THE JOURNAL OF THE MINNESOTA MEDICAL ASSOCIATION

MINNESOTA MEDICINE

MARCH 2014

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Minnesota Medical Association

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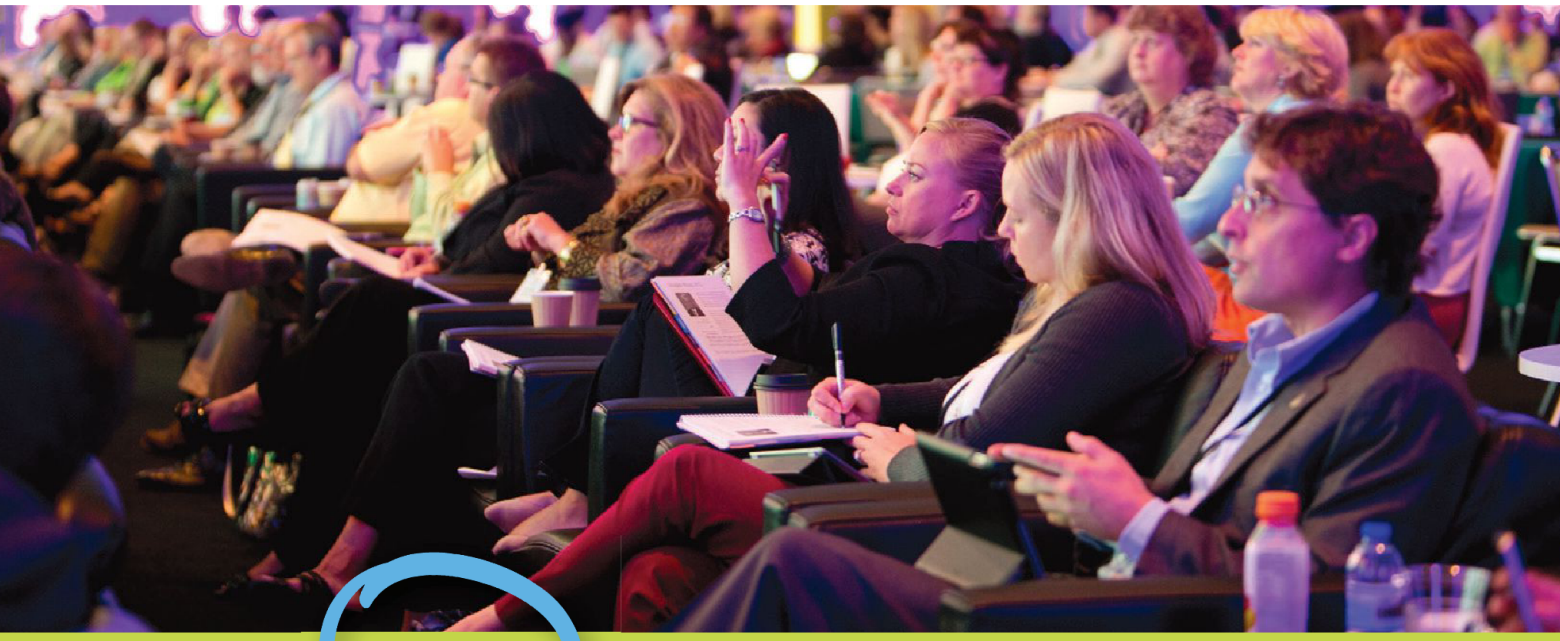

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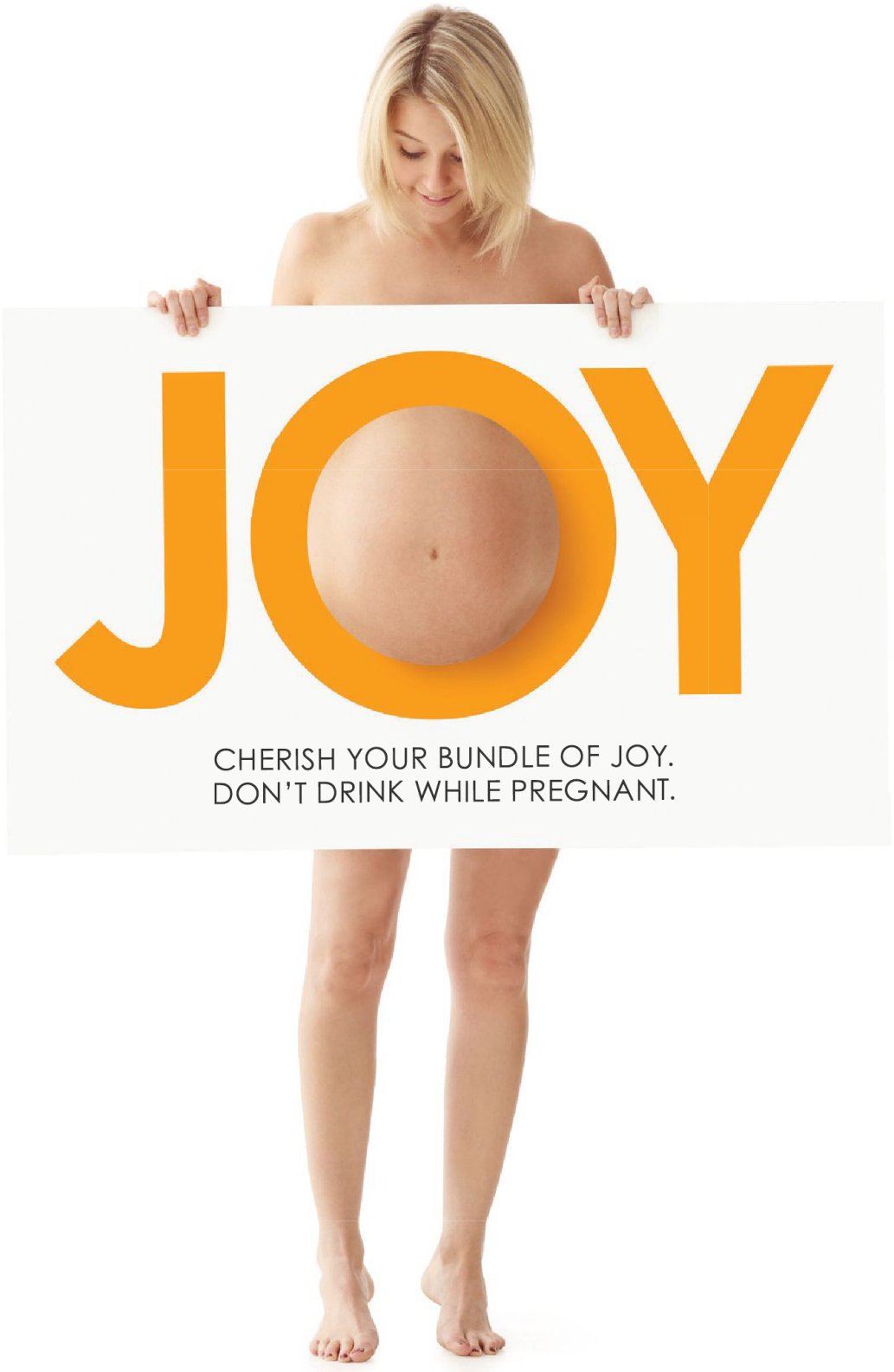

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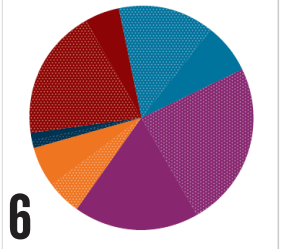

MINNESOTA MEDICINE

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

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

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PHOTO BY SCOTT WALKER

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

A woman's place

Women have come a long way and, hopefully, so has the rest of the medical profession.

The first contact with the medical profession that I remember was as a cross-eyed 3-year-old in need of strabismus surgery. My surgeon was Beulah Cushman, M.D. My hazy recollection of her was sharpened recently after reading a full obituary I found through the magic of Google. The picture of her with short, curly hair, trim physique, clear-rimmed glasses and thin smile dredged up memories I didn't think still existed. Reading the obit, I discovered that she was a giant in her field, authoring dozens of papers and multiple books, including one entitled *Strabismus: Diagnosis and Treatment,* which can still be purchased on Amazon. The obit cited her "extreme kindness and gentle manner" as "great assets in the handling of children."

I do remember feeling very comforted in her presence. I never thought about her being a woman, and I don't recall my parents talking about it. Yet she was a rarity in 1951. The growth of women's medical schools in the late 19th century had faded by the early 20th, and in 1949 only 5.5 percent of entering medical students were women. In 1974, when I graduated from medical school, they still comprised only 20 percent of new M.D.s. When I entered practice in 1977, doctors' lounges had the air of a men's club, lacking only the paneled walls and brandy snifters.

The last 30 years could fairly be dubbed the era of the woman in American medicine. Today, most medical school classes are about half female. Many specialties including obstetrics/gynecology and pediatrics are dominated by women. And doctors' lounges seem much more representative of the American demographic.

This has been no small feat. After female physicians conquered the overt bias restricting their admission into the medical profession in the early 20th century, they still faced the skeptical eyes of existing practitioners and wary patients whose preconceived notions about "who was a doctor" led them to shy away from female practitioners. Today, the complex juggling act of balancing medical practice and family life is a tricky feat distaff physicians frequently perform.

Some female M.D.s have added on leadership roles, piloting medical associations, specialized and general, through the turbulent waters of health care in 2014.

Viewing the accomplishments of Beulah Cushman and some of the physicians featured this month, I can't fathom the discrimination that once kept women in the home and out of medical schools. One notorious Harvard professor, Edward H. Clarke, proclaimed in 1875 that women seeking advanced education would develop "monstrous brains and puny bodies [and] abnormally weak digestion." Perhaps similar bizarre theories were at the root of medical societies banning women as members. Women have come a long way and, hopefully, so has the rest of the medical profession.

I'm told that the repair of strabismus, especially 60 years ago, was part art and part science. How well you balance the eye movements determines how well the patient's vision tracks for the rest of their life. Many times during my eye exams, ophthalmologists have commented on how well my eye movements were corrected and asked "Who was your surgeon?" I answer "Beulah Cushman," and they nod knowingly. **MM**

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

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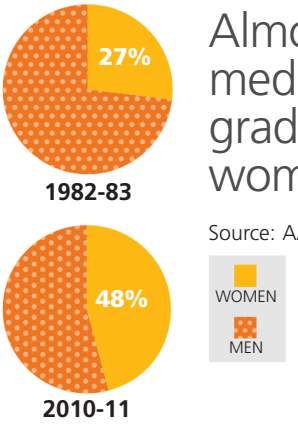
Women in medicine

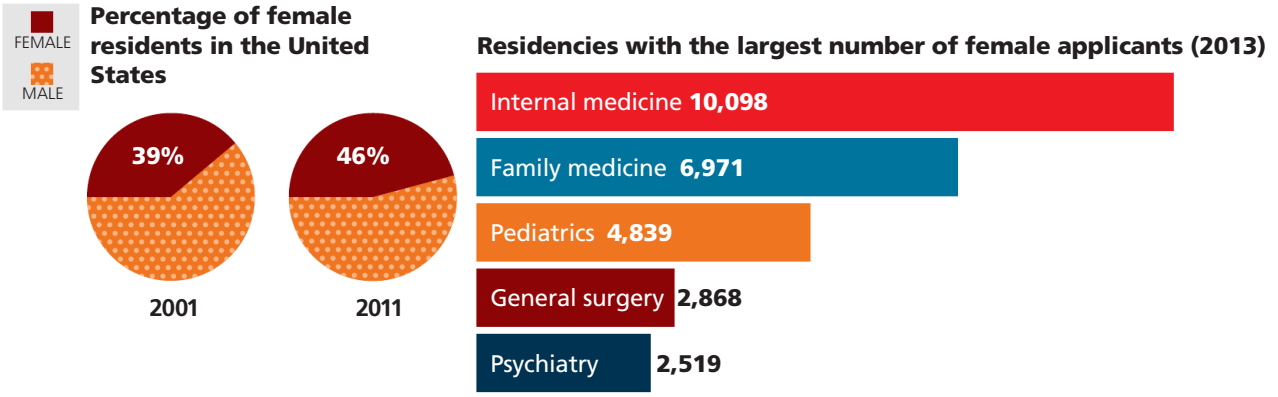
In recent years, women have made gains in some aspects of medicine. But as the numbers show, there are still areas in which they lag behind men.



Almost half of medical school grads are now women

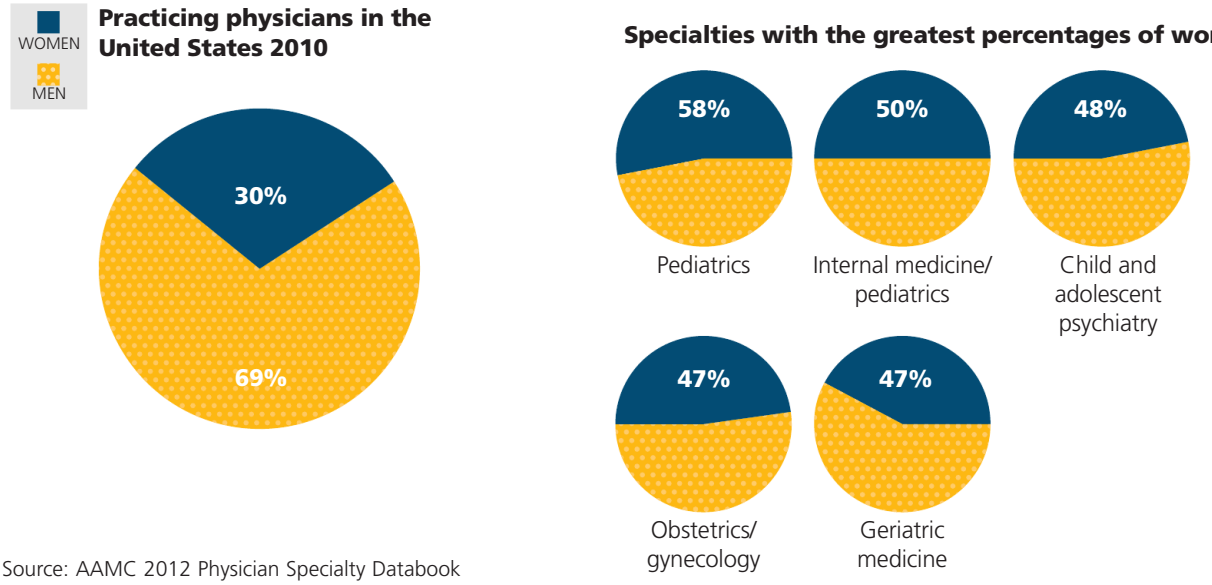
Source: AAMC

They're gaining in residencies



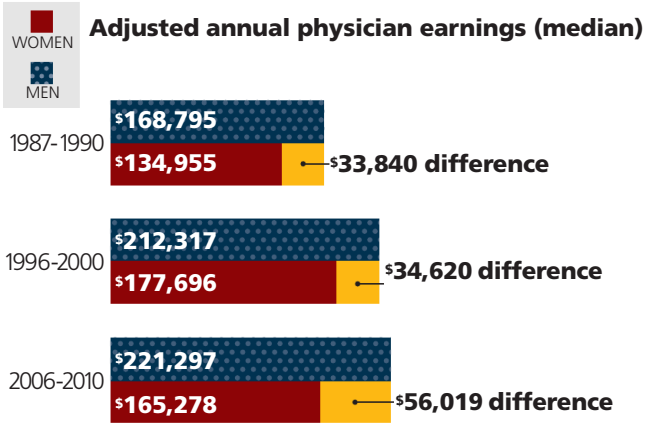
Source: AAMC, Women in U.S. Academic Medicine and Science, 2012 Physician Specialty Databook

They still make up less than a third of practicing physicians



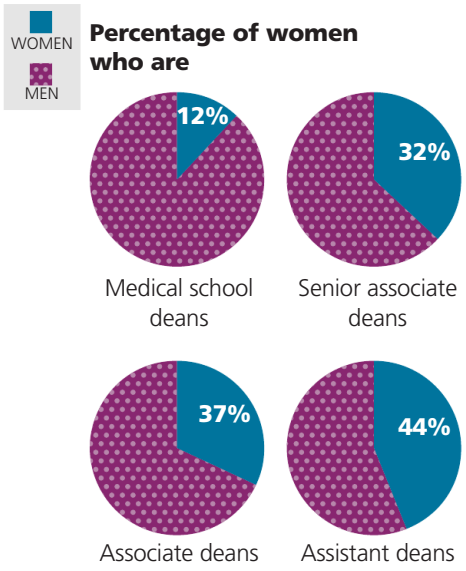
Source: AAMC 2012 Physician Specialty Databook

The earnings gap persists



Source: Seabury S, Chandra A, Jena A. Trends in the earnings of male and female health care professionals in the United States, 1987 to 2010. JAMA Int Med. 2013;173(18):1748-50.

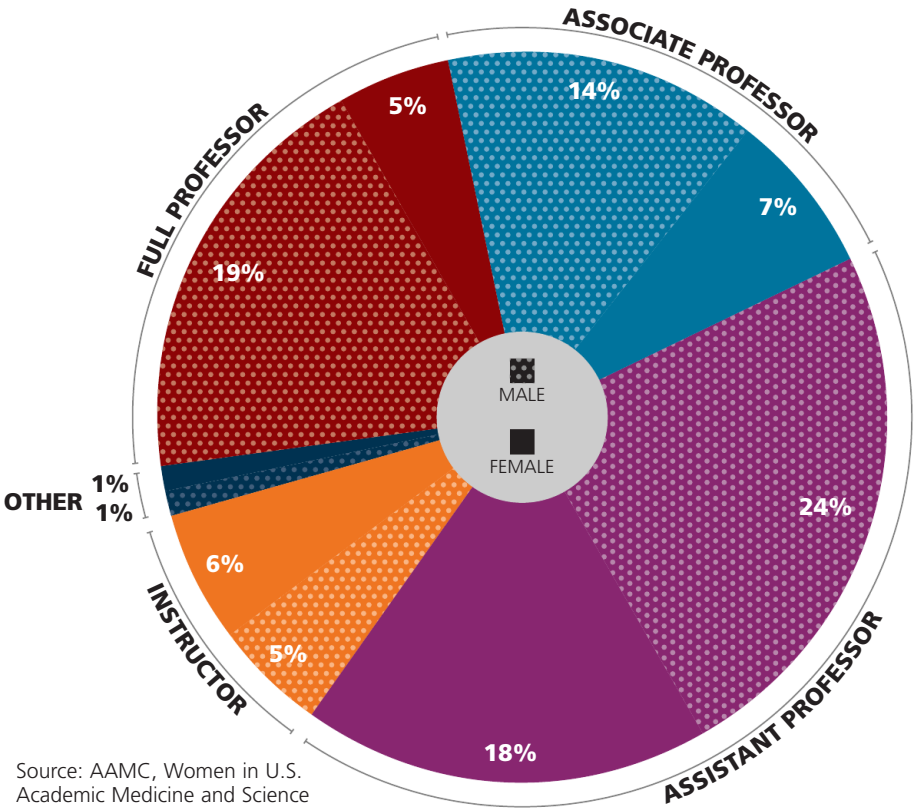
The dean's office is a man's world



Source: AAMC, Women in U.S. Academic Medicine and Science, 2011 data

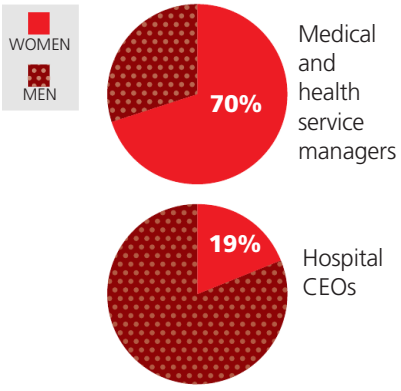
Many are assistants, few are professors

Full-time U.S. medical school faculty, 2012



Source: AAMC, Women in U.S. Academic Medicine and Science

Women lead on the wards, but few occupy the corner office



Source: XX in Health: State of Women in Healthcare 2013

Laboring women choosing alternative care

Women are frequently opting for nonmedical methods to induce labor and manage pain during childbirth, according to a University of Minnesota study.

Researchers led by Katy B. Kozhimannil, Ph.D., M.P.A., analyzed 1,382 survey responses from women who gave birth in U.S. hospitals. Among their findings:

- 30 percent of women reported using nonmedical methods to induce labor
- 70 percent used nonmedical techniques (such as massage, breathing, etc.) to manage pain
- Having a doula was the strongest predictor of using nonmedical methods.

In a report published in the December 2013 issue of *Birth*, the researchers wrote clinicians need to become more aware of alternative and nonmedical options in order to ensure patient safety and more research on these strategies is needed.

Source: Kozhimannil KB1, Johnson PJ, Attanasio LB, Gjerdingen DK, McGovern PM. Use of nonmedical methods of labor induction and pain management among U.S. women. Birth. 2013;40(4):227-36.

Reassurance for older mothers

Among studies presented at the Society for Maternal-Fetal Medicine's annual meeting in New Orleans in February is one from Washington University in St. Louis that found women 35 years of age and older have a decreased risk for having a child with a physical abnormality as compared with younger women. (Older women's increased risk for having a child with chromosomal abnormalities is well-established.)

Analyzing 18 years of patient information, researchers found that women 35 years of age and older had a 40 percent decreased risk of having a child with one or more major congenital malformations.

The authors suggested that an all-or-nothing phenomenon seems to be in play in older mothers, making it more likely that anatomically normal fetuses will survive.

Source: Goetzinger K, Shanks A, Odibo A, Macones G, Cahil A. Advanced maternal age and the risk of major congenital anomalies: survival of the fittest? Annual Meeting of the Society for Maternal-Fetal Medicine, February 6, 2014, New Orleans, LA.

Value of mammography screening called into question

The second phase of a study following nearly 90,000 women over 25 years has found that annual mammography screening does not reduce mortality specific to breast cancer.

Canadian researchers conducted a trial involving nearly 90,000 women ages 40 to 59, who were randomly assigned to a group that received annual mammography for five consecutive years or to a control group that received no mammography. Women in both groups received physical breast exams each year and were followed for mortality from breast cancer for 25 years.

The key finding was that 25-year cumulative mortality from breast cancer was similar between the mammography arm and control arm. The authors concluded that based on the data, "the value of mammography screening should be reassessed."

Source: Miller AB, Wall C, Baines CJ, Ping S, To T, Narod SA. Twenty-five year follow-up for breast cancer incidence and mortality of the Canadian National Breast Screening Study: randomized screening trial. BMJ 2014;348:g366.

Necessary OR obsolete?

A look at **women-only** professional organizations

BY MICHELE ST. MARTIN

Back in the days when women in medicine were scarce, female medical students and physicians formed their own associations in order to meet and support one another. But today, a medical school graduate is as likely to be female as male. So are women-only medical associations still relevant?

For Karin Tansek, M.D., co-president of Minnesota Women Physicians (MWP), the answer is a resounding yes, although she admits much has changed since she first joined the organization. "When I first moved to Minnesota [in 1984], I was the second woman ENT in the state," she says of why she sought out the company of other female physicians. "We would all meet for lunch and talk about how to find someone to date, how to have a family, find a residency," she recalls.

Tansek says much has changed for the better since then, "although today, women are still underrepresented, especially in surgical subspecialties and on med school faculties." The numbers bear out her claim: Just over a third of U.S. physicians and surgeons are women, as are only 36 percent of medical school faculty members.

"I think women doctors still have unique needs," says Judith Kashtan, M.D., who has been an MWP member and who chaired the Minnesota Psychiatric Society's Committee on Women for more than 20 years. She notes that women may not enjoy some of the politics that go along with being part of an organization that is led predominantly by men. "Men are more comfortable disagreeing; women are more attuned to wanting to get along. When women do speak up, we're more likely to be seen as strident, pushy," she says. "Organizations that are just for women don't always have that element."


Karin Tansek, M.D.

Kashtan currently serves on the American Psychiatric Association's (APA) Board of Trustees. She says one of the most important benefits of her involvement is meeting other female physicians. She recalls one gathering in particular—an APA women's mentoring breakfast. "We were women of all different ages, backgrounds and psychiatric specialties. One woman psychiatrist was a commanding officer in Afghanistan. Another was doing studies on women and violence. It was the highlight of the whole meeting for me. I like to get things done, make policy; but a lot of what I go for is the connections, getting to know people, learning what goes on in the world."

The camaraderie with other female doctors is important to Tansek, too. "We need to learn about each other's areas of expertise. Our specialties are so far afield, but we're all interested in medicine, science, patient outcomes." She says the dynamic of MWP meetings is different from that of her specialty society, where she says: "If I don't know anyone when I walk in, I won't know anyone when I walk out."

Opportunities for mentorship

Aside from networking with other practicing physicians, MWP members also interact with young women coming into medicine. "It's really fun to mentor medical students and residents. It keeps me fresher—they ask why you do it this way, instead of that way," Tansek says. A few she has met through the organization have gone into otolaryngology.

Katie Grey and Ashley Tollefson, both second-year medical students at the University of Minnesota, are among those who have benefited from MWP mentoring. They are co-presidents of Women in Medicine (WIM), a student association that often interfaces with MWP. Tollefson and Grey especially value opportunities to shadow female physicians. "It provides us with a nice opportunity to bridge the gap between medical school and practice," Tollefson says.

Medical students also appreciate seeing how women who have gone before them balance their work and personal lives. "They're our teachers and mentors; they grew up when there weren't many women in medicine. But there's still a leadership gap between women and men, and we

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share a bond with [these] women doctors," Tollefson says.

Grey, who became involved with WIM during her first year of medical school, says it didn't take her long to see value in the group. "The more things I went to, the more I realized how great the mission of empowering women to provide excellent health care was," she says. "It's a neat experience to work with a group of women who all have the same goals."

Membership challenges

Although the women involved in MWP extol its virtues, membership numbers are dropping. According to MWP Executive Director Linda Vukelich, the organization had approximately 300 members 25 years ago; today, that number is closer to 50.

Grey says declining numbers haven't been a problem for WIM, which has a core group of about 30 or 40 active members and draws many more attendees to its events. "When we have events, we'll often have 80 to 100 attend," she explains. Its Sexual Assault Fundamentals Education conference, for example, drew both male and female classmates.

Barbara Ford Olson, M.D., a family physician and MWP co-president, notes that doctors and medical students don't have to be dues-paying members to attend the association's events. "We have a huge email list," she says. "When we have an event, we'll get people from around the state that we've never seen before," she says.

Decreasing membership isn't just a Minnesota problem. According to Eliza Lo Chin, M.D., executive director of the American Medical Women's Association (AMWA), their membership is down, as well. She says that's because there are now more specialty organizations for women. (She notes AMWA, which has existed since 1915, is trying to collaborate with those organizations.)

According to Vukelich, who manages a number of professional associations, recruitment and retention are common challenges for all physician organizations. "Many doctors are hired by big groups, and they get a certain amount of money per year for conferences and memberships," Tansek says. For that reason, they often have to pick and choose which ones they join. Because they have to earn a certain number of CME credits to maintain licensure and retake an exam for board certification every few years, many choose to join their specialty society and attend meetings where they can get education related to their field, review for upcoming exams and connect with peers.

Kashtan contends balancing career and home can leave little time for professional organizations. "The messages we get are really hard—you have to be a perfect mother and excel at your career," she says.

She advocates for having the kind of events that might help alleviate some of the stress female physicians feel, with lots of time for education, talking and listening. "Not the kind where we are asking people to sign up for jobs, but the kind that allow for collegiality ... and not at 7 a.m. before work, but at times when you could have a babysitter at the meeting so the kids could be there.

Judith Kashtan, M.D.

"We have to organize events that are meaningful, and meet women where they're at." **MM**

Michele St. Martin is a St. Paul writer.

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BREAKING THROUGH

THE WOMEN WHO ARE LEADING MINNESOTA'S MEDICAL SOCIETIES

BY HOWARD BELL

Glance at the wall in the MMA's office where photographs of its past presidents hang, and you'll get the impression that organized medicine in Minnesota has been a men's domain. For the most part, it has. But that's changing. This year, a woman is sitting in the top leadership spot not only at the MMA but also at a number of other regional medical societies and state specialty societies. We spoke with three to find out why they decided to run for office and what they think they, as women, bring to their organizations.

Amy McIntosh, M.D.

Mayo Clinic pediatric orthopedic surgeon Amy McIntosh, M.D., is the current president of the Minnesota Orthopaedic Society (MOS). She's not the first woman to hold the job, nor will she be the last: St. Paul orthopaedic surgeon Julie Switzer, M.D., served as president four years ago and Minneapolis hand surgeon Julie Adams, M.D., will take on the role next year.

McIntosh has been a member of MOS since she was a resident in 2002; she has also served as its secretary, treasurer and vice president. Inspired by Switzer, McIntosh feels it is important to help shape health policy and bring a woman's perspective to the table. Now she hopes to inspire others. "It's important for future physicians to see women in leadership roles—to see that leadership roles are attainable." In addition, she says, there are conditions in orthopedics including scoliosis and hip dysplasia that affect women more than men, making it all the more important that female orthopedic surgeons' voices are heard.

Although the organization has a preponderance of male members, McIntosh says she never felt she was entering a "guy's club." "We're all physicians with similar concerns," she says. One of those is maintaining Medicare reimbursement for hip and knee replacements. The reimbursement rates are based on a state's average cost of living. McIntosh and her MOS colleagues have made numerous visits to state and federal lawmakers to urge them not to decrease those payments. "We can't afford to have them go any lower than they are," she says, adding that it's hard to provide quality care if you're not breaking even.

Last August, McIntosh co-authored a letter that appeared in the *Minneapolis Star-Tribune* responding to an article about Ameri-

"For me it's important to not sit in the stands and hope things work out."

– AMY MCINTOSH, M.D.

cans traveling to Europe to get their hips replaced because the surgery was less expensive there. The article referred to U.S. physician fees that were 12 times higher than the average fee charged in Minnesota. McIntosh wanted Minnesotans to know that the article didn't reflect the situation here and that high-quality, low-cost hip replacements are available in their own back yard.

These days, female orthopedic surgeons are far more likely to be involved in MOS than men. Approximately 10 percent of the 602 orthopedic surgeons in Minnesota are women. Eighty percent of them are MOS members; that compares with 46 percent of the state's male orthopedic surgeons. (At the national level, 4.7 percent of the American Academy of Orthopaedic Surgery's members are women.) "Women are socially aware, good at getting things done by consensus and teamwork, and we encourage each other to run for office," she says. Five of MOS's 16 board members are women.

McIntosh says she often hears women who aren't involved say the reason is because they don't have time. As the mother of a 2-year-old and a 5-year-old, she understands. "You have to make choices and be happy with the choices you make. For me it's important to be a mother and have a voice, to not sit in the stands and hope things work out. And my husband agrees. It's all about shaping change instead of responding to it, creating the future we want for us and our patients."

Audrey Park-Skinner, M.D.

Audrey Park-Skinner, M.D., joined Lake Superior Medical Society (LSMS) 22 years ago as a way to meet people. New in town, she had just started working at what is now Essentia Health as a general surgeon subspecializing in breast surgery.

It didn't take long before she was working on issues for LSMS as well. After speaking out at a LSMS-sponsored forum attended by area politicians, Park-Skinner was asked to be vice president in 2013 and was elected president for 2014. Her goal is to foster more interest in health care reform among members.

"Physicians tend not to get involved with public policy," she says, "but with the changes occurring in health care because of the ACA, I believe it's a great opportunity for physicians to help shape cost-efficient, thoughtful changes." She explains that if physicians don't get more involved, health care costs will continue to rise with little or no added value for physicians or their patients.

Park-Skinner believes informed physicians are more likely to engage in reform, which is why last month the LSMS and the Minnesota Academy of Family Physicians held a panel discussion on health care reform at the University of Minnesota-Duluth. "We're empowering our members with information so that they can help shape the changes we're in the midst of."

She is particularly pleased about LSMS's effort to ban the sale of bath salts and other synthetic drugs in local head shops. Park-Skinner worked with other LSMS members to organize a community forum and produce a video called "Ground Zero: Duluth's Battle Against Synthetic Drugs" that got national media attention.

LSMS was then asked to provide state agencies, nonprofits and schools with information about the medical effects of synthetics, which often brought users to local emergency departments, psychiatric units or even the morgue. "We testified, educated and publicized and drove the sale of synthetics out of town," she says of the closing of the notorious head shop Last Place on Earth last year. "That's something our members did to improve the health of the community."

Gone, too, are sugared soft drinks from the cafeterias in Duluth's hospitals, thanks to LSMS's support of an initiative by Duluth's Institute for a Sustainable Future. "Selling sugared soft drinks in a hospital sends the wrong message in an age of rampant diabetes and obesity," Park-Skinner says.

About 25 percent of LSMS members are women and many of them have been behind the society's recent initiatives. The bath salts ban and soda initiative, for example, were both the idea of family physician Maria Barrell, D.O. "Our female members are socially minded and civically aware," Park-Skinner says. And they don't hesitate to roll up their sleeves and get involved. "A woman will squeeze one more thing on her plate if she's passionate about it."

Park-Skinner believes the number of women involved in LSMS will grow, now that about half of medical students are women. "I think a membership balance will naturally happen as more women become doctors."

"A woman will squeeze one more thing on her plate if she's passionate about it."

– AUDREY PARK-SKINNER, M.D.

Cindy Firkins Smith, M.D.

Gender balance was certainly absent when Cindy Firkins Smith, M.D., joined the MMA in 1982 as a University of Minnesota medical student. But even then she says there were enough women involved to make her feel comfortable participating. The Willmar dermatologist became the MMA's fourth female president last September.

"To be honest, being president scared the hell out of me," Smith says, "because of the time commitment, time away from my patients and fear that I might say or do something stupid." But after serving on 11 MMA committees over the years, she decided it was her time to step up.

She says her main goal is to keep physicians working together during this time of great change in health care. "Change can be stressful, and there's a temptation to turn on each other rather than stick together and find solutions to our challenges," she says.

Part of sticking together means making sure women's voices are heard. "Men and women process information differently and the most successful committees are those with members of both genders. We need all physicians—women and men, from all races and locations, all specialties and political philosophies—to help us find solutions to problems that are making it hard to provide the best care to our patients," she says.

She cites passage of Minnesota's Clean Indoor Air Act as an example of the impact physicians can have when they work together. "Think of all of the lives improved or saved because of this one piece of legislation spearheaded by physicians in organized medicine," she says.

Smith became active in the MMA in 1994 partly because she felt female and rural physicians needed to be better represented. The gender gap has narrowed considerably since then. In 2012, women made up 31 percent of the MMA's total membership (approximately 33 percent of physicians in Minnesota are women). Among medical student members, 45 percent are women. Among residents, it's 41 percent.

But the gap widens when it comes to leadership. "Only 22 percent of our board members are women," she says, adding that the percentage of women participating on committees and task forces is 32 percent and 36 percent, respectively.

As for leadership style, Smith thinks women are still struggling to figure out what works best for them. "The answer is that one size doesn't fit all. To say a woman sometimes thinks differently than a man is accurate, but to say that she's more socially aware insults many of my very socially compassionate male colleagues."

Getting more women to become active has been a challenge, Smith says. "Most of my female colleagues are burning the candle

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at both ends, so the last thing I want to do is give them more to do that takes more time from home life, or make them feel guilty for not being involved. But I've found that many women do find a way to get involved because they do want to make a difference."

She says the MMA is working on issues that affect all physicians' work and home lives. One of those is the administrative burdens created by electronic health record (EHR) systems, which are especially troublesome for primary care physicians. They "are turning physicians—the most important cog in the system—into data-entry clerks," she says of EHRs and the increasing amount of documentation required in medicine. She says the MMA is trying to identify ways to reduce those burdens so physicians can spend more time with their patients "and maybe get out of the office an hour or two earlier."

Smith says the MMA is trying to make it easier for busy doctors to be involved in the organization by holding policy forums, where members can share ideas somewhat informally, and bringing more meetings to members, either at their workplaces or electronically.

In order to encourage more women to get involved, she would like to see the MMA make some of its events more family friendly. "If a physician has to choose between bringing a baby to a meeting or staying home, I say bring the baby. I'll hold her." She says she wants to hear from members who would like to be more involved but feel they can't. "Help us create the tools to break those barriers," she says. "We want a diverse, vibrant, enthusiastic MMA." **MM**

"If a physician has to choose between bringing a baby to a meeting or staying home, I say bring the baby. I'll hold her."

– CINDY FIRKINS SMITH, M.D.

Howard Bell is a frequent contributor to *Minnesota Medicine*.

FOUR OF MINNESOTA'S 22 COMPONENT MEDICAL SOCIETIES HAVE FEMALE PRESIDENTS:

Sandra Johnson, M.D., Alexandria Clinic, South Park Region Medical Society

Audrey Park-Skinner, M.D., Essentia Health, Lake Superior Medical Society

Lisa Mattson, M.D., University of Minnesota–Boynton Health Service, Twin Cities Medical Society

Mary Jane Tetzloff, M.D., Allina Medical Clinic–Fairbault, Rice County Medical Society

SEVEN OF MINNESOTA'S 30 SPECIALTY SOCIETIES HAVE FEMALE PRESIDENTS:

Susan Berry, M.D., University of Minnesota, Minnesota Academy of Pediatrics

Shelagh Cofer, M.D., Mayo Clinic, Minnesota Academy of Otolaryngology-Head and Neck Surgery (2012-2013)

Heather Gantzer, M.D., Park Nicollet Internal Medicine, Minnesota Chapter American College of Physicians

Amy McIntosh, M.D., Mayo Clinic, Minnesota Orthopaedic Society

Carrie Borchardt, M.D., Children's Hospitals and Clinics Minnesota, St. Paul, Minnesota Psychiatric Society

Rochelle Torgerson, M.D., Ph.D., Mayo Clinic, Minnesota Dermatological Society

Jennifer Johnson, D.O., Mayo Health System Mankato-Northridge Clinic, Minnesota Osteopathic Society

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.

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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

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novo nordisk®

VICTOZA®
liraglutide (rDNA origin) injection

Ten AT THE Top

Women physicians on their journey into leadership

BY CARMEN PEOTA AND KIM KISER

Medicine is becoming an equal-opportunity profession. Today, women and men are entering and graduating from medical schools in nearly equal numbers. But that wasn't always the case. And the numbers are still far from equal if you're looking at leadership in the upper echelons. Studies show only 12 percent of medical school deans and 19 percent of hospital CEOs are women.*

Yet women are making their way to the top. For some, the ascent has been gradual: They've seen a problem that needs fixing or discovered a better way of working that leads to their being elected to a committee, named department chair and appointed to a board. For others, the climb has been steep and quick.

We spoke with 10 Minnesota women physicians who have earned a place at the top of their organizations. We asked what inspired them, what discouraged them and what it will take for women to achieve the same sort of parity in the corner office, board room or dean's office that we're seeing in medical schools.

*AAMC, XX in Health: State of Women in Healthcare 2013

Sanne Magnan, M.D., Ph.D.

President and CEO
Institute for Clinical Systems Improvement

Growing up in Oxford, North Carolina, Sanne Magnan was encouraged to follow in the footsteps of her pharmacist father. But while studying at the University of North Carolina, the idea of going into medicine kept nagging at her. "I wanted to prove to myself that I could do it, so I took a physical chemistry course," she says.

Magnan did well and decided to transfer to the premed program. "I went to the dean of the pharmacy school to get him to sign the transfer slip, and he wouldn't sign it. He said, 'Your family wouldn't want this.' And he was right, my family didn't want it."

Today, she's grateful for that response. "I think it was a really good thing I didn't get into medical school then," she says. "I had time to grow and mature and learn new skills." Instead, she came to Minnesota in 1974 to earn a doctorate in medicinal chemistry, working as a pharmacist at the old Metropolitan Medical Center on weekends.

But her interest in medicine persisted, and after earning her Ph.D. in 1979, she enrolled in the University of Minnesota Medical School. She specialized in internal medicine and today still practices one half-day a week in the St. Paul-Ramsey County Public Health Department's TB clinic.

In her first clinical job, Magnan began noticing ways to do things better. "We were a teaching clinic," she says of the facility, which is now part of HealthPartners. "One of the No. 1 procedures we did was a Pap smear. We had a lot of residents rotating through, and I thought, 'How are we going to make sure no Pap smear results fall through the cracks? How can we create a system?'" She saw improving systems and policies as a way to help patients get better care.

When she was approached by leaders at Blue Cross and Blue Shield of Minnesota in 1993 about becoming associate medical director for its BluePlus health plan, she viewed it as an opportunity to bring her ideas to a wider population. "It wasn't a big leap for me to go from taking care of patients to taking care of a population of Blue Cross members," she says.

In 1996, while working at Blue Cross, she got a call from the Institute for Clinical Systems Improvement's (ICSI) search committee. Their president, Gordon Mosser, M.D., was retiring, and they wanted to know if Magnan, who was an alternate board member at the time, was interested in leading the organization. "The more I talked with them about what they were looking for and the opportunity to take the clinical work I was doing and the work I was doing at Blue Cross to an even bigger population, the more it caught my interest," she says.

Fifteen months into being named president of ICSI, Magnan got another unexpected call—this time from the office of Gov. Tim Pawlenty, who asked her to interview for the state's commissioner of health job. In 2007, Magnan became the first physician in many years to head the state's health department, a position she would hold until 2011. Under her watch, Minnesota would begin a multiyear initiative to address public health issues such as tobacco use and obesity, standardize quality and cost measures, increase transparency and reduce costs, and establish health care homes among other things.

Magnan, who was reappointed as president and CEO of ICSI in 2011 after her term as commissioner ended, admits she has struggled to balance her career and personal life. She says she learned a hard lesson as a resident when she attended one brother's wedding but missed her second brother's wedding two months later. "I was on a very critical service without an intern," she recalls. Although another resident was willing to cover for her, she decided not to go to North Carolina. "I was so dedicated—too dedicated. I couldn't see how to make it work, and I've regretted my decision to this day."

> "The magic happens outside your comfort zone."

A lesson of a different kind came from former Blue Cross CEO Mark Banks, M.D., who asked her to serve on the foundation's finance and audit committee. Having no experience with finance, she questioned whether she was the right person. "He said, 'You as a physician leader don't need to do finance and audits, but you do need to understand and appreciate the critical components.'" She says sitting on that committee helped her deal with financial issues not only at Blue Cross but also at ICSI and the Department of Health.

Magnan urges other women to take opportunities that come their way, even if they may not be something they think they can do. "The more you step outside your comfort zone," she says, "the more versatile you will be. The magic happens outside your comfort zone." **—KK**

Kathleen Watson, M.D.

Senior associate dean for undergraduate medical education, University of Minnesota Medical School

In the late 1960s when she was in high school in Detroit Lakes, Minnesota, Kathleen Watson was only dimly aware of the women's movement. When she and her friends started a hockey team for girls, it was simply so they could have fun. "It wasn't political, it was more like, 'Why can't we do this?'"

That question might be the theme for her career. While at Carlton College, she began asking Why can't I study medicine? And after spending a year working in a research lab in Indianapolis, she was confident she could take on the challenge.

When Watson entered medical school at the University of Minnesota in 1974, only 20 percent of her classmates were women and few women were on the faculty, so the female students supported one another. About a half dozen of them began meeting to talk about women's health and things that "irked" them in the classroom. They eventually started a women's health clinic in Minneapolis' Cedar Riverside neighborhood, where they saw patients and practiced doing exams on each other. "There were women peers, but there were very few women whom I'd call mentors," Watson notes. "Maybe that happened for other people, but it didn't for me."

> "If you don't get coaching and mentorship and encouragement, it's hard to do all the things you need to do to cross the barriers and achieve the milestones."

Instead, men became mentors. Manny Kaplan, M.D., a hematologist at the Veterans' Affairs Medical Center, cultivated her interest in internal medicine. "We had cases together. He put together the clinical signs, the human factors, the science, the morphology of blood cells under the microscope, and showed me how we could make a difference. He took me under his wing and I learned so much from him." Charlie Moldow, M.D., got her interested in hematology. She recalls him telling her to keep up the good work after she gave a presentation and then asking if she wanted to see a particular patient with him. "If you don't get that kind of coaching and mentorship and encouragement, it's hard to do all the things you need to do to cross the barriers and achieve the milestones," she notes.

Watson says throughout her career, she's sought out problems to solve rather than positions. "I followed a meandering path looking for opportunities. Looking back, it's finding the obvious problems and trying to create change that have been the leadership opportunities."

She's not sure why more women don't seize those opportunities. "Maybe they have more responsibilities. Maybe they'd rather seek a path that's more family friendly. Maybe it's not worth it to them to be leaders," she says.

Then she adds, "What I really believe is that there are so many ways to lead and so many problems in medicine, there's more than one way to accomplish that." **–CP**

Rebecca J. Hafner-Fogarty, M.D.

Chief medical officer, Zipnosis

Rebecca Hafner-Fogarty's leap from farm girl in tiny Fairmount, North Dakota, to chief medical officer of Zipnosis, a Minneapolis online health care delivery start-up, might seem like a long one to some. But as Hafner-Fogarty tells her story, coming from a small, rural community was anything but a handicap. In fact, she says it offered advantages.

"My high school was so small they didn't have a home ec department, so I escaped what happened to a lot of young women in those days—being slotted into quote-unquote girls' courses," she says. There were eight students in her graduating class. "So everybody took chemistry and everybody took physics and everybody took advanced algebra." When Hafner-Fogarty arrived at the College of St. Benedict in St. Joseph, Minnesota, in 1970, she found herself well-prepared to study the sciences, even though medicine wasn't yet on her radar—she wanted to be a veterinarian.

When doubts about whether she could get into vet school crept in, she began to think about other options. She decided to take the MCAT, surprised herself by doing well and applied to the University of North Dakota Medical School. When her acceptance letter arrived, she was both relieved and nervous. "I still wasn't sure being a physician was what I wanted to do," she says. "But at that point, I felt the choice had been made and I was at least going to try."

Her reception to medical school in 1974 was a male colleague informing her that his best friend hadn't gotten in because she had taken his spot. Although such overt signs of hostility would prove rare, Hafner-Fogarty realized she and the other 10 women in her class of 68 would not only need to master the material, they'd need to break new ground. Eleven was the most women the school had ever had in a single class.

"One of the difficulties we faced was that we had no women physician role models at the medical school," she says. So she and one of her classmates went looking for them. They contacted women physicians practicing in North Dakota and northwestern Minnesota and invited them to campus for a conference. "We said, 'Tell us what it's like. Not the book learning. What do we need to know? How do we do this?'" she says. "I think it was important to hear those answers from people who looked like us."

Hafner-Fogarty graduated in 1978, completed an internship and then practiced for 10 years in Breckenridge, Minnesota. But after a move to St. Cloud, she was unhappy with the way her career was going and started considering other options. "In fact, I was so unhappy I was thinking of leaving medicine," she says. "My mental calculus at the time was, If I'm not going to practice, I'd better equip myself with some other marketable skills if I want to get a job."

She decided to go for an M.B.A. at the University of St. Thomas and found herself in class alongside lawyers, accountants and engineers. The coursework was stimulating. "It was a different way of looking at the world," she says.

When she finished, she heard St. John's University was looking for a campus physician. She applied for the job and proposed turning what had been a part-time position into more. "I said there's a lot of great potential here to make this position a resource for the students and the monastic community and the entire campus. I sort of took a part-time retirement job and built it into a combination clinical and executive position," she says.

> "I wanted to build something that was interesting and innovative."

She continued to combine her clinical and administrative interests as chief medical officer for MinuteClinic, as a member of the Board of Medical Practice and as a leader in the Minnesota Medical Association. One of the things she likes about her current position at Zipnosis is that it allows her to be creative. "I wanted to build something that was interesting and innovative," she says. "I'm working with people at least a generation younger, and they're all smart—probably smarter than I am."

Hafner-Fogarty bristles at the conventional notion that women bring a collaborative style to leadership: "It's not that simple," she says. As she sees it, all leaders are called to make judgments about when it's important to be collaborative and when it's important to be decisive.

Hafner-Fogarty points to the small number of women medical school deans as one piece of evidence that the glass ceiling still exists for women in medicine. But she emphasizes that the world has changed dramatically since she started out in medicine. "The fact that in a generation, we've moved from a situation where No women need apply to a situation where the doors are pretty wide open—at least the entry point—is amazing. And it's good." **–CP**

Bobbi Daniels, M.D.

CEO, University of Minnesota Physicians

Bobbi Daniels believes being a nephrologist is much like running an organization. "Understanding how the kidney works is very much like understanding the operations of a big business," says the CEO of University of Minnesota Physicians (UMP).

Today, Daniels practices her specialty (she still takes call on weekends) and leads the $470 million physician organization. In both roles, she tries to improve the way complex systems work. "My personality is such that if I'm standing in line at the grocery store, I think 'If they did this differently, it would work better.' I do that all the time," she says.

Daniels' current challenge is the multimillion-dollar five-year integration of the University of Minnesota's hospitals and clinics with Fairview Health Services. Under a 2013 agreement, a board created by the two entities will jointly manage services they both perform.

Figuring out how to make this work has been testing Daniels' leadership and problem-solving skills—as well as those of her colleagues. One person she's working closely with is University of Minnesota Medical Center president, Carolyn Wilson. "What we're trying to do in working together is not divide the pie in a way that there are winners and losers, but to try to quickly reach some happy medium between the organizations that's a win-win," Daniels says.

She admits that hasn't always been the case when it comes to the university's relationship with Fairview, which took over operation of its medical center in 1997. (The university's academic bent and Fairview's bottom-line focus haven't always meshed.) She attributes the tenor of the current talks to hers and Wilson's style. "We share common values and vision, and we've been able to find solutions that have been difficult to achieve in the past," she says, adding "I do think women tend to be more open, less territorial and more focused on problem-solving."

> "Be flexible, not rigid, and have no preconceived notions. Sometimes the outcome is good, sometimes it's not, just adjust and move on."

Daniels' UMP leadership team happens to be composed of three women and one man. "That's just how it evolved," she says.

"Evolution" describes her career interests as well. A native of Nampa, Idaho, she fell in love with research and chemistry while studying at Gonzaga University in Spokane, Washington. When she weighed becoming a chemistry professor against going to medical school, the scales tipped toward medical school.

At the University of Washington Medical School in Seattle, Daniels became inspired by a group of nephrology researchers. Internship and residency brought her and her husband to Minnesota in 1981, where she joined a handful of other women in her residency program and in nephrology. "There clearly was a significant preponderance of men," she says of the specialty at the time. "It's just the way it was."

As a member of the University of Minnesota Medical School faculty and a UMP staff physician, Daniels was named to UMP's board of directors in 1996, serving on a number of committees and chairing the clinical practice committee. In 2003, she became chief medical officer, overseeing the care provided by the group's physicians as well as its ambulatory clinics. In 2009, she was named CEO. "Other than applying for internships," she says, "the only job I have officially ever applied for—except for detassling corn in Idaho—is the one I'm in now."

Daniels says her career path has been somewhat illustrative of her approach to life. "Be flexible, not rigid, and have no preconceived notions," she says. "Sometimes the outcome is good, sometimes it's not, just adjust and move on."

She would like to see other women physicians follow that lead. "In medicine, we're serving a diverse population," she says, "and the more diverse the leadership is, the better off we will be." **–KK**

Kathleen Brooks, M.D., M.B.A., M.P.A.

Director, Rural Physician Associate Program, University of Minnesota

A question that might lead some women to step back from responsibility—How can I do this job and have a family?—is the one that started Kathleen Brooks, who now directs the Rural Physician Associate Program at the University of Minnesota, on her path to becoming a leader.

In the mid 1980s, Brooks wanted to work part time in order to care for her young children. No physician at Douglas Family Physicians, where she and her husband both worked, had yet done that. Brooks made a proposal to her partners, and they gave it a try. "Our senior partners were really quite wonderful," she says.

In figuring out that plan, Brooks learned something about herself: She enjoyed thinking about broader organizational issues. For the next few years, she found herself paying attention as the group wrestled with contract negotiations with health insurers and other concerns. When her youngest daughter was getting ready to start kindergarten, she decided to start working toward an M.B.A. at the University of St. Thomas.

The weekend classes gave Brooks the chance to look at health care from a new vantage. "The combination of providing direct patient care and then stepping back was really stimulating," she says. As part of her coursework, she traveled with former U.S. Sen. Dave Durenberger to Washington, D.C., to learn about health policy making. "I realized that that was where the levers of change were," she says. The experience whetted her appetite. So she decided to apply for a Bush fellowship, with the aim of studying at Harvard's Kennedy School of Government. She spent 1997 and '98 traveling between the Twin Cities, where her family was, and Boston.

With the second master's degree under her belt, doors opened in Washington, but Brooks decided not to go. Her children were in high school and her mother was in a nursing home at the time. "There were a lot of compelling family reasons to stay in Minnesota," she says. Over the next decade, Brooks applied her policy expertise as medical director of the state's Medicare Part B program and as a consultant to the state on its Medicaid programs. She also helped develop a leadership curriculum for St. Thomas. In 2005, she joined the University of Minnesota Medical School faculty.

As Brooks looks back, she realizes she came of age at a special time for women. In the late '60s and early '70s when she was a student at Minneapolis' Regina High School, the nuns who were her teachers were coming out of habits and convents. "While I was taking drivers' ed, they were taking it. We were stepping into the world with them."

At the University of Minnesota, Brooks majored in psychology and went on to medical school, thinking she'd go into psychiatry. A clerkship pointed her instead toward family medicine. She matched with the residency program at North Memorial Medical Center in Robbinsdale, where hers was the first class to have a female majority. "It caused all sorts of consternation at the hospital because they weren't accustomed to having that many women," she says. "There were issues about lockers and where to put us and where we changed clothes." She was the second woman in the program to have a baby during residency. "That was a new experience to see residents working who were pregnant." Having children brought extra scrutiny. "I had to really prove that I was still interested in my medical career and that I was engaged and that I'd try to prove my worth," she says.

> "I don't hear any of us telling women 'Don't have children' or 'Don't marry someone with a career.' It feels in medicine like we're further along than that."

Brooks thinks medicine is now ahead of other fields in terms of welcoming women. She notes that her daughter, who has an M.B.A., was recently told at a mentoring event for women to consider marrying someone who would be willing to stay home with the children because it would otherwise be hard to balance a career in business with a family. "I don't hear any of us telling women 'Don't have children' or 'Don't marry someone with a career.' It feels in medicine like we're further along than that." **–CP**

Ann Lowry, M.D.

President and CEO,
Colon and Rectal Surgery, Minneapolis

When Ann Lowry told her parents she was going to medical school, neither was surprised. Both were internists, and they knew their daughter could handle the rigors of medicine. But when she later announced the specialty she had chosen, they had a different reaction. "They thought I was nuts to do surgery," says Lowry, now president and CEO of Colon and Rectal Surgery Associates in Minneapolis.

The prevailing thinking even in the late 1970s, when Lowry was finishing medical school at Tufts University, was that the OR was a man's turf. It wouldn't be easy for a woman to handle the demands of training and the erratic lifestyle of practice. The one woman Lowry knew who'd finished a surgery residency wasn't exactly encouraging: "Her comment was, 'If you'd like to live like a nun, then general surgery makes sense,' basically implying it wasn't possible to get married and have a family and practice."

But Lowry persisted. She enjoyed working with her hands and looking at problems, rather than having to conceptualize them. "It was what I was interested in and what I felt I had some talent for." And she'd seen her mother practice internal medicine during a time when few women worked at all. "It seemed possible to me," she says.

But Lowry had to prove herself to others. She was asked if she could pull her weight. Others who knew her were asked if they thought she could do it. "I don't think they were asking that of the men," she says.

> "It was uncomfortable because I was saying I needed something different than what the men needed."

Lowry landed a residency position at Tufts. Although she was the only woman in the program, she enjoyed it. "I was extremely lucky about where I was training. I had fellow residents who were very supportive and faculty who overall were accepting." She practiced in the Boston area for four years, then did a residency in colorectal surgery at the University of Minnesota, where again she was the only woman. She joined Colon and Rectal Surgery Associates in 1987.

Lowry says her partners accepted her into the practice and primary care physicians referred patients to her, most of whom were women. But there was a challenge: The surgeons were expected to take their own call during the week. "I had had our first child during training. It became clear that it was not going to work if I was going to be on call every night." She found herself having to ask her partners to make a change. "It was uncomfortable because I was saying I needed something different than what the men needed. At the time, I'm pretty sure all the men in the practice had wives who stayed home. They had trouble understanding that I didn't have anybody taking care of all this stuff," she says.

Lowry now fields such requests from others. And she considers it her job to ensure that the women and men in the practice are treated fairly.

She is dismayed by the small number of female leaders in medicine and is part of a group of women from around the country who meet to talk about the problem. "From the point of view of an organization, it's like saying you're not going to look at the whole spectrum of people who might be available [to fill a position]. At least in theory, you're going to be missing out on talent." And she points out that if women in mid-career are not visibly succeeding, younger women will become discouraged.

Although Lowry acknowledges that medicine is much more welcoming of women today than it was when she entered the profession, she does not think sexism is a passé issue. She recently learned the American Society of Colon and Rectal Surgery executive council failed to nominate a single woman to its board. (Lowry was president in 2005-2006.) Someone told her they couldn't think of "good women" to nominate. "My reply was, 'There's a telephone. I know many good female candidates.'" **–CP**

Ruth Lynfield, M.D.

Minnesota state epidemiologist

Ruth Lynfield knew early on that she wanted to be a doctor and that she wanted to study infectious diseases. "There's always something new happening," she says of working with organisms that are constantly changing.

Studying medicine in Manhattan in the early 1980s, she had a front row seat to what would become one of the biggest infectious disease stories of our time—the AIDS epidemic. "They were just beginning to understand why people were presenting with really unusual infections," she says.

After residency and a fellowship in pediatric infectious diseases at Massachusetts General Hospital in Boston, she stayed on at the hospital and also worked for the New England Regional Newborn Screening Program. She got her first taste of leadership when she was named assistant director of the program in 1992. "In that world, if you worked hard and were competent, you were able to advance."

A desire on the part of her physician husband to come home to Minnesota brought the couple and their three children to the Twin Cities in 1997. At the time, Minnesota's state epidemiologist Mike Osterholm, Ph.D., M.P.H., was starting an emerging infections program. He hired Lynfield as a part-time epidemiologist. The position not only fit her interests, it also gave her flexibility. "My youngest was a year old, and I could spend a lot of time with her and volunteer at my older children's school," she recalls.

Within two years, Lynfield became supervisor of the health department's emerging infections unit. In 2003 she was appointed medical director for infectious diseases, and in 2007 she became Minnesota's first female state epidemiologist. In that role, she is in charge of tracking and monitoring diseases, investigating outbreaks and making sure the state is ready in case of a pandemic or other public health threat.

Lynfield says being a woman—and being a mother in particular—has given her a perspective that's proved advantageous. "It may not be a gender thing as much as a caretaker thing."

She recalls leading an initiative to vaccinate first responders, public health workers and emergency physicians against smallpox. "The vaccine is a tough one," she says. It has numerous contraindications and side effects, a many physicians were unfamiliar with it. Knowing she was asking younger physicians who had no experience with the vaccine to administer it, she made sure they had support. In addition to training them, she set up a network of experts for them to consult. "These were the days before cameras on cell phones, so we made sure the clinics had access to digital cameras so they could email images of takes and rashes," she says. "This enabled the clinicians to feel more comfortable with vaccinating."

> Being a woman can be an advantage. "It may not be a gender thing as much as a caretaker thing."

As for being a woman in medicine, Lynfield views herself as a member of a bridge generation. Her mother, a dermatologist, was one of two women in her medical school class. By the time Lynfield graduated from Cornell University Medical College in 1985, women made up about 30 percent of all medical school graduates in the United States.

She says she knew women a few years older than she who felt they had to choose between medicine and family. But Lynfield had seen her mother manage both. "She was a great role model for me. She was chair of her department, saw patients and had a family, so I had a sense it was doable."

And when Lynfield did encounter people who told her mixing family and medicine would be too difficult, she says, "I didn't take them seriously." **–KK**

Penny Wheeler, M.D.

President and chief clinical officer, Allina Health

Penny Wheeler laughs when she describes how life has taken her exactly two blocks—from Abbott Northwestern Hospital in Minneapolis, where she was born, to the executive suites of its parent organization, Allina Health, where she serves as president and chief clinical officer.

Calling herself a "Triple Gopher," Wheeler has always stayed close to home. She earned her undergraduate and medical degrees from the University of Minnesota and did her residency in obstetrics/gynecology there. She was drawn to the specialty because she saw the relationships physicians seemed to have with each other and with their patients. "It's a very collaborative specialty," she says. It's also one in which physicians can see their patients for the long haul. "We're the primary care givers for two-thirds of the women in the reproductive age group, and we follow them through menopause."

A conversation while she was a resident in 1988 with then ob/gyn department chair Leo Twiggs, M.D., launched Wheeler on a path toward leadership. After finishing a difficult rotation, he took her aside and told her she needed to be a leader—to stretch herself in order to do good and help others.

Wheeler took that message to heart, eventually becoming chair of Abbott Northwestern's ob/gyn department and the hospital's first, and so far only, female chief of staff. It was during her tenure as chief of staff that she became "radicalized" around improving care—a passion that led to her being asked to join Allina's board of directors and chair of the quality committee.

"Since it was so integral to our mission, I pushed for accountability and transparency about how well we did caring for our patients," she says. "I think the CEO at the time got tired enough of me saying it that he said, 'You try it.'" In 2007, she was named chief clinical officer, a role that put her in charge of clinical efforts at Allina's 12 hospitals and 90-plus clinics.

> "I still think we live in a world where we have some institutional bias be it around ethnic lines, racial lines, gender lines."

At the time, Wheeler was one of two women and the only physician on the executive leadership team (today, four out of the eight members are women and three are physicians). "At first, I was cowed," she says. "Acronyms were coming at me that I didn't understand. I felt I didn't know anything."

She soon realized that as the only M.D. at the table, she brought a perspective to the conversations that others didn't have. "I could explain the ramifications of decisions on the care of the patient and the physicians and caregivers who served them," she says. "That was a big 'aha' moment." Last October, she added the presidency of Allina to her responsibilities.

Although she has felt supported in her role and would like to believe women and men are treated equally as leaders, she says it isn't always the case. "There are subtle things you see now and again." She recalls reading the minutes from a credentialing meeting in which all the male participants were referred to as "doctor" and she as "Penny."

"I still think we live in a world where we have some institutional bias be it around ethnic lines, racial lines, gender lines. I think it's subtle, but at times I wish it were more overt. Like with Archie Bunker, at least you knew it was there," she says.

Yet she encourages other women physicians to lead. "They need to get involved because of the collaborative way they approach challenges and the compassionate and holistic way many approach care," she says. "We need that." **–KK**

Sherine Gabriel, M.D., M.Sc.

Dean, Mayo Medical School

Sherine Gabriel started her medical career wanting to solve mysteries. Her passion eventually shifted to teaching, and now, as the first female dean of Mayo Clinic's Medical School, she has become the ultimate champion for training the next generation of medical sleuths.

"I've been very interested in teaching and mentoring and learning my whole career," she says. "A lot of medicine is learned at the hands of more senior people. When you go on rounds, even as a senior resident, you're teaching the junior residents and medical students. We're always teaching."

A desire to work with people and an interest in science drew Gabriel to medicine. "What got me into medicine wasn't very novel," she admits. "But being an immigrant plays into this. I had motivation and drive." (She's the daughter of an architect and school teacher, who brought the family to Saskatchewan from Cairo, Egypt, in 1967, when Gabriel was 10 years old.)

At the University of Saskatchewan College of Medicine, she became fascinated with rheumatology. "At the time, rheumatology was almost a black-box specialty," she says. Residency and fellowship brought her to Mayo Clinic, where she discovered solving the mysteries of the immune system wasn't her only interest.

The more she read about the state of medical education, the more she wanted to try to improve it. She developed new programs to train clinical researchers and won a number of teaching awards for those and other efforts.

That work led to her appointment as chair of the department of health sciences research. She eventually joined Mayo's executive board and became medical director for its Office of Strategic Alliances and Business Development. "My intent wasn't really to go into leadership," she says. "I never had a goal to be something. I was more interested in doing something."

When Terrence Cascino, M.D., stepped down as dean of the medical school, Gabriel was named to the position in November 2012. She is currently one of a handful of female medical school deans in the United States.

Gabriel disagrees with those who've suggested it's more difficult for women to move ahead in academia. "You do have to produce academically—write grants, write papers, travel to meetings and present your research," she says. "But early on in academia, you have to do a lot of writing, and that sort of work has more flexibility than patient care."

When her sons, now 23 and 25, were young and she was doing research, she could pick them up from school, come home and play with them, and then work on writing grants after they had gone to bed. In addition, both she and her husband, an internist and pathologist, reduced their work hours so they could share the parenting responsibilities. "No one questioned my going part time," she says. But when her husband went part-time, colleagues asked if she had become ill.

Gabriel attributes much of her success to staying focused on what she was trying to achieve professionally, and she counsels other women to do the same. "It's very easy to be taken off track by someone's perception of what you ought to be doing or society's perception of what you ought to be doing. But the person who really knows best in terms of what you can do and need to contribute to our profession is you. Trust yourself." **–KK**

"The person who really knows best in terms of what you can do and need to contribute to our profession is you. Trust yourself."

Kathryn Lombardo, M.D.

President and CEO, Olmsted Medical Center

In 1987, Kathryn Lombardo made a career decision that few physicians were making at the time: to go into health care administration. She wanted to use her medical training, but in a different way. "Now all organizations have physician leaders," she says. "That wasn't the case in the late 1980s."

She found an opportunity with the Federal Medical Center in Rochester, where she was hired as an assistant hospital administrator. Three and a half years later, Lombardo did a psychiatry residency at Mayo Clinic, with the idea of getting back into clinical practice. That led to a position at Olmsted Medical Center, where she's worked since.

Lombardo has always been one to try things. Raised in Brookings, South Dakota, she was encouraged to aim high by her father, a physician who was active in the AMA and South Dakota State Medical Association. Growing up, she spent considerable time with him at the clinic and hospital and on house calls. By the time she was in high school, she knew she wanted to be a physician.

For Lombardo, the detour to the Federal Medical Center turned out to be an invaluable experience. Sort of an immersion M.B.A., it offered her hands-on lessons in managing people and budgets, training that has proved useful, especially now that she is president and chair of the board of governors of Olmsted Medical Center.

As Olmsted's physician leaders are required to have a clinical practice, she still sees patients four hours a day. "I believe it keeps you closer to your clinician colleagues," she says. "It probably allows me to recognize how changes [in health care] are impacting clinicians within our organization." For many more hours a day, she's thinking about her administrative responsibilities. "As president of an organization, I have to stay at a higher level and look out for the long-term interests of the organization."

Having graduated from medical school in 1986, Lombardo says she missed the most difficult years for women in medicine. "Women made up at least 40 percent of my medical school class," she notes. She compares this with her father's class, which had only one or two women. "I am fortunate to be a product of a different time with changing norms."

She's aware that there aren't many women in positions like hers and thinks a reason for that may be that women still feel the tug of family demands. "But that's changing. Family demands aren't placed only on women now, so the barriers that might interrupt people's careers are changing." She says the support of her husband and sons has been critical to her success.

Lombardo hopes young women will realize they can be leaders. "I think as young women view women taking larger roles in society, they're going to recognize that they have every opportunity to see themselves in those roles, too." **–CP**

A FEW MINUTES WITH

Sen. Julie Rosen

Drug-related issues are her priority.

BY MELISSA MRACHEK

Being christened "Senator Meth" might not seem like a compliment, but Sen. Julie Rosen (R-Fairmont) wears the edgy moniker like a badge of honor.

In 2005, Rosen and a task force of about 30 people helped pass legislation aimed at addressing the top five factors contributing to the burgeoning meth epidemic in Minnesota. One provision removed pseudoephedrine-based cold and allergy medications, which can be used to manufacture meth, from store shelves and placed them behind pharmacy counters.

Rosen worked for two years to convince lawmakers to pass the bill. Thus, colleagues began referring to her as "Senator Meth."

"That bill set the tone for addressing meth across the nation," she says. "I was asked to speak in many other states about how we worked with law enforcement and other key groups to get it done."

Rosen is one of a handful of state lawmakers who have zeroed in on health-care related issues during their tenure at the Capitol. In addition to fighting the meth epidemic, she has also been a player in combating prescription opioid abuse—one of several MMA priorities for the 2014 legislative session.

Rosen believes stopping opioid abuse will require the involvement of a number of stakeholders. "To make significant changes, whether it's a prescription monitoring program or treatment dealing with methadone clinics, you have to make sure everyone is at the table. The worst thing we can do is force through legislation," she says, adding that it takes a lot of money to eventually fix poorly conceived legislation.


Sen. Julie Rosen

"To make significant changes, whether it's a prescription monitoring program or treatment dealing with methadone clinics, you have to make sure everyone is at the table."

– SEN. JULIE ROSEN

Marijuana and Minnesota

Colorado, ground zero in the marijuana debate, is Rosen's home state. She grew up among the Rocky Mountains, went to college at Colorado State University and still has family in the Fort Collins area. As a go-to lawmaker on drug-related legislation, she will likely be at the table if the issue of medical marijuana comes up in Minnesota.

When asked what she thinks about Colorado's decision to legalize marijuana, she mentions that not one of her relatives voted for the Constitutional amendment. "I am absolutely, 100 percent opposed to legalizing marijuana," she says.

Some argue that medical marijuana can provide relief to people living with chronic pain. Rosen, however, says she believes there are other viable options. And that's where the medical community can contribute to the debate.

"When you stop listening to the advice of adolescent psychologists [who oppose medical marijuana], when you stop listening to law enforcement and to the treatment world, I have a problem with that," she says.

MNsure and the session ahead

Aside from drug-related issues, Rosen will be keeping an eye on the ongoing struggles of MNsure, the state's health insurance exchange. She says she will continue to work with legislators on both sides of the aisle to improve the website.

"I honestly wish it was working the way it is supposed to," she says. "I was not comfortable with the [MNsure] bill, but I stood at the press conference a year ago to say, 'I want to work on this and make this thing work.'"

Rosen says she feels MNsure was unnecessary because Minnesota was already leading the way in terms of residents having health insurance coverage. According to the Census Bureau, 8.7 percent of Minnesotans lacked health insurance in 2011-12; the national rate for the same period was 15.4 percent.

"We have such progressive, all-inclusive health care in our state anyway," she says. "Most states look at us and want to mirror what we had in our health care reform in 2008—coordinated care, consumer-driven health care—and now we have just complicated it with something, I feel, is going to take a lot of money to fix. And I don't know if it can be fixed."

Doctors know best

Rosen encourages physicians to speak up on issues related to health care. "Physicians are the experts in their field and can provide information on trends and what they are seeing," she says. "We can make a big mess at the Capitol if we don't have the best people in the field coming to us and sharing their perspective."

Her key piece of advice for physicians who wish to get involved in legislative issues: "Pick your battle." She advises them to be strategic and targeted in their message and address problems that are on the table. "Don't come to us talking about universal health care—that is the last thing Republicans in general want to hear," she says.

What keeps Rosen from becoming frustrated and disheartened by politics is talking with people she represents. "I fall in love with my job all over again when I get back out in my district," she says. "You can start to spin on yourself at the Capitol thinking you are doing the right thing, and then you get home and you understand it's more complicated. It's not about your ego or winning; it's about doing the right thing for your state, your district and your constituents."

News briefs

MN Supreme Court hears two MMA-backed cases

In early February, the Minnesota Supreme Court heard cases on end-of-life decision making and physician autonomy, two topics that are vital to the MMA and its physician members.

The Court took both cases—*The Guardianship of Jeffers A. Tschumy* and *Medical Staff of Avera Marshall Regional Medical Center vs. Avera Marshall Regional Medical Center*—under advisement and will not likely issue a ruling for several months. Watch future issues of *MMA News Now* for developments.

Tschumy addresses whether a court-appointed guardian may authorize termination of a ward's life support. The appeal arose after a Hennepin County district court ordered that all guardians must obtain court approval before authorizing termination of life support. As a "friend of the court," the MMA supports the position that end-of-life decisions are best made in a medical setting by family, friends, guardians and other interested parties, in consultation with physicians and other providers.

The Avera case considers two issues crucial to physicians: first, whether a medical staff is a "legal" entity with the capacity to bring suit on its own behalf and second, whether medical staff bylaws constitute a contract between the medical staff and the hospital. The MMA has supported the medical staff since the dispute arose, and, along with the AMA and other state and national medical societies, acted as an amicus on the staff's behalf.

State launches HPV vaccination campaign

In an effort to increase human papillomavirus (HPV) vaccination rates, the Minnesota Department of Health is launching a public awareness campaign geared toward families of adolescents. The campaign includes mailing vaccination reminders as well as educational opportunities for health care providers. These efforts are made possible through a $600,000 grant from the Centers for Disease Control and Prevention (CDC).

Despite its cancer-fighting ability, the vaccine is greatly underused, health officials say. According to a 2012 survey, only 33.1 percent of young women in Minnesota had received the full three doses, mirroring the national rate of 33.4 percent; slightly more than 59 percent of Minnesota girls had received the first dose. Among teenaged boys, to whom the recommendation was more recently expanded, first-dose vaccine coverage was only 20.8 percent.

"Taking into account cervical cancer alone, if we could vaccinate 80 percent of young women in the U.S. today, we could prevent 98,800 cases of cancer and 31,700 deaths, according to CDC estimates," says Kristen Ehresmann, director of infectious disease epidemiology and control for the health department. "Our goal in Minnesota is to reach that 80 percent coverage level of three doses of HPV vaccine for females age 13 to 15 by 2020."

Health officials plan to offer a variety of in-person and online opportunities for the health care community to update their knowledge about the vaccine and learn how to discuss its importance with teens and their parents. According to Ehresmann, "Provider education is important because studies consistently show that a strong recommendation from a provider is the single best predictor of vaccination and an important factor in a parent's decision to vaccinate their child."

Julie Anderson, M.D., (right), poses with her U.S. representative, Michele Bachmann.

Two MMA members attend State of the Union speech

Two MMA members were in the audience at President Obama's State of the Union speech on January 28.

John Noseworthy, M.D., president and CEO of Mayo Clinic, attended as a guest of Sen. Amy Klobuchar. St. Cloud family physician Julie Anderson, M.D, was a guest of her congresswoman, Rep. Michele Bachmann.

Anderson contacted Bachmann by email in early January regarding a durable medical equipment issue and the larger concern of increasing administrative burdens on practices. Bachmann followed up with a phone call and then invited Anderson to Washington for the speech.

Anderson spent most of the day with Bachmann discussing health care, witnessing the lawmaker in news interviews and even sharing Chinese take-out in Bachmann's office. "I really received the royal treatment," Anderson says. "It was pretty amazing and such an honor to be asked to attend."

Regarding the president's remarks about America's health care system, Noseworthy told the *Rochester Post-Bulletin*: "I thought

it was very important for the president to acknowledge and state explicitly that the health care system in America is broken. And to say that as president, for the American public to hear the president say that, is really a call to action that we need to fix the health care system."

Mayo physician wins award for palliative care

A Mayo Clinic palliative care specialist has received an early career physician award as part of the 2014 Hastings Center Cunniff-Dixon Physician Awards.

Elise C. Carey, M.D., FAAHPM, chair of the section of palliative medicine in the division of general internal medicine at Mayo Clinic, and four others were selected for having "distinguished themselves in advancing the practice of palliative care and modeling exemplary skill and compassion at the bedside." Carey was chosen for her national leadership in palliative care education and for significantly expanding palliative care services at Mayo Clinic from oncology patients to patients with multiple conditions.

The awards were made in three categories: a senior award and a mid-career award (each winner received $25,000) and three early career awards ($15,000 each). All of the recipients have been exemplary in one or more of the following areas: medical practice, teaching, research and community.

The Cunniff-Dixon Foundation, whose mission is to enrich the doctor-patient relationship near the end of life, funds the awards. The Hastings Center, a bioethics research institute that has done groundbreaking work on end-of-life decision-making, co-sponsors them. The Duke Institute on Care at the End of Life oversees the selection process. The prize recipients were selected by a committee convened by The Hastings Center.

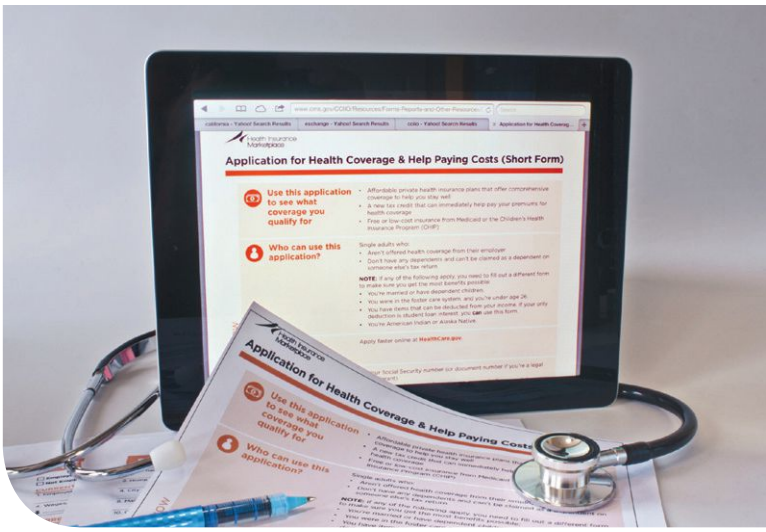
MMA leadership nomination process underway

The MMA is seeking nominations for the following positions in 2014-15: president-elect, three board of trustees members and two AMA delegates and two alternate delegates.

One of the trustees must be from the North Central district; the other two can be from anywhere in the state. In order to keep a representative balance on the board, the nominating committee will be sensitive toward nominees from non-primary care specialties and large groups.

The deadline for nominations is April 25. The nominating committee will meet in early May and in July will recommend a slate of candidates for each position. The MMA's first member-wide electronic election will occur in mid-July. Results will be announced at the 2014 Annual Meeting in Brainerd in September.

Contact Shari Nelson (snelson@mnmed.org) with questions or to submit your nominations.



MMA asks CMS to change Basic Health Program funding

In January, the MMA sent a letter to the Centers for Medicare and Medicaid Services (CMS) asking the agency to alter its funding methodology for the Basic Health Program (BHP). The current methodology could short-change Minnesota by up to $91 million, according to estimates by the Minnesota Department of Human Services (DHS).

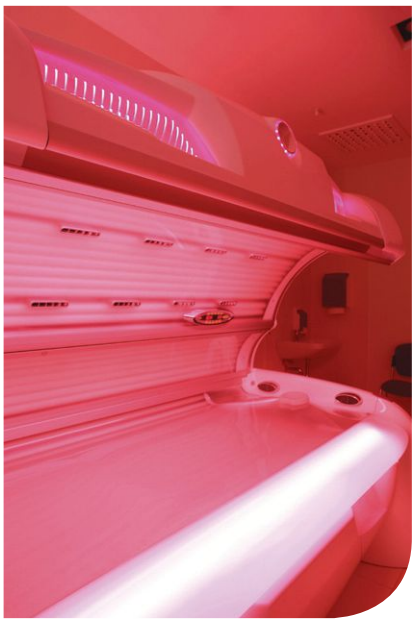
The Affordable Care Act allows states the option of establishing a BHP for individuals between 138 and 200 percent of poverty as an alternative to their purchasing coverage on the insurance exchange. The purpose of the BHP is to provide a financially vulnerable population with an option for more affordable coverage.

Minnesota made changes to the MinnesotaCare program during the 2013 legislative session to allow it to serve as Minnesota's BHP.

According to the ACA, a state would receive 95 percent of the premium and cost-sharing subsidies that BHP enrollees would otherwise have received had they purchased coverage on the insurance exchange. But the Obama Administration delayed implementation of the BHP until 2015. As a result, MinnesotaCare is continuing in 2014 with federal support comparable to what the state currently receives for Medicaid.

Critics say the proposed rules fail to take into consideration several of Minnesota's unique efforts to keep individual coverage affordable, such as the continuation through 2014 of MinnesotaCare and Minnesota Comprehensive Health Association, the state's high-risk pool.

Representatives from the Minnesota Hospital Association and DHS along with several members of Minnesota's congressional delegation are submitting letters to CMS in support of modifying the proposed funding methodology.



Minnesota teens still tanning indoors, despite warnings

A survey released in January by the Minnesota Department of Health (MDH) shows that a large percentage of Minnesota high school girls are still tanning indoors. In fact, 34 percent of 11th grade white females reported they had tanned indoors in the last year, and more than half of them tanned indoors 10 or more times.

"This is very disturbing news," says MMA President Cindy Firkins Smith, M.D. "Melanoma has increased exponentially in my practice. I've diagnosed this terrifying cancer in many young patients and have had two 30-year-old women die of metastatic disease. The young woman who died last year told me that if she could change one thing in her life it would be that she would never have stepped in a tanning bed. Obviously, our current education and parental restrictions are not working. You can be assured that the MMA will be fighting for restrictions on indoor tanning during this year's session."

According to MDH, indoor tanning beds deliver 10 to 15 times more ultraviolet (UV) radiation than natural sunlight, boosting the user's risk of developing melanoma by at least 59 percent. The World Health Organization's International Agency for Research on Cancer has declared UV radiation from indoor tanning beds a carcinogen.

Melanoma is the second most common cancer among females ages 15 to 29 years, according to Minnesota cancer registry data. The number of non-Hispanic white women ages 20 to 49 years diagnosed with melanoma is increasing 5 percent each year, a trend that has been observed for 15 years.

In an effort to educate teens about the dangers of indoor tanning, the health department is sponsoring a contest, called the UVideo Challenge, which encourages high school students to create 30-second anti-tanning videos.

Newborn screening blood spots destroyed

The Minnesota Department of Health (MDH) destroyed approximately 1 million blood spots after reaching a settlement in January regarding its newborn screening program.

The news was not taken well by the Minnesota Chapter of the American Academy of Pediatrics (MNAAP) and the MMA, which support the program and the use of blood spots for research.

"Saving newborn screening blood spots and test results is critical to saving lives," says Robert M. Jacobson, M.D., FAAP, MNAAP president. "Destruction of blood spots and data rob children and families of a tremendous, life-saving resource."

The storage of blood spots came under fire in early 2010 when a number of families, with the assistance of the Citizen's Council for Health Freedom (CCHF), filed suit against the state of Minnesota and MDH. The suit alleged that the department was in violation of the state's 2006 genetic privacy act for collecting, storing, using and disseminating newborn blood and DNA without first obtaining the written informed consent of the parents.

As part of the settlement, the state agreed to pay court fees of nearly $1 million for the families who sued and destroy the stored blood spots.

"It's a very disappointing turn in this matter," says Eric Dick, the MMA's manager of state legislative affairs. "An incredibly rich resource for the development of new tests and test quality assurance measures has been destroyed and will never again be available."

The MMA will be asking the 2014 Legislature to restore the program to its previous nation-leading status.

After lower courts ruled against CCHF, the Minnesota Supreme Court agreed to hear the case. In November 2011, the Court ruled that the state could continue to screen newborns for various childhood diseases but could not store, use or disseminate blood samples for new test development, quality assurance, calibration and other research activities without parental consent.

In 2012, lawmakers revised newborn screening laws allowing MDH to retain all negative blood spots for 71 days from the date they were received and all positive blood spots for two years. All

blood spot test results (positive and negative) can be kept for two years, then must be destroyed. Parents can consent to retain both the blood spots and test results for a longer period of time.

"The bottom line is that the information collected through newborn screening has saved more than 5,000 lives," Jacobson says. "MNAAP will do everything in its power to reverse these changes, restore the program, and save as many babies as possible from unnecessary death, disability and impairment." The state's newborn screening program has long been viewed as a national leader. But court and legislative action since 2011 has left Min-

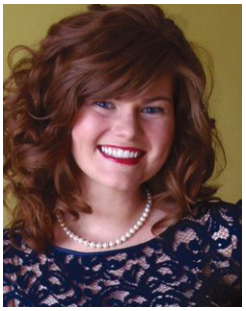
nesota as arguably the weakest state in the nation, Jacobson says. "In fact, Minnesota is the only state that destroys newborn screening results soon after birth."

MMA staffer earns Certified Association Executive credential

Dave Renner, the MMA's director of state and federal legislation, received the Certified Association Executive designation from the American Society of Association Executives (ASAE) in late January. It is the highest professional credential in the association industry.

To receive the designation, Renner had to spend a minimum of three years working in nonprofit organization management, complete a minimum of 100 hours of specialized professional development and pass an exam.

ASAE is a membership organization of more than 21,000 association executives and industry partners representing 10,000 organizations.



MMA adds grassroots staff member

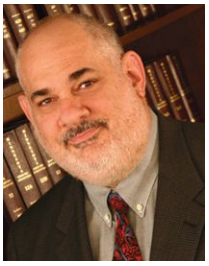
The MMA has hired Evelyn Clark as its manager of grassroots and political engagement. She will be responsible for engaging more physician members in legislative and advocacy activities. She will also serve as staff director of MEDPAC, the MMA's political action committee. Previously, Clark worked with the Medical Association of Georgia, the American Academy of Ophthalmology, and other advocacy groups in the area of health care policy.

Kathleen Baumbach

Brian Strub

Barbara Daiker

Mandy Rubenstein



Robert Meiches, M.D.

Donald Jacobs, M.D.

MMA in action

In January, **Cindy Firkins Smith**, M.D., MMA president, spoke about dermatology at the Minnesota Academy of Family Physicians' winter meeting. In February, she attended the Minnesota Medical Directors Association board meeting. That same month, she took part in a meeting between specialty groups and MMA leadership. She also took part in the Minnesota College of Cardiology board meeting by phone.

Dave Renner, the MMA's director of state and federal legislation, provided legislative updates to the Minnesota Radiology Society board (joined by Smith and **Kathleen Baumbach**, MMA manager of physician outreach); Minnesota Society of Anesthesiology Board (with Smith); and St. Croix Orthopedics (with **Brian Strub**, MMA manager of physician outreach). In February, he presented "Advocacy 101: Influencing National and State Health Care Legislation" to Essentia Health's St. Mary's Medical Center and Duluth Clinic. He also discussed health care reform and its impact on primary care at the Gateway Clinic in Moose Lake. In addition, Renner discussed the importance of legislative engagement for physicians and medical students at a "Policy and a Pint" gathering with the University of Minnesota Medical Student Primary Care Interest Group. Finally, he started his two-year term as chair of the AMA's Advocacy Resource Center's Executive Committee. This is a committee of 14 state medical society representatives that provides direction for the AMA Advocacy Resource Center staff.

Barbara Daiker, the MMA's manager of quality, took part in the Minnesota e-Health Initiative Health Information Exchange Workgroup in January and the Minnesota Violence Prevention in Healthcare Workplace task force in February.

In February, **Mandy Rubenstein**, MMA manager of physician outreach, met with administrators at St. Cloud Medical Group. She also met with CentraCare leadership in St. Cloud along with **Robert Meiches**, M.D., MMA CEO, Renner, **Marilyn Peitso**, M.D., an MMA board member, and **Patrick Zook**, M.D., president of the Stearns Benton Medical Society.

Strub and **Nancy Bauer**, associate director of the Twin Cities Medical Society (TCMS), met with staff at Bluestone Physician Services in Stillwater to discuss their priorities for growth. Strub and Baumbach joined **Donald Jacobs**, M.D., MMA president-elect, and the resident leadership team at Hennepin County Medical Center in Minneapolis to discuss ways the MMA and TCMS can help support residents.

The **MMA Medical Student Section** met in early February to discuss potential solutions to improve well-child visits and obstacles to achieving them with MMA board of trustees member **Fatima Jiwa,** MBChB.

In February, Baumbach took part in a resident leadership meeting at the University of Minnesota to discuss the "Transition to Practice" curriculum.

VIEWPOINT

We need more female physicians to lean in

Cindy Firkins Smith, M.D.

Facebook COO Sheryl Sandberg tells us that women will never run the world if they don't lean in. She quotes statistics showing that although they have comprised more than 50 percent of U.S. college graduates for more than 30 years and have slowly gained ground in the workforce, women have barely cracked the surface of leadership. According to Catalyst, a nonprofit organization devoted to expanding opportunities for women in business, women comprise 51.5 percent of the business workforce in the United States yet hold only 16.9 percent of board seats, fill 14.6 percent of executive offices and hold 4.6 percent of CEO positions. And, as Sandberg points out in her book, *Lean In*, only 17 of the 195 independent countries in the world are led by women.

I don't think we go into medicine because we want to run the world. I believe we do it because we want to help people, safeguard their health and make their lives better. And we certainly do that, day by day, patient by patient.

But what if we could do that for *thousands* of patients *for generations?* Most of us aren't going to invent a vaccine for HIV or find a magic cure for obesity, but we can do great things by getting involved and advocating for patients outside the clinic and hospital. We can do that in organized medicine, through the MMA and our component and specialty medical societies. Some of the issues these organizations promote, such as restricting teens from using tanning beds, do have the potential to save thousands of lives long after we've closed our practice doors.

I'll be blunt. We don't have enough women actively involved in organized medicine. We know that more than 33 percent of physicians in Minnesota are women. Thirty-one percent of MMA members are women, which is wonderful. But only 22 percent of MMA board members are women and in the MMA's 160-year history, there have been only four female presidents. Guys are great. I've loved a few, married a really good one and work with some superstars. But let's face it: Men and women sometimes do things *differently* —not better, not worse, just differently. (OK, to be honest, women do some things better.) We often approach the same problem with different solutions. To find the answers, we need brains of both genders seated at the same table, working together.

I have been involved in the MMA for 20 years and have consistently heard the same reason from women who choose to stay by the sidelines: "I don't have time." Of course you don't. If you're waiting until you do, forget it, you never will. Physicians are busy, no matter their gender, geography or specialty. Female physicians, in particular, have demands on their time that feel insurmountable.

We must make time to stand up for what we believe is important, though. We must show our children by our actions that volunteering to make a difference has the potential to do enormous good in the world. We cannot leave this important work to someone else. We must make it a priority.

So whether we sit down, stand up or lean in, let's get involved. I don't want to run the world, but I sure want to change it a little.

We must show our children by our actions that volunteering to make a difference has the potential to do enormous good in the world.

Midlife and medicine

The time has come to change the way we care for women in midlife.

BY TARA GUSTILO, M.D.

I am a board-certified obstetrician/gynecologist as well as a board-certified acupuncturist. My training in Western medicine honed my skills of deduction and taught me to focus on "pertinent findings." My training in acupuncture taught me that many things that may not seem pertinent on first blush are, in fact, very important when developing a care plan for a patient. I am also a North American Menopause Society-certified menopause practitioner. As such, I see a number of women in midlife in a my practice.

From my perspective, our health care system, more often than not, has us addressing aspects of a woman's health in isolation. With this siloed approach, we fail to recognize the impact one health concern may have on others or the unintended consequences a recommended treatment may have on the body. Our system is also confusing for the patient.

Consider the case of a 48-year-old woman who goes to her primary care physician complaining of disturbed sleep—insomnia, restlessness and waking unrefreshed. During their discussion, she mentions that she snores at night; her doctor recommends a sleep study. The woman then brings up the problem with her gynecologist. During their discussion, she says she is having hot flashes and night sweats. Her gynecologist recommends hormonal therapy. Next, she goes to her psychologist. They discuss life stressors as a potential cause of her sleep disturbances, and the psychiatrist recommends an anti-anxiety medication. Finally, she sees an herbalist, who diagnoses her with adrenal fatigue and perimenopause and recommends Ashwagandha herbs and black cohosh.

At this junction, the woman has seen four practitioners, each of whom has given her a different explanation for her sleep disturbances (all of which may play a part) and a very different treatment option. She is on her own to decide which, if any, to act on and feels confused and frustrated.

These physicians are practicing medicine in the same way the three blind men in the ancient Indian story examine the elephant: In the story, one man feels the ear and says the elephant is like a fan; another feels the belly says it is like a wall; the third man feels the tusk and compares it with a pipe. Each is correct. But it isn't until they compare notes that they get the true picture of the elephant. Similarly, each practitioner may be correct in his or her assessment; but if they had an opportunity to converse with one another, they would get a more comprehensive picture of what is going on with the patient.

Mixed messages

Caring for women at menopause is an issue of growing importance. In 2010, there were 33 million women in the United States between the ages of 45 and 60—an increase of 21 percent (or about 6 million women) over 2000.[1]

One indication that we are not serving these women well is the fact that 54 percent to 80 percent of them use some sort of complementary and alternative medical (CAM) therapy to treat their symptoms. Not only are they using these therapies, they are not telling us about them. Studies have shown that up to 81 percent of patients do not divulge their CAM use to their physicians and up to 63 percent of people on prescription medications use at least one CAM product without consulting their physician.[2-5] Ideally, we would not only be aware of the therapies our patients are using but also involved in their decision to use them.

Women in midlife are dealing with change on a number of fronts: those related to aging in general, such as cardiovascular issues, endocrine issues, cancer or musculoskeletal disorders, and those related to menopause. In addition, women often experience life changes that have an impact on their health and well-being such as children growing up, career changes, spouses developing medical problems, a change in marital status and parents aging. Further, women experiencing the menopause transition may be at significantly higher risk for mood disorders, particularly depression.[6]

Although the problems women in midlife experience often span the expertise of multiple specialists, our care systems are not set up so that physicians can easily communicate with one another. Moreover, our patients are so used to a siloed approach to their care that they often share their general medical issues only with their internist, their "female parts" issues only with their gynecologist and their emotional/stress issues only with their psychologist.

New paradigm needed

In an ideal situation, all facets of a woman's life and health would be taken into consideration and the impact each has on the other discussed and accounted for. But to achieve that, we would need a new care delivery paradigm, one that encourages both the providers of care as well as the patient to think more globally about her health.

Under this new paradigm, women would have both a primary care physician and a gynecologist. Both physicians would have expertise in the menopause transition and the medical issues women face as they age. Furthermore, these physicians would openly collaborate with one another and with the patient, perhaps even seeing the patient together or in close succession. All three parties would be involved in conversations about the patient's care. In addition, the patient would have access to the other specialists most needed by women in this age group: psychiatrists and psychologists, endocrinologists, radiologists, breast doctors, sleep specialists, orthopedists, nutritionists, physical therapists, cardiologists, herbalists and acupuncturists. These specialists would be involved in developing a care plan for the patient.

In such an environment, physicians and other care providers would begin to consider aspects of the woman's life and health that they might otherwise have overlooked. They would discuss a more comprehensive list of therapeutic options. And they would help the patient decide on a treatment plan that's right for her.

In the case of the woman with sleep problems, her concerns would be considered and managed much differently. Because her care providers would be involved in real-time discussions, they would be aware of all the possible causes of her sleep disturbance and have a more thorough understanding of her concerns. Although the treatment options might be the same, the patient would not be left to sift through them on her own. Rather, she could ask questions and hear her caregivers' thoughts about how to proceed. At the end of the discussion, everyone would be on the same page, with the patient making decisions with the support and understanding of all her caregivers.

In most of our organizations, we have a long way to go before we formally adopt such an approach. But we physicians can begin by opening up the lines of communication with one another and with our patients so we can better address the complicated health concerns of women in their middle years. **MM**

Tara Gustilo is an obstetrician-gynecologist and an acupuncturist at Hennepin County Medical Center.

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Cigarette Smoking among Women
How Can We Help?

BY SHARON S. ALLEN, M.D., PH.D.

Cigarette smoking remains a concern in the United States. Although more men than women in this country smoke, the gap appears to be narrowing. The risk for disease among women who smoke has risen sharply over the last 50 years and is now equal to that of men for lung cancer, chronic obstructive pulmonary disease and cardiovascular diseases. Female smokers also face health risks associated with pregnancy and use of oral contraceptives, menstrual irregularities, early menopause, osteoporosis and cervical cancer. In addition, they are less likely to have success quitting smoking. This article discusses some of the reasons why women have difficulty quitting, which can help guide physicians in assisting them with smoking cessation.

Cigarette smoking is the leading cause of preventable morbidity and mortality in the United States.[1] Although we have come a long way since the first Surgeon General's Report on the health harms of smoking in 1964, when 40% of U.S. adults smoked and smoking was an accepted behavior, smoking is still prevalent. The U.S. adult smoking rate is 18%.[2] The rate among women is lower than that among men (17.3% versus 21.5% in 2010), but the gender gap is narrowing.[3] A number of troubling findings suggest that smoking may continue to negatively affect the health of women for some time.

Although 70% of smokers say they want to stop smoking, annual (unaided) quit rates are only 3% to 5%.[3-5] Compared with men, women are less successful at quitting[4,6,7] and have worse outcomes.[5] According to a recent report by the Surgeon General, "The disease risks from smoking by women have risen sharply over the last 50 years and are now equal to those for men for lung cancer, chronic obstructive pulmonary disease and cardiovascular diseases."[8] Additionally, women who smoke face health risks associated with pregnancy and use of oral contraceptives, menstrual irregularities, early menopause, osteoporosis and cervical cancer.[5] Further, although the hazards of smoking are substantial in women up to age 40, the hazards associated with continuing to smoke beyond age 40 are 10 times greater (90% of excess mortality caused by continuing to smoke beyond age 40).[9]

In the last 25 years, researchers have explored why women may be less successful than men at quitting smoking and identified barriers that may prevent them from giving up tobacco. If clinicians are to help women quit, they need to be aware of the factors that influence their reasons for smoking. They also need to be aware of how women's concerns and attitudes affect their decision to quit and their use of smoking-cessation therapies.

Specific Barriers to Quitting

Concern about Weight Gain

Weight gain is a big concern for women who smoke. Women are more than twice as likely as men to anticipate gaining weight if they quit,[10] and younger women are far more likely than men to report weight gain as their reason for smoking relapse.[11] In fact, on average, women do gain more weight than men post cessation.[11] Smokers who are concerned about weight gain are less likely to want to quit,[12] report having more withdrawal symptoms if they do quit[13] and have poorer abstinence outcomes.[14] Further, they are more likely to drop out of treatment.[15] Several medications including nicotine gum and patches attenuate weight gain, but only during active treatment.[16,17] Unfortunately, adding a weight-control behavioral component to a cessation program has not been shown to be of benefit.[18,19] Cognitive behavioral therapy, however, has been shown to improve abstinence in women who were concerned about weight gain.[20]

Social Factors

Some evidence suggests that social factors may have more of an influence on smoking patterns in women than in men.[21] Such factors include the proximity of the person's work area to the designated smoking area, the length of employees' break times and a person's social circle. Interestingly, researchers found when more people were present for social interaction during break times, women smoked fewer cigarettes and men smoked more cigarettes. This might suggest that having more social interactions or "support" at work will lead to less smoking among women. Another study found, however, that social support during cessation counseling may be less helpful for women than men.[22]

Both men and women are equally likely to seek support when quitting.[23] Spousal support has been shown to be more useful for men than for women. That may be because women are more likely to be caregivers and, therefore, may be more effective in a supporting role. Further, women report more sensitivity to negative experience, which may occur more frequently when a

male spouse is their primary support system.[24] In the case of both men and women, support from a nonsmoker or ex-smoker is associated with better abstinence than support from a current smoker.[23]

Menstrual Phase

Recent research has examined the relationship between the menstrual cycle (as a proxy for sex hormones) and success with smoking cessation. One study found the follicular phase (low progesterone/high estrogen) seemed favorable for smoking cessation when nicotine replacement therapy (NRT) is used.[25] Yet others found that in the absence of NRT, trying to quit during the luteal phase (low estrogen/high progesterone) may lead to more favorable outcomes.[26,27] Although specific mechanisms are unknown, sex hormones appear to play a role in addictive behaviors.[28,29]

Environmental Cues

Smoking persists because of nicotine, the pharmacological component of tobacco. The behavior also is modulated by a wide variety of environmental stimuli called "cues" to which a smoker becomes conditioned. Such cues include the sight and smell of a lit cigarette. Some evidence suggests that women are more responsive than men to smoking cues[30] and might benefit more from interventions that attenuate their responses to such cues. Women also are more likely than men to report the sensorimotor effects (eg, handling, hand-to-mouth activity) of cigarettes as a reason for smoking.[31] Recommending that women find alternative behaviors when confronted with smoking cues may be helpful. Therefore, it is essential to counsel women about how to respond to these environmental cues.

Depression

Depression is a common comorbidity in smokers,[32,33] and women are more likely than men to experience major depression. A few studies suggest that a history of depression predicts a poor smoking-cessation outcome, particularly in women.[34-36] Spring and colleagues observed a greater increase in positive affect after smoking among women with a history of depression compared with women without a history of depression, suggesting that women with a history of depression might have a difficult time quitting.[37] Furthermore, negative mood is more likely than positive mood to precipitate smoking relapse in women as compared with men.[38] Since women may be more likely than men to smoke in order to temporarily alleviate symptoms of depression,[39,40] use of antidepressant medications during smoking cessation could be more effective in women than men.

Women and Use of Smoking-Cessation Aids

Evidence regarding the efficacy of pharmacological aids for women is conflicting. Some studies report that NRT is less effective in women than in men[41,42] and that women are less successful than men in quitting smoking when using nicotine patches.[43] One study looked at 15-week cessation outcomes for 504 smokers who used nicotine replacement products—gum, patch, spray and inhaler.[44] Abstinence rates were lower in women who used gum, patches and spray than in men who used them; however, among those who used the inhaler, abstinence rates were higher in women than in men. Although the pharmacokinetics of these different forms of NRT are similar, inhalers may more closely mimic the sensory aspects of smoking (handling, act of inhalation, throat and mouth sensations) and for that reason be effective in women.

Two non-nicotine pharmacological aids for smoking cessation are available by prescription. Bupropion has been shown to improve one-year smoking-cessation rates in both men and women who were not depressed.[45] Varenicline also has been shown to be efficacious in both men and women.[46] Other non-nicotine medications such as naltrexone, clonidine and mecamylamine are considered second-line treatments but are not readily used in practice.[47] Some studies have shown the efficacy of combinations such as bupropion SR and the nicotine patch[48] and varenicline and bupropion.[49] These medications might be more beneficial in women with a history of depression. Be aware of the black box warnings on bupropion and varenicline with regard to suicide and depression.

Even if gender differences in outcome with NRT versus non-NRT drugs are confirmed in further research, it would not necessarily justify limiting NRT use in women. NRT is clearly effective and is likely to be safe and readily available.

Electronic cigarettes entered the U.S. market in 2007 and have become widely available. They are regulated neither as a tobacco product nor as a medication, and clinical trials do not yet show them to be effective for smoking cessation in men or women, suggesting that Food and Drug Administration-approved medications should be the first-line therapy.

Smoking Cessation during Pregnancy

Pregnancy is a special consideration for women who are trying to quit smoking. In general, medications for smoking cessation are not recommended for pregnant women, although NRT has been suggested as appropriate if its benefit can be shown to clearly outweigh risks for placenta previa, placental abruption, and premature rupture of membranes, preterm delivery and restricted fetal growth.[50,51] All NRT medications are category D. Bupropion and varenicline are category C. The long-term effects of NRT use on the fetus are not known, but short-term exposure has shown little impact.[52]

Summary

Although we have made progress in our fight against smoking, tobacco use continues to kill and cause disease in far too many people. Clinicians are instrumental in lessening the toll of tobacco use. Multiple tools are available to help them accomplish this.

When assisting women in quitting smoking, it is important to be aware of several issues. These include women's concern about weight gain, any history of depression, whether they are pregnant, where they are in their menstrual cycle, the influence of social support and the

importance of smoking cues. Behavioral counseling needs to be tailored to women. Further, clinicians need to be aware that women may benefit more from NRT if it is combined with other medications and counseling. Clinicians need to be aware of and consider these issues when making treatment recommendations for women who are trying to stop smoking. **MM**

Sharon Allen is a professor of family medicine and community health at the University of Minnesota. She has been involved in women's health and smoking cessation research for more than 20 years.

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Care of Breast Cancer Survivors after Treatment

BY NICOLE P. SANDHU, M.D., PH.D., FACP

More than 200,000 women in the United States will be diagnosed with breast cancer in 2014. It is estimated that by 2022, the number of survivors will climb to nearly 4 million. Breast cancer survivors require regular follow-up care, some of which requires the skills of an oncologist and some of which can be provided by a primary care physician. This article looks at common conditions affecting survivors and discusses ways that oncologists and primary care physicians can work together to best serve this population.

Breast cancer is the most common malignancy in women, striking one in eight during their lifetime. It is estimated that more than 200,000 women will be diagnosed in 2014.[1] Because of improvements in detection and treatment, there are nearly 3 million breast cancer survivors in the United States today, accounting for nearly 25% of all cancer survivors in this country. By 2022, it is estimated that the number of breast cancer survivors will climb to nearly 4 million and the number of survivors of all cancers to nearly 18 million.[2,3] In Minnesota, more than 3,500 invasive breast cancers were diagnosed between 2003 and 2007, with the age-adjusted rate in 2007 being 132.1 new cases per 100,000 women. Among women 50 years of age and older, the age-adjusted rate was 362 new cases per 100,000 in 2009.[4,5] Most breast cancers are diagnosed at a stage in which the malignancy is localized; thus, with appropriate care, long-term survival is anticipated.

Breast cancer survivors require regular follow-up care, some of which is specialized and some of which can be provided by a primary care physician. Often, having both an oncologist and a generalist involved is optimal.

According to a study commissioned by the American Society of Clinical Oncology (ASCO), by 2020 there will be a shortage of as many as 4,000 oncologists in the United States.[6] This shortage will occur at the same time the population is aging and the number of long-term cancer survivors is growing. Thus, it is clear that the demand for oncology care will be greater than the supply of oncologists needed to provide it. It should be noted that mid-level providers will play an increasingly important role in the care of oncology patients.[7]

Although survivors' needs related to breast cancer (surveillance, treatment-related concerns) are typically well-managed, their general health care needs often are unwittingly overlooked.[8-11] In considering how those needs could best be met, one must consider the role primary care physicians can play in the care of breast cancer survivors. In fact, ASCO has suggested involving them in the care of survivors. Their participation will not only ensure that these patients will receive important screenings and care for comorbid conditions; it also will free up oncologists to see newly diagnosed patients. Ideally, a collaborative care model involving oncology specialists and primary care physicians would result in appropriate care without duplication of efforts.

Health Care Needs of Breast Cancer Survivors

Excellent evidence-based guidelines for follow-up care of breast cancer survivors are available from both ASCO (asco.org)[12] and the National Comprehensive Cancer Network (nccn.org). Surveillance should include a health history and physical exam, and regular mammography (except after bilateral mastectomies), with the first happening no sooner than six months after completing radiation therapy. Regular assessment for local/regional and distant recurrence as well as complications secondary to radiation, chemotherapy or endocrine therapy is necessary. (Note: endocrine therapy typically continues for five years.) The health care needs of breast cancer survivors extend beyond those directly related to the malignancy and its treatment, however. Physicians also must address concerns such as diabetes, cardiovascular disease and depression as well as age-appropriate screenings for other cancers and immunizations.

They should also discuss lifestyle. There is an increasing volume of literature related to the impact of diet, alcohol use, physical activity or lack thereof, and excess body weight on breast cancer recurrence.[13-15] Given the potential positive impact of healthy lifestyle choices, physicians should strongly encourage patients to embrace them and advise them to avoid potentially harmful behaviors.

Intensive surveillance (eg, laboratory serologies, bone scans, abdominal ultrasounds, chest X-rays, CT scans) of asymptomatic breast cancer survivors is not recommended.[16,17] ASCO and NCCN guidelines clearly advise against intensive surveillance and instead recommend that clinical decisions be based on history and physical examination.

Signs of Possible Recurrence

After completing therapy for breast cancer, survivors should be regularly monitored for recurrence, which may be local/regional (in the skin, chest wall, breast or

regional nodal basin) or distant. Distant relapse is most likely to occur in the bone, liver or lung, although it can be present in other sites.

Although the first five years after diagnosis and treatment is considered the time of highest risk of relapse, survivors (especially those who had estrogen-receptor positive disease) remain at elevated risk beyond that time period.[18] A primary care physician will likely follow patients for many years after active follow-up by their treating oncologist, so it is essential that they are comfortable assessing patients for potential relapse and referring them to oncology when appropriate.

Symptoms to carefully consider in breast cancer survivors include anorexia or other constitutional symptoms, GI or GU symptoms, neurological changes, abdominal pain, unexplained cough or dyspnea, bone pain or spine pain, and unexplained headaches. Signs of potential relapse include a change found through clinical breast or axillary exam; skin lesions without other explanation in the region of the primary malignancy (may indicate skin recurrence) or contralateral breast/chest wall; abnormal pulmonary, abdominal or pelvic examinations; vertebral or other bone point tenderness; or a fracture with minimal or no trauma.

Other symptoms or signs that do not have a logical explanation should be evaluated with clinically indicated laboratory and/or imaging investigations. It should not automatically be assumed that such abnormalities are the result of recurrence; they should be evaluated appropriately to determine etiology. Referral to oncology once recurrence (local/regional or distant) is diagnosed must be prompt.

Potential Sequelae of Breast Cancer Therapy

A number of potential consequences of breast cancer therapy should be considered during follow-up and long-term surveillance. The most potentially concerning ones are pathologies of the cardiovascular and pulmonary systems or secondary malignancies.

Cardiovascular Pathologies

Cardiovascular disease (CVD) is the leading cause of death in women, including breast cancer survivors. Thus, careful attention to risk factors for CVD is essential, as cancer treatment may compound risk for CVD.[19]

Improvements in chemotherapy have resulted in significant reductions in cardiovascular damage. However, there is still potential for cardiac toxicity, including from novel biologic (targeted) agents, and physicians must be aware of both early and late effects of treatment.[20] Significant improvements in radiation therapy have also led to dramatically reduced cardiovascular damage. Careful targeting of radiation to limit exposure of cardiovascular structures as well as newer techniques of administering radiation continue to drive down the risk for cardiovascular damage. However, increased risk of ischemic heart disease in breast cancer survivors after radiotherapy remains a concern.[21] It must be noted that radiation-induced CVD is generally related to treatment done in the past. Although the late cardiovascular effects of modern radiotherapy remain unclear, the degree of risk is likely to be significantly lower.

Potential cardiovascular sequelae of breast cancer therapy include cardiomyopathy with eventual heart failure, pericardial disease, valvular disease, coronary artery disease and arrhythmias. Presentation may be early (during or shortly after therapy and almost certainly recognized by the treating oncologist) or late. For that reason, primary care physicians who work with survivors must be cognizant of the potential late effects of therapy.

Pulmonary Pathologies

The chemotherapeutic and targeted agents used to treat breast cancer generally do not have a direct effect on the pulmonary system, although there have been reports of pulmonary toxicity.[22] Modern radiotherapy techniques reduce the risk substantially; but adjuvant radiation therapy may cause pulmonary changes including altered pulmonary function, changes on high-resolution CT and pneumonitis.[23,24] Toxic pulmonary effects are more likely to be identified in patients treated years ago than in patients who completed treatment more recently; therefore, physicians should be aware of potential late effects.

Secondary Malignancies

Survivors treated with radiation therapy may develop angiosarcoma, a rare but highly aggressive malignancy.[25] Evaluation of any suspicious skin finding in the field of radiation must be undertaken without delay. Other skin abnormalities such as atypical vascular lesions or malignancies such as basal cell carcinoma may also be seen more often after radiation therapy. Secondary leukemia, though uncommon, may develop following chemotherapy.[26,27] Patients presenting with new or abnormal skin findings or symptoms that could indicate a hematologic abnormality must be promptly evaluated.

Other Health Concerns

Breast cancer patients may face other health concerns related to treatment for which early identification and management can lead to improved outcomes and quality of life. These include:

Lymphedema

Lymphedema (swelling secondary to disrupted lymphatic flow) affecting the upper extremity and/or breast may occur after breast cancer treatment. Arm lymphedema is a well-recognized potential complication of treatment, which can result from axillary nodal surgery and axillary nodal basin irradiation, as well as other factors.[28,29] Breast lymphedema is less well-recognized; risk factors include breast surgery and axillary nodal surgery. A recent study demonstrated a significantly increased risk regardless of the type of axillary nodal surgery or number of nodes removed.[30]

Lymphedema is a risk factor for cellulitis, pain and decreased upper extremity function. Of note, lymphedema may develop at any time after treatment—both

early and late presentations have been observed. Early recognition of lymphedema and involvement of specialists improves both short- and long-term outcomes.

Musculoskeletal Issues

Breast cancer survivors can experience physical limitations involving the shoulder girdle, arm and chest wall after treatment.[31,32] Attending to such limitations early is essential to keeping them from progressing and affecting a person's quality of life. Prescribing physical therapy early on is encouraged. Additionally, there is emerging evidence about the benefits of yoga and Pilates in both reducing and managing musculoskeletal problems in breast cancer survivors.[33,34]

Bone Health

Breast cancer survivors who develop chemotherapy-induced premature ovarian failure, who are premenopausal and taking tamoxifen, or who were postmenopausal at diagnosis and are taking aromatase inhibitors must pay special attention to bone health. Tamoxifen and the aromatase inhibitors (AIs) are the cornerstones of endocrine therapy for estrogen receptor-positive breast cancer and are known to reduce recurrence and improve survival.[35,36] Although tamoxifen is known to improve bone density in postmenopausal women, it has been associated with bone-density loss in premenopausal women.[37] AIs (exemestane, letrozole and anastrozole) can reduce bone density in postmenopausal women, a population already at risk for osteopenia and osteoporosis.[38] Therefore, bone-density monitoring at appropriate intervals, weight-bearing exercise, and adequate calcium and vitamin D consumption are strongly recommended. Initiation of a bisphosphonate during endocrine therapy may be appropriate and should be based on estimated fracture risk.

Sexual Dysfunction

Both the effects of breast cancer treatment and the emotional and psychological impact of a cancer diagnosis can impair sexual function in women. Mastectomy or breast-conserving therapy that has an unsatisfactory cosmetic result can affect body image. Chemotherapy-induced ovarian suppression and endocrine therapy often result in significant vaginal atrophy, which can lead to dyspareunia. Libido changes may also develop during and after therapy.

Over-the-counter vaginal moisturizers and vaginal lubricants are safe and can help relieve some symptoms. Vaginal estrogen may be considered for intractable symptoms. Physicians should do a careful risk-benefit analysis before prescribing vaginal estrogen and should do so in collaboration with an oncologist. Involvement of a specialist in sexual and menopausal health is strongly encouraged for women suffering from these symptoms.

Uterine Health

Breast cancer survivors taking tamoxifen have a small-but-increased risk of uterine dysplasia and malignancy, particularly if they are postmenopausal.[39] Thus, regular pelvic exams and appropriate evaluation of suspicious symptoms such as vaginal spotting must be promptly evaluated. Additionally, even though premenopausal women treated with tamoxifen may have menstrual irregularity or even amenorrhea, conception is still possible. Despite inconclusive studies in humans, teratogenicity observed in animals has led the FDA to classify tamoxifen as a Pregnancy Category D drug. Caution must be taken to prevent pregnancy using nonhormonal contraceptive methods.

Vasomotor Symptoms

Chemotherapy and endocrine therapy are strongly associated with vasomotor instability, which can significantly impair quality of life. The frequency and severity of symptoms is variable. Wearing loose, light-weight clothing that "breathes" and appropriate dietary choices can be helpful.[40,41] Acupuncture has been found to relieve hot flashes and is considered safe.[42] Studies have been done on the effect of multiple drugs on vasomotor symptoms, including but not limited to selective serotonin reuptake inhibitors. Venlafaxine, in particular, has demonstrated benefit but is not tolerated by all patients. Drugs that use CYP2D6 in the cytochrome P450 pathway (eg, paroxetine) may interfere with tamoxifen metabolism; therefore, it is important to consult with a patient's oncologist when considering drug therapy to manage vasomotor symptoms.

Depression and Anxiety

Breast cancer survivors frequently struggle with psychological distress.[43] Undiagnosed depression and/or anxiety may lead to significant morbidity and impaired quality of life. Several well-validated easy-to-use tools can be used to identify patients who may be suffering. They include the Patient Health Questionnaire-9 (PHQ-9), Patient Health Questionnaire-2 (PHQ-2) and Beck Depression Index (BDI) for depression and the Generalized Anxiety Disorder-2 (GAD-2) questionnaire for anxiety. Early involvement of a psychologist and/or psychiatrist is encouraged.

Conclusion

Although it might be natural to assume that an oncologist would be the best person to care for a breast cancer survivor, involving both oncology specialists and primary care physicians will likely lead to the best outcomes for patients. ASCO guidelines specify that transferring a patient's care to a primary care physician one year after diagnosis and treatment for early stage breast cancer is acceptable with re-referral to oncology as needed. Despite this endorsement, oncologists often still provide both breast cancer-related care *and* general medical care to survivors, even those who have had early-stage disease. [44] One could argue that this is not the best use of the oncologist's time and expertise. Furthermore, such care is within the purview and expertise of the primary care physician. There is an emerging body of literature regarding the role of primary care physicians in the care of cancer survivors.[45,46]

Primary care physicians are best equipped to manage comorbidities (eg, diabetes, hypertension, thyroid disease) during active cancer treatment. Following treatment, they can provide ongoing care for such conditions, screen for emerging health concerns and provide appropriate

preventive care such as immunizations and other age-appropriate cancer screenings (primarily cervical and colon cancer). With the guidance of oncologists, they can also monitor for cancer recurrence and sequelae of cancer therapy and help manage side effects of endocrine therapy. Additionally, primary care physicians can screen for and manage depression and anxiety during and after active treatment.

Coordinated care and diligent communication among physicians and with survivors, along with use of survivorship care plans,[47] can result in improved outcomes and quality of life for breast cancer survivors. **MM**

Nicole Sandhu is an assistant professor of medicine and consultant in the Division of General Internal Medicine's Breast Diagnostic and Cancer Clinics at Mayo Clinic.

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2013 Minnesota Academy of Pediatrics Poster Competition Winners

The Minnesota Academy of Pediatrics invites medical students and residents to take part in an annual scientific poster competition. Residents and students from the two pediatric training programs in the state (the University of Minnesota's and Mayo Clinic's) submitted a number of entries for consideration at the chapter's annual meeting in Minneapolis last May. Submissions were in the following categories: clinical vignette, research and medical student. A People's Choice award winner was also selected.

Posters were judged by practicing pediatricians, pediatricians from the state's academic medical centers and peers. The judges used clinical relevance, originality, and written and visual presentation as their criteria for evaluating the entries during a "poster rounds" session. Special thanks to Andrew Olson, M.D., from the University of Minnesota for coordinating the competition.

The winners presented their posters at the American Academy of Pediatrics annual meeting in Orlando in October 2013. Congratulations to all who participated on their excellent work.

Medical Student Winner

Nonclassical Presentation of Transient Myeloproliferative Disorder in a Patient with Down Syndrome

BY WADE SCHULZ, MALINI DESILVA AND R. SCOTT VELDERS, UNIVERSITY OF MINNESOTA

Transient myeloproliferative disorder (TMD) is a leukemia found in approximately 10% of newborns with trisomy 21 (Down syndrome). Although this disorder normally resolves spontaneously within the first few months of life, patients are at increased risk of developing acute myeloid leukemia later in life. Studies have shown that mutations in GATA1 lead to a proliferation of multiple cell types that are responsible for this syndrome. Documented cases of TMD reflect this proliferation with a predominance of blasts in the peripheral blood.

Case Description: A full-term female infant born to a mother of advanced maternal age was found to have physical exam findings suggestive of Down syndrome including hypotonia, a flat nasal bridge, epicanthal folds, low-set ears and macroglossia. A karyotype revealed trisomy 21.

The infant developed hyperbilirubinemia. As part of the evaluation, a complete blood count (CBC) was obtained. The CBC was significant for a white blood cell count of 35.2 x 10e9 cells/L in the absence of fever; the differential showed an eosinophilic predominance (44%). Because this was not a traditional presentation for TMD, other potential sources of hyperbilirubinemia associated with eosinophilia, including congenital cytomegalovirus or toxoplasma infection, were evaluated and found to be negative. A peripheral blood smear was obtained and the final pathologic diagnosis was transient myeloproliferative disorder.

Hyperbilirubinemia resolved within several days and was thought to be physiologic. During the newborn's hospitalization, her white blood cell count declined to 22.5 x 10e9 cells/L and the percentage of eosinophils decreased to 19% by the eighth day of life. The infant was discharged and the family received instructions to follow-up with a primary care physician. The leukocytosis subsequently resolved with no acute sequelae. The child will have ongoing follow up to monitor for the development of AML, which can occur in up to 30% of patients with a history of TMD.

Discussion: The classic laboratory finding in TMD is leukocytosis with a predominance of blasts in the peripheral blood. However, this case demonstrates that TMD can involve other cell types, such as eosinophils, that are also regulated by GATA1. As evidenced by this case, TMD is often asymptomatic and found incidentally. However, hepatic fibrosis, respiratory failure and congestive heart disease can occur from continued proliferation and differentiation of the megakaryocytic lineage. Cases of TMD with an eosinophilic predominance have not been previously documented in the literature, and the association between hypereosinophilia and TMD is an important finding. It is also important to note that despite this atypical presentation, the natural course of spontaneous resolution remains true. As with all children who are diagnosed with TMD, close follow up is warranted because of the increased risk of AML.

Research Winner

Electronic Cartoon Picture to Improve Adherence to a Traumatic Brain Injury Clinical Decision Rule

BY OLUFUNMILAYO SALAMI, M.D., M.SC., AND MANU MADHOK, M.D., M.P.H., CHILDREN'S HOSPITALS AND CLINICS OF MINNESOTA AFFILIATED WITH REGIONS HOSPITAL AND THE UNIVERSITY OF MINNESOTA

Traumatic brain injury (TBI), which is a cause of childhood morbidity and mortality, is usually evaluated by CT. There is growing concern about radiation exposure from head CT. The Pediatric Emergency Care Applied Research Network (PECARN) developed a Clinical Decision Rule (CDR) that can potentially reduce the number of unnecessary head CTs. However, physicians' poor recollection of CDRs during patient encounters may result in nonadherence. Studies suggest that visual cues may play a role in reminding them to use CDRs.

Objective: To assess the effectiveness of cartoon pictures illustrating key components of PECARN's TBI CDR embedded in the electronic health record (EHR) in reducing the rate of head CT for TBI.

Methods/Design: The study involved children 0 to 18 years of age who presented to the ED of Children's Hospitals and Clinic of Minnesota within 24 hours of TBI who had a GCS of ≥14. Data were collected by chart review. Exclusion criteria were CTs done in an outside facility; obvious penetrating TBI; trivial injury with no signs or symptoms of head trauma other than scalp abrasions or lacerations; known brain tumors, pre-existing neurological disorders complicating assessment, ventricular shunts or bleeding disorders. Use of CDR was evaluated before and after the intervention. The pre-implementation phase included 1,250 total patients (424<2 years of age, 826≥2 years of age). The post-implementation phase included 1,125 patients (373<2 years of age; 752≥2 years).

Intervention: Working with a graphic designer and the hospital's information technology team, we developed cartoon pictures illustrating the key components of the PECARN TBI CDR that pop up the first time a provider opens the electronic chart of a patient with a TBI-related chief complaint (Figure).

Results: We looked at the use of head CT before and after implementation and found a statistically significant decrease in head CT utilization rates for the total sample and for children younger than 2 years of age. The decrease for children 2 years and older, though clinically significant, was not statistically significant (Table).

Conclusion: Cartoon pictures illustrating key components of the PECARN TBI CDR embedded in an EHR may reduce the rate of CTs done for head injuries, especially in children younger than 2 years of age.

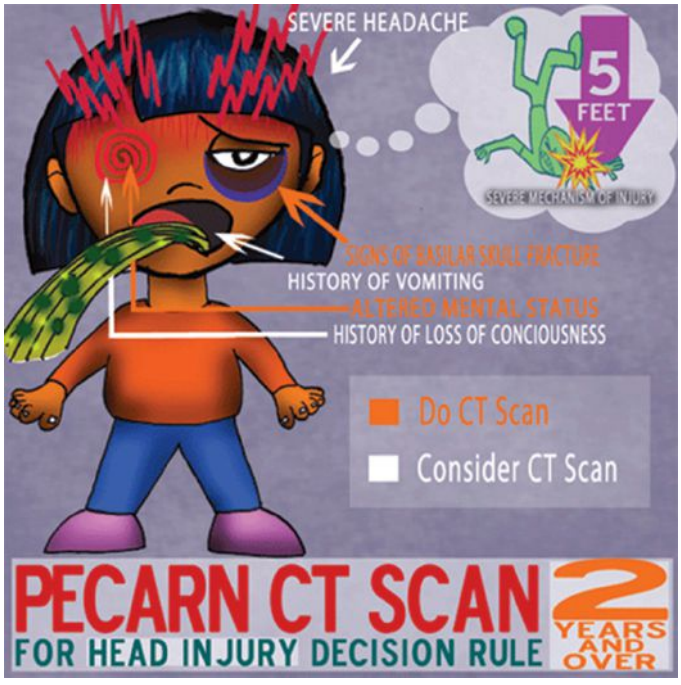
TABLE

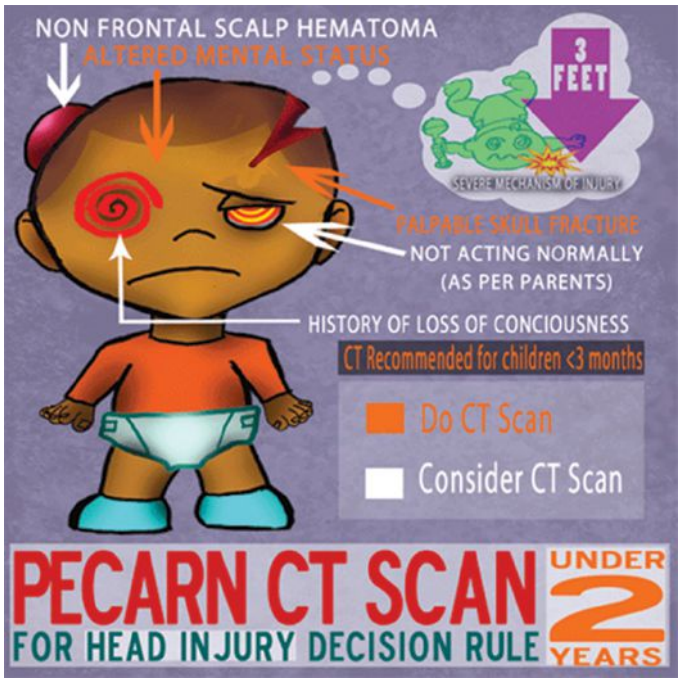
Head CT Utilization by Age Group

AGE GROUP	PRE-IMPLEMENTATION FREQ. OF PATIENTS SEEN (% CT DONE)	POST-IMPLEMENTATION FREQ. OF PATIENTS SEEN (% CT DONE)	CHANGE PRE- TO POST* (95% CI)	P VALUE
Total	1,250 (39.4)	1,125 (34.3)	4.9 (1.1 to 8.7)	0.01
<2 years	424 (40.6)	373 (33.0)	7.9 (1.4 to 14.5)	0.02
≥2 years	826 (38.9)	752 (35.0)	3.3 (-1.3 to 8.0)	0.16

*Estimate adjusted by provider training

FIGURE **Pictures Used to Remind Physicians of the PECARN TBI CDR**





Clinical Vignette Winner

Thrombotic Thrombocytopenic Purpura with Associated Posterior Reversible Encephalopathy Syndrome in a 16-year-old Female—A Rare Clinical Presentation

BY ADAM FOSS, M.D., UNIVERSITY OF MINNESOTA

Thrombotic thrombocytopenic purpura (TTP) is a relatively rare condition with the classic pentad of microangiopathic hemolytic anemia, thrombocytopenia, fever, renal failure and neurologic symptoms. This case involved a 16-year-old female with end-stage renal disease secondary to lupus nephritis, who presented with new onset seizures, anemia with hemoglobin of 7.9 g/dL and thrombocytopenia with platelets of 49,000. Lactate dehydrogenase was elevated at 2,189 U/L with haptoglobin less than 6 mg/dL. A peripheral smear was done showing schistocytes. Because of new onset seizures, the patient underwent an MRI of the brain showing findings consistent with posterior reversible encephalopathy syndrome (PRES). This case is a rare presentation of TTP and is confounded by the patient having PRES.

People's Choice Winner

Evolution of the Heart Rate Corrected QT Interval in Premature Infants during the First Week of Life

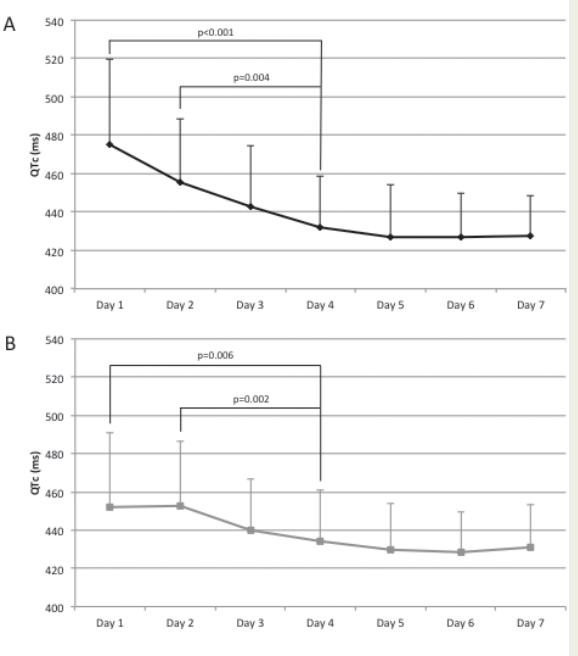
BY TIM ULRICH, M.D., MARC ELLSWORTH, M.D., BRIANNA MACQUEEN, M.D., ADEEL ZUBAIR, CHRISTOPHER COLBY, M.D., WILLIAM CAREY, M.D., AND MICHAEL ACKERMAN, M.D., MAYO CLINIC

Validation of automated QT interval monitoring in the hospital setting has allowed for its expanded use in clinical and research domains. Understanding of the heart-rate corrected QT interval (QTc) and its evolution in premature infants is important in determining its clinical utility in this specific population.

Methods: All infants older than 31 weeks and younger than 37 weeks estimated gestational age (GA) admitted to our institution's level II neonatal intensive care between December 2012 and March 2013 were included in the study. The infants were stratified into two cohorts: 31– 33 6/7 weeks GA (cohort A) and 34 - 36 6/7 weeks GA (cohort B) for analysis. For each infant, automated QTc values were obtained every 15 minutes and recorded in the electronic medical record. A prospective analysis of the QTc values was performed during the first week of life for each infant. A student's t-test was used to compare QTc value means between and within cohorts. A Fisher's exact test was used to compare the number of infants exceeding a proposed QTc screening cut-off.

FIGURE

QTc Means (+1 SD) During the First Week of Life for Infants 31 to <34 Weeks (A) and 34 to <37 Weeks (B) Gestational Age



Results: A total of 21 and 39 premature infants were in cohort A and cohort B, respectively. The mean QTc value on Day 1 of life for those in cohort A was significantly higher compared with those of cohort B (474 ± 71 ms versus 449 ± 50 ms; P <0.0001). The QTc means within each cohort declined significantly (P<0.05) until Days 4 and 5 for cohort A and B, respectively (Figure). The QTc values on Day 7 of life were similar for the two cohorts (427 ± 26 ms versus 428 ± 30 ms; P=0.312). During the first 48 hours, 18 infants (30%) in the two cohorts would have exceeded a proposed QTc screening cut-off mean value of 470 ms compared with only two (3.3%) infants after 96 hours (P=0.0002).

Conclusion: Automated QTc monitoring demonstrated that premature infants showed significant elevation of QTc values in the first 24 to 72 hours of life before reaching a stable and less variable baseline. This electrophysiologic transition period coincides clinically with the similar transition from fetal to extrauterine circulation. Any evaluation of QTc in premature infants has to be done in the context of this transition period; our data suggest that true determination of QTc values in this population should not be explored until after the first 72 to 96 hours of life to minimize false positives. **MM**

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St. Cloud VA Health Care System

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- Psychiatrist
- Urgent Care Physician (IM/FP/ER)

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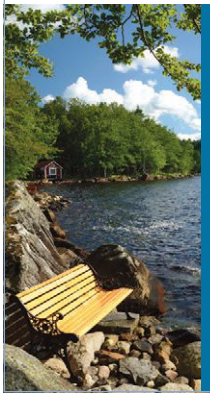

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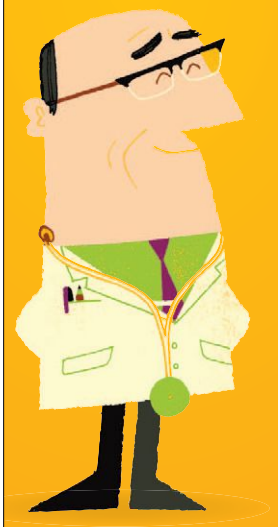

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The Wish

How hope enables one patient to rise to a very special occasion.

BY RYAN FABRIZIUS, M.D.

When I first met you, I could see that your time was short. The green-yellow hue of your face told the story of the invading malignancy in your liver. The way your skin clung to the bones on your face, like a sheet draped over an old rocking chair, spoke of vitality draining away. The lines and tubes, buzzing among a monotony of alarms, conveyed your persistence in gaining every extra moment possible. The end was near, and you were not occupied with false hope. But there was something that brought light to your jaundiced eyes and a smile that dimpled your bony cheeks: The Wish. An impossible dream—to be at your son's wedding in one week, 2,000 miles away.

The tears that came when you told me about The Wish showed that your hope was fading. Sepsis had seized an opportunity afforded by a biliary blockage, pushing the limits of the small reserve remaining in your battle-worn body. It seemed to be the fatal blow. Despite the vanishing possibility, The Wish became the sole focus of every conversation, medication and procedure. The hospital staff, hearing of The Wish, pooled their hope, skills and prayers. Doubt and perseverance, grief and belief, fear and faith tangled in each of our hearts.

Then a miracle happened. An adjustment to a drain released a current of purulence. We had found the source of sepsis that had brought you so near the edge of eternity. Your vital signs and laboratory tests improved, a ray of light returned to your countenance, and hope began to stir among your supporters. Plans were forged. The journey would be made.

The day you left the hospital, the look on your face was resolute, knowing that the stage had been set, but The Wish was not yet reality. You promised to return. Prescriptions filled, hospital gown replaced with pants, drains concealed and eyes set forward.

I did not say goodbye, but in your absence I thought of you daily. I imagined you walking down the aisle in a brightly adorned church, exchanging glances, laughter and tears with your family and friends. I pictured you sharing stories of times past and making new memories that they would hold in their hearts after your passing. I could hear you telling your dearest ones how deeply you love them. I could feel your heart torn between the joy of the occasion and the pain of your imminent departure.

You returned. In your eyes, I saw that The Wish had been granted in full. It had changed your life and mine. Thank you for believing in The Wish. **MM**

Ryan Fabrizius is a resident in the med/peds program at the University of Minnesota.

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South Metro and Southeast Minnesota

Mandy Rubenstein
mrubenstein@mnmed.org
Northwest, Southwest and Central Minnesota

Brian Strub
bstrub@mnmed.org
North Metro and Northeast Minnesota

Terry Ruane
truane@mnmed.org
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