THE JOURNAL OF THE MINNESOTA MEDICAL ASSOCIATION

MINNESOTA MEDICINE

MAY 2014

GUIDELINES HOW TEST PROTOCOLS

REAL-WORLD RESEARCH

Practicing physicians test new guidelines and protocols in the settings where they'll be used. PAGE 20

PHYSICIANS STUDY PATIENTS EVIDENCE CLINICS PROOF WHEN TOOLS

Minnesota Medical Association

Thriving IN Change

Meeting the challenges of modern medicine

MMA's new, revamped

2014 Annual Conference

September 19-20
Madden's on Gull Lake, Brainerd

For more information go to **mnmed.org/AC2014**.

Minnesota Medical Association

Thanks to our sponsors

MMIC Group

Alcohol is more harmful to an unborn baby than cocaine, marijuana or heroin. Drinking during pregnancy can cause Fetal Alcohol Spectrum Disorders (FASD) which permanently harm the way your baby learns and behaves.

049 - ZERO ALCOHOL FOR NINE MONTHS.

MOFAS.org

THERE IS NO SAFE AMOUNT OF ALCOHOL DURING PREGNANCY.
FETAL ALCOHOL SPECTRUM DISORDERS (FASD) ARE 100% PREVENTABLE.

CONTENTS

May 2014 | VOLUME 97 | ISSUE 5

FEATURES

ON THE COVER

FEATURES

Student, Resident AND Fellow Research

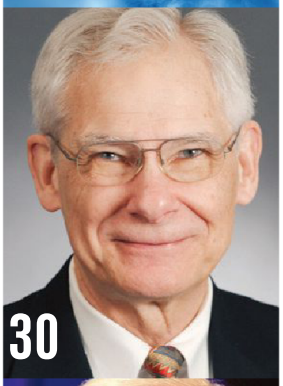
DEPARTMENTS

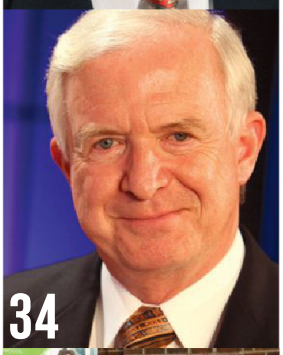
PERSPECTIVE

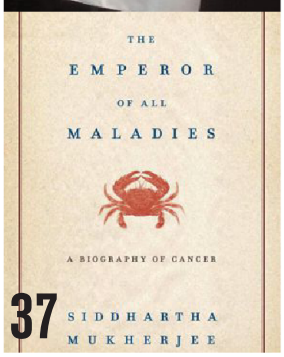
BOOK REVIEW

END NOTE

Clinical AND Health Affairs







MINNESOTA **MEDICINE**

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

OWNER AND PUBLISHER
Minnesota Medical Association

EDITOR IN CHIEF
Charles R. Meyer, M.D.

EDITORS
Carmen Peota
Kim Kiser
Jeanne Mettner

PHYSICIAN ADVOCATE WRITER
Dan Hauser

ART DIRECTOR
Kathryn Forss

MMA COMMUNICATIONS DIRECTOR
Terry Ruane

CIRCULATION / WEB CONTENT
Mary Canada

SUBSCRIPTIONS
Annual subscription: $45 (U.S.) and $80 (all international)

MISSING ISSUES AND BACK ISSUES
Missing issues will be replaced for paid subscribers at no additional charge if notification is received within six months of the publication date. Replacement of any issues more than six months old will be charged the appropriate single back issue price. Single back issues of *Minnesota Medicine* can be purchased for $25 (U.S.) and $30 (Canada, Mexico, and other international). Send a copy of your mailing label and orders to Mary Canada, 1300 Godward Street, Ste 2500, Minneapolis, MN 55413 or fax it to 612-378-3875.

Minnesota Medicine is intended to serve as a credible forum for presenting information and ideas affecting Minnesota physicians and their practices. The content of articles and the opinions expressed in *Minnesota Medicine* do not represent the official policy of the Minnesota Medical Association unless this is specified. The publication of an advertisement does not imply MMA endorsement or sponsorship.

To submit an article
Contact Carmen Peota at cpeota@mnmed.org.

The editors reserve the right to reject editorial, scientific, or advertising material submitted for publication in *Minnesota Medicine*. The views expressed in this journal do not necessarily represent those of the Minnesota Medical Association, its editors, or any of its constituents.

PHOTO BY SCOTT WALKER

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

The research requirement

Without research, medicine treads water, stuck with the mistakes and misconceptions of yesterday.

Pondering the idea of a medical career as a high school student, I sampled the research side of medicine by working in the rat lab at Presbyterian-St. Luke's Hospital in Chicago. Every day during one summer I would travel the Congress Street El, don my white coat and help a senior medical student attempt to create a blood-loss, iron-deficiency anemia in white rats who proved to be very stingy about giving up their blood. It was messy work with uncooperative and occasionally hostile subjects, and by the end of the summer we had little to show for our efforts. The next summer I "graduated" to the dog lab, where the subjects were marginally more cooperative and the research projects no more successful. My next premedical summer job was working as an orderly in our local hospital tending to humans. Since then, I've stuck to humans.

Yet I have not escaped research. Indeed, no physician can. Regardless of specialty, research is really the food that nourishes clinical medicine. Without research, medicine treads water, stuck with the mistakes and misconceptions of yesterday. With research, medicine moves forward, delving and discovering, revising and renovating.

Interpreting and using the results of research should be part of each physician's training, a formally taught skill just like anatomy or pathology. When I was in medical school, unless you specifically chose a research track, you were expected to pick up those skills along the way. As this month's articles reveal, that deficiency has been corrected. Most incoming medical students have done some research prior to medical school, and some unsuccessful medical school applicants are advised to do a year or two of research before reapplying. Many residency programs have a mandated year of research built into their rotations. Today's medical training has elevated research to a virtual requirement so that incipient doctors don't wander into the wilds of medical knowledge without the training to find their way.

Even after today's physicians are launched on their career, research is possible within the world of medical practice. Clinicians during their patient care time can participate in practice-based research, which frequently tests and tweaks proposed guidelines.

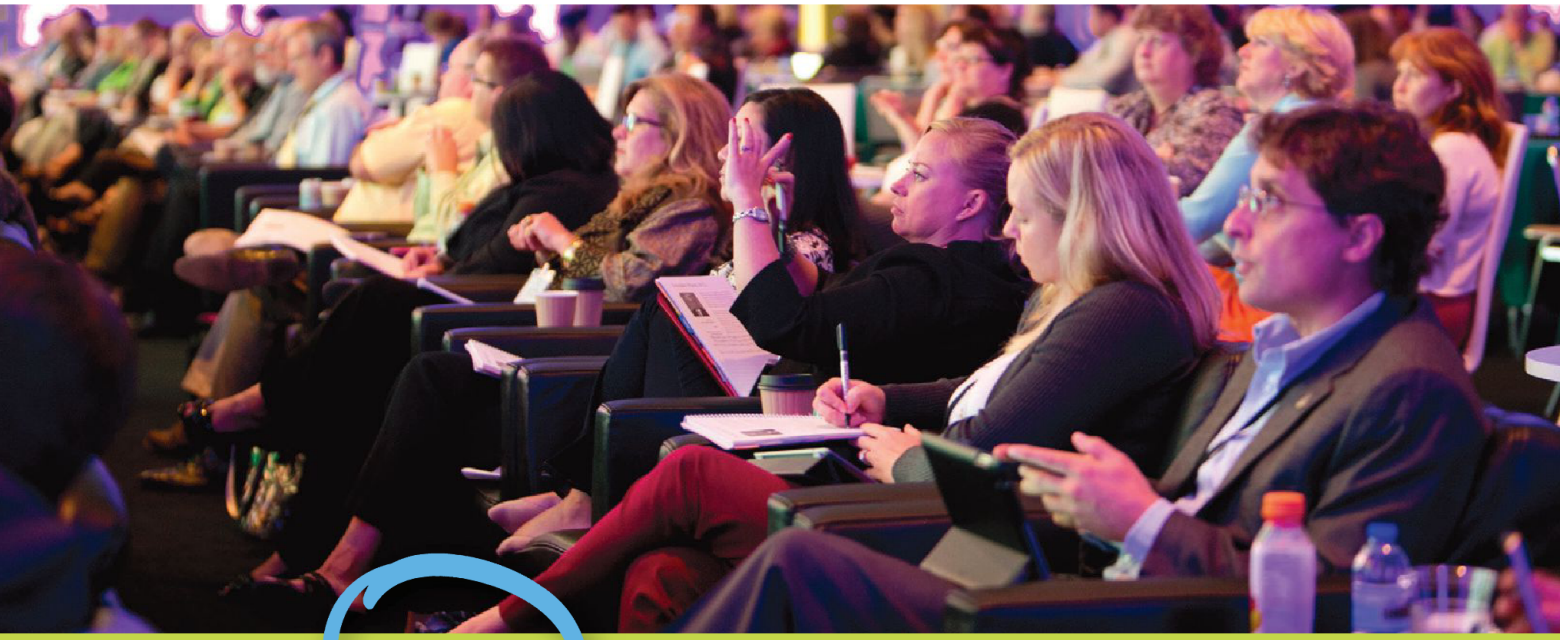
Throughout their career, physicians have to ingest massive amounts of information. "Staying current" is a concept drilled into the DNA of medical students. As the journals arrive thick and fast (I'm convinced that the *New England Journal* comes out more often than once weekly), practicing physicians need a triage system to sift the important from the unimportant and to sort out what is relevant to their professional life. Being able to read a research paper and decide whether it merited the light of publication is challenging but vital. Even though papers utilizing meta-analysis have eased the burden somewhat, a first-hand exposure to research is indispensable.

During my last medical school rotation, I wrote a paper that retrospectively reviewed cases of acute renal failure at one of the Northwestern University hospitals. Although it did eventually get published, it didn't advance the field of nephrology very far. Yet I learned how to glean information from sometimes illegible medical records and fashion it into a cogent analysis. Whether it's dusty medical records or rats, a taste of research is good preparation for a life in medicine. **MM**

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

MAYO CLINIC

TRANSFORM 2014



YOU SHOULD BE HERE

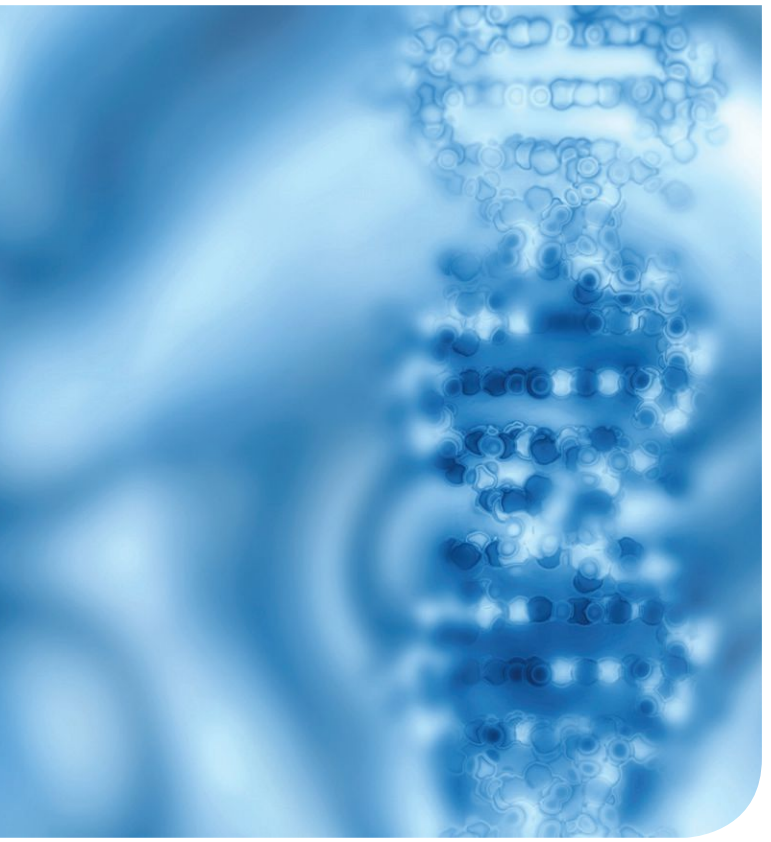
REGISTER TODAY

Sept. 7-9, 2014
www.mayo.edu/transform

Mayo Clinic's Transform Symposium addresses tough questions, focuses on results and engages attendees to catalyze practical innovation for health and health care. Join this growing community of thought leaders, innovators and disruptors all focused on transforming the experience and delivery of health care as only as Mayo Clinic can by attending the annual Transform Symposium on Sept. 7-9, 2014.

Five Reasons to Attend Transform:

- Learn from thought leaders from around the world
- Ask tough questions and understand patient perspectives
- Build a network of collaborators across multiple industries
- Springboard and promote your own innovation efforts
- Positively impact the health care delivery system



Off-campus study

It used to be that the majority of medical research took place in large academic centers. Although a great deal of work continues to be done in those settings, many health systems and insurers in the region now have their own research arms. Where once these entities might have existed solely to oversee safety and compliance for their organization's clinical trials, in recent years many have expanded the scope of their work to include health systems delivery, comparative effectiveness and even population health studies. Researchers from these entities work independently on their own studies, collaborate with academic centers or join research networks. Increasingly, their findings are being published in peer-reviewed journals and presented at meetings. Here's a look at what nine of these organizations are doing.

Allina Health Division of Applied Research, Minneapolis

Year founded: 2008

Research focus: Care delivery and population health. Areas of study include primary care, emergency services, critical care, end-of-life care, health care equity and community health. Studies involve Allina's clinics and hospitals as well as its home care, community services and emergency services entities. Research efforts are designed to be instructive to other care delivery organizations, and results are published in peer-reviewed journals. Several research entities exist within Allina Health including the Virginia Piper Cancer Institute and Courage Kenny Research Center.

Essentia Institute of Rural Health, Duluth

Year founded: 2010

Research focus: Improving the patient experience, improving the health of the population, eliminating health disparities and reducing the cost of health care. Projects on primary care redesign, team delivery of behavioral health care, rural health care delivery and other topics may be initiated by investigators or at the request of Essentia Health. Clinical trials and translational research focuses on the prevention and treatment of cancer and heart and vascular disease. The institute has 116 active studies taking place.

HealthEast Research, St. Paul

Year founded:1994 (as HealthEast Medical Research Institute)

Research focus: Improving service and patient care; drug and device trials. Recent projects include studies of diabetes care among acute-care patients, measures of excellence for care of patients with kidney stones and for home care after hospital discharge, and clinical trials of cardiology drugs and devices. Also maintains registries on specific patient populations that are used for study.

HealthPartners Institute for Education and Research, Bloomington

Year founded: 1990. In 2012, HealthPartners Research Foundation and HealthPartners Institute for Medical Education were combined.

Research focus: Chronic diseases, critical care, cancer care, child and maternal health, health economics, Alzheimer's disease/neuroscience, mental health and oral health/dentistry. Types of studies conducted include behavioral intervention studies, survey-based studies, clinical trials, medical records research and basic science research. Many are initiated by institute staff or HealthPartners clinicians and involve HealthPartners clinics and Regions Hospital; investigators also work with research networks including the Midwest Research Network, Cardiovascular Research Network, Mental Health Research Network and HMO Research Network. More than 300 studies are underway at any given time, and institute research yields about 200 published articles a year.

Medica Research Institute, Minneapolis

Year founded: 2010 (began operating in 2011)

Research focus: The patient experience, the health of the community and care delivery. Current studies are looking into questions about ACOs and their impact on cost and quality; how health care can be delivered in an equitable fashion; emergency-department utilization patterns; consumer engagement and the role of health coaches; how social determinants of health affect the health experience and outcomes. Twenty-five papers have been published in peer-reviewed journals since 2012.

Minneapolis Medical Research Foundation (Hennepin County Medical Center), Minneapolis

Year founded: 1952

Research focus: Basic science research, clinical trials, outcomes studies, translational research in addiction, cancer, HIV/AIDS, aging, tobacco treatment and more. MMRF's Berman Center is involved in evaluating treatments for conditions such as high blood pressure, heart disease, kidney disease, stroke, neurological disorders, diabetes, breast cancer and osteoporosis. The center has participated in the NIH's Women's Health Initiative Observational Study, the ACCORD study on the relationship between type 2 diabetes and cardiovascular disease and the SHARP study assessing the effect of cholesterol-lowering medications on cardiovascular events in people with chronic kidney disease. MMRF's Chronic Disease Research Group evaluates public health issues related to chronic illness and its treatment.

Olmsted Medical Center Research Department, Rochester

Year founded: 1990

Research focus: Advancing medical practice and supporting best practices and evidence-based care. Projects include translational research and implementation studies related to asthma, COPD, spirometry and postpartum depression; epidemiology studies on the prevalence, natural history and burden of chickenpox, irritable bowel syndrome, heart disease in women and chronic pain; clinical trials (eg, on therapies for black adults with asthma conducted in collaboration with Harvard); and screening studies (eg, evaluating school-based screening for scoliosis, COPD screening and asthma screening). Researchers receive funding from the NIH, CDC and AHRQ and have published more than 300 articles in peer-reviewed journals.

Park Nicollet Institute, St. Louis Park

Year founded: 1959

Research focus: Industry-sponsored and investigator-initiated studies to evaluate the safety and efficacy of medications, medical devices and procedures. Practice-based and health services research and quality-improvement projects to examine cost and value of care and patient-provider interactions. Areas of study include diabetes, oncology, cardiovascular health, Parkinson's disease and orthopedics. Research is conducted throughout Park Nicollet's primary care and specialty clinics and at Methodist Hospital and TRIA Orthopaedic Center. The institute was involved in 158 active studies in 2013.

Sanford Research, Fargo

Year founded: 2006

Research focus: Biomedical research with an emphasis on clinical and bench-to-bedside investigations. Areas of study include children's health, type 1 diabetes, health outcomes and prevention, cancer biology, and genomic and molecular medicine.

Homegrown research network

About three years ago, representatives from Minnesota's key research institutions came together to determine how they could more effectively address some of the questions they were all trying to answer. The group formed the Midwest Research Network in order to do more robust (and better funded) studies together than they could on their own.

"We're hoping it will be a great resource for investigators and stakeholders who want to bring forward key questions and issues where scientific rigor is necessary for assessment," says Kristina Bloomquist, executive director of the Medica Research Institute and chair of the network's steering committee.

Some members are already collaborating on projects. One group is looking at how to provide higher-quality, lower-cost care to Medicare beneficiaries at high risk for cardiovascular problems. Another is studying how to reduce hospital readmissions for patients with mental illnesses. Two others are involved in AHRQ-funded projects focused on empowering patients through public reporting and developing an infrastructure to investigate diversity in comparative effectiveness. In addition, the network has interest groups on mental health, aging, informatics and clinical-decision support.

Bloomquist says other states are taking note of the network and see it as an example to follow. "Minnesota is often referred to as the 'Land of 10,000 Collaborations.' We want to build on that legacy."

The network's members

Allina Health
Center for Chronic Disease Outcomes Research
Children's Hospitals and Clinics of Minnesota
Community Health Information Collaborative
Essentia Institute of Rural Health
Fairview Health Services
HealthEast
HealthPartners Institute for Education and Research
Hennepin County Medical Center
Institute for Clinical Systems Improvement
Mayo Clinic
Medica Research Institute
Minnesota Community Health Worker Alliance
Minnesota Community Measurement
Minnesota Department of Health
Minnesota Department of Human Services
Park Nicollet Institute
Stratis Health
UCare
University of Minnesota

SURVIVING THE SHORTFALL

Decreased research funding from traditional sources has led some investigators to get creative.

BY JEANNE METTNER

Fifteen years ago, Daniel Saltzman, M.D., chief of pediatric surgery at the University of Minnesota Amplatz Children's Hospital, conceived a novel—and self-admittedly "crazy"—way to kill solid cancer tumors: inject them with modified strains of salmonella, a bacteria that has the ability to penetrate solid masses and deliver cancer-fighting immune-modulating genes. When tested in a clinical trial involving dogs with metastatic osteosarcoma, Saltzman's investigational therapy had a 38 percent success rate (six of 16 dogs with bone cancer who were treated with it survived).

Even though subsequent research in Saltzman's lab revealed ways that the salmonella can disarm what he calls the "force field" of tumor immunosuppression, he knew the chance of getting funding for his work from traditional sources was slim. "You can go to a funding agency like the NIH and say, 'Look, I want to treat cancer with a bacteria that would normally give you horrible diarrhea and belly pain'—and they'd laugh you out of the room simply because of the idea of it," Saltzman says. "Here we are 15 years later and we find that it really works; but a granting agency is still not going to be the one to take a chance and give money for it."

Frustrated with his inability to clinch federal grant money, Saltzman took his pleas to cyberspace. With the help of two Minneapolis agencies, he created ProjectStealth.org, a crowdsourcing website that provides information about his research and allows individuals to contribute dollars to support his research. Saltzman also has done a TEDx talk and created Twitter and Facebook accounts for ProjectStealth to generate interest in his work. Thus far, he has raised about $175,000. When he reaches $500,000, Saltzman says he will have the funds needed to complete the research required to file an Investigational New Drug application with the Food and Drug Administration. In the meantime, his lab has stayed open with the help of smaller philanthropic grants and proceeds from fundraisers. "We've had crowdsourcing donations ranging from $5 to $35,000," he says.

A crisis of inflationary proportions

Although Saltzman's approach to securing funding is decidedly unconventional, it illustrates the hoops researchers must now jump through to ensure their investigations survive in a time when federal funding for research has faced repeated cuts. Perhaps

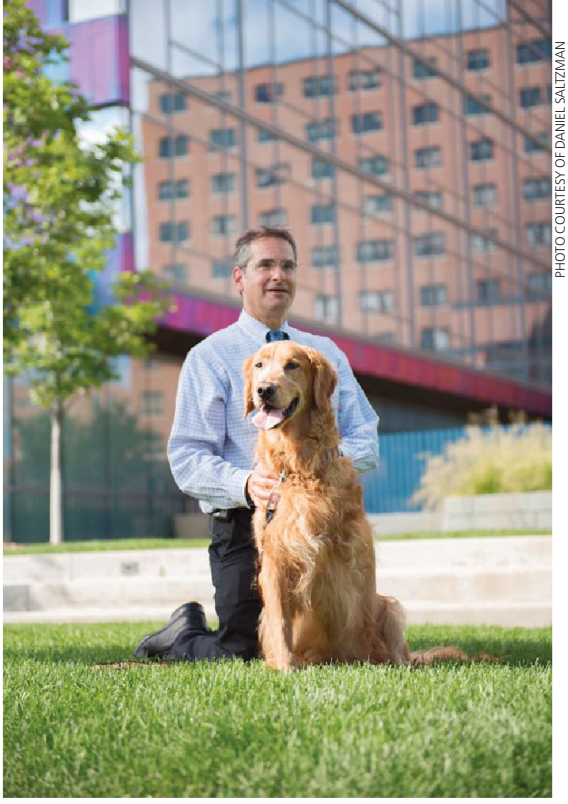


PHOTO COURTESY OF DANIEL SALTZMAN

Daniel Saltzman, M.D., with Buddy, a 6-year-old golden retriever who lost his front leg to bone cancer and is now cancer-free as a result of the treatment strategy developed in Saltzman's lab.

hardest hit has been the National Institutes of Health, which funds 40 percent of the biomedical research in this country. In 2013, when sequestration forced a 5 percent cut to the NIH budget, the agency had, in effect, $4.7 billion (22 percent) less in inflation-adjusted dollars than it had a decade earlier. In 2013, the NIH funded 20 percent fewer research grants than it did in 2003; the number of R01 grants (large, multi-year grants) funded during that same period fell by almost 30 percent.

IN 1980, THE AVERAGE AGE AT WHICH AN M.D./PH.D. RECEIVED HIS OR HER FIRST RO1 GRANT WAS 36. TODAY, IT'S 44.

The cuts have proved challenging for researchers in Minnesota and throughout the United States. For example, the University of Minnesota Medical School's NIH funding went from $152 million in 2012 to $145 million in 2013. Mayo Clinic's NIH budget fell from $223 million to $211 million during that same period.

"As far as disciplines being impacted—whether it's cancer, neuroscience, genetics, cardiovascular, infectious disease, everybody has felt it," says Tucker LeBien, Ph.D., a professor of laboratory medicine and pathology and vice dean for research at the University of Minnesota Medical School. Although he is unaware of any lab closures that have resulted from the NIH cuts, he knows many that were forced to downsize. "A lot of these labs are like small businesses. If you have five or six employees and you lose one, it has a tremendous impact," he explains. "You end up having to narrow the scope of your activities."

The decade of incremental decreases in NIH dollars has also prompted a climate change in the biomedical research world. Stephen Riederer, Ph.D., chairman of research finance and professor of radiology at Mayo Clinic, says the erosion of support has been particularly challenging for young investigators. In 1980, the average age at which an M.D./Ph.D. received his or her first R01 grant was 36. Today, it's 44. "I am concerned about this because it's causing some young investigators to question whether they want to stay in academic research at all." He adds that researchers who are completing their

advanced training are instead taking jobs in the biotechnology or pharmaceutical industries.

Making up (part of) the difference

To compensate for the lost federal dollars, both Mayo and the University of Minnesota rely on philanthropic donations and provide financial support to researchers through internal funding programs. The university's Wallin Neuroscience Discovery Fund, which was established by the family of former Medtronic and Pillsbury executive Winston Wallin, for example, commits $500,000 a year for novel neuroscience research. And a Mayo Clinic-funded source called NIH Relief allocates money for projects that receive a high rating but do not receive NIH funding. Riederer says the hope is that this short-term funding will allow investigators to address some of the issues identified in their NIH summary statements and improve their studies, so they can reapply for multi-year grants.

Although helpful, philanthropic funding offers little or no support for indirect expenses such as utility costs, space rental, and IT and human resources support. For each NIH grant awarded, an academic institution is given an additional amount of funding—over and above the grant award—to cover those expenses. The amount received is based on a set percentage that the institution and the federal government have negotiated based on actual expenses. At the University of Minnesota, the rate amounts to 52 percent of every federal grant dollar awarded. At Mayo, it is 59 percent. That amounts to significant money for research institutions. "Only the federal government pays full indirect costs, so making up that difference becomes a serious challenge," LeBien says.

An uncertain future

Although the mandated 5 percent cut from the 2013 sequestration was returned to the NIH budget in 2014, the overall funding available remains less than what it was in 2012 (see box). In short, 10 years of uncertainty in the area of biomedical research funding has resulted in scientists having to get creative in the way they raise research dollars. "I think we are going to have to find some innovative ways to address this fiscal crisis, if it ends up being permanent," Riederer says. "Even today, we are encouraging investigators to be entrepreneurial. We're trying to foster an environment where they can work with their colleagues for funding or partner with other organizations or industries to accomplish their research goals." For example, Mayo gastroenterologist David Ahlquist, M.D., creator of the Cologuard stool testing system (a DNA test), worked with Exact Sciences, a Madison, Wisconsin, company to develop the test kit, which is awaiting FDA approval.

Whether crowdsourcing becomes a viable way to raise dollars for biomedical research remains to be seen. Neither LeBien nor Riederer are aware of any other investigators who are using the method to raise funds. And Saltzman has not been approached by others who want to learn more. "If crowdsourcing emerged a few years from now as a major source of revenue, we'd have to take a hard look at whether we can do business that way," LeBien says. "From an institutional standpoint, pursuing research funding should be done through the right channels because you are representing the university. … You can have enthusiasm for your project, but on the other hand, the language has to be vetted to make sure you get it right."

Saltzman admits his approach has raised eyebrows among university officials but says he wouldn't do things differently. "Are my ways of raising my research dollars unconventional? Absolutely. But it's either go this route or close my lab. Desperate times call for desperate measures." **MM**

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

NIH FUNDING AT A GLANCE

2012: $30.86 BILLION

2013: $29.15 BILLION*

2014: $30.15 BILLION

2015: $30.36 BILLION (PROPOSED BY PRESIDENT OBAMA)

*REPRESENTS MANDATED 5 PERCENT CUT DUE TO SEQUESTRATION

"IF CROWDSOURCING EMERGED AS A MAJOR SOURCE OF REVENUE, WE'D HAVE TO TAKE A HARD LOOK AT WHETHER WE CAN DO BUSINESS THAT WAY." – **TUCKER LEBIEN, PH.D.**

Victoza®—a force for change in type 2 diabetes.

A 52-week, double-blind, double-dummy, active-controlled, parallel-group, multicenter study. Patients with type 2 diabetes (N=745) were randomized to receive once-daily Victoza® 1.2 mg (n=251), Victoza® 1.8 mg (n=246), or glimepiride 8 mg (n=248). The primary outcome was change in A1C after 52 weeks.

novo nordisk®

The change begins at **VictozaPro.com**.

VICTOZA®
liraglutide (rDNA origin) injection

Indications and Usage

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

Date of Issue: April 16, 2013

Version: 6

Manufactured by: Novo Nordisk A/S, DK-2880 Bagsværd, Denmark

Victoza® is covered by US Patent Nos. 6,268,343, 6,458,924, 7,235,627, 8,114,833 and other patents pending. Victoza® Pen is covered by US Patent Nos. 6,004,297, RE 43,834, RE 41,956 and other patents pending.

 0513-00015682-1 5/2013

novo nordisk®

VICTOZA®
liraglutide (rDNA origin) injection

CRITICAL THINKER

A conversation with health services researcher **Timothy J. Wilt, M.D., M.P.H.**

INTERVIEW BY CARMEN PEOTA

If you look at the long list of papers he's published during his career, you might question whether Timothy J. Wilt, M.D., M.P.H., has had a focus. You'll see articles about such diverse topics as trazadone for erectile dysfunction, fish oil for plasma cholesterol and botulin toxin for urinary incontinence. And there are multiple titles on heart disease; knee arthroplasty; breast, colorectal and prostate cancer; and myriad other maladies. The broad range of subjects belies the fact that Wilt has indeed had a goal: to identify clinical practices that work.

Wilt started on that quest not long after completing his residency in internal medicine at the University of Minnesota in the late 1980s. Researchers then were just beginning to systematically analyze published research in order to identify the evidence for certain clinical practices. The approach would come to be called "evidence-based medicine" in the 1990s.

In 1987, he took a position at the Minneapolis Veterans Affairs Medical Center, where his first section chief, Richard Lofgren, M.D., encouraged him to think critically. At the time, the VA was just starting to introduce clinical performance measures, and that got Wilt asking questions about why doctors were doing certain things. He read an article that questioned the value of surgery for patients with early prostate cancer, and he read others about the overdiagnosis of the disease. Those things prompted him to propose that the VA fund a study on prostate cancer treatment.

"There is clear science that demonstrates that a large portion of health care in the United States is unnecessary, ineffective or even harmful, and that it costs a lot of money."

Wilt was then asked to lead a Cochrane Review Group on prostate and urological diseases. "I was doing this prostate cancer treatment trial, and the director of health services research at the VA was looking to kind of get into this new methodology of doing systematic reviews and called me up and said, 'Would I be interested and did I think I could do it?' I said, 'Yes and yes.'"

Wilt had gotten in on the ground floor of the evidence-based medicine movement. "To be honest, it was serendipity," he says.

In 2002, he became co-director with Robert Kane, M.D., of the Minnesota Evidence-Based Practice Center, a collaboration between the VA and University of Minnesota funded by the Agency for Healthcare Research and Quality. He took the helm of the Minneapolis VA Evidence-Synthesis Program, and over the years has served on committees that turn that evidence into guidelines. He is a member of the VA Preventive Medicine Advisory Committee and the American College of Physicians Clinical Guideline Committee and a former member of the U.S. Preventive Services Task Force.

In 2012, Wilt was thrust into the national spotlight when his article on the prostate cancer trial he launched in the 1990s, the Prostate Cancer Intervention Versus Observation Trial (PIVOT), was published in the *New England Journal of Medicine*. That study demonstrated a lack of benefit and increased harm from radical prostatectomy for most men, causing urologists and primary care physicians around the world to change their practices.

In March, Wilt received the 2014 VA Under Secretary's Award for Outstanding Achievement in Health Services Research. He hopes to use the financial support that comes with the award to establish a center at the VA where students, clinicians, policymakers and researchers can learn and expand their thinking about high-value care. We asked him about his work.

What motivates you to do this kind of research?

There is clear science that demonstrates that a large portion of health care in the United States is unnecessary, ineffective or even harmful, and that it costs a lot of money. There's also evidence that there's very effective health care that has acceptable harms and costs and is underutilized. I believe we have an important opportunity and obligation to deliver health care services that are high-value.

What do you mean by high-value care?

The highest quality health care provides benefits that clearly justify its harms and the costs.

There are two ways to provide it. One is to reduce the number of services that are known to be of low value. Reducing unnecessary treatments and the costs and harms associated with them allows us more space, as it were, for getting effective health care for those who need it. The other is to promote those interventions that may be of higher value.

What are examples of this kind of care?

One area that we know about is screening for breast, cervical and prostate cancer. For a long time, we have had a belief that higher-intensity screening—screening more people more frequently and with a test that looks harder and harder—was what was necessary. We'd say, "Find the cancer, treat it early, and it could save your life—it did mine." What we now know is that screening really is a two-edged sword. It can provide incredible personal and public benefits; but it also has harms. We can, however, find an optimal balance.

For breast cancer, the science shows that screening women beginning at age 50 or, if they strongly desire it, at age 40 every two years provides nearly identical benefit in reduction of breast cancer deaths with far fewer harms and lower costs than what we once did. For cervical cancer, we now know that screening women beginning at age 21 rather than earlier, and screening them every three years with the Pap smear, or beginning at age 30 every five years with the combination of the Pap test and the HPV test, and ending at age 65 for women who've had normal tests, provides the optimal balance of benefits and costs. Finally, we now know that prostate cancer screening—as it is currently practiced—is low-value care. At best, it results in a very small reduction in prostate cancer deaths, with no reduction in all-cause mortality over 10 to 15 years. Yet it results in considerable harms and has a high cost. Thus, recommending against a PSA blood test is a high-value and good health care choice.

Isn't it hard to convince clinicians, patients and organizations to change their thinking?

It's both a difficult and an exciting and important challenge. We've begun to work on how to effectively communicate this to physicians and patients. Change is hard, but change is really important when the science tells us we need to change. We now have clear evidence that sometimes less health care is better health care.

We're working on developing shared decision-making tools that effectively communicate information to patients, and allow them to incorporate their values in treatment decisions and more fully understand the trade-offs that are made between possible benefit and known harms.

You've done studies on so many different diseases and treatments. How can you work in so many areas?

I'm a generalist. That's my personality. There are others who really like digging deep. I'm not saying I'm at the 40,000-foot view, but I look at things from a primary care generalist's point of view and collaborate with very talented individuals possessing additional disease content or research methods expertise. I might not know the exact nuances of the biochemistry or all the physiology or exact methods of a surgical or radiation procedure. But I understand if those things are likely to be really important difference makers for patients, clinicians and policy makers.

You spend 20 percent of your time seeing patients. Why do you do that?

I'm a physician first. I think of my patients when I'm doing research. They're not just kidney disease, they're humans who have a variety of cares and concerns, and that really informs how I do my work.

Furthermore, the research that I do informs my clinical practice. For example, my study of prostate cancer has helped me more effectively counsel men about treatment options. Seeing patients keeps my research practical rather than strictly academic.

How can other practicing physicians access the evidence that researchers like you are providing?

They can turn to trustworthy sources of information, including the Choosing Wisely campaign. There are good summaries of information and good CME courses by groups that have low conflicts of interest and provide a balanced set of recommendations.

Some have called the evidenced-based medicine movement cookbook medicine. What's your response to that?

Some critics say let's have individual patient-centered medicine. But if you take that to the extreme, it's silly. If you say everybody is completely unique, then you can't do research on anything. Then any study you do is not applicable to the patient you see.

The clinical science that I and others provide is the evidence foundation on the benefits, harms and costs. We put that into guidelines, not proscriptive mandates. The idea is to help guide physicians and patients to the highest-quality care. The word "guideline" came from mountain guides. They would mark a route up a mountain. It's not the only way up the mountain, but it's probably the best and safest way. That's what guidelines should be.

Yes, but that isn't always what happens, is it?

Sometimes guidelines get turned into performance measures and mandates. Sometimes physicians don't have the opportunity to digest fully what those guidelines say. Sometimes health care systems rigidly look at them without thinking them through. Physicians need to have more time to look at the considerations.

If there's one thing that discourages me about medicine, it's that we have some of the best and brightest minds in the world, but sometimes with all of the requirements to do so much with so little time, we destroy not only physicians' creativity but their ability to think critically and have healthy skepticism. Physicians need more time both to engage with their patients and to read and keep up with information. They should not just be box-clickers. I advocate for physicians having more time for patients and for learning.

Are we moving in the right direction in terms of providing more high-value and less low-value care?

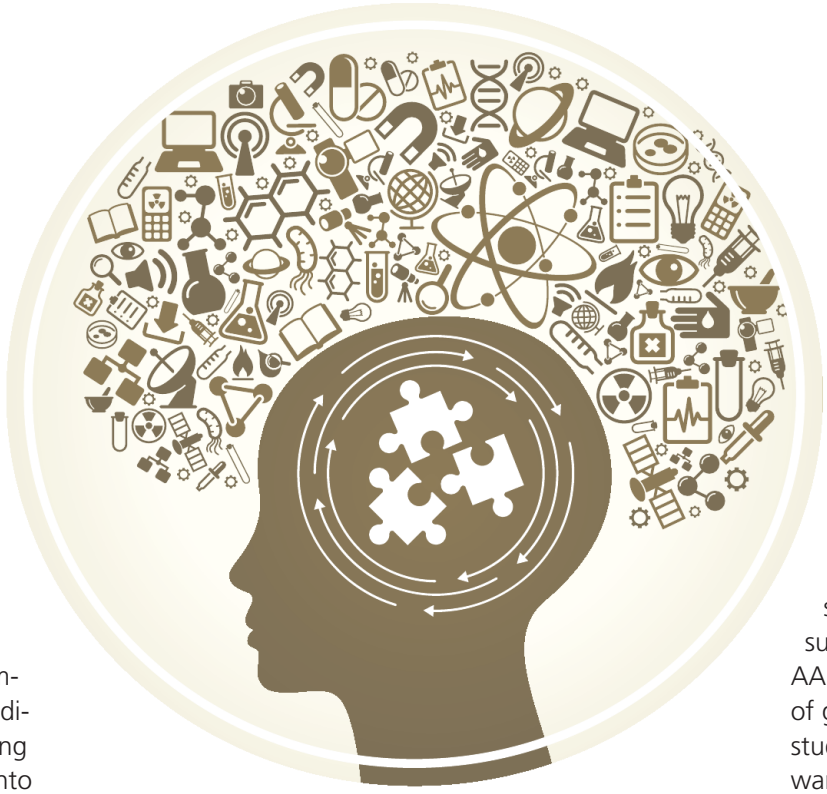
Yes. The U of M now has a curriculum for medical residents in high-value, cost-conscious care and the American College of Physicians includes having knowledge about high-value cost-conscious care as part of the internal medicine accreditation process. It is now one of the key components of internal medicine training.

And there's a greater appreciation that screenings and treatments have harms as well as benefits and costs. With regard to prostate cancer, the American Urological Society and the American Cancer Society have adjusted their recommendations. No organization now recommends routine PSA testing. That's a marked change from 10 years ago.

Even with breast cancer and cervical cancer screening, there's been considerable change in terms of awareness about overdiagnosis and harms from screening and treatment. OB/GYN societies now agree that cervical cancer screening less intensively rather than more intensively is a better option. And women and patients now understand that less care can be better care. *JAMA Internal Medicine* runs a regular series titled "Less is more."

This is not a movement to primarily save costs. It is driven by science that is informing us about what is good care for our patients as well as what is wise stewardship of our resources. That's good health care. That's improving the quality of care we deliver. **MM**

Carmen Peota is managing editor of *Minnesota Medicine*.



RESEARCH SAVVY

More medical students than ever are engaging in research while in school.

BY SUZY FRISCH

Going to medical school is all about discovery—in the classroom, in the lab, in the clinic and in the community. Increasingly, medical students are extending that spirit of discovery into research. In addition to uncovering findings that can improve treatment, a generation of physicians is becoming better prepared to practice evidence-based medicine.

Research by medical students has grown in importance in recent years, both in Minnesota and nationwide. A study published in *BMC Medical Education* last year found an "exponential" increase in student research between 1980 and 2010. Researchers looked at 350 journal articles by medical student authors. Just 3.4 percent were published before 1990, while 46.3 percent were published after 2010.

Medical schools in the United States started championing student research in 2008 after the Association of American Medical Colleges (AAMC) recommended they incorporate clinical and translational (bench-to-bedside) research into their core competencies. Since then, many have added required or elective courses in clinical and translational research.

Before the recommendation, which was later adopted by the Licensing Committee for Medical Education, fewer than half of U.S. medical schools required students to take courses in clinical and translational research; in 2012, 84 percent did. There also has been a boost in interest among students. According to surveys conducted by the AAMC, about two-thirds of graduating medical students in 2010 said they wanted to pursue options for research, compared with half in 2004.

"Medical students need to start thinking about research during their training, so that once they are out in the world it becomes an integral part of who they are and how they approach their practice," says Ann Bonham, Ph.D., chief scientific officer for the Washington, D.C.–based AAMC.

Charting more opportunities

The University of Minnesota has put a renewed focus on student research lately, acknowledging that its track record hasn't been great, says Mark Rosenberg, M.D., vice dean for medical education. Last year, the medical school surveyed students and found that just about one-third of the fourth-year class did research while earning their degree.

"Anyone who is going to be a physician needs to understand scholarship and the importance of discovery," he says. "They need to know how new knowledge is created and what role you can play in creating the new knowledge. How do you look at causes of disease, the best treatments, and how it applies to your practice? I'd like for them to be exposed to that, even if research isn't going to be their career option."

When Rosenberg joined the university in 2012, he led a task force charged with increasing all manner of medical student research including clinical or quality-improvement studies. The group looked at how to improve students' access to research opportunities, funding and the culture of research. Its recommendations included emphasizing the importance of research among students, providing them with research opportunities, marketing those opportunities to students, lining up more grant funding for student projects, and engaging affiliate sites such as Regions Hospital, the Minneapolis VA Health Care System and Hennepin County Medical Center.

The university now offers grants from the Lillehei Heart Institute that will support five students doing research this summer. Another new grant program provides opportunities for student research in infection and immunity. The University of Minnesota Foundation (formerly the Minnesota Medical Foundation) also provides grants for medical student research. Those awards have funded student projects including one on whether internal jugular vein collapse predicts low central venous pressure and another that investigates the

JESSICA ADEFUSIKA OLAYANJU

Mayo Medical School

As Jessica Olayanju starts her residency in ophthalmology this summer, she brings the confidence and know-how to turn clinical questions into solid studies. Doing research during medical school motivated her to pursue a career that combines treating patients and academic research.

A native of Nigeria who grew up in Rhode Island, Olayanju arrived at Mayo with basic science research experience gained during a summer program at the University of Massachusetts. She then got involved with projects at Mayo while considering different specialties. Olayanju helped gynecologists study a rare type of ovarian cancer; she worked on dermatology studies of treatments for excessive sweating and a study of primary mucinous carcinoma of the skin, a rare cancer. She also studied complications from glaucoma surgery. These efforts resulted in multiple presentations and publications.

While working at a free clinic sponsored by Mayo, Olayanju became inspired to look for ways to break down language barriers when treating foreign-language speakers in order to prevent miscommunication and medical errors. Some of the ideas she came up with were improving processes for using lay interpreters, making interpreters available by telephone, and teaching physicians and other providers how to work with interpreters. She published an essay about her experience and her observations last spring in *New Physician* (www.onlinedigeditions.com/display_article.php?id=1384114).

As she heads to residency at the University of North Carolina–Chapel Hill, Olayanju is grateful for the opportunities she had to participate in the full spectrum of research while in medical school. She says she gained insight into how to translate discoveries into improving patient care and a deeper understanding of how to read and evaluate papers.

"I learned that research is a never-ending process, and it's been an enriching experience to understand the process from proposal to publication," she says. "It boosts my confidence to know that when I leave here, I will be able to use what I have learned not only to continue with research endeavors but also to improve patient care. It's one of those things no one can take away from you."

characterization and treatment of infantile nystagmus.

In addition, the medical school recently launched a Craig's List–style website where students can easily search for research opportunities (http://secure.ahc.umn.edu/MedSchool/researchopps/home.cfm).

Third- and fourth-year students who want to do research can do so as an elective. Other students opt to participate in the university's Flexible M.D. program, which allows them to pause between their second and third years to focus on research, participate in a global health program, or earn a master's degree in public health or business administration. At both Mayo and the university, a small group of students do significant research while earning both M.D. and Ph.D. degrees.

Research in the curriculum

So far, research hasn't played a major role in the university's curriculum, although first-year students now learn how to interpret evidence for diagnostic and screening tests using original literature in four sessions called mastering evidence-based medicine, says Kathleen Watson, M.D., senior associate dean for undergraduate medical education.

However, it has been a part of the curriculum at Mayo Medical School since it opened in 1972. Students spend at least one quarter during their third year doing research, and they must produce a paper or other written piece before they graduate. Their projects can cover basic science, clinical or community-health topics, and it's up to the students to find a mentor to guide them through a project or include them in their ongoing research.

In 2013, 95 percent of Mayo's students published a paper—more than twice the national average. Through that process, students develop skills that they'll use throughout their medical careers, including critical thinking, tenacity, dedication, and writing and speaking prowess, says Susan Romanski, M.D., chair of Mayo Medical School's admission committee.

Having done research in medical school also makes them more competitive for residencies. "They can really appreciate the scientific process and learn discovery and query," she says. "And they learn teamwork and how to integrate research into patient care and education." **MM**

Suzy Frisch is a Twin Cities writer.

ANNA LARSON

University of Minnesota Medical School

When Anna Larson started medical school at the University of Minnesota in 2008, she thought she wanted to pursue pediatric neurology. But after spending nearly two years doing research at Massachusetts General Hospital in Boston, she now hopes to focus on translational epilepsy research as well as patient care.

Larson, who is in the Flexible M.D. program, spent time between her second and third years working with two pediatric neurologists who conduct clinical research related to epilepsy, Angelman syndrome and tuberous sclerosis complex. During her time in Boston, she contributed to several studies, including one that looked at dietary therapy for children with epilepsy and another on the health and clinical needs of adults with Angelman syndrome. She also presented at an international conference and co-authored five articles.

Larson, who recently matched into the child neurology residency program at Massachusetts General Hospital, says her experience cultivated a passion for translational research and epilepsy care. "In the future, I hope to not only care for patients but also work with research teams to improve our understanding of disease and treatment options."

KIRK WYATT

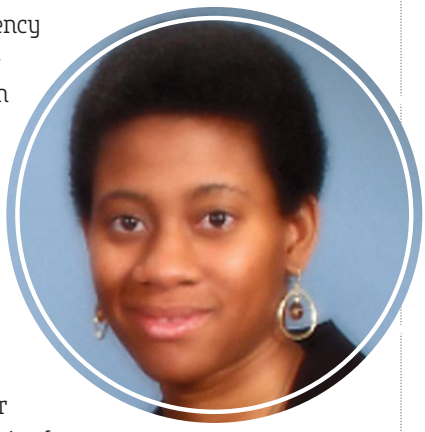
Mayo Medical School

Kirk Wyatt views research as an effective way to bridge the gap between the lab and the exam room. During his four years at Mayo Medical School, Wyatt immersed himself in several projects including one where he helped develop and evaluate a tool physicians can use for shared decision-making with patients.

As he pursues a career in pediatrics, he aims to continue balancing

OLUDARE ODUMADE

University of Minnesota Medical School



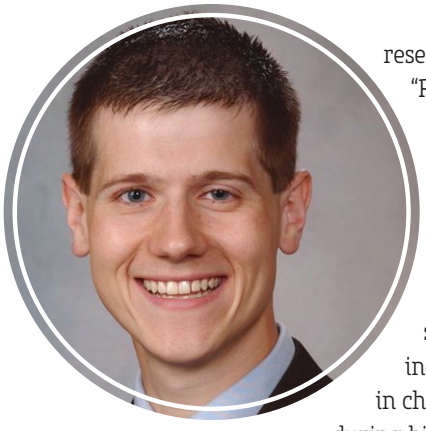
Doing research has taken Oludare Odumade to Kenya, to labs at Johns Hopkins University and the University of Minnesota, and to a field she had not imagined pursuing. Odumade came to medical school intending to become a psychiatrist, but volunteering in a lab at the university shifted her interest to pediatric immunology and infectious diseases.

"Immunology was more tangible and objective in terms of what you can measure. I want to do something very translatable that can have an impact sooner," she says. "Immunology has a close impact on patient care, and it can be broadly applicable to all sorts of patients."

Odumade, who is in the M.D./Ph.D. program, started medical school in 2007, completing two years before earning her Ph.D. in microbiology, immunology and cancer biology in 2011. Born in the Twin Cities, she grew up in Nigeria and always was interested in global health. Thanks to a Doris Duke Charitable Foundation Fellowship and an Infectious Diseases Society of America fellowship, Odumade spent the majority of this past year in Kenya doing research on malaria. After graduating this spring, she will start her residency in pediatrics at the University of California, San Diego.

Odumade's work has run the gamut from helping to investigate diet-induced thyroiditis at Johns Hopkins to studying the immunological risk factors for developing mononucleosis after Epstein-Barr infection for her doctoral thesis. She is now examining the immune response to malaria in pursuit of a vaccine.

She believes being involved in a variety of research settings and projects has been invaluable. "I've learned how to think and ask questions, how to write grants and read papers—all of the things that are useful when you're trying to do evidence-based medicine," says Odumade, who has published 11 papers. "If you learn to ask the right questions, you can answer questions that have a big impact on people. Sometimes a paper can become the standard of care."

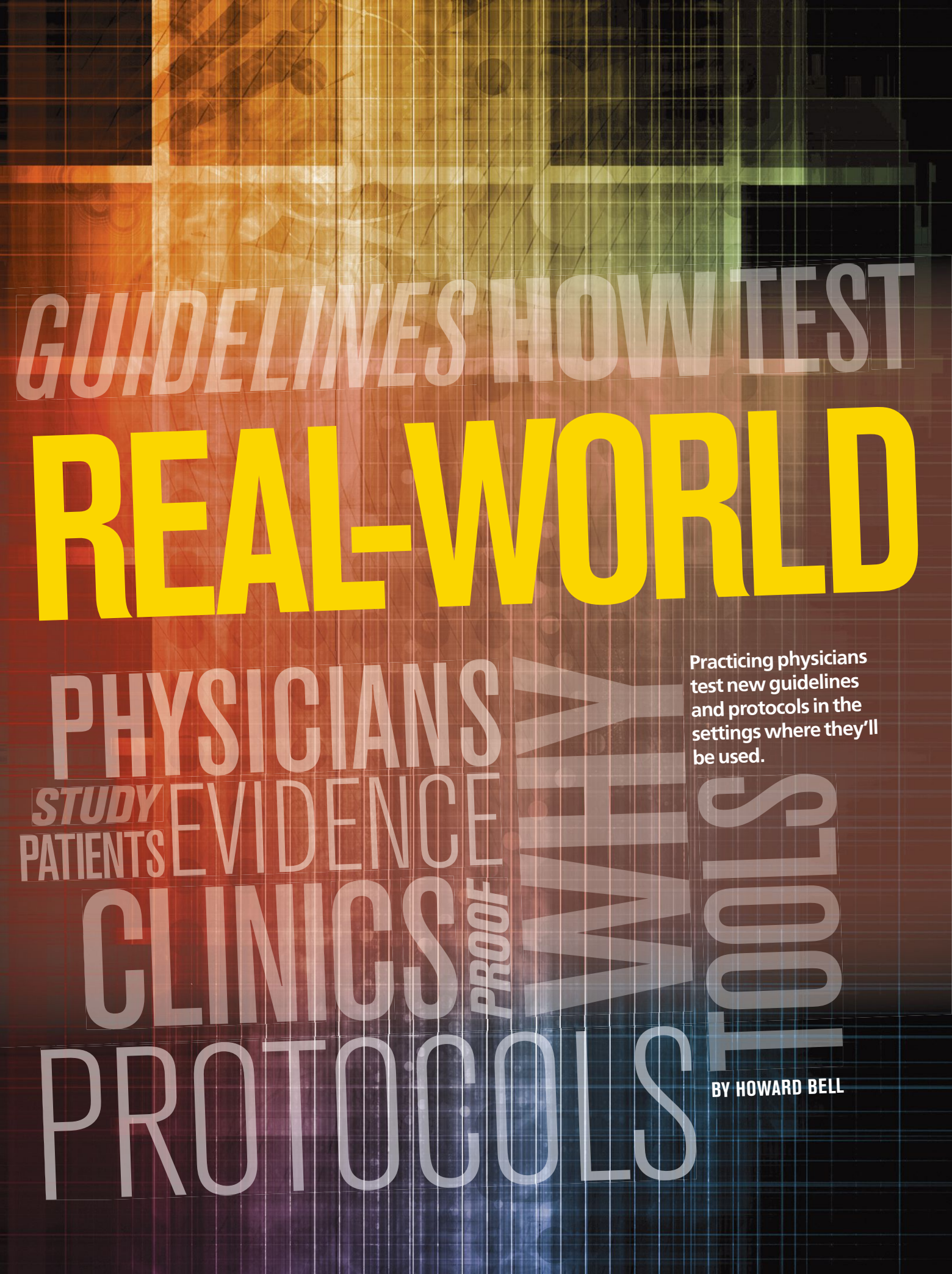


research with patient care. "Research lets me express my creative side, and it's really exciting to be able to change practice," he says.

Wyatt entered medical school with significant experience, including basic research in chemistry that he gained during his undergraduate years at Grand Valley State University in Michigan. He also spent two summers as an undergraduate research associate at Mayo doing clinical studies related to smoking-cessation therapies. (Although Mayo Medical School does not require its incoming students to have research experience, most come with some.) Wyatt became intrigued by the work of endocrinologist Victor Montori, M.D., on shared decision-making and has been working with one of Montori's colleagues, emergency physician Erik Hess, M.D., to develop a tool physicians can use with parents in the emergency department to determine whether their child should have a CT scan following a head injury. He also led a study that evaluated videos from hundreds of examinations involving physicians who used shared-decision making tools with patients.

Wyatt has published several articles and travelled to Peru in 2013 to present at an international conference on shared decision-making.

As he starts his pediatrics residency at the Mayo Clinic this summer, he brings with him extensive knowledge about how to conduct a well-designed study—a skill he plans to use in the future.



REAL-WORLD GUIDELINES: HOW PHYSICIANS TEST PROTOCOLS IN CLINICS

Practicing physicians test new guidelines and protocols in the settings where they'll be used.

BY HOWARD BELL

RESEARCH

Eden Prairie pediatrician Theodore Jewett, M.D., likes doing practice-based research because he gets to test whether recommendations in clinical guidelines actually work in his practice. "Sometimes they seem a little off target," he says. For example, a guideline for diagnosing and treating febrile infants designed at a large academic medical center proved too cumbersome for a typical pediatrics clinic to adopt—and doing so didn't improve outcomes anyway. "One reason practice-based research is valuable is because sometimes guidelines inform a practice and sometimes the practice informs the guidelines, which in this case are being changed to reflect the realities of everyday practice." Such real-world research not only results in improved care for Jewett's patients, it also makes him a more informed physician because it often requires him to do additional reading and shines a spotlight on how he handles a particular condition. And he says, "It's refreshing when my patients can help improve things for a population of patients."

Primary care physicians do practice-based research in their clinics while they care for patients full-time. By taking part in studies, they help create, test and sometimes incorporate into their practice such things as patient questionnaires and decision-making tools that can improve outcomes, boost clinic efficiency, reduce unnecessary patient visits, and maybe even cut costs for treating concerns such as diabetes, COPD, asthma, kidney disease, congestive heart failure, depression, memory loss and obesity.

Such grassroots studies are usually done by networks of physicians, such as those who participate in the Minnesota Academy of Family Physicians' (MAFP) Practice-Based Research Network (PBRN), the largest network of its kind in the state.

Practice-based research is crucial, says network director Kevin Peterson, M.D., M.P.H., because new guidelines won't achieve much unless they're developed and tested where they'll be used. Most quality-improvement research is done at tertiary academic centers and doesn't always translate well to community clinics because the big centers have different patient populations, deeper pockets and larger staffs for implementing change, he explains. Furthermore, he says, "most patients get most of their care most of the time at small community clinics, not tertiary centers. If we want evidence-based practice, we need practice-based evidence."

To help get that evidence, MAFP's PBRN formed in 1979. It is one of the oldest practice-based research networks in the United States. Its 248 members work in 107 clinics statewide. Most are family physicians, but that's not a requirement. Nor do they have to be a member of MAFP. The network, with offices in St. Louis Park, is affiliated with the University of Minnesota Medical School's Department of Family Medicine and Community Health and the Center of Excellence in Primary Care, for which Peterson is research director.

He and his staff of seven spend considerable time and energy recruiting physicians to participate in studies and finding ways to pay for those projects. Funding is different for each one and includes grants

from the NIH and other federal agencies, philanthropic foundations such as the Robert Wood Johnson Foundation, health plans, health system foundations, the MAFP Foundation and the Agency for Healthcare Research and Quality (AHRQ), which provides grants to PBRNs around the country.

Mayo Clinic Health System has the only other primary care PBRN that's based in Minnesota. Created in 2007, the network is made up of primary care practices in the Rochester area as well as those from Mayo Clinic Health System. Physicians in the network have completed more than 100 projects and are currently working on six studies, according to Lisa Schrader, research operations coordinator and administrative lead.

> "IF WE WANT EVIDENCE-BASED PRACTICE, WE NEED PRACTICE-BASED EVIDENCE."
>
> – KEVIN PETERSON, M.D., M.P.H.

A mix of studies

Historically, Minnesota's two primary care PBRNs did mostly homegrown projects, in which a clinician comes up with an idea for a study and the network finds funding for it and physicians to participate in it. For example, a rural family physician in northern Minnesota has noticed that his Native American patients have a much lower incidence of Lyme disease than his other patients. He wants to find out if they have resistance to the infection that could prove useful in a vaccine or treatment. Peterson says that study isn't funded yet. "But it's a good example of how novel areas of investigation arise from a clever and observant doctor working in primary care."

Sometimes the research addresses a problem physicians see in their practice or a desire to improve workflow. Peterson says one of the first practice-based projects done in Minnesota in the early 1980s was on how to better handle after-hours phone calls. The study was published in the *Journal of Family Practice* in 1984.

These days, only 20 percent of the MAFP network's projects are initiated by practicing physicians. The other 80 percent are national or regional studies. In one such study, Minnesota physicians helped test the APGAR asthma tool. In another, 100 clinicians in 24 Minnesota clinics took part in the Kidney Disease Outcomes Quality Initiative that determined the best method for teaching clinicians how to use treatment guidelines from the National Kidney Foundation. "The evidence for effectiveness we helped build encouraged others to adopt these national guidelines," Peterson says.

The shift from studies that are small-scale and homegrown to ones that are large-scale and national happened partly because researchers discovered the value of using PBRNs, Peterson says. But no matter how well-funded a national practice-based research project might be, "We only take on the projects that have practical relevance to our members," he says of the MAFP network.

Mayo Clinic Health System's network has stayed more local in its focus, according to Schrader. "Anyone with an observation that might improve care can propose a study," she says. That includes patients, one of whom proposed testing a program in which patients with diabetes can mentor each other to supplement the education and support already being offered. The project is now being piloted in Mayo Clinic Health System practices.

Kathy MacLaughlin, M.D., a Mayo family physician in Rochester, led a team that designed a study to improve the timing and process for Group Strep B screening in pregnant women. "We made changes in how and when the test is ordered to decrease the need for repeat testing, while maintaining consistency with CDC guidelines," she says. They have since incorporated the new screening protocol into the electronic health record (EHR).

Another Mayo physician in Rochester responded to a request from the community to improve chronic disease management outcomes for Somali immigrants by using community health workers to help the immigrants overcome barriers to getting health care such as language, lack of transportation and no health insurance coverage. "Among other improvements, we saw improved diabetes management outcomes and increased rates of preventive services such as immunizations [among immigrants]," Schrader says.

Because of his first-hand experience with "electronic health record fatigue and frustration," another Mayo physician came up with a plan to work one-on-one with Mayo Clinic staff to improve specific EHR skills and increase physician job satisfaction.

Some Minnesota physicians like Jewett participate in national networks as well as local ones. He is a member of the Pediatric Research in Office Settings (PROS) Network. Through the PROS network, he has studied a protocol for treating febrile infants and is helping oversee evaluation of a decision-support tool embedded in EHRs. He explains that many studies involve delivering a prescribed practice method and at the same time keeping records of how that method affects a specific measurable health parameter. "As a participant in a study, your task is usually to record observations," he says.

In all cases, a network's members choose which studies they want to participate in and the extent to which they want to be involved. Some may only want to enroll patients and learn a new protocol. Others may want to take it a step further and analyze data or write up results for publication. Many practice-based research findings are published in peer-reviewed journals.

Building buy-in

Getting primary care physicians to do practice-based research is more crucial than ever, according to Peterson. "Primary care clinicians make up only 25 percent of the nation's health care workforce," he says, "but they provide more office visits than do all other specialists combined." Thus, primary care practices are living laboratories for patient-centered care, medical homes, accountable care and other innovations in health care delivery. Any improvements are more likely to be adopted—and adopted more quickly—if they're developed and tested in the primary care setting. But just when it's so important for primary care doctors to participate in such studies, it's also getting harder to recruit them, Peterson says.

Lack of time is the No. 1 culprit. "The primary care provider is working harder than ever," he says. "Our doctors have less time to do this kind of research." EHRs are also part of the problem. "They're a blessing and a curse," Peterson says. "They make data collection, analysis and dissemination easier, but physicians are so overwhelmed with what they're expected to do with EHRs they don't have time to participate in things that are a bit more fun—like using it for practice-based research."

PBRNs are using social media, mobile devices and Internet technologies to make it easier for primary care physicians to participate in studies. Mayo Clinic Health System, for example, used Twitter to collect observations during a diabetes study.

Another issue is the fact that most community clinics are now owned by big health systems, which sometimes don't allow their physicians to participate in outside research. "Participation can be difficult for physicians who work for

BETTER CARE THROUGH TECHNOLOGY

Electronic health records and patient-accessible web portals are already transforming medicine, but the Mill City Innovation and Collaboration Center (ICC) intends to take the electronic transformation of medicine to the next level.

Mill City is the nation's first practice-based research lab where technology vendors and health care providers collaborate on ways to use apps, medical devices, wireless sensors, mobile devices, electronic health records and other technologies to reduce costs while improving outcomes and patient satisfaction, according to Kevin Peterson, M.D., M.P.H., the ICC's research director. He is also research director for the University of Minnesota's Center of Excellence for Primary Care.

Peterson says they "hope to use technology to reduce unnecessary face-to-face in-clinic visits by 40 percent, while improving patient care and satisfaction." He adds that the focus of the ICC's work will be on using new technology to manage chronic diseases, especially diabetes, congestive heart failure, COPD and memory loss. "We're here to show that when these technologies are developed in collaboration with health care systems, physicians will want to use them because they have great value for them and their patients."

For example, a physician might recommend that a patient with type 2 diabetes purchase a glucometer. A medical software company collaborating at the ICC would then develop an app for the glucometer that syncs its readings to the patient's electronic health record. Peterson says this is an example of how an app could be used to inform and motivate patients, improve communication between the patient and the physician, reduce office visits and phone calls, and improve the quality and lower the cost of care.

The ICC is in the process of moving from what Peterson calls the "conceptualization stage" to the "demonstration stage." It hopes to attract hardware, software and telecommunication companies, as well as health care systems and academic institutions that want to play a role in what he refers to as "the redesign of primary care." The concept comes from Eric Topol's book *The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Health Care*, which asserts that the biggest improvements in health care are being driven by a convergence of technologies.

The 4,000 square-foot nonprofit ICC is in downtown Minneapolis next to University of Minnesota Physicians' Mill City Clinic, which will serve as a testing ground for innovations. "Research is best conducted in settings where it will be used," Peterson says. "And new technologies will be adopted much faster when the health care systems that will use the technology help develop it."—H.B.

THE HISTORY OF PRACTICE-BASED RESEARCH NETWORKS

Practice-based research started in Minnesota in the mid-1970s. At that time, Milton Siefert, Jr., M.D., Barbara Yawn, M.D., Patricia Cole M.D., Thomas Mayer, M.D., Leif Solberg, M.D., and colleagues were conducting studies on their own about ways to improve care and efficiency in their clinics.

"You soon realize you don't have enough patients to do a proper study and that your patient population isn't diverse enough," says Yawn, who is director of research at Olmsted Medical Center in Rochester. "You need to band together with other practices."

So began the Minnesota Academy of Family Practice's Practice-Based Research Panel in 1979. About that time, Solberg, Mayer, Siefert and Cole did a study on how to better handle after-hours phone calls, which was published in the *Journal of Family Practice*. "We didn't call it a network," says Solberg, "because we were just a group of like-minded docs sharing ideas on practice-based research." The panel changed its name in 1984 after it received its first grant. It is one of the three oldest continually operating practice-based research networks in the country.

Today, there are 152 practice-based research networks certified by the Agency for Healthcare Research and Quality (AHRQ). Most are sponsored by medical societies and many are affiliated with a medical school. Some networks include different types of primary care specialists. Others like MAFP's are specialty-specific. (Family physicians make up at least 75 percent of MAFP's network.)

Some PBRNs are state-based. MAFP's network and the Minnesota Department of Health's Public Health Practice-based Research Network are examples. Others, including the Pediatrics Research in Office Settings (PROS) Network and the American Academy of Family Physicians Network, are national. Still others, such as Mayo Clinic Health System's Practice-Based Research Network, are health system-based. There also are national networks for nurses, dentists and pharmacists.

More common today are networks focused on a specific type of care innovation such as medical homes or a specific area of practice. In Minnesota, networks of providers interested in behavioral health, sports medicine and women's health are in the early stages of development.

Networks provide just one way physicians collaborate on practice-based research. Another is through the Rochester Epidemiology Project, a collaboration of Olmsted Medical Center, Mayo Clinic, Mayo Clinic Health System and the Rochester Family Medicine Clinic. The project's medical records data are used by researchers trying to improve the health of Olmsted County residents by better understanding the causes of illnesses and the outcomes of various treatments. "This way," Yawn says, "we can figure out the true population-based frequency of certain conditions and how many patients improve with a particular treatment." The NIH has funded the Epidemiology Project's practice-based research for more than 45 years.

Health systems are also embracing this kind of population practice-based research. Solberg now directs Health Partners' Care Improvement Research Department, which supports such research. Several Minnesota health systems now collaborate with the University of Minnesota and other networks on practice-based projects that have a systems perspective through the Midwest Research Network.

Such collaborative practice-based research is extremely important to medicine's future, Yawn says, because the proof really is in the practice. "Practice-based research is something all physicians can participate in and should be allowed to participate in," she says. "Research is not a four-letter word."—H.B.

systems where there's a lot of top-down micromanagement of local clinics," says Barbara Yawn, M.D., a family physician and director of research at Olmsted Medical Center in Rochester and a national expert on practice-based research. Yawn is one of Minnesota's practice-based research pioneers. She got her start when she was a resident 45 years ago and now serves as a principal investigator for national studies.

Like Peterson, she beats the bushes looking for participants and knows firsthand how hard it can be to recruit primary care physicians who work for big health systems. "For practice-based research to thrive today," Yawn says, "the big systems need to give their docs a little flexibility in how things get done."

Often, these systems don't allow their physicians to be paid for participating in practice-based research. "In the old days, you could pay them, or maybe buy them some needed office equipment," Peterson says. "But now the money often goes into a general fund."

Yawn still pays stipends (about $1,500 to $3,000 a year) to some practices that participate. "It's a token, and everybody knows it," she says, "but it helps cover some support staff time spent on the project."For a study she is doing on ways to better manage COPD in small clinics, Yawn provided participants with free spirometers and trained their staffs how to use them and interpret the results. When the study was over, the clinics were able to keep the spirometers, which still generate revenue for them.

Poor study design can also discourage participation. "Studies must be designed well, and they must be relevant and interesting to a busy primary care doc," Peterson says. "Enrolling patients in practice-based studies isn't easy, but it's surprising how often investigators assume that it happens magically. Or the workload expectations they have for physicians and

> "FOR PRACTICE-BASED RESEARCH TO THRIVE TODAY, THE BIG SYSTEMS NEED TO GIVE THEIR DOCS A LITTLE FLEXIBILITY."
>
> – BARBARA YAWN, M.D.

office staff are entirely unrealistic." For those reasons, he says PBRNs encourage investigators to collaborate closely with participating physicians to make projects minimally time-consuming and maximally pertinent to their practice.

Some practice-based investigators employ research facilitators who help ease the process by training clinic staff on what's expected of them and incorporating a study's methodology into the clinic's workflow as seamlessly as possible. Last summer, the MAFP network helped develop a 16-week course to train practice facilitators. Peterson likens the 20 facilitators trained so far to extension agents who go out into the field and help clinics conduct practice-based research and adopt new practices that come out of the research.

Family physician Stephanie Jakim, M.D., who works at a two-provider branch of Olmsted Medical Center in Preston, participated in a study to test the effectiveness of screening for COPD in order to identify and start treating patients earlier. She says the fact that the investigators did a lot of the legwork for them "made it a good experience for all of us."

Mayo Clinic Health System's network calls its facilitators "practice-based research coordinators." They help clinics taking part in research projects retrieve patient data from medical records, interview patients, clean up data and, sometimes, do analysis.

Keeping physicians from losing interest in a study is another challenge. Yawn referred to it as "voltage drop" in an article she published in a 2013 issue of the *Journal of the American Board of Family Medicine*. "Practices usually begin a study with enthusiasm and willingness to learn," she says. "But over time, the reality of a busy practice erodes their enthusiasm to keep participating."

> "THERE'S VALUE IN HAVING THE PEOPLE WHO PROVIDE DIRECT PATIENT CARE COME UP WITH THE IDEAS FOR PRACTICE IMPROVEMENT.
>
> – KATHY MACLAUGHLIN, M.D.

She says having a research coordinator to communicate about a project, give lots of positive feedback and infuse a dash of fun into the work can help maintain the enthusiasm.

Worth the effort

For nurse practitioner Penny Louise Flavin, D.N.P., R.N., C.N.P., the time and effort required to do practice-based research is worth it. She's helped Olmsted Medical Center in Pine Island test and adopt new guidelines on COPD, cholesterol, asthma and diabetes. She took the lead on one project that involved getting diabetic patients' input on method and route for taking medications, identifying what frequency and expense they're willing to incur for medications and supplies, and creating talking points for the pre-diabetic patient with glucose levels of 100 to 126 mg/dL. She says such work has equipped her to better deal with patients' misgivings.

As part of this study, she created "YIPPEE cards" that she now gives all of her diabetes patients who meet Minnesota Community Measurement's goals for diabetes control. The cards, with the word YIPPEE! across the front, congratulate patients for meeting benchmarks for blood pressure, exercise and A1c. "Patients love them," she says. "They put them on their fridge and are disappointed if they didn't make the YIPPEE board at the clinic. It's definitely an incentive and reinforcement tool, and it helps me build great relationships with my patients."

Fergus Falls family physician Patty Lindholm, M.D., who participated in a study on asthma designed and coordinated by Yawn and her team and a depression study through what is now the American Academy of Family Physicians' research network, says taking part in practice-based research allows her the intellectual challenge of conducting research without having to apply for grants or design the study. "It prompts me to study a topic in greater depth and evaluate my own practices," she says.

MacLaughlin says being part of practice-based research improves practice in ways that are measurable and sustainable. "There's value in having the people who provide direct patient care come up with ideas for practice improvement," she says.

Practice-based research also improves the health of clinics, according to Yawn, who published an article on the benefits to physicians and their staff in a 2010 issue of the *Journal of the American Board of Family Medicine*. "Physicians learn that nurses and other staff can do more," she says. "Everyone on the staff learns new skills and they work better as a team." She says it also improves staff retention and the self-esteem of all clinic staff who participate.

Yawn says the physicians who do best at practice-based research want a little more stimulation than they get seeing one patient at a time. "They're interested in quality improvement and contributing to a greater good that improves health care for lots of people. And isn't that why most of us went into medicine?" **MM**

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

Attention medical students, residents and fellows

Minnesota Medicine is seeking **abstracts of original research** and **clinical vignettes**.

DEADLINE FOR SUBMISSION:
June 21, 2014

Learn more and submit your abstract or vignette at

www.minnesotamedicine.com/abstracts

The virtues of irrelevance

Why our opening comments are so important

BY DANIEL R. WOLPAW, M.D., AND DAN SHAPIRO, PH.D.

"Interesting belt—where did you get that?"

"I see you are from Youngstown. The key question is, are you a Steelers fan or a Browns fan?"

These are not the usual opening questions we teach for the medical interview. The answers are not included in the chief complaint, history of present illness, past history, social history, family history, review of systems, medications or allergies. There is no hat or belt section in the physical exam. Differential diagnoses on sports, clothing or food preferences are not a highly valued component of clinical reasoning. But often these opening comments and questions are the most important. They can be our tickets and our guides, ways to establish the connections that allow us to actually care for the person in front of us.

We believe that these "irrelevant" opening comments and questions serve four key purposes. First, they convey that we see the patient as a unique individual. Given the speed of medical practice, it is not surprising that patients worry that their individual concerns will not be heard. Second, these questions reveal that we have had shared experiences, that despite our training and attire we are not so different from the patient. Third, they communicate that we are observant and attending to details, which patients find comforting. And finally, they indicate that we are open to a conversation with the patient.

There are additional benefits. Seemingly irrelevant comments convey a message similar to the act of sitting down: "I have time for you." When patients meet with their physicians, they are often anxious, and these opening conversations give them a chance to "warm up" while speaking about topics that are comfortable and easy to discuss. Opening with casual banter also conveys that we are probably not the bearers of terrible news, and it may thus help to allay the patient's worst fears.

Sometimes it helps to try to inject a little light humor. "I see you've been sampling our cuisine. Do you have any comments or special requests for the hospital chef?" A quick shared laugh can be a balm during difficult times.

Experienced clinicians recognize that these comments are often an essential warm-up for the conversation and shared decision-making that follow. When patients are in the presence of observant, authentic, connected clinicians, they are more likely to share their observations, fears and questions. They are also more likely to move past the distrust that so often accompanies the perception of clinicians' "otherness" and collaborate in addressing next steps that are scary, unknown or unknowable.

We have all had the frustrating experience of trying to help patients who prefer the advice of neighbors, aunts or hairdressers to our recommendations: they connect with those people, share a space with them. We believe that clinicians can also share this space, and it often doesn't take much to get there. Just noticing may be enough. Share a laugh, admire a family-reunion T-shirt or an elegant walking stick, and you can become a kind of neighbor.

For many years, physicians regularly visited patients' actual neighborhoods. In the 1930s, four out of 10 physician-patient contacts were house calls.[1] Because physicians were embedded in the community and visited patients' homes, conversations naturally included shared experiences and nonmedical observa-

tions. It may be impossible to recreate the intimacy of a house call in a brief outpatient or inpatient visit, but it is possible to take a few opening moments to reach beyond the immediate medical agenda and connect with the patient first.

> "Medical education actively stunts conversational skills, at least temporarily."

Numbers of home visits and durations of office conversations and hospital stays have been shrinking over the past half-century, and the nature of our interpersonal relationships inside and outside of medicine has changed as well. Patients often at least partially vanish into their electronic health record—becoming the "iPatient," as described by Abraham Verghese.[2] "Speed dating" has entered our vocabulary and our social landscape, focusing on the first few minutes of meeting a stranger. Cognitive neuroscientists teach us that we make judgments exceptionally quickly—and yet often accurately. Studies of "thin slices," as these rapid assessments were described by Ambady and Rosenthal, reveal that "a great deal of information is communicated even in fleeting glimpses of expressive behavior."[3]

In a similar fashion, our patients are judging us from our first moments of interaction.

They are deciding whether we are trustworthy, capable and interested. How we handle those first moments is critically important. Perhaps counterintuitively, we are arguing that it is often more important to be human than to be medical in those first moments, that our commitment to connecting is an important prerequisite for exchanging medical information.

Making this connection is natural for some clinicians, less so for others. It is hard to translate into checkboxes or manuals. There are no questions or comments that will always work. In the end, "working" depends on reading the signs, gauging the distance, accounting for professional boundaries, and genuinely, even a little vulnerably, showing your hand, acknowledging shared humanity: "I am interested in you, I could be where you are, we are not so different after all." This behavior can be modeled and encouraged, and we believe it can be learned—or rather, relearned.

Most students come to medical school with reasonable social skills. Among friends, they usually know how to start a conversation in a humorous, interested or insightful way. The idea that we would need to teach this skill is a little absurd. But unfortunately, medical education actively stunts conversational skills, at least temporarily, loading students with lists of questions and pages of checkboxes that can eclipse authentic relating. Even displays of "empathy" are often scripted. Teaching the "irrelevant" comment or question is really just a matter of endorsing and modeling what students already know from their social development and extra-clinical lives.

We would argue that this nod to irrelevance is more than a nice touch or an effective communication strategy. It is a necessary part of our personal and professional lives, which have been increasingly threatened by the pressure for ubiquitous relevance. Everything is supposed to count, or be counted. Purposeless moments—moments for deep breaths, surprises and insights into ourselves and others—are an endangered species. It is time for us to recognize, validate and support these genuine connections between doctors and patients. **MM**

Daniel Wolpaw and Dan Shapiro are from Penn State College of Medicine in Hershey.

REFERENCES

1. Jauhar S. House calls. N Engl J Med. 2004; 351:2149-51.

2. Verghese A. Culture shock — patient as icon, icon as patient. N Engl J Med. 2008;359:2748-51.

3. Ambady N, Rosenthal R. Thin slices of expressive behavior as predictors of interpersonal consequences: a meta-analysis. Psychol Bull. 1992;111:256-74.

PHOTO BY KATHRYN FORSS

Huntley addresses a group of medical students as part of the MMA's 2014 Day at the Capitol event.

Moving on but not fading away

Parting thoughts from longtime legislator Tom Huntley

BY MELISSA MRACHEK

PHOTO COURTESY OF MN HOUSE

Rep. Tom Huntley

In 1992, when Rep. Tom Huntley (DFL-Duluth) was first elected to the Minnesota House of Representatives, the Mall of America had just opened, Dennis Green was in his first season as the Vikings' head coach and Arne Carlson was governor. Obviously, a lot has changed since Huntley first took a seat in the House chamber.

Now, he is just weeks away from retirement.

As he looks back on his 22 years at the Capitol, he can't help but reflect on the work he has been involved in and the role he has played in shaping health care in Minnesota.

"Rep. Huntley brought a unique set of skills to the Minnesota Legislature," says Dave Renner, the MMA's director of state and federal legislation. "It's hard to look back on any piece of health care legislation passed in the last 22 years that Tom Huntley was not directly involved in."

Homing in on health care

Prior to his career at the Capitol, Huntley taught biochemistry at the University of Minnesota, Duluth. Perhaps it was that background or the fact that he was named to the Health and Human Services Committee when he arrived at the Capitol that cultivated his interest in health care legislation. During his tenure at the Legislature, Huntley has played a role in the passage of some significant pieces of legislation. One of his greatest accomplishments, he says, was serving as chief author of the Freedom to Breathe Act, which banned smoking in public places when it went into effect in 2007. "It was somewhat controversial with only 65 percent support," Huntley recalls. "Now 80 percent of people support what we did."

That same year, Gov. Tim Pawlenty tapped Huntley to help spearhead health care reform in Minnesota. "He asked us to head up a committee aimed at getting more people insured, spending less money and improving health care," Huntley says. One of the major outcomes of that work was the establishment of health care homes.

"The whole idea was to try to keep people healthier rather than waiting until they ended up in the hospital," he says. "We set up the health care home system to coordinate care for people. And it has proved very successful."

Just this year, the Minnesota Department of Health released results of a three-year study showing a 9 percent reduction in health-care related costs for Medicaid beneficiaries who used a clinic that has been designated by the state as a health care home. In addition, the study found health care home clinics outperformed other clinics on quality measures.

A number of Huntley's ideas for health care reform that were included in 2008 legislation ended up as provisions in the Affordable Care Act (ACA). He says because Minnesota has been a leader on issues such as health care homes, accountable care organizations (ACOs), quality measures, implementing health care technology and a statewide health improvement initiative, the

PHOTO BY KATHRYN FORSS

Huntley has been advocating for health care legislation for most of his 22-year career at the Captiol.

feds looked to our state when crafting the ACA.

Once the ACA passed, Huntley championed many of its major initiatives in Minnesota. He served as chief author of the legislation that expanded Medicaid, known as Medical Assistance in Minnesota. As a result, thousands more Minnesotans have access to care.

Still work to be done

Health care reform is an ongoing effort. Huntley says the focus now needs to shift toward changing the way we pay for care. "We don't pay for results," he says. For that reason, he says, the current fee-for-service model must be eliminated. Minnesota is experimenting with new models in which providers receive bonuses if they show they have saved money and improved health outcomes.

"I think we are one of only eight states given money to set up accountable care organizations," he says. "And it's changing the way providers think about what they are doing."

Measuring results is key to changing the payment structure. If there is one piece of advice Huntley would give physicians, it's to measure results and not be afraid to share them. "It's a lot of work, but you have to know your results." He adds that physicians need to be talking with one another. "I'm a big believer that all the important things happen in the world because of who you bumped into in the hallway," he says. "Talking to other physicians and educating each other is the most important way to improve."

The next chapter

Even though 2014 will be his last session as a lawmaker, Huntley plans to remain involved in health care issues. In particular, he is interested in helping solve one of MMA's top priorities—alleviating the impending primary care physician shortage in the state. "The whole emphasis on health care reform is to emphasize primary care so people don't have to go to the hospital or see a specialist," he says, adding that reform won't work if there aren't enough primary care physicians.

Aside from his work on health care legislation, Huntley says he'll miss the people: "I have some very good friends here," he says of both lawmakers and the lobbyists who have helped him understand complex issues.

However, he won't miss the pace. "What I won't miss is 10 hours of debate on the House floor when nobody's mind is being changed whatsoever. We have 134 House members. We often say 'Everything's been said, but not everybody has said it.'"

Nor will he miss the partisanship. "Minnesota used to have a tradition of working between the two parties," he says. "People used to be able to argue an issue and then go out and have a beer together. That doesn't seem to happen much anymore."

LEGISLATIVE UPDATE

TOP MMA PRIORITIES
Where things stand

PRIORITY: Physician-led team-based care

Advanced practice registered nurses (APRNs) are pushing for more independence (for example, prescribing authority). The MMA supports collaborative physician-led team-based care in order to make sure patients receive the best care possible from the right practitioner.

Status: Negotiations continued as this issue went to press. The main sticking point continues to be preventing certified registered nurse anesthetists from practicing interventional pain relief.

PRIORITY: Regulating e-cigarettes

The MMA supports prohibiting the use of e-cigarettes in public indoor spaces such as workplaces and bars by expanding the Freedom to Breathe Act. The MMA is also looking at additional retail regulations such as requiring tobacco sellers to obtain a license to sell e-cigarettes and requiring them to place the product behind their counters. Having them disclose ingredients on the product's packaging is also being considered.

Status: Legislation that will regulate e-cigarette use appears imminent, but prohibiting their use indoors is still being debated.

PRIORITY: Battling prescription opioid misuse

The MMA supports strengthening the Minnesota Prescription Monitoring Program so that alerts are sent to prescribers regarding patients who are potentially "doctor shopping." The MMA also supports "911 Good Samaritan + Naloxone" legislation that is designed to prevent opioid overdose deaths by providing immunity to those who call 911 in good faith to save a life and increasing public access to the antidote naloxone. The law would allow first responders to carry naloxone and make the drug available through community-based agencies that work with intravenous drug users.

Status: The bill allowing first responders to carry naloxone passed unanimously on the Senate floor. The bill to strengthen the state's prescription monitoring program is expected to pass as well.

PRIORITY: Prohibiting tanning bed use by minors

The MMA supports legislation to prohibit the use of indoor tanning devices by minors, require a warning notice be provided to each consumer and update posted warning signs at tanning facilities.

Status: This bill is moving quickly without opposition from outside groups.

PRIORITY: Restoring the newborn screening program

The MMA is urging the Legislature to restore the state's newborn screening program to its previous nation-leading status by removing the retention periods for test samples and data established in 2012.

Status: This legislation is well-positioned. It will allow the Department of Health extended storage of the blood spots and test data as well as allow for new test development. It also requires parental consent for use of the spots for research.

PRIORITY: Cost and quality data for hospitals and clinics

The MMA supports eliminating provider peer grouping and focusing more attention on the all-payer claims database as the tool for creating public comparisons of the cost and quality of care provided by hospitals and clinics.

Status: This legislation has made it through all committees with no changes. It continues to be supported by the MMA, Minnesota Hospital Association and the Department of Health. The only opposition has come from a handful of legislators who don't believe the state should have any medical data. The MMA expects this bill to pass.

PRIORITY: Expediting the provider tax phase-out

In 2011, legislators voted for the phase-out and eventual repeal of the provider tax by the end of 2019. The 2 percent tax has driven up the cost of health care and falls more heavily on sick and low-income Minnesotans. The MMA will continue working to ensure the repeal and will oppose any efforts to use money from the Health Care Access Fund for any new purposes.

Status: It appears the fund will not be touched this session.

PRIORITY: Aligning clinical data sharing

The MMA supports legislation that would bring the Minnesota Health Records Act into alignment with the federal HIPAA standards governing the sharing of health information. Enhanced information sharing is crucial to the functioning of accountable care organizations, health care homes and total cost of care arrangements. Appropriately shared clinical data will increase the quality of patient care and decrease costs.

Status: This legislation did not receive a committee hearing this session.

News briefs

MMA launches contest to promote Choosing Wisely

MMA members have until July 1 to submit a short video (five minutes or less) promoting the Choosing Wisely campaign.

The entries will be judged by the MMA's Choosing Wisely Advisory Committee; three contestants will win gift cards of $100, $200 or $300. Entries will also be considered for a People's Choice award, in which all MMA members and nonmembers can vote for their favorite video. The People's Choice winner will receive $100.

For more details go to www.mnmed.org/ChoosingWisely.

MMA and MMA Foundation hand out awards

In April, the MMA and MMA Foundation presented their annual quality, community service and excellence in medical journalism awards.

Tim Hernandez, M.D., (to the right) who leads the quality efforts at Entira Family Clinics, an independent 12-clinic practice in the St. Paul area, received the Physician Leadership in Quality Award.

In presenting the award, MMA CEO Robert Meiches, M.D., noted Hernandez' long-standing involvement in quality efforts at both Entira and with various state groups including the Institute for Clinical Systems Improvement, Minnesota Community Measurement and the Community Health Network. Hernandez has also been involved with the Consultation for Mental and Substance Abuse Disorders Task Force and the Health Care Reform Baskets of Care Subcommittee on OB Care.

Brian Sick, M.D., received the Community Service Award for his work with the Phillips Neighborhood Clinic in south Minneapolis. Since 2007, Sick has acted as the free clinic's medical director, volunteering his time to guide students in providing accessible, culturally appropriate, high-quality health care to those in need, and cultivate compassionate health care leaders.

KSTP-TV reporter **Naomi Pescovitz** (below) received the Excellence in Medical Journalism Award for a story the ABC affiliate aired in April 2013. The story concerned a team of doctors at the University of Minnesota (including MMA member John Wagner) that saved a 12-year-old's life by curing him of HIV and leukemia. Pescovitz interviewed the doctors before and after the child received a cord blood transplant.

Each year, the MMA and the Foundation recognize Minnesota physicians for their work in the community and on quality efforts. The groups also recognize a print or broadcast journalist who has demonstrated excellence in communicating with the public on a topic related to medicine.

MMA board member Roger Kathol, M.D., (white shirt) listens to concerned health care workers at a meeting in Cambridge on mental health needs.

MMA teams up with state leaders on mental health initiative

Since the mid-March closure of Riverwood Centers Behavioral Health's five offices in east central Minnesota, the MMA, the departments of health and human services, and other mental health advocates have been working to raise awareness and provide services to the reported 3,000 patients left without care.

In late March, several physicians, including MMA board members Randy Rice, M.D., and Roger Kathol, M.D., gathered in Cambridge for a group discussion on mental health needs in the Riverwood service area, which includes Chisago, Isanti, Kanabec, Mille Lacs and Pine counties.

Lucinda Jesson, state commissioner of human services, and MMA member Paul Goering, M.D., of Allina Health, led the meeting of nearly 100 mental health providers, health system leaders, state and county officials, patients and local advocates for mental health services.

The meeting included a discussion of the statewide needs for improved mental health services, an assessment by small workgroups of existing service gaps and ideas for serving the immediate needs of affected patients, and a discussion of next steps.

Participants discussed the usefulness of Fast-tracker, an online resource sponsored by the Minnesota Psychiatric Society that can be used to help connect patients with available mental health providers. Other steps include conducting a more local needs assessment and making plans to bring the group back together in three to six months to monitor and reassess the needs of patients and the community.

Riverwood Centers, formerly known as Five Counties Mental Health Centers, had offices in Braham, Cambridge, Milaca, Mora, Pine City and North Branch.

The MMA plans to help raise awareness about the crisis, identify resources and work with the Department of Human Services and the Department of Health in providing a needed safety net for clients in the area. For more information on resources, visit www.mnmed.org/Advocacy/MentalHealthIssue.

Congress patches SGR, delays ICD-10 and "two midnight" rule

The day before a 24 percent physician payment cut was to take effect as part of the Medicare sustainable growth rate (SGR) formula, the U.S. Senate passed a measure postponing it until April 1, 2015. The House had passed a similar bill four days earlier, and President Obama signed the legislation into law. This was the 17th time Congress has approved a patch since SGR became law in 1997.

The MMA, AMA and dozens of other physician organizations lobbied Congress unsuccessfully for a full repeal of SGR.

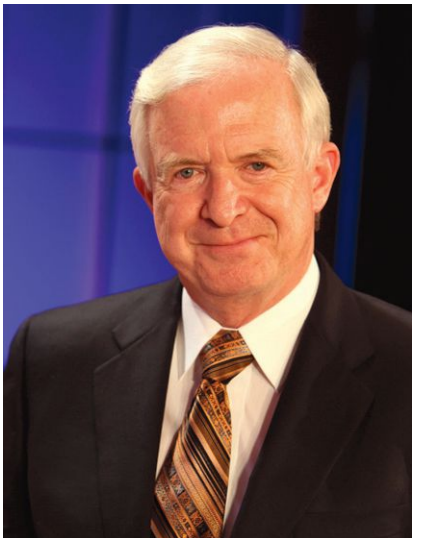
"We are certainly disappointed with another temporary patch," says Dave Renner, the MMA's director of state and federal legislation. "We had bipartisan, bicameral support of an SGR repeal developed and making progress in Washington, and then lawmakers got cold feet."

Congress also delayed implementation of ICD-10 until at least October 2015 and put off enforcement of the "two midnight" rule for six months. This new Medicare rule stipulates that hospital stays lasting fewer than two midnights must be treated and billed as outpatient services.

The Centers for Medicare and Medicaid Services had been pushing toward an October 2014 ICD-10 launch despite opposition from the AMA and other groups.

Now with 18 additional months to prepare, Minnesota physicians will be able to learn the fundamentals of the new coding system from two online, on-demand educational programs offered by the MMA in partnership with the Wisconsin Medical Society. The programs, which were developed by the Wisconsin society, provide a general overview for all physicians along with specific information about how ICD-10 will affect 20 different specialties. CME credit is available. Visit the MMA website (www.mnmed.org) for details.

National speakers announced for Annual Conference



John Nance

Quint Studer

Pieces are falling into place for the MMA's new Annual Conference with the selection of two national speakers. The conference will take place September 19 and 20 at Madden's on Gull Lake in Brainerd.

On Friday, September 19, attorney/author John Nance, J.D., will discuss the "Team Approach to Creative Problem Solving" and health care expert Quint Studer will discuss creating a culture of excellence in today's fast-changing health care environment.

The morning activities, which will be presented jointly with the Minnesota Hospital Association and Aging Services of Minnesota, will be capped by a gubernatorial debate featuring incumbent Gov. Mark Dayton and his challengers.

"This year's Annual Conference will be unlike any previous meeting," says Mandy Rubenstein, MMA manager of physician outreach and the event's organizer. "We are working on creating an inclusive event that really gets our members thinking about how health care and medicine are being transformed."

In addition to talks by Nance and Studer and the gubernatorial debate, the conference will include a policy council meeting, policy forums, Saturday morning CME sessions, a poster symposium, and time for members and their families to enjoy the Brainerd Lakes area. In addition, the conference will feature leadership inaugurations, awards and networking opportunities.

June health disparities forum taking shape

The MMA continues to move forward with planning for its forum on Minnesota's health disparities and inequities June 17 from 5:30 to 8 p.m. at the Wilder Center in St. Paul.

Forum participants will hear keynote speaker Health Commissioner Edward Ehlinger, M.D., MSPH, discuss the health department's efforts to address disparities and inequities in the state. In addition, the event will feature a panel including Shana Sniffen, M.D., from the HealthEast Roselawn Clinic and Tamiko Morgan, M.D., FAAP, CMO/medical director of Metropolitan Health Plan and an associate professor at the University of Minnesota.

The event will also provide an opportunity for physicians to share their best practices for working with minority populations and discuss what physicians can do to address health disparities.

The cost is $25 for members ($40 for nonmembers and $10 for students). The event is sponsored by the Minnesota Association of Black Physicians, the American Indian Cancer Foundation and the Minnesota Department of Health's Office of Minority and Multicultural Health.

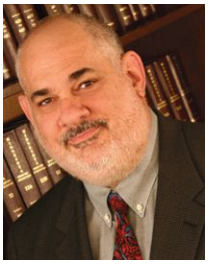
To register, visit www.mnmed.org/disparities.

MMA and the U of M = Quite a Match

MMA staff members Evelyn Clark (left), Kathleen Baumbach and Brian Strub were on hand for Match Day at the University of Minnesota Medical School on March 21.

Janet Silversmith

Teresa Knoedler



Robert Meiches, M.D.

Cindy Firkins Smith

Kathleen Baumbach

Eric Dick

MMA in action

Janet Silversmith, MMA director of health policy, presented on MNsure to a group of physicians at Sanford-Bemidji in mid-March. Silversmith, **Teresa Knoedler**, MMA's policy counsel, MMA CEO **Robert Meiches**, M.D., and member **George Schoephoerster**, M.D., met with the Minnesota Council of Health Plans and medical directors from Blue Cross Blue Shield, Medica, HealthPartners, Preferred One and UCare to discuss prescription drug prior authorization processes. Meiches and Silversmith also took part in a telephone interview with Econometrica and the Urban Institute to analyze the state's implementation of MNsure and the Affordable Care Act.

In mid-April, MMA President **Cindy Firkins Smith**, M.D.; **Kathleen Baumbach**, MMA manager of physician outreach; **Eric Dick**, MMA manager of state legislative affairs; and **Dave Renner**, MMA director of state and federal legislation, met with Minnesota Academy of Ophthalmology members in St. Paul. Smith also participated in a specialty society presidents' update with Renner and attended a Minnesota Academy of Pediatrics board meeting with Dick.

Smith also attended the North Central Medical Conference in mid-March in Bloomington, the Wisconsin Medical Society annual meeting in early April, and the Iowa Medical Society annual meeting in mid-April.

Barbara Daiker, MMA manager of quality, presented on health care quality and measurement to physicians and staff of Sanford in Luverne in mid-March.

Juliana Milhofer, MMA policy analyst, attended the American Medical Association's Commission to End Health Care Disparities spring meeting in Massachusetts in early April.

Brian Strub, MMA manager of physician outreach, **Evelyn Clark**, MMA manager of grassroots and political engagement, and **Nancy Bauer** of the Twin Cities Medical Society attended Transition Day at the University of Minnesota Medical School. This annual event is designed to help prepare second-year students to transition from the classroom to the clinical setting.

Several MMA staffers including Baumbach; Strub; Daiker; **Mandy Rubenstein**, MMA manager of physician outreach; and **Terry Ruane**, MMA director of membership, marketing and communications, attended the two-day Minnesota Academy of Family Physicians' Spring Refresher in St. Paul.

VIEWPOINT

The muddling of medicine

Cindy Firkins Smith, M.D.

I like to think of myself as fairly progressive, but every once in a while my "old-schooledness" declares itself. Be warned; this is one of those times. As part of my work, I see patients in the Resident Consortium Clinic at the University of Minnesota, an endeavor I treasure because it allows me the opportunity to work with residents and medical students. I like to think I teach them something, though in truth they probably teach me more.

I love to hear the students talk about their experiences, hopes and dreams. It takes me back to my own medical school days. Some were miserable, but many were truly magical. I suspect every physician can remember the first "real" patient he or she examined. I certainly remember mine on the neurology service at the old VA. (Most important lesson learned: Do the mental status exam FIRST, not after you've spent two hours getting a confabulated history.)

While in clinic recently, I overhead a group of students taking part in a conversation that I felt compelled to interrupt. In the context of their discussion, they referred to themselves as "providers."

I hate this term, and I'm not alone. The MMA asked members what they thought of the term last year, and most who responded said they disliked it as well. I'm not even sure what it means. According to Wikipedia, a health care provider is "an individual or an institution that provides preventive, curative, promotional or rehabilitative health care services." Pretty broad. And very vague because, according to this definition, an individual health care provider could be anyone from a dental assistant to a neurosurgeon.

So why is the word used? The noncynic in me says "provider" has become a pervasive reference to medical professionals because it's easy. Why use multiple references when one will do? Why actually verify a professional's credentials when one term encompasses them all? I call this my "Save a Tree Theory." Using "provider" is a trend borne of laziness, not subversive intent. I have another theory, though, which I call the "Nefarious Theory." It posits that this lumping of professionals is an intentional ploy to deprofessionalize medicine. After all, if every medical professional is a provider, we are all one and the same, and one is as good as the next, no matter the context. Need a doctor? A medical assistant will do. They are both "providers" so what does it matter?

It matters.

Every medical professional should object to this assault on their education, training and expertise. We all chose our specific area of medicine for a reason. A physician chose to practice medicine, a nurse to practice nursing, a dentist to practice dentistry. We all have as a common goal doing what's best for our patients. Therefore, we should champion transparency—and not engage in this muddling of medicine.

I understand that "provider" is convenient and we have probably lost that battle when it comes to insurance forms and government contracts, but we should never succumb to the temptation to join them in referring to ourselves as anything other than what we are. I always ask my students to think about what they do and why they are doing it. That day in the clinic, I asked them to think about what they are and what they will soon become. When they graduate, it will not say "provider" on their medical school diploma; it will say "medical doctor." They will be physicians. I hope I taught them something.

I understand that "provider" is convenient, but we should never succumb to the temptation to refer to ourselves as anything other than what we are.

Cancer's story

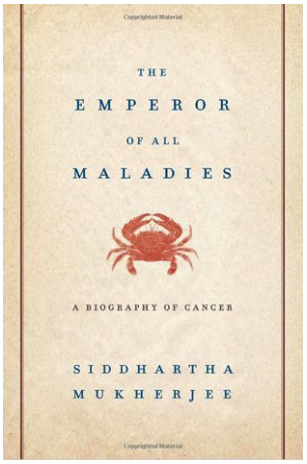
A Columbia University researcher chronicles where our fight against cancer has taken us.

REVIEW BY CHARLES R. MEYER, M.D.

Disease is a person. Like an uninvited party guest, it enters unbidden into a patient's life, sometimes with subtle introductions, sometimes with brash announcements. It confronts its victims in a very personal way, starting a dialogue that can go on for years. The patient gets to know this guest intimately, sampling his character and then reacting to his fury and calculating how to rid him from his or her life. So it's not inappropriate to call a history of a disease like cancer a "biography," which Columbia University cancer clinician/researcher Siddhartha Mukherjee does in his book *The Emperor of All Maladies: A Biography of Cancer.*

Like the tales of most diseases, the story of cancer is an odyssey of discovery that involves physicians and researchers meandering among known medical knowledge and, with sagacity and serendipity, pushing understanding and treatment of the disease toward greater refinement. Mukherjee reaches back to the age of Galen, when physicians thrashed among the humors to find a coherent explanation for tumors and struggled to find options to treat them, when "the idea of surgical removal of cancer as a curative treatment was entertained only in the most extreme circumstances. When medicines and operations failed … [they employed] an intricate series of bleeding and purging rituals to squeeze the humors out of the body as if it were an overfilled, heavy sponge."

Few improvements on leeches and purging were made until anesthesia's advent and Lister's antisepsis revelations in the mid-19th century unleashed surgeons to tackle the excision of cancers in all corners of the body. And excise they did, cutting ever-widening swaths around tumors. The guru of this approach was Johns Hopkins surgeon William Halsted, who in 1882 devised and promoted the radical mastectomy as *the* operation to treat breast cancer. Despite the fact that "the superiority of radical surgery in 'curing' cancer still stood on shaky ground," Halsted's doctrine of "radicalism" ruled cancer therapy for decades, "fossilizing into dogma," according to one historian.



The Emperor of All Maladies: A Biography of Cancer, Siddhartha Mukherjee, 2010, Scribner

Even as Halsted's radical surgery dominated thinking, others were searching for the "magic bullet" described by physician Paul Ehrlich that might take cancer treatment out of the hands of surgeons. The first bullet ironically emanated from the battlefields of World War I, when doctors treating victims of mustard gas noticed patients' precipitous drop in blood counts. This observation led to the first use of nitrogen mustard for treatment of lymphoma in 1942. In steady succession, 6-mercaptopurine, antifolate drugs and cisplatin were thrown at cancers, in hopes of striking the right balance between toxicity and therapy.

Yet all these efforts seemed like a game of blind darts, never targeting a known property of cancer. They were blunt tools at best. With the advent of tamoxifen, which aimed at the newly discovered estrogen receptors on breast tumors, cancer therapy entered the era of designer drugs. At the same time, the concept of adjuvant chemotherapy that targeted undetectable tumor cells was born. Mukherjee calls these "brave new paradigms of treatment, [which] had thus arisen out of the ashes of old paradigms, Halsted's fantasy of attacking early-stage cancers was reborn as adjuvant therapy. Ehrlich's 'magic bullet' for cancer was reincarnated as antihormone therapy for breast and prostate cancer." The discovery of the genetic basis of cancer and oncogenes triggered therapies pinpointing DNA-based cancer etiologies, thus catapulting current day oncology into refined strategies undreamed of by early researchers. We abandoned earlier approaches that directed therapy at cancer's two known deficits—local occurrences that can be removed and rapidly growing cells that can be killed by meds that target them.

Mukherjee weaves story after story of discoveries and developments in the treatment of cancer with those about the power and the politics necessary to keep the research advancing. His heroine in this battle was socialite Mary Lasker, who devoted much of her life to promoting cancer research through what became the American Cancer Society. Among the "fiery activists" pushing these campaigns, Mary Lasker was "its nucleating force, its queen bee," according to Mukherjee.

In a mere and masterful 470 pages, Mukherjee has sketched the first years of cancer's life. It's not dead, so its story continues. **MM**

Charles Meyer is editor in chief of *Minnesota Medicine.*

Synthetic Marijuana Use and Development of Catatonia in a 17-year-old Male

BY DEREK LEROUX SMITH, M.D., AND CAROLINE ROBERTS, UNIVERSITY OF MINNESOTA PSYCHIATRY RESIDENCY PROGRAM

Synthetic marijuana or "K2" is marketed as being "legal and safe," despite the U.S. Drug Enforcement Administration's (DEA) classification of its five most common active ingredients as Schedule I controlled substances.[1] Manufacturers of synthetic marijuana avoid legal restrictions by substituting various chemicals in their mixtures, while the DEA continues to update its list of banned cannabinoids. Such manufacturing practices result in widely variable chemical composition of these products. Although youths experiment with synthetic marijuana because of its availability and purported safety, accounts of its deleterious health effects have started to emerge.

Case Report

A 17-year-old male with no history of psychosis was admitted to psychiatry for worsening confusion and bizarre behavior. On admission, he displayed posturing, stereotyped movements, a fixed look of distress, mutism and rigidity. Aside from mild hypertension, his vital signs were normal. Labs were unremarkable except for a urine toxicology screen that was positive for cannabinoids. Head CT was negative. Scheduled neuroleptics were initiated. Because the patient's symptoms were consistent with excitatory catatonia, a diagnostic lorazepam challenge of 2 mg IM was administered and neuroleptics were discontinued. After the challenge, the patient's catatonic symptoms improved, and he was able to converse. He described auditory and visual hallucinations and disorganized thought process. His catatonic symptoms recurred approximately seven hours after the lorazepam challenge, consistent with the expected therapeutic response. Because of the patient's marked response to lorazepam and negative organic work-up, the diagnosis of psychosis with catatonic features was confirmed.[2]

Oral lorazepam was scheduled, but the patient's improvement plateaued, and he relapsed into a catatonic state. Electroconvulsive therapy (ECT) was indicated and pursued.[2] By his sixth ECT treatment, the patient showed complete resolution of motor symptoms, denied hallucinations, and was tolerating a cautious titration of olanzapine. It was at this time that he disclosed he used an estimated 2 to 3 g of synthetic marijuana (K2) daily for two months prior to admission.

Discussion

This case underscores the danger of synthetic cannabinoids. Some of the synthetic cannabinoids used in K2 have a higher affinity for the receptor that binds to tetrahydrocannabinol (THC) than others. The variable contents of K2 and this higher affinity binding contribute to the sometimes amplified and unpredictable response users have to the drug,[1] with psychosis being reported in some cases.[3] Currently, there are limited data on the effects of synthetic marijuana on the brain. This case clearly demonstrates the urgency with which the medical and scientific community must address the many unknowns that surround synthetic cannabinoids. **MM**

REFERENCES

1. National Institute of Drug Abuse. Drug Facts: Spice ("Synthetic Marijuana"). Available at: www.drugabuse.gov/publications/drugfacts/spice-synthetic-marijuana. Accessed March 26, 2014.

2. Weder N, Muralee S, Penland H, Tampi RR. Catatonia: a review. Ann Clin Psychiatry. 2008; 20(2): 97-107.

3. Leibu E, Garakani A, McGonigle DP, Liebman LS. Electroconvulsive therapy (ECT) for catatonia in a patient with schizophrenia and synthetic cannabinoid abuse. J ECT. 2013; 29(4): e61-2.

Congenital Epulis in a Newborn

BY JUSTIN YEE, M.D., UNIVERSITY OF MINNESOTA, PEDIATRIC RESIDENCY PROGRAM

Congenital epulis is a rare, benign intraoral tumor of the newborn that is most frequently located on the mucosa of the anterior maxillary alveolar ridge. First described by Neumann in 1871, these tumors appear smooth, pedunculated and pink, and are distinguished from other soft-tissue tumors by their maxillary or mandibular alveolar location.

Case Report

A full-term female infant was born through normal spontaneous vaginal delivery. The pregnancy was uncomplicated, and prenatal labs indicated the presence of group B streptococcus, for which the mother was adequately treated with antibiotics. Apgar scores were 9 and 9 at one and five minutes, respectively.

Shortly after birth, four soft-tissue masses were observed in the anterior maxillary and mandibular ridges of the infant's mouth. These masses were all round, pedunculated and protuberant without noticeable fluctuance. The infant's hard and soft palates were intact. She appeared vigorous and not in respiratory distress. However, she was unable to close her mouth completely, and the masses were affecting her ability to breast- and bottle-feed. A feeding tube was subsequently placed.

Diagnosis

Otolaryngology was consulted and the masses were excised under general anesthesia. Pathology revealed a granular cell tumor, also known as congenital epulis.

The baby tolerated the procedure well. Oral feedings were initiated immediately after surgery, and she was discharged to home breastfeeding exclusively. Six weeks after surgery, there was no recurrence of these masses. The infant was gaining weight and thriving.

Discussion

Congenital epulis occurs more frequently in females than males (8:1 ratio). Most cases involve a solitary mass. Approximately 10% involve multiple lesions.[1]

The etiology of the condition is unknown. Several theories exist on the cellular origin of these masses including that they may be of odontogenic, myoblastic, neurogenic, fibroblastic, histocytic or endocrinologic origin.[2]

The differential diagnoses for masses in the neonatal oral cavity include congenital malformations such as encephalocele or dermoid cysts, and neoplasms including hemangioma, lymphoma or rhabdomyosarcoma. CT imaging and MRI can help determine the extent and characteristics of congenital epulis masses.

Because these masses can interfere with feeding or respiration, surgical excision is generally indicated. Spontaneous regression of congenital epulis has been reported in a few cases; one could opt for watchful waiting if the mass is small and not causing feeding or breathing difficulties. There have been no published cases of recurrence following excision.[1] MM

REFERENCES

1. Eghbalian F, Monsef A. Congenital epulis in the newborn, review of the literature and a case report. J Pediatr Hematol Oncol. 2009;31(3):198-9.

2. McGuire TP, Freilich MM, Sándor GKB. Congenital epulis: a surprise in the neonate. J Can Dent Assoc. 2006;72:747-50.

In 2013, Minnesota Medicine *became aware of the need to highlight research being done by the state's medical trainees. It was pointed out that not only fellows but also medical students and residents were conducting studies that would be of interest to a larger audience.*

We decided to invite medical students, residents and fellows to submit brief papers describing original research or a clinical case. We would publish the best ones in a special section. Submissions were to be brief yet adequately describe the research or case.

Two dozen manuscripts were submitted and reviewed. The following were selected for publication in this issue. The deadline for submissions for fall publication is June 21.

We thank those who submitted manuscripts and our reviewers Peter Kernahan, M.D., Ph.D.; Barb Elliott, Ph.D.; Barbara Yawn, M.D.; and Angie Buffington, Ph.D.

Driveline Infection after HeartMate II Associated with Lower Rates of Cardiac Transplantation and Increased Incidence of Sepsis in Bridge-to-Transplant Population

BY LAURA HARVEY, M.D., CHRISTOPHER HOLLEY, M.D., REBECCA COGSWELL, M.D., PETER ECKMAN, M.D., MONICA COLVIN-ADAMS, M.D., KENNETH LIAO, M.D., PH.D., AND RANJIT JOHN, M.D., UNIVERSITY OF MINNESOTA DEPARTMENTS OF SURGERY AND CARDIOLOGY

Driveline infections are common after left ventricular assist device (LVAD) implantation and have been associated with increased mortality. We analyzed data from a large single-center LVAD database to assess the impact of driveline infections on clinical outcomes after LVAD placement.

Methods

Our cohort consisted of 239 patients who had HeartMate II LVADs implanted between June 2005 and June 2013. Standard Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) definitions were used for driveline infection and sepsis. Baseline characteristics were assessed to determine risk factors for subsequent driveline infection. A mutivariable cox regression analysis was then performed to assess the effect of driveline infections on the rate of cardiac transplantation.

Results

Over a follow-up period of 364 person-years, 62 patients who received LVADs developed driveline infections for an event rate of 0.17 infections per year. Patients who developed driveline infections were younger (53 vs. 58 years, $P<0.05$) and had higher pre-op BMIs (31 vs. 28 kg/m^2, $P<0.01$). Although women comprised 15% of the cohort, they contracted 26% of the infections ($P=0.13$). There was no statistical difference in the risk of infection with regard to several other variables including pre-op bridge to transplant or destination status, INTERMACS profile or presence of diabetes or chronic kidney disease. In the bridge-to-transplant (BTT) population, development of a driveline infection was associated with a 51% reduction in the rate of transplantation (rate ratio 0.49, $P<0.01$), which remained significant after adjusting for age and BMI (HR 0.53, $P<0.05$). Driveline infections were also associated with longer median times to cardiac transplantation (409 vs. 232 days, $P<0.05$). Subsequent sepsis was common in patients with driveline infections (11 of 62 patients, 18%).

Conclusion

In this large single-center study, BTT LVAD patients who developed driveline infections experienced overall lower rates of cardiac transplantation even after adjusting for age and BMI. The longer wait times combined with higher rates of sepsis may explain the previously observed increase in mortality in this population.[1] Continued strategies to decrease the risk of driveline infections along with development of totally implantable pumps will improve clinical outcomes for these patients. **MM**

REFERENCE

1. Goldstein DJ, Naftel D, Holman W, et al. Continuous-flow devices and percutaneous site infections: clinical outcomes. J Heart Lung Transplant. 2012;31(11):1151-7.

Rare Cause of Pancreatitis in a 20-year-old Female

BY RHONDA K. GAUGH, D.O., AND KEITH STELTER, M.D., M.M.M.,
UNIVERSITY OF MINNESOTA FAMILY MEDICINE RESIDENCY PROGRAM MANKATO

Eighty percent of pancreatitis cases are caused by alcohol or gallstones.[1] Some medications such as HIV drugs, diuretics, anticonvulsants and estrogen may cause pancreatitis.[2] When no obvious cause can be identified, a genetic one should be considered.[3]

Case Report

A 20-year-old woman presented to urgent care with dull, non-radiating abdominal pain in the right upper quadrant that lasted for one day. She was treated symptomatically with ibuprofen and a gluten-free diet. Three days later, she presented to the emergency department with the same symptoms. Her past history was notable for "stomach problems" throughout childhood. She had been diagnosed with irritable bowel syndrome and had undergone a colonoscopy, which was normal. Her lipase was elevated at 237 (normal to 120), and she was diagnosed with acute pancreatitis and admitted to the hospital for management. She reported having no more than eight to 10 alcoholic drinks in her lifetime. Her medications included a combination oral contraceptive and ibuprofen as needed. Her lipid panel on admission was normal.

During her hospital stay, abdominal ultrasound, esophagogastroduodenoscopy (EGD) and magnetic resonance cholangiopancreatography (MRCP) studies were done and results were normal. After 24 hours of IV fluids and NPO status, her lipase improved and the pain resolved. She presented to our family medicine clinic two weeks after hospital discharge.

We elected to pursue genetic testing in this patient. A genetic panel looking at the three different inheritance patterns of pancreatitis (CFTR, SPINK1, PRSS1) was done. Our patient was found to be heterozygous for mutations in the CFTR gene, which predisposed her to pancreatitis. Because of the complexities involved, the patient was referred to a pancreatitis center for ongoing management.

Discussion

This young patient had no classic risk factors for pancreatitis, and her case illustrates the value of considering genetic causes of pancreatitis. It is important to identify patients with hereditary pancreatitis because nearly 50% of them will develop type 1 diabetes by mid-adulthood.[4] Their risk for pancreatic cancer is also elevated, especially among those who also smoke, use alcohol, have type 1 diabetes, or have a family history of cancer.[5] MM

REFERENCES

1. Goldman L, Schafer An. Goldman's Cecil Medicine 24th Edition 2012. Saunders. 2012;937.

2. Feldman M, Friedman LS, Brandt LJ. Sleisenger and Fordtran's Gasterointestinal and Liver Disease 9th Edition. Elsevier. 2010; 959-83.

3. Tenner S, Baillie J, DeWitt J, Vege SS. American College of Gastroenterology guideline: management of acute pancreatitis. Am J. Gastroenterol. 2013;108:1400-15.

4. Howes N, Lerch MM, Greenhalf W, et al. Clinical and genetic characteristics of hereditary pancreatitis in Europe. Clin Gasteroenterol Hepatol. 2004;2(3): 252-61.

5. Rebours V, Boutron-Ruault MC, Schnee M, et al. The natural history of hereditary pancreatitis: a national series. Gut. 2009;58(1):97-103.

THE *TICK*ING HEART

A Case and Review of Acute Lyme Cardiac Complications

BY LIVIA T. HEGEROVA, M.D., AND TIMOTHY C. OLSON, M.D., DEPARTMENT OF INTERNAL MEDICINE, MAYO CLINIC

Lyme disease is common in Minnesota; 912 cases were reported to the state health department in 2012.[1] Cardiac complications occur in up to 10% of patients who contract the disease.[1-3] We report a case of mild Lyme myocarditis, which responded to outpatient treatment, and discuss ambulatory triage of cardiac complications.

Case Report

An otherwise healthy 25-year-old woman presented to the emergency department with one day of fever, frontal headache and neck stiffness. She had no rashes on her skin. Results of the remainder of the complete multi-system examination and neurologic evaluation were unremarkable. Lumbar puncture revealed a normal protein, glucose and cell count. She was provided oxycodone for pain and advised to follow-up with internal medicine.

Two weeks later, her headache had resolved, but she had persistent fatigue and a new rash on her abdomen, arm and thigh. Examination revealed scattered 2 cm to 10 cm annular erythematous plaques. Laboratory evaluation was significant for a positive Lyme-specific IgM on Western blot. ECG showed first-degree AV block with PR interval of 232 msec. She was diagnosed with acute Lyme disease and started on oral doxycycline. Repeat ECG two weeks later was normal with a PR interval at 144 msec. Her symptoms had completely resolved by then.

Discussion

The most common clinical feature of Lyme myocarditis is variable degrees of AV block, which occurs in nearly all patients.[4] The majority of those who have cardiac involvement will also have typical symptoms of Lyme disease; however, there are reports of isolated cardiac involvement in the absence of usual systemic symptoms.[4,5]

Given the frequency of cardiac complications in Lyme disease, we would recommend that clinicians have a low threshold in obtaining an initial ECG at the time of clinical diagnosis. If normal or first-degree AV block with PR interval less than 300 msec is noted, outpatient antibiotic treatment is appropriate, as these patients are at very low risk for progression to complete heart block.[4] Hospitalization with cardiac monitoring and intravenous antibiotics are recommended for ambulatory patients presenting with cardiac symptoms, first-degree AV block with PR interval greater or equal to 300 msec, or higher degrees of AV block.[6,7] The Infectious Disease Society of America recommends parenteral ceftriaxone for patients with the previously stated ECG changes.[2] The recommended duration of treatment is 10 to 21 days. The majority of conduction abnormalities have a benign prognosis and usually resolve within a week if the infection is treated appropriately.[7] MM

REFERENCES

1. Minnesota Department of Health. Lyme Disease 2012. Disease Control Newsletter. 2013;40(1):3. Available at: www.health.state.mn.us/divs/idepc/newsletters/dcn/sum12/lyme.html. Accessed March 26, 2014.

2. Wormser GP, Dattwyler RJ, Shapiro ED, et al. The clinical assessment, treatment, and prevention of Lyme disease, human granulocytic anaplasmosis, and babesiosis: clinical practice guidelines by the Infectious Diseases Society of America. Clin Infect Dis. 2006;43:1089-134.

3. Sigal LH. Early disseminated Lyme disease: cardiac manifestations. Am J Med. 1995;98 (4A):25S-8S; discussion 8S-9S.

4. Costello JM, Alexander ME, Greco KM, Perez-Atayde AR, Laussen PC. Lyme carditis in children: presentation, predictive factors, and clinical course. Pediatrics. 2009;123(5):e835-41.

5. Steere AC, Batsford WP, Weinberg M, et al. Lyme carditis: cardiac abnormalities of Lyme disease. Ann Intern Med. 1980;93(1):8-16.

6. Pinto DS. Cardiac manifestations of Lyme disease. Med Clin North Am. 2002;86(2):285-96.

7. Lelovas P, Dontas I, Bassiakou E, Xanthos T. Cardiac implications of Lyme disease, diagnosis and therapeutic approach. Int J Cardiol. 2008;129(1):15-21.

Quantitative Analyses of REM Sleep without Atonia in Children and Adolescents with REM Sleep Behavior Disorder

BY KATIE L. HANCOCK, ERIK K. ST. LOUIS, M.D., STUART J. MCCARTER, DAVID J. SANDNESS, SURESH KOTAGAL, M.D., ROBIN LLOYD, M.D., AND BRADLEY F. BOEVE, M.D., MAYO MEDICAL SCHOOL

Evidence suggests that REM sleep muscle tone is higher in children, potentially complicating the distinction between pathologic REM sleep without atonia (RSWA) and normal developmental variants of REM sleep muscle atonia during childhood and adolescence.[1,2] Furthermore, it remains unknown whether children and adolescents diagnosed with REM sleep behavior disorder (RBD), who are likely to have different etiologies than adults with RBD, have abnormal REM sleep muscle tone.

Our group recently described RBD in children.[3] To our knowledge, RSWA metrics in pediatric RBD have not been previously described. Having these metrics available would improve the accuracy and consistency of the diagnosis of RBD in the pediatric population. We aimed to quantitatively analyze RSWA in pediatric patients with RBD in comparison with controls, with the hope of determining whether there is a true quantitative difference between them. Demonstration of a quantitative difference and, in turn, cutoff values for the diagnosis of RBD, could assist physicians in diagnosing pediatric RBD patients in an accurate, standardized way.

Methods

Quantitative RSWA was manually scored and automated REM atonia index (RAI) performed in nine clinically diagnosed patients with RBD and nine age- and gender-matched controls with primary snoring. Percentage densities of phasic, tonic and "any" muscle activity were compared in the submentalis (SM) and anterior tibialis (AT). Phasic muscle activity burst durations (SM and AT) and SM RAI in the two groups were compared using Kruksall-Wallis tests. Chi square analyses were used to compare categorical variables. Multiple linear regression analysis was performed using JMP statistical software (SAS Institute, Inc., Cary, North Carolina).

Results

Each group included six boys and three girls, with a mean age of 10 years. RAI was significantly lower in the children with RBD than in those without RBD (0.82 vs. 0.93, P=0.0006) and combined SM/AT muscle activity was significantly higher in those with RBD, as measured by both phasic (28.5% vs. 12.9%, P=0.0134) and "any" muscle activity (29.4% vs. 12.9%, P=0.0134) percentage densities. SM phasic and "any" muscle activity densities were higher in the children with RBD than in the controls (16.9% vs. 8.1%, P=0.0423, and 17.4% vs. 8.2%, P=0.0423, respectively). AT phasic and "any" muscle activity densities (both 14.4% vs. 5.3%, P=0.1333) were similar in the two groups, as were durations of muscle activity bursts for both SM (0.71 vs. 0.63 seconds, P=0.7911) and AT (0.70 vs. 0.67 seconds, P=0.5317).

Conclusion

Like adults with RBD, children and adolescents with RBD have significantly greater amounts of RSWA than those who do not have RBD. This is driven by higher phasic densities in the SM muscle. These results may aid in the accurate and standardized diagnosis of RBD in the pediatric population. Larger confirmatory studies of patients with defined etiologies such as narcolepsy or brain lesions will be necessary to distinguish the neurophysiologic spectrum of RSWA accompanying clinical RBD in children and adolescents and to enable comparative analyses with adult RBD. MM

REFERENCES

1. Kohyama J. REM sleep atonia: from basic background to clinical application. J Med Dent Sci. 2001;48(2):29-39.

2. Ferri R, Bruni O, Fulda S, Zucconi M, Plazzi G. A quantitative analysis of the submentalis muscle electromyographic amplitude during rapid eye movement sleep across the lifespan. J Sleep Res. 2012;21(3): 257-63.

3. Lloyd R, Tippmann-Peikert M, Slocumb N, Kotagal S. Characteristics of REM sleep behavior disorder in childhood. J Clin Sleep Med. 2012;8(2):127-31.

Re-irradiation of the Head and Neck Using Highly Conformal Tomotherapy Intensity-Modulated Radiation Therapy

BY DANIEL A. JONES, M.D., ZACHARY LOPATER, M.D., RYAN SHANLEY, M.S., JAMIE ORNER, M.D., CHUNG LEE, M.D., AND MARGARET REYNOLDS, M.D., UNIVERSITY OF MINNESOTA RADIATION ONCOLOGY RESIDENCY PROGRAM

There is no standard of care regarding re-irradiation of the head and neck. The challenge of balancing the benefit of tumor control with risk of increased toxicity to normal tissue may be partially negated with proper patient selection and highly conformal radiation therapy. The purpose of this study was to analyze the outcomes of patients with a second primary and/or recurrent head and neck cancer who were treated with re-irradiation and to identify which patients are most likely to benefit from this treatment.

Methods

We retrospectively reviewed the cases of 24 consecutive patients who received re-irradiation to the head and neck between March 2008 and July 2012. Initial primary tumor presentations include nine of the oral cavity, six of the oropharynx, three of the larynx, two of the hypopharynx, three of the nasal cavity/paranasal sinus, and one of the nasopharynx. Seventeen patients had recurrent tumors, five had second primary cancers, and two had both second primary cancers and recurrences. In describing recurrences, 12 were local only, five were neck only, three were local plus neck, and three were local plus distant. Three patients had tumors that were unresectable and underwent biopsy only, and four underwent subtotal resection. Seventeen patients underwent gross total resection—13 with positive margins. All but two of the patients were treated with conventionally fractionated tomotherapy IMRT. Fourteen underwent concurrent chemoradiation, typically with platinum-based regimens.

Results

Patients were followed for a median of 10 months (minimum eight months among survivors). They were treated with a median dose of 60 Gy (44 to 70 Gy). Kaplan-Meier estimates for one-year local control, recurrence-free survival and overall survival were 58% (95% CI 36-75), 40% (95% CI 20-59) and 68% (95% CI 44-83), respectively. Kaplan-Meier estimates for two-year local control, recurrence-free survival and overall survival were 41% (95% CI 17-64), 20% (95% CI 6-41) and 25% (95% CI 8-46), respectively. Median survival was 15 months (95% CI 10-20). Our study included three long-term survivors, (24, 24 and 32 months), all of whom are disease-free. Toxicity was significant, as 50% of the cohort required permanent feeding tube placement and two patients experienced fatal carotid artery bleeds.

Conclusion

In our series of re-irradiation to the head and neck, outcomes were similar to those achieved in other published series.[1,2] Local control at one and two years was encouraging at 58% and 41%, and re-irradiation likely reduced morbidity associated with local progression. The heterogeneity and small sample size limit our ability to generalize the results of this study to patient management. Treatment with highly conformal techniques such as tomotherapy IMRT improves the ability to control disease and reduce toxicity, and it remains an option for those who progress after primary and salvage treatments. Future investigations should focus on optimizing selection criteria for those likely to benefit from re-irradiation. **MM**

REFERENCES

1. Spencer S, Harris J, Wheeler R, Machtay M, Schultz C, Spanos W, et al. Final report of RTOG 9610, a multi-institutional trial of reirradiation and chemotherapy for unresectable recurrent squamous cell carcinoma of the head and neck. Head Neck. 2008;30(3):281-8.

2. Salama J, Vokes E, Chmura S, Milano M, Kao J, Stenson K, et al. Long-term outcome of concurrent chemotherapy and reirradiation for recurrent and second primary head-and-neck squamous cell carcinoma. Int J Radiat Oncol Biol Phys. 2006;64(2):382-91.

Quantitative Assessment of Pediatric Hand Function Using Touchscreen Technology

BY DAVID SHIN, DEBORAH BOHN, M.D., SARA CRONQUIST, KATY LINDSTROM, JULIE AGEL, AND ANN VAN HEEST, M.D., UNIVERSITY OF MINNESOTA MEDICAL SCHOOL

The role touchscreen technology plays in our society has increased in recent years. Currently established objective assessments of upper extremity function, such as the Jebsen-Taylor Hand Function Test[1] and the Functional Dexterity Test, [2] were designed long before touchscreens became ubiquitous.

The purpose of this project was to develop a novel hand-function test using touchscreen technology and then test its validity in children with neuromuscular and congenital problems as well as those with normal hand function. The goal was to create a valid clinical tool for evaluating upper-extremity function.

Methods

The test was developed on the Apple iOS platform using an Apple iPhone 4. We designed four different tasks that are believed to be representative of ability to use a touchscreen. These included touching dots on a 3x4 grid, dragging shapes, using the camera and texting using the onscreen keyboard. The test was designed to take between 60 and 120 seconds, with each patient performing a pre-test in order to become familiar with the tasks. Each section was timed independently, and an overall time was recorded.

A total of 161 patients were included in our study. Their ages ranged from 3 to 25 years. Patients younger than 9 years of age were not asked to complete the texting portion of our test, and those with less than 6 months of touchscreen experience were excluded. Demographic information collected included the patient's age, gender, years of experience with touchscreens, dominant hand and diagnosis.

Results

Patients were classified as having either normal (n = 87) or impaired (n = 74) hand function based on assessment by a pediatric orthopedic hand specialist. The group with impaired hand function was comprised exclusively of patients with neuromuscular and congenital problems. Each patient was placed into one of seven age groups (3 to 4 years, 5 to 6 years, 7 to 8 years, 9 to 10 years, 11 to 12 years, 13 to 14 years, and 15 years and older). No gender or dominant-hand differences were observed. In patients without impaired hand function, completion time decreased with increasing age. When the test times of patients with neuromuscular and congenital deficiencies were compared with those of patients with normal upper extremity function, T-test showed a statistically significant increase in completion time ($P<0.05$) in four of the seven age groups tested.

Conclusion

These data show that our test potentially discriminates between age-matched patients with normal hand function and those with impaired hand function caused by neuromuscular and congenital abnormalities such as brachial plexopathies and syndactyly. Expansion of sample size is likely necessary to achieve statistical significance within the age groups that did not demonstrate it in our study. In addition to evaluating for the differences between patients with and without upper extremity impairments, we believe our test could serve as a reliable and standardized method to assess recovery in patients after major upper extremity surgery. Our upper extremity test using touchscreen technology is novel and relevant to the way many people interact with their environments, and it allows for a valid unbiased quantification of upper extremity function. **MM**

REFERENCES

1. Jebsen RH, Taylor N, Trieschmann RB, Trotter MJ, Howard LA. An objective and standardized test of hand function. Arch Phys Med Rehabil. 1969;50(6):311-9.

2. Gogola GR, Velleman PF, Xu S, Morse AM, Lacy B, Aaron D. Hand dexterity in children: administration and normative values of the functional dexterity test. J Hand Surg Am. 2013;38(12):2426-31.

SPLENIC ARTERY PSEUDOANEURYSM

An Unusual Cause for Melena

BY DANIEL KUPSKY, M.D., RAINA SHIVASHANKAR, M.D., AND
CONOR G. LOFTUS, M.D., MAYO CLINIC INTERNAL MEDICINE RESIDENCY PROGRAM

Splenic artery pseudoaneurysms are uncommon and often arise as a result of pancreatic disease or trauma. They can have a wide variety of presentations, thereby making diagnosis challenging. Rupture or erosion into the bowel is the most feared complication of these pseudoaneurysms.

Case Report

A 42-year-old woman with a history of alcohol abuse, chronic pancreatitis and Roux-en-Y gastric bypass surgery presented with persistent mid-epigastric abdominal pain of several days' duration, hypotension and melena. She was anemic with a hemoglobin of 5.1 g/dL. CT of the abdomen was performed and revealed a 6.2 x 4.7 cm pseudoaneurysm of the splenic artery, chronic pancreatitis and a thrombosed splenic vein. After she received intravenous fluids and a blood transfusion, emergent esophagogastroduodenoscopy (EGD) was performed. EGD did not reveal a source of bleeding.

A repeat abdominal CT performed 48 hours later showed aneurysmal growth to 7.5 x 8.7 cm. The patient underwent urgent coil embolization of the artery out of concern for potential rupture. Following the procedure, she had continued melena with a dropping hemoglobin. She then underwent double balloon enteroscopy of the pancreatico-biliary limb (Roux-en-Y gastric bypass) and was found to have an ulcerated site with a blood clot in the duodenum. This was caused by the pseudoaneurysm. Because she had already undergone coil embolization and was a high-risk surgical candidate, no further interventions could be performed. The patient was discharged from the hospital with a stable hemoglobin. Follow-up CT one month later indicated near resolution of the aneurysm.

Discussion

This case demonstrates erosion of a splenic artery pseudoaneurysm into the bowel that presented as an upper GI bleed. These pseudoaneurysms are uncommon, with approximately 200 recorded incidents in the literature. They can be associated with pancreatitis, pseudocysts and in rare instances peptic ulcer disease. Symptoms can include abdominal pain, melena, hematemesis and hematochezia.[1] In cases involving pancreatitis, the pathophysiology is thought to be the result of pancreatic enzymes causing a direct necrotizing arteritis leading to destruction of the vessel wall.[2] Direct angiography is the gold standard in diagnosis, although CT imaging can accurately identify lesions of various sizes. The natural history of these aneurysms is largely unknown, and even those as small as 2 cm have been known to rupture. Risk of rupture is 37%, and mortality rate when ruptured approaches 90%.

Splenic artery pseudoaneurysm should be considered in a patient who presents with abdominal pain, history of pancreatitis and no identifiable source of bleeding. Because of the high risk associated with splenic pseudoaneurysms, urgent management is essential, and intervention should be considered when they are identified.[1] MM

REFERENCES

1. Tessier DJ, Stone WM, Fowl RJ, Abbas MA, Andrews JC, Bower TC, Gloviczki P. Clinical features and management of splenic artery pseudoaneurysms: case series and cumulative review of literature. J Vasc Surgery. 2003; 38:969-74.

2. Puri SN, Nicholson AA, Breen DJ.. Percutaneous thrombin injection for the treatment of a post-pancreatitis pseudoaneurysm. Eur Radiol. 2003; 13[suppl 4]:L79–L82.

Development of a Neuroscience Research Registry

BY LAURA LI, M.D., AND RAHUL KORANNE, M.D., M.B.A., FACP

There is little data on the long-term health outcomes of patients with neurological conditions treated at long-term acute care specialty hospitals. In order to learn more about these patients and the most effective way to care for them, Bethesda Hospital in St. Paul created a neuroscience research registry. The registry's target population is patients with complex neurological conditions such as aneurysm or intracranial bleed, stroke, seizures, delirium and confusion and traumatic brain injury. This article describes the development of the registry, which has enrolled 857 patients thus far, and what is being learned about those patients.

Patients cared for at Bethesda Hospital, a long-term acute care specialty hospital (LTACH) in St. Paul, include those with complex neurological conditions. In most cases, LTACH patients have survived an initial medical event but are still suffering from persistent emotional, social and financial effects of it. Some may be ventilator-dependent and experiencing multi-organ system failure, extreme weakness and cognitive dysfunction. Most arrive from the intensive care units of short-term acute care hospitals (STACHs). Their average length of stay at Bethesda is 25 days.

Currently, there is little data on the long-term health outcomes (five-plus years) of these patients; in addition, there is limited clinical evidence on how best to care for them once they leave the ICU.[1-4] Published studies have had a limited impact on practice[5,6] because of small scale, lack of long-term follow-up and insufficient funding. Thus, we have had little insight into how to help patients achieve optimal outcomes cost-effectively.

About three years ago, Bethesda Hospital decided to build a neuroscience research registry in order to gather data on the care provided to this vulnerable patient population and the costs associated with that care. The goal is to identify which care pathways and protocols are most strongly associated with successful long-term outcomes. The hope is that better understanding can lead to better, more appropriate care and services for this patient population. The data collected through the registry will be shared within HealthEast Care System (Bethesda's parent organization), among its community partners and with the broader medical community.

Specifically, the information will be used to help promote evidence-based, cost-effective patient management; address the lack of standardized management of this patient population; identify new diagnostic and therapeutic interventions; control overutilization; help families make more informed care decisions; and improve outcomes. Our overarching goal is to redefine the standard of care provided to LTACH patients with neurological conditions. We are not aware of any other data collection project of this magnitude focused on this patient population in the United States.

About the Registry

The registry's target population is patients with complex neurological conditions such as aneurysm or intracranial bleed, stroke, seizures, delirium and confusion and traumatic brain injury. These are the patients with the most challenging care needs, as some are also ventilator-dependent and have other chronic medical conditions or complex wounds, are transplant recipients, or require multi-specialty support from infectious disease, hematology, oncology, nephrology, cardiology or endocrinology. They have been admitted to Bethesda Hos-

pital after being in an ICU for two weeks or longer and are unable to ambulate independently.

The registry uses REDCap tools[7] to capture demographic, physiological, treatment, cost and long-term follow-up data (up to 10 years post-discharge) from the electronic medical records of participating patients. Data are also gathered through questionnaires filled out by patients. Informed consent is obtained from all registry participants and/or from a legally authorized representative.

The registry tracks

- Demographic information including the patient's name, date of birth, medical record number, address, phone number, race, education level
- Significant medical history including history of stroke, neuropathy, myopathy, COPD, Parkinson's disease and congestive heart failure; smoking status; and drug and alcohol use
- Diagnosis and treatment data including results of laboratory tests and radiographic assessments, medication use, number and type of interventional procedures performed, and blood pressure, temperature and respiratory status
- Results of physical, cognitive and neuropsychological assessments such as the Glasgow Coma Scale, Barthel Index,[8] Modified Rankin and Fisher Grade scores
- Indicators of long-term outcome including discharge disposition; survival time; functional status at three, six and 12 months post-discharge and yearly thereafter
- Employment status (or activity level if retired)
- How frequently the patient sees family or friends
- Number of times the patient has returned to a hospital for an unscheduled visit.

FIGURE

Registry Population by Race/Ethnicity (N=857)

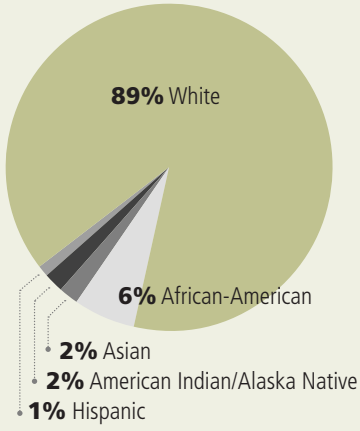


TABLE 1

Registry Population by Age and Gender (N=857)

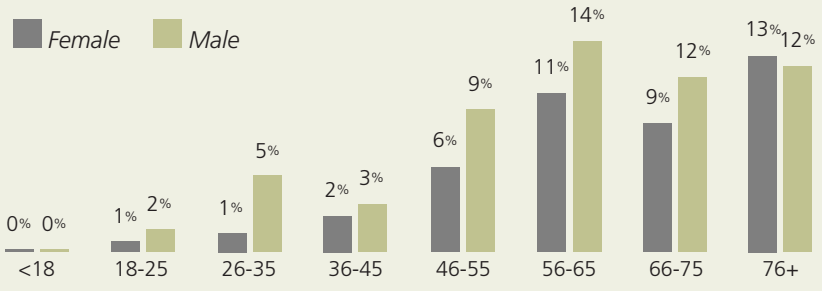
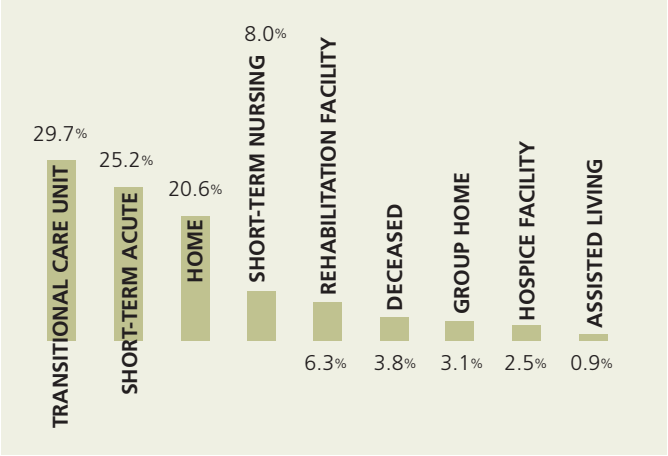


TABLE 2

Discharge Disposition for Registry Patients



Preliminary Data

Since November of 2011, the registry has enrolled 857 patients, with an average of 285 new patients enrolled each year. To date, 68% of registry patients have completed their one-year follow-up. None of these individuals has received monetary incentive for participation.

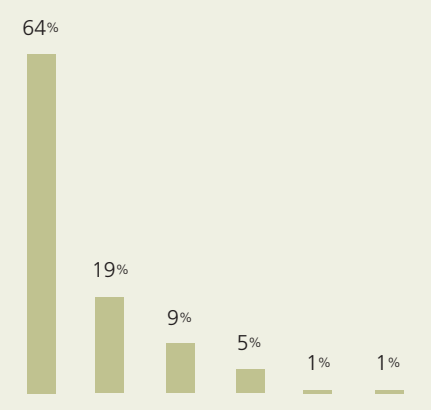
Demographic information is shown in the Figure and Table 1. A preliminary analysis suggests that participant demographics closely mirror the hospital's overall inpatient population. Registry patients are discharged from Bethesda Hospital primarily to transitional care units (29.7%), short-term acute care hospitals (25.2%) and home (20.6%) (Table 2).

Registry participants between the ages of 56 and 65 years represent the highest proportion (28.3%) of patients discharged to a STACH. The reasons patients return to STACHs vary but include planned second surgical procedures (eg, a second intracranial procedure necessary for the patient's recovery). A majority of these patients return to Bethesda at some point in time. Two-thirds (66.5%) of discharged patients have indicated at their three-month follow-up assessment that they have not experienced an unplanned STACH visit since leaving the facility (Table 3). An in-depth analysis of complication rates, deaths and STACH re-admissions is underway to clarify the causes of re-admissions, identify trends and reduce complications. Data review and analysis should be completed within the next six to 12 months.

Additional information on procedures, therapies and follow-up assessments will be collected and used for research on such

TABLE 3

STACH Visits Three Months following Discharge from Bethesda



things as the cost of care during the acute rehabilitation phase and the effects of psychotropic medication use on short- and long-term recovery.

Conclusion

We hope the knowledge generated from this registry will be used to advance medical science and to guide local and national policy makers, including CMS and MedPAC, in future health care reform efforts. Thus far, registry data have been shared with representatives from Medica, the University of Minnesota, national LTACH groups and a delegation of hospital CEOs from China. Our goal is to publish or present on this work within the next 12 months. To date, we are not aware of any changes in care related to this data.

Our initial goal has been to raise awareness of the registry and to populate it with patient information. Now that we are successfully accomplishing that, we can begin looking at the data and sharing what we are learning with others. **MM**

Laura Li, a board-certified neurologist and neurophysiologist, is medical director of Bethesda Hospital's inpatient and outpatient neurological services and the principal investigator for this registry and its associated research. Rahul Koranne is vice president and executive medical director for Bethesda Hospital and Community Services.

REFERENCES

1. Bernat JL. Ethical aspects of determining and communicating prognosis in critical care. Neurocrit Care. 2004;1(1):107-117.

2. Giacino J, Zasler N. Outcome after severe traumatic brain injury: coma, the vegetative state, and the minimally responsive state. J Head Trauma Rehabil.1995;10:40-56.

3. White BD, Braddock CH 3rd, Bereknyei S, Curtis JR. Toward shared decision making at the end of life in intensive care units: opportunities for improvement. Arch Intern Med. 2007;167(5):461-67.

4. Bullock MR, Prolishock JT, eds. Guidelines for the management of severe traumatic brain injury. J Neurotrauma. 2007;24:S1-S106.

5. Thompson Hj, Rivara FP, Jurkovich GF, et al. Evaluation of the effects of intensity of care on mortality after traumatic brain injury. Crit Care Med. 2008;36(1)282-90.

6. Clifton GL, Choi SC, Miller ER, Intercenter variance in clinical trials of head trauma—experience of the National Acute Brain Injury Study: Hypothermia. J Neurosurg. 2001;95(5):751-5.

7. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCAP)—A metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009; 42(2): 377-81.

8. Mahoney FI, Barthel D. Functional evaluation: the Barthel Index. Maryland State Med Journal. 1965;14:56-61. Available at: www.strokecenter.org/wp-content/uploads/2011/08/barthel.pdf. Accessed April 16, 2014.

THE VACCINE-HESITANT PARENT

How You Start the Conversation Matters

BY DOUGLAS J. OPEL, M.D., M.P.H., AND LYNN BAHTA, R.N., P.H.N.

Immunization rates are one of the many measures of quality care that are of interest to physicians. Immunization rates for children younger than 3 years of age in Minnesota have held steady between 80% and 90%. One reason they have not increased is because of emerging hesitancy among some parents to vaccinate their children. This article describes what research has taught us about working with vaccine-hesitant parents and how starting a conversation in a way that presumes parents will vaccinate may improve the odds of children getting immunized.

Immunization coverage rates for 19- to 35-month-old children in Minnesota are between 80% to 90%, depending on the vaccine. Those rates have been stagnant since 1996. Moreover, the rate of completion of the combined series of vaccines for Minnesota children in this age group sits steady at 66.2% (±7.6).[1] Although the overwhelming majority of Minnesota parents are vaccinating their children, vaccine hesitancy has likely contributed to our inability to attain the Healthy People 2020 goal of 80% vaccination coverage for the childhood series.[2] Evidence suggests that 13% of parents of children ages 6 months to 6 years in the United States request an alternative immunization schedule for their child.[3]

Some parents who are vaccine-hesitant may simply need more information or reassurance before accepting all vaccines; others may delay or accept some vaccines but not others. About 1% of parents refuse all vaccines. Research has shown that most vaccine-hesitant parents perceive their child's physician as having an important influence on their decisions when it comes to vaccinating their children. In a 2003-2004 study of parents, the largest portion of those who initially planned to delay or not vaccinate their child but eventually did cited talking to their child's physician as their reason for changing their minds.[4]

Talking to a Parent

Conversations in which parents refuse recommended vaccines can be difficult for both physicians and parents. When having the vaccine conversation, experts advise that physicians and other providers use plain language, remain nonjudgmental, listen to all the parents' concerns, and show compassion and understanding.[5] The CDC and other organizations have developed tools to help guide clinicians when they're talking to vaccine-hesitant parents (see box).

In addition, it is important to recognize the barriers to having an effective conversation with a vaccine-hesitant parent. Lack of time is commonly cited. Given the competing demands physicians and other health care providers face, they may not have enough time to adequately address a parent's concerns regarding vaccines during well-child visits. Another barrier is the physician's ability to balance his or her obligation to promote the health of the child with the parent's autonomy. Finally, there has been a glaring lack of evidence regarding communication strategies that are effective in changing parents' behaviors when it comes to vaccinating their children.

This is changing. New evidence suggests that the way clinicians start the vaccine conversation matters. For instance, one study demonstrated that when providers initiated the conversation in a way that presumed the parents would be vaccinating their child (eg, saying "It's time to start all those vaccines. We're going to give two live vaccines today: MMR and chickenpox"), rather than in a way that didn't make this assumption and instead simply invited parents to be involved in the decision (eg, saying "So what are we going to do about vaccines today?"), fewer parents expressed resistance to vaccinating their children (26% vs. 83%, respectively).[6] This association remained statistically significant even after controlling for parental hesitancy status, parent and child demographics, and visit characteristics.

Why might a presumptive format for initiating vaccine recommendations be preferable to one that is more participatory? One reason may be because of how we as humans make decisions. When making what we perceive to be a complicated decision, we tend to have a status quo bias. Many parents—hesitant or not—perceive the vaccination decision to be a complicated one. When it is presented to them that their child will receive vaccines (ie, by using the presumptive format), parents may inherently be inclined not to challenge the recommendation, as they see having a child vaccinated as what most people do. A study of how parents make vaccination decisions showed "exposure to social norms"—with vaccination being the expected norm—was a major influence on their decisions.[7]

We are also beginning to understand the importance of physicians and other health care providers making their recommendations even if the parent is hesitant. Among parents who initially resisted a provider's vaccine recommendation, 47% changed their mind when their provider continued to discuss their recommendation.[6] When having a discussion about your recommendation, you should explore the parent's concerns and provide them with additional information that can assuage those concerns. Doing so can make a difference.

Improving the Odds

How you initiate and discuss your vaccine recommendation can be important in determining whether a parent chooses to vaccinate, even if the parent may be hesitant. Remember that as a physician, you have influence with parents when it comes to vaccine decisions and that you can harness this influence by soliciting parents' concerns and taking the time to address them. Don't be afraid to start the vaccine conversation with your recommendations and pursue them if the parent resists. Taking this approach while still being respectful, empathetic and understanding can improve the chance that a parent will accept your recommendations. **MM**

Douglas Opel is an assistant professor in the Divisions of Bioethics and General Pediatrics, Department of Pediatrics, at the University of Washington School of Medicine and an investigator at the Center for Clinical and Translational Research and Treuman Katz Center for Pediatric Bioethics at Seattle Children's Research Institute. His current research on improving provider communication with vaccine-hesitant parents is funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development of the National Institutes of Health. Lynn Bahta is the immunization clinical consultant for the Minnesota Department of Health's Immunization Program.

REFERENCES

1. Centers for Disease Control and Prevention. National, state and local area vaccination coverage among children aged 19-35 months—United States, 2012. MMWR. 2013; 62(36):733-40.

2. U.S. Department of Health and Human Services. 2020 Topics and Objectives: Immunizations and Infectious Diseases. 2012. Available at: http://healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23. Accessed March 11, 2013.

3. Dempsey AF, Schaffer S, Singer D, Butcher A, Davis M, Freed GL. Alternative vaccination schedule preferences among parents of young children. Pediatrics. 2011;128(5):848-56.

4. Gust DA, Darling N, Kennedy A, Schwartz B. Parents with doubts about vaccines: which vaccines and reasons why. Pediatrics. 2008:122(4);718-25.

5. Bryant KA, Wesley GC, Wood JA, Hines C, Marshall GS. Use of standardized patients to examine physicians' communication strategies when addressing vaccine refusal: a pilot study. Vaccine. Jun 2 2009;27(27):3616-3619.

6. Opel DJ, Heritage J, Taylor JA, Mangione-Smith R, Showalter Salas H, DeVere V, Zhou C, Robinson JD. The architecture of provider-parent vaccine discussions at health supervision visits. Pediatrics. 2013;132(6):1037-46.

7. Brunson EK. How parents make decisions about their children's vaccinations. Vaccine. 2013;31(46):5466-70.

The Centers for Disease Control and Prevention (CDC) offers resources to help physicians and other providers have vaccine conversations with parents. They are available on the CDC website www.cdc.gov/vaccines/hcp/patient-ed/conversations/index.html.

FAMILY MEDICINE OPPORTUNITIES *in Minnesota*

SANFORD™ HEALTH

Sanford Health is seeking Board Eligible/Board Certified Family Medicine physicians to join its primary care groups. Opportunities can include a combination of inpatient, outpatient, obstetrics and emergency medicine throughout the following locations:

Alexandria
Bagley
Bemidji
Canby
E Grand Forks
Moorhead
New York Mills
Perham
Thief River Falls
Walker
Wheaton
Windom
Worthington

Sanford Health offers a competitive salary with an excellent retention incentive, comprehensive benefits package, paid malpractice and relocation assistance. Practice and live in a rural Minnesota community. Minnesota offers clean air, safe communities, superb schools and the ability to experience the beauty of all four seasons.

LEARN MORE:
practice.sanfordhealth.org

CONTACT:
Celia Beck, 218-333-5056 or
celia.beck@sanfordhealth.org

Mary Jo Burkman, 605-328-6996 or
mary.jo.burkman@sanfordhealth.org

Jill Gilleshammer, 701-417-4852 or
jill.gilleshammer@sanfordhealth.org

WANTED
QUALITY INTERNISTS AND FAMILY PHYSICIANS

Top 20% income as a partner!
Full time = 4 office days per week!
Independent practice with ownership!

Lakeview Clinic is seeking BE/BC physicians to join our independent, multispecialty, physician-owned group in the southwest metro. Enjoy the best of both worlds, from rural to suburban in one of our 4 sites. Our top-notched group consists of family physicians, internists, pediatricians, OB/GYNs, and surgeons.

CONTACT: Sandra Beulke, MD
PHONE: 952-442-4461
EMAIL: administration@lakeviewclinic.com
WEB: **www.lakeviewclinic.com**

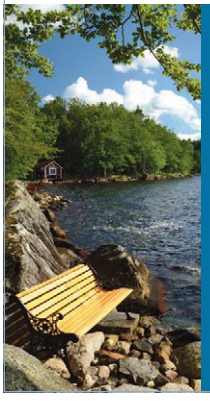
Lakeview Clinic Ltd.

St. Cloud VA Health Care System
OPPORTUNITY ANNOUNCEMENT

Opportunities for full-time and part-time staff are available in the following positions:

- Dermatologist
- Geriatrician/Hospice/Palliative Care
- Internal Medicine/Family Practice
- Medical Director, Extended Care & Rehab (Geriatrics)
- Psychiatrist
- Urgent Care Physician (IM/FP/ER)

Applicants must be BE/BC.



Located sixty-five miles northwest of the twin cities of Minneapolis and St. Paul, the City of St. Cloud and adjoining communities have a population of more than 100,000 people. The area is one of the fastest growing areas in Minnesota, and serves as the regional center for education and medicine.

Enjoy a superb quality of life here—nearly 100 area parks; sparkling lakes; the Mississippi River; friendly, safe cities and neighborhoods; hundreds of restaurants and shops; a vibrant and thriving medical community; a wide variety of recreational, cultural and educational opportunities; a refreshing four-season climate; a reasonable cost of living; and a robust regional economy!

Since 1924, the St. Cloud VA Health Care System has delivered excellence in health care and compassionate service to central Minnesota Veterans in an inviting and welcoming environment close to home. We serve over 38,000 Veterans per year at the medical center in St. Cloud, and at three Community Based Outpatient Clinics located in Alexandria, Brainerd, and Montevideo.

Competitive salary and benefits with recruitment/relocation incentive and performance pay possible.

For more information:
Visit www.USAJobs.gov or contact
Nola Mattson (STC.HR@VA.GOV)
Human Resources
4801 Veterans Drive
St. Cloud, MN 56303
(320) 255-6301
EEO Employer

SEEKING PHYSICIAN / PART-TIME OWNER

to join in a practice dedicated to:
• Generating health •
• Preventing diseases of aging •
• Reducing health care costs •

Innovative Directions in Health
is the leading Midwest Anti-Aging and Preventive Medicine Clinic specializing in Bio-Identical Hormone Therapy.

The practice, started by Dr. Khalid Mahmud, a quadruple board-certified physician, draws patients from all neighboring states and Canada.

No night calls, no weekends!

Located in Edina, MN
Call (952)922-2345 or send resume to:
Lisa@idinhealth.com
www.idinhealth.com

Innovative Directions in Health
ANTI-AGING & NATURAL HORMONE THERAPY

ACMC
Affiliated Community Medical Centers
Multispecialty Health Network

The perfect match of career and lifestyle.

Affiliated Community Medical Centers is a physician owned multi-specialty group with 11 affiliated sites located in western and southwestern Minnesota. ACMC is the perfect match for healthcare providers who are looking for an exceptional practice opportunity and a high quality of life. Current opportunities available for BE/BC physicians in the following specialties:

- ENT
- Family Medicine
- Gastroenterology
- General Surgery
- Hospitalist
- Infectious Disease
- Internal Medicine
- Med/Peds Hospitalist
- Oncology
- Orthopedic Surgery
- Outpatient Internist/ Geriatrician
- Pediatrics
- Psychology
- Psychiatry
- Pulmonary/Critical Care
- Rheumatology
- Urgent Care
- Urologist

For additional information, please contact:

Kari Bredberg, Physician Recruitment
karib@acmc.com, 320-231-6366
Richard Wehseler, MD
rickw@acmc.com

THE PERFECT BLEND

A rewarding practice and a great family lifestyle.

Mankato Clinic @ Daniels Clinic in St. Peter, MN has an opportunity for a BC/BE physician, with or without OB to join four busy primary care providers: two Family Physicians, one Pediatrician and one Physician Assistant.

You will have access to four exam rooms for your busy practice. Daniels Family Practice Call schedule is 1:8 for local hospital coverage.

The River's Edge Critical Access Hospital in St. Peter has 18 beds and an ER covered by physicians 24/7. There is also telephone triage support for your patients from a 24-hour Nurse phone-answer line.

This college town, home to Gustavus Adolphus College, has a population of 10,000. It is located 15 miles north of Mankato, less than an hour from the Twin Cities, Mall of America and Minneapolis/St. Paul International Airport. No commuting hassles for this job; get to know your patients!

CONTACT: Dennis Davito Director of Provider Services Mankato Clinic
1230 East Main Street Mankato, MN 56001
PHONE: 507-389-8654
FAX: 507-625-4353
EMAIL: ddavito@mankato-clinic.com

MANKATO CLINIC
www.mankato-clinic.com

Fairview Health Services

Opportunities to fit your life

Fairview Health Services seeks physicians to improve the health of the communities we serve. We have a variety of opportunities that allow you to focus on innovative and quality care. Be part of our nationally recognized, patient-centered, evidence-based care team.

We currently have opportunities in the following areas:

- Dermatology
- Emergency Medicine
- Endocrinology
- Family Medicine
- General Surgery
- Geriatric Medicine
- Hospice
- Hospitalist
- Internal Medicine
- Med/Peds
- Ob/Gyn
- Orthopedic Surgery
- Pediatrics
- Psychiatry
- Rheumatology
- Sports Medicine
- Urgent Care

Visit **fairview.org/physicians** to explore our current opportunities, then apply online, call **800-842-6469** or e-mail **recruit1@fairview.org**

Sorry, no J1 opportunities.

fairview.org/physicians
TTY 612-672-7300
EEO/AA Employer

FAIRVIEW

Here to care

At Allina Health, we're here to care, guide, inspire and comfort the millions of patients we see each year at our 90+ clinics, 11 hospitals and through a wide variety of specialty care services throughout Minnesota and western Wisconsin. We care for our employees by providing rewarding work, flexible schedules and competitive benefits in an environment where passionate people thrive and excel.

Make a difference.
Join our award-winning team.

EOE/AA

Madalyn Dosch,
Physician Recruitment Services
Toll-free: 1-800-248-4921
Fax: 612-262-4163
Madalyn.Dosch@allina.com

allinahealth.org/careers

13273 0213 ©2013 ALLINA HEALTH SYSTEM
® A TRADEMARK OF ALLINA HEALTH SYSTEM

Allina Health

Make your secondary home your primary home.

Cuyuna Regional Medical Center (CRMC) is seeking physicians for its growing multi-specialty clinic and hospital. Located in a resort community in central Minnesota, CRMC has been named a Top Workplace by the Minneapolis Star Tribune.

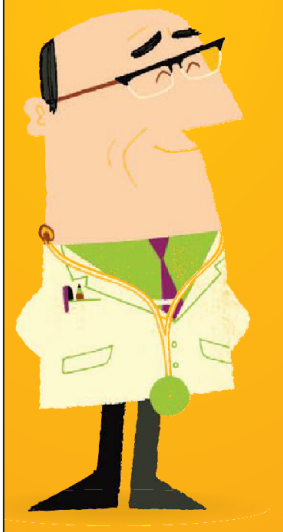
Family Medicine
- Outpatient practice with or without OB
- Practice with 13 FM colleagues and 4 PAs

Hospitalist
- 25 bed critical access hospital with average census of 17.5 supports an advanced surgery department and admissions
- Multi-specialty support with 35+ physicians and APCs

Both positions supported by locally based subspecialty providers in cardiology, internal medicine, OB/GYN, orthopedics, urology, surgery and more. Very competitive comp package, generous signing bonus, relocation and full benefits. Within two hours of Minneapolis/St. Paul you will find a personal and professional fit in Crosby, MN.

CRMC
CUYUNA REGIONAL MEDICAL CENTER
Dedicated to You. Every Day.

Contact: Todd Bymark, tbymark@cuyunamed.org
(866) 270-0043 / (218) 546-4322 | www.cuyunamed.org



Urgent Care

We have part-time and on-call positions available at a variety of Twin Cities' metro area HealthPartners Clinics. We are seeking BC/BE full-range family medicine and internal medicine pediatric (Med-Peds) physicians. We offer a competitive salary and paid malpractice.

For consideration, apply online at **healthpartners.com/careers** and follow the Search Physician Careers link to view our Urgent Care opportunities. For more information, please contact **diane.m.collins@healthpartners.com** or call Diane at: 952-883-5453; toll-free: 1-800-472-4695 x3. EOE

HealthPartners® Medical Group

healthpartners.com

OLMSTED MEDICAL CENTER™

Olmsted Medical Center, a 160-clinician multi-specialty clinic with 10 outlying branch clinics and a 61 bed hospital, continues to experience significant growth.

Olmsted Medical Center provides an excellent opportunity to practice quality medicine in a family oriented atmosphere.

The Rochester community provides numerous cultural, educational, and recreational opportunities.

Olmsted Medical Center offers a competitive salary and comprehensive benefit package.

Opportunities available in the following specialty:

Dermatology
Rochester Southeast Clinic

Family Medicine
Byron Clinic
Pine Island Clinic
SE Rochester Clinic

Hospitalist
Rochester Hospital

Internal Medicine
Women's Health Pavilion/Hospital

Sleep Medicine
Rochester Northwest Clinic

Urologist
Rochester Hospital

Send CV to:
OlmstedMedical Center
Administration/Clinician Recruitment
102 Elton Hills Drive NW
Rochester, MN 55901
email: dcardille@olmmed.org
Phone: 507.529.6748
Fax: 507.529.6622
EOE

www.olmstedmedicalcenter.org

Sioux Falls VA Health Care System

"A Hospital for Heroes"

Working with and for America's Veterans is a privilege and we pride ourselves on the quality of care we provide. In return for your commitment to quality health care for our nation's Veterans, the VA offers an incomparable benefits package.

The Sioux Falls VAHCS is currently recruiting for the following healthcare positions.

- Cardiologist (part-time)
- Endocrinologist
- Oncologist
- Primary Care (Family Practice or Internal Medicine)
- Psychiatrist
- Pulmonologist

Applicants can apply online at www.USAJOBS.gov

They all come together at the Sioux Falls VA Health Care System. To be a part of our proud tradition, contact:

Human Resources Mgmt. Service
2501 W. 22nd Street
Sioux Falls, SD 57105
(605) 333-6852

The Best Care The Best Careers

www.siouxfalls.va.gov

Being called

Reflections on becoming a physician

BY MEGAN SAN GIACOMO

October 18, 2012

The scalpel flashes as mom yells in distress. I thought epidurals were supposed to work better than this, I tell myself. I try not to trip over my gown as I dance around the attending physician and resident. Blood splatters everywhere.

Everything changes for mom once the baby arrives and is scooped onto her chest. She couldn't care less about the placenta or the bloody, messy laceration as she looks at the baby she waited so long for, worked so hard for. Everything changes for the doctors, too. We're no longer listening to decelerations, coaching mom onto her hands and knees, or evaluating for that episiotomy as we run through the ABCDEs of an assisted vaginal delivery. Mom has been through pit, mag, cytotec—this baby must have wanted a fight. We clean up the mess, resurface the battlefield and enjoy by association the bewildered relief of this newly enlarged family.

Dad gets tears in his eyes the minute he sees his firstborn son. The resident interposes his gloved hand between baby's belly and the father's shaking hand as he gets ready to the cut the umbilical cord. "What do you think of your newborn son?" the attending physician later asks him. "I don't know," Dad replies, after taking a long pause to consider the question. He can't stop looking at his child.

October 20, 2012

I'm nervous, overwhelmed and short on sleep. As I gulp my milk and tater-tot casserole, the resident joins me for lunch. Instead of commenting on the news or the weather, he asks me why I am going into medicine. This is the resident, itinerant from Duluth, who gave me a crash course in OB, sat with me to deliver my first baby, modeled quiet listening in patient care, and actually inquired about and learned names of the staff. I decide he can be trusted, so I tell him about the gynecologist I shadowed in Peru who loved medicine and feared God and genuinely cared for patients who had hopeless medical and social problems because he was called to do so. I recount that I too have been called, compelled by my concern for people and my love for God. He nods. The resident challenges me to not forget my calling and, despite my love for medicine, to keep my priorities in order.

I'm on the wards, with my stethoscope around my neck. I didn't get here without a fight. I have been through rejection letters, cadaver lab, biochemistry and boards, but everything is different now that I have patients. I worked for this and dreamed of this for so long, and here I am looking at my patients, my new life in medicine. I feel inadequate, and my hand shakes when I use scissors. I return home with my pager and am not sure what I think about this device threatening to interrupt my life at any moment. Yet I know that I am not here by accident, and I am not alone. It took a resident interposing himself into the bewildering blur of my first month in rural medicine to help me remember that I've been called. **MM**

Megan San Giacomo is a fourth-year medical student at the University of Minnesota. This story is adapted from journal entries she made during her nine months in the Rural Physician Associate Program. She would like to thank Matt Hansmeier, M.D., from the University of Minnesota Duluth Family Medicine Residency Program, where she will begin residency this summer.

Closing the gap

Addressing Minnesota's health disparities

TUESDAY, JUNE 17, 2014

- Learn more about the state's efforts to address health disparities
- Share your best practices for working with minority populations
- Discuss what role physicians can play in addressing health disparities

KEYNOTE
Health Commissioner Edward Ehlinger, M.D., M.S.P.H.

PHYSICIAN PANEL
- Shana Sniffen, M.D. | HealthEast Roselawn Clinic
- Tamiko Morgan, M.D., FAAP | CMO/medical director with Metropolitan Health Plan and Associate Professor at the University of Minnesota

LOCATION
Wilder Center | 451 Lexington Parkway North, St. Paul

TIME
5:30-6 pm Registration and Social Hour
Heavy hors d'oeuvres will be served.

6-8 pm Program

REGISTER
www.mnmed.org/disparities

COST
Members: $25
Nonmembers: $40
Students: $10

SPONSORS
- American Indian Cancer Foundation
- Minnesota Association of Black Physicians
- Office of Minority and Multicultural Health at the Minnesota Department of Health

Minnesota Medical Association

Minnesota Association of Black Physicians

American Indian Cancer Foundation

Minnesota MDH Department of Health

OMMH Office of Minority and Multicultural Health

Looking for a better way to manage risk?

Get on board.

At MMIC, we believe patients get the best care when their doctors feel confident and supported. So we put our energy into creating risk solutions that everyone in your organization can get into. Solutions such as medical liability insurance, physician well-being, health IT support and patient safety consulting. It's our own quiet way of revolutionizing health care.

MMIC

To join the Peace of Mind Movement, give us a call at **1.800.328.5532** or visit **MMICgroup.com.**