THE JOURNAL OF THE MINNESOTA MEDICAL ASSOCIATION

MINNESOTA MEDICINE

AUGUST 2014

How 10 High Achievers DO IT

CLINICS SHARE THEIR *Quality-Improvement* STRATEGIES

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Minnesota Medical Association

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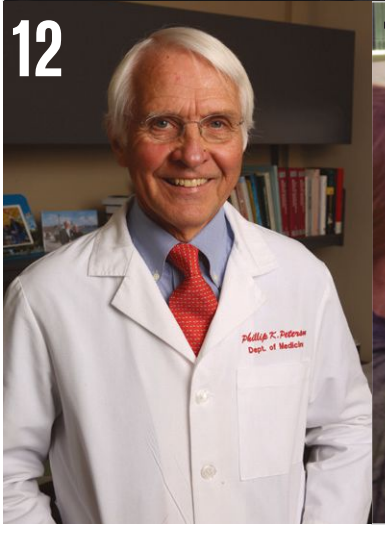

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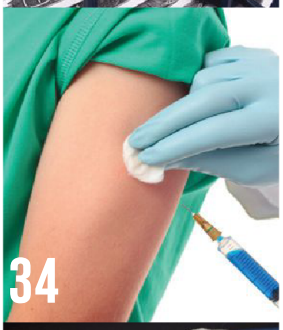

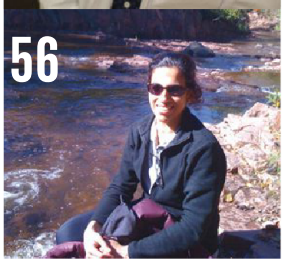

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PHOTO BY SCOTT WALKER

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

Under surveillance

At every step of our career, the quality of our work has been watched and judged.

I'm being watched. I know it sounds a little paranoid, but I'm sure of it. In fact, I'm sure all physicians are being watched. Now that I think of it, we've been watched for most of our careers.

It started in medical school, as our attendings oversaw our patient workups on the wards. As residents, our senior residents and attending physicians monitored our care of patients, keeping us on a variable-length leash and doling out our autonomy in careful measure, hoping we wouldn't kill somebody in the process of learning. Once in practice (in the old days), the watchers were the Board of Medical Practice (BMP) and the quality committees at the hospitals where we worked, who looked for patient-endangering missteps. At every step of our career, the quality of our work has been watched and frequently judged. But now doctor-watching has been refined to a science, and the judgments of the watchers are beginning to hit doctors' pocketbooks. Talk about a reason to feel paranoid!

It is not just life-threatening, never-happen events that get noticed these days. Patients' and fellow providers' allegations about bad outcomes or dangerous practices—sentinel events that may point to a more general pattern of poor quality practice—now trigger BMP or hospital quality committee interest. Implicit in their investigations is the threat of disciplinary action or, at least, a mandate for education. In addition, a physician has a quality profile that is a pastiche of measurements of how we handle our patients and their medical problems. We're tracked on hemoglobin A1Cs to indicate how we manage patients with diabetes, blood pressure readings to see if we're controlling hypertension, statin use to tell if we're working to prevent vascular disease and, most recently, patient satisfaction to see how our patients grade our practice habits. I've even had a "shadow" at work, critiquing my interaction with patients. Getting holiday food baskets from patients is no longer an indication that a physician is doing a good job. If it's not measurable, it doesn't count.

MN Community Measurement, insurance companies, self-insured employers and provider organizations all want to know what kind of a job we're doing. That's been true for years, but with the advent of pay-for-quality insurance plans, the feedback now has monetary teeth.

One reaction to the current quality movement has been physician groups organizing their own watching committees. Peer review is an ancient, revered concept; but practicing physicians are now devising innovative variations that adapt to the way we practice in 2014 and monitor physicians "in house."

Over the years, physicians have sometimes bristled at all this watching, saying "leave me alone, so I can practice medicine." Shouldn't passing the gauntlet of medical training be proof enough that you know what you're doing? It isn't. We physicians are entrusted with people's lives, and we should be held accountable. With aging physician brains, the petrifaction of ritual and the relentless march of medical science, an M.D. degree and board certification are no guarantee that your quality will remain perpetually high.

So I'll try to restrain my paranoia, smile at my shadow and realize that all those people watching me have my and my patients' interests at heart.

Charles Meyer can be reached at meyer073@umn.edu.

The faces of expertise

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SPEAKING of SAFETY

Mastering medical terminology used to mean learning Latin roots and the prefixes and suffixes to go with them so you could describe parts of the body. Today, the medical lexicon includes a whole new vocabulary related to patient safety. If you're not yet fluent, here are a few key terms and their definitions.

ADVERSE EVENT: Any injury caused by medical care. Identifying something as an adverse event does not imply error, negligence or poor quality.

BLUNT END/SHARP END: The sharp end refers to the personnel or parts of the health care system in direct contact with patients. The blunt end is the many layers of the health care system not in direct contact with patients (those setting policy, managing institutions, and designing devices). For example, an error programming an intravenous pump would represent a problem at the sharp end, while the institution's decision to use multiple types of infusion pumps (making programming errors more likely) would represent a problem at the blunt end.

ERROR: An act of commission (doing something wrong) or omission (failing to do the right thing) that leads to an undesirable outcome or the potential for such an outcome.

FIVE RIGHTS: Administering the Right Medication, in the Right Dose, at the Right Time, by the Right Route, to the Right Patient.

JUST CULTURE: An organizational culture in which frontline personnel feel comfortable disclosing errors—including their own—while maintaining professional accountability. In a just culture, it is recognized that competent professionals make mistakes but there is zero tolerance for reckless behavior.

MEDICATION ERROR: Any preventable event that may cause or lead to unintended and incorrect medication use or patient harm while the medication is in the control of the health care professional or patient.

MISTAKE: A failure that requires conscious thought, analysis and planning. Mistakes typically involve insufficient knowledge, failure to correctly interpret available information, or application of the wrong rule (for example, choosing the wrong diagnostic test or ordering a suboptimal medication for a given condition).

NEAR MISS: An event or situation that did not result in patient injury, but only because of chance (for example, a patient with penicillin allergy receives penicillin but has no reaction or a nurse happens to realize that a physician wrote an order in the wrong patient's chart).

NEVER EVENTS: Adverse events that are unambiguous, serious, preventable and usually devastating to patients.

RED RULES: Simple and easy-to-remember rules that must be followed to the letter. Any deviation from a red rule will bring work to a halt until compliance is achieved. An example is "No hospitalized patient can undergo any test or procedure if they are not wearing an identification bracelet."

ROOT-CAUSE ANALYSIS: A structured process for identifying the cause of or contributing factors underlying adverse events.

SAFETY CULTURE: A commitment to safety that permeates all levels of an organization.

SENTINEL EVENT: An adverse event in which death or serious harm to a patient occurs (for example, an operation on the wrong patient or body part).

SLIP: A failure resulting from a lapse in concentration.

SWISS CHEESE: A model illustrating the idea that the ideal health care system has multiple layers of defense against failure. The system is like a stack of Swiss cheese slices; the holes represent spots where a process can fail. In a well-designed system, the holes are not aligned. If a problem passes through a hole in one layer, it is caught in the next. **MM**

Sources: Institute for Healthcare Improvement (www.ihi.org/education/ihiopenschool/resources/Pages/Tools/QualityImprovementAndPatientSafetyGlossary.aspx), Agency for Healthcare Research and Quality's Patient Safety Network (http://psnet.ahrq.gov/glossary.aspx)

ADVERSE EVENT REPORTING IN MINNESOTA

For the last decade, Minnesota law has required hospitals and outpatient surgery centers to report adverse events to the Minnesota Department of Health. Information about the events is submitted to a registry maintained by the Minnesota Hospital Association. The time, location and injury, and the root-cause analysis and corrective action plan must be reported. There are 29 reportable events in these categories: surgical, product or device, patient protection, care management, environmental and criminal.

In 2013, 258 adverse events were reported. Pressure ulcers (95) and falls (81) were the ones most commonly cited. Of the 99 incidents that led to serious disability or death, 81 were falls.

Last year, the Department of Health surveyed all hospitals and licensed surgery centers about their experience with the reporting system. They asked respondents to list suggestions for ways the Department of Health, Minnesota Hospital Association and Stratis Health could help them improve patient safety. Among the most frequent responses: "Provide assistance developing physician/surgeon champions to build support for safety initiatives."

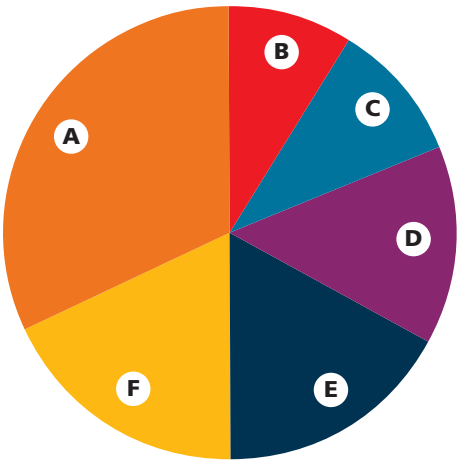
To see the 2014 report, go to www.health.state.mn.us/patientsafety/ae/2014ahereport.pdf.

ADVERSE EVENTS *by* CATEGORY, 2013

Source: Minnesota Department of Health

ROOT CAUSES *by* CATEGORY, 2013

When an adverse event occurs, facilities are required to examine the factors and circumstances that led to it and report their findings to the Minnesota Department of Health.



- **A RULES/POLICIES/PROCEDURES** (32%)
- **B HUMAN FACTORS** (9%)
- **C PHYSICAL ENVIRONMENT AND PRODUCTS/EQUIPMENT** (10%)
- **D TRAINING/EDUCATION** (14%)
- **E COMMUNICATION/INFORMATION** (17%)
- **F NO ROOT CAUSE** (18%)

Source: Minnesota Department of Health

Measured to the max

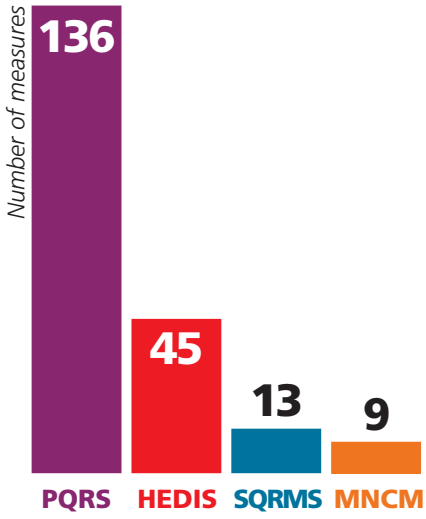
Hospitals, clinics, physicians and health plans all are being evaluated on what they do and how well they do it. Although payers (insurers and the federal and state governments) drive many of the efforts to quantify quality, employers and health care provider organizations are interested in the numbers as well. Physicians are at the heart of all the measurement activity, as they are the ones who submit the data that is ultimately used for these assessments.

Here's a look at the measurement in Minnesota.

Special thanks to Barbara Daiker, Ph.D., R.N., MMA manager of quality, who compiled the data.

Multiple measures

Physicians in Minnesota provide data for these efforts



PHYSICIAN QUALITY REPORTING SYSTEM (PQRS). The Center for Medicare and Medicaid Services' pay-for-reporting program that gives eligible professionals who treat Medicare patients incentives if they report on quality measures. Beginning in 2015, the program will adjust payments to those who opt not to report.

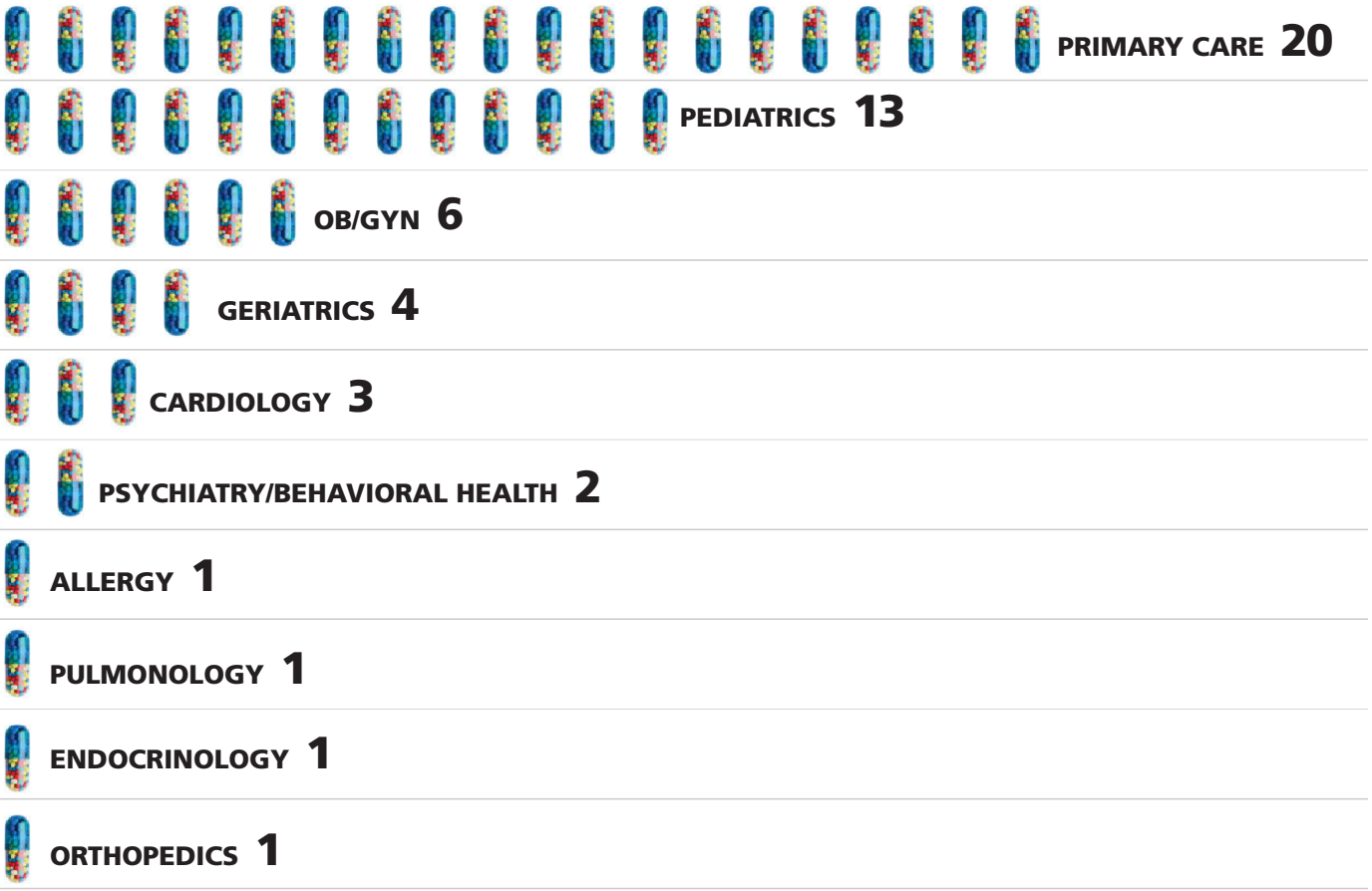
HEALTHCARE EFFECTIVENESS DATA AND INFORMATION SET (HEDIS). The National Committee for Quality Assurance's set of measures used for assessing health plan quality. HEDIS uses claims data from physicians' offices.

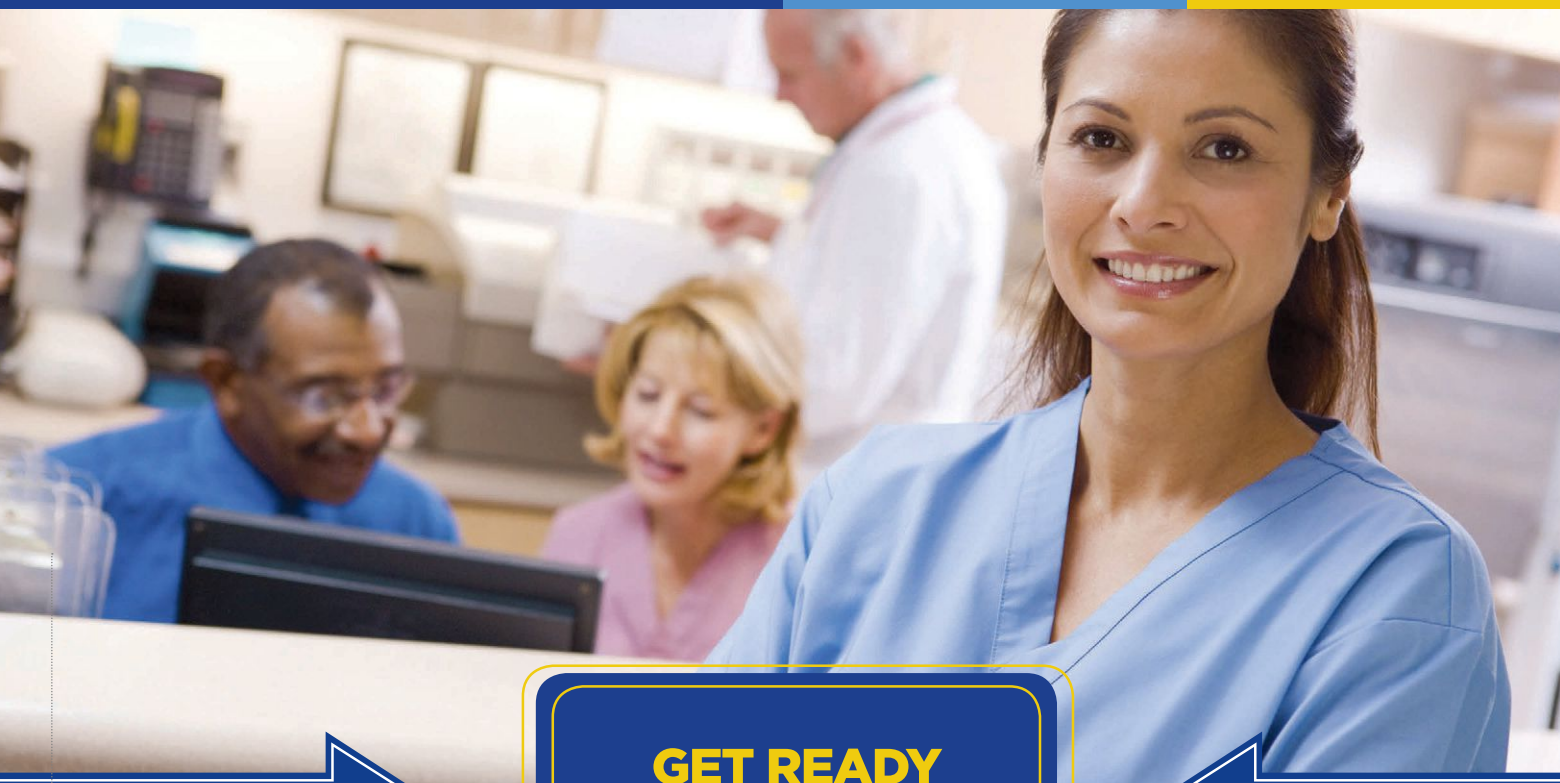
THE MINNESOTA STATEWIDE QUALITY REPORTING AND MEASUREMENT SYSTEM (SQRMS). As part of the health reform legislation passed in 2008, all hospitals, physician clinics, and ambulatory surgical centers in Minnesota were required to submit to the state data on quality measures for the purpose of public reporting.

MN COMMUNITY MEASUREMENT (MNCM). A nonprofit that manages quality measurement and reporting activities for the state of Minnesota; helps providers collect, analyze and report clinical data; and develops and refines measures.

The number of measures by specialty

Includes all measures required by the state





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Data IN A NEW light

How one clinic has gone beyond quality reporting.

BY CARMEN PEOTA

As director of information technology for Edina Sports, Health and Wellness, Christopher Murgic was fully aware of the potential of the clinic's electronic health record (EHR) system. But he thought the staff at the family and sports medicine clinic didn't quite appreciate it. The EHR had created extra work for the physicians, and although staff were using the data it stored to generate reports for MN Community Measurement and others, they weren't doing much more than that with the information. They also had come to view quality reporting as tedious. "We'd gotten fatigued with looking at our diabetes and vascular scores," he says. "We'd been doing that for seven or eight years; there wasn't a lot that was interesting anymore."

Murgic decided he wanted to show the power of data in a new light. He realized he needed to demonstrate it could be used not only for work the clinicians had to do but for things they wanted to do. It would be a little sugar with the medicine, or as he puts it, he'd "horse trade the tacky work [mandatory quality reporting] for what they're really interested in [providing better care for their patients]."

Asking the question

At the clinic's quality meetings, he began asking the clinical staff what they wanted to see. What was important to them? What might help them provide better care for patients? And they began sharing their thoughts and wishes.

One of the physician assistants said she was concerned that too many of their teen patients started but hadn't finished the HPV vaccine series. Murgic generated a list of patients who had had only the first shot so the clinic staff could call them back in. "That was a pretty easy thing to do," he says.

Someone else suggested he delve into information stored in their DEXA scanner. "We've had the DEXA scanner longer than we've had the EHR, so there was a whole bunch of data sitting in the scanner that wasn't in our EHR system," he explains. That information has now been entered into the EHR, so staff can identify patients needing follow-up care. "That was a way to make sure we're not missing people who were developing much more significant osteopenia or even osteoporosis without us being aware and having a treatment plan," says Rochelle Taube, M.D., who founded the clinic in 2002.

Taube says she regularly finds herself starting a sentence, "We ought to be able to know ..." Then Murgic comes up with a way to provide the information. An example was when the recommendations for the hepatitis A vaccination changed. "There is a small group of pediatric patients who didn't get any hep A because the vaccines changed when they were little," she says. She told Murgic about it and he identified the patients who hadn't been immunized. Those patients' families were then contacted about their child's need for the vaccine.

Such projects can pay for themselves, Murgic says. Bringing patients in the door "converts to volume, which converts to income, which is offset against the expense [of the technology and his time]," he says. They can also lighten the load of staff. For example, last year, when they learned the

PHOTO BY STEVE WEWERKA

HIT expert Christopher Murgic is winning the doctors at his clinic over to the benefits of their EHR.

Food and Drug Administration changed the Ambien dose recommended for women, Murgic generated a list of everyone who was on the drug. They were sent a letter that explained the change. "Hopefully it alleviated pressure on the nurses, so they didn't get a ton of calls [asking about the FDA's change]," he says.

More important, according to Taube, is that the information Murgic provides helps physicians and other clinical staff know how they're performing. "We all have perceptions of how we practice or what we do, or how we manage patients," she says. "It's a completely different experience to have it [the data] right in front of you."

Interaction is key

Murgic says that in many clinics, there's a disconnect between the IT staff, who don't understand clinical concerns, and the clinical staff, who don't understand information technology. "They don't always know what's possible," he notes. He realizes he's in a unique position, given his access to the clinic's four physicians and three physician assistants. "I know the data pretty well. The doctors can briefly describe what they want to do, and it doesn't take very long to generate a project that works," he says. "I'm thinking that in larger systems, there's not the interaction we have."

Since she began working with Murgic on solving problems unique to the clinic, Taube has become a believer in information technology and what it can do. "I'm 53 years old and type with two fingers, but I would never go back to not having electronics both on the health record side but also on the side of managing our patients overall." And she's looking ahead. "I feel we're just in the beginning of this; there's so much potential. The EHR is like your smartphone. It can do a lot more than we use it for." **MM**

Carmen Peota is an editor of *Minnesota Medicine*.

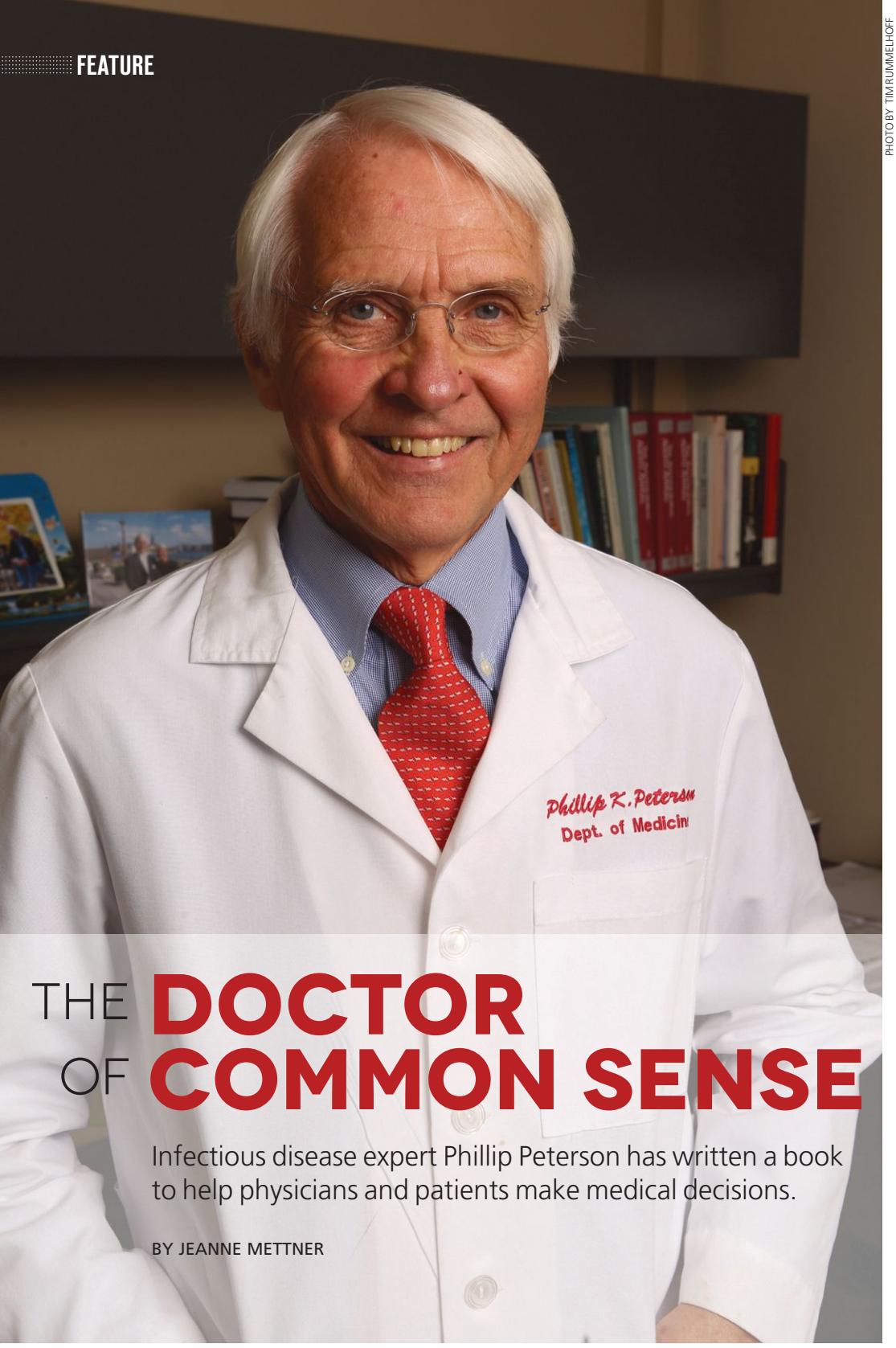


PHOTO BY TIM RUMMELHOFF

Phillip Peterson shares his common-sense approach to medicine in his book, *Get Inside Your Doctor's Head: 10 Commonsense Rules for Making Better Decisions about Medical Care.* It is available through Johns Hopkins Press and as an e-book through Kindle, Nook, Sony, Google Editions, Apple, HFS Digital, Amazon.com, SITB, Overdrive and Kobo.

THE DOCTOR OF COMMON SENSE

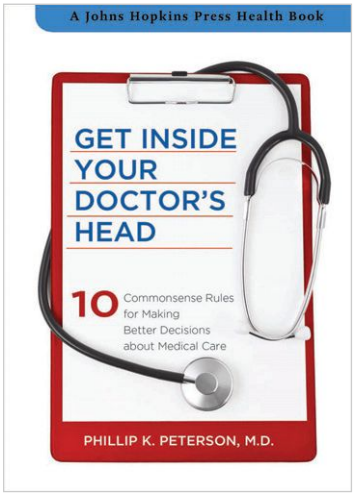
Infectious disease expert Phillip Peterson has written a book to help physicians and patients make medical decisions.

BY JEANNE METTNER

When he began teaching medical students in 1977, infectious disease specialist Phillip Peterson, M.D., started coming up with practical "rules" that he thought his students could follow as they were deciding which symptom to focus on, which diagnostic test to order and which treatment to initiate. Slowly, Peterson began to realize that his common-sense principles might also be useful for lay people who were making decisions about their health care. So he compiled them and last year published the hardcover version of *Get Inside Your Doctor's Head: 10 Commonsense Rules for Making Better Decisions about Medical Care*.

With the newfound emphasis on shared decision-making in health care, the timing seemed perfect to him. "In all honesty, it was a little accidental, maybe serendipitous," says Peterson, a professor of medicine at the University of Minnesota Medical School. "My aim was to give patients some tools for making decisions they need to make. But it became more obvious that this was right down the alley of what we want to do with patient-centered care: improve communications bi-directionally between patients and their physicians. The whole impetus for shared decision-making is that we want patients to speak up."

Peterson starts each chapter by describing an interesting case from his practice. He then states his rule, describes how it can be applied and explains the circumstances under which it can also be broken. For Rule No. 1 ("If you don't know what you're doing, don't do anything"), he describes the case of a 76-year-old woman who was suspected of having viral encephalitis but whose diagnosis could not be confirmed through lab and imaging tests. One doctor started treating the brain inflammation with acyclovir, then discontinued it because the patient was showing signs of kidney failure. Soon after, a neurologist examined the patient and



PHILLIP PETERSON'S **10 RULES**

1. If you don't know what you're doing, don't do anything.
2. If what you're doing seems to be working, think about continuing it.
3. If what you're doing doesn't seem to be working, think about doing something else.
4. Don't agree to an invasive procedure without understanding why it's needed—and without getting a second opinion.
5. If you don't have symptoms, a doctor can't make you feel better.
6. Never trust anyone completely, especially purveyors of conventional wisdom.
7. Most things are what they seem to be, except when they're not.
8. What your doctor doesn't know could kill you.
9. Timing is everything, and sometimes time is the cure.
10. Caring is always important medicine.

hypothesized that the inflammation might be caused by an autoimmune disease and recommended a high dose of steroids.

The patient's primary care physician, concerned that steroids could interfere with her immune system, ultimately advised the patients' daughters not to initiate therapy. The woman's condition improved on its own. In the end, doing nothing was the right thing to do. The team didn't know what condition they were dealing with, and they didn't want to subject the patient to further risk.

Peterson advises readers to ask their doctors about the evidence for and against withholding treatment—especially when the cause of their ailment is unknown. He explains that the exception to Rule No. 1 is when doing nothing would likely result in death or serious harm.

Although Peterson believes his rules can benefit patients with any condition, he drew his cases from his specialty—infectious diseases—in part because he wanted to be able to present firsthand accounts from his practice and because he believes infectious disease cases are the most interesting. "I am certainly biased, but I think the infectious disease cases present the most challenging clinical problems, and they are quick to draw the interest of patients as well," he says. "These days, you can't pick up a newspaper without seeing something about Ebola and chikungunya."

Peterson doesn't have a favorite rule, but he does believe Rule No. 6 ("Never trust anyone completely, especially purveyors of conventional wisdom") is the most useful. "We are constantly barraged with medical advice—take vitamins every day no matter what, eat only fat-free foods. These things that are so-called 'conventional wisdom' turn out not uncommonly to be wrong [when well-designed studies are done]," he says.

Peterson is unaware of how his book is selling or who is reading it. He suspects that the people most interested in it are those who have an existing health issue or who are caring for someone who does. "When you are healthy, your health is the last thing you are thinking about; but as soon as you have a health problem, all of a sudden, these rules become very helpful," he says. "My own bias is that every pre-medical student, medical student and trainee should read this book." **MM**

Jeanne Mettner is a frequent contributor to *Minnesota Medicine.*

Aaron Milbank, M.D., takes part in role-playing.

Choosing *(your words)* wisely

Guthrie actors help physicians navigate difficult conversations with patients.

BY KIM KISER

PHOTOGRAPHY BY KATHRYN FORSS

On a rainy April afternoon, 17 physicians and medical students gathered on the eighth floor of the Guthrie Theater in Minneapolis. The participants pair off. One is to play the physician, the other the patient. As the only non-doc or non-doc-in-training in the group (I was there to write about the event), I get to play a pushy patient.

My job is to convince my partner, Alex Feng, a first-year University of Minnesota medical student, that I need an MRI of the knee I hurt while working in my yard.

Alex, playing the doctor, walks into our mock exam room and introduces himself. He welcomes me and asks about my drive to the clinic. Then he moves into my reason for the visit. How did I hurt my knee? Did I hear a sound when I hurt it? What did it feel like? How had I been treating it?

He listens to my explanations, sometimes repeating parts of what I say and nodding in understanding.

"Did you try icing it?" he asks.

I tell him, yes, I did that the day I hurt it.

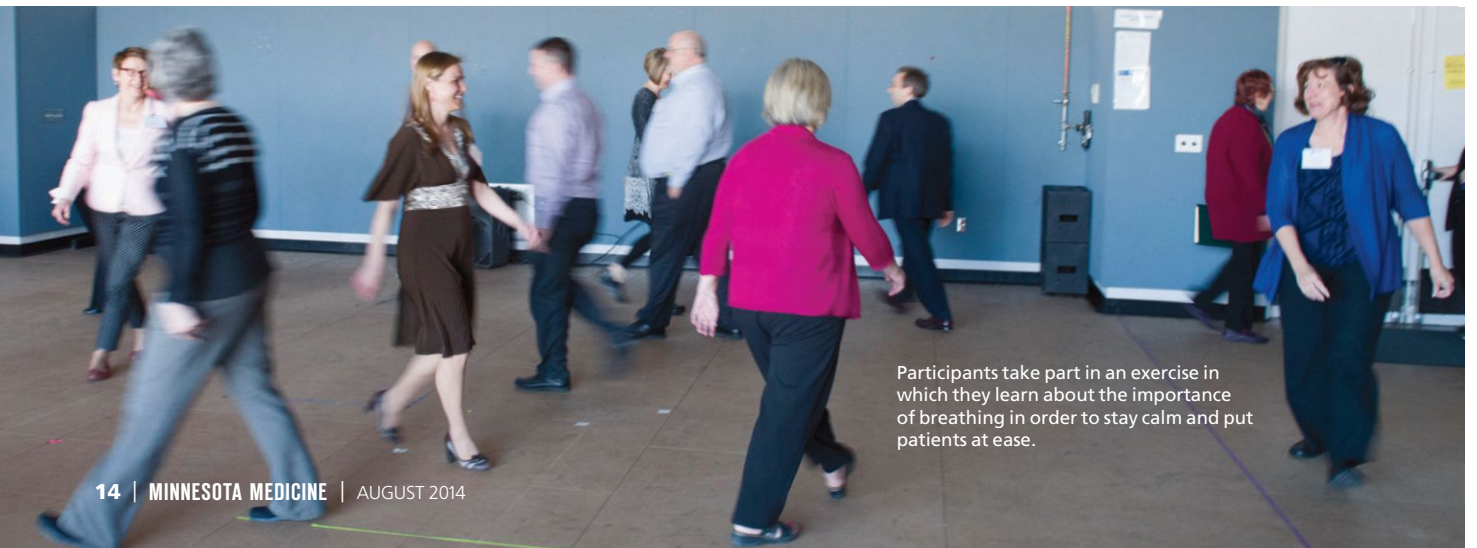
"But it didn't help. Something's wrong, and isn't it true that only an MRI can show what was going on with the tendons and ligaments? That's what I read on the Internet," I tell him. "If we don't really know what is going on, how can I get it treated and get back to running and the other things I like to do as quickly as possible?"

Alex explains how icing it for just one day may not be enough. I need to rest, ice, elevate and compress it for at least two or three days. The more I use it, the longer it will take to heal. Then he tells me that if it isn't any better after a week, I should schedule another visit, and we can discuss a possible MRI.

Aside from some suggestions from one of the teaching actors about his body language, Alex gets positive feedback. He has accomplished his goal: to get me to reconsider a costly test that may not be necessary—at least for now.

Questions encouraged

Encouraging physicians and patients to have conversations about whether a treatment is appropriate or necessary is the goal of the Choosing Wisely campaign, an initiative sponsored by the American Board



Participants take part in an exercise in which they learn about the importance of breathing in order to stay calm and put patients at ease.

of Internal Medicine (ABIM) Foundation. The campaign, which was created in 2012, has worked with more than 60 medical specialty societies to identify more than 135 tests and procedures they say are overused and to encourage physicians to talk to patients who want them about whether they are appropriate.

Last year, the ABIM Foundation awarded grants to 20 organizations around the country, including the MMA, to educate physicians about Choosing Wisely.

The MMA has been using its grant money to help raise awareness about the program and work with seven medical groups to implement it (see p.16 for a list of the participants). In addition to providing them with materials and educational programs, MMA staff approached the Guthrie Theater last year about training physicians from those clinics how to navigate sometimes-difficult conversations. "The heart of the Choosing Wisely campaign is the conversation between physician and patient. We decided to do something more fun and out of the box than a lecture or article in a magazine," says Janet Silversmith, MMA director of health policy. "So we're having actors translate the skills."

Two sessions were held in April for medical students and physicians from the seven participating groups. Two more will be held October 11 and 30; those sessions will be open to all MMA members.

Building rapport, relationships

We begin the afternoon learning how to breathe. We walk around the room faster and faster and then are told to stop. "How many of you held your breath?" asks Michelle Hutchison, one of the actors leading the session. "When you're stressed, you tend to hold your breath. It's fight or flight. You're tense, your voice changes, and it projects onto others." She then explains that when actors breathe in a deep, methodical way, they can recall their lines better. And when doctors breathe in such a way, they will put patients at ease when talking to them.

We then pair up and interview each other. We learn our partner's name, a couple of things we have in common, and something we otherwise wouldn't know about them. We then engage in "active listening." We listen to our partner and begin our response with the last few words they said.

The participants then tell a story about why they became interested in medicine—without their partner asking questions or interrupting. Their partner must then repeat the story back to them. Actor Chris Carlson, who is teaching the session with Hutchison, ties the lesson to medicine when he notes that studies show 50 percent of patients who leave a doctor's office can't repeat back what they heard during the visit.

All the exercises are components of what Hutchison and Carlson call the "Circle of Communication"—connecting with the patient, actively listening and building trust. "Choosing Wisely has an objective for the conversation, and you may not get that outcome," Carlson explains. "But you can build rapport and relationships and eventually move the needle."

Plan ahead

Plan to attend a Choosing Wisely training session at the Guthrie Theater in Minneapolis:

SATURDAY, OCTOBER 11
8:30 A.M. TO NOON

THURSDAY, OCTOBER 30
2:30 P.M. TO 6 P.M.

Go to http://mnmed.org/Advocacy/Choosing-Wisely for details.

SCENES FROM THE FIRST TRAINING SESSION AT THE GUTHRIE THEATER. TOP LEFT: Charles Kim, M.D. TOP RIGHT: Tom Kottke, M.D., (left) and Robert Koshnick, M.D., (center) with one of the Guthrie actors BELOW: Roberta Midwinter, M.D., (left) and Marilyn Peitso, M.D., act out a physician/patient scenario.

As the physicians and students become more comfortable with the idea of role-playing, Hutchison and Carlson ask about some of the situations in which they have found themselves having difficult conversations.

Several bring up instances of patients wanting imaging studies:

"What do you say when a patient complains of aches and pains and wants an MRI?"

"How do you convey to another physician that a CT scan may not be necessary for a patient with a suspected appendicitis?"

"How do you deal with a breast cancer patient whose friend, who also had breast cancer, told her she should be getting PET scans as follow up? What do I say when she wants to know why she isn't getting the same treatment?"

Another mentions patients who come in wanting antibiotics: "What do you say to a patient with an upper respiratory infection who expects antibiotics and doesn't get what they want?" That participant noted that with physicians now being assessed on patient experience, it's difficult to send a patient away satisfied if they don't get an antibiotic.

We again pair up and this time begin acting out such scenarios, with those cast as the physician trying to get the patient to reconsider a request or try another approach.

Hutchison and Carlson walk around the room, stopping to watch and offer advice. In the end, they applaud our efforts. "You're doing a lot right—99 percent," Carlson tells the group, as they debrief and the doctors reveal whether they were able to get their patients to reconsider their requests.

All agree that the skills they've learned will help them when they're dealing with real patients about any issue. "This is the best thing for patient satisfaction ever," one physician wrote after the training.

"Listening and demonstrating that you're listening are skills every physician could use a refresher on," says Gary Christenson, M.D., chief medical officer of the University of Minnesota's Boynton Health Service, who took part in the training. He says he found the analogies between how actors and doctors approached their work especially helpful. "Going into a scene is like going into an exam room except with a patient, it's not just a scene, it's a whole new script that you have to read and interpret," he says.

Feng says he thinks the training will help him as he moves from the classroom to the bedside. "Being a physician doesn't entitle you to think for the patient. You have to listen for what the patient thinks is important, not what you think is important," he says. "Empathy is something you can't fake." **MM**

Kim Kiser is an editor of *Minnesota Medicine*.

Clinics Implementing Choosing Wisely

Integrity Health Network
Metro Urology
Boynton Health Services
St. Croix Orthopedics
Ridgeview Medical Center
Specialists in General Surgery
Emergency Physicians Professional Association

HOW 10 High Ac DO IT

CLINICS SHARE THEIR *Quality-Improvement* STRATEGIES

BY HOWARD BELL

Since 2011 all Minnesota clinics and hospitals have had to submit their quality improvement (QI) numbers annually for a variety of measures to MN Community Measurement. In addition, some submit them to payers, who use them to determine reimbursements. And some even use the information to determine compensation. This emphasis on measurement has led organizations to take QI seriously. Many have changed the way they work—and that hasn't always been easy. Along the way, clinics and hospitals have learned that QI takes time, doesn't have to cost money and even little changes can make a big difference in the lives of patients. Here, 10 clinics share what they have learned about making changes for the better.

Always AT THE TOP

1 STRAIGHT TALK ABOUT DIABETES

When Scott Jensen, M.D., and his three colleagues at Catalyst Medical Clinic in Watertown were told they had to start submitting QI numbers to MN Community Measurement, they weren't happy about it. "It was just one more time-consuming regulatory intrusion," he says. "But you play the cards you're dealt, so we had a 15-minute meeting to vent, then rolled up our sleeves and got to work." Since then, they've grown the percentage of patients with diabetes who meet certain benchmarks from 40 percent in 2011, which was already above the state average, to 65 percent in 2013, which made them one of the state's top performers. (And they did this without an electronic health record.)

How did they do it? First, they picked the right person to be the QI leader. In their case, that person was clinic manager Gae Lueck. Next, they reviewed the five benchmarks for diabetes they were expected to reach and deemed all but one reasonable. "It's not fair for us to get a black mark because a diabetic patient keeps smoking," Jensen says. "We told Community Measurement that was out of our control and suggested we instead have the patient sign a paper saying we helped them try to quit, but Community Measurement said no."

Next, they drew up a plan for exactly what they needed to do and learned the lingo of MN Community Measurement and began speaking it in the clinic. "We made it clear to all staff there's no wiggle room on this," Jensen says. "These are the goals you need to hit for every patient."

To remind them of those goals, they now post cheat sheets inside exam room cupboards listing the benchmarks for A1C, blood pressure, LDL cholesterol, aspirin therapy and smoking. They also share that information with patients, which motivates them. So does straight talk.

Jensen says they're frank with patients about the consequence of uncontrolled diabetes. They tell them: "We don't want to amputate your toes or watch you get kidney disease, so work with us on this." Or "If we can get your sugar under control, you have a better chance of not losing vision due to diabetes. Do you want to be able to watch your grandkids play basketball? Do you want to be able to play catch with them?" He says most patients appreciate the honesty.

Jensen says he and his colleagues are quicker than many primary care doctors to put patients on once-a-day long-acting insulin. "Many doctors hesitate to start insulin because patients don't want to do injectables, but we tell our patients, and firmly believe, they'll be less likely to need an amputation or suffer other serious effects if we can get good solid control of their diabetes." And sometimes that means using insulin.

Patients who aren't hitting goals are asked to come in more often. "We chat," Jensen says. "We tell them 'Let's roll up our sleeves and get this done.' We negotiate with patients all the time. Good docs are good salespeople. If I can't sell a patient on the importance of this, it's not going to happen."

Advice and lessons learned:

- Pick the right person to manage QI. They need to be diligent about watching the numbers and good at letting the doctors know when certain patients need to improve.
- Have all staff learn QI lingo. Make it part of your clinic's culture.
- Sell the importance of QI to patients and staff.

FIRST in QUALITY

2 BREATHING EASIER

Allergy and Asthma Specialty Clinic in Willmar has always tracked its asthma care outcomes. So in the summer of 2011, when they were required to start submitting numbers to MN Community Measurement, they just needed to forward them on. In 2013, staff made a change in their practice that improved their numbers.

A nurse from the clinic now calls patients with acute problems one month after they are seen to ask how they're doing and give them a repeat Asthma Control Test (ACT)—the questionnaire patients complete at their appointments. "It gives us the chance to make sure they're understanding and following the doctor's advice," says James Ellingson, clinic administrator in charge of QI. "We can find out if they're having any problems with their medications and if they're noticing any improvement. It also helps our outcome scores because the follow-up ACT is usually better than the first one."

In 2013, 86 percent of the children with asthma treated at Allergy and Asthma Specialty Clinic met MN Community Measurement criteria for having their condition "well-controlled," as compared with the state average of 49 percent. Likewise, 94 percent of adults had well-controlled asthma as compared with the state average of 40 percent. "Our adult scores improved from 73 percent in 2011 to 94 percent in 2013 largely because of the follow-up phone calls," Ellingson says. On two of the measures, "risk of exacerbation" and "patient education," the clinic's scores have been at 100 percent for both adults and children for the past three years.

Because the clinic didn't have an EHR until June of 2014, their biggest challenge has been compiling their numbers. "Searching and merging Excel worksheets is very laborious," Ellingson says. "And

then we had to pull data from charts and add it to the worksheets." Yet with or without an EHR, the clinic has consistently been one of the state's top performers in asthma care.

Advice and lessons learned:

- Follow up with patients.
- Remember why you are collecting the data. It's easy to view QI as just gathering data and improving scores rather than making sure the patient's health improves and their condition is well-managed.

3 MORE HPV VACCINATIONS

When Kristine Matson, M.D., M.P.H., joined Pediatric and Adolescent Care of Minnesota in West St. Paul, she noticed the clinic wasn't giving many human papillomavirus (HPV) vaccinations. "When I got my master's in public health, I learned about health care interventions, so I decided to put my knowledge to work and try to increase our HPV vaccination rates. I also needed to complete a quality improvement project for American Board of Pediatrics re-certification and thought this would do nicely."

Her first step was getting buy-in from her three physician partners, which at first was "a bit of a struggle." "I was naïve and assumed there would be immediate and total buy-in," she recalls. One partner was concerned that HPV vaccinations gave kids the go-ahead to be sexually active. Another thought it would be too much work for too little gain, and feared patients and parents would resist the idea. When Matson researched the subject and found HPV vaccinations do not increase sexual activity among teens, her partners agreed to support the initiative.

The next step was to bring the nurses on board. "They were immediately supportive and were the front line for making it work," she says. Their role was to discuss the vaccine with parents of patients older than 9 years of age who hadn't been vaccinated as part of the rooming process. They provided printed information and answered questions. "We stressed that this is about cancer prevention—that many of us know someone who has had cervical cancer and that HPV also causes throat cancer and genital cancers in both girls and boys," Matson explains.

Response from parents was more positive than anticipated, and many patients received the first of their three vaccinations during that first appointment. "We feared not as many boys would get vaccinated, but they did," Matson says. "We explained that HPV is transmissible from boys to girls. Around that time, actor Michael Douglas' throat cancer was in the news. Most likely it was caused by HPV, and we used that as an example of how HPV affects men, too."

From June through August of 2013, the physicians and nurses met several times to discuss their progress. During those three months, vaccination rates were 126 percent higher than for the same three months the previous year. Two months after the project ended, the clinic had a party to celebrate its success. "HPV vaccinations are important, and it made us all feel great that we did this," Matson says.

Those higher vaccination rates continue today.

Advice and lessons learned:

- Just do it. Jump in and be positive.
- Prepare for colleagues to resist change. When talking to them, build your case with data.
- Parents and patients were more accepting than expected.

4 BETTER MENTAL HEALTH CARE

For many years, Dale Dobrin, M.D., and his colleagues at South Lake Pediatrics in Minnetonka noticed that depression and other mental health problems were common among their young patients. "But most of us in primary care pediatrics weren't trained to adequately deal with mental health issues," he says.

Between 2010 and 2013, South Lake dramatically improved the quality of the mental health care their patients were getting. They hired care coordinators, created a registry to track the care patients were getting, established relationships with mental health care providers, and helped their physicians become more comfortable treating mental health conditions, including prescribing medications. It boiled down to integrating mental health care into their practice.

Hiring a mental health care coordinator with grant money from the Minnesota Department of Human Services turned out to be the key to their success, according to Dobrin. Instead of physicians setting up a referral to a mental health professional or having parents make the call, the care coordinator takes care of it.

Before making the changes, only about half of South Lake's mental health patients actually scheduled and showed up for their first appointment, which is comparable to the national average, Dobrin says. Now their "initiation" rate is nearly 90 percent. Financial issues, the stigma of seeking mental health care and disagreements between parents about whether to even get care for their child all used to get in the way. "Now the coordinator helps resolve these issues and acts as an intermediary between doctor, nurse, patient, parents and mental health professional, so we can provide timely, appropriate care," he says.

The coordinator also makes sure patients are getting to appointments and taking their medications.

Previously, 12.5 percent of South Lake's mental health patients needed emergency or inpatient care at some point, which is typical of primary care clinics, according to Dobrin. In 2013, the rate was down to 1.7 percent. The average age of a patient's first hospitalization was also down, from 15 or 16 years to 12. "That's good," Dobrin says, "because the earlier you screen and intervene, the less likely a problem will become more serious."

JoAnne Hoffman-Jecha, M.D., South Lake's medical director of mental health services, teaches clinicians the treatment and referral process. She's also a medication management expert. "She's made all of us much more comfortable with treating and prescribing for mental health conditions," Dobrin says.

Two committees at South Lake keep the ball rolling. An integrated mental health work group meets every two months. A steering committee (clinicians, staff, parents and representatives from local school districts) meets quarterly.

To keep the care coordinator positions funded, South Lake is looking at additional grant support and is having discussions with health plans that might be interested. So far, four plans are partially supporting these services at all six clinic locations. One has begun reimbursing for mental health care coordination services.

In addition, South Lake's program was a reason it was certified as a Health Care Home by the state of Minnesota. "The Affordable Care Act encourages integrating care across previously separate areas, and there's no reason mental health care can't be part of primary care," Dobrin says.

Advice and lessons learned:

- Have a champion for change.
- Get buy-in from clinicians, staff and all levels of management including your board.
- Establish relationships with mental health providers.
- Establish relationships with health plans in order to get reimbursed for care coordination and registry management.

5 FEWER MEDICAL ERRORS IN THE CLINIC

After the Institute of Medicine's 1999 report "To Err is Human" noted that medical errors were common in hospitals, Tim Hernandez, M.D., and his colleagues at Entira Family Clinics in the Twin Cities decided that errors must be happening in clinics, too.

With Hernandez taking the lead, physicians at Entira's 12 clinics started documenting errors and potential problems and sharing them at staff meetings. At first, it was "pretty unscientific," Hernandez says. But in 2006, they instituted formal processes to both create a culture of safety and reduce errors.

Entira formed a safety committee that includes nonclinical staff as well as patients. They set up a way for staff and patients to anonymously report an error or safety concern. (Staff could do this through their EHR; patients would do it verbally or in writing.) The safety committee would address these reports at their regular meetings.

But reports weren't coming in. "We realized quickly," Hernandez says, "that in order to reduce medical errors, staff and patients need to feel comfortable reporting errors." That comfort level wasn't there, according to results of a questionnaire all staff completed. Although physicians said they felt lines of communication were healthy, many staff members didn't agree. So Hernandez and his team set about changing the culture at the clinic. With help from an MMIC grant, they developed a curriculum called "Just Culture" that includes videos and vignettes that help staff understand the difference between human error and risky, reckless behavior. They coached staff who exhibited risky behavior and offered support for those cases where there was human error. "Just Culture has made us much more comfortable discussing errors, even with our patients in the room," Hernandez says.

Reducing labelling errors was one of Entira's earliest and biggest successes. "By switching from hand-written to preprinted labels, we were able to almost completely eliminate patient specimen identification errors," he says. Vaccine and medication errors are down, too, primarily because of workflow changes. For example, the person who prepares a vaccine or other injectable is now the one who gives the injection. That wasn't the case before. "We rarely see a vaccine error now," he says.

Entira also built in redundancies. For example, when rooming a patient, the person is identified twice. "When we call for patient John B and we have two John Bs waiting, it's embarrassing at minimum and potentially dangerous to room the wrong John B. Our physicians are expected to confirm they have the right patient, even if

they've known that patient for years," Hernandez explains.

Each month, one of Entira's clinics receives a "Catch of the Month" gift certificate for identifying and addressing a safety problem. In 2008, Entira received Medica's Innovator Award for its work in reducing medical errors.

Advice and lessons learned:

- Embed safety into your clinic's culture.
- Include patients on your safety committee. Their insights enrich the conversation and increase motivation to change.
- Find a way for staff to easily report events, both errors and "good catches."

WE TREAT YOU LIKE A FRIEND

6 PERSONALIZED DIABETES CARE

Cromwell Medical Clinic in Cromwell, Minnesota, has proved that size isn't a barrier to excellence. With one full-time physician, a nurse, an office manager and four part-time employees, the clinic has been a consistent high performer for optimal diabetes care. "Our numbers have been good," says clinic manager Teri Shelton. "But they've gotten better, and we've gotten better at tracking our data." In 2013, 58 percent of Cromwell's 110 patients with diabetes met all diabetes measures, compared with 21 percent in 2010.

Staying in touch with patients is key. "We remind them of appointments, discuss results and goals, and follow-up between appointments as needed," she says. "Our patients don't fall through the cracks—even if they would like to. They know we'll get on them if they slack off and we will do all we can to get them back on track."

The clinic's small size works to their advantage, Shelton says, as it allows them to build close relationships with patients and continuously monitor their care. In addition to the EHR they've used for six years, Cromwell staff use spreadsheets to help them keep track of their diabetic patients. Staff take the time to coach, educate and encourage patients. "By staying in close touch and providing ample education, compliance rates are higher and outcomes are much better," she says.

The clinic also informs patients about their QI efforts. "All of our patients know about our quality improvement process," Shelton says. "When they see they aren't just a number and that we're truly invested in their health, they're more likely to work

with us to get quality numbers where they need to be."

Advice and lessons learned:

- Build strong relationships with your patients. The more engaged both the patient and clinic are in QI, the better your numbers will be.
- Communicate, educate, follow-up.
- Encourage patients to take the lead in getting their diabetes under control.

7 CLOSING THE GAPS

After the Institute of Medicine's report "Confronting Racial and Ethnic Disparities in Healthcare" came out in 2002, HealthPartners began collecting data on patients' race and ethnicity so it could identify disparities among populations of patients. "Our data showed that we had the greatest potential for closing gaps for breast and colorectal cancer screenings and diabetes management," says Beth Averbeck, M.D., HealthPartners associate medical director for primary care.

Before making any changes, they asked their patients of color why they weren't getting screened or managing their diabetes. Lack of transportation, child care and time were reasons they often cited. "Some came from countries where there is no preventive care," Averbeck says, "so they didn't understand why they should have a test when they feel fine."

What they've learned has prompted action. For example, HealthPartners nurses created what they call the "pink-slip mammography service." A woman who's due for a mammogram but is in the clinic for a different reason is given a pink ticket that gets her in for her mammogram within 20 to 30 minutes after her scheduled appointment. It includes a friendly escort to radiology, where she is introduced to the mammography staff. Using this approach, they were able to narrow the gap between white women and women of color who get mammograms from 8 percent to 4 percent between 2008 and 2013.

For colorectal cancer screening, Averbeck and colleagues learned that many patients thought colonoscopy was the only option. "We explained stool sampling and changed to an easier-to-use sample card that required a less-restrictive diet," says Brian Rank, M.D., HealthPartners medical director. Between 2009 and 2013, the gap between whites and persons of color who get screened declined from 26 percent to 13 percent.

For diabetes, the gap between white patients and patients of color receiving optimal care decreased from 12 percent in 2009 to 9 percent in 2013.

Ideas like the pink ticket, which has spread to all HealthPartners clinics, are celebrated within the organization. Clinics periodically get their "gap" scores so they can see how they're improving. "All staff—clinical and non-clinical—are on the same page and alert for patients who haven't had a screening," Rank says. For example, when a patient called HealthPartners' nurse line about an upper respiratory infection, the nurse noticed the patient hadn't had a mammogram in five years. She encouraged her to get one and they found a small breast cancer lesion. Likewise, when a Somali mother brought her child in for a cold, they updated the child's immunizations during the same visit.

"It's about engaging the patient, not educating them," Rank says. "We view these disparities as our failure, not the patient's."

In 2010, HealthPartners was honored by the American Medical Group Association for its work on disparities.

Advice and lessons learned:

- First, learn from patients. Engage them and their families in all improvement efforts.
- Listen to all members of the care team: receptionists, nurses and clinicians.
- Remember that all health care is local. Build reliable systems across your clinics, then customize them to engage particular patient populations.
- Share progress reports and celebrate successes.

8 REACH OUT AND SCREEN SOMEONE

Last year, CentraCare's River Campus and Health Plaza clinics were among the state's top performers in colorectal cancer screening, screening 91 percent and 89 percent of eligible patients, respectively. CentraCare's systemwide average was 85 percent.

Those clinics' rates started climbing steadily in 2005, when CentraCare partnered with the Stearns County Colorectal Cancer Initiative. "That allowed us to reach out to the community in more ways in more places," says Angela Nathan, CentraCare's quality data analyst.

Every March (National Colon Cancer Awareness Month), CentraCare offers free fecal occult test kits at the St. Cloud hospital pharmacy's drive-up window and at the Coborn Cancer Center. In addition, Nathan says CentraCare's GI doctors have expanded their outreach visits to nearby towns. And early on in the QI initiative, they spoke with primary care staff about different screening options and best practices.

To make sure physicians know which patients who are coming in need screening, CentraCare started pre-visit planning, using flagged notes in the EHR, paper notes and verbal reminders from medical assistants.

The GI department provides primary care clinics with brochures to give patients who need a GI referral. And they assumed responsibility for scheduling the colonoscopies, which reduces the work load at the primary care clinics.

To spell out expectations, CentraCare's Best Practice Committee and its Quality Council created process and workflow guidelines for everyone to follow when working with a patient who is due for screening.

Physicians receive their QI data along with that of their colleagues. "We share individual provider data for all areas, which we find very effective at motivating clinicians at every site," says George Morris, M.D., CentraCare Clinics' medical director.

Today, CentraCare's screening rates continue to improve. They still promote screening but have shifted their focus to narrowing racial disparities in screening rates.

Advice and lessons learned:

- Use a team approach and engage specialists, primary care physicians, nurses, administrators and QI staff.
- Involve patients in the process.

WE AIM TO PLEASE

9 SATISFIED PATIENTS

Lakewood Health System's Pillager Clinic ranked first among all Minnesota clinics for patient satisfaction with clinic staff and physician communication, according to MN Community Measurement's 2013 report. All five of Lakewood's central Minnesota clinics received high scores, but Pillager set the bar. Ninety-eight percent of patients surveyed said Pillager's staff was exceptional, and 93 percent said its physicians were exceptional. How did they do it?

"We try to stay on top of our game every day, for every patient, for every visit," says Craig Wolhowe, Lakewood's hospital and clinics vice president. "It comes down to every staff member understanding how important patient experience is."

At monthly QI meetings, they review their scores for patient satisfaction (among other quality measures), address issues, and ask What can we do better? On "Measurement Mondays," nurses review their scores from the previous month. Scores for Lakewood's clinics are displayed in a glass frame at each nurses' station. "There's competition," says Wolhowe. "None of the clinics wants to be the lowest scoring."

Wolhowe recalls how a newly hired physician assistant saw her scores jump as soon as she began asking patients, "Is there anything I can do for you? I have the time." "That's all it took," Wolhowe says.

Lakewood also has found that physicians score better when they sit at eye level when talking to patients in the hospital than when they stand at the foot of their bed. "Patients feel more at ease, and it creates a better connection."

And staff members explain why they're doing certain things. Instead of just closing the patient's door, they say "I'm going

to close your door now so you have privacy." Or, "I'm using this hand sanitizer for your safety."

When a physician is running late, a receptionist lets the patient know. Those facing a longer wait are offered a cafeteria gift card or asked to leave their cell phone number for a call-back. "Many patients are missing work and get paid by the hour," Wolhowe says. "So we streamline things the best we can."

When Lakewood opened its new building in Staples in 2006, Wolhowe began having staff call new patients after their appointment to ask them how their visit went. That was so appreciated by patients, they started calling all patients in 2009. "Patients can always go somewhere else, but we want them to come here," Wolhowe says. "We want them walking out that door feeling good about the service we gave them—every patient, every day, every time."

Advice and lessons learned:

- Understand what patients experience. View your operations from their perspective.
- Take to heart what patients tell you so you can make improvements.
- Treat patients the way you would like to be treated.
- Share QI data with all staff and make sure everyone understands how important customer service is.

10 MOTIVATING PHYSICIANS

After 10 years of steady improvement in their vascular care scores, Fairview Medical Group's improvements aren't as dramatic as they once were. Still, they're making progress. Several strategies have helped them.

For one thing, they've made all QI data transparent. "Everyone sees everyone else's scores," says Valerie Overton, D.N.P., vice president of quality and innovation. And with transparency comes competition and peer pressure. Fairview also changed its physician compensation model to put more emphasis on quality and less on productivity.

They also standardized the workflow. Understanding who does what, when and how helps clinics achieve high scores, says William Nersesian, M.D., chief medical officer for Fairview Physician Associates, a network of 2,400 physicians in the Twin Cities metro area. They also have a physician champion for QI at every clinic. "Without one, clinics usually don't get far," Nersesian says. (Because Fairview has been doing this for so long, getting buy-in is no longer an issue.)

To help physicians get it all done, Fairview's EHR makes tests, refills and other aspects of care that need attention easy to see. And it has a vascular disease registry, which Overton says "is really, really fundamentally important to our success. You have to be watching your panel of patients outside of seeing them in the clinic. That list tells us whose vascular disease is in control and who needs to be seen to get them back on track."

Fairview uses both elaborate and simple tools. Although it has an electronic QI dashboard, where physicians can view a patient's status, it also provides the same information on paper. "Paper is easier and immediate and doesn't take six clicks to get to, which is a burden and a barrier during a busy day," she says.

In 2013, 54 percent of Fairview Medical Group's vascular patients were receiving optimal vascular care, up from 35 percent in 2010. "Love it or hate it, even those who don't like Community Measurement acknowledge it's made a positive difference," Overton says.

Advice and lessons learned:

- An EHR is critical.
- If you can't measure it, you can't improve it.
- Have a physician champion for QI at each clinic. If physicians buy into QI, other staff will as well.
- Create a patient registry.
- Follow a standardized, agreed-upon workflow. **MM**

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

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Victoza® (liraglutide [rDNA origin] injection) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Because of the uncertain relevance of the rodent thyroid C-cell tumor findings to humans, prescribe Victoza® only to patients for whom the potential benefits are considered to outweigh the potential risk. Victoza® is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise.

Based on spontaneous postmarketing reports, acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis has been observed in patients treated with Victoza®. Victoza® has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for pancreatitis while using Victoza®. Other antidiabetic therapies should be considered in patients with a history of pancreatitis.

Victoza® is not a substitute for insulin. Victoza® should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

Victoza® has not been studied in combination with prandial insulin.

Important Safety Information

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

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

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

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

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

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

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

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

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

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

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

Please see brief summary of Prescribing Information on adjacent page.

1013-00018617-1 December 2013

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

More detailed information is available upon request.

For information about Victoza® contact: Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, NJ 08536, 1-877-484-2869

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Dominic Decker worked as a scribe in two hospital emergency departments before starting medical school.

PHOTOS BY KATHRYN FORSS

A scribe's story

A medical student reflects on what he learned.

BY DOMINIC DECKER

Before my first day of medical school, I had already seen more than 2,500 patients. They had presented with problems ranging from an ingrown toenail to being found without a pulse. I watched as a young woman was told she had MS. I was present when a man newly diagnosed with HIV admitted to a suicide attempt. I backed away as a distraught son lunged at a physician, screaming that he had let his mother die before breaking down in tears. All before my first day of orientation.

In June 2010, two weeks after graduating from college in Washington, D.C., I returned home to Minnesota to begin work as a scribe at two Twin Cities emergency departments. The job was advertised as being ideal for a pre-med student: It would entail being paired with a physician, nurse practitioner or physician assistant, accompanying them into the exam room and documenting patient encounters. The learning curve would be steep, I was warned, but the payoff would be worthwhile: I would be intimately involved in the delivery of care to a diverse patient population with a variety of complaints. It would bolster my status on medical school applications.

The scribe position fit what I was seeking at the time. I had entered college knowing that I wanted to become a physician but planned to study English literature first. My English studies informed how I interpreted information and, importantly, how I relayed it to other people. As a scribe, I would get to transform a patient's words and physician's findings into a cohesive narrative that became a permanent part of the electronic medical record.

Use of scribes—not only in emergency departments but in primary care and specialty clinics—had become pretty routine by the time I started my job. The first ones appeared in Minnesota at Abbott Northwestern Hospital in 2006. At the time, Allina Health, then Allina Hospitals and Clinics, was transitioning to Epic software to host their medical records. Scribes were hired in the emergency department to cut down on the amount of time doctors and other providers spent charting. Initially, four scribes provided coverage for a few physicians at one hospital.

By the time I was applying to medical schools in the fall of 2012, we applicants were routinely asked if we had worked as a scribe. On more than one occasion, more than half of the prospective students in my group raised their hands.

Working as a scribe taught me that medicine delivered on the frontlines can be both thrilling and mundane, stimulating and frustrating. It is never provided in the same way twice because treatment is rendered to a patient, not a disease. I learned not only what the acronyms HPI and ROS stood for but also how to translate the patient's reported symptoms into the language of medicine. I discovered pertinent positives and negatives and began to anticipate the line of questioning when seeing someone with a suspected head injury. I deciphered what radiologists said on the dictation line and was quickly introduced to hundreds of words and phrases that are now in my vernacular.

These are the things I expected to do. But being a scribe had an even more profound impact on me. A scribe is a silent observer of the clinical encounter, standing at a distance—usually in the corner of the room—watching both patient and provider during their exchange. The scribe enters the very private space of the exam room not to act within it but rather to document the action occurring. As such, I witnessed instances of both good and bad care.

I watched a young physician, with remarkable interpersonal and technical skills, review the history of each patient before proceeding with the exam, inviting the patient to correct any part of the story that was wrong. In doing so, he handed control of the encounter back to the patient and ensured that everyone was on the same page. More times than not this brief recounting of the patient's history exposed aspects of the case that were missed or misunderstood. Now on clinical rotations, I have started to use this technique as I interview patients. It takes less than a minute to do, organizes my thinking about the chief complaint and allows the patient to confirm my understanding.

On another occasion, I entered the room of a patient dressed as woman, wearing makeup, nail polish and jewelry. The chart identified this patient as a male. The physician I was working with conducted the interview and exam as usual, but after stepping out of the room referred to the patient alternatively as a "he/she" and an "it." As a scribe, I felt powerless to intervene. Later, another scribe shared a similar story. She saw an opportunity to enter the patient's room and ask about gender identity and pronoun preference to ensure that her note matched how the patient presented. I have since learned that the electronic medical record can perpetuate misinformation. Discrepancies between the chart and a patient's lived experience should be addressed and understood, rather than mocked.

The role of the scribe

Recognizing the expanding role medical scribes were playing, the Joint Commission defined it in 2012 as "an unlicensed person hired to enter information into the electronic medical record or chart at the direction of a physician or practitioner." The Joint Commission said scribes could assist practitioners in navigating the electronic health record and in locating information such as test and lab results, and that they could support workflow and documentation for medical record coding. Scribes could not, however, participate in order entry. Very few other regulations pertain specifically to scribes.

Source: The Joint Commission.

Using scribes has been viewed as good for clinicians, as it frees them from charting so they can focus on patient care; good for students, who are gaining valuable experience before entering medical school; and good for patients, who spend less time waiting. We know that providers and scribes can benefit one another. We don't yet know what patients think about them. In a qualitative research methods class I took in graduate school, I interviewed scribes and clinicians about the scribe's role in the clinical encounter. The most interesting comment came from a nurse practitioner, who referred to "triangulation" of the patient-provider relationship. By introducing a third person into the room, the dynamic of the encounter changed. The nurse practitioner said it was not clear that patients were less forthcoming about their concerns when scribes were present. But the question about the impact on the patient-provider relationship when a scribe is in the room needs to be answered.

As use of scribes continues to grow, we need to be asking another important question: Is their use appropriate in all circumstances? I recall being in the exam room when a woman broke down crying, saying she felt her life was no longer worth living. It felt wrong for me to be there typing on a keyboard.

The impact that being a scribe will have on how future physicians practice is also unclear. From my experience, being a scribe has given me models to follow (the doctor who summarized each patient's concerns) and to reject (the doctor who made transphobic statements about a patient). What I think scribing brings to medical training is the opportunity to observe and to learn about humility and mutual respect—elements that are necessary for building relationships with patients. **MM**

Dominic Decker is a third-year medical student at the University of Minnesota.

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HOT TOPIC

MMA to discuss single payer at August forum

BY DAN HAUSER

It's hard to imagine a topic provoking more passion from MMA members than medical cannabis. But if there is one, single-payer health care may be it. Just mention "single payer" and you're liable to get an earful, as the topic incites tremendous passion on both sides.

It's a subject that members have discussed in hallways, at meetings and, periodically, at the MMA Annual Meeting. (A number of times, the House of Delegates considered resolutions related to single-payer health care.) Now a more focused discussion is planned for August 19. "A Conversation about Single Payer: What is it? How might it work at a state level? What are its limitations?" will take place from 5:30 to 8 p.m. at the University of Minnesota Continuing Education and Conference Center in St. Paul.

"The MMA does not have a position on single payer," notes Cindy Firkins Smith, M.D., MMA president. "This forum is being designed to be educational, so attendees can hear both sides of the issue, sift through available facts and learn something."

The MMA is co-hosting the forum with the Minnesota Academy of Family Physicians (MAFP) and the Minnesota Chapter of Physicians for a National Health Program (PNHP).

MAFP convened a task force last year to consider developing a position on having a single-payer system in Minnesota, says Virginia Barzan, MAFP's executive vice president. That task force presented a report to the 2014 MAFP House of Delegates that discussed definitions of single payer, problems with the current payment system, how a single-payer system might address those problems and a description of the challenges of implementating such a system.

"The most appealing aspects of a single-payer system for family physicians would be universal coverage and a significant reduction in administrative burdens," Barzan says. "The task force recognized that development of a new system would pose many

"The task force recognized that development of a new system would pose many challenges, especially in actual implementation, and felt strongly that physicians need to be educated and actively involved."

– Virginia Barzan, Executive Vice President, MAFP

challenges, especially in actual implementation, and felt strongly that physicians need to be educated and actively involved."

The MAFP has not taken a position on specific single-payer legislation. However, its House voted to continue the task force for another year. Further, it passed a resolution directing the MAFP to promote the advantages of a Minnesota single-payer system as one method of fulfilling the AAFP's Principles of Health Care Reform. It also calls for the MAFP to actively participate in health care reform deliberations to inform and guide those promoting a single-payer approach in Minnesota.

"The opportunity to co-sponsor the forum on August 19 fits very nicely into plans for implementing this resolution," Barzan says.

Whereas the MMA and the MAFP are approaching the forum as an opportunity to educate physicians and generate discussion, PNHP members hope it opens some eyes.

LIVE ONLINE

In a first for the MMA, the single-payer forum will be streamed live on the Internet for those who are unable to attend the event in person.

"We've heard from many members in greater Minnesota that it's difficult to get to the Twin Cities on a weeknight," says MMA President Cindy Firkins Smith, who hails from Willmar, two hours west of the metro. "So we are experimenting with live streaming so that those members can take part from their homes or clinics."

If there is enough interest and the technology works well enough, the MMA might live-stream more events. Because there is a cost for live streaming, members who take part in the event online need to pay $15. Physicians who are interested in watching as a group can pay a flat rate of $50. Once you have successfully registered for the event, the MMA will send a link for the live stream. To register, go to www.mnmed.org/singlepayer.

"We hope to help other Minnesota physicians understand the attributes of single payer, clear up misconceptions and respond to concerns," says Dave Dvorak, M.D., an emergency physician with Emergency Physicians Professional Association and member of the Minnesota chapter of the PNHP. "We hope to illuminate the profound ways that single-payer reform would benefit our patients, contain spiraling health costs and enhance the professional satisfaction of Minnesota physicians."

Some MMA members who oppose single payer have not waited for the forum to state their opinions. After receiving news of the forum, one long-time member wrote: "I believe I would be in the silent majority for Minnesota physicians, those of us who want fair representation for our profession and do not support single payer." He went on to note: "I personally do not have the faith that government alone can provide all of the fixes we need [in health care]."

"We hope to help other Minnesota physicians understand the attributes of single payer, clear up misconceptions and respond to concerns."

– Dave Dvorak, M.D.

Dvorak, however, says the time is right to consider single payer. "While the implementation of MNsure has decreased the number of uninsured, there are still 264,000 Minnesotans without health coverage, leaving them at risk for declining health and premature death," he says. "The rise of high-deductible policies is breaking family budgets and creating barriers to accessing needed health care. Additionally, the recent Supreme Court decision in Burwell versus Hobby Lobby illustrates the problems with our employment-based health insurance system." He notes that a provision of the ACA gives individual states the opportunity to apply for waivers from the federal law beginning in 2017. That is the year in which Vermont will launch its single-payer plan. "This is a big opportunity for Minnesota to get it right. As such, we expect that single-payer legislation will be introduced in our state Legislature in 2015," Dvorak says.

At this point, the MMA is not planning on supporting any single-payer legislation next session. "The goal of this forum is to really open up a dialogue, to educate, inform and generate discussion on the topic, both pro and con," Smith says.

News briefs

Thriving IN Change

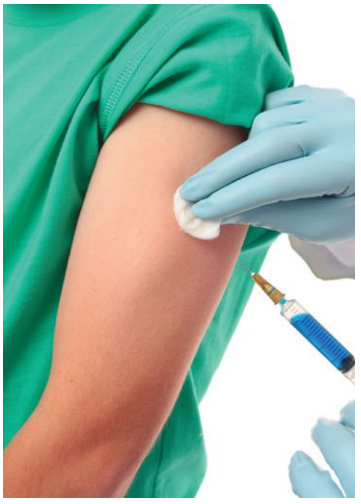
Meeting the challenges of modern medicine

Registration now open for 2014 Annual Conference

Physicians will have the opportunity to hear national and local speakers, earn 8.5 CME credits and participate in policy discussions at the MMA's 2014 Annual Conference, which takes place September 19 and 20 at Madden's on Gull Lake in Brainerd.

"Thriving in Change: Meeting the Challenges of Modern Medicine" will feature sessions on organizational, team and personal leadership; physician well-being; how to avoid burnout; and innovation and technology. It will also offer a lively gubernatorial debate and three MMA policy forums.

For more information and to register, visit www.mnmed.org/AC2014.



Stearns Benton campaign leads to fewer pertussis cases

A campaign to eliminate whooping cough in the St. Cloud area appears to be working, according to the Minnesota Department of Health.

The Central Minnesota Community Immunization Campaign kicked off in May 2013 with the goal of eliminating whooping cough by promoting the importance of vaccinations in Stearns and Benton counties.

In 2012, there were 165 cases of pertussis in those counties. In 2013, the number decreased nearly 50 percent to 84 cases.

A St. Cloud Walgreen's reported a 254 percent increase in the number of vaccinations given between the November prior to the campaign and the November after the launch. The Stearns Benton Medical Society helped fund nearly 20 percent of those vaccinations.

The campaign was created by several St. Cloud-area community partners that were brought together by the Stearns Benton Medical Society.

MMA members to decide new uses for state database

Roger Kathol, M.D.

MMA members Roger Kathol, M.D., and John Chandler, M.D., have been appointed to a work group that will explore new uses for the state's all-payer claims database.

The group will develop recommendations on the parameters for future allowable uses, the type of governing body that should guide the release of data, the type of funding or fee structure needed to support expanded use, and the sort of privacy and security protections that are needed. The group's report is due to the Legislature by February 1, 2015.

Kathol, also an MMA board member, is founder and president of Cartesian Solution, Inc. Chandler is chief health information officer for analytics and informatics at Hennepin County Medical Center.

MMA urges end to health care violence

The MMA, along with five other state health care organizations, is calling for making workplace violence prevention a top priority.

The coalition, which consists of the MMA, the Minnesota Department of Health, the Minnesota Hospital Association, Aging Services of Minnesota, Care Providers of Minnesota and the Minnesota Nurses Association, defines violence in health care as "behaviors including physical violence and threats that make employees, visitors, patients and residents concerned for their personal safety."

According to the Bureau of Labor Statistics, 81,000 health care industry workers nationally were assaulted during a 15-month

Upcoming MMA Events

Event	Date	Location
Single-Payer Forum	August 19	U of M, St. Paul campus
Annual Conference	September 19-20	Madden's on Gull Lake, Brainerd
Medical Malpractice Forum	October 2	TBD
Pre-Diabetes Conference	October 7	Ramada Plaza Minneapolis
Quality Measurement Summit	October 25	Double Tree by Hilton, Bloomington

Check the MMA's website (www.mnmed.org/events) for more information and to register.

period in 2003-2004 (the most recent data). Federal workplace injury data show that physicians, nurses and mental health workers are more likely than others to be assaulted on the job. The share of health care employees who missed work because of injuries caused intentionally by others was 6.5 per 10,000 workers in 2011—four times the overall U.S. rate.


Edward Ehlinger, M.D.

Forum examines health disparities in Minnesota

About 75 physicians, residents, medical students and public health workers gathered in St. Paul in mid-June to discuss Minnesota's health and health care disparities, and to help inform the MMA's efforts to encourage and support physician leadership in reducing disparities between racial and ethnic groups.

The event, titled "Closing the Gap: Addressing Minnesota's Health Disparities," featured keynote speaker Edward Ehlinger, M.D., Minnesota Commissioner of Health, and a panel of physicians who shared their perspectives on working with underserved and minority populations.

Ehlinger touted the health of the population overall and the quality of health care in the state, including Minnesota's ranking as one of the healthiest states in the nation. But he then added, "The good life of Minnesota is not being experienced by everybody," and provided disturbing data illustrating the gap between the health of the overall population and that of various minority groups. "We have some of the greatest disparities in the country when it comes to infant mortality," he said.

Ehlinger said that to begin to remedy the problem, the state needs to recognize disparities as unacceptable and make achieving health equity a goal. He called for health care, communities of color, social services, and political and corporate leaders to work together to achieve that goal. He talked about the multiple social determinants of health and noted that medical care is only part of the problem. "We can't treat our way to health equity," he said.

After Ehlinger's talk, Walter B. Franz III, M.D., of Mayo Clinic, Tamiko Morgan, M.D., FAAP, of Metropolitan Health Plan, and Shana Sniffen, M.D., of HealthEast Roselawn Clinic, shared their experiences and then answered audience questions.

Following the discussion, the MMA surveyed attendees about a number of topics. They found:

- About 70 percent said they were either confident or very confident that increasing the diversity of the physician workforce would help reduce health disparities.
- 42 percent said Minnesota physicians and other health care providers unfairly treat people based on their race somewhat often, 26 percent said it happens often often, and 13 percent said it happens very often.
- 47 percent said financial insecurity is the main barrier to improving racial/ethnic health disparities.

Member receives pediatric award

MMA member Daniel Broughton, M.D., FAAP, received the 2014 Distinguished Service Award from the Minnesota Chapter of the American Academy of Pediatrics (MNAAP) at the group's annual meeting in June.

Broughton, a past president of MNAAP, has been an advocate for abused and neglected children. He was a founding member and eventual chair of the board of directors for the National Center for Missing and Exploited Children. He was also instrumental in starting and became the medical director of the Mayo Clinic Children's Advocacy Center and Mayo Clinic Family Advocacy Program.

St. Cloud doctors unite to battle opioid abuse

Nearly 50 St. Cloud area physicians, pharmacists, nurses and community volunteers met in June to discuss the prescription opioid crisis. The event was sponsored by Stearns Benton Medical Society.

"It was a very good discussion," says Patrick Zook, M.D., president of the medical society. "The ultimate goal and prime motivation of the group is to develop community guidelines and policies for handling controlled substances."

During the meeting, participants broke into small groups to discuss the problem and how to address it as a community.


Patrick Zook, M.D.

They identified several factors that contribute to opioid abuse: inconsistent diagnosis and treatment, the inability to determine whether a patient is actually in pain, not being able to share records across systems and societal pressure to be 100 percent "pain free."

The group also discussed possible solutions to the problem including working toward consistency in prescribing, encouraging the use of the state's Prescription Monitoring Program, developing and sharing best practices, creating a contract that patients sign vowing not to abuse opioids, and not giving out prescriptions for opioids at the first visit.

The group plans to meet again in August.

MMA Foundation launches volunteer program

The MMA Foundation (MMAF) introduced its new Physician Volunteerism Program (PVP) in June.

"The program was created as a result of a survey of Minnesota physicians," says Dennis Kelly, MMAF CEO. "We received a lot of enthusiastic support for the idea of creating a volunteer resource specifically for physicians."

Nearly 70 percent of the 726 respondents indicated that they had already volunteered in some capacity during the last year, and more than 90 percent said they would volunteer if they could find the right opportunity. Respondents represented a range of specialties. Full-time, part-time and retired physicians were all represented in significant numbers, too.

After the physician survey, MMAF staff interviewed and surveyed community clinics and found they have a need for volunteer physicians and were willing to use the program as a resource to reach physician volunteers.

The MMAF is now testing the concept, working out bugs and trying to discover the most effective ways to attract potential volunteers to the program. During this pilot phase, the website features volunteer positions for primary care and a selection of other specialties at a limited number of community clinic sites in the Twin Cities.

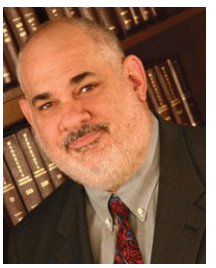
"With the learnings from the pilot phase, we will expand the program," Kelly says. "We expect the PVP to grow into a statewide resource for physicians, community clinics and others."

Read more about the program at www.mmafoundation.org/Making-a-Difference/Physician-Volunteerism-Program.

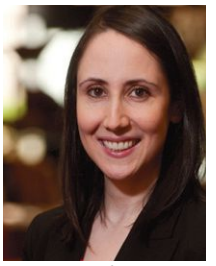

Cindy Firkins Smith, M.D.


Eric Dick


Janet Silversmith


Robert Meiches, M.D.


Teresa Knoedler


Juliana Milhofer

MMA in action

Cindy Firkins Smith, M.D., MMA president, and **Eric Dick**, MMA manager of state legislative affairs, attended a celebration of the passage of the Tan-Free Kids legislation in St. Paul in June. The event, sponsored by the American Cancer Society, honored the authors of the legislation, Rep. JoAnn Ward (DFL-Woodbury) and Sen. Chris Eaton (DFL-Brooklyn Center). Both the Minnesota Dermatological Society and the MMA were recognized as key partners in the successful effort to bar minors' access to artificial tanning facilities.

Dave Thorson, M.D., MMA board chair, and **Janet Silversmith**, MMA director of health policy, attended The Physicians Foundation Physician Leadership Academy at Duke University in North Carolina in mid-June.

Robert Meiches, M.D., MMA CEO, Silversmith, Dick, **Teresa Knoedler**, J.D., MMA policy counsel, **Juliana Milhofer**, MMA policy analyst and **Barbara Daiker**, MMA manager of quality, met in early July with staff from the Minnesota Hospital Association to talk about post-session follow-up, the all-payer claims database work group, the health care workforce and other issues.

Daiker represented MMA at the Minnesota Department of Health public hearing on the Statewide Quality Reporting and Measurement System measures for 2015 in late June in St. Paul.

In mid-June, **Terry Ruane**, MMA director of membership, marketing and communications, **Brian Strub**, MMA manager of physician outreach, and **Evelyn Clark**, MMA manager of grassroots and political engagement, exhibited at the University of Minnesota's resident and fellow orientation day in the Mayo Auditorium on the Minneapolis campus. The trio discussed the value of the MMA and the programs it offers residents. Ruane and Strub also exhibited at the University of Minnesota Family Medicine resident orientation on the university's St. Paul campus.

Mandy Rubenstein, MMA manager of physician outreach, represented the MMA at the Stearns Benton Medical Society's event on "Bringing our Community Together—Solutions to the Opioid Crisis" in late June.

VIEWPOINT

A lot at stake

PHOTO BY STEVE WEWERKA

Dave Thorson, M.D.
MMA Board Chair

Mid-term elections rarely get the attention they deserve. When the president is not on the ballot, many voters, unfortunately, choose to stay home. But every election is important for physicians—especially when more and more nonclinicians want to have a say in how health care should be practiced in this state.

This November, voters will decide who will be governor for the next four years as well as who will fill each seat in the state's House of Representatives.

Most health care issues don't fall into partisan buckets, so I'm not advocating for siding with red or blue here. Rather, I'm asking you to just get involved. Study the candidates, and then vote for the one who supports your values in medicine during the primary on August 12 and in the general election on November 4. Think of the big picture. Avoid focusing on one particular issue.

The candidates we elect in November will be working on a new biennial budget next year. At this point, we don't know whether the state will have a surplus or deficit. But we do know that funding for Health and Human Services makes up one-third of the budget and includes Medical Assistance reimbursements, which have not adequately covered the cost of much of the care we provide.

In addition to the budget, candidates who are elected will be debating several other issues that all physicians should care about—one of which is how we produce the future physician workforce through medical school and residency programs. We must find innovative ways to train more doctors in order to prevent a projected primary care physician shortage.

We also need to make sure the 2 percent provider tax repeal stays in place because, believe me, many of these candidates will be eyeing the funds collected through that tax as a potential pot of gold to mine for their projects.

We'd also like to remind these candidates that they need to pass legislation that gives us the tools we need to do a better job of coordinating care (something I wrote about in the February 2014 issue of *Minnesota Medicine*). Currently, we are one of only two states with health privacy laws that are not aligned with the Health Insurance Portability and Accountability Act. We need to be able to access data from other clinics and hospitals to better care for patients.

Other health care-related issues will arise that we can't anticipate today. That's why we need to support pro-medicine candidates in November.

I'm asking you to get involved. Study up on the candidates. Decide who best represents your views on health care. Another option is to contribute to MEDPAC, the MMA's political action committee.

To influence the debate in St. Paul, physicians must be engaged even earlier—while politicians are on the campaign trail. We enjoyed tremendous successes during the 2014 session, but we shouldn't become complacent.

Please take the time to get involved. As physicians, we have an obligation to advocate for what's best for the profession and our patients. And that begins at the ballot box.

Most health care issues don't fall into partisan buckets, so I'm not advocating for siding with red or blue here. Rather, I'm asking you to just get involved.

The Patient Experience

Mining the Data to Improve Your Score

BY BARBARA DAIKER, PH.D., R.N.

As part of Minnesota's 2008 health care reform legislation, the Minnesota Department of Health was required to identify a standard set of measures of clinics' and physicians' quality, one of which was patient experience. In 2012, the first statewide patient experience survey was conducted. The results were made public the following year. This article discusses how clinics and physician groups can use the data from the survey to improve their patient experience scores.

There are certain truths that occur to us, which we cannot convey in words, but requires a personal experience to grasp more vividly.—MICHAEL BASSEY JOHNSON

Mrs. Thompson arrives at her clinic 20 minutes early for her appointment, as she does every time she goes to the doctor. She doesn't want to keep him waiting or risk not seeing him because she is late. Arriving on time is important to Mrs. Thompson. When she stops at the clinic's front desk, she is handed a number of forms. She is told to initial here, sign there and check the appropriate boxes. She does as she is instructed, although she really doesn't understand what she is signing. Mrs. Thompson has been a patient at this clinic for 10 years, and she trusts that everything is in order. But as she waits for her appointment, she is nervous. She wonders if there will be a surprise or something unexpected. You never know; everything can seem fine and then it isn't.

This scenario isn't unusual or problematic, but it's important, as it describes Mrs. Thompson's experience. We are beginning to recognize that patient experience indicates the quality of a clinic and the physicians who work there.

Many clinics have long collected patient satisfaction data, sharing the information internally with the physicians and other staff. As part of the 2008 health care reform legislation, the Minnesota Department of Health was required to identify a standard set of quality measures for health care providers and created the Minnesota Statewide Quality Reporting and Measurement System (SQRMS). Among the measures was "patient experience of care."

Medical practices first collected data for this measure in 2012 using the Clinician and Group Consumer Assessment of Healthcare Providers and Systems survey (CG-CAHPS). Each had to survey patients ages 18 and older who had a face-to-face visit at the clinic between September 1, 2012, and November 30, 2012. It was the largest statewide patient experience survey ever done in the United States, with more than 230,000 surveys completed.[1] Although the results showed patients were generally happy with their clinic experiences, variations in performance were evident. The findings were posted on the MN Community Measurement website (mnhealthscores.org).

In addition to patients using this information to select providers, two payers—HealthPartners and the state of Minnesota (Medical Assistance and MinnnesotaCare)—are now using patient experience findings in their pay-for-performance metrics. A pay-for-performance metric in a contract means that a clinic can get financial rewards for reaching certain levels

or achieving specific goals. The patient experience survey is also required for accountable care organizations (ACOs) certified by the Centers for Medicare and Medicaid Services. Currently, physicians and clinics are not penalized for lower performance, but that could happen in the future.

Physicians and clinics who want to improve their performance can use the information as well. There is still time to institute changes in an effort to improve your scores before the next survey takes place (starting September 1 and ending November 30, 2014). The challenge is to pick one that will be meaningful.

What is Patient Experience?

In many cases, the terms "patient satisfaction" and "patient experience" are used interchangeably. Both are based on patients' perceptions of their medical visit. British researchers Salisbury, Wallace and Montgomery differentiate satisfaction from experience, stating that satisfaction rates the care and experience is the sum of the interactions.[2] These concepts have subtle differences. For example, if Mrs. Thompson is seeing her ophthalmologist for chronic blepharitis and her physician's recommendation relieves her symptoms, she is satisfied. But if her physician made her wait too long and then didn't seem to know her history, Mrs. Thompson might say she had a poor experience. The concepts of satisfaction and experience are interconnected and nonlinear. Satisfaction influences a patient's experience and vice versa. Patients view medical visits through a filter of their previous experiences and their expectations.

How patient experience relates to patient outcomes is not clear, but experience and outcomes are related. A 2010 study by Glickman and colleagues that looked at patient satisfaction, guideline adherence and changes in predicted survival for acute myocardial infarction patients[3] found a strong relationship between higher satisfaction scores and lower risk-adjusted inpatient mortality rates. It suggests that a patient's assessment of the care they receive provides important and valid information about the overall quality of their care. In the same study, there was no relationship between satisfaction and the facility; satisfaction is not about the building and waiting room.[3] This research needs to be replicated and tested in the ambulatory setting.

Improving Your Score

Understanding your own patient experience score is the first step toward improving it. When looking at your score, the first thing to note is that the results are in four categories: getting care when needed (access), communication, courteous and helpful staff, and overall rating of the physician. What MN Community Measurement presents on its website is only a glimpse into your data.

In order to identify improvements you can make, you will need to obtain the raw data from your patient experience survey. This likely will require you to contact the vendor who helped you implement the CG-CAHPS survey. Some practices have found that their 2012 vendor contracts do not allow them to obtain raw data unless they pay a fee. As you are contracting for the 2014 data collection, make sure you understand whether you will have access to the information in the future.

Once you have the raw data, you can open it in a spreadsheet, even if it comes in a comma-separated value (CSV) file format. In a CSV file, each patient will have a row and his or her answers to questions will be placed in columns. Sometimes the headings for the columns are coded. The vendor will be able to give you the key to those codes, as well as the codes used for the survey answers. With the data and the key to the codes, you can look at your performance according to patient demographics, clinic demographics and other differentiating factors. For example, you can look at how patients rate your wait time by their age, gender, ethnicity, perception of health, whether they are new vs. established patients and many more characteristics. Looking at the data in this way will allow you to identify differences among subgroups of patients. In some cases, you will have explanations for a low score. For example, if a very popular physician has cut her hours as she prepares for retirement, patients may have difficulty getting an appointment in their desired time frame and thus give a lower score. When you do not have an explanation, the data opens the possibility to explore ways to improve care.

If your clinic's experience rating is lower than expected, you can identify possible reasons and test your hypotheses. In an analysis of survey data from two different clinics, we found that patients who rated their health as "poor" when asked "In general, how would you rate your overall health? Excellent, very good, good, fair, or poor" also rated communication with/from the clinic staff lower than patients who gave their health a better rating. The clinics came up with some possible explanations:

- The patients who rated their health as "poor" may have had higher expectations because they have had more experience with health care providers.
- They may have brought a number of problems to the visit and felt they were not being addressed.
- They may have been less able to comprehend what was being said because they were not feeling well.

The clinics could test these hypotheses by making changes and asking patients the same CG-CAHPS questions about communication to see if they're working.

The two clinics are now identifying the patients with poor health at the beginning of the clinic visit and modifying the way they communicate with those patients.

The raw data from the survey also can be used to answer specific questions. These questions might be about satisfaction among different subsets of patients, but they also can relate to long-standing concerns. Maybe you have wondered if patients who have to wait for certain physicians are experiencing better communication than those whose physicians stay on schedule. Are they getting more time with the physician? Do they understand the reason for a delay in the schedule? Are the patients who are new to the practice experiencing the same level of communication as established patients? Answers to these questions can be found in your survey results.

Conclusion

Patient experience is a key aspect of quality, as it can influence outcomes. Data about patient experience also are important to accountable care organizations, integrated health partnerships and pay for performance programs.

The state of Minnesota does not provide guidance or support to physicians who wish to improve their patient experience ratings—that is up to you and your organization. The window of time before the next survey is closing. But there is still time to make changes in your practice that could result in an improved patient experience score. The challenge is to use the data from the previous survey to prioritize your efforts. **MM**

Barbara Daiker is the Minnesota Medical Association's manager of quality improvement.

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Teaching Patients to Protect Themselves during Care Transitions

A Patient Safety Campaign

BY MARIE DOTSETH

Patient safety can be compromised at any time, but a disproportionate number of problems occur when patients are transitioning between care settings and care providers. Therefore, those trying to improve patient safety need to focus particular attention on times of transition. This article describes a public education campaign to change patients' behaviors during those periods.

Threats to patient safety can occur any time, but a disproportionate number come up during care transitions such as when patients move from the hospital to home or from home to a nursing facility or when care is transferred from a patient's primary care physician to a specialist.

During transitions, communication between the patient and/or caregiver and clinician or among clinicians can easily break down. As a result, the patient and/or caregiver may not understand the patient's condition or may be confused about his or her treatment needs. In addition, an estimated 60% of medication errors, in which a patient takes the wrong medication or the wrong dose or the right medication at the wrong time, occur during times of transition.[1] And about one in five (19%) patients has an adverse event following discharge from a hospital, with an estimated 61% of those events happening because of inadequate communication with the physician who is to provide follow-up care.[2]

These miscues can be costly on both a human and financial level. Failures of care coordination cost an estimated $35 billion per year. Overtreatment, which often results from lack of coordination, costs about $192 billion per year.[3]

Both clinicians and patients contribute to safety-related problems that occur during transitions. Clinicians may not share information with other clinicians. A study of referrals by 122 pediatricians in 34 states found that no information was sent to the specialist in 49% of cases, and the referring physician received feedback from the specialist only 55% of the time.[4]

Physicians also may not do a good job of sharing information with patients. According to a study by Boohaker, 75% of the time physicians don't routinely contact patients about their test results, and 33% of the time they don't notify patients of abnormal results.[5]

Patients contribute to the problem as well, as many do not follow clinical recommendations. A study from the Northeastern Ohio Network found 14% of patients never make recommended appointments with specialists.[6] In addition, about 31% of prescriptions go unfilled.[7] Finally, patients often don't monitor or promptly address warning signs associated with their conditions.

Patients are uniquely positioned to improve communication between themselves and members of their health care team. After all, they have a comprehensive view of their own health and medical history: They know their symptoms and diagnoses, what tests they have had, the medications they are taking and treatments they have undergone, their preferences, and any complications they have experienced. If engaged in their own care, patients could help improve care coordination by sharing information about the medications they are taking, test results and their health histories with their physician and other providers.

Why Aren't Patients More Engaged?

Members of the Minnesota Alliance for Patient Safety (MAPS), which is dedicated to improving patient safety across all care settings, and its partners recently wondered why patients weren't doing more to coordinate their own care. So we asked them.

We hired a firm to conduct online conversions with a group of 100 patients from across the state who have chronic conditions including high blood pressure, heart disease, type 2 diabetes and high cholesterol. In online chat rooms that were open 24 hours a day over five days, participants were asked a number of questions, including these: What is your sense of the patient's role in coordinating medical care? Why aren't you more active in documenting and sharing medication lists and test results? What would you think if you were asked to take a more active role in coordinating your health care? Participants were

encouraged to share their thoughts with the facilitator as well as with each other.

Here are some things we learned from those discussions:

- **Patients perceive that little is expected of them**. When it comes to care coordination, many patients believe it's not their job. They say they aren't told to do more to coordinate their own care, so they believe doing more is unnecessary. They believe that their care management responsibilities are modest to nonexistent, particularly when it comes to gathering and sharing test results with members of their health care team.
- **Patients have a false sense of security**. Many patients feel "the health care system" is meeting every one of their care coordination needs, making patient-driven coordination unnecessary. Extensive marketing about the benefits of electronic medical records in care coordination as well as the traditional "trust your doctor" culture inform this conclusion.
- **Patients need specific instructions.** Another reason patients aren't more engaged is because they aren't sure what they can do. Simply encouraging them to "get more engaged" is not enough. Many patients in our focus group indicated that they are willing to do more to prevent safety problems, but they need clearly defined and articulated instructions about what to do.
- **Patients are drowning in information.** Yet another reason patients aren't sufficiently engaged is because they don't comprehend the information they receive about their condition or their discharge instructions. This shouldn't be surprising, given that patients being discharged from the hospital are handed on average 70 pages of instructions.[8] Patients told us that they want jargon-free materials that they can quickly and easily read and understand.

A Campaign to Engage Patients

Using grant funding from the Minnesota Hospital Association, we are incorporating what we learned from the focus group into a patient engagement campaign called You: Your Own Best Medicine (www.ownbestmedicine.mn). The goal of the campaign is to educate patients about how they can reduce their risk during care transitions. It uses best practices identified by a MAPS Advisory Committee.

As the name indicates, the campaign encourages patients to play a central role in their own care and help their health care team help them. This message is new for many patients who sometimes feel as if the health care system wants them to be compliant, rather participate in their care.

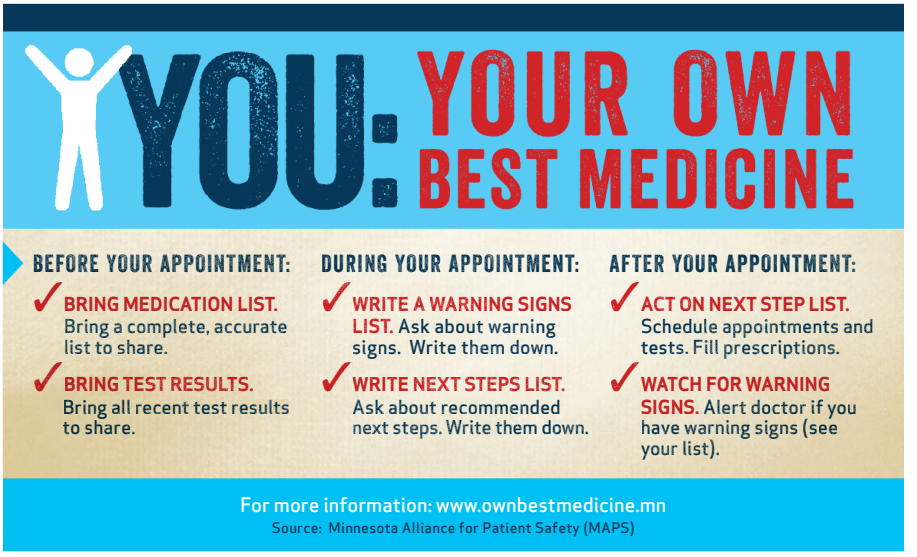
The centerpiece of the campaign is a brief to-do list with four tasks:

1. Maintain a medications list and continually share it with your health care team.
2. Collect and save test results and continually share them with your health care team.
3. Ask your caregiver about warning signs associated with your condition, monitor them and promptly act on any problems you may experience.
4. Promptly follow up on your health care team's recommended next steps after each appointment or encounter.

These tasks are brief, clear and specific (the patients surveyed emphasized the importance of this). The list can be used to supplement the more detailed information providers are often required to give patients.

FIGURE

The Label on the Patient Safety Packets



MAPS has created patient safety packets, which are currently being given to individuals at 11 sites (see box). The packets provide them with a pen and paper and a template for creating a medication list.

They also include a bright red expandable folder with a label on it to encourage them to develop the new habit of keeping all of their test results in one place (Figure). In addition, the packets contain a refrigerator magnet and stickers reminding them of the items on the to-do list. In the coming months, MAPS will make available a smartphone app, which will send users reminders and help them keep their medication list, follow-up instructions and test results organized and readily available. MAPS also will launch a radio and print advertising campaign to educate the public about the importance of being engaged in your own health care.

The folders, pens, tablets, magnets, stickers and smartphone app not only are practical tools, they also send a message: "If my caregiver is taking the time to actually give me all of these tools, I guess my involvement is important and expected."

Patient Empowerment Focus Needed

The Own Best Medicine campaign is very much in its infancy. Results from the test of the patient safety kits will be evaluated this fall. If the packets yield the desired

results, they could be used by other health care providers in the future. Regardless of what we learn through our study, empowering patients to better understand and become involved in their care will continue to be a focus of MAPS. Both clinicians and patients play important roles in preventing expensive and tragic problems. We cannot ignore the need for patient engagement. **MM**

Marie Dotseth is the executive director of the Minnesota Alliance for Patient Safety.

Organizations testing the MAPS patient safety packets

Arrowhead Area Agency on Aging, Duluth
Cambridge Medical Center Behavioral Health Unit, Cambridge
Central Minnesota Council on Aging, St. Cloud
The Colony at Eden Prairie Senior Living, Eden Prairie
Essentia Health—St. Joseph's Medical Center, Brainerd
Fairview Lakes Medical Center, Wyoming
Glacial Ridge Health System, Glenwood
Land of the Dancing Sky Area Agency on Aging, Warren
Metropolitan Area Agency on Aging, North St. Paul
Minnesota River Area Agency on Aging, Mankato
Southeastern Minnesota Area Agency on Aging, Rochester

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Pediatric Emergency Care in Minnesota

It's Time to Bring Up Our Grade

BY PAULA FINK KOCKEN, M.D.

The National Pediatric Readiness Project is a partnership of Emergency Medical Services for Children, the American Academy of Pediatrics, the American College of Emergency Physicians and the Emergency Nurses Association. The first phase of the project, a national assessment of hospitals' ability to treat children with emergent needs—both illnesses and injuries—was completed in July 2013. All Minnesota hospitals providing care for children responded. The overall score for Minnesota was 63, six points lower than the national overall score. This article explains what was assessed, why Minnesota's results may be sub-par and what hospitals need to do to become "peds ready."

Case 1. *It is 1 a.m., and you are on call for your group when you get a call from a woman whose 2-month-old daughter has had a fever all day. The girl is now listless and does not want her bottle. You advise the mom to quickly get her to the nearest hospital for an evaluation. The family lives in northwestern Minnesota. Will the local hospital be able to evaluate, stabilize and treat this patient?*

Case 2. *It is 4 p.m. on a cold February day in central Minnesota. It has been snowing since noon, and the roads are getting slick. You get a call from the hospital informing you that a school bus has slid off the road and many injured children are being taken to the emergency department. You are asked to come in and help treat these children. Will the rural hospital be able to handle a busload of injured students? Does it have enough appropriately sized equipment to treat the victims? How will the staff organize the surge of patients?*

Case 3. *You are driving along the Gunflint Trail. You see a car accident with several victims and stop to help. One is a child who has chest trauma and is having trouble breathing. An ambulance arrives and takes the child to the nearest hospital. Will the staff be able to stabilize and treat or transfer the child if needed?*

Are these hospitals ready for these cases? Do they have the "right stuff" to handle pediatric emergencies? Do their staffs have the right training and protocols for treating children?

Ensuring that hospitals can handle situations such as the ones described is the focus of the National Pediatric Readiness Project, a nationwide multiphase quality-improvement initiative designed to ensure that all U.S. emergency departments (EDs) have the plans and resources in place to provide effective emergency care to children. The project is a partnership among the Emergency Medical Services for Children (EMSC), the American Academy of Pediatrics, the American College of Emergency Physicians and the Emergency Nurses Association. It also has received support from the Joint Commission, the Healthcare Corporation of America and other organizations.

Why the Focus on Pediatric Readiness

Children younger than 18 years of age account for about 25% of all visits to emergency departments in the United States.[1] Most of those children are in communities far from major medical centers or specialized pediatric hospitals.[1]

Concern about whether hospital EDs were equipped and ready to treat sick or injured children grew after a 2003 survey on pediatric readiness showed that only 55% of all EDs in the United States were indeed ready and able to do so.[2] The 2006 Institute of Medicine report "Emergency Care for Children: Growing Pains" further spotlighted the need for improvement in pediatric emergency care.[3] Summarizing the situation, its authors wrote: "For decades, policy makers and providers have recognized the special needs of children, but the emergency and trauma care system has been slow to develop an adequate response to those needs." The report highlighted three areas of need: disaster preparedness, pediatric training and research/data collection.[2]

Pediatric emergency care has been recognized as an area of concern in Minnesota since 2006. The statewide trauma system, which was established in 2005, improved our ability to get injured kids to definitive care quicker. But questions about the quality of pediatric care in EDs remained.

Emergency Medical Services for Children (EMSC) of Minnesota has led the state's work on pediatric readiness, pulling together nurses, physicians and trauma coordinators from the major trauma and pediatric centers in the state. EMSC of

Minnesota facilitated Minnesota's involvement in the National Pediatric Readiness Project.

The National Assessment

The first phase of the National Pediatric Readiness Project was to evaluate pediatric readiness in hospitals across the nation. A total of 5,017 facilities with EDs that care for children were assessed. These included children's hospitals, community-based hospitals, military hospitals and freestanding EDs. The assessment was completed in August of 2013.

The questionnaire, which was comprehensive and lengthy, was to be filled out by a hospital representative (often the ED manager). It assessed the EDs in six areas: administration and coordination; competency of physicians and other providers; quality- and process-improvement efforts; patient safety; policies, procedures and protocols; and equipment, supplies and medications. Each hospital could earn a maximum of 100 points. Scores were made available to hospitals upon completion of the questionnaire.

Eighty-three percent of the nation's hospitals responded. The national overall readiness score was 69, meaning on average, hospitals in the United States have 69% of the suggested staff, plans, and equipment and medications in place to adequately care for very sick or injured children. Clearly, there is room for improvement.

TABLE 1

Minnesota Average Scores Compared with National Average Scores

ASSESSMENT SECTION *(possible points)*	MINNESOTA	NATIONAL
Administration and coordination *(19)*	9.6	10.1
Competency of ED staff *(10)*	3.2	5.3
Quality improvement/process improvement *(7)*	2.0	2.9
Patient safety *(14)*	10.4	10.8
Policies, procedures and protocols *(17)*	9.0	10.5
Equipment, supplies and medications *(33)*	28.8	29.4
Overall score *(100)*	63	69

Source: National Pediatric Readiness Project (http://pediatricreadiness.org/)

Minnesota's Readiness

The good news for Minnesota is that 100% of eligible hospitals and EDs in our state participated in the national assessment. The bad news is that Minnesota's overall readiness score, 63, was below the national overall score (Table 1). It should be noted that scores varied by region (Table 2) and there was variability within regions as well. For example, in the metro region, scores ranged from 40 to 100.

So why did the state, which considers itself to be "above average" in so many areas, score below the national average on pediatric readiness? There are several possible explanations. One is simply that the wrong person may have filled out the assessment in some cases. Although EMSC staff attempted to have the individual with the most knowledge about the ED (typically nurse managers or trauma coordinators) complete the assessment, some may have delegated the task to another person on staff, and that person may have incorrectly answered certain questions.

Another possible reason for Minnesota's low score is the fact that many ED staff in Minnesota are trained in Comprehensive Advanced Life Support (CALS). CALS addresses the care of pediatric patients but is not nationally recognized like Pediatric Advanced Life Support and other similar courses. Therefore, the assessors may not have given credit for CALS training and scored Minnesota EDs lower on staff competency.

Such factors, however, do not entirely explain our low score, and it is clear we have deficits. The biggest problem Minnesota EDs had was not having guidelines in place for administration and coordination of care for ill and injured children. Simple policies, such as weighing every child in kilograms rather than pounds and notifying caregivers of abnormal vital signs, are missing from many of them. In addition, many hospitals lack protocols for such things as handling suspected child abuse. Guidelines for quality assurance and performance improvement relating to

TABLE 2

Summary of Average Scores by Region

	Central	Metro	NE	NW	South Central	SE	SW	West Central
Coordination	9.5	10.3	11.9	7.3	8.7	12.7	9.9	3.2
Staffing	4.3	5.6	3.1	2.3	1.7	4.2	1.7	0.6
QI/PI	1.5	3.5	1.5	0.8	1.5	2.6	2.4	1.2
Safety	9.8	12.2	10.2	9.5	10.2	12.0	9.7	8.1
Policies	9.3	11.9	8.3	6.8	9.3	10.7	8.2	6.2
Equipment	30.1	31	28.7	28.6	26.2	30.0	27.3	27.0
Overall Score	65	75	64	55	58	72	59	46

Source: National Pediatric Readiness Project (http:/pediatricreadiness.org/)

pediatric patients are also lacking in some hospitals. Hospitals with low pediatric volumes had the lowest scores in this area may lack the resources they need to focus on these issues.

Going Forward

With the assessment complete, it is time to work on improving the quality of pediatric emergency care in the state. As a first step, hospitals should identify a staff person who will champion pediatric readiness. Often, it takes only one committed nurse, physician, physician assistant, nurse practitioner or emergency medical technician, who can focus on advancing the care of children in the ED, to begin the improvement process. The next step is to examine the deficits highlighted by the assessment. Then the pediatric "point person" can begin to work on such things as developing protocols, getting staff educated and initiating reviews of pediatric cases.

A number of resources are available to help that person. Templates for protocols can be easily downloaded from the EMSC website (www.emscnrc.org/EMSC_Resources). Experts from the state's pediatric trauma centers can be brought in to train staff or lead case reviews. In addition, representatives from EMSC of Minnesota will be meeting with each region's trauma advisory committee about issues identified through the assessment. As of July, EMSC representatives had visited five communities and planned to visit a sixth by the end of the year. At these meetings, staff explain the results and describe how to improve the emergent care of children.

The medical advisors from EMSC of Minnesota are also creating a shorter Minnesota-specific assessment that will focus on what they consider to be the most important aspects of pediatric emergency preparedness. This more specific evaluation will help them as they advise EDs and facilitate improvements in care.

Picturing Peds-Ready Care

The goal of these efforts is to have all hospitals in Minnesota ready and able to provide excellent pediatric emergency care—that their staffs are trained, their emergency departments have appropriate equipment for babies and children, and protocols for care and transfer of care are in place.

What might such care look like? In Case 1, the infant would have been seen in the ED immediately and recognized as being very ill. The ED staff would have quickly assessed her vital signs, including taking her temperature using a rectal thermometer. The physician assistant on duty, concerned about the baby's poor tone and lethargy, would have had the nurse place an IV to give fluids and obtained blood for laboratory tests. She would have called the referral hospital to arrange for transfer and asked for advice regarding treatment of the patient. The ambulance would have arrived and transported the child to the regional referral hospital.

In Case 2, the nurse manager at the rural hospital would have remembered the discussion from two months ago on "pediatric surge" and printed out the protocol on how to handle a large number of injured children. He would have asked an administrative assistant to contact the on-call nurses and other providers about helping with the incoming patients. He would have set up a triage area at the ED entrance and divided the ED and clinic area into zones of high, medium and low acuity. He would have told the staff to ready the pediatric equipment and the length-based treatment tapes.

In Case 3, the emergency responders would have radioed the local hospital, advising them that they were bringing in a child who may have a pneumothorax. The ED staff would have pulled out the pediatric equipment and called the helicopter dispatch, knowing that the child would need to be transferred after being stabilized. When the child arrived, the nurse in the ED would have used the length-based tape to determine the size of equipment needed and the physician would have recognized that the child had a tension pneumothorax. Recalling a similar scenario during her CALS course, she would have "needled" the child's chest so that the child's respiratory distress would improve. The helicopter would have arrived and transported the child to a hospital in Duluth.

As these scenarios show, all hospitals in Minnesota can deliver high-quality emergency care. Now that hospitals know where their deficits with regard to pediatric emergency care lie, they can begin taking the steps to improve. There is much we can do now to ensure that next time we are assessed for pediatric emergency readiness, our score will be very far above average. **MM**

Paula Fink Kocken is a pediatric emergency medicine physician at Children's Hospitals and Clinics of Minnesota and medical director of Emergency Medical Services for Children of Minnesota.

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For more information

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Minnesota Medical Association

Comparative Effectiveness Research in Clinical Practice

BY WILLIAM F. LAWRENCE, M.D., M.S., STEPHANIE CHANG, M.D., M.P.H., ROBERT L. KANE, M.D., AND TIMOTHY J. WILT, M.D., M.P.H.

The Agency for Healthcare Research and Quality (AHRQ) has funded systematic reviews of comparative effectiveness research in 17 areas over the last 10 years as part of a federal mandate. These reviews provide a reliable and unbiased source of comprehensive information about the effectiveness and risks of treatment alternatives for patients and clinicians. This article describes comparative effectiveness research, provides an overview of how physicians can use it in clinical practice, and references important contributions made by the Minnesota Evidence-based Practice Center.

Given the growing volume of medical literature, it has become increasingly difficult for clinicians to keep up with what's current and easy for them to miss relevant studies, potentially leading to a biased view of the available research.[1] One strategy for keeping up with the literature is to read systematic reviews, in which the evidence on various topics is synthesized. Of particular relevance to clinicians are studies on the effectiveness and risks of treatment alternatives and outcomes in "real-world" settings. Such research has come to be called "comparative effectiveness research."

Systematic reviews of comparative effectiveness research (also known as comparative effectiveness reviews) are important, as the results of an individual study are rarely sufficient for decision-making. Over the past 10 years, the Agency for Healthcare Research and Quality (AHRQ) has funded the systematic review of comparative effectiveness research in 17 areas (Table 1). These reviews provide a reliable and unbiased source of comprehensive information on topics for patients and physicians in clinical practice. Some of this work has been conducted in Minnesota by the Minnesota Evidence-Based Practice Center, one of 11 AHRQ-supported research centers that produce comparative effectiveness reviews or effectiveness reviews on medications, devices and other health care services. The evidence-based practice centers are funded by the Patient-Centered Outcomes Research Trust Fund, a revenue source established by the Patient Protection and Affordable Care Act of 2010. The Minnesota center is a collaborative venture of the University of Minnesota School of Public Health and the Minneapolis VA Health Care System.

What is Comparative Effectiveness Research?

Definitions of comparative effectiveness research have been put forth by several organizations, including the Institute of Medicine and the Federal Coordinating Council for Comparative Effectiveness Research, which was established under the American Recovery and Reinvestment Act of 2009. Although definitions vary, comparative effectiveness research is characterized by several attributes: 1) Its goal is to inform decisions about health care; 2) it compares both the benefits and harms of interventions and tests; 3) it evaluates outcomes in real-world patients and settings and emphasizes outcomes that matter to patients; and 4) it considers the effect of interventions on subgroups that may have heterogeneous outcomes.[2-4]

The AHRQ was the first federal agency with a legislative mandate to conduct such research through its Effective Health Care Program. Section 1013 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 directed AHRQ to support research with a focus on outcomes; comparative clinical effectiveness; and appropriateness of pharmaceuticals, devices and health care services.[5]

The teams that develop comparative effectiveness systematic reviews typically include a project manager (a Ph.D.-level researcher who is responsible for leading the research review and writing the bulk of the report on it), one or more clinical experts who know the topic, research assistants and a project director who provides general oversight. These teams are supported by a panel of technical content experts who provide insights and advice at various stages.

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Free summaries of research reviews from the Agency for Healthcare Research and Quality's Effective Health Care Program are available online and in print. (Printed summaries are available in bulk quantities.) Continuing medical education modules, downloadable slide presentations and other evidence-based resources for clinicians are also offered. For more information, go to www.effectivehealthcare.ahrq.gov or call 800/358-9295.

TABLE 1

The 17 Systematic Review Priority Areas

Brain and nerve conditions
Breathing conditions
Cancer
Developmental delays, ADHD, autism
Diabetes
Digestive system conditions
Genitourinary conditions
Gynecology
Heart and blood vessel conditions
Infectious disease and HIV/AIDs
Mental health
Muscle, bone and joint conditions
Nonclinical topics
Obesity
Ophthalmologic conditions
Pregnancy and childbirth
Renal disease

Once a topic is identified and assigned to a team, the team refines it and develops key questions that form the basis for the review. This involves consulting a broad range of stakeholders to be sure that the answers to the questions will provide useful information and that the questions are formulated in a way that they can be reasonably answered with the resources available. The team then searches various databases to identify potentially relevant articles and winnows those down to a few by reviewing abstracts and/or the original articles. Selected articles are abstracted and the data summarized. Each study is assessed for risk of bias and strength of evidence for each major outcome. The reports identify what is known and the confidence that can be placed in the knowledge that is currently available. Gaps in knowledge form the basis for recommendations for future research; however, a primary goal of these reviews is to provide actionable information to assist clinicians and policy makers.

Clinician and Patient Resources

Since 2005, AHRQ's Effective Health Care Program has completed more than 140 reviews, which compare treatments and testing options on clinical conditions ranging from diabetes to cancer to depression. To encourage the use of the evidence in those reports in shared decision-making between clinician and patients, AHRQ packages the information in brief, practical summaries. Summaries for consumers provide useful background information on health conditions as well as plain-language information about the benefits and harms of treatment alternatives. Summaries for clinicians provide more detailed scientific information, a "Clinical Bottom Line" on the report's findings, and a rating of the strength of the evidence behind the reports' conclusions. The research summaries are not clinical recommendations or guidelines and should not be interpreted as such; rather, they are intended to inform decision making while allowing for individual choices. Table 2 lists some examples of research summaries that have been completed.

These reviews and others are used for a variety of purposes. More than 600 organizations representing practicing clinicians, consumers, researchers, public health professionals and others have signed on to help promote the use of research summaries and other offerings from the AHRQ's Effective Health Care Program. More than 40,000 clinicians have earned continuing education credit by completing modules based on the reviews. In addition, more than 4 million Effective Health Care Program publications have been distributed to patients at health fairs and through grocery and pharmacy chains and to clinicians at professional meetings.

Comparative Effectiveness Research in Minnesota

The Minnesota Evidence-Based Practice Center has made important contributions to AHRQ's growing inventory of resources and tools. Funded since 2002, the Minnesota center has conducted more than 40 systematic reviews on a variety of topics and has received funding to conduct comparative effectiveness reviews in the area of disabilities. Among the topics studied are long-term care for older adults, treatment for restless legs syndrome, migraine in children and adults, physical therapy for knee pain secondary to osteoarthritis, and nonsurgical treatments for urinary incontinence in adult women. (For more information, go to www.mnepc.org.)

Some of the reviews compiled by the Minnesota center have been used to inform clinical practice guidelines. Among those are:

- Recurrent Nephrolithiasis in Adults: Comparative Effectiveness Review of Medical Preventive Strategies (July

TABLE 2

Examples of Research Summaries

Comparative Effectiveness of Diagnosis and Treatment of Obstructive Sleep Apnea in Adults

Attention Deficit Hyperactivity Disorder in Children and Adolescents

Insulin Delivery and Glucose Monitoring Methods for Diabetes Mellitus: Comparative Effectiveness

Managing Chronic Gastroesophageal Reflux Disease

Recurrent Nephrolithiasis in Adults: Comparative Effectiveness of Preventive Medical Strategies

ACEIs, ARBs or DRI for Adults with Hypertension

Comparative Effectiveness of Treatments for Chronic Hepatitis C Virus Infection in Adults

Treatment for Depression After Unsatisfactory Response to SSRIs in Adults and Adolescents

Effectiveness of Outpatient Case Management for Adults With Medical Illness and Complex Care Needs

Childhood Obesity Prevention Programs: Comparative Effectiveness

Comparisons of Medical, Laser and Incisional Surgical Treatments for Open-Angle Glaucoma in Adults

Progestogens for Prevention of Preterm Birth

Management of Chronic Kidney Disease Stages 1–3

2012), which was used by the American College of Physicians and American Urological Association to inform clinical practice guidelines for their professional societies

- Nonsurgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness (April 2012), which was used by the American College of Physicians
- Chronic Kidney Disease Stages 1-3: Screening, Monitoring and Treatment (January 2012), which was used by the American College of Physicians and the U.S. Preventive Services Task Force to inform their recommendations.

The recommendations of professional medical societies, as well as the U.S. Preventive Services Task Force, influence how care is provided. Hospitals and health systems in Minnesota and around the country implement these clinical practice guidelines as they see fit in order to improve how care is provided to patients.

Conclusion

The goal of comparative effectiveness research is to inform those making decisions about health care. Systematic reviews provide a comprehensive view of what we know from existing research and illuminate gaps in our knowledge. Because comparative effectiveness research focuses on interventions and tests and outcomes that are important to patients, these reviews can help clinicians and patients as they discuss options and make decisions. The hope is that by disseminating the research, we are ensuring that clinicians and patients have the information they need to improve the overall quality of patient care. **MM**

William Lawrence and Stephanie Chang are with the Agency for Healthcare Research and Quality. Robert Kane and Timothy Wilt are with the Minnesota Evidence-based Practice Center.

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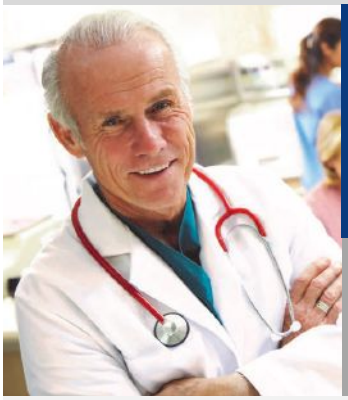

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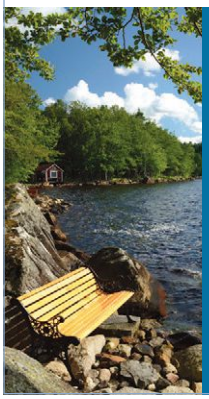

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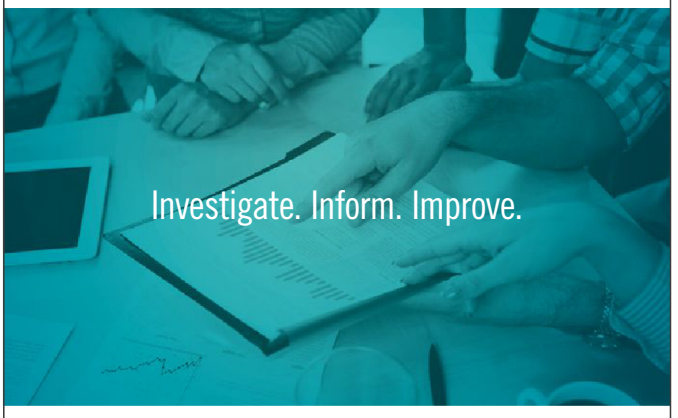

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My final electronic signature

BY SAPNA SADARANGANI, M.B.B.S.

All the moments culminate
Watching the monitor
Patients
In states of Calm,
In Extremis and
In Death
Each moment unique

I stand and ponder
My very own moments
The paradox
The Banality and the Elegance

The nondescript, relentless repetition
Understated but
Essential

The electronic march
Through the myocardium
Rhythm of the Arc

And in that one moment
Forgetting
Slowing
Widened Intervals
A pause that is too long
Or Chaos

All degenerates into
Nothingness

The point of no return
A moment of discovery
With no opportunity for
Awareness
My final electronic signature.

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