process improvements that targeted these deficiencies. In the control phase, we re-measured our performance to determine whether these interventions were successful.

Results: Six months after implementation of the interventions, VDRL and HIV status were absent from 9% and 0% of maternal records, respectively.

Conclusion: A formal QI approach enabled our institution to improve the rates of maternal VDRL and HIV screening and documentation. MM

PEDIATRIC RESIDENT CLINICAL VIGNETTE WINNER

The Link between Erythema Multiforme Major, Mycoplasma Infection and Incomplete Kawasaki Disease

BY MAGDALENA KAPPELMAN, D.O., ELISABETH HURLIMAN, M.D. AND JENNIFER MCENTEE, M.D., UNIVERSITY OF MINNESOTA

Mycoplasma has several diverse presentations including atypical pneumonia, hemolytic anemia and bullous myringitis. Mycoplasma is also one of the leading causes of erythema multiforme major. There are several case reports correlating mycoplasma infection and incomplete Kawasaki disease. This case report further supports that link. Other case reports describe annular skin lesions as the initial presenting feature of incomplete Kawasaki disease, further expanding the index of suspicion needed when evaluating a child with rash and fever.

Case: A 9-year-old previously healthy, immunized boy presented with seven days of fevers, purulent conjunctivitis, pharyngitis, cough, mucositis and rash. His only drug exposures were to ibuprofen and over-the-counter cold medicine. On admission, he was afebrile and his vital signs were normal. He had purulent bilateral conjunctivitis and extensive mucositis involving his mouth and urethra; bilateral, tender anterior cervical lymphadenopathy; and numerous targetoid plaques with central bullae and peripheral pallor ranging in size from 1 to 3 cm covering his body and extremities. He was also noted to have painful dactylitis of his fingers.

On admission, his labs were remarkable for an elevated erythrocyte sedimentation rate of 128 mm/h and an elevated C-reactive protein of 78.8 mg/L. His white blood cell count, hemoglobin, platelet count, alanine aminotransferase and albumin were normal. He did have a sterile pyuria (5 white blood cells per high power field) attributed to his mucositis. His mycoplasma IgG was negative and his mycoplasma sputum PCR was positive.

His exam findings were consistent with erythema multiforme major caused by active mycoplasma infection. Despite treatment with azithromycin and supportive care, he was persistently febrile on hospital day four, so a transthoracic echocardiogram was obtained that showed coronary artery ectasia and left anterior descending artery dilatation to 5.8 mm (Z-score 2.5) with no frank aneurysm formation.

A diagnosis of incomplete Kawasaki disease was made and high-dose aspirin and IV immunoglobulin were administered. At follow-up, his skin lesions had improved and his coronary artery dilatation had stabilized.

Discussion: This case illustrates the elusive nature of Kawasaki disease. Once the etiology is better understood, there will undoubtedly be a decline in late or missed diagnoses. In the meantime, pediatricians must have a high index of suspicion for this diagnosis even if there is another explanation for erythema multiforme, given the growing association between mycoplasma infection and incomplete Kawasaki disease. MM

PEOPLE'S CHOICE WINNER

Glut-1 Deficiency Syndrome Misdiagnosed as Febrile Seizures

BY PETER SCHOETTLER, TIFFANY WANG, CALLA BROWN, M.D., AND CHEE VANG, M.D., UNIVERSITY OF MINNESOTA

Glut-1 deficiency syndrome occurs as a result of impaired glucose transport across the blood-brain barrier. Mutations in the Glut-1 gene are responsible for a spectrum of phenotypes thought to be dependent on the level of glucose transporter function preserved in vascular endothelial cells. Characteristic symptoms include infantile seizures, microcephaly, ataxia and developmental delay. A ketogenic diet is an effective treatment in most patients, as ketones bypass the transporter deficiency and diffuse across the blood-brain barrier to fuel the brain's metabolism.

Case: A 34-month-old female with a history of recurrent complex febrile seizures and developmental delay presented with worsening seizure activity. At 14 months of age, the patient was diagnosed with febrile seizures. At the time, work-up included multiple normal electroencephalograms (EEG) and brain magnetic resonance imaging (MRI). Over the next year, she experienced four seizure events with peri-ictal ataxia despite treatment with anti-epileptics including levetiracetam and oxcarbazepine. As the seizures subsequently increased in frequency to three times per week, the patient's mother distinguished a prodrome in which the patient appeared "drunk" with an abnormal gait that was indicative of an impending seizure.

The patient was admitted for work-up of increased frequency and severity of seizures. EEG, MRI and numerous serum assays including serum glucose were unremarkable. Because of concern for a metabolic disease, a lumbar puncture was performed. Cerebral spinal fluid (CSF) glucose was 34 ng/dL and serum glucose was 97 ng/dL with a ratio of 0.36, well below the normal ratio of 0.67.

The patient initially required intravenous dextrose to prevent neuroglycopenia and associated symptoms of restlessness, ataxia and altered levels of consciousness. In order to begin a ketogenic diet, the patient needed to be weaned from the dextrose. Because of the recurrence of symptoms and parental concern, weaning from IV dextrose required a stepwise approach over three days.

The patient was then started on a ketogenic diet with gradual increases in the fat-to-protein plus carbohydrate ratio. A therapeutic ketogenic diet resulted in resolution of seizure activity with transient side effects of nausea and vomiting. Genetic testing for SLC2A1 mutations were pending at the time of submission.

Discussion: The hallmark finding of Glut-1 deficiency syndrome is hypoglycorrhachia, with the mean CSF glucose: plasma glucose ratio of 0.37. Approximately 500 cases have been reported since the syndrome was first described in 1991. However, it may be underdiagnosed given its rarity and complex clinical and genetic features. In this case report, it appears that the correct diagnosis was masked by febrile illnesses, which induced anorexia and hypoglycemia, exacerbating underlying hypoglycorrhachia and triggered seizure activity. Following establishment of a ketogenic diet with avoidance of fasting, the patient's seizure activity and gait disturbances should continue to improve. **MM**

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Blood on my pearls

BY ELIZABETH HALLER

There's blood on my pearls tonight.
It came from a man, shot through his brain,
There's blood on my pearls tonight.

When we met he was dead, no more pain,
We fought to pump blood through his veins.
Twice resuscitated, twice denied.
At last, we admitted he had died.

Night shift wanes, day draws nigh;
But before I move on, I cannot deny
There's blood on my pearls tonight.

2014 **Writing Contest**
HONORABLE MENTION

Elizabeth Haller is in her fourth year at Mayo Medical School.

On what inspired this poem:

It was a late night in the emergency department. A man had committed suicide, and I was part of the resuscitation team. Our tug-of-war swayed twice in our direction as his heart regained its beat. Yet, ultimately, his injury led to his death.

The shock of meeting someone while he wavered between worlds left me with many questions: Why had he chosen death over life? Would he want us to restart his heart? If we did, what sort of life lay before him?

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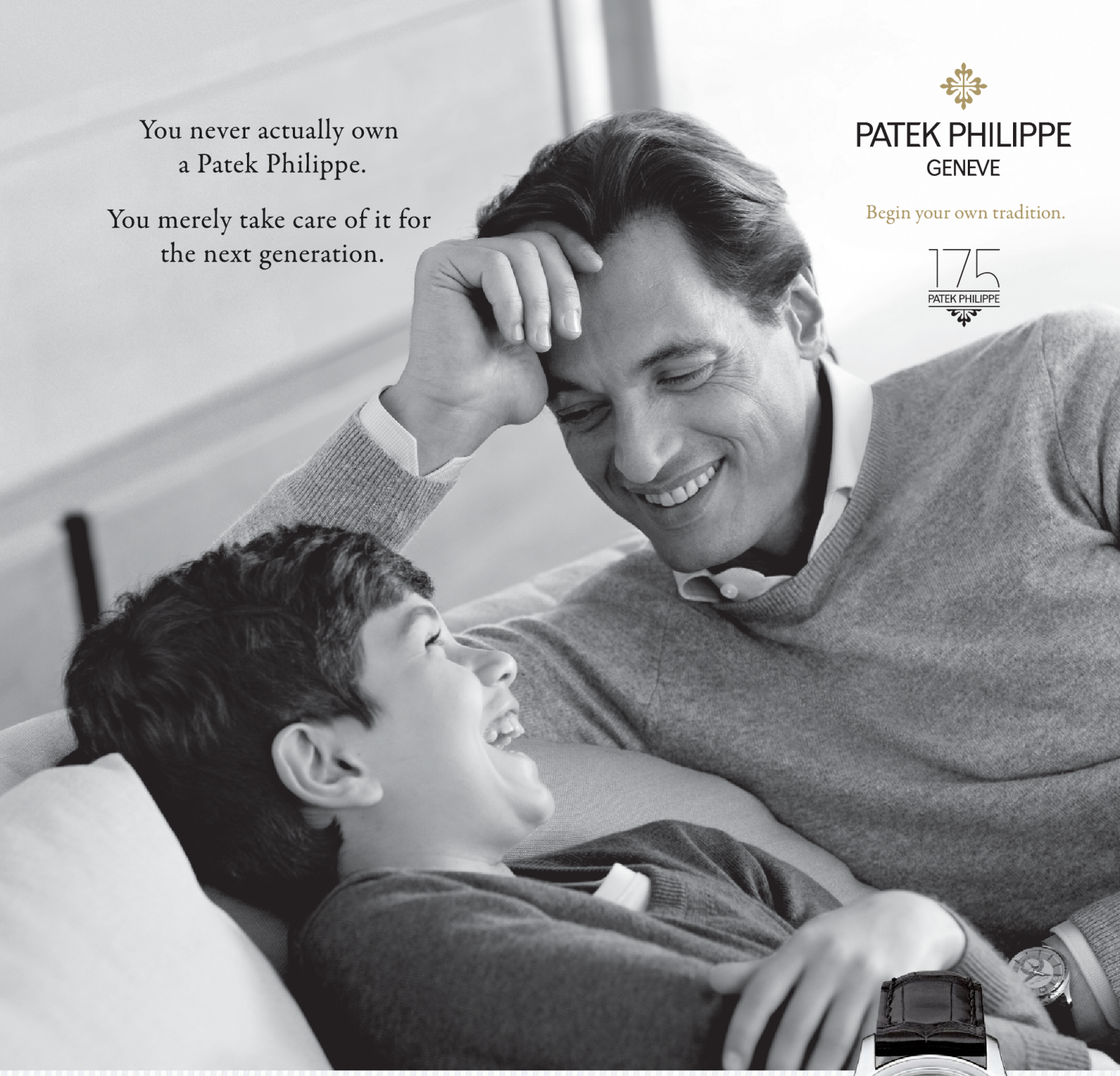

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