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PHYSICIAN RETIREMENT

» Why doctors work longer
» Knowing when the time is right
» Tips for life after medicine
here is nothing more frustrating to physicians than knowing a patient needs a certain test or medication and having them not be able to get it because their health insurance company won’t cover it. All too often, many services require prior authorization (PA).

It wouldn’t be so bad if the insurance companies made the guidelines they use to make these determinations readily apparent to those practicing medicine. However, these guidelines are created by the insurance company (with a main goal being cost containment rather than evidence-based medicine), unavailable to treating clinicians, and often they use decades-old recommendations. We are often left to predict the payer’s decision.

Many of us feel that it is like playing an epic game where we try to give our best care to our patients, while the insurance companies deny as many tests as possible to increase their profits. The loser of this game is not the one who was able to get the least amount of services covered or earned the least money. Rather, it is the patient: delayed diagnoses/treatment, denied tests, forced to use less effective medications based on formularies developed by insurance companies using their own guidelines, and footing increased costs. How can this PA game be played for better odds of winning?

**Have your evidence.** Whoever does the PA needs to have the progress notes in front of them. They will be asked clinical data and it should be at their fingertips.

**Learn what is needed to get an approval.** With certain insurance companies, every time I order an MRI of the lower back, they want the patient to have had a plain X-ray first. Why? There is no evidence that X-rays are a good test to diagnose back problems. In fact, if I am looking for a herniated disc, a plain X-ray will not show it but rather an MRI is needed. Sometimes the only way to get the patient to get the test is to do it anyway.

**Don’t give up.** If a test is denied, appeal it and keep appealing it. I find that this is not often successful but sometimes is. Plus, the insurance company should not be given an easy pass for refusing to cover something a patient needs.

**Get the patient involved.** They should be contacting their insurance company as well. They will be talking to member services and sometimes they find a sympathetic ear who helps them get coverage or reveals the holy grail of coverage determination to them. They are often successful when we are not.

**Remember human resources.** If a patient works at a company that has a HR department, have the patient get them involved. Insurance companies do not want to lose any covered lives so if they find a company is unhappy with the services provided, this can be a very effective weapon.

**Ask for the medical director.** Most of them were practicing medicine at some point and understand our struggles on the frontlines. If we present our medical reasoning with them, they often are able to authorize a test. Not always.

While these tips may help get some services covered, they often still do not work. The insurance companies hold a lot of power over these medical decisions. The most important thing is to keep fighting the ones we don’t medically agree with.

The day we all quit the battle is the day we lose the game and big insurance companies win and determine medical care. We must remain diligent in our fight for optimal clinical outcomes in all and each of our patients.

Linda Girgis, MD, is a family physician in private practice in South River, New Jersey.
Physician retirement

Why doctors work longer careers

COVER STORY

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THE LAST WORD

Minimize EHR-induced stress

The key is to handle factors you can control, and stop worrying about the ones you can’t, writes Catherine Hamby, PhD.

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How Medicare coverage of genetic counseling could decrease care costs and improve quality

A new bill recently introduced to Congress would not only reduce barriers to genetic counseling for Medicare patients, but also could significantly decrease costs of caring for elderly and low-income patients.

The bill—known as the “Access to Genetic Counselor Services Act of 2018” (H.R. 7083)—would reimburse certified genetic counselors for counseling provided to Medicare patients. Currently, certified genetic counselors are not recognized by CMS as providers, even though genetic counseling is a covered benefit. As a result, today, genetic counseling for Medicare patients can only be provided:

- Under direct supervision of a physician
- To patients who are established patients of the physician practice

The bill would help to eliminate disparities in care for low-income and elderly patients. Many patients don’t live in areas where genetic counseling is easily accessible under the current guidelines. Improved access to genetic counseling, including telephonic counseling, supports increased availability of potentially life-saving information and treatments. It also ensures those who qualify for tests, as well as their providers, are fully informed before and during the testing process.

The bill would change the way in which providers and genetic counselors interact with one another—and that could drive down costs related to genetic tests and therapies. Each day, up to 10 new genetic tests are introduced. Yet only a fraction of patients who could benefit from these advancements have access to them. Meanwhile, patients who wouldn’t benefit from genetic tests and therapies often are still being tested, primarily due to a lack of genetics education on multiple fronts.

Consider that one out of every three genetic tests is ordered incorrectly. This leaves payers and providers vulnerable to orders for the wrong test at the wrong time for the wrong patient—and the increased financial and emotional toll of these decisions.

To read more, visit bit.ly/Medicare-genetic-counseling.
Direct pay practices benefit the few, not the many

see more and more articles about direct patient care (DPC) practices and how wonderful they are, including a recent article by Rob Lamberts, MD (The Last Word, December 10, 2018 issue). These articles all sing the praises of converting to DPC, how it eliminates burnout for the physicians

“We all know that there is a primary care shortage. Every time a traditional practice converts to a DPC model, the gap grows wider.”

and allows them to spend much more time with the patients.

But there is a dark side to the conversion that nobody in the DPC camp ever seems to talk about. While the new practice model might be great for the select group of patients who agree to stay on and pay their monthly fees, what about everyone else? Dr. Lamberts wrote that he averages 8 to 11 patients per day. I wonder how many he was seeing before he made the switch. In my practice, I was routinely seeing 25 to 30 patients per day. Had I jumped on the DPC bandwagon, that would have meant that about 20 patients per day would have been displaced and forced to find a new family doctor.

We all know that there is a primary care shortage. Every time a traditional practice converts to a DPC model, the gap grows wider. It benefits the few at the expense of the many. There aren’t nearly enough other family practices to absorb all of those patients. So while the switch might be great for the provider who does it, what burden is it putting on the healthcare system overall? How many more unnecessary emergency department visits are there as a result of decreased access? How many patients with chronic conditions like diabetes and hypertension become uncontrolled because they aren’t able to find a new doctor in the area? Other area physicians are often forced to close to new patients any time another local doctor retires or otherwise leaves the neighborhood. That happened a couple of times in my practice. I can only imagine that the same thing happens when a practice converts to DPC and cuts loose a couple thousand patients who suddenly need to find a new doctor.

None of this is to suggest that doctors shouldn’t do what’s best for themselves and their practices. I myself left private Family Practice and moved to Urgent Care. I just can’t help but wonder where the thousands of patients who get displaced are supposed to go for care once their family doctors can no longer see them. Urgent Care picks up a lot of the slack for acute care needs (I still see 25 to 30 patients per day) but they don’t handle chronic conditions. Especially as the population ages, there is an ever-growing need for better primary care access. It seems to me that a growing DPC movement will make the access situation even worse.

I certainly don’t have the answer but it’s definitely a problem that needs attention.

Steven Gitler, DO
CHERRY HILL, N.J.

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Is private equity coming for your practice?

When private practices are sold, the typical buyer is a nearby hospital or larger group practice. Yet increasingly private equity firms are looking to purchase physician practices, according to a study review published by the *Annals of Internal Medicine*.

Private equity firms typically acquire a practice in a community that is “large, well managed and reputable,” according to the study authors. Once that firm is purchases, the private equity owners will boost their value by *acquiring smaller practices, increasing revenue* and *cutting costs*.

Once the value is boosted, the private equity firms sell the practice—either to other private equity firms or to hospitals—and reap the profits.

**Acquiring smaller practices**
Healthcare consolidation has made it more difficult for small practices to thrive, the authors note, thus leaving physicians more interested in selling their practice. When private equity comes calling:

1. **The firms typically take 60% to 80% ownership stake**
2. **The value of the firm can increase from anywhere from 2- to 12-times the original practice value**
3. **Practice owners are usually paid as much as $1 million to $2 million per physician**

**Increasing revenue, cutting costs**
Private equity firms boost value by increasing revenue and cutting costs.

They grow revenue by:
- Focusing on specialties that allow them add ancillary services. Dermatology has been a major focus.
- Use larger size for negotiating leverage with payers

They cut costs by:
- Replacing physicians with physician assistants
- Spreading fixed costs across a larger organization

**Does it hurt patient care?**
Critics argue that private equity focuses first and foremost on profitability, perhaps at the expense of patient care. There has been no peer-reviewed evidence on the link between private equity acquisitions and the quality of patient care.

“These well-capitalized purchasers offer ‘shelter from the storm’ in the rapidly changing environment, as well as the regular work hours and freedom from running a small business.”

—*Annals of Internal Medicine*, Jan. 8, 2019
Why doctors work longer
Knowing when the time is right
Tips for life after medicine

by JAMES F. SWEENY  Contributing author

eventy-year-old William Keimig, MD, doesn’t like to think about what’s coming.
“I’ll feel really old when I retire—really old,” says the internist with the Henry Ford Health System in Detroit.
Keimig is past the average retirement age for physicians, but he’s still working 55-hour weeks and hasn’t set a date for when he will stop practicing. Maybe 2020, he says, adding that he doesn’t like to contemplate life as a retiree. “One of the most satisfying and cool things you can do is to be a physician,” he says. “I know I’ll really miss it.”

RETIREMENT BY THE NUMBERS
The popular stereotype of older workers is that everyone is counting the days until they can retire, but that’s not the case for many physicians, who have a more complicated relationship with retirement than do many other professionals.
And as the country’s physician workforce ages, it’s an issue with which more doctors will have to grapple. According to the 2016 U.S. Census, 30 percent of physicians are 60 or older, up from 26 percent in 2010. And the average age of active licensed doctors is 51.
In a 2017 survey of physicians age 50 and older by healthcare staffing firm CompHealth, respondents, on average, said they intend to retire at age 68. By comparison, the average retirement age for all Americans is 63.
THE REASONS WHY
If physicians, on average, work longer than other people, it’s partly because they started their careers later.

Four years of medical school and three years or more of residency mean many physicians do not begin earning substantial incomes until they’re 30 or older, well after their peers who pursued most other professions.

That means fewer years in which to accumulate enough savings for retirement while simultaneously paying expenses such as mortgages and children’s college educations. For doctors who combine an expensive lifestyle and a lack of financial acumen, that can mean working past the age at which they’d like to retire, says Joel Greenwald, MD, CFP, a Minnesota financial planner who works primarily with physicians.

That’s not the case with Keimig, who says he can afford to retire now, but likes still having an income. “It is nice to have that paycheck coming in on a regular basis,” he says.

Keimig, who has been with Henry Ford Health System his entire career, says the support of its administrative and medical staffs has made it easier for him to keep practicing by allowing him to focus on providing medical care rather than performing ancillary tasks.

IDENTITY CRISIS
For some doctors, it’s hard to say goodbye to a career they’ve loved and one which has formed a large part of their identity. In the CompHealth survey, physicians identified losing social interactions at work, a loss of purpose and boredom/loneliness/depression as their top concerns about retirement.

Cardiologist David Mokotoff, MD, says his decision to retire in 2015 at age 67 provoked something of an identity crisis.

Being a physician was at the core of who he was and he worried how he would feel without the work and the status that accompanied it. On the other hand, he says, he wanted to retire while he was still healthy and able to enjoy physical activities. When a good friend and fellow physician contracted Parkinson’s disease and died, that convinced Mokotoff it was time to retire.

“I’ll feel really old when I retire—really old. One of the most satisfying and cool things you can do is to be a physician. I know I’ll really miss it.”

— WILLIAM KEIMIG, MD, HENRY FORD HEALTH SYSTEM, DETROIT

Physician concerns about working past full retirement age

<table>
<thead>
<tr>
<th>Concern</th>
<th>%</th>
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<tbody>
<tr>
<td>Ability to stay competitive in a changing healthcare environment</td>
<td>38%</td>
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<tr>
<td>Concerns about declining personal health</td>
<td>37%</td>
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<tr>
<td>Ability to provide quality patient care</td>
<td>26%</td>
</tr>
<tr>
<td>Concerns about technology</td>
<td>23%</td>
</tr>
<tr>
<td>Concerns about spouse or partner</td>
<td>21%</td>
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<tr>
<td>Other</td>
<td>6%</td>
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Physicians’ ideal retirement

<table>
<thead>
<tr>
<th>Ideal</th>
<th>%</th>
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<tbody>
<tr>
<td>Being financially stable</td>
<td>88%</td>
</tr>
<tr>
<td>Having more time for personal activities</td>
<td>85%</td>
</tr>
<tr>
<td>Spending more time with family/friends</td>
<td>75%</td>
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<tr>
<td>Less stress</td>
<td>74%</td>
</tr>
<tr>
<td>Still working</td>
<td>51%</td>
</tr>
<tr>
<td>Mission/volunteer work</td>
<td>40%</td>
</tr>
<tr>
<td>More time to focus on health</td>
<td>35%</td>
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Source: CompHealth
Why more physicians are postponing retirement

By Keith Loria contributing author

There was a time when doctors looked forward to retiring after a successful career, looking to vacation, play golf and spend more time with their families. But these days, it seems more physicians are halting retirement plans.

A 2017 study from CompHealth examined late-career physicians' sentiments toward retirement and revealed that many aren't looking to hang up their scrubs and stethoscopes anytime soon.

According to the study, social interaction topped the list of retirement concerns, while 91% of doctors still feel they can provide a useful service to patients. It’s no wonder that many physicians are holding off on retiring for as long as they can.

Larry Good, MD, a gastroenterologist in Lynbrook, N.Y., has been in practice nearly 40 years in a wide range of settings, including academic, director of a clinical department, lecturer, researcher and presenter at national and international medical meetings.

“I have not thought about retirement. I am involved in many projects, including a pharmaceutical development project. I deeply believe that I provide a very valuable service to my patients and profession,” he says. “Being active allows me to be more effective clinically in areas of research and pharmaceutical consulting.”

In the study, 51% of respondents said that working occasionally or part-time is part of their ideal retirement plans.

Murray Grossan, MD, part of a five-person ENT group at Cedars Sinai Center in Los Angeles, California, says there is evidence that being creative slows aging, so despite being in his 90s, he still works four half-days a week.

“I've certainly thought about retiring, but when you consider what gives you energy, it turns out to be doing medicine and solving medical problems,” he says. He compares the field of medicine to the music industry, where many musicians continue to tour well into their post-retirement-age years.

“They are most energized when they do music; similarly, doctors went into medicine for the love of medicine, and they feel fulfilled, just like the musician,” Grossan says. “Social interaction...
In retirement, Narraway is doing a lot of reading about basic science, learning Spanish online and tending to his three acres of property. “I’m very busy and I can’t find enough time to do everything I want to do,” he says, adding that he did not keep his medical license current.

“You’re either in or you’re out,” he says. “To be halfway in is no way to go."

**RETIREE EXTREME**

It’s uncommon for physicians to retire well before the traditional age, but that’s what is also a factor—I’ve seen too many examples of a person retiring and expiring.”

Joe Heider, president of Cirrus Wealth Management, has more than 30 years’ experience working in retirement, estate, tax and business planning with a focus on the financial concerns of medical professionals.

“When it comes to retirement and physicians, although a large percent of physicians do not want to retire, there is a substantial percent that do,” he says. “Just like other professions, the burnout happens over time due to stress and work hours as well as increasing government intrusion into their practice. The physicians that do not want to retire have found a way to focus on what they love to do, which is working and treating patients.”

Heider says physicians should establish a financial plan early on so that they have the freedom to pursue what they want to do upon reaching retirement age without having to worry about money issues.

**EXPERIENCE MATTERS**

While some older doctors might slow down in their later years, it doesn’t mean that their skills can’t be put to good use. After all, as Grossan notes, “We’ve seen a thing or two.”

“A huge amount of experience in the senior doctor can be of value,” he says. “The senior doctor comes from where you palpated muscles, listened to the heart, and made pretty good diagnoses without $3,000 lab tests. We see today’s doctors who barely touch a patient and they can’t get to feel the abdomen because all those sensors cover it.”

Many seniors would love to continue practicing, but Grossan says EHRs and expensive recertification costs force them out of practice.

**IT’S WHAT THEY KNOW**

Physicians tend to be very busy and very involved in their work, and Good says many haven’t developed a lot of outside hobbies or other interests throughout the course of their career.

“I think my generation of physician believe that medicine is a calling,” Good says. “Many of us would be kind of lost without medicine. There is an old psychology 101 test where you are asked to describe yourself—man, woman, son, daughter, etc. Most physicians say doctor first and then everything else, which admittedly is a little psychologically flawed.”

He agrees with the CompHealth study that the loss of social interaction is a concern for physicians considering retirement.

“Physicians spend all day talking to patients,” Good says. “My friends who have retired do report loneliness and isolation and those considering [retirement] note it is a concern.”

Still, 76% of respondents indicated that they would like to travel more in full retirement, and while making the decision to call it a career is hard, it’s something that many could look forward to one day.

“[Retirement] was very strange at the beginning. So much of my identity was wrapped up in this, I didn’t have time to develop outside interests.”

— VALERIE JONES, MD

“I think my generation of physician believe that medicine is a calling.”

— LARRY GOOD, MD
When Patricia Kloser, MD, MPH, FACP, retired from her professorship at Rutgers New Jersey Medical School in 2013, she wasn’t ready to stop practicing medicine.

Instead, the internist and infectious disease specialist has taken her practice on the road. Kloser, who is in her 70s, has been working as a locum tenens physician since retiring. Based in New York City, she has taken assignments in Georgia, Florida, Wyoming, and Alaska, among other states. “I absolutely love it. I can’t imagine doing anything else,” she says.

Locum tenens assignments are one option for physicians who’ve retired, but there are many alternatives to the traditional retirement of leisure, hobbies and travel. Retired doctors who still want to use their medical skills can volunteer, teach, consult and even go back to work part-time.

Kloser says she wasn’t ready to stop practicing medicine and locum assignments let her control where, when, and how much she works. A typical assignment is six to 12 months, and she takes breaks between jobs to enjoy her hobbies of hiking, travel and photography. When she’s home, she still sees some long-time patients.

Locum work is not for everyone, she says, and requires flexibility as well as a tolerance for living in hotels and adjusting to unfamiliar surroundings. “I’ve done some really wonderful things,” she says. “The only downside is I’ve met some wonderful people and it’s hard to say goodbye, but I know there is an adventure down the road.”

Like Kloser, George Meyer, MD, knew he would not spend his retirement on the couch. Since retiring from Kaiser Permanente in 2013, the 77-year-old gastroenterologist from Sacramento has been a medical volunteer through Health Volunteers Overseas, a U.S.-based nonprofit that trains healthcare workers in underserved countries.

He has been to Mexico, Costa Rica, Uganda, Bhutan, Nicaragua and elsewhere. He also finds time to volunteer with The Flying Samaritans, which provides free healthcare in Baja California, Mexico, and he teaches a medical course in Japan each year.

“It allows you to maintain your skills. It allows you to meet wonderful people while helping the countries develop medically,” Meyer says. “I get more out of it than I give. It truly is an absolutely wonderful experience.”

An increasingly popular option for retirees is to become a telemedicine provider, which usually can be done from home on a part-time basis, does not require in-person interaction with patients, and largely deals with simple cases.

The ideal retirement means something different for every physician, depending on their individual circumstances, desires, health and other factors. However, it’s clear that the valuable skills they spend their careers developing afford physicians the opportunity to continue to contribute even after they retire.
Valerie Jones, MD, did in 2016. At age 37, the Maryland resident walked away from her practice as an ob/gyn, only seven years after completing her residency.

“That was never the plan. I had intended to practice indefinitely,” she says. However, a health scare and a growing dissatisfaction with the state of medicine caused her to re-assess her plans and retire.

“(Medicine) had morphed into something I really wasn’t interested in anymore,” she says, citing the loss of autonomy, lack of time to form deep relationships with her patients and an ever-growing emphasis on productivity. The mother of three says she and her husband have lived frugally and invested well and that has allowed her to avoid having to get another job.

Jones says she had a hard time adjusting to the new reality: “It was very strange at the beginning. So much of my identity was wrapped up in this, I didn’t have time to develop outside interests.” However, she hasn’t left medicine behind entirely. She keeps her license current, writes the blog OB Doctor Mom, and is considering volunteering, teaching, and writing a book about her decision to retire.

At the other end of the age spectrum from Jones is James Hutchinson, MD, a 95-year-old family physician practicing in San Mateo, Calif. The solo practitioner graduated from medical school in 1950 and opened his practice in 1953.

Now in his 65th year of practice, he still sees patients four days a week, including some great-grandchildren of patients he saw when he began practicing. Hutchinson, who until recently walked 10 miles a day to stay fit, has a ready answer for those who ask when he will retire.

“I’ll practice until the river rises,” he says, noting with a laugh that there are no rivers in San Mateo. “What else can I do? I’ve done this all my life and I live in a one-horse town—there’s nothing else to do.”

Having outlived his wife and eldest child, Hutchinson says spending whatever time he has left as a retiree holds no appeal: “I love what I’m doing. I enjoy people and I enjoy helping them. I’m not missing out on anything; I’ve had a full life.”

AN IDEAL RETIREMENT

For many people, retirement is attractive because it means no longer working at jobs they don’t like or find rewarding, but that doesn’t seem to be the case with most physicians.

When respondents in the CompHealth survey were asked what they most looked forward to after retiring, traveling more, pursuing other interests, and spending more time on hobbies topped the list. Only 32 percent said they looked forward to no longer working while 48 percent said they intended to work part-time or volunteer.

When he finally retires, Keimig says he might volunteer, teach an English as a second language class or even earn a master’s degree in literature, but none of those prospects is as alluring as continuing to practice medicine.

“General MacArthur said old soldiers never die, they just fade away. I think it’s the same way with doctors,” he says.
No matter how skilled you are at time management, realistic scheduling, and organizational protocols within your practice, it’s pretty much expected that patients are still going to have to wait to see you.

And that wait is getting longer. According to a September 2017 survey from Merritt Hawkins, the wait time for a new patient appointment with a physician for a non-urgent visit has increased by 30 percent since 2014 in the 15 major metropolitan areas studied.

Most doctors these days face a steady stream of patients and a seriously stressed system. But doctors must make sure patients feel they are worth the wait. Here are six steps you can take to enhance the experience patients have when they arrive to see you.

1. Create a pleasant waiting area. The initial thing your patients feel when they enter your door is your practice’s ambience. Tattered furniture, faded paint, and outdated reading material leave a less-than-stellar first impression. Sprucing up your waiting room needn’t cost a lot of time or money, and the investment will be appreciated. Replace scruffy chairs, freshen up the walls, stream some music or video, and subscribe to a variety of contemporary publications that are of interest to all populations.

2. Provide realistic updates. Ask your receptionist to keep patients updated about delays and schedule changes. Provide as much lead time as possible to notify them about unforeseen cancellations or appointment changes.

3. Review the chart before you enter the examination room. Take a moment to familiarize yourself with the patient’s complaint, referral note, or history before you walk in the door. Naturally, you’ll determine both subjective and objective perspectives of their presenting condition during your assessment and examination. But having them sit there watching you read can cause an uncomfortable gap in the relationship.

4. Be patient. Most of us feel harried when we’re hurried. That sensation is contagious. When you’re feeling rushed, so will your patients. One of the ways hurrying rears its head is through impatience, which is often manifested by interrupting, finishing people’s sentences, sighing, or ceasing to listen.

Avoid these pitfalls by taking a deep breath and imagining the person in front of you is one of your own loved ones. How would you want them to be treated and spoken to? Keeping that image in the back of your mind will help you find the patience to hear people out.

5. Honor your commitments. Patients will take you at your word. If you say you’ll follow up in two weeks, do it. If you promise to send a referral letter that day, send it. And if you ask a patient to book an appointment the following week, make sure you’re going to be in town. While time flies by for you, it can stand still for your patients. That’s why it’s so critical that you do what you say, when you say you’ll do it.

6. Provide realistic updates. Ask your receptionist to keep patients updated about delays and schedule changes. Provide as much lead time as possible to notify them about unforeseen cancellations or appointment changes.

If you’re running more than 30 minutes behind, consider having a staff member call or text patients with an update so they can amend their plans. Yes, it sounds labor intensive, but it’s also respectful. And for those who are already in your waiting room, make sure someone updates them with accurate wait times.

Sue Jacques is a professionalism expert, keynote speaker, consultant, and author who specializes in medical and corporate civility. Send your practice management questions to medec@ubm.com.
Communication tips for dealing with non-adherent patients

by DEBORAH ABRAMS KAPLAN Contributing author

A round 125,000 people die per year in the U.S. due to failure to properly take medication, and 50 to 60 percent of those taking medications for chronic disease don’t take them as prescribed, according to the National Council on Patient Information and Education.

Convincing patients to improve their health requires a mindset shift and changing from a transactional relationship to a partnership. “They have a need, and you have a need,” says Ellen L. Singer, MD, an internist with Northwest Permanente in Portland, Ore. The key, Singer says, is drawing out the patient’s story. Some of her best techniques were learned through an improv coach, including how to move the story along and connecting with a patient to keep the door open, instead of closing it.

RECOGNIZE NON-ADHERENCE
Recognizing non-adherence is the first step in helping the patient stick with a plan. If noting that a patient’s blood pressure isn’t getting better, the physician should ask an open-ended question like “how is everything going with your medications?” instead of a closed-ended one with a yes or no answer, like “have you taken the medication?” The patient is more likely to answer a closed-ended question untruthfully, not wanting to disappoint the doctor, says Douglas Drossman, MD, an internist and gastroenterologist and president of the Drossman Center for the Education and Practice of Biopsychosocial Care in Durham, N.C.

If a patient says they have not taken their medication, Drossman would avoid making a judgmental response, like “why not?” Instead he would tell the patient that sometimes there are challenges to taking a medication, and asking what the patient sees as pros and cons of taking it. The physician can then help address the reasons why the patient didn’t take it.

Some patients are averse to pills because they remind them they have a medical condition, they’re a nuisance to take, or they’re too expensive, says Wayne Weston, MD, a board member of the Institute for Healthcare Communication and co-author of Patient-Centered Medicine: Transforming the Clinical Method. He may ask a patient, “what do you think about taking medications for the rest of your life?” It’s a big change for patients who had a heart attack and need four different pills daily, for example.

Whether accurate or not, patients have their own health explanatory models, where their understanding of their illness or condition is influenced by prior experiences, social or cultural contexts, and this helps them make decisions. If they believe a medication is harming them, they won’t take it.

If a hypertension medication causes erectile dysfunction, they may not take it. They may view it as treating one condition that doesn’t cause pain, but negatively impacting another part of life. Asking an open-ended
question lets patients share their reasoning, allowing the doctor to find a different medication or approach, or challenge their view.

A non-judgmental approach that aims to listen to what the patient says can help make the patient feel more comfortable sharing, and not feel they have to please their doctor with the answer.

Offering medical advice without getting the patient’s permission, however, isn’t advisable, says Auguste Fortin, MD, MPH, a New Haven, Conn. internist and past president of the Academy of Communication in Healthcare. Asking permission empowers patients and puts them in the driver’s seat, he says, allowing them to feel in charge. By granting permission, a patient is more open to receiving the information.

This has an added benefit to doctors, who may feel exhausted trying to get patients on the right path. Fortin recommends that doctors think of themselves as coaches or advisers, offering suggestions and encouragement. “It’s up to the patient, not us, to do the work,” he says. “Sometimes we hold ourselves to a higher position than we should.”

**MOVE THE NEEDLE**

Weston recommends focusing on three things for a successful patient interview during a visit: what the doctor thinks the problem is, what the patient thinks the problem is, and each of their goals. The problems and goals may not be the same, he says. The doctor may realize that the patient’s problem is not going away, so the patient should find a way to comfortably live with it. Ultimately, if the patient doesn’t feel heard, they may not follow the doctor’s suggestions.

A patient will feel heard if the doctor uses reflective listening, reflecting back what the patient said and asking to hear more about it. Showing empathy—sharing the patient’s concerns—is next.

“The patient needs to know that you really do understand what it’s like for them and that you care for them, even if you totally disagree with them,” Weston says.

Using motivational interviewing techniques, the physician can elicit what would encourage the patient to stick to a plan. Motivational interviewing helps encourage people to make positive adjustments by asking nonjudgmental questions to draw out a person’s reasons for wanting for to change.

“The patient may be motivated by wanting to fit into a dress, or wanting to look good at the beach,” Fortin says, rather than being motivated by their hemoglobin A1C level. He’ll say to the patient: “that sounds like a good reason to make some changes. What might you be able to do?”

Even if he thinks their proposed changes are inadequate, Fortin supports them fully. “If they’re successful with that, they may want to do something else,” he says. He helps them set a SMART (specific, measurable, actionable, relevant, and time-limited) goal, asking them about contingency plans and when they want to start.

He also asks how confident they are on a scale from one to 10 that they can carry out the plan. Instead of trying to get them to a higher number, he asks why that number so high and what makes them feel they can make the change. Research shows that if they get to seven or higher, their likelihood of making the change increases, he says.

If they’re under seven, he may ask what it would take for them to increase their confidence level. In addition, he asks how important the patient feels it is to make this change, using the same scale and the same follow-up questions about their choice.

After discussing the patient’s proposed plan and how they’ll deal with contingencies, he asks them to repeat back the plan. “When you say something out loud, you’re much more likely to do it,” Fortin says.

**TAILOR THE DISCUSSION**

Recognizing where the patient is in their journey is important, too. Patients will only make a change if they’re at the right stage, says Weston. The four stages include pre-contemplation, contemplation, action, and maintenance and identification. In pre-contemplation, the patient hasn’t thought about changing, or decided not to.

The next is contemplation; the patient thinks it’s a good idea, but recognizes the difficulty. “People can stay in that ambivalent stage for years,” Weston says. In the action stage, the patient develops a plan and begins, though they are vulnerable to slipping back. Next is maintenance and identification, where a patient identifies with the change. If they stopped smoking, they identify as a nonsmoker, for example.

“It’s important to tailor what you do to the stage,” Weston says. If they’re in the pre-contemplation stage, there’s no point in sharing...
strategies to quit smoking. Instead you can explain why you’re concerned.

The contemplation stage is the best time to develop strategies. Assessing confidence and interest are good strategies at this point, using the techniques of having the person rate his or her confidence and interest on a scale of one to 10. If a person is confident he or she could quit smoking but doesn’t want to, the discussion could focus on why it’s important.

**WORKING WITH COMPLEX PATIENTS**

Sometimes a person doesn’t adhere to treatment because the problem is overwhelming. If someone with diabetes has out-of-control blood sugar and lipids, Singer may let the patient choose their biggest concern, or she’ll suggest just one change. She might say, “I’d like to think about starting you on a statin. Are you okay talking about that, or do you want to wait two weeks?” A patient may shut down and not be able to process a lot of information at one office visit.

Singer helps the patient understand the risks in not taking care of themselves. “With diabetes, I’ll say, ‘When your blood sugar is high, you’ll be tired, and your body is inflamed. These are strategies to make you feel better,’” Singer says.

She tells them if they take their pills once a day and are willing to exercise, they’ll feel better in 4-6 weeks. She may suggest a follow-up visit or phone call. “I don’t care about

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**By Todd Shryock, Managing Editor**

Richard Bryce, DO, a primary care physician in Detroit, has seen the effects that socioeconomic challenges have on his patients at the community clinic he oversees. “Unfortunately, a lot of these social challenges play a huge role in their health,” he says.

For example, patients may want to exercise, but are afraid to leave their house because the neighborhood isn’t safe, says Bryce. Poverty or lack of education can lead to poor food choices, even when healthier foods are readily available.

Jay Bhatt, DO, MPH, FACP, a practicing internist and chief medical officer of the American Hospital Association, says patients with food insecurity are at high risk for chronic diseases such as diabetes and obesity.

So how does a physician who is responsible for keeping patients healthy deal with these socioeconomic challenges that stretch far beyond the walls of the practice, especially when the financial viability of their practice may be on the line?

“You can either look at the problems faced by patients and ignore them or try to address them, even if you are not medically trained to address them,” says Bryce. “Social determinants make keeping patients healthy hard, but when you can find solutions that are not always medical in nature, it can be really rewarding.”

**IDENTIFYING THE PROBLEM**

Physicians need to understand the specific problems their patients are facing before addressing social issues, and the only way to do that is to ask, experts say. Jeremy Long, MD, MPH, an internist in Denver, runs a clinic for the underserved and says it’s necessary to build trust to get the patient to open up about non-medical issues that may be affecting their health.

“Try to build rapport with them and introduce them to the whole team to show them how invested you are,” says Long. “When they see that, it helps them let their guard down.”

Long’s clinic uses a seven-page intake form that includes the standard medical questions along with details about the patient’s life. Questions about substance abuse, employment, insurance, style of learning, goals of care and incarceration help to gain a complete picture of the person’s life and the challenges he or she faces.

Bhatt says that physicians can start with screening questions that take the form of, “Do you have trouble getting here?” “What kind of neighborhood do you live in?” and “Are you having difficulty getting food for yourself or your family?”

“Though these questions are personal, they can help physicians build relationships with their patients and give them

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**Overcome socioeconomic obstacles to improve adherence**

**“YOU HAVE TO MEET THE PATIENT WHERE THEY ARE AT.”**

MedicalEconomics.com
the interval—I’ll let them have some control about the time," Singer says.

Another approach is: "I’ve seen people in your condition and they’ve really struggled with this. Then something bad happens like a stroke, and they find a new way of doing things. I’d love to prevent that," Singer says, and then asks if they think they could commit to a specified plan of action.

Another negative technique is to try and frighten the patient into changing, by saying "if you don’t stop smoking, you’ll die of lung cancer," or "your kids will get asthma and it will be all your fault," Weston says.

Learning new communication skills isn’t easy. "There’s a sense that I should know how to do this," Singer says. Organizations like the Foundation for Medical Excellence, the Institute for Healthcare Communication and the Academy of Communication in Healthcare offer courses in communication.

With diabetes, I’ll say, ‘When your blood sugar is high, you’ll be tired, and your body is inflamed. There are strategies to make you feel better.’

— ELLEN L. SINGER, MD, INTERNIST, PORTLAND, ORE.
In the early years after college, when many of their peers are beginning to save for retirement and buy a home, physicians continue their medical education and training while simultaneously postponing earnings—sometimes by as much as 10 years.

For physicians, then, traditional retirement savings vehicles may be insufficient to make up for lost time in saving for their golden years. Of course, another factor that threatens retirement savings for physicians is being in high tax brackets. Because of their higher incomes, physicians receive little to no financial aid for their children’s educations, and college savings for children inevitably impacts physicians’ own retirement savings.

This may sound a bit bleak, but don’t be discouraged. If physicians build a diversified portfolio and pursue alternative investments, they may lessen the impact of a delay in retirement savings.

One alternative investment for physicians to consider is purchasing or investing in their own medical office building.

By establishing a separate Limited Liability Company (LLC) to buy the building, physicians and their partners can become landlords of their own medical practice. If there are additional tenants in the space, the LLC earns that revenue too.

Additional advantages of owning one’s own medical office building include the ability to control costs, thereby effectively eliminating the possibility of falling victim to ever-increasing rent as well as the freedom to expand or change the space as desired.

Of course, owning a building has the potential to be lucrative from a return on investment standpoint, but certain costs and conditions can negatively impact value.

Before signing on the dotted line, physicians must complete a thorough due diligence and thoughtful consideration of all of the costs associated with property ownership, including utilities, ongoing maintenance, and upkeep. In addition, physicians should be careful to buy opportunistically and avoid overpaying as well as over-leveraging themselves prior to purchase.

Partners in a medical office building are well advised to come to an agreement on certain processes ahead of a property purchase. Otherwise, they run the risk of disagreements that could threaten the success of the venture.

Ideally, investing in a medical office building will help physicians recover some of the savings they forfeited earlier in their career, but it’s not a guarantee. Pursuing alternative investment solutions such as this is one way for physicians to hedge their bets and potentially improve retirement savings outcomes.

Questions before investing

Here are questions practices/partners/physicians need to first ask themselves before making a decision:

- What is the process for making decisions?
- What is the process for accepting a new investor?
- Who is allowed to invest in the medical office building? How many will be allowed to invest?
- How are ownership shares transferred (and what are the restrictions)?
- What are the policies for distributions and redemptions?
- Who is authorized to act on behalf of the partnership/LLC?
- What happens if a physician leaves the practice? Will he/she be obligated to sell his/her interest?
- How will the building be valued? How often should valuations be done?
**INDICATION**

• GARDASIL 9 is a vaccine indicated in females 9 through 45 years of age for the prevention of cervical, vulvar, vaginal, and anal cancers caused by human papillomavirus (HPV) Types 16, 18, 31, 33, 45, 52, and 58; precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58; and genital warts caused by HPV Types 6 and 11.

• GARDASIL 9 is indicated in males 9 through 45 years of age for the prevention of anal cancer caused by HPV Types 16, 18, 31, 33, 45, 52, and 58; precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58; and genital warts caused by HPV Types 6 and 11.

• GARDASIL 9 does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening.

• Recipients of GARDASIL 9 should not discontinue anal cancer screening if it has been recommended by a health care professional.

• GARDASIL 9 has not been demonstrated to provide protection against diseases from vaccine HPV types to which a person has previously been exposed through sexual activity.

• GARDASIL 9 is not a treatment for external genital lesions; cervical, vulvar, vaginal, and anal cancers; or cervical intraepithelial neoplasia (CIN), vulvar intraepithelial neoplasia (VIN), vaginal intraepithelial neoplasia (VaIN), or anal intraepithelial neoplasia (AIN).

**SELECT SAFETY INFORMATION**

• GARDASIL 9 is contraindicated in individuals with hypersensitivity, including severe allergic reactions to yeast, or after a previous dose of GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant].

• Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following HPV vaccination. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion.

• Safety and effectiveness of GARDASIL 9 have not been established in pregnant women.

• The most common (≥10%) local and systemic adverse reactions in females were injection-site pain, swelling, erythema, and headache.

• The duration of immunity of GARDASIL 9 has not been established.

**INDICATION (continued)**

• Not all vulvar, vaginal, and anal cancers are caused by HPV, and GARDASIL 9 protects only against those vulvar, vaginal, and anal cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58.

• Vaccination with GARDASIL 9 may not result in protection in all vaccine recipients.

**DOSAGE AND ADMINISTRATION**

• GARDASIL 9 should be administered intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.

  ° For individuals 9 through 14 years of age, GARDASIL 9 can be administered using a 2-dose or 3-dose schedule. For the 2-dose schedule, the second dose should be administered 6–12 months after the first dose. If the second dose is administered less than 5 months after the first dose, a third dose should be given at least 4 months after the second dose. For the 3-dose schedule, GARDASIL 9 should be administered at 0, 2 months, and 6 months.

  ° For individuals 15 through 45 years of age, GARDASIL 9 is administered using a 3-dose schedule at 0, 2 months, and 6 months.

Please read the adjacent Brief Summary of the Prescribing Information.
Human Papillomavirus
9-valent Vaccine, Recombinant

**BRIEF SUMMARY OF PRESCRIBING INFORMATION**

**Indications and Usage**

**Girls and Women**

GARDASIL®9 is a vaccine indicated in girls and women 9 through 45 years of age for the prevention of the following diseases:
- Cervical, vulvar, vaginal, and anal cancer caused by Human Papillomavirus (HPV) types 16, 18, 31, 33, 45, 52, and 58.
- Genital warts [condyloma acuminata] caused by HPV types 6 and 11. And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58:
  - Cervical intraepithelial neoplasia (CIN) grade 2/3 and cervical adenocarcinoma in situ (AIS).
  - Cervical intraepithelial neoplasia (CIN) grade 1.
  - Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3.
  - Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3.
  - Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3.

**Boys and Men**

GARDASIL 9 is indicated in boys and men 9 through 45 years of age for the prevention of the following diseases:
- Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58.
- Genital warts [condyloma acuminata] caused by HPV types 6 and 11. And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58:
- An intraepithelial neoplasia (AIN) grades 1, 2, and 3.

**Limitations of Use and Effectiveness**

The health care provider should inform the patient, parent, or guardian that vaccination does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening. Women who receive GARDASIL 9 should continue to undergo cervical cancer screening per standard of care. Recipients of GARDASIL 9 should not discontinue anal cancer screening if it has been recommended by a health care provider.

GARDASIL 9 has not been demonstrated to provide protection against disease from vaccine HPV types to which a person has previously been exposed through sexual activity.

GARDASIL 9 has not been demonstrated to protect against diseases due to HPV types other than 6, 11, 16, 18, 31, 33, 45, 52, and 58.

GARDASIL 9 is not a treatment for external genital lesions; cervical, vulvar, vaginal, and anal cancers; CIN, VIN, VaIN, or AIN.

Not all vulvar, vaginal, and anal cancers are caused by HPV, and GARDASIL 9 protects only against those vulvar, vaginal, and anal cancers caused by HPV 16, 18, 31, 33, 45, 52, and 58. GARDASIL 9 does not protect against genital diseases not caused by HPV. Vaccination with GARDASIL 9 may not result in protection in all vaccine recipients.

**Dosage**

Each dose of GARDASIL 9 is 0.5-mL.

Administer GARDASIL 9 as follows:

<table>
<thead>
<tr>
<th>Age</th>
<th>Regimen</th>
<th>Schedule</th>
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</thead>
<tbody>
<tr>
<td>9 through 14 years</td>
<td>2-dose</td>
<td>0, 6 to 12 months*</td>
</tr>
<tr>
<td>15 through 45 years</td>
<td>3-dose</td>
<td>0, 2, 6 months</td>
</tr>
</tbody>
</table>

*If the second dose is administered earlier than 5 months after the first dose, administer a third dose at least 4 months after the second dose.

**Method of Administration**

For intramuscular use only.

Shake well before use. Thorough agitation immediately before administration is necessary to maintain suspension of the vaccine. GARDASIL 9 should not be diluted or mixed with other vaccines. After thorough agitation, GARDASIL 9 is a white, cloudy liquid. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use the product if particulates are present or if it appears discolored.

Administer GARDASIL 9 intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.

Observe patients for 15 minutes after administration.

**CONTRAINDICATIONS**

Hypersensitivity, including severe allergic reactions to yeast (a vaccine component), or after a previous dose of GARDASIL 9 or GARDASIL®.

**WARNINGS AND PRECAUTIONS**

**Syncope:** Because vaccines may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following HPV vaccination. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position.

**Managing Allergic Reactions:** Appropriate medical treatment and supervision must be readily available in case of anaphylactic reactions following the administration of GARDASIL 9.

**ADVERSE REACTIONS**

**Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

The safety of GARDASIL 9 was evaluated in seven clinical studies that included 15,703 individuals who received at least one dose of GARDASIL 9 and had safety follow-up. Study 1 and Study 3 also included 7,378 individuals who received at least one dose of GARDASIL 16 as a control and had safety follow-up. The vaccines were administered on the day of enrollment and the subsequent doses administered approximately two and six months thereafter. Safety was evaluated using vaccination report card (VRC)-aided surveillance for 14 days after each injection of GARDASIL 9 or GARDASIL 9.

The individuals who were monitored using VRC-aided surveillance included 9,087 girls and women 16 through 26 years of age, 1,394 boys and men 16 through 26 years of age, and 5,212 girls and boys 9 through 15 years of age (3,438 girls and 1,778 boys) at enrollment who received GARDASIL 9, and 7,078 girls and women 16 through 26 years of age and 300 girls 9 through 15 years of age at enrollment who received GARDASIL 9.

**Injection-Site and Systemic Adverse Reactions:** Injection-site reactions (pain, swelling, and erythema) and oral temperature were solicited using VRC-aided surveillance for five days after each injection of GARDASIL 9 during the clinical studies. The rates and severity of these solicited adverse reactions that occurred within five days following each dose of GARDASIL 9 when compared with GARDASIL in a Study 1 (girls and women 16 through 26 years of age) and Study 3 (girls 9 through 15 years of age) are presented in Table 1. Among subjects who received GARDASIL 9, the rates of injection-site pain were approximately equal across the three reporting time periods. Rates of injection-site swelling and injection-site erythema increased following each successive dose of GARDASIL 9. Recipients of GARDASIL 9 had numerically higher rates of injection-site reactions compared with recipients of GARDASIL 9.

**Table 1:** Rates (%) and Severity of Solicited Injection-Site and Systemic Adverse Reactions Occurring within 5 Days of Each Vaccination with GARDASIL 9 Compared with GARDASIL (Studies 1 and 3)

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<thead>
<tr>
<th></th>
<th>GARDASIL 9</th>
<th>Post-dose 1</th>
<th>Post-dose 2</th>
<th>Post-dose 3</th>
<th>Post any dose</th>
<th>GARDASIL</th>
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<tr>
<td><strong>Girls and Women 16 through 26 Years of Age</strong></td>
<td></td>
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<tr>
<td>Injection-Site Reactions</td>
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<tr>
<td>Pain, Any</td>
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<td>0.6</td>
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<td>0.6</td>
<td>0.6</td>
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<td>Swelling, Severe</td>
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**Girls through 15 Years of Age**

**Injection-Site Reactions**

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<tr>
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**Table 1**: Rates (%) and Severity of Solicited Injection-Site and Systemic Adverse Reactions Occurring within 5 Days of Each Vaccination with GARDASIL 9 Compared with GARDASIL (Studies 1 and 3)
GARDASIL® 9 Human Papillomavirus, 9-valent Vaccine, Recombinant

Table 1 (continued)

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<td>Temperature &gt;102°F</td>
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<td>1.0</td>
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</tbody>
</table>

The data for girls and women 16 through 26 years of age are from Study 1 (NCT00543543), and the data for girls 9 through 15 years of age are from Study 3 (NCT01304498). N=number of subjects vaccinated with safety follow-up n=number of subjects with temperature data Pain, Any=mild, moderate, severe or unknown intensity Pain, Severe=incapacitating with inability to work or do usual activity Swelling, Any=any size or size unknown Swelling, Severe=maximum size greater than 2 inches Erythema, Any=any size or size unknown Erythema, Severe=maximum size greater than 2 inches Unsolicited injection-site and systemic adverse reactions (assessed as vaccine-related by the investigator) observed among recipients of either GARDASIL 9 or GARDASIL in Studies 1 and 3 at a frequency of at least 1% are shown in Table 2. Few individuals discontinued study participation due to adverse experiences after receiving either vaccine (GARDASIL 9 = 0.1% vs. GARDASIL <0.1%).

Table 2: Rates (%) of Unsolicited Injection-Site and Systemic Adverse Reactions Occurring among ≥1.0% of Individuals after Any Vaccination with GARDASIL 9 Compared with GARDASIL (Studies 1 and 3)

<table>
<thead>
<tr>
<th>Girls and Women 16 through 26 Years of Age</th>
<th>GARDASIL 9 N=6398</th>
<th>GARDASIL N=6398</th>
<th>GARDASIL 9 N=6398</th>
<th>GARDASIL N=6398</th>
<th>GARDASIL 9 N=6398</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsolicited Injection-Site Adverse Reactions (1 to 5 Days Post-Vaccination, Any Dose)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pruritus</td>
<td>5.5</td>
<td>4.0</td>
<td>4.0</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td>Bruising</td>
<td>1.9</td>
<td>1.9</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>Hematoma</td>
<td>0.9</td>
<td>0.6</td>
<td>3.7</td>
<td>4.7</td>
<td></td>
</tr>
<tr>
<td>Mass</td>
<td>1.3</td>
<td>0.6</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>1.0</td>
<td>0.7</td>
<td>1.0</td>
<td>2.0</td>
<td></td>
</tr>
<tr>
<td>Induration</td>
<td>0.8</td>
<td>0.2</td>
<td>2.9</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Warmth</td>
<td>0.8</td>
<td>0.5</td>
<td>0.7</td>
<td>1.7</td>
<td></td>
</tr>
<tr>
<td>Reaction</td>
<td>0.6</td>
<td>0.6</td>
<td>0.3</td>
<td>1.0</td>
<td></td>
</tr>
</tbody>
</table>

Systemic Adverse Reactions (1 to 15 Days Post-Vaccination, Any Dose)

<table>
<thead>
<tr>
<th>Boys and Men 16 through 26 Years of Age</th>
<th>GARDASIL 9 N=300</th>
<th>GARDASIL N=299</th>
<th>GARDASIL 9 N=300</th>
<th>GARDASIL N=300</th>
<th>GARDASIL 9 N=300</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsolicited Injection-Site Adverse Reactions (1-5 Days Post-Vaccination, Any Dose)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pruritus</td>
<td>5.5</td>
<td>4.0</td>
<td>4.0</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td>Bruising</td>
<td>1.9</td>
<td>1.9</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>Hematoma</td>
<td>0.9</td>
<td>0.6</td>
<td>3.7</td>
<td>4.7</td>
<td></td>
</tr>
<tr>
<td>Mass</td>
<td>1.3</td>
<td>0.6</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>1.0</td>
<td>0.7</td>
<td>1.0</td>
<td>2.0</td>
<td></td>
</tr>
<tr>
<td>Induration</td>
<td>0.8</td>
<td>0.2</td>
<td>2.9</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Warmth</td>
<td>0.8</td>
<td>0.5</td>
<td>0.7</td>
<td>1.7</td>
<td></td>
</tr>
<tr>
<td>Reaction</td>
<td>0.6</td>
<td>0.6</td>
<td>0.3</td>
<td>1.0</td>
<td></td>
</tr>
</tbody>
</table>

The data for girls and women 16 through 26 years of age are from Study 1 (NCT00543543), and the data for girls 9 through 15 years of age are from Study 3 (NCT01304498). N=number of subjects vaccinated with safety follow-up n=number of subjects with temperature data Pain, Any=mild, moderate, severe or unknown intensity Pain, Severe=incapacitating with inability to work or do usual activity Swelling, Any=any size or size unknown Swelling, Severe=maximum size greater than 2 inches Erythema, Any=any size or size unknown Erythema, Severe=maximum size greater than 2 inches Unsolicited injection-site and systemic adverse reactions (assessed as vaccine-related by the investigator) observed among recipients of either GARDASIL 9 or GARDASIL in Studies 1 and 3 at a frequency of at least 1% are shown in Table 2. Few individuals discontinued study participation due to adverse experiences after receiving either vaccine (GARDASIL 9 = 0.1% vs. GARDASIL <0.1%).

Table 3 (continued)

<table>
<thead>
<tr>
<th>Unsolicited Injection-Site Adverse Reactions (1-5 Days Post-Vaccination, Any Dose)</th>
<th>Injection-Site Hypersensitivity</th>
<th>Injection-Site Pruritus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boys 9 through 15 Years of Age</td>
<td>7.3</td>
<td>1.0</td>
</tr>
<tr>
<td>Unsolicited Systemic Adverse Reactions (1-15 Days Post-Vaccination, Any Dose)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>7.3</td>
<td></td>
</tr>
<tr>
<td>Pyrexia</td>
<td>2.4</td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>1.4</td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>1.1</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>1.0</td>
<td></td>
</tr>
</tbody>
</table>

Serious Adverse Events in Clinical Studies: Serious adverse events were collected throughout the entire study period (range one month to 48 months post-last dose) for the seven clinical studies for GARDASIL 9. Of the 15,705 individuals who were administered GARDASIL 9 and had safety follow-up, 354 reported a serious adverse event, representing 2.3% of the population. As a comparison, of the 7,378 individuals who were administered GARDASIL and had safety follow-up, 185 reported a serious adverse event, representing 2.5% of the population.

Deaths in the Entire Study Population: Across the clinical studies, ten deaths occurred (five each in the GARDASIL 9 and GARDASIL groups) none were assessed as vaccine-related. Causes of death in the GARDASIL 9 group included one automobile accident, one suicide, one case of acute lymphocytic leukemia, one case of hypovolemic shock, and one unexplained sudden death 678 days following the last dose of GARDASIL 9. Causes of death in the GARDASIL control group included one automobile accident, one airplane crash, one cerebral hemorrhage, one gunshot wound, and one stomach adenocarcinoma.

Systemic Autoimmune Disorders: In all of the clinical trials with GARDASIL 9 subjects were evaluated for new medical conditions potentially indicative of a systemic autoimmune disorder. In total, 2.2% (351/15,703) of GARDASIL 9 recipients and 3.3% (240/7,378) of GARDASIL recipients reported new medical conditions potentially indicative of systemic autoimmune disorders, which were similar to rates reported following GARDASIL AHAS control, or saline placebo in historical clinical trials.

Clinical Trials Experience for GARDASIL 9 in Individuals Who Have Been Previously Vaccinated with GARDASIL: A clinical study (Study 4) evaluated the safety of GARDASIL 9 in 12- through 26-year-old girls and women who had previously been vaccinated with at least three doses of GARDASIL. The time interval between the last injection of GARDASIL and the first injection of GARDASIL 9 ranged from approximately 12 to 36 months. Individuals were administered GARDASIL 9 or saline placebo and safety was evaluated using VRC-AIDed surveillance for 14 days after each injection of GARDASIL 9 or saline placebo in these individuals. The individuals who were monitored included 608 individuals who received GARDASIL 9 and 305 individuals who received saline placebo. Few (0.5%) individuals who received GARDASIL 9 discontinued due to adverse reactions. The vaccine-related adverse experiences that were observed among recipients of GARDASIL 9 at a frequency of at least 1.0% and also at a greater frequency than that observed among saline placebo recipients are shown in Table 4. Overall the safety profile was similar between individuals vaccinated with GARDASIL 9 and 305 individuals who received saline placebo in historical clinical trials.
with GARDASIL 9 who were previously vaccinated with GARDASIL and those who were naïve to GARDASIL. Among the exception of numerically higher rates of injection-site swelling and erythema among individuals who were previously vaccinated with GARDASIL (Tables 1 and 4).

Table 4: Rates (%) of Solicited and Unsolicited* Injection- Site and Systemic Adverse Reactions among Individuals Previously Vaccinated with GARDASIL Who Received GARDASIL 9 or Saline Placebo (Girls and Women 12 through 26 Years of Age) (Study 4)

<table>
<thead>
<tr>
<th>Adverse Reaction (1-5 Days Post- Vaccination, Any Dose)</th>
<th>GARDASIL 9 N=604</th>
<th>Saline Placebo N=304</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection-Site Pain</td>
<td>90.3</td>
<td>38.0</td>
</tr>
<tr>
<td>Injection-Site Erythema</td>
<td>42.3</td>
<td>8.5</td>
</tr>
<tr>
<td>Injection-Site Swelling</td>
<td>48.0</td>
<td>5.9</td>
</tr>
<tr>
<td>Oral Temperature (≥38.0°C)*</td>
<td>6.5</td>
<td>3.0</td>
</tr>
<tr>
<td><strong>Unsolicited Injection-Site Adverse Reactions (1-5 Days Post- Vaccination, Any Dose)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection-Site Pruritus</td>
<td>7.7</td>
<td>1.3</td>
</tr>
<tr>
<td>Injection-Site Hematoma</td>
<td>4.8</td>
<td>2.3</td>
</tr>
<tr>
<td>Injection-Site Reaction</td>
<td>1.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Injection-Site Mass</td>
<td>1.2</td>
<td>0.7</td>
</tr>
<tr>
<td><strong>Unsolicited Systemic Adverse Reactions (1-15 Days Post-Vaccination, Any Dose)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>19.5</td>
<td>18.0</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>5.1</td>
<td>1.6</td>
</tr>
<tr>
<td>Nausea</td>
<td>3.9</td>
<td>2.0</td>
</tr>
<tr>
<td>Dizziness</td>
<td>3.0</td>
<td>1.6</td>
</tr>
<tr>
<td>Abdominal pain, upper</td>
<td>1.5</td>
<td>0.7</td>
</tr>
<tr>
<td>Influenza</td>
<td>1.2</td>
<td>1.0</td>
</tr>
</tbody>
</table>

The data for GARDASIL 9 and saline placebo are from Study 4 (NCT01047345). *Unsolicited adverse reactions reported by ≤1% of individuals N=number of subjects vaccinated with safety follow-up For oral temperature: number of subjects with temperature data GARDASIL 9 N=604; Saline Placebo N=304. Safety in Concomitant Use with Meningococcal and Influenza Vaccines: There is limited post-marketing experience regarding co-administration of GARDASIL 9. However, the post-marketing safety experience with GARDASIL is relevant to GARDASIL 9 since the vaccines are manufactured using the same process and have overlapping compositions. Subjects who were determined to be pregnant were instructed to defer vaccination until the end of their pregnancy. Despite this pregnancy screening regimen, some subjects were vaccinated very early in pregnancy before human chorionic gonadotropin (hCG) was detectable. An analysis was conducted to evaluate pregnancy outcomes for pregnancies with onset within 39 days before or after vaccination with GARDASIL 9 or GARDASIL. Among such pregnancies, there were 62 and 55 with known outcomes (excluding ectopic pregnancies and elective terminations) for GARDASIL 9 and GARDASIL, respectively, including 44 and 48 live births, respectively. The rates of pregnancies that resulted in a miscarriage were 27.4% (17/62) and 12.7% (7/55) in subjects who received GARDASIL 9 or GARDASIL, respectively. The rates of live births with major birth defects were 0% (0/44) and 2.1% (1/48) in subjects who received GARDASIL 9 or GARDASIL, respectively.

In one developmental toxicity study, 0.5 mL of a vaccine formulation containing between 1 and 1.5 – fold of each of the 9 HPV antigen types was administered to female rats prior to mating and during gestation. In another study, animals were administered a single human dose (0.5 mL) of GARDASIL 9 prior to mating, during gestation and during lactation. These animal studies revealed no evidence of harm to the fetus due to GARDASIL 9.

Data
Human Data
In pre-licensure clinical studies of GARDASIL 9, women underwent pregnancy testing immediately prior to administration of each dose of GARDASIL 9 or control vaccine [GARDASIL]. [Data from GARDASIL are relevant to GARDASIL 9 because both vaccines are manufactured using the same process and have overlapping compositions.] Subjects who were determined to be pregnant were instructed to defer vaccination until the end of their pregnancy. Despite this pregnancy screening regimen, some subjects were vaccinated very early in pregnancy before human chorionic gonadotropin (hCG) was detectable. An analysis was conducted to evaluate pregnancy outcomes for pregnancies with onset within 39 days before or after vaccination with GARDASIL 9 or GARDASIL. Among such pregnancies, there were 62 and 55 with known outcomes (excluding ectopic pregnancies and elective terminations) for GARDASIL 9 and GARDASIL, respectively, including 44 and 48 live births, respectively. The rates of pregnancies that resulted in a miscarriage were 27.4% (17/62) and 12.7% (7/55) in subjects who received GARDASIL 9 or GARDASIL, respectively. The rates of live births with major birth defects were 0% (0/44) and 2.1% (1/48) in subjects who received GARDASIL 9 or GARDASIL, respectively.

A five-year pregnancy registry enrolled 2,942 women who were inadvertently exposed to GARDASIL within one month prior to the last menstrual period (LMP) or at any time during pregnancy, 2,569 of whom were prospectively followed. After excluding elective terminations (n=107), ectopic pregnancies (n=5) and those lost to follow-up (n=814), there were 1,640 pregnancies with known outcomes. Rates of miscarriage and major birth defects were 6.8% of pregnancies (111/1,640) and 2.4% of live born infants (37/1,527), respectively. These rates of assessed outcomes in the prospective population were consistent with estimated background rates.

In two post-marketing studies of GARDASIL (one conducted in the U.S., and the other in Nordic countries), pregnancy outcomes among subjects who received GARDASIL during pregnancy were evaluated retrospectively. Among the 1,740 pregnancies included in the U.S. study database, outcomes were available to assess the rates of major birth defects and miscarriage. Among the 489 pregnancies included in the Nordic study database, outcomes were available to assess the rates of major birth defects. In both studies, rates of assessed outcomes did not differ significantly compared to the administration of GARDASIL during pregnancy.

Animal Data
Developmental toxicity studies were conducted in female rats. In one study, animals were administered 0.5 mL of a vaccine formulation containing between 1 and 1.5 – fold of each of the 9 HPV antigen types 5 and 2 weeks prior to mating, and on gestation day 6. In a second study, animals were administered a single human dose (0.5 mL of GARDASIL 9) 5 and 2 weeks prior to mating, on gestation day 6, and on lactation day 7. No adverse effects on pre- and post-weaning development were observed. There were no vaccine-related fetal malformations or variations.

Lactation: Risk Summary: Available data are not sufficient to assess the effects of GARDASIL 9 on the breastfed infant or on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for GARDASIL 9 and any potential adverse effects on the breastfed child from GARDASIL 9 or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

Pediatric Use: Safety and effectiveness have not been established in pediatric patients below 9 years of age.

Geriatric Use: The safety and effectiveness of GARDASIL 9 have not been evaluated in a geriatric population, defined as individuals aged 65 years and over.

Immunocompromised Individuals: The immunologic response to GARDASIL 9 may be diminished in immunocompromised individuals.
It’s been a long day. You managed to squeeze in three extra patients—and the only thing between you and the door is a few chart updates. Just as you finish, you are alerted to a new email from what looks like a well-known insurance company, complete with a recognizable logo. You recall your office manager mentioning that this company had recently declined several reimbursement claims. The email refers to you and your office manager by name—and informs you that you can clear up your reimbursement issues if you just click a link and provide some extra information. What do you do?

Many healthcare professionals would click without a second thought—and, in doing so, they might very well be inviting a hacker into their networks via a sophisticated electronic communications scam called spearphishing. These personalized attacks are on the rise in healthcare and can have serious consequences for organizations of all shapes and sizes.

“In today’s day and age, hackers are going after people instead of the technology directly,” says Anahi Santiago, CISM, chief information security officer at Christiana Care Health System in Wilmington, Del. “And the breaches that happen as the result of these attacks not only give hackers access to protected patient data but also the ability to disable networks which, essentially, can disable providers and organizations from being able to effectively care for their patients.”

As noted in Verizon’s 2018 Breach Investigations Report, phishing, a form of cybercrime that uses emails purportedly from a known organization to persuade individuals to provide sensitive data, including passwords or financial information, is linked to more than 90 percent of data breaches—making it the most common attack method for hackers. Parham Eftekhari, executive director of the Institute for Critical Infrastructure Technology, a cybersecurity think tank, says that spearphishing is a more sophisticated form of phishing, targeting a specific organization or individual.

“With phishing, the hacker doesn’t necessarily care who clicks, he or she is casting a wide net in hopes of getting someone to do so,” he says. “But spearphishing uses a tailored lure—a spear, so to speak—to make the email with those links more appealing to a specific victim.”

In a recent American Medical Association (AMA) survey, 4 out of 5 survey respondents said they had been the target of a cyberattack, with more than half of those stating the attack was the result of a phishing lure. Eftekhari says that is not a surprise—and that providers often are an easy mark for hackers because the healthcare environment is so fast-paced.

“Physicians are busy and their focus is on helping patients. There’s more and more technology in practices, and that technology can often be frustrating for them,” he
Technology

Spearphishing

says. “So if they do get an email, and it looks somewhat legit, it’s not surprising they might click and download and execute a malicious payload.”

Few medical schools discuss the ins and outs of cybersecurity, even though medical practice has become more technology-intensive—and hacks can affect both patient safety and patient satisfaction. James Kaplan, MBA, a partner specializing in information technology (IT) infrastructure and cybersecurity for the management consulting firm McKinsey & Company, says that providers should be concerned about the consequences. Those consequences may include the theft of protected health data—and the consequent fines from the U.S. Department of Health and Human Services’ Office for Civil Rights—as well as the loss of the practice’s financial data.

But more concerning is the possibility of being locked out of EHRs or medical devices and IT systems that play a critical role in providing patient care. The AMA survey reported that the majority of physicians who had been hacked suffered up to four hours of downtime, with many reporting they were unable to provide care for an entire day.

PROTECT YOUR ORGANIZATION, PROTECT YOUR PATIENTS

Leslie Saxon, MD, a cardiologist and executive director at the University of Southern California Center for Body Computing, says that protecting an organization from spearphishing and other cyberattacks starts with education about “cyber hygiene,” or common practices individuals and organizations can undertake to help improve network security.

“It’s hard to create awareness, especially since cybersecurity really is a shared responsibility between providers, clinical and office staff, and even patients,” she says. “That’s why the right education is so important. It’s like handwashing or any other hygienic practice. You have to teach the basics throughout the system in order to be successful.”

The AMA has published specific cybersecurity guidelines for physicians on its website to promote proper cyber hygiene. It also recommends that physicians familiarize themselves with cybersecurity recommendations offered by the Department of Homeland Security. Eftekhari says that provider practices can also benefit from contacting IT organizations that likely have local chapters in their area, like the Healthcare Information and Management Systems Society (HIMSS) or the International Information System Security Certification Consortium (ISC2).

“Cybersecurity can be a challenge for smaller organizations—but that’s no excuse not to practice good cyber hygiene,” he says. He explains that organizations like HIMSS or ISC2 have education materials available that can help educate physicians and their staff, and often hold meetings or seminars to help raise awareness of different cyber threats and how to best deal with them. He says they may also be able to connect your practice with a local expert who can train your staff about appropriate cyber hygiene for a fee.

But Santiago says that practices can adopt cyber hygiene basics before any formal training. She says that provider practices should make sure to keep all network systems patched and updated to help protect them from any potential attacks. Some systems can be set to do so automatically. And she says that maintaining good password hygiene is also critical to success.

“With so many technologies in use, I understand why people want to use one password for a bunch of different systems or keep passwords written on a post-it note somewhere,” she says. “But don’t do it.”

Cybersecurity experts recommend that passwords be difficult to guess—no children’s names or birthdays—and at least eight characters long. Santiago recommends using passphrases so they are easy for physicians to remember but difficult for hackers to crack.

“In today’s day and age, hackers are going after people instead of the technology directly.”

—ANAHI SANTIAGO, CISM, CHIEF INFORMATION SECURITY OFFICER, CHRISTIANA CARE HEALTH SYSTEM, WILMINGTON, DEL.
"It’s hard to create awareness, especially since cybersecurity really is a shared responsibility between providers, clinical and office staff, and even patients. That’s why the right education is so important."

— LESLIE SAXON, MD, CARDIOLOGIST AND EXECUTIVE DIRECTOR, UNIVERSITY OF SOUTHERN CALIFORNIA CENTER FOR BODY COMPUTING

“For an electronic health record system, your password could be a phrase like ‘I love to care for patients,’” she says.

But most importantly, Santiago recommends that physicians and clinical staff always slow down and think before they click. “All it takes is one person to click on the wrong link to result in a breach,” she says.

Kaplan says there are several indicators that an email or social media message may be a spearphishing attack in disguise. He says that emails telling recipients they need to click immediately, or have return email addresses or web links with Os replaced with zeros or Ls with ones mean that recipients are likely clicking at their peril. If it is unclear whether the message is legitimate, Santiago recommends logging in to the company’s website or to pick up the phone instead of clicking.

She adds that physicians also need to understand that cybersecurity attacks don’t happen just on laptop and desktop computers. Personal and professional mobile devices can also put their networks—and their patients—at risk.

“Mobile devices are no different than computers. They can be hacked and they can have viruses—many people don’t realize that,” she says. Today, she says, mobile devices often hold more information than desktop computers—and that requires physicians and clinical staff to be vigilant about how they use their tablets and phones. The same guidelines regarding passwords and links apply.

“You really need to guard your phone,” she says. “I like to say ‘treat your phone the same way that you would treat your wallet.’”

What about outsourcing cybersecurity efforts to protect from spearphishing attacks? While many vendors offer cybersecurity solutions, Kaplan says there is often a “security poverty line,” with smaller organizations lacking the resources to hire dedicated information security staff or procure good IT software to support cybersecurity efforts. But with that said, he says that organizations can get some degree of security investment by utilizing cloud-based services.

“When you procure cloud-based services, even if it’s just for your email and calendar, you are also investing in the security infrastructure of the vendor you choose,” he says. “While it doesn’t absolve your organization of responsibility, it does make being more secure less resource intensive.”

There is no one-size-fits-all approach to cybersecurity, but experts agree that good cybersecurity is a community effort. Providers need to make a point of educating and training staff about proper cyber hygiene practices. And as more individuals use their personal devices to interact with EHRs or provide medical information, share those practices with patients, too.

“This is about changing the culture in your practice to promote cyber hygiene and integrate cybersecurity as part of your values,” says Eftekhar. “This goes beyond talking the talk—physicians need to walk the walk to protect their networks and, ultimately, their patients from spearphishing attacks.”
The state of ACOs

Physicians should weigh the pros and cons of participating in accountable care organizations

by JULIE MILLER contributing author

Transitioning the U.S. healthcare system from one driven by volume to one driven by value could take another 15 to 20 years, experts say. For the independent physician, there is ample opportunity to consider a leadership role in the evolution by joining an accountable care organization (ACO).

Federally regulated, fee-for-service Medicare ACOs are setting the standards for value-based payment structures nationwide, and participation remains voluntary. In Medicaid programs, 12 states are actively pursuing ACOs, with another 10 states pursuing the option. In the commercial market, all the large payers have their own versions of accountable care with a variety of benchmarks and reimbursement details. About half of all ACO contracts cover commercial populations, according to consulting firm Leavitt Partners.

David Muhlestein, PhD, JD, chief research officer for the consulting firm Leavitt Partners, says there are approximately 1,000 ACOs in existence, with the majority organized around partnerships between hospitals and physician groups.

Among Medicare ACOs, 30 percent are physician-led, according to the Centers for Medicare and Medicaid Services (CMS). Their collective results indicate quality improvements and notable savings, but value-based models are still evolving. "ACOs are neither super successful nor a disaster," says Muhlestein.

He says a successful ACO needs three key ingredients:

1. Acceptance among staff and clinicians with an acknowledgement that the value-driven delivery model requires significant process changes;
2. Understanding the needs of the population served and the necessary interventions to improve outcomes; and
3. The ability to track, communicate, and share information across the organization—typically through technology interfaces.

Even though pockets of experimentation exist, by and large, providers are still functioning in a fee-for-service structure, Muhlestein says. It’s not so much an indicator of resistance to the ACO concept, but more a reflection of how they’re getting paid.

Here are pros and cons for primary care providers to consider regarding ACO participation.

**PROS**

- **ACO bonus payments can be significant.** In 2017, CMS distributed $780 million in performance payments to ACOs under the Medicare Shared Savings Program (MSSP). In 2016 providers earned $700 million, according to CMS. But ACO participation by itself doesn’t guarantee a bonus.
Muhlestein says about 20 percent of ACOs achieve enough savings to qualify for the extra payments in their first year. Among those in existence for five years or more, about half are sharing savings.

Practices can earn bonus payments from commercial payers as well, but each payer has its own unique model, he says. The population served, care needs, and even geography can factor into how a commercial accountable care contract might be structured.

Cigna, for example, reports that its accountable care program generated $424 million in savings from 2008 through 2016, and participating providers have seen a return on investment of 2-to-1.

Linda F. Delo, DO, owner of Delo Medical Associates in Port St. Lucie, Fla., says her practice is a patient-centered medical home and has earned $22,000 in bonus payments from a Blue Cross plan with a 50 percent shared savings model.

She’s also earning shared savings through participation in Palm Beach ACO (PBACO), which ranks as Medicare’s top performer, based on savings. In 2017, PBACO saved the program $63 million and earned more than $28 million in performance payments. Physician-led, the ACO includes 275 primary care providers and 175 specialists.

**ACOs bring practices closer to patient-centered care delivery.**

Performance data for the MSSP from 2012 through 2016 show that providers are achieving average quality scores of 91 percent, according to CMS. Virtually all ACOs have demonstrated continuous quality improvement, says Elias Matsakis, JD, senior partner of law firm Holland & Knight in Chicago.

And there’s a spillover effect: Practices meeting Medicare’s ACO benchmarks will likely improve care for patients not covered by Medicare. According to Muhlestein, experienced ACOs have been able to change delivery practices, and as they do so, they’re taking on additional value-based contracts.

“Yes, those bonus payments are great, but if you’re doing it just because you think you’re going to get paid, that’s probably not a reason to join an ACO,” Muhlestein says. “You should be doing it because you believe it will actually lead to better care and a better delivery system.”

While patients probably won’t know their care is coming from an ACO, they will notice when they begin receiving new services, such as medication management or nutrition classes for those with diabetes, he says. Because those types of services traditionally weren’t reimbursed, practices didn’t offer them prior to becoming part of an ACO.

**ACOs support independent practice.**

“It’s tough for a primary care provider to sustain alone, be financially solvent, and practice the way he really wants to,” says Sharab Mohamed, MD, an internist in Greenacres, Fla., and a founding member of PBACO. He believes the ACO structure is one of the best ways a practice can remain independent today.

Access to benchmarking data is another benefit of joining an ACO, Mohamed says. PBACO’s participating providers receive detailed performance data on a regular basis, and by understanding their relative progress on cost and quality measures, they can work toward improvement.

Thanks to its larger infrastructure, the organization also can monitor patients across a broader continuum than a single practice could. For example, PBACO can alert providers when an assigned patient presents in an emergency department or is admitted to a hospital.

Delo notes an independent physician practicing as part of an ACO is better positioned for the future and will be able to meet the growing need for population health management, which payers of all types are asking for as a cost-containment strategy.

**CONS**

**Accountable care models require fundamental retooling.**

The biggest challenge for practices implementing value-based care via an ACO is engineering a new business model that achieves the intended goals in quality and cost savings, according to Muhlestein.

Until the advent of value-based payment structures, physician practices and hospitals focused strictly on building volume. It made sense because volume is what gen-
erates revenue in fee-for-service. However, providers today still largely focus on building volume, so many ACOs remain bogged down with fundamental retooling tasks.

“If you still get 90 percent of your revenue through traditional fee-for-service, it’s really hard to invest in a new delivery system that might hurt fee-for-service and take away some of that ongoing revenue,” Muhlestein says.

Transitioning to the value-based model will take years for a practice to achieve, not to mention significant capital investment in care programs and technology support. “It’s not just a little bit of marginal improvements around the edges,” he says. “It’s rethinking the delivery process.”

Matsakis says the biggest differentiator for ACO success comes down to experience. ACOs that have experience in improving outcomes with efficient interventions or pathways to more appropriate sites of care fare better. Those with care coordination and chronic disease management tools will meet more quality benchmarks than will groups of providers that are essentially just rebranding themselves under an ACO label.

“The challenge is to identify and engage the patients to comply with their health directives and ultimately to steer them to lower cost interventions or to quicker access to medical care before a condition becomes too acute,” Matsakis says.

**ACOs are expected eventually to take on downside risk.**

CMS designed a six-year ramp-up for the MSSP, in which Medicare ACOs could gain experience solely with shared savings (upside risk) before taking on both upside and downside risk (shared savings and losses). Recent proposed rules have sought to shorten the transition period from six years to two, while reducing the proportion of savings ACOs would be entitled to keep from 50 percent to 25 percent.

In 2018, 82 percent of ACOs are in Track 1, which has no downside risk. Another 10 percent are in a new, transitional structure known as Track 1+. The Track 1+ option includes limited downside risk for participat-

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**THE BENEFITS OF PHYSICIAN-LED ACOs**

Not all ACOs are created equal, according to Linda F. Delo, DO, owner of Delo Medical Associates, a family practice in Port St. Lucie, Fla. She says that her initial ACO experience was disappointing because the organization offered little support and didn’t follow through with reporting, causing Delo to miss out on some bonus payments.

She ultimately abandoned that ACO but has since found one that is a better fit: Palm Beach ACO (PBA- CO), based in Florida. “They are a large ACO, physician-owned, and they are excellent,” Delo says.

Ranked as Medicare’s top performer in savings, PBACO delivers care to approximately 80,000 Medicare patients as well as another 80,000 commercial insurance beneficiaries who are covered under value-based programs. Some 275 primary care and 175 specialty physicians participate. PBACO is currently in Track 1, but officials say the organization is considering taking on risk in the near future.

“One of the most important things is to go with a physician-owned ACO,” Delo says. “Be sure you’ve got physicians running it with experience in the managed care model. I’m concerned that hospital ACOs have a different focus, which is to make the hospital profitable as opposed to placing emphasis on patient care and cost efficiency.”

Internal medicine, general practice, family practice, and geriatric medicine providers billing with a taxpayer identification number can only participate in one Medicare fee-for-service ACO at a time, as per federal regulations, so making the right choice is imperative.

In 2017, PBACO saved Medicare $63 million, for a total savings of $274 million over its five-year history. Intense engagement among the primary care practices is the most crucial factor contributing to its performance, the ACO’s leaders say.

“We’re not outside investors,” says Sharab Mohamed, MD, a founding member of PBACO, who practices internal medicine in Greenacres, Fla. “We have a stake in the game, and we’re working for ourselves.”

Practices receive quality and cost data regularly, and quarterly performance meetings are mandatory, he says. The communication helps keep the group moving toward benchmark targets—and bonus dollars.
“It took a lot to get the doctors in the field who were working in their own silos to come together and trust that we’re going to do the right thing,” says Lenny Sukienik, DO, an internist practicing in Loxahatchee, Fla., and a founding member of PBACO. “With primary care doctors, there’s a feeling out there that everybody’s out to get you, so getting that trust is the first step.”

Sukienik says there’s no secret as to how PBACO has been able to make the model work. Frequent communication and access to performance data helps the physicians identify opportunities for care improvement and cost savings.

For example, Sukienik has access to Medicare data through an online portal. He supplements his EHR system with real-time patient data to help inform decisions at the point of care, and he relies on the ACO’s app for updates on his patients’ status.

Primary care physicians have long been considered the hubs for comprehensive patient care. For ACOs, primary care is a priority because it lowers costs.

“What we’ve seen over the years is that spending more money does not equal better care,” says Sukienik.

Instead, he advises practices to make more informed decisions by paying attention to data. For example, imaging costs can be avoided if providers don’t repeat services such as MRIs. Quality can be maintained while costs are reduced.

Indeed, that’s the big-picture vision that the ACO model was built upon. “In 2011, no one knew an MRI is 30 percent more expensive at a hospital, but in 2018, no one doesn’t know that in our business,” says Sukienik.
Manage patients with atrial fibrillation to boost payments under MIPS

by LISA A. ERAMO, MA  Contributing author

As many as six million people in the United States have atrial fibrillation (Aﬁb), a quivering or irregular heartbeat, and this number continues to increase with an aging population, according to the Centers for Disease Control and Prevention (CDC).

There’s another driver of Aﬁb patients: Health and ﬁtness wearables, most notably the newest Apple Watch Series 4 set to include an FDA-approved built-in EKG sensor.

“There’s a tsunami of Aﬁb patients coming,” says Jim Collins, CPC, physician educator and chart auditor with Cardiologycoder.com Inc. in Saratoga Springs, N.Y. “We’ll be more aware of patients with Aﬁb who are completely asymptomatic. These are individuals who would have never sought medical therapy if it weren’t for their smart watch telling them to contact their physician.”

James Allred, MD, a cardiologist and CEO of CV Remote Solutions, a remote monitoring consulting company in Greensboro, N.C., agrees. “I think we’ll see an explosion in the detection of patients with atrial fibrillation over the next few years, and there’s a huge opportunity for internal medicine,” he says.

Rising numbers of Aﬁb present primary care physicians, many of whom make the initial diagnosis, with opportunities to prescribe heart rate-controlling and/or anti-coagulant medication as quickly as possible to prevent costly ED visits and hospitalizations. Doing so not only improves outcomes, but can also boost payments under the Medicare Access and CHIP Re-authorization Act of 2015 (MACRA), the federal law that seeks to reform Medicare payments while improving outcomes and reducing costs.

Beginning in 2019, physicians in the Merit-based Incentive Payment System (MIPS), one of two participation tracks under MACRA, will be penalized if their costs exceed anticipated amounts or rewarded for keeping costs under the projected amounts.

By prescribing warfarin or another FDA-approved anti-coagulant medication for certain patients with non-valvular Aﬁb or atrial flutter, physicians choosing to report on related MIPS measures may boost their quality scores and receive a ﬁnancial bonus.

With MIPS, reducing costs is critical, says Collins. Medical costs for individuals with Aﬁb are more than $8,000 higher per year than for individuals without it. Aﬁb causes more than 750,000 hospitalizations each year and costs the United States approximately $6 billion annually, according to the CDC.

“Everybody will hit that button saying they prescribed warfarin or another anti-coagulant. That’s basic medicine,” says Collins. However, he adds, to win under MIPS, physicians also need to reduce costs, meaning they must ensure that their patients cost less to treat, on average, when compared with other providers in their specialty.

ASSESS RISK FOR A THROMBOEMBOLIC EVENT

Physicians gain points under MIPS when they use the CHA2 DS2-VASc assessment to determine risk for patients with non-valvular Aﬁb or atrial flutter. This assessment addresses certain risk factors, including congestive heart failure, hypertension, age (65 or older), diabetes mellitus,
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Managing atrial fibrillation

Santa Maria, CA—A new quality measure designed to assess whether patients with atrial fibrillation (Afi b) are receiving optimal anticoagulation care is being tested for inclusion in the Merit-based Incentive Payment System (MIPS) under the 2019 Alternative Payment Models (APM) incentive payment program.

As part of the APM program, Medicare patients with Afi b who have normal kidney function are to be included in the MIPS measure if they have received a score of one or greater, per the recently released Clinical Quality Measure Specifications 2019 (http://tinyurl.com/5vmsffk) document draft.

PRESCRIBE MEDICATIONS, MONITOR INRS

Novel anti-coagulants should be the first line of defense for patients with non-valvular Afi b who have normal kidney function, says Allred. “Warfarin has a higher risk for intracranial bleeding, and there are more drug interactions and food interactions with warfarin than the newer drugs,” he says. “You also need to monitor warfarin frequently.”

However, one challenge is that newer anti-coagulants are expensive, says Nitin Damle, MD, an internist at South County Internal Medicine in Wakefield, R.I. and past president of the American College of Physicians. He frequently refers patients to drug manufacturer coupons and rebate programs.

“If the drug companies would price these medications appropriately to begin with, we wouldn’t need to jump through all of these hoops to help patients get discounts,” he adds.

Warfarin costs as little as $4 while Xarelto, a newer anticoagulant, is at least $424.69, according to GoodRx.com.

Even though warfarin requires frequent INR monitoring, Melissa Lucarelli, MD, FAAFP, a primary care physician in Randolph, Wisc., uses a fingerstick INR machine so she can check patients’ levels at the point of care and receive immediate results.

“We have standing orders saying that if patients are between two and three, they stay on their same dose for four weeks,” Lucarelli says. “If they’re outside of that range, then someone contacts me while the patient is still in the office so I can address the dosing.”

Some of Lucarelli’s patients—particularly those that are immobile—also use a home INR monitoring machine. She’s able to bill for setting up this service using CPT code 93792 (patient/caregiver training for initiation of home INR monitoring) that pays $55.08 on average. She reports anticoagulation management every four weeks using CPT code 93793 that pays approximately $12.24 on average.

COORDINATE CARE WITH CARDIOLOGISTS

For patients with symptomatic Afi b, best practice is to involve a cardiologist as soon as possible, says Allred. “Our ability to achieve and maintain normal rhythm decreases the longer the patient is in a-fib,” he adds.

Damle consults with cardiologists frequently to identify the optimal course of treatment—chemical or electrical cardioversion versus ablation therapy. Cardiologists also help him determine whether warfarin, coumadin, or a new anticoagulant is the best option to manage atrial fibrillation.

Documentation tips for Afi b

Jim Collins, CPC, physician educator and chart auditor with Cardiologycoder.com Inc. in Saratoga Springs, N.Y., says physicians can ensure accurate payment for treating patients with Afi b by including the following five elements in their documentation:

Current medications
This list must include warfarin or another FDA-approved anticoagulant drug.

Afi b vs. atrial flutter
To ensure specificity, document the following:
- Type of Afi b (i.e., paroxysmal, persistent, chronic, or unspecified)
- Type of atrial flutter (i.e., typical, atypical, or unspecified)

Risk of a thromboembolic event
Patients with low risk of a thromboembolic event (i.e., those with a CHA2 DS2-VASc risk score of 0 or 1) are excluded from the MIPS measure. Physicians must document either the numeric score or all of the individual risk factors assessed to support an assessment of the CHA2 DS2-VASc score.

Comorbidities
Obesity, sleep apnea, and hypertension frequently contribute to Afi b and atrial flutter and may generate higher payments in some risk-adjusted payment models.

Other MIPS exclusions
Document any of the following, when applicable:
- Comfort care (i.e., those receiving hospice, palliative, and supportive treatment for a terminal illness or who have refused life-sustaining treatment)
- Transient or reversible cause of Afi b (e.g., pneumonia, hyperthyroidism, pregnancy, or cardiac surgery)
- Medical reason for not prescribing warfarin or another FDA-approved anticoagulant (e.g., atrial appendage device in place)
- Patient reason for not prescribing warfarin or another FDA-approved anticoagulant
- System reason for not prescribing warfarin or another FDA-approved anticoagulant (e.g., patient is currently enrolled in a clinical trial for treatment of Afi b or atrial flutter)
Managing atrial fibrillation

option given the patient’s other comorbidities.

“We want to try and discourage internists from practicing in a silo and taking care of these Afib patients on their own,” says Allred. “By partnering with a cardiologist, they’ll also see a bigger savings because patients will be in normal heart rhythm, feeling well, and not in the ED or hospital.”

CREATE AN AFIB CLINIC

Another way to reduce costs is to create an Afib clinic in which patients have immediate access to a dedicated provider. This is often a nurse practitioner or physician assistant who can advise patients when they start to experience symptoms of the condition, says Allred, who runs a dedicated clinic in his own cardiology practice and provides consulting services around creating similar care models.

Allred’s clinic, which is staffed by a nurse practitioner who sees 15-30 patients daily, resulted in an 8% reduction in ED visits over the course of one year.

“I’ve seen a dramatic decrease in ED visits and hospitalizations when patients are managed in an Afib clinic,” says Allred.

“These clinics are a fairly new concept, but they can really help you win the MIPS game,” says Collins. Here’s how: Even though frequent outpatient visits and labs may add several hundred dollars on the ambulatory side, they reduce costs on the inpatient side—costs that often exceed $10,000 for a single Afib-related hospital admission or $100,000 or more for a stroke-related admission, he adds.

Afib clinics also make it easier to focus more aggressively on lifestyle modification that can reduce the impact of the condition, such as weight management, sleep apnea management, and tobacco and alcohol cessation counseling, says Allred.

Having a dedicated Afib clinic may also make it easier to bill for services such as transitional care management and chronic care management, says Collins.

CONSIDER REMOTE MONITORING

Remote monitoring cardiac devices (e.g., pacemakers, defibrillators, and implantable loop recorders) can also reduce costs, improve outcomes, and generate additional revenue, says Collins. In particular, physicians can report CPT code 99091, which denotes the collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified healthcare professional requiring a minimum of 30 minutes. This code pays an average of $58.68.

PROVIDE PATIENT EDUCATION

Setting patient expectations about Afib management is an important part of cost savings. “Afib is a lifelong disease state, but it’s not life threatening unless you have a stroke,” says Allred. “We need to give patients a plan for the next time they have Afib—as-needed medicines and what to do when symptoms arise. It’s about helping patients learn to live with their disease.”

FOCUS ON ADHERENCE

Medication adherence can also reduce costs, says Damle. South County Internal Medicine is part of an accountable care organization that has hired a part-time (two days per week) pharmacist who checks in with patients every few months. “They report back to us so we can make sure the patient is on the right medication and dosage and is taking that medication appropriately,” Damle explains. “This prevents additional ED visits and hospitalizations.”

Seven important Afib and atrial flutter ICD-10-CM diagnosis codes to know

The following seven Afib and atrial flutter ICD-10-CM diagnosis codes drive relevant MIPS measures:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I48.0</td>
<td>Paroxysmal Afib</td>
</tr>
<tr>
<td>I48.1</td>
<td>Persistent Afib</td>
</tr>
<tr>
<td>I48.2</td>
<td>Chronic Afib</td>
</tr>
<tr>
<td>I48.3</td>
<td>Typical atrial flutter</td>
</tr>
<tr>
<td>I48.4</td>
<td>Atypical atrial flutter</td>
</tr>
<tr>
<td>I48.91</td>
<td>Unspecified Afib</td>
</tr>
<tr>
<td>I48.92</td>
<td>Unspecified atrial flutter</td>
</tr>
</tbody>
</table>
The New Yorker

BY CATHERINE HAMBLEY, PHD

FOR THE STRESSORS THAT YOU CANNOT CONTROL

(i.e., EHRs are here to stay), here are some brain resilience practices to consider.

Focus on your mindset. We all have a negativity bias—our brains are wired to pay more attention to threats and negative experiences, to feel them more intensely, and to remember them more than we do the positive. And under conditions of stress, that negativity bias becomes even stronger, further exacerbating stress. It manifests in what gets our attention and what we focus on, whether it be outside events or in our self-talk. We need to be intentional about combating negative bias by deliberately noticing the good stuff and by “catching” ourselves and others doing things right. Frequent, specific, and genuine appreciation and acknowledgement goes a long way. Create positive expectations, express gratitude, and believe in yourself and others.

Be present: A Harvard study found that the more time people spend in what is termed the “narrative” or “default” mode of thinking, where our minds are focused on the past, the future, planning, social interactions, etc., the less happy we are. The more time spent in “direct experience” mode where we are focused on what is happening in the moment, the happier we are. So stay present—you, your staff, and your patients will appreciate it.

Sleep: This is one of the most critical factors impacting our ability to cope with stress, especially ongoing stress. Aim for 7 to 8 hours a night and remember the strategies for getting a better night’s sleep—avoid alcohol before bedtime and excessive caffeine, limit exposure to light-emitting devices (like your computer!) before bed, exercise during the day, and spend time outdoors.

Exercise: You know the physical and emotional benefits of regular exercise. Did you also know that it is associated with improved cognitive functioning, neuroplasticity, and enhanced social connections? Exercise helps prevent aging effects in the brain because it encourages release of brain derived neurotrophic factor (BDNF) helping to strengthen the telomeres on chromosomes.

Diet: Fasting and caloric restriction are also associated with BDNF production and tends to improve mood, sleep, and life satisfaction. Even going 12 hours of fasting between dinner and breakfast can help.

Meditate and practice mindfulness: The evidence is convincing—developing a regular habit of meditation lessens amygdala reactivity and strengthens emotional regulation. That adds up to lessening the negative impact of stress and improved coping.

Laugh: It really is good medicine. Laughter helps build brain resiliency and improves cognitive functioning.

Catherine Hambley, PhD, is a consulting psychologist who offers brain-based strategies to organizations, leaders, teams, and healthcare providers.

HOW TO MINIMIZE EHR-INDUCED STRESS

It may not be surprising to hear that the rate of physician burnout is on the rise. What might be particularly surprising is the cause.

Work-life balance has typically been identified as the primary culprit, but now burnout is more often linked directly to time spent engaged in computer documentation. A recent article in The New Yorker titled “Why Doctors Hate Their Computer” describes the impact that computerization has had on physicians. The author highlights two alarming statistics: one is that healthcare workers spend twice as much time on the computer as they do interacting with patients. The other is that the average workday for family physicians is now 11.5 hours—this is mostly attributed to the need to be behind a computer screen.

Computerized records are not going away, so it is imperative that the healthcare profession develops strategies to mitigate and cope with the stress EHRs are causing. To do so, first identify what factors you have some level of control over and those that you do not.

FOR FACTORS YOU CAN CONTROL:

1. Brainstorm new ways that your staff can get more involved in easing the burden of documentation-related responsibilities. Maybe they can take on new responsibilities that not only help you, but also provide opportunities for their own professional growth and development.

2. Prioritize face time with your patients. While there is expense involved in hiring a scribe, the rewards may far outweigh the costs by giving you more quality time with patients, lessening the amount of time you spend documenting, and allowing you to spend less time at the office.

3. Acknowledge to staff and patients that you understand their frustration—labeling emotions helps mitigate their impact.

4. Prioritize off-time—you need time to unwind, relax, travel, be with family, and so on.
“It’s up to the patient, not us, to do the work. Sometimes we hold ourselves to a higher position than we should.”

AUGUSTE FORTIN, MD, MPH, INTERNIST, NEW HAVEN, CONN.

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“I’ll practice until the river rises. What else can I do?”

JAMES HUTCHINSON, MD, FAMILY PHYSICIAN, SAN MATEO, CALIF.

PAGE 12

$6 billion annual cost of treating atrial fibrillation in the U.S., according to CDC

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