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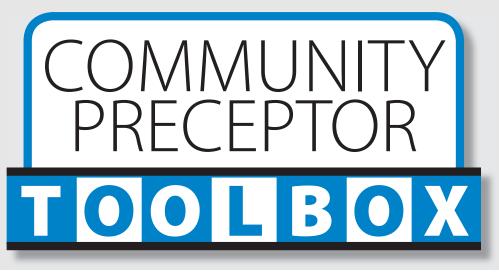
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#### CONTACT US

Minnesota Medicine 1300 Godward Street, Suite 2500 Minneapolis, MN 55413 PHONE: 612-378-1875 or 800-DIAL-MMA EMAIL: mm@mnmed.org WEB AND DIGITAL EDITION: mnmed.org

OWNER AND PUBLISHER Minnesota Medical Association

EDITOR IN CHIEF Charles R. Meyer, MD

EDITOR Scott A. Briags

PHYSICIAN ADVOCATE Dan Hauser

ART DIRECTOR Kathryn Forse

CIRCULATION / WEB CONTENT Mary Canada

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#### **EDITOR'S NOTE**



Charles R. Meyer, MD, Editor in Chief

When comparing the economics of computers and drugs, analogies fail. Computer users require no benefit manager to negotiate their deals and no doctor-broker to tell them what to buy.

# **Apples and oranges**

Our drug pricing system does not compute.

y first computer was an Apple II Plus. Bought in the early 1980s, it had a monochrome screen with a slightly sickening greenish hue, a 5 1/4-inch floppy drive that cranked for minutes to boot up, and 64K of RAM. It cost \$2,100. Today, in my pocket is another Apple product: an iPhone 6 with a sharp, colorful screen, no disc drive (what's that?) and 16 GB of internal memory. After a rebate on my previous iPhone, it cost about \$500.

In 2017, while Apple Stores teem with consumers anxious to get the latest products at prices they find acceptable, patients blanch at the sticker shock they encounter when they visit their pharmacy. Why can't drugs be more like computers?

There are some similarities. As computers have made our lives better (though more complex), drugs have dramatically improved medical care. During the past three decades, new classes of drugs to treat hypertension, hyperlipidemia, coronary artery disease and peptic ulcer disease have emerged, and those pharmaceuticals have changed the medical landscape, causing the incidence of atherosclerotic disease to plummet and making surgery for ulcer disease virtually a museum piece.

Like drugs, computers have improved through research and development. LCD technology has led to mothballing of large, chunky monitors, and miniaturization has ushered us into a Star Wars-esque era of "gee whiz" gadgetry. Few would advocate for a return to the limitations of a 1980 product—be it the Apple II Plus for computer work ... or Maalox for ulcers.

When comparing the economics of computers and drugs, however, analogies fail. Computer production follows the classic track of a consumer product coming to market. Companies deliver their wares to buyers through mail orders or retail outlets. Although patents abound in the digital world, multiple companies produce similar products and compete on quality and price. Dell battles Lenovo, which battles Acer, which, in turn, battles Dell to win the mind and loyalty of the buyer. And over the years, prices for equivalent products have tended to drop. Computer users require no benefit manager to negotiate their deals and no doctor-broker to tell them what to buy.

As Howard Bell's article in this month's issue shows, the drug market wallows in a distorted version of competition. Drug patents lasting 20 years or longer allow pharmaceutical companies to market a drug free from the generic competition that will eventually moderate the price. Even when initial patents expire, gaming the system by developing new drug delivery mechanisms or interfering with the proliferation of generic competitors allows drug companies to prolong their lock on a lucrative drug's profits.

Recent years have seen other aberrations of the generic drug market, including a new entity: the generic monopoly, leading to sometimes obscene price escalation of a previously cheap drug. Recently, one of my patients reported that their generic drug, which a few months ago cost \$4 per month, now costs \$18 per month. Pharmacy benefit managers were supposed to "unionize" buyers to get better prices but, as noted in Bell's article, that system has its corruptions. As Alice said in Wonderland, "Curiouser and curiouser."

If the present system of patent protection for the fruits of R&D remains in place, perhaps we need a bigger "union" to negotiate for *patient* protection. The obvious candidates are Medicare and Medicaid, currently barred by law from negotiating drug prices. For sure, something needs to curb the craziness in drug prices before our system goes down the rabbit hole.

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

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### →SHORT TAKES | DOWNTIME



# Wing man

On a gray March day, Stephen Wagner, MD, putters in the large hanger where he keeps his

#### Beechcraft King Air E90.

The 40-year-old turboprop, like the concrete floor it sits on, is shiny and white. With screwdriver in hand, Wagner is rounding on his "bird," opening up compartments and moving parts.

Wearing a brightly striped shirt and a baseball cap, the anesthesiologist looks the part of a man on vacation, which he is. Spending it in his hanger in New Richmond, Wisconsin, however, wasn't the plan. He intended to fly his family to Key West for spring break. But his three teenage sons had their own ideas for the week—and traveling with Dad in the 10-seater wasn't among them.

Wagner isn't sure why none of his sons has caught the flying bug. "I try to encourage them, but I'm not going to force them," he says. "Honestly, it's expensive and risky."

Wagner himself needed no encouragement at age 12, when he found himself in an airplane hanger in Indiana. He'd moved from California to live with an aunt and uncle after his mother died of cancer. His uncle managed the hanger and ran the local flying club. "I spent time there, and I got to know the airport and fly things," Wagner recalls. "It was exhilarating. It was fun. I wasn't afraid of it."

By the time he was 16, Wagner had his private pilot license, and when he graduated from high school, he had commercial and instructor licenses. He continued flying during breaks from college (Harvard) and medical school (Stanford).

Wagner was in his residency at Mayo Clinic when he decided to buy his first plane. He found a Beechcraft Bonanza owned by a man in Seattle. "He put me up in his place, cooked all the meals for me, stuffed me in the plane, told me how to fly it, and sent me on my way," Wagner says. His first attempt failed when heavy cloud cover over the Columbia River Gorge forced him to turn back. But he made it to Rochester the next day. "That was a neat trip," he recalls, a bit wistful.

#### **Risk reduction**

Wagner says it's not unusual for pilots to like a little adventure. "A lot of people drawn to it have certain risk-taking proclivities," he confirms. He also points out

### DOWNTIME | SHORT TAKES <

it's not uncommon for physicians to be pilots.

But medicine and flying can be a bad combination, he notes. Although physicians may have the inclination and money to get into flying, too many don't have the time to keep up their skills. "It's a nottoo-unheard-of event that doctors kill themselves in planes because they don't stay current," he says. "They even named a plane after it: the 'V-tail doctor killer." That infamous nickname was coined for the Beechcraft Bonanza—the model Wagner owned at one time.

Wagner finds it fascinating to read the literature on aviation accidents and learn about contributing factors. "I see people making what look like reasonable decisions that I've made," he says. "It's just that they ended up in an accident and I didn't. It's somewhat sobering." The risks are greatest for both very new and very experienced pilots. Wagner attributes problems affecting the latter group to complacency setting in. "They skip the checklists, they cut the corners," he says.

With about 40 years of flying experience, Wagner now makes more conservative choices than he once might have, and he's diligent about keeping up his skills. He routinely does simulator training, which is required for his Airline Transport Pilot certificate—"the PhD of flying," as he calls it. And he makes sure he spends lots of time in the air. He averages 15 to 20 hours a month, trying as often as possible to fly for work-related purposes—for example, to attend a conference or to get training in a new pain management procedure.

#### Work-flight balance

Anesthesiology dovetails well with flying because it allows for a predictable schedule with chunks of time off. And some of the qualities that make Wagner well-suited for his specialty—his abilities to stay calm under pressure, be vigilant for long periods and pay attention to details—are needed in the air, too.

Such skills have proven especially valuable during tense moments at the controls, including the night he approached an airport in the Rocky Mountains while in the clouds, picking up ice. On another occasion, an air traffic controller directed him to fly into a line of thunderstorms near Miami. For the most part, however, Wagner is relaxed in the sky. "It's a wonderful feeling," he says.

That's clear as he sits in his King Air, his hands moving assuredly from lever to lever. Without prompts, he runs through his preflight checks. He nods when he hears the engines ignite. Then, grinning as the scent of fuel and the thumping of propellers waft into the cockpit, Wagner radios to no one in particular and takes off. – CARMEN PEOTA



#### SHORT TAKES | PHARMACOGENOMICS



# **Precise prescriptions** Mayo uses **pharmacogenomics** to help match medications to patients' genetic makeup.

Mayo Clinic physician who's about to prescribe a medication receives an alert: There's a known genetic variation that could cause consequences for people taking this drug. Would the doctor like to order genetic testing?

By analyzing the patient's blood or saliva, the physician can discover whether the drug is likely to be effective or cause side effects for that person. This is one way Mayo is bringing pharmacogenomics—the study of how peoples' genetic makeup influences their response to medication from the lab to the bedside.

Though it's not the only Minnesota provider involved with pharmacogenomics, Mayo has been a pioneer in the field, spearheading research since the 1980s. Currently, Mayo doctors are alerted whenever they're preparing to prescribe to a patient, for the first time, any one of 19 drugs known to cause concerning reactions when used by someone with a particular genetic variant. At that point, the physician can order a test to determine if the patient has that variant—or one of several others. By the end of this year, Mayo expects a single test panel will screen for many more variants at once.

Test results go into the patient's medical record. Capturing this information will help the organization use pharmacogenomics more proactively in the future. Instead of waiting for a prescription to trigger an alert, Mayo envisions having potentially harmful—or effective—medications automatically flagged in a patient's electronic health record (EHR), based on relevant genetic data already stored there.

Pharmacogenomics received a boost in 2015 from former President Barack Obama's Precision Medicine Initiative. The program funded a \$215 million research effort—involving more than 1 million volunteer patients—to move medicine from a "one-size-fits-all" approach to a treatment model that takes into account each individual's genetics, environment and lifestyle.

Mayo has already collected genetic samples from 60,000 volunteers (most of whom are local) to build a biobank, which will eventually also store the samples from all participants in the national initiative. For its pharmacogenomics work, Mayo is now in the process of sequencing 10,000 samples from local patients for many genetic variants known to influence a person's response to a medication. Findings will be loaded into the patients' EHRs. Mayo wants to investigate the value of having this genetic data on file preemptively, to determine whether the cost of testing ahead of time is justified by gaining the ability to prescribe a medication sooner, which may lead to better treatment outcomes.

"It takes seven to 10 days to extract DNA and get the genotyping test back," says

#### PHARMACOGENOMICS | SHORT TAKES <

Richard Weinshilboum, MD, co-director of the pharmacogenomics program at Mayo Clinic's Center for Individualized Medicine. "The pre-emptive approach makes the most sense because it's cost-effective and time-effective. What you really want is to have the information available at the point of care, as the prescription is written."

Though widespread application of proactive pharmacogenomics is several years out, the science is headed in that direction. Already, Mayo uses pharmacogenomics testing for patients with a variety of health concerns—including cancer, high cholesterol and HIV/AIDS—to help guide treatment decisions.

Other patient segments ripe for pharmacogenomics implementation include people who use pain medications and antidepressants. Currently, the Mayo Depression Center doesn't order genetic tests for all its patients, but clinicians there do employ pharmacogenomics for people whose conditions are treatment-resistant. With more than 20 FDA-approved antidepres-



Richard Weinshilboum, MD

sants available, it usually takes trial and error to find the most effective medication for a given person. Genetic variations can affect how people metabolize drugs in the liver and receive drugs in the brain.

"Pharmacogenomics helps me rule out medicine that has a low yield of being helpful," says Mark Frye, MD, chair of Mayo's psychiatry and psychology department. "It helps the clinician give more precision to their treatment selection."

Small studies have shown investments in pharmacogenomics to be worthwhile.



Mark Frye, MD

To spur broadened use of proactive testing —and to help make a case for insurance coverage of it—Frye advocates for additional, larger-scale research.

"In the realm of health care economics, we are obliged to assess the value this test brings," he says. "Do patients get better faster? Do they have a better overall response rate and fewer side effects? Small studies suggest it's the case, but we need more research in that area." – SUZY FRISCH



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ON THE COVER

# DRUG PRICES are increasingly hard to swallow.

Effective remedies prove elusive.

SIVE M **BY HOWARD BELL** 

wo lawsuits filed this year in federal court claim that three drugmakers have colluded in order to simultaneously raise the price of insulin. One case cites several patients with diabetes who, no longer able to afford the drug at \$900 per month, resorted to injecting themselves with expired insulin or starving themselves to control their blood sugar. Some patients even allowed themselves to slip into diabetic ketoacidosis so they could get insulin from hospital emergency departments.

Such scenarios aren't shocking to Macaran Baird, MD, MS, who heads the Family Medicine and Community Health Department at the University of Minnesota. After 39 years of practicing medicine, he's never seen as many people struggle to pay for their medicine as he does today.

"Patients don't fill their prescriptions for hypertension or diabetes," he reports.

PENSIVE ME "They split pills or skip taking their medications until there's a crisis that costs far more to treat than if they'd taken the medicine." Nationally, nonadherence to drug treatments is estimated to cost the health care system between \$100 and \$289 billion per year. "It's getting common," Baird says. "We're heading backwards."

A variety of drugs are commanding high prices these days. New medicines that help people with serious conditions live longer can be enormously expensive. For example, some newer oncology drugs cost \$200,000 per year. But prices of older, everyday drugs are also on the rise. Previously inexpensive drugs, including insulin, albuterol, tetracycline and epinephrine, which are used for treating common

chronic conditions, have skyrocketed in price, sometimes to levels that make headlines.

Insurers struggling to absorb these increases raise deductibles, copays and coinsurance, making it even harder for patients to afford their medicine. Employers, meanwhile, are increasingly putting employees in high-deductible plans that don't pay for anything until the employee spends \$3,000 or more out of pocket.

As out-of-pocket costs go up, adherence to treatment goes down, worsening outcomes. "It puts physicians in a hard place,"

Baird says. "We want to treat our patients, but our patients can't afford the treatment."

#### **SPENDING INCREASES**

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Between 2009 and 2013, Minnesotans increased how much they spent on prescription drugs by 21 percent, reaching \$7.4 billion, according to the Minnesota Department of Health. America's Health Insurance Plans, an industry association, recently reported that for the first time, more is being spent on prescription drugs than on physician or hospital services. "Drugs are now the biggest slice of the health care cost pie," says Stephen Schondelmeyer, PharmD, PhD, a pharmaceutical economist and director of the University of Minnesota's PRIME Institute, which studies economic and policy issues surrounding pharmaceuticals.

Drug spending increases are only partly caused by higher prices, however. Spending is also up because more prescriptions are being filled than ever before. Physicians have grown increasingly reliant on treating conditions with drugs, and more people have obtained drug coverage through the Affordable Care Act, Medicaid expansions and Medicare Part D, which didn't exist until 2006.

#### **PRICE HIKES**

Nevertheless, rising drug prices merit concern, Baird assures. "Even though just about everything in health care is getting more expensive, the fastest-growing cost is the price of prescription drugs," he says. Between 2008 and 2015, the consumer price index increased by 12 percent, but prices for the most commonly used brandname drugs increased 164 percent.

As board chair for the UCare health plan, Baird sees impacts not only from the patient care perspective, but from the payer perspective as well. "We might sign a contract for a drug at a certain price," he notes, "and six months later, it goes up 1,000 percent. Drugmakers raise the price because they can. It's unconscionable."

#### **GENERICS AREN'T IMMUNE**

As brand-name drug prices rise, generic equivalents are, in many cases, a better deal than ever before. While the average brand-name drug now costs more than \$500 per prescription, the average generic drug runs about \$40, according to Schondelmeyer. "Ten or 15 years ago, that cost difference was only about 3-to-1 or 4-to-1," he says. "Now it's 10-to-1 or 12-to-1."

Yet even though most generic drug prices have remained fairly stable, 400 generics increased in price more than 1,000 percent between 2008 and 2015. The price of generic captopril used for hypertension and heart failure rose by more than 2,800 percent between November 2012 and November 2013. During that same period, clomipramine, a generic tricyclic antidepressant also used for obsessivecompulsive disorder, rose in price from 22 cents to \$8.32 per pill.

#### WHY SO HIGH?

After accounting for rebates many buyers receive, drug prices in the U.S. are 15 to 50 percent higher than those in Canada and Western Europe—for a number of reasons.

**Lack of price control.** According to Schondelmeyer, the U.S. is the only major developed nation that allows drugmakers

The state of the most commonly used brand-

**Patent protection.** Patents give makers of new drugs government-granted protection against competition that lasts, on average, 12 to 15 years—and can last as long as 20 years. "Patent-protected brand-name drugs account for only 15.7 percent of prescriptions in the U.S.," says Schondelmeyer, "but they account for 85.2 percent of drug spending."

**Lack of price negotiation.** While a drug is patent-protected, the primary way of reducing its price is for payers to negotiate lower prices. But payers face negotiating barriers.

Medicare accounts for 29 percent of U.S. outpatient drug expenditures, but federal law prohibits the program from negotiating lower prices—even though Medicare negotiates prices for just about every other health care service. In addition, the Centers for Medicare & Medicaid Services (CMS) isn't allowed to interfere with negotiations between drug companies and individual Part D vendors, such as those offering Medicare Advantage Plans. Nevertheless, Medicare is required to cover all drugs in certain drug classes—such as oncology—regardless of cost.

Medicaid is required to cover all FDAapproved drugs, regardless of cost, even if a particular drug has an alternative that's safer, more effective or cheaper. Unlike Medicare, Medicaid receives a 23 percent rebate on the manufacturer's price for most branded drugs. And Medicaid is protected from price increases that exceed inflation.

Private payers use pharmacy benefit managers (PBMs) to negotiate prices on their behalf. PBMs pool large volumes of insured patients together to negotiate bet-

ON THE COVER

ter rebates from drugmakers than payers could obtain on their own. PBMs also decide which drugs end up on a health plan's formulary—and on which out-of-pocket cost tiers they're available.

E

EXPENSIVE

Although they save payers money, aggressive price negotiation is not the norm for PBMs, according to a 2016 report in *JAMA*. The authors found that the PBM business model has a built-in conflict of interest: The more money PBMs save insurers, the less profit they make.

That's because a big part of a PBM's profits comes from rebates that drug companies pay to get favorable placement on formularies. In some cases, the PBM receives a portion of the rebate it negotiates. That can result in a drug ending up on a health plan's formulary because it had the highest percentage rebate, not because it was the cheapest available drug.

For example, a PBM might choose a brand-name proton pump inhibitor such as Nexium that costs \$8 per day instead of a generic equivalent that costs 25 cents per day, because the PBM can get a 50 percent rebate off the Nexium list price. The PBM can report saving the insurer 50 percent; that can result in the payer's formulary including Nexium for \$4 or more—but not including the 25-cent generic equivalent.

"This is becoming more common," Schondelmeyer says. "Insurers chase rebate percents and dollars saved rather than the lowest net cost." While PBMs have a right to make a profit, he notes, "It's a problem when PBMs prefer a brandname drug for an insurer that costs more than another similar drug because they get a bigger percent or dollar amount of a rebate."

Additionally, because rebates are confidential, payers, physicians and pharmacists don't know the actual price a PBM has paid to buy a drug on their behalf. "If physicians and payers don't know the price," Schondelmeyer asks, "how can they make value-based prescribing decisions for their patients?"

# Does R&D justify high drug prices?

Drugmakers often say that prices for brand-name drugs must rise to pay for research and development. But a 2016 report in *JAMA* found that large drug companies spend only 10 to 20 percent of their revenue on R&D. And that portion is considerably smaller when only taking into account work on truly innovative drugs, not changes to older drugs. A higher percentage of revenue is spent on advertising, promotion and administrative costs.

Some argue that the best way to stimulate innovation is to increase funding for the National Institutes of Health (NIH). That's because new drugs are often initially developed at research universities using NIH money. A recent analysis of the most transformative drugs of the past 25 years found that more than half of those drugs or drug classes originated in publically funded research centers. Many others were developed by small companies funded by venture capital.

**Specialty drugs.** Drug industry revenue drivers are shifting from traditional brand-name drugs to a growing number of specialty drugs, including expensive biologics. More than half of the 56 medications approved by the FDA in 2015 were specialty drugs, according to the pharmacy trade group Pharmaceutical Research and Manufacturers of America (PhRMA). Currently, more than 900 new specialty drugs are under development.

Some specialty drugs target small groups of patients—and have price tags that reflect their limited market. The hepatitis C drug Sovaldi, for example, costs about \$84,000 for a four-week treatment. Although specialty drugs represent less than 1 percent of prescriptions filled in the U.S., they account for one-third of total prescription drug spending, according to the Congressional Research Service. The amount spent on specialty medicines doubled between 2010 and 2015, contributing 70 percent of the overall growth in medicine spending during that period.

Generic specialty drugs, once they become available, are expected to cost 20 to 40 percent less than their brand-name counterparts—welcome relief, no doubt, but far less impactful than the savings of

# **/E MEDICINE**

# **EXPENSIVE M**

80 percent or more achieved with traditional generics.

**Generic delays.** Nevertheless, generics remain the most effective way to lower drug prices for patients and insurers. They account for 86 percent of all filled prescriptions and saved the U.S. health care system \$1 trillion between 2002 and 2012. But arrivals of new generics are often delayed or blocked by legal and business strategies.

Some drugmakers have refused to provide samples of their products to generic manufacturers that need them to do bioequivalence studies before they can manufacture a generic version. More commonly, drugmakers extend a nearly expired patent—for up to another 20 years—by making small changes to an existing drug product. They might combine two drugs into one "new" pill, create an extendedrelease version, or change a drug's delivery method from capsule to tablet or inhaler. In 2015, 30 brand-name reformulations of older drugs came to market.

Insulin, for example, is an 80-year-old drug, yet no generic is available in the U.S. Drugmakers keep changing the formulation and securing new patents for molecular manipulations or new delivery devices. Often these new formulations work better, but the product is still insulin.

"Pay for delay" is another tactic that curbs development of generics. The maker of a brand-name medication pays a generic drugmaker—sometimes millions of dollars—to stall or abort introduction of a generic equivalent.

FDA backlogs also delay the availability of many generics. In 2015, 4,300 applications were awaiting FDA approval to make generic versions of drugs no longer patentprotected.

#### Shrinking competition

**for generics.** Some generic prices aren't as low as they could be because not enough competing companies are making generic versions of a particular drug. Sometimes, multiple drugmakers stop making a generic because it's no longer profitable. If just one manufacturer remains—becoming what Schondelmeyer terms a "functional monopoly"—it has no need to compete on price, so that older generic drug can suddenly become much more expensive.

In other cases, drug companies buy the competition and then sharply increase prices for the generics they've acquired. In 2015, for example, Turing Pharmaceuticals bought the rights to generic daraprim for toxoplasmosis and raised the price from \$13.50 to \$750 per dose. No one else makes the drug, which treats a relatively small population of cancer and HIV/AIDS patients. The same year, Valeant Pharmaceuticals purchased the right to make the heart drug isoproterenol and then raised the price of a single dose from \$180 to as high as \$1,472.

**Brand-name coupons.** Brand-name drugmakers sometimes offer consumers coupons providing steep discounts on out-of-pocket or copay costs for a drug. Payers, however, still must cover their share of the drug's price. Studies indicate that such coupons cause a rise in overall drug spending because they increase sales of branded drugs by 60 percent while reducing sales of cheaper, bioequivalent generics. The financial impacts on payers can ultimately lead them to increase their insurance plans' premiums, copays, deductibles and out-of-pocket maximums.

**TV commercials.** Drug companies spend twice as much—or more—on marketing their products as they do on researching and developing new drugs. Baird considers direct-to-consumer (DTC) advertising of brand-name drugs a major driver of increases in drug prices and spending. "Patients pressure their doctor to prescribe the new, more expensive drug they saw on TV," he says, "even though it may not work any better than the cheaper generic and may even have more side effects."

DTC advertising also takes a toll on already limited doctor-patient time in the exam room—an indirect cost to doctors and health systems, Schondelmeyer notes. "It's a nuisance when doctors have to waste time during a patient visit explaining why the drug they saw on TV isn't worth the cost," he says.

#### WHAT TO DO? FEDERAL ACTION

Drug prices, spending and affordability are national issues that need national solutions. A number of federal actions have been proposed.

**Set drug prices.** Although not politically feasible at this time, the most effective way to reduce drug prices would be to set prices, as most countries with national health care plans do. Perhaps a more feasible option would be international reference pricing, which could push U.S. drug prices closer to those in other countries.

**Change patent law.** Changing how the United States Patent and Trademark Office defines "novelty" could stop patents from being awarded to clinically irrelevant tweaks of older drugs. Many feel this would also stimulate innovation because drug companies would need to earn more of their revenue from new drugs and rely less on extending brand-name protection for existing drugs.

Allow Medicare and Medicaid to negotiate lower drug prices. "This alone would save some serious money," says Baird. "Every effort to allow this has been blocked by drug company lobbying."

**Speed up approval of generics.** In the past, manufacturers have waited three to four years to get FDA approval to produce a generic drug. Recently, the FDA has said it's shortened that wait to an average of 15 months.

# EDICINE

# **EXPENSIVE MEDICI**

**Ban DTC advertising.** "The U.S. and New Zealand are the only civilized nations that allow direct-to-consumer advertising of branded drugs," says Baird. "Europeans are astounded that we allow this, then we complain about high drug prices." In addition, Schondelmeyer adds, "Many affluent nations that don't allow it have better health care systems and better outcomes than we do."

#### **STATE ACTION**

Although drug affordability is a national problem, actions at the state level can be effective. In Minnesota, most health care systems have already banned free samples and visits from drug company representatives or taken steps to curtail increasing use of brand-name drugs.

Last year, the MMA's Minnesota Action to Reduce Costs in Healthcare (MARCH) committee began meeting to come up with more ways Minnesota can deal with rising drug costs, spending and affordability. The committee has developed several recommendations.

**Ban coupons.** Medicare and Medicaid already prohibit use of drugmaker coupons or other discounts for drugs that have a generic equivalent. Private payers in Minnesota should do the same. Schondelmeyer points out that the federal government considers such coupons to be "kickbacks" and "a form of consumer fraud."

"The patient saves money out of pocket," says Baird, "but the health plan doesn't because the drug still costs the same. Some of the cost has just been shifted to the payer, who then raises the patient's premiums to cover the cost."

#### Allow biosimilar substitutions.

While still letting physicians write a "dispense as written" prescription, Minnesota should allow pharmacies, upon receiving a prescription, to substitute a less expensive

# **Drug-related number crunching not always conclusive**

Drug company profits may not be growing as fast as some think, thanks to more aggressive negotiating by pharmacy benefit managers (PBMs). According to a QuintilesIMS Institute study, list prices for brand-name drugs grew 12.4 percent in 2015, but net prices—the amount buyers paid after rebates and discounts increased only 2.8 percent.

The gap between list and net prices for drugs has grown dramatically over the past three years, the report says, partly because consolidation within the PBM industry has created fewer, larger PBMs with more power to negotiate lower prices with drugmakers. The portion of cost savings passed through to insurers is not easily known, as that information is proprietary and confidential. However, after accounting for rebates and discounts, the report concludes that "drug spending growth is comparable to growth in other parts of the health care system."

But conclusions about drug spending vary depending on what data is cited and how it's evaluated. For example, a report from the Centers for Medicare & Medicaid Services (CMS) shows that Medicare and Medicaid spending on prescription drugs rose 9 percent in 2015, outpacing spending increases in other areas of health care.

However, data from Express Scripts, the nation's largest PBM, show that a large portion of drug spending growth can be attributed to the increase in the number of prescriptions being filled—a trend that might be considered positive and partly due to increased access to health care enabled by the Affordable Care Act and Medicaid expansions.

#### ON THE COVER

drug that is biosimilar or interchangeable. This would produce cost savings—especially for expensive biologics—when more biosimilars become available. Only a handful of FDA-approved biosimilar biologics are available now, but many more will arrive in the near future.

An MMA bill to allow biosimilar substitutions has passed through all committees of both houses of the Minnesota Legislature, without opposition. It now awaits action in the House and Senate.

Increase formulary transparency. Although most insurers post their formularies on their websites, comparing plans' drug lists and costs is often extremely difficult. Health plans should be required to publicize their formularies prior to consumers' open enrollment periods in a way that clearly shows what drugs are covered, how much they cost, and how much enrollees will pay for them out of pocket. Improved communication about formularies is part of the MMA's prior authorization bill now pending in the Legislature.

**Increase PBM transparency.** Minnesota should require PBMs to be more transparent about conflicts of interest, rebate practices and price spreads—i.e., the difference between what the PBM pays for a drug and the price the insurance company pays.

Increase transparency of assistance programs. Some drug companies offer financial assistance programs to help consumers purchase medications. These programs can be helpful, but they ought to provide more information up front about the dollar value of assistance they provide, the number of patients who benefit, the criteria used to determine eligibility, and the average length of time the program's assistance lasts.

"Drugmakers use these programs the way they use coupons—to increase sales of more expensive branded drugs," says Baird. "Then they get a corporate tax credit for the expense." Patients often qualify for only three to six months of the reduced price for a drug; then they must switch to a different drug or begin paying full cost out of pocket. "Drug switching



and erratic care is not the proper way to treat chronic conditions," Baird says.

Make advocacy connections more clear. Minnesota should require greater transparency about drug company involvement in patient advocacy groups for such conditions as diabetes, multiple sclerosis, fibromyalgia and inflammatory bowel disease. Drug companies sometimes sponsor these groups as a way to promote the use of more expensive medications.

**Encourage evidence-based reimbursement.** "I have a patient who developed a rare vasculitis that required a biologic that the insurer denied," says Douglas Wood, MD, a Mayo Clinic cardiologist who chairs the MMA's Board of Trustees and sits on the MARCH committee. "The insurer would apparently rather pay more to treat complications of the disease than pay for the drug that prevents the complications—in this case, the loss of a leg and the need for dialysis."

When a new branded drug is safer and more effective than an older generic, Wood says, health plans should adjust out-of-pocket costs to make the new drug more affordable. "Newer blood thinners are safer and more effective than warfarin, but they cost \$220 to \$400 per month, while warfarin costs \$40 per month," he says. "The better, safer medicine is too costly, so patients endure needless blood testing and changes in lifestyle and diet, and they face a higher risk of bleeding, including intracranial bleeding. Insurers won't adequately cover the most effective drug, but they'll cover the cost of hospitalization to treat bleeding complications that could be avoided."

**Educate providers.** Statewide drugdetailing seminars should provide evidence-based information about drug safety and cost-effectiveness, presented by unbiased health care professionals. Some large health systems, including HealthPartners and Mayo Clinic, already do this.

Adjust prior authorization requirements. The MARCH committee recommends that physicians who follow evidence-based prescribing guidelines embedded in electronic health records

#### ON THE COVER

and e-prescribing platforms should be exempt from prior authorization—similar to what's already done for high-tech diagnostic imaging. The change would reduce administrative costs associated with prescribing medications.

#### **PHYSICIAN ACTION**

In their own practices, with their own patients, physicians also can take steps to combat high drug prices and spending.

**Practice rational prescribing.** According to Baird, physicians make their greatest and most direct contribution toward drug spending reductions when they practice rational prescribing. The most obvious examples of this are prescribing generics when possible and not prescribing antibiotics for viral infections.

Baird also cautions against overprescribing. For example, he says antipsychotics should never be prescribed for straightforward, midlevel depression or insomnia—yet he sees this happen a lot. "It's like using a shotgun to kill a mosquito, and it's a major reason for rising drug spending in nursing homes," Baird says. "These are powerful drugs effective only for serious psychiatric disorders. They're expensive and hard to taper off of."

#### Help patients find assistance.

Physicians who have patients struggling to pay for drugs should refer them to useful information and resources, including the Minnesota Department of Health's Low Cost Options for Prescription Drugs, available at health.state.mn.us/ clearinghouse/prescription.pdf.

Physicians and other clinic staff members can help make sure eligible patients are enrolled in MinnesotaCare or Medical Assistance. Some large health systems also help patients complete forms to apply for drug company patient assistance programs. The forms can be complicated, and they sometimes ask a lot of personal financial questions, but the programs can save patients money, even if only for a few months.

#### **NO SINGLE SOLUTION**

The highly complex challenges posed by rising drug costs must be faced on many fronts. "Nothing we can do in Minnesota totally fixes the problem," says Schondelmeyer. Even at the federal level, from which he believes the most effective solutions must come, "we have no silver bullet to solve it," he concedes. "A machine gun of silver bullets wouldn't solve it."

That may sound daunting, but it shouldn't keep physicians from doing what they can: prescribing generics, practicing evidence-based prescribing, and telling patients that when drug ads come on TV, hit the mute button. MM

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



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Doug McMahon, MD

# Epinephrine entrepreneur

A Minnesota allergist continues his quest to build a better—and cheaper—drug injection device for people with severe food allergies.

#### BY SCOTT A. BRIGGS

ast summer, Doug McMahon, MD, garnered a brief burst of media attention. As public outrage erupted over the soaring price of the EpiPen (from \$100 to \$600 in less than a decade), the owner of Allergy and Asthma Center of Minnesota was featured in local and national news outlets ranging from KARE 11 and City Pages to CNN and Fortune.

Why did reporters flock to McMahon? He's developing an EpiPen alternative called AllergyStop. Like the EpiPen (sold by global pharmaceutical company Mylan), AllergyStop can deliver an emergency injection of epinephrine to someone experiencing a severe allergic reaction. But McMahon aims to make his device more portable and more affordable than the competition.

The Twin Cities allergist's flurry of media appearances subsided in September, but he's continued his entrepreneurial pursuit, hitting new milestones—and obstacles—along the way.

#### FDA reaction

Earlier this year, a pre-investigational new drug meeting with the Food and Drug Administration (FDA) did not go as McMahon had hoped.

"We said, 'These are our plans," McMahon recalls. "They came back and said, 'We strongly urge you against going this route."

The FDA's response stemmed from concerns that an AllergyStop prototype required some assembly before use-a necessity, McMahon explains, to keep the device as small as possible. Long before the EpiPen raised hackles with its high prices, miniaturization was one of McMahon's key goals in designing his product. He's had severe food allergies since childhood, so he's not surprised by studies that indicate fewer than 13 percent of people who are prescribed epinephrine have the drug on hand when they need it. McMahon says the EpiPen's bulk-it's about the size of a jumbo hot dog-discourages many people from taking it along when they leave home.

"The FDA thinks somebody won't be able to put our device together in a time of need," McMahon says. "I can understand that. But you have to look at the bigger picture. EpiPens are too big. People aren't carrying them. Studies show that. So, to make it smaller, it has to be slightly disassembled. My argument is, I'd rather have to take that extra 30 seconds to assemble it than not have the device on me."

#### Time and expenses

The FDA's skepticism was particularly frustrating given how much effort McMahon has already expended on his endeavor. What began as tinkering in a wood shop has evolved into a massive commitment. Boxes of AllergyStop-related materials fill McMahon's home office, where he spends a few hours most nights—and much of his weekend time—working on the project. Recently, he stopped seeing patients on Fridays so he could focus even more energy toward AllergyStop.

meeting stringent

safety standards.

That doesn't

mean AllergyStop

is bound for

shelves soon,

however. Dur-

ing McMahon's

meeting with the

FDA, the agency

insisted on a

lengthier test-

ing period than

the AllergyStop

team proposed.

The FDA called

pharmacy

"It's a lot harder than I was expecting," he admits. "If I was going to be making a new cardiac defibrillator, I can maybe see that being so much effort. But my device is so simple. It's not rocket science."

At least that's how it seemed three years ago, when McMahon created a single AllergyStop device for himself. After attaching it to his keychain—where it remains today—he began to learn what it takes to bring a new pharmaceutical product to market.

"We had to patent it and find companies that could make it, get the epinephrine, and test the devices," he explains. "I had to get people who understand all of this to work with me, and I had to find people to do what's called quality assurance, which is kind of crazy. I have to pay somebody some absurd amount of money to basically follow every step I do and document it. At the end of the day, the FDA is going to want that."

McMahon says the cost of the epinephrine inside each AllergyStop device is about 15 cents. "Yet estimates are 3 million dollars to get this to a place where somebody can use it," he says. "Not to make a lot of them—just to make one device. I carry my device. I know it works. I know it's safe. So 3 million dollars from now, I'm going to be in the exact same place.

"And this is without me even taking a salary," he points out. "I've worked on this for thousands of hours and I haven't taken a dime."

#### **Finding funding**

Several news stories about McMahon highlighted his attempt to raise money for AllergyStop via Indiegogo, a crowdfunding website that helps individuals back business start-ups. The online campaign generated some capital—about \$12,000 from more than 300 contributors—but less than McMahon expected.

"People might have thought, 'He's a doctor, he's got enough money, why doesn't he just do it?" McMahon says. However, once he turned his attention toward more traditional investors, McMahon's day job might have strengthened his pitch. "That 'MD' behind you gives people some confidence," he reports. devices. He chose the local facility after visiting contenders in several states. To pass muster, the company needed capacity to store enough parts and build enough devices to satisfy customer demand, while



The original AllergyStop prototype required some assembly before use, which helped keep it highly portable. Doug McMahon is developing a new version that will be larger but fully assembled.

"Some of the lawyers were shocked at how quickly I got investors on board." McMahon was led to expect a six-month process, but, he says, "It took me, like, a week."

McMahon acknowledges that investors bring expectations of a healthy financial return. But he's confident that those behind AllergyStop share his commitment to a reasonable price tag.

"I've told investors we're going to try to cap it at 50 dollars, no matter what." he says. "I've always stressed I want this in patients' hands. I don't need to be sitting on a yacht drinking piña coladas all day. If we make a profit, great. But getting this out to people is our main goal."

#### Forging ahead

In light of the FDA's qualms about approving a device that requires assembly before delivering its injection, McMahon recently—reluctantly—decided to alter his AllergyStop design and create a larger version that can be sold fully assembled. "I don't love it," he admits, "but it will still be a good product." He hopes that eventually the FDA can be swayed to see the value in his original concept.

Meanwhile, he's found a Minnesota firm he expects will manufacture his

for at least 12 months of studying the epinephrine-filled devices to ensure the drug inside them remains sterile and potent during its projected shelf life. McMahon argues that an abbreviated testing period should suffice, given that other companies developing similar products have already run nearly identical tests.

"I wrote to the FDA and said, 'In the two weeks since you guys denied this, probably seven people have died of an anaphylactic reaction," he says. "Every other day, on average, one person in the United States dies from an anaphylactic reaction."

McMahon now predicts that AllergyStop could become available within 18 months to two years if no new major hurdles arise. Despite the stalls and setbacks so far, he remains motivated by patients who can't pay exorbitant prices for epinephrine—or who laugh when he advises them to carry the EpiPen everywhere they go.

"I have a strong passion for this," he says. MM

Scott A. Briggs is editor of *Minnesota Medicine*.



# The merits of MIIC

Minnesota's immunization information system excels at population health surveillance.

BY ZEKE J. MCKINNEY, MD, MHI, MPH

mmunizations are a critical part of clinical practice for all specialties because children and older adults are more vulnerable to certain diseases; immunizations are required for schools and certain jobs; and acute treatment sometimes requires prophylactic immunization. Prompt access to a patient's immunization record is a necessary element of providing care, to ensure that the right immunization is administered to the right patient at the right time. In addition to improving care quality, administering immunizations accurately helps achieve public health goals. Although public health data collection raises issues of privacy, there are immense benefits to aggregating data at the population level. Minnesota is fortunate to have a cutting-edge immunization information system (IIS) that is improving immunization rates, informing providers about their patients and enhancing data-driven public health surveillance.

#### **MIIC history**

Minnesota's IIS, the Minnesota Immunization Information Connection (MIIC), was created in 2002 by the Minnesota Department of Health (MDH) from a conglomeration of many pre-existing regional registries in Minnesota. The system was established using a freely available IIS software platform developed by the Wisconsin Immunization Registry and currently used by 18 states and municipalities.<sup>1</sup> MIIC earned supplemental funding from the Centers for Disease Control and Prevention (CDC) by being named one of six CDC IIS Sentinel Sites, indicating excellence in data-quality standards and evaluation of population-based data. MIIC is available at no cost to users.

#### A multifunctional tool

MIIC is used both to assist in clinical practice and to conduct epidemiologic surveillance of vaccination rates in Minnesota.

When a patient visits a clinic, the clinic can query MIIC about the patient's immunization history, and MIIC can provide clinical decision support recommendations based on immunization indications for that patient. This functionality is smoothly integrated into electronic health record (EHR) systems. From within a patient's clinical chart, a single click pulls up the MIIC web interface displaying that patient's immunization data.

To date, 4,972 institutions are submitting data to MIIC. Those organizations include clinical health care settings, schoolbased clinics, pharmacies and public health institutions.<sup>2</sup> As a result of this level of engagement by vaccine providers, MIIC contains immunization data for 93 percent of Minnesota residents who are between 4 months and 5 years of age (Figure 1).<sup>3</sup> In all, vaccination information about more than 7 million people resides within MIIC.

Increasing vaccination rates, especially among children, is an ongoing MIIC goal. During infectious disease outbreaks such as a recent measles outbreak in Hennepin County—the system can help direct care for people living in affected areas. Especially when a vaccine for the disease exists, evaluating MIIC data can determine who has and hasn't completed a full series of vaccinations, which helps identify those at risk of contracting the disease.

Epidemiologists and researchers have used MIIC data to evaluate undervaccination and overvaccination rates and to assess the success of immunization-based interventions. Currently, researchers seeking to measure immunization rate changes in certain medically underserved immigrant populations are using MIIC as a validation source. Such investigations are congruous with MIIC's goal of reducing disparities in vaccination rates. At least a dozen publications in the medical literature describe uses of MIIC or present data collected by MIIC.

#### Meeting new demands

As health care transitions from volumebased to value-based delivery, information systems like MIIC can enhance providers' quality of care in several ways.

Reimbursement legislation under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) now includes the Merit-Based Incentive Payment System (MIPS), which includes care-quality improvement measures as well as EHRbased integration incentives and requirements.

Evaluating MIIC data can help health care systems ensure that they deliver appropriate immunizations and submit

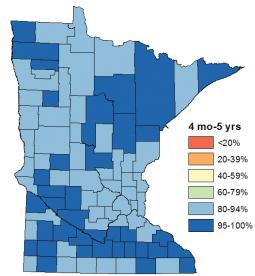


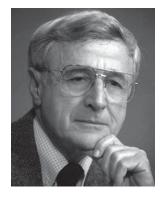
FIGURE 1

By county, percent of children aged 4 months to 5 years who have two or more immunizations recorded in MIIC. (Source: Minnesota Department of Health)

quality-based metrics that comply with evolving reimbursement guidelines included in MACRA (previously included in the Physician Quality Reporting System,



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or PQRS). Meanwhile, integrating MIIC into an EHR is a key way to satisfy health care information technology requirements (formerly known as "meaningful use"). Thus, MIIC is well-aligned with contemporary changes in health care; using it can only benefit a clinical practice's care quality and reporting.

### Maximizing potential while protecting privacy

Privacy is the most contentious point about collecting medical data for use in registries like MIIC. For this reason, a unique health identifier (UHI) does not exist in the U.S. Similarly, because of laws limiting the use of social security numbers (SSNs) as identifiers, MIIC does not collect SSN data. Thus, records are primarily linked based on name and date of birth. Access to data without specific consent is limited, based on a Minnesota statute, to health care providers, insurers, educational institutions and public health entities. Individuals must submit a form to request their own records because there is no reasonable way to provide individual access to data without a unique identifier.

While respecting individual privacy is of utmost importance, this need must be weighed against the risk of limiting the value of public health surveillance systems. Actual risks of allowing public health systems to store UHIs can be minimized with appropriate data governance. The primary benefit of a UHI is the ability it provides to correctly identify an individual's record without needing algorithms to match demographic information such as name and date of birth. Along with allowing individuals access to their own records, a UHI could be used and cross-referenced among all sorts of health care information systems.



From within a patient's clinical chart, a single click pulls up the MIIC web interface displaying that patient's immunization data.

#### The more data, the better

The value of an information source like MIIC can only be fully realized when there is complete or near-complete saturation of captured immunization data—and fully integrated exchange of that data. This would consist of including the state's entire population and all of the state's immunization providers—a difficult goal to achieve based on the limitations of present data collection methods and the separation of present data systems.

For example, MIIC cannot include people who move to Minnesota until they receive immunizations in the state. Likewise, evaluating the proportion of the state's immunization providers submitting data to MIIC is difficult because the precise number of locations providing immunizations in Minnesota is unknown.

Because immunizations pertain to people's health care, as well as to their birth, their travel and their work, further integration of MIIC and other population-health information systems will improve the ability to collect and use immunization-based data.

### Increased use and evaluation leads to improvement

To continue to optimize the benefits gained via MIIC, providers not already participating in the system—including those in smaller clinics and independent health care delivery settings—should start submitting and retrieving data. Working with MIIC will help ensure they provide patients with correct immunizations. Moreover, continued use of MIIC, as evidenced by increasing provider queries over time, will help further efforts to fund and sustain this powerful resource.<sup>2</sup>

At the same time, health informaticists must continue to identify MIIC data coverage gaps and develop means by which these gaps can be closed. Such efforts must include continual evaluation of personal and health care data identifiers, data privacy concerns, new population-based information systems, and methods of integrating disparate datasets regarding population and health. MM

Zeke J. McKinney is a board-certified physician in occupational medicine and in clinical informatics. He is assistant residency director for the HealthPartners Occupational Medicine Residency, works as a clinical investigator at the HealthPartners Institute, and practices clinical occupational and environmental medicine at the HealthPartners clinic in Anoka, Minnesota. He is also a member of the *Minnesota Medicine* advisory committee.

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# The session so far

BY DAN HAUSER

nly a few weeks remain in what has been a frustrating legislative session for physicians (it must conclude by May 22). Here's a rundown of the MMA's priorities.

#### Pass prior authorization reform

For the third session in a row, the MMA's efforts to reform medication prior authorization have been thwarted by political maneuvering. The MMA continues to make progress through the Senate but the House has proven to be quite vexing. Despite revisions to the bill so that there is no state fiscal note tied to it, the House refused to hear it before the committee deadlines.

In March, the chief author of the

House version, Rep. Rod Hamilton (R-Mountain Lake), held a press conference to encourage his colleagues to hear the bill. The effort resulted in the bill being re-referred to a more sympathetic committee where it will get a hearing. Because this happened after the committee deadlines, the stand-alone bill did not move forward.

In early April, the Senate included the measure as an amendment, authored by Sen. Carla Nelson (R-Rochester), in its health and human services budget bill. Whether it survives after it goes into conference committee with representatives from both bodies remains to be seen.

The current version of the bill emphasizes:

- Prohibiting plans from withdrawing coverage for a drug a patient is on during the patient's enrollment year.
- Improving communication during the enrollment process so that enrollees know exactly what medications are covered and what their cost-sharing obligations will be.

• Requiring any formulary change to be communicated to prescribers and enrollees at least 60 days prior to the change.

Gov. Mark Dayton has expressed an interest in supporting the bill, but it certainly isn't one of his top priorities.

#### → Maintain the provider tax repeal

Thanks to a bipartisan 2011 budget agreement between the then-Republican-led Legislature and Gov. Dayton, the 2 percent provider tax is set for repeal on December 31, 2019. The repeal remains on track, but there are plenty of legislators who want to keep the tax as a funding source for health care programs. Meanwhile, in late January, as part of his budget bill, Dayton recommended repealing the repeal.

"I believe it would be a serious mistake to eliminate such an essential source of state funding for health care, just as our citizens' needs are increasing and continued federal support is uncertain," the governor said.

The MMA has fought against the provider tax for more than 20 years. (The MMA sent an Action Alert to physicians on January 25 encouraging them to contact their state representatives and senators to oppose Dayton's provider tax recommendation.)

# → Address the opioid epidemic in Minnesota

Entering the session, many expected the opioid crisis to be a top issue. While it generated a variety of bills, it hasn't gained as much attention as anticipated.

Rep. Dave Baker (R-Willmar) has stood out as the most vocal proponent of legislation to curb the opioid epidemic. He lost a

son to a heroin overdose. Baker's bills sought to require pharmacists to hand out printed materials about the dangers of opioids. He also pushed to limit the doses of opiates dentists and ophthal-

mologists can prescribe, while calling for

mandatory use of the state's Prescription Monitoring Program (PMP).

The MMA supports requiring prescribers to register for the PMP and has been working to encourage physicians to use the tool. While the MMA opposes mandatory use for all opioid prescriptions, it did support a mandate for emergency room and urgent care prescriptions for which there is no exist-

ing physician-patient relationship.

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While the PMP can be a great tool to help prescribers determine whether a patient has been elsewhere to obtain opioids, it's not always the easiest tool to use. The MMA's ultimate goal is to embed the PMP into the patient's medical record to remove the administrative burden of the PMP.

#### → Align quality measures

MMA-crafted legislation to limit the number of state-mandated quality measures for physician practices has made its way through the Senate but has stalled in the House. Chances look good for it to pass because there are no dollars attached to it.

The bill would require the quality measures included in the Statewide Quality Reporting and Measurement System (SQRMS) to align with Medicare's Merit-Based Incentive Payment

System (MIPS) measures. Currently, the state health department contracts with MN Community Measurement to manage specific SQRMS functions, including measure refinement and development; data collection and validation; and data analysis. There are 19

SQRMS measures that apply to physician practices.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) establishes new quality reporting and performance requirements as a condition of Medicare physician payment. Physician practices need to participate in the new payment system via one of two primary paths—MIPS or alternative payment models (APMs). Most physicians are subject to MIPS, which requires most practices to submit data on six quality measures. Practices may select the six they use from 271 MIPS measures.

Only three of the 19 SQRMS measures overlap with the MIPS measures, and even for those, the reporting timelines differ somewhat. The MMA's proposed legislation would limit the number of SQRMS measures to six (for single-specialty practices) or 10 (for multispecialty practices). In addition, all SQRMS measures would need to be selected from the 271 MIPS measures to allow common data collection and measurement across federal and state programs.

#### Other health care issues

#### AGRICULTURAL COOPERATIVE PROGRAM

Farmers and others in the agriculture industry will be able to pool together and purchase health insurance as a group in an effort to lower their costs.

#### FOR-PROFIT HMOS

Minnesota will now allow for-profit HMOs to operate in the state.

#### INTERSTATE MEDICAL LICENSURE COMPACT

Legislation designed to bring Minnesota into federal compliance with its Interstate Medical Licensure Compact law appears headed for passage. The bill is a technical fix to provide the Board of Medical Practice authority to conduct criminal background checks on physicians who choose to seek licensure through the Compact.

#### NARROW NETWORKS

Physicians and other providers now may appeal a waiver of network adequacy requirements granted to a health plan by the health department. Under current law, the health department may grant waivers of network requirements—including access within 30 minutes/30 miles to primary care physicians, a general hospital and mental health services—if the health plan demonstrates with specific data that the network requirements are not feasible in a particular area. Appeals of those waivers will take place before an administrative law judge.

#### PREMIUM RELIEF

The state will provide \$326 million in premium relief to Minnesotans who buy coverage on the individual market in 2017. The relief will come in the form of subsidies to health plans that will retroactively reduce enrollee premiums by approximately 25 percent.

#### PUBLIC OPTION

Gov. Dayton proposed a "public option" for those who buy their health coverage on the individual market. This option would be modeled on the current MinnesotaCare program, which currently provides coverage to Minnesotans earning less than 200 percent of the federal poverty level (FPL).

As proposed, anyone purchasing through MNsure would have an option to purchase MinnesotaCare, regardless of their income. For those with incomes between 200 and 400 percent of the FPL, federal tax credits would be available to subsidize the insurance plan's cost; all others would pay the full premium.

The MMA opposed this proposal because payments to physicians and other providers would be significantly lower than what commercial insurers reimburse, putting clinics at a financial hardship. The likelihood of passage is very low.

#### REINSURANCE

Insurers that offer coverage in the individual market will receive a subsidy for any enrollee who has costs of more than \$50,000 in one year. For costs exceeding \$50,000, the state will cover 80 percent up to \$250,000. Any costs over that amount would be covered by the insurer alone. According to estimates, providing the subsidies will cause premiums in the individual market to be reduced by 20 percent next year. This funding is for 2018 and 2019 only.

#### UNEXPECTED BILLING

For care provided at an in-network facility, patients will not have to pay out-of-network rates when they receive care from a non-network provider without having advance understanding or ability to choose. This is expected to affect specialties such as anesthesia, pathology and radiology if they are not part of a patient's insurance network and are practicing at an in-network hospital or surgery center.

A disclosure provision applies to specimens collected by a physician and referred to an external lab, pathologist or other testing facility. The MMA was concerned that this would hurt physicians' ability to be fairly compensated for their work, so the association lobbied lawmakers to revise the original language. As passed, the bill directs physicians and health plans to negotiate the out-of-network rate. If the parties can't reach an agreement, either side can seek review by an independent arbitrator. Arbitrators will reference a number of sources, including a national database gathered by an independent nonprofit that tracks all payers to determine a usual, customary and reasonable payment for physicians.

# **News Briefs**

#### Governor appoints four MMA members to BMP

Gov. Mark Dayton announced three new physician appointments and one reappointment to the state Board of Medical Practice (BMP) in March. All four physicians are MMA members.

- **Christopher Burkle**, MD, is an anesthesiologist at Mayo Clinic. His term runs through January 4, 2021.
- **Kathryn Lombardo**, MD, is a psychiatrist and the president of Olmsted Medical Center. She is also an AMA alternate delegate for the MMA. Her BMP term runs through January 1, 2018.
- William Parham III, MD, is an internist at Abbott Northwestern Hospital. His term runs through January 4, 2021.
- **Maria Statton**, MD, is a family practice physician for Sanford Health. She has been reappointed to the BMP through January 4, 2021.



#### Top court rules on "informal conference" statute

In February, the Minnesota Supreme Court voided a Court of Appeals ruling in Howard v. Svoboda, a case dealing with the "informal conference" statute that allows medical malpractice defense attorneys to speak with a plaintiff's treating physician without taking a deposition.

The issue began when the District Court agreed with the plaintiff/patient (Howard) to severely limit the scope of informal conferences and ordered the defense (Dr. Svoboda) not to ask questions about the opinions of the treating physician. The defense appealed that order. The Court of Appeals considered the issue and reversed the District Court decision, holding that the informal conference statute permits defense attorneys to ask about any information or opinions the treating physician provides.

The plaintiff appealed the Court of Appeals ruling to the Minnesota Supreme Court, which ruled on a mostly technical aspect of the case, deciding that the Court of Appeals lacked jurisdiction to reverse the original District Court decision. In doing so, the Supreme Court did not rule on the case's main issues, which were: 1) what can be said during "informal discussions"; and 2) whether the District Court has discretion to impose additional limits on "informal discussions."

The MMA filed an amicus in the case because informal conferences—without restrictions—are a helpful, physician-friendly and cost-containing tool in medical malpractice defense. Conferences take place unrecorded and are not admissible in subsequent litigation. Defense attorneys are given an early opportunity to gather facts about the treatment provided and to assess the adequacy of the treatment at issue. This helps separate out the cases that should be settled from those that should be defended.

The original malpractice case is currently under appeal by the plaintiff.



#### New opioid lectures now available online

Four more lectures in the Pain, Opioids and Addiction series are now available online at mnmed.org/painseries. The free lectures include: "What Is Addiction?"; "Drugs of Abuse From A to Z"; "Opioid Antagonists"; and "Communicating With Chronic Pain Patients." The series is a collaboration of the MMA, the Steve Rummler Hope Foundation and the University of Minnesota Medical School. CME and MOC are available.

#### On the calendar

Event	Date	Location
Physicians' Social – Twin Cities	May 23	Lake Monster Brewing Company, St. Paul
Physicians' Social – Rochester	May 24	Bleu Duck Kitchen
Physicians' Social – St. Cloud area	June 1	Urban Lodge Brewery & Restaurant, Sauk Rapids
Physicians' Social – Duluth area	June 7	The Boat Club Restaurant & Bar at Fitger's
Annual Conference	Sept. 23	Rochester – Mayo Civic Center

#### MMA settles lawsuit with Constellation/MMIC

Constellation Inc. (and its subsidiary, MMIC) and the MMA announced in March the successful resolution of a dispute concerning a trademark licensing agreement between the parties. Terms of the resolution were not disclosed.

With the resolution, Constellation and MMA expressed appreciation for the contributions each has made over the many years of their working relationship, along with a commitment to continue their efforts independently to advance patient safety improvements and the practice of good medicine.

Minneapolis-based Constellation is a holding company of policy holder-owned insurers and other organizations providing medical liability insurance and services that support physicians and other health care providers. Through partnership offering



Robert Meiches, MD



Juliana Milhofer



Dave Renner



Elizabeth Anderson

### **MMA** in action

MMA President **David Agerter**, MD, presented an award at the University of Minnesota Medical School's Dean's Tribute to Excellence in Education event on May 3. He was joined by MMA CEO **Robert Meiches**, MD, and **Juliana Milhofer**, MMA policy analyst.

**Dave Renner**, MMA director of state and federal legislation, presented twice at the Minnesota Academy of Family Physicians (MAFP) Spring Refresher in April. One presentation covered the MAFP's legislative priorities and the other dealt with fostering legislative leaders among family physicians.

MMA Chair **Douglas Wood**, MD, President-Elect **George Schoephoerster**, MD, trustee **Marilyn Peitso**, MD, Meiches and **Elizabeth Anderson**, the MMA's new membership manager, visited with leadership at CentraCare in St. Cloud in early April.

Meiches and **Janet Silversmith**, MMA director of health policy, met in early April with **Dan Trajano**, MD, senior medical director for the STARS and Risk Adjustment Center of Excellence at Blue Cross and Blue Shield of Minnesota, to discuss gaps in diagnostic coding in the state.

Silversmith also presented at the Mankato Clinic's board retreat in late April on legislative issues, MACRA and quality measurement.

#### THE PHYSICIAN ADVOCATE MMA NEWS

solutions that help providers deliver better quality patient care, a better patient experience and lower costs of care, Constellation, founded in 2012, is a leader in health care provider support and risk solutions.



#### Nominations are open for MMA officials

The nominating process will remain open for MMA presidentelect, trustees, and AMA delegates and alternate delegates through May 19. Five trustees will be elected this year:

- One must be from the North Central Trustee District (threeyear term).
- One must be a resident/fellow (three-year term).
- One must be a medical student (two-year term).
- The other two trustee positions may reside anywhere in Minnesota (three-year terms).

The nominating committee will be instructed to focus on nonprimary care specialty physicians, as the current board is underrepresented in this category.

Two AMA delegates and two AMA alternate delegates will be elected this year to three-year terms.

Please send any nominations you have for president-elect, trustees, or AMA delegates or alternate delegates to Shari Nelson (snelson@mnmed.org) by May 18.

The nominating committee will meet later in May to recommend a slate of candidates for each position. The member-wide election will begin in August and close 30 days later. Election results will be announced as soon as possible. New leadership will assume their roles following the Annual Conference in September.



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MMA Foundation thanks the Otto Bremer Trust, the Saint Paul Foundation, and the F.R. Bigelow Foundation for their generous support. VIEWPOINT

# A concerted effort

n early March I testified before the Senate Health and Human Services Finance and Policy Committee in St. Paul on behalf of the MMA's efforts to reform medication prior authorization legislation. Having practiced medicine for more than 30 years, I've experienced a wide range of experiences, but none quite like going before a group of lawmakers. I have to admit that it's a bit intimidating sitting there in front of a group of somber elected officials. But I believe in the cause.

Every legislative session, the MMA is lucky to have a group of dedicated physicians and physicians-in-training willing to go before legislators to fight on behalf of all Minnesota doctors, their patients and their practices. It's a crucial role. Legislators want to hear from the people who are on the front line providing health care in the state.

As MMA president, such work comes with the territory. But there are others who deserve recognition for moving our priorities forward.

People like **Macaran Baird**, MD, a professor and head of the University of Minnesota Department of Family Medicine and Community Health, who has been at the Capitol on behalf of the U's medical school testifying in support of residency funding.

Or **Jeremy Springer**, MD, a family physician who directs the U's Methodist Hospital Family Medicine Residency and serves as medical director of the Park Nicollet continuing medical education department. He testified for the MMA on a bill establishing a preceptor tax credit.

Or **David Thorson**, MD, a family physician and MMA immediate past president, who testified for our association on a bill that called for mandating the use of the Minnesota Prescription Monitoring Program. Thorson worked with MMA staff and Rep. Dave Baker (R-Willmar) to help assess what a reasonable mandate might look like.

Physicians-in-training are helping out, too. This session, **Lauren Williams**, MD, a University of Minnesota resident, testified in support of physician training.

These are just a few examples of physicians and physicians-in-training who have testified on behalf of the MMA over the years. Their efforts really do make a difference.

Meanwhile, our professional peers' civic participation isn't limited to time spent addressing legislative committees. Throughout Minnesota, many physicians serve as state senators, mayors, school board members, city council members and county commissioners.

In addition, many MMA members participate in our annual Day at the Capitol. This year's event turned out to be the largest in recent memory. When physicians sit down with their elected officials to talk health care, you can believe it has a significant impact.

We've also had tremendous participation in our Action Alerts this session. We've asked members to write to lawmakers about medication prior authorization, the provider tax and health care reform. The response has been fantastic.

Keep up the good work. Together, we can influence change at the Capitol and in Washington.



David Agerter, MD MMA President

When physicians sit down with their elected officials to talk health care, you can believe it has a significant impact.

# The changing landscape of drug abuse

What's new? What can we do?

#### BY CAROL FALKOWSKI

Editor's note: *This is the first of four articles in this issue, spanning pages 30-39, that address topics related to drug abuse and addiction.* 

very corner of the country is touched by drug abuse and addiction—Minnesota is no exception. Drug-induced deaths have tripled since 1990 and now outnumber fatalities from motor vehicle accidents. Deaths from opioid overdoses in particular have skyrocketed; they now outnumber cocaine and methamphetamine overdose deaths, combined.

### Opioid epidemic stems from several sources

The opioid epidemic is fueled by nonmedical use of prescription opioids and a record-high supply of high-purity, lowcost heroin. These substances have high liability for abuse, addiction and overdose. They produce pain relief, euphoria, respiratory depression, mental clouding, physical tolerance and dependence. As a result, addiction, hospitalizations, overdoses and funerals are enveloping communities and families like a dense fog—one that seemingly won't lift.

Compounding the problem are counterfeit pills. Sold on the black market, these "knock-offs" are clandestinely produced with inconsistent ingredients of varied sometimes lethal—potency. These products are not made in controlled laboratory settings. Their manufacture includes no quality control. The pills look exactly like their legitimately prescribed counterparts, but often, even the people selling them have no specific information about their composition.

In recent years, one mystery ingredient has become increasingly prevalent. To-

day's counterfeit opioid pills often include highly potent synthetic fentanyl manufactured in China. The powerful drug is responsible for clusters of overdoses and deaths that have occurred throughout the U.S. Last year in Minnesota, the drug was implicated in the death of the musician Prince. Synthetic fentanyl also has appeared in powdered form in street drugs such as heroin and cocaine.

### Methamphetamine makes a comeback

The numbers of known methamphetamine labs—and rates of methamphetamine abuse—significantly declined after passage of a 2005 federal law restricting retail sales of over-the-counter products containing pseudoephedrine. But in recent years, Mexican-produced methamphetamine has flooded the market, and law enforcement seizures of the drug now surpass previous peak levels reached in 2005. Last year, more than 11,000 methamphetamineaddicted patients received addiction treatment services in Minnesota, a record-high number reflecting a 72 percent increase over the total for 2005.

Meanwhile, sales of other imported synthetic chemical compounds persist in spite of federal and state bans. Such substances include products marketed as bath salts, research chemicals or synthetic THC.

#### Marijuana's popularity grows

The emerging hazardous drug-abuse patterns we see today occur against a backdrop of ever-popular—and increasingly acceptable—marijuana use. According to a 2016 Gallup poll, 60 percent of Americans favor the drug's legalization. In 1969, just 12 percent of the population expressed such approval. Currently, more adolescents smoke marijuana than smoke cigarettes. According to the National Survey on Drug Use and Health conducted by the Substance Abuse and Mental Health Services Administration, more than 111 million Americans have used marijuana at least once during their lifetime; 22 million are current users (i.e., they used it during the past month); and 8 million are daily users. In 2014, an estimated 4.2 million people aged 12 or older had had a marijuana-use disorder during the past year.

Today, 29 states and Washington, D.C., Guam and Puerto Rico have comprehensive medical marijuana programs, according to the National Conference of State Legislatures. In addition, 21 states and Washington, D.C., have decriminalized small amounts of marijuana, and eight states and Washington, D.C., have legalized adult recreational use of the drug. Voters in Colorado and Washington started this movement in 2012, followed by citizens of Oregon, Alaska and Washington, D.C., two years later. In November 2016, California, Maine, Massachusetts and Nevada were added to the list.

In spite of these largely voter-initiated, state-level changes, marijuana remains a Schedule I drug under the Federal Controlled Substances Act of 1970, a designation reaffirmed in 2016. Voters, not scientists or medical practitioners, have determined medical practice and implemented systems that successfully circumvent both the usual FDA-driven drug approval process and federal law. Promarijuana advocates are well-organized, and entrepreneurs within the burgeoning marijuana industry have prospered despite numerous obstacles.

# Abuse and addiction require a multifaceted response

So where does this leave us?

Historically, addressing a drug abuse epidemic has relied upon three prongs: prevention, law enforcement and treatment.

Effective prevention boils down to consistent messages delivered by different messengers: families, schools and communities. Yet too often, these messengers fall short of exercising their greatest potential influence. Parents, uncertain how to broach the topic, often say nothing at all. To many adolescents, this silence is perceived as implicit approval. Schools cover the topic of drugs in class, but often leave discussions beyond that up to their students' parents. Communities can be reluctant to step up and actively address drug abuse problems due to fear of being labeled a drug abuse epicenter.

Law enforcement curtails the supply of illegal drugs. Prescription monitoring programs curtail "doctor shopping"—patients obtaining the same prescriptions from multiple providers.

Treatment for substance use disorders, sometimes including medications, helps many addicts modify their attitudes and behaviors, develop responses to life stressors that do not involve substance abuse, and adopt healthier life skills.

#### Medicine must broaden its role

When it comes to addressing the opioid crisis, however, our efforts need to extend beyond traditional tactics. We must examine the practice of medicine—and acknowledge that our prescribing practices aren't all that require scrutiny and improvement.

Medical education, for example, must expand beyond the immediately obvious topics of pain management tools and new opioid prescribing guidelines. Long-standing inadequacies in medical training about addiction must be remedied. Current and future medical practitioners need comprehensive, formal training about addiction that is on par with training they receive about other chronic diseases. When doctors are not adequately educated, addiction frequently goes unnoticed, undiagnosed and untreated.

Practitioners must learn how to initiate conversations with patients about highrisk drinking and drug use behaviors that, left unchecked, can progress to addiction or produce other adverse effects. And screening for addiction must be integrated within primary care settings in the same manner that routine screening is used

#### Online resources for medical professionals

- National Institute on Drug Abuse
   NIDAMED: Medical & Health Professionals
   drugabuse.gov/nidamedmedical-health-professionals
- National Institute on Alcohol Abuse and Alcoholism Helping Patients Who Drink Too Much: A Clinician's Guide niaaa.nih.gov/guide
- Substance Abuse and Mental Health Services Administration

SBIRT: Screening, Brief Intervention, and Referral to Treatment integration.samhsa.gov/ clinical-practice/SBIRT

to identify other chronic diseases with behavioral components, such as diabetes, hypertension and asthma. Screening, Brief Intervention and Referral to Treatment (SBIRT) is an evidence-based practice used to identify, prevent and reduce problematic use of—and dependence on—alcohol and illicit drugs.

To help patients access effective treatment, doctors must maintain an up-todate knowledge base about the range and efficacy of various addiction treatment options. It is still true today that most addiction goes untreated, and very few referrals to treatment come from medical practitioners.

Medication-assisted treatments for opioid addiction include use of methadone (Dolophine, Methadose), buprenorphine (Suboxone, Subutex, Probuphine) and naltrexone (Vivitrol). The FDA has approved two prescription medications for nicotine addiction: bupropion (Zyban) and varenicline (Chantix). Three medications are FDA-approved for treating alcohol addiction: naltrexone, acamprosate (Campral) and disulfiram (Antabuse). Yet some doctors are unaware of these options, and many addiction treatment providers remain reluctant to use them.

#### Action is overdue

For decades epidemiologists have sounded alarms about the changing nature and extent of substance abuse and addiction. Yet concerted improvements have been slow to materialize within homes, schools, communities, legislative chambers and doctors' offices.

When it comes to marijuana, many consider its use "no big deal," and state and federal laws collide on an ongoing basis. Concerning opioids, some policymakers are so befuddled they take little action at all, while parents cling to the notion that it can't happen in their family until it does. As for addiction treatment, models based on ideology, not science, abound, and many providers routinely fail to use effective medications. When pursuing pain management, many doctors still struggle to find viable options to help long-term opioid patients for whom functionality has steeply declined.

The bottom line? Problems surrounding drug abuse are serious, complicated and widespread. And the more we proceed with business as usual, the more the body counts will continue to rise. There are small steps people on many fronts can take today to contribute to more effective solutions.

What are we waiting for? MM

Carol Falkowski is CEO of Drug Abuse Dialogues, former director of the Alcohol and Drug Abuse Division of the Minnesota Department of Human Services, and former director of research communications at Hazelden Betty Ford Foundation. For 30 years she has represented the Twin Cities in a nationwide drug abuse epidemiology network of the National Institute on Drug Abuse. She also is the author of the reference book *Dangerous Drugs*.

# **Tackling addiction in primary care**

In the exam room, providers can identify—and often treat—patients who need help with a substance use disorder.

#### BY BRIAN GRAHAN, MD, PHD

Editor's note: This is the second of four articles in this issue, spanning pages 30-39, that address topics related to drug abuse and addiction. Following this commentary, in the Clinical and Health Affairs section, Gavin Bart (Dr. Grahan's colleague and director of the Hennepin County Medical Center Division of Addiction Medicine) provides further details—and data—about treating substance use disorders in a primary-care setting.

pioids seem to be everywhere—in the streets; in the news; and in disturbing, tragic statistics. Yet despite much public discussion about an opioid epidemic, many physicians are uncertain about whether—or how—to change their practice in response.

Opioid use disorder (OUD) is often colloquially described as "opioid addiction." Addiction is a disease that has long plagued our patients, friends and colleagues. Therefore, many providers may feel as if they'll know it when they see it. They might picture past patients who frequented emergency departments or hospitals with bouts of alcohol withdrawal. Or they may recall others who came in asking for Dilaudid because they purportedly had allergies to morphine and codeine.

Such patients likely had a severe use disorder. But physicians' memories of those past circumstances can lead to cognitive bias and missed diagnoses in the present. Many people who suffer from OUD (or any use disorder, really) have a moderate form of the condition that is responsive to treatment in the primary care setting. Yet many of those patients pass through our doors undetected.

#### Short screenings

To better identify substance use disorders (SUDs) in patients, screening tools are often promoted. Some can be challenging to use in primary care due to the time they require or the difficulty of incorporating them into an electronic medical record. But among the more feasible options, providers can choose the Tobacco, Alcohol, Prescription Medication, and Other Substance Use (TAPS) tool<sup>1</sup>—an effective screening tool for the electronic health record—or a brief two-item screener,<sup>2</sup> which lends itself to brief recall.

The two-item screener asks, "How many days in the past 12 months have you used drugs other than alcohol?" A response of seven or more days meets that criterion. The second question is, "How many days in the past 12 months have you used drugs more than you meant to?" A response of two or more days is a positive result. Of course, with screening tools a positive result leads to more follow-up questions and a potential need to treat. That can prompt frustration among providers. ("More time? I'm not trained for this! Aaaargh!") However, as with any procedure in medicine, if we provide potentially risky therapy, it's imperative that we know how to manage complications that might arise.

True, the diagnostic criteria for an SUD can be daunting. Few providers can remember all 11 SUD criteria in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), let alone ask about all of them during a visit. But while assessment of all criteria provides the most complete picture of diagnostic severity, a few of those criteria carry the most meaning. For example especially among patients on chronic opioids—endorsements of compulsive use and social consequences ("taking larger

#### FIGURE 1

#### DSM-5 opioid use disorder diagnostic criteria

CATEGORY	CRITERIA
Compulsive use (impaired control)	*Use in larger amounts or longer periods than intended. *Unable to cut down or control use. *Excessive time spent to obtain, use or recover. *Craving or preoccupation.
Social consequences (dysregulated reward salience)	*Failure to fulfill major role obligations (work, home, school). *Persistent or recurrent use-related social or interpersonal problems. *Important social, occupational or recreational activities given up.
Risky use	*Recurrent physical hazardous use. *Use despite persistent physical or mental harm from drug.
Physical dependence (N/A for patients prescribed opioids for 6 or more weeks)	*Tolerance. *Withdrawal.

amounts than expected" and "giving up activities") are far more indicative of a use disorder (i.e., addiction) than are tolerance or withdrawal.<sup>3</sup>

Moreover, the 11 SUD criteria can be lumped into four easier-to-remember categories: compulsive use (impaired control), social consequences, risky use and physical dependence (Figure 1). Asking a general question or two about each of these categories can often lead to a diagnosis, since a simple count of criteria provides the best assessment of the severity of the disorder. A moderate use disorder is defined by meeting four to five criteria; a severe disorder is suggested when a patient endorses six or more criteria.

#### Management with medication

Critical to office-based management of OUD is opioid agonist therapy (i.e., buprenorphine). Antagonist therapy (i.e., naltrexone) also has a role. Without medication therapy, more than 80 percent of people with a moderate to severe use disorder relapse to problematic opioid use.<sup>4-6</sup>

Appropriately dosed buprenorphine simply helps patients feel normal; they do not get high. Indeed, almost all illicitly used buprenorphine is taken to stave off withdrawal symptoms rather than to get intoxicated.

It's ironic that we can prescribe opioids for any indication aside from a use disorder without a specific certification, but to address the problems opioids can create, we're required to acquire a special waiver from the Drug Enforcement Administration. To obtain that waiver and prescribe buprenorphine (or a buprenorphine/ naloxone combination product) for OUD, physicians must complete eight hours of training. For physician assistants and nurse practitioners, the requirement is 24 hours. Training is offered free of charge by Providers' Clinical Support System for Medication Assisted Treatment (PCSS-MAT) through online courses and live sessions in many states, including Minnesota. (For details, see pcssmat.org.)

#### **Group effort**

It's critical that the entire clinical team not just the provider—commits to the management of OUDs. The most important components to have in place for bolstering physician efforts are administrative support (including staff who assist with prior authorizations and feel comfortable fielding patient questions); behavioral health support; and waivered colleagues who can cover absences and discuss challenging patients.<sup>7</sup>

For many patients, no specialty addiction treatment is necessary beyond agonist therapy and brief counseling in clinic.<sup>8,9</sup> Those are the people who benefit most when primary care providers screen for and manage—OUDs. Undoubtedly, some patients will need more support, and they should be referred to an addiction specialist or a local rehabilitation program. But many people don't seek treatment because they assume that a rehabilitation program would be required when, in fact, primary care-based treatment could achieve similar outcomes.

As you figure out how to manage patients who struggle with an OUD, find additional colleagues who are like-minded in their desire to help. Support groups promote change—even among providers! In addition to resources in your local community, mentors available through the Minnesota Chapter of the American Society of Addiction Medicine are accessible online through PCSS-MAT. And soon, forums offering provider-to-provider teleconsultation support will be available through Project ECHO, a collaborative medical education system.

Many people struggle emotionally when they feel they've lost control over their drug use. Often, with support from staff and colleagues, primary care providers have the capacity to treat OUDs in clinic. Screening patients during visits can start a process that provides hope—and in some cases, saves lives. MM

Brian Grahan is an internist in the Division of Addiction Medicine at Hennepin County Medical Center and an assistant professor of medicine at the University of Minnesota.

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# Addressing the opioid epidemic in general medical settings

As awareness of the opioid epidemic in this country has grown, so has the number of efforts to respond to it. This article reviews national and state efforts involving the medical community. It also reports on new funding coming to Minnesota with passage of the 21st Century Cures Act, and it calls for increased involvement at the health system level. The hope is that with greater awareness of these efforts, health care providers will be better equipped to address the full spectrum of the epidemic.

#### BY GAVIN BART, MD, PHD, FACP, DFASAM

Editor's note: *This is the third of four articles in this issue, spanning pages 30-39, that address topics related to drug abuse and addiction.* 

t seems that hardly a day goes by that we do not hear about America's opioid epidemic. News media carry regular reports, law enforcement engages in public education campaigns, celebrities die from opioid overdoses, and our friends, families and patients all seem to know someone affected by an opioid use disorder (OUD), ie, addiction.

Nationally, prescriptions for opioids increased 8% between 2002 and 2014, with higher rates in specialties such as internal medicine and family medicine.<sup>1</sup> While Appalachia and New Hampshire have been particularly affected by the opioid epidemic, Minnesota has also seen an increase in opioid-related problems. Between 2009 and 2014, Minnesota had a 21% increase in opioid-related inpatient hospitalizations and an 83% increase in opioid-related emergency department visits.<sup>2</sup> Overdose deaths in Minnesota during the beginning of 2017 appear to be outpacing those of 2016, with the rise of illicit fentanyl as a leading contributor.<sup>3</sup>

During a time of great division—Republican versus Democrat; urban versus rural; the 1% versus everyone else—dismay over the opioid epidemic appears to be a unifying force. As a result, several parallel processes and initiatives are in place to address opioid use in the United States. A few are described below. The challenge will be to make sure that these processes do not remain siloed, so providers and health systems can address the full spectrum of the epidemic with efforts that range from prevention of opioid misuse to treatment of OUDs.

#### **Reducing risk**

As it is for most epidemics, prevention is the most potent intervention. Reducing the number of people exposed to opioids will result in fewer opioid-associated risks, including adverse events, opioid misuse, overdose and incident OUDs. Unfortunately, we do not have strong predictors for who is at risk for these outcomes, and known associated factors may differ among the various risks being evaluated.

Recent associative data in an outpatient setting have found that approximately 6% of those receiving an initial opioid prescription of at least 1 day's length will continue to be on opioids 1 year later. Following this initial prescription, the median time to stopping opioids is 7 days, but factors increasing the probability that opioid use will extend beyond 1 year include initial prescription length for more than 10 days, receiving more than 2 opioid prescriptions, and a cumulative dose of more than 700 morphine milligram equivalents (MME).<sup>4</sup> Additionally, opioid-related deaths are associated with daily opioid doses greater than 100 MME, coingestion of benzodiazepines, and several other factors, such as mental health and chronic disease diagnoses.<sup>5</sup> At this point in time, however, there is inadequate evidence to tell us whether modifying these factors (for example, by preventing patients from exceeding a daily dose >100 MME or by

lowering the dose for those already on doses >100 MME) will result in reduced morbidity and mortality.

In Minnesota, the Institute for Clinical Systems Improvement (ICSI) has published a guideline on the management of both acute and chronic pain.<sup>6</sup> In order to provide evidence-based management of pain and to reduce potential risks of opioids, the guideline emphasizes nonopioid approaches to pain management, multimodal pain treatment and, when opioids are deemed necessary, shortterm prescriptions (lasting <1 week) for acute pain, ongoing risk assessments, and daily doses of <100 MME for patients in chronic pain (<50 MME for those with known substance use disorders and other risk factors).

At a national level, the Centers for Disease Control and Prevention (CDC) has published a guideline on prescribing opioids for chronic pain that makes 12 key recommendations in areas related to determining whether-and how-to prescribe opioids and to assessing the risks and harms of opioids. (See the report and associated clinical tools at cdc. gov/drugoverdose/prescribing/resources. html.) Key recommendations include shifting goal-setting from a pain outcome (eg, pain rating score) to a functional outcome; interdisciplinary care with emphasis on nonopioid pain management for chronic pain; using the lowest possible opioid dose and re-evaluating the patient when daily doses >50 MME are reached; regular queries of prescription drug monitoring programs (PDMPs); avoidance of co-prescribed opioids and benzodiazepines; and access to medication-assisted treatment for those identified as having an OUD. Meanwhile, the surgeon general has issued Facing Addiction in America, the nation's first such report on alcohol, drugs and health, which, like the CDC guideline, calls for providers to screen for and diagnose OUDs in order to decrease opioidrelated morbidity and mortality.7

While use of PDMP data to inform prescribing is prudent and can result in reductions of opioids in the community, we have little data to show that PDMPs actually reduce opioid-associated adverse events. Some people may assume that identifying a person who has multiple providers prescribing opioids (ie, the "shopper") will lower morbidity and mortality, but it is likely that shopping is merely an indicator of other problems, such as substance use disorder, mental health disorder and chronic illness, and that once these factors are controlled for, we will find there is no difference in overdose risk between opioid shoppers and those who receive opioids from a single provider. Thus, there are likely some limitations to the scope of the impact PDMPs will have on adverse outcomes such as overdose.

To reduce the risk of opioid overdose, naloxone is increasingly being recommended as a co-prescription for those on opioids. Naloxone, an opioid antagonist, can reverse the effects of opioids and the respiratory suppression that results in death. Providers are allowed to prescribe naloxone to patients, and lay people are allowed to use it in the setting of overdose. Sufficient data support the lay public being able to use naloxone effectively with minimal training (eg, a brochure or brief internet video). Communities adopting overdose education and naloxone distribution programs have seen a nearly 50% reduction in overdose deaths.8 Coprescribing naloxone to patients receiving opioids has been associated with reduced emergency department utilization.9 Most commercial- and government-funded insurers in Minnesota cover the cost of naloxone. Providers, pharmacists and health systems can learn more about naloxone prescribing and dispensing at prescribetoprevent.org.

#### Treatment

While the ICSI and CDC guidelines, participation in PDMPs, and naloxone distribution may reduce the amount of opioids in the community and provide tools for overdose prevention, none specifically addresses OUDs. To do this, we must first identify those who may have OUDs. Implementing and institutionalizing OUD screening procedures within health systems through validated screening instruments is key. We must shift away from unvalidated, intermittently used drug-use assessments that are buried within the social history section of the medical record. Integrating results from validated screening tools into patient flow sheets allows for longitudinal tracking and brings results of screening to the provider's attention. While several screening tools are available, the Tobacco, Alcohol, Prescription Medication, and Other Substance Use (TAPS) is a brief tool that has been validated in general medical settings.<sup>10</sup> While the TAPS's sensitivity in identifying prescription opioid use risk is not ideal, the tool has a good positive diagnostic likelihood ratio. In busy clinical settings, it is brief and can help stratify patients into low-risk versus moderate-to-high-risk for OUD. Other online screening tools are also available. (See drugabuse.gov/nidamed and assistportal.com.au.) Once an OUD is identified, treatment should be offered or a referral for treatment should be made.

The National Institutes of Health National Institute on Drug Abuse (NIDA) has devoted hundreds of millions of dollars to better understanding the science of OUD and its treatment. The good news is that of all addictions out there (eg, nicotine, alcohol and methamphetamine), we have the most successful treatments for OUD. Our ability to successfully treat OUD is on par with our ability to successfully treat hypertension, diabetes and major depressive disorder. The bad news is that fewer than 75% of those with OUD receive any form of treatment and, of those who do, few receive treatment with the most effective evidence-based interventions. Evidence-based guidelines are available, however, and multiple studies demonstrate effectiveness of treating OUD in general medical settings.<sup>11,12</sup> This later point is critical because very few patients with undiagnosed or untreated OUD see an addiction specialist, yet most do see a primary care provider. Hence, it is incumbent that the general medical setting be

the key locus in identifying and treating OUD.

When treatment for OUD is provided, it is very effective. OUD treatment medications such as methadone, buprenorphine and extended-release naltrexone reduce mortality, hospital and emergency department utilization, spread of HIV and viral hepatitis, and overall health care costs when compared to no treatment or treatment that does not entail the use of medication.<sup>13</sup> Short-term provision of medication may result in short-lived improvements, but once medication is discontinued, whether after less than 30 days or after more than 6 months, most patients will return to opioid use and are subject to increased odds of death.<sup>14</sup>

Therefore, chronic medication management is generally recommended for all patients (including adolescents and pregnant patients) with a moderate to severe OUD. Just as some patients on antihypertensives have intermittently high blood pressures and should not be considered treatment failures requiring discontinuation of their antihypertensive, patients receiving an OUD treatment medication may have an intermittent opioid positive drug test, but the overall treatment effect is positive and these patients should continue their medication with additional adjustments in care, as indicated.

Discussion of the pharmacology, risks and benefits of FDA-approved medication to treat OUD is beyond the scope of this article, and information is available elsewhere.<sup>13</sup> In brief, methadone is highly effective but can be provided only in specialized treatment settings. There may be patients for whom these settings are most appropriate; yet many patients can be managed in general medical settings using buprenorphine or extended-release naltrexone. Buprenorphine is a Schedule III medication that requires a specific prescriber waiver to use. (Physicians require 8 hours of CME training, which is accessible

online.) Recently, the Substance Abuse and Mental Health Services Administration extended waiver options to advanced practice providers who have completed 24 hours of CME training. However, there remain restrictions on the total number of patients to whom a provider may prescribe buprenorphine. (See www.samhsa. gov/medication-assisted-treatment.) Extended-release naltrexone is intramuscularly administered every 28 days and can be prescribed by any provider, although its use requires lead-in abstinence from opioids. Results to date are not as good as those seen with methadone and buprenorphine, yet it may be a good option for those not wanting these medications and for those for which medication adherence is a concern.

#### Federal funding

To help reduce the enormous treatment gap for those with OUD, in November 2016 the U.S. Congress passed the 21st Century Cures Act, which includes \$495 million dedicated to addressing the opioid epidemic. At least 80% of those funds must be spent on improving access to treatment for OUDs. Minnesota anticipates receiving two installments of \$5.3 million each from the 21st Century Cures monies, and the Minnesota Department of Human Services has established priorities for how this funding should be spent. These priorities include easing access to treatment for patients with OUD, integrating OUD treatment into general medical settings, increasing the number of providers who have received waivers to prescribe buprenorphine, and increasing availability of naloxone for overdose reversal.

Projects being planned as a result of the 21st Century Cures money coming to Minnesota include statewide teleconferencing and multidisciplinary case presentations through a teleconference learning collaboratory available to all health systems in the state. Also being planned are collaborative care models of providing a continuum of stepped care, which community providers treating OUD can access when patient need exceeds provider resources and an interdisciplinary addiction and metal health team is needed before returning the patient back to the community provider. Other approaches to addressing OUD through the 21st Century Cures money will be announced later in 2017.

The Minneapolis Medical Research Foundation is home to the NorthStar node of the National Institute on Drug Abuse Clinical Trials Network (CTN). The goal of the CTN is to test addiction treatment and prevention strategies in real-world clinic settings. A project for which the NorthStar node is taking the lead is the development and testing of a clinical decision support tool for OUD. Once developed, this tool, integrated into any electronic medical record, will guide providers through the OUD screening process and show them how to perform risk assessments, engage in shared decision-making regarding treatment of OUD, and begin treatment for OUD. HealthPartners is a national leader in the development of clinical decision support tools and is actively engaged in this project.

#### Health systems involvement

Finally, it is worth addressing the need for health systems-level interventions. Provider education and increasing the number of providers with buprenorphine waivers can do only so much, and unless clinical workflows and reimbursement structures support providers in addressing OUD, the treatment gap will remain. Hopefully, increased teleconferencing and the development of the clinical decision support tool will help at the provider level. But steps such as institutional commitments to adopt and support implementation of practice guidelines (such as those developed by ICSI and CDC) are required.

The Minnesota Hospital Association has committed to addressing opioidrelated practices. To that end, substancerelated quality measures exist, and hospitals throughout Minnesota should be encouraged to adopt them. For example, the Joint Commission Substance Use Measure 3 (SUM-3) assesses the proportion of patients that receive a prescription at hospital discharge for a medication used to treat an alcohol or drug use disorder or who have received a referral for addiction treatment. Commitment to adopting this measure likely would result in increased OUD screening and provision of OUD treatment while bringing downstream improvements in mortality, healthcare utilization and overall costs.

#### Conclusion

In conclusion, addressing the opioid epidemic in the health system requires a multipronged approach. While safer prescribing and reducing the overall amount of opioids in the community are key, we must also improve efforts to identify those with OUDs and ultimately integrate their treatment into the general medical setting. MM

Gavin Bart is director of the Division of Addiction Medicine at Hennepin County Medical Center and an associate professor of medicine at the University of Minnesota.

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# Substance abuse and insomnia

Insomnia is a common complaint among people with substance use disorders. The relationship between sleep problems and substance abuse is bidirectional: People who have trouble sleeping may medicate with alcohol or illicit drugs or misuse prescription medications. And taking certain substances can interfere with sleep. This article reviews that relationship and presents information about the two evidence-based treatments for insomnia: prescription sleep medications and cognitive behavioral therapy for insomnia. Clinicians treating people with a substance use disorder or insomnia should be aware of the risks of comorbidity, and they should understand the risks and benefits of treatment for the insomnia.

#### BY MARK ROSENBLUM, PSYD, LP, CBSM

Editor's note: *This is the fourth of four articles in this issue, spanning pages 30-39, that address topics related to drug abuse and addiction.* 

Substance abuse is an ongoing and serious public health concern, as evidenced by the current opioid epidemic. For example, in the U.S., heroin overdoses tripled from 2010 to 2015,<sup>1</sup> and in 2014, there were 28,000 deaths from heroin overdose.<sup>2</sup>

Efforts to curb substance abuse include focusing on areas of health care that may reduce the spread of illicit drug use, drug abuse and misuse of prescription medications. Treatment of sleep disturbances is one such area worthy of attention.

Sleep disturbances are common in alcohol and drug users and appear to play an etiological role in substance abuse.<sup>3</sup> In one study, nearly 70% of patients entering treatment for detoxification complained of sleep disturbances at admission.<sup>4</sup> Alcohol and illicit drugs are being used to selfmedicate insomnia symptoms,<sup>3</sup> untreated insomnia has been linked to increased relapse rates for those in recovery from alcohol and drug dependency,<sup>5</sup> and prescription sleep medications carry risks for abuse and dependency themselves.<sup>6</sup>

Abuse of illicit drugs and alcohol, as well as misuse of prescription drugs, have been linked to a variety of sleep disorders, including restless legs syndrome,<sup>7</sup> sleepdisordered breathing,<sup>8</sup> narcolepsy<sup>9</sup> and circadian rhythm sleep disorders.<sup>10</sup> While all of these disorders merit attention, this article focuses on the most common sleep disturbance, insomnia.<sup>11</sup>

#### What is insomnia?

Insomnia involves difficulties with falling or remaining asleep or waking up too early in the morning. It can be a symptom or a condition. Up to half of the population experiences insomnia symptoms periodically, and estimates of people experiencing chronic insomnia during their lifetime range from 5% to 10% of the population.<sup>12-14</sup>

Untreated, insomnia increases risks for medical conditions (eg, heart disease, high blood pressure and diabetes), psychiatric conditions (eg, depression and anxiety), daily functioning disturbances (eg, motor vehicle accidents and diminished work productivity), and alcohol and drug use and abuse. People more susceptible to developing insomnia include women, the elderly, and those with medical and psychiatric conditions.<sup>14</sup>

# Connections between substance abuse and insomnia

Insomnia and substance abuse interrelate in a variety of ways. For instance, alcohol consumption is among the most common strategies people use to manage insomnia symptoms.<sup>15</sup> This is despite the fact that insomnia is both a common complaint among those dependent on alcohol and a risk factor for relapse among individuals in recovery from alcohol dependence.<sup>16</sup> Likewise, marijuana is also used as a sleep aid, even though insomnia is a common complaint found in chronic marijuana users and a risk factor for relapsing among those in recovery from marijuana dependence.<sup>17</sup> Insomnia is also a common complaint for cocaine users and can be present for up to three weeks after chronic cocaine users have been abstinent.<sup>18</sup> Cocaine is seen as a cause for what some term "occult insomnia," which is "degraded sleep accompanied by deteriorated cognitive functioning without the sensation of lack of sleep."19 Insomnia has also been found in opioid users while they go through methadone detoxification, as well as during the early part of abstinence.20

#### Insomnia treatments

There are two evidence-based insomnia treatments: 1) prescription sleep medications (PSMs) and 2) cognitive behavioral therapy for insomnia (CBT-I). PSM and CBT-I have similar success rates, though they differ in their advantages and disadvantages.<sup>15</sup>

PSMs have been available for years and their use is growing. According to the Centers for Disease Control and Prevention, the number of prescriptions written for sleep aids in the U.S. tripled from 1998 to 2006.<sup>21</sup>

Among the most well-known PSMs today are the nonbenzodiazepine "Zdrugs," which include zolpidem, zopiclone and zaleplon.<sup>21</sup> The primary advantages of PSMs include their availability, their ease of use and the public's awareness of them as a treatment option. At the same time, they are associated with potential health risks including misuse, abuse and dependency.<sup>22</sup> In 2010, the Drug Abuse Warning Network (DAWN) found that there were 20,793 emergency room visits in the U.S. linked to zolpidem use, and overmedication was the cause of these visits in 33% of cases.<sup>23,24</sup> It is also important to note that although the current generation of PSMs may not be as physiologically addictive as their predecessors,<sup>22</sup> there are still risks for psychological dependence.<sup>25</sup>

CBT-I is an effective and safe technique for treating chronic insomnia.<sup>26</sup> It consists of multiple components including sleep restriction, stimulus control, cognitive reframing, sleep hygiene, paradoxical intention, relaxation training and mindfulnessbased therapy.<sup>16, 26</sup> CBT-I conceptualizes insomnia as a condition and addresses the underlying behavioral and psychological causes of it. This is one reason that gains from CBT-I tend to be durable.<sup>26</sup> In fact, the American College of Physicians released guidelines in 2016 recommending that adults with chronic insomnia first attempt CBT-I and then consider PSM if the CBT-I is not effective.<sup>26</sup> The stability of the improvements from CBT-I was one of the reasons behind this guideline.

The primary challenges of CBT-I include difficulty finding providers, improvements that are not immediate, and limited public awareness of it as a treatment option.

#### Conclusion

The opioid epidemic has heightened awareness within the health care community of the health risks associated with drug use. Insomnia and the treatment of insomnia appear to be factors that can affect use and abuse of substances, including opioids. Given the bidirectional relationship between substance abuse and insomnia, it is recommended that insomnia screenings in medical settings include questions that attempt to capture this potentially problematic comorbidity. Questions should gauge 1) whether alcohol or illicit drugs are ever used to treat insomnia, 2) whether illicit drugs are ever used to manage fatigue secondary to nighttime insomnia and 3) whether the patient shows signs of developing a tolerance or dependency to their PSM.

Ultimately, it is advised that physicians should base their treatment decisions on risk-benefit analyses personalized to the needs of each patient. Such analyses should consider both the advantages and disadvantages of available treatment options, including the risks for substance abuse and dependency. MM

Mark Rosenblum, PsyD, LP, CBSM, is the director of the Minnesota Sleep Institute Insomnia Program and the sleep psychologist for Northstar Sleep Center. He provides CBT-I to adolescents and young adults suffering from substance abuse and dependency. Dr. Rosenblum is also the owner and moderator of The Online Insomnia Center at sleeppsychologist.com. He can be reached at doc@sleeppsychologist.com.

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# Tularemia in Minnesota: an emerging and underappreciated infection

BY TORY WHITTEN, MPH, JENNA BJORK, DVM, MPH, DAVE NEITZEL, MS, KIRK SMITH, DVM, PHD, MPH, MAUREEN SULLIVAN, MPH, AND JONI SCHEFTEL, DVM, MPH

Tularemia is a rare but often serious infectious disease caused by *Francisella tularensis*, a bacterium with an extremely low infectious dose and the ability to cause illness through several routes including arthropod bites, contact with infected animals and exposure to contaminated water, food or soil. Tularemia is found throughout the northern hemisphere, and cases have occurred in all U.S. states except Hawaii. Thirteen cases have been reported to the Minnesota Department of Health since 1994, including 3 in 2016. This article presents the 2016 cases as well as data on all the reported cases. Clinicians should consider tularemia in patients with a compatible clinical illness and exposure history, particularly those who present with acute fever and regional lymphadenopathy. Treatment should be initiated early in highly suspect cases, without waiting for laboratory results.

ularemia is a rare but often serious infectious disease that can be fatal if not treated promptly and appropriately. Milder forms of illness can lead to underrecognition and underreporting of cases.<sup>1</sup> The infection is caused by *Francisella tularensis*, a bacterium with an extremely low infectious dose and the ability to cause illness through several routes, including arthropod bites (particularly from ticks and deer flies), contact with infected animals and exposure to contaminated water, food or soil.<sup>2,3</sup>

The severity of the disease is dependent on the virulence of the associated strain (ie, type A or type B), infectious dose and route of exposure.

There are 6 main clinical forms of the disease, and all include fever. Typhoidal tularemia is characterized by nondescript symptoms including an abrupt onset of fever, headache, malaise and body aches, without any localizing symptoms. Ulceroglandular (cutaneous ulcer with regional lymphadenopathy) and glandular (lymphadenopathy) tularemia typically result after percutaneous inoculation. Pneumonic tularemia can result after an inhalational exposure and also if other forms of tularemia are left untreated. Oropharyngeal (sore throat, oral ulcers, tonsillitis and regional lymphadenopathy) tularemia can result after ingestion of contaminated food or water. And oculoglandular (ocular irritation and inflammation with lymphadenopathy) tularemia can occur if the bacteria enter the eye.<sup>4</sup> The incubation period in humans ranges from 2 to 14 days,

but people generally become ill 3 to 5 days after exposure.

Tularemia is found throughout the northern hemisphere, and cases have occurred in all U.S. states except Hawaii.4 Nationally, the disease is relatively uncommon, with sporadic cases and outbreaks occurring most commonly from May through September.<sup>4</sup> From 2001 through 2010, a total of 1,208 cases (median, 126.5 cases per year) were reported in the U.S., with highest incidence among children ages 5 to 9 years and men >55 years.<sup>4</sup> Six states accounted for 59% of reported cases: Missouri, Arkansas, Oklahoma, Massachusetts, South Dakota and Kansas.<sup>4</sup> The geographical foci may be due to reporting patterns, human behavior such as small game hunting, distribution of arthropod

#### FIGURE 1

#### Human tularemia cases reported to the Minnesota Department of Health by month of illness onset

1994-2016 (n=13)

MONTH OF ILLNESS ONSET	NUMBER OF CASES
JANUARY	NONE
FEBRUARY	NONE
MARCH	<b>Å</b>
APRIL	NONE
MAY	<b>Å</b> Å
JUNE	<b>*</b> * <b>*</b>
JULY	Ť
AUGUST	<b>'n</b> ŕ
SEPTEMBER	Ť
OCTOBER	<b>Å</b> Å
NOVEMBER	NONE
DECEMBER	NONE

vectors (notably *Dermacentor variabilis*, the American dog tick, and *Amblyomma americanum*, the lone star tick), and local ecology in reservoir hosts. While the epidemiology of tularemia is complex and not fully understood, risk factors likely include exposure to arthropods, fresh water activities, hunting and trapping small game animals such as rabbits, gardening and landscaping, and occupational, recreational and residential exposures to potentially infected animals experienced by veterinary staff, wildlife handlers and pet owners.

#### Tularemia in Minnesota

From 1994 through 2016 (the period for which detailed information about cases is available), 13 confirmed cases of tularemia were reported to the Minnesota Department of Health (MDH) (Table 1). Most of the cases have been identified since 2008. Ten (77%) cases were male, and the median age for all cases was 48 years (range, 2 to 87 years). Illness onset ranged from March through October (Figure 1). The majority of cases had the ulceroglandular form of the disease (n=9, 69%), followed by the typhoidal (n=2, 15%) and glandular (n=1, 8%) forms and 1 (8%) unknown form. Patients reported fever (9/11, 82%) with a median high temperature of 103° F (range, 102° F to 104° F); lymphadenopathy (9/11, 82%) of the inguinal (n=4), axillary (n=3), cervical and occipital (n=1), and hyaline (n=1) lymph nodes; skin lesions or ulcerations (10/13, 77%); chills (7/10, 70%); weakness (6/10, 60%); myalgia (5/9, 56%); headache (4/9, 44%); sweats (4/10, 40%); weight loss (3/9, 33%); arthralgia (2/7, 29%); cough (1/11, 9%); and vomiting (1/11, 9%). Ten (77%) cases were diagnosed by culture from ulcer or wound (n=7), blood (n=2), or lymph node (n=1); 3 cases (23%) were diagnosed by a documented increase in serum antibodies to F. tularensis. Tularemia subtype was determined for 8 (80%) of those with positive cultures; 7 (88%) cases were type B and 1 (12%) was type A.

Eleven patients had documented treatment for tularemia: Oral antibiotics [doxycycline (n=3), ciprofloxacin (n=1), doxycycline and ciprofloxacin dual therapy (n=2), and ciprofloxacin changed to doxycycline (n=1)] were used to treat 7 (64%) cases; oral ciprofloxacin was initiated in 1 (9%) case and changed to intravenous (IV) gentamicin after development of a rash; 2 (18%) cases were started on IV gentamicin and transitioned to oral ciprofloxacin or doxycycline; and 1 (9%) case was treated with gentamicin alone. Nine (69%) patients were hospitalized, for a median duration of 6 days (range, 1 to 10 days); all cases with a documented outcome survived (n=10). The route of exposure was vectorborne (n=7, 54%), followed by waterborne (n=2, 16%), inoculation by a contaminated wood sliver (n=2, 16%), zoonotic (n=1, 8%) and unidentified (n=1, 8%) (Table 1).

In all 3 cases reported in 2016, tularemia was not initially considered as a diagnosis by the health care provider. These cases highlight the complex pathophysiology and epidemiology of tularemia.

#### Case 1

On May 26, 2016, a 5-year-old boy had onset of headache, bilateral eye pain and fever. He was seen that evening at urgent care, where he was noted to have a fever of 103° F and he tested negative for Group A *Streptococcus*. He was sent home with recommendation to follow up if there was no improvement. The patient's mother noted that earlier that day, she found a nonengorged tick (unknown species) embedded in the skin behind the boy's right ear; she removed the tick with a tweezers.

On May 27, the boy developed pain at the site of the tick bite, dizziness, and malaise. He was seen at his primary care provider on May 28; a second rapid strep test was negative, and amoxicillin was prescribed for an undiagnosed infection. Over the next few days, the boy developed increased pain, swelling and ulceration at the bite site. His temperatures decreased, but the patient continued to have lowgrade fevers in the evenings. The patient was seen again by his primary care provider on June 1 after inadequate response to amoxicillin; the antibiotic was changed to trimethoprim/sulfamethoxazole.

At this time the parents proposed the possibility of tularemia after researching tickborne diseases on the internet. The boy was referred to a pediatric infectious disease specialist who saw him the next day and agreed the clinical presentation fit tularemia. Acute serology for *F. tularensis* antibodies was ordered, and the patient was admitted to the hospital for empiric ulceroglandular tularemia treatment. The patient completed 3 days of intravenous

TABLE 1

YEAR	TULAREMIA SUBTYPE	AGE (YEARS)	SEX	CLINICAL FORM	COUNTY OF RESIDENCE	COUNTY/STATE OF EXPOSURE*	ONSET DATE	MOST LIKELY EXPOSURE ROUTE
1994	Unknown	48	М	Ulceroglandular	St Louis	St Louis	5/27/1994	Inoculation - wood sliver
1997	Unknown	42	Μ	Unknown	Houston	South Dakota	6/1997	Vectorborne - tick
2000	Unknown	52	М	Ulceroglandular	Clay	Ottertail	6/12/2000	Vectorborne - biting fly
2003	Туре В	72	F	Ulceroglandular	Hennepin	Cass	9/9/2003	Inoculation - wood sliver
2008	Туре В	2	М	Ulceroglandular	Stearns	Stearns	7/18/2008	Vectorborne - biting fly
2008	Unknown †	40	М	Glandular	Hennepin	Hennepin	10/9/2008	Zoonotic - feline⁵
2009	Type A	45	М	Ulceroglandular	Sherburne	South Dakota	8/22/2009	Vectorborne - tick
2012	Туре В	86	М	Typhoidal	ltasca	ltasca	3/1/2012	Vectorborne - tick
2012	Туре В	61	F	Ulceroglandular	Hubbard	Hubbard	8/1/2012	Waterborne
2012	Туре В	87	М	Typhoidal	Chisago	Chisago	10/25/2012	Unidentified
2016	Unknown	5	М	Ulceroglandular	Hennepin	Hennepin	5/26/2016	Vectorborne - tick
2016	Туре В	67	F	Ulceroglandular	Sherburne	South Dakota	6/21/2016	Waterborne
2016	Type B	8	М	Ulceroglandular	St Louis	Itasca	8/3/2016	Vectorborne - biting fly

# Summary of human tularemia cases reported to the Minnesota Department of Health 1994-2016 (n=13)

\*Most likely county/state of exposure

† Not diagnosed by culture; however, associated cat was confirmed with Type A tularemia

gentamicin and was discharged with oral doxycycline, which was later changed to oral ciprofloxacin after the patient developed a rash while on doxycycline. Oral therapy continued through June 14.

Antibodies to *F. tularensis* were not detected in the acute serum specimen (immunoglobulin (Ig) M=8 U/mL, IgG= 1 U/mL). Convalescent serum was collected on July 6 and demonstrated a significant increase in *F. tularensis* antibodies (IgM= 43 U/mL, IgG= 19 U/mL), confirming the diagnosis of tularemia. No additional antibiotic therapy was indicated and the boy made a full recovery.

#### Case 2

On June 18, 2016, a 67-year-old female was fishing on a freshwater lake in northeastern South Dakota. While removing a hook from a fish, the hook penetrated the pulp of the patient's left middle finger. On June 21, she developed pain and swelling at the site of the puncture. She was seen at an urgent care center where she received an injection of ceftriaxone and was prescribed oral cephalexin. The pain and swelling did not improve, and she was seen by her primary care provider the next day.

Because of concern for a joint infection, the patient was referred to an orthopedic specialist, who saw her on June 23, at which time an enlarged, tender left axillary lymph node was noted. The orthopedist drained the finger wound, collected a swab of cloudy, nonpurulent fluid for culture, and changed the patient's antibiotic to ciprofloxacin. On June 27, the MDH Public Health Laboratory was notified by the sentinel laboratory that the culture could not be ruled out as *F. tularensis*. The MDH Public Health Lab confirmed *F. tularensis* type B on June 28.

After confirming a diagnosis of tularemia, the patient was seen again by the orthopedist. By this time, the patient had developed an eschar-like ulcer. An infectious disease consultation was obtained, ciprofloxacin was discontinued, and a 4-week treatment course of doxycycline was initiated. By July 8, the lymphadenopathy had resolved and the ulcerated wound was improving.<sup>6</sup>

#### Case 3

During July 22-24, 2016, an 8-year-old boy was camping with his family in a state park in northern Minnesota. On July 25, the boy's parents noticed an insect bite, likely acquired while camping, on his right lower leg. The bite was consistent with a deer fly bite, and deer flies were noted to be prevalent at the beach where the boy swam. On August 3, the boy developed fever with leg and groin pain. On August 4, he was seen in the emergency department where a palpable lump in the right inguinal area was noted. An ultrasound showed an enlarged inguinal lymph node. An accompanying assessment documented an inguinal hernia and undescended testicle as well.

The patient was transferred to a pediatric hospital for right orchioplexy and right inguinal node excision. Pathologic sections of the lymph node showed a necrotizing lymphadenitis, and subsequent tissue culture grew Gram negative coccobacilli that could not be ruled out as *F. tularensis*. The MDH Public Health Lab confirmed *F. tularensis* type B on August 8. After confirming a diagnosis of tularemia, an infectious disease consult was obtained. The patient was readmitted to the hospital for 5 days of IV gentamicin and discharged home with 5 additional days of oral ciprofloxacin.

The boy's symptoms resolved after the lymph node excision, and he remained asymptomatic.

#### Implications for clinicians

In the past, tularemia was commonly known as rabbit fever and associated with rural areas because hunters and trappers were

primarily at risk through contact with infected rabbits. However, in the latter half of the twentieth century, the disease became less common as human behavior, land use and human-animal interactions evolved. In Minnesota, human and animal cases have been reported from suburban as well as rural areas. Animal cases can serve as sentinels for human risk; in 2016, 14 cases in cats and rabbits were identified, many from southern Twin Cities suburbs.

Clinicians should consider tularemia in patients with a compatible clinical illness

and exposure history, particularly those who present with acute fever and regional lymphadenopathy.

Diagnosis of tularemia typically involves culture of the organism from affected tissues (e.g., wound exudate or lymph node tissue) or paired acute and convalescent serology. Laboratories should be alerted to the suspicion of tularemia prior to submission so appropriate precautions can be taken to avoid occupational laboratory exposure to *Francisella* bacteria.

Treatment should be initiated early in highly suspect cases, without waiting for laboratory results. Antibiotics effective against tularemia include gentamicin, streptomycin, doxycycline and ciprofloxacin. Doxycycline has been associated with a higher relapse rate and should be given for at least 14 days.<sup>7</sup> Ciprofloxacin is an alternative oral agent and has been used successfully to treat patients with tularemia but is not approved by the Food and Drug Administration for this indication.<sup>7</sup> Depending on the clinical illness and type of antibiotic used, duration of antibiotic treatment is typically 10-21 days.<sup>7,8</sup> The prognosis is generally good for patients treated in a timely and appropriate manner, although symptoms may not completely resolve for several weeks.

Prevention of tularemia is multifaceted, as the disease can involve several different routes of transmission. When possible, avoid contact with wild animals such as rabbits, squirrels and other rodents; gloves should be worn when picking up dead animals. Also, care should be taken to avoid mowing over dead animals and rabbit nesting areas when landscaping. For pet owners, cats should be kept indoors to decrease hunting of rabbits and other wildlife. For outdoor enthusiasts who spend time in wooded or grassy habitats, precautions should be followed to prevent tick and deer fly bites (eg, use insect repellent containing 20-30% DEET or 0.5% permethrin).

#### Conclusion

Although tularemia remains a rare disease in Minnesota, clinicians should be aware of it and consider it in patients with a compatible clinical illness and exposure history, particularly those who present with acute fever and regional lymphadenopathy. MM

To discuss a suspected case of tularemia with an MDH epidemiologist, call 651-201-5414.

For more information on tularemia and how to report cases to the MDH, visit the following websites:

#### health.state.mn.us/divs/idepc/ diseases/tularemia cdc.gov/tularemia

Tory Whitten, Jenna Bjork, Dave Neitzel, Kirk Smith and Joni Scheftel are part of the Foodborne, Waterborne, Vectorborne and Zoonotic Diseases Section at the Minnesota Department of Health. Maureen Sullivan is part of the Public Health Laboratory Division.

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# **From the Island to Medical School**

BY KIRSTEN LARSON, MS3, UNIVERSITY OF MINNESOTA MEDICAL SCHOOL

Sometimes I think back to my island life before medical school those mornings I woke up to the sunrise over the West Indie Sea those afternoons I spent running around banana fields and climbing palm trees for coconuts those nights I spent snorkeling among coral and diving for sand dollars

Sometimes I think about the moment I was accepted to medical school suddenly the black sand beaches seemed unimportant suddenly playing soccer with a papaya seemed immature suddenly gazing at the stars from a sailboat seemed like a waste of time

Sometimes I think about my island life while I am in the lecture hall When we learn about HIV, I am with Laura as her mother dies from this disease When we learn about starvation, I am with those children trying to convince tourists to give up their sweets When we learn about tropical disease, I am with Lea as she stumbles through a soccer game with chikungunya virus

Sometimes I am distracted from medical school when tragedy strikes my island When a tropical storm destroyed the people, I couldn't listen to my renal physiology lectures When a bus carrying kids on their way home from school drove off the cliff, I couldn't culture cells for my research When a ledge of the volcano tumbled down upon the village below, I couldn't focus on my pleural cavity dissection

Sometimes I realize that the island is impacting how I practice medicine I am calm with patients because the island taught me the importance of peace I listen to my colleagues because the island taught me the importance of collaboration I have faith that my patients can get well because the island taught me the importance of hope

Sometimes I think back to my island life



Kirsten Larson is in the class of 2018 at the University of Minnesota Medical School. For a year before starting medical school, she lived on

the island of St. Vincent in the West Indies.

#### ABOUT THIS PIECE

"I was inspired to write this poem after a patient told me that I had healed her pneumonia by listening to her stories. This patient interaction caused me to reflect on the impact that my experiences on the island have had on me as a medical student."

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