THE CYBER THREAT

Three ways hackers will attack—and how to stop them

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THE CYBER THREAT
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How to defeat the cyber threat

Right now, there’s a good chance a cybercriminal wants to break into your practice. Emails are being sent in the hope one of your employees will click on a link that will install ransomware, hackers are exploiting security flaws in medical equipment with internet connections, and information is being gathered from social media to trick staffers into revealing patient or financial records.

As a result, physicians must be more vigilant than ever to protect their patient data. Our cover story in this issue explains the three major ways hackers will try to breach your cyber defenses.

Cybercriminals have many resources and are highly knowledgeable about how technology works and its vulnerabilities, experts say. But they also tend to take the path of least resistance, meaning the harder they have to work to hack a practice, the more likely they are to move on to an easier target. As the bad guys re/shape their tactics, practices must continue to be vigilant, especially against the most common threats.

“You can’t just throw your arms up and say there’s nothing that can be done,” Rob Tennant, the director of health information technology policy for MGMA, told our editors.

Speaking of risks, in this issue we also examine other risks that physicians deal with in their career, including the malpractice threat, and speak to experts about how to mitigate those risks, and secure the financial future of both yourself and your practice.

In addition, this issue features articles covering:

- Practical tips for engaging with patients during an exam;
- The latest solutions for patients for dealing with chronic pain; and
- An interview with a researcher on how primary care has lost its way, and what can be done to reclaim it for physicians and patients.

As always, if you have feedback on our content, story ideas, or would like to contribute to Medical Economics, please reach out to our editors at medec@mmhgroup.com.
visits to primary care doctors have been falling for decades in the U.S., and rising out-of-pocket costs are the main, although not the only, reason why.

That is the conclusion of two recent studies of trends in visits to primary care physicians (PCPs). It calls into question the widely-held assumption among policymakers that lack of insurance is the main obstacle patients face in seeking primary care.

One of the studies, published in *Annals of Internal Medicine*, focuses on trends in visits to PCPs among a cohort of people age 18 to 64 enrolled with a national commercial insurer between 2008 and 2016. The authors examined records of 1.42 million primary care visits among 94 million member-years (defined as the total number of months those in the study were enrolled divided by 12).

After adjusting for changes in age, income and location among enrollees, the study found a 24 percent decline in PCP visits. Moreover, by the end of the period, 46 percent of the people in the study had no PCP visits in a given year, up from 38 percent at the start of the period.

The authors offer three possible explanations for the trend: first, that patients are becoming more comfortable with going online to get information for addressing non-acute needs. Second, more adults are enrolled in commercial plans with deductibles and/or copays for primary care visits and the payment amounts required for both have been increasing, thus discouraging people from seeking care.

The third possibility is that patients are replacing PCP visits with visits to specialists, or obtaining primary care at urgent care centers, retail clinics, or via telemedicine.
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Why doctors and patients are dissatisfied
Any talk about cybersecurity in healthcare will undoubtedly cover one or more of a hacker’s favorite tactics: Ransomware, phishing, or exploiting poor device security.

While none of these threats are new, they continue to pose major risks to medical practices, partly because they are often not taken seriously enough by practice owners who think they will not become a target, according to experts.

“For hackers, money is the motivation,” says Kevin Haynes, chief privacy officer for Nemours Children’s Health System in Orlando, Fla. Hackers want patient’s health records because they can use them to order medical supplies or bill payers for services that weren’t provided.

A younger patient’s social security number might be used for years for fraudulent activity before anyone realizes it’s been compromised. “Small practices don’t have the same tools to manage risk, but they do retain personal information that can make cybercriminals money,” says Haynes.

Audrius Polikaitis, CIO of UI Health in Chicago, says that health records are one of the hottest commodities on the black market, with a single record able to fetch $200 to $300, compared to $15 to $20 for a credit card number. “For anyone who maintains health records, we all face the same risks and challenges,” says Polikaitis. “From a small practice...
perspective, there is no reason to think that your records are any less valuable than those from a university or larger health system.

A practice’s vulnerability to hackers can create a risk for business disruption, a loss of reputation if a breach occurs, or even hefty HIPAA fines if health records are compromised.

“As larger organizations improve their defenses, I think there is a distinct possibility that hackers move downstream to smaller practices,” says Polikaitis. “Like a house, if someone wants to break in to your network, they’ll find a way. You just need to make your house less attractive to thieves than your neighbor’s.”

Experts say practices can reduce their risk of being hacked by taking some basic preventative measures and educating staff on the most common threats.

Ransomware
Ransomware receives a lot of publicity because it has crippled some high-profile health systems and government agencies in the last several years. When ransomware hits a network, all its files are encrypted and held hostage, effectively shutting down the organization until either a ransom is paid—usually in Bitcoin—to release the encrypted files, or backup files are brought online to replace the encrypted ones.

“Ransomware seems to have died down slightly, but that doesn’t mean it’s something a practice doesn’t need to be vigilant about,” says Rob Tennant, director of health information technology policy for the Medical Group Management Association. “The most important thing is to make sure you have a very good backup system. If you had to shut down your server and start from scratch, it wouldn’t be pleasant, but it wouldn’t affect patient care, and that’s critical.”

“The bottom line is that when you suffer a ransomware attack, you only have two options to get your data back—have an up-to-date backup of your affected systems or pay the ransom,” says Cesar Cerudo, chief technology officer at IOActive, a Seattle-based cybersecurity firm. “Unfortunately, despite the wave of ransomware attacks, many hospitals and medical practices still don’t have a good backup policy, making paying seem like the easiest and cheapest option.”

Haynes says that while ransomware is still the biggest threat, staff awareness and software that identifies and blocks attacks are starting to have a tangible effect. Polikaitis agrees, noting that while detection and technology that isolates malicious attachments are improving, having backups is still vital.

Phishing
Many of the biggest cyber threats are delivered directly to a physician’s or staff member’s inbox via email. Attachments with malicious code only require the recipient to click on a link to activate software that might do anything from launching a ransomware attack to stealing financial information stored on a server.

For hackers, the biggest challenge is getting someone to click on the link, and the best way they’ve found to do that is through what’s known as phishing: pretending to be a trusted source so as to not arouse suspicion. Several years ago, the attempts were easier to identify, because the emails often had misspellings or looked unprofessional.
and not work related.

"Now, they are getting more sophisticated," says Tennant. "There are no misspellings, the tone is right, and the sender’s email address looks legitimate." Emails might also include logos or other branding information to add legitimacy.

It’s these advanced phishing attempts that worry Polikaitis the most, because the average person won’t necessarily be suspicious. "The real good emails are where someone has taken the time to look at the organization and the person," Polikaitis says. "Relationships are their favorite angle to use. Two years ago, there was an email that made it look like a CFO was sending their direct report requests for things. Whoever sent it took the time to understand that relationship."

Serious hackers will take the time to study staff lists on web pages and look at profiles on social media, including LinkedIn, where they can learn more about an organization’s hierarchy. With that information they can construct an email that looks like it’s from a person in charge and direct it to someone who might ordinarily receive emails from that person.

"The bad guys expect that people are busy and won’t pay too much attention, and that they have more email than time and are just ripping through them," says Polikaitis.

"Unfortunately, smaller practices don’t have the same security tools to warn users and social engineering is becoming easier to exploit due to consumers freely sharing their personal details publicly," says Haynes.

There are strategies practices can use to lower their risks from phishing attacks.

“If you have someone on staff that is an IT expert and you’re not sure about a message, send it to them to take a look,” says Tennant. "Don’t open or click on attachments that you are not sure about. If the person included a phone number, call them and ask them to verify. Pay attention to details like return email addresses and pause to think whether a request makes sense. "If a message doesn’t look right, assume the worst."

Haynes says using a third-party email provider, such as Office 365 or Google, can help reduce the number of phishing emails that get through to a practice.

CONNECTED DEVICES

Connected medical devices offer yet another path of attack for hackers.

If a medical device, no matter how innocuous, is connected to the internet, it is potentially connected to the internet, it is potentially...
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*Source: https://phoenixnap.com/blog/healthcare-cybersecurity-statistics
vulnerable to hackers, experts say. "Connected devices are a whole new concern," says Polikaitis. "We all want the devices to output data so it can be collected and used for daily patient care or research, but if they are connected, the bad guys can get in and do nefarious things." An IV pump could have its rate changed, or an image could be altered to show a tumor—or have the evidence of one removed.

“You need a list of security questions to ask your vendors,” says Tennant. He advises asking them about how the devices are protected, what are their vulnerabilities, what should be done if they are hacked, and if there are backups to any critical information. The practice also needs to consider how to provide continuity of care if a device is compromised.

Polikaitis says that vendors may claim the devices are FDA-regulated, and therefore they can’t update anything. “The vendor may try to hide behind that, but it isn’t true,” he says. For older devices with little security, vendors need to go back and look at how the devices were installed and reconfigure them to offer the most protection possible.

EDUCATION AS A BROAD DEFENSE
Cyberthreats are varied and constantly evolving. Each time an effective defense is developed, hackers find a new way to exploit a network vulnerability. While this cycle of measures and countermeasures is being waged across the globe, doctors just want to take care of patients and not have to be cybersecurity experts on top of their other responsibilities.

Experts say that the best defense a practice can use is continual education and reminders to staff about the dangers of clicking on links in emails and how to identify ones that may be phishing schemes.

“We do mock phishing attacks three to four times a year,” says Polikaitis. “We send them out and see who clicks on them and then follow-up with education.” There are companies who can provide this service to practices who can’t do it in-house.

He says it is important not to approach the process in a punitive manner, but to keep pushing the educational aspect, even if the results are disappointing at times. For example, Polikaitis sent a fake phishing email with a link to 6,000 health system employees asking for usernames and passwords. About 600 clicked on the link and 150 provided their username and password.

“Despite all our educational push, we still got a fraction that gave up their credentials,” he says. “I’m still amazed people fall for that, but continual education is important.” If the same people continue to click on dangerous links despite being warned not to, then the physician or practice administrator will have to assess whether that person is worth the risk they are introducing to the practice.

“It’s the human being that’s indispensable, but also introduces the greatest risks to the organization through what they do,” Polikaitis says.

Haynes says education is the easiest low-or no-cost way to stop hackers. “Spend more time on keeping the medical practice staff aware of threats and vulnerabilities on the systems they use every day—the internet, email, and phones.”

As technology continues to change healthcare, the cyber risks will always be there. “It’s part of the cost of living in a connected society,” says Polikaitis. “There are a lot of benefits to sharing data between institutions, but there is a cost to it and new risks are introduced with sharing of that data.”

“Small practices don’t have the same tools to manage risk, but they do retain personal information that can make cybercriminals money.”

— KEVIN HAYNES, CHIEF PRIVACY OFFICER, NEMOURS CHILDREN’S HEALTH SYSTEM, ORLANDO, FLA.
We’ve come a long way in medicine over the last decade, but the struggle to merely access quality health services for the 15 to 20 percent of patients who live in rural areas across the United States remains real, leading to frustration and serious health consequences.

The good news is, recent surges in telehealth deployments from healthcare organizations around the country are providing a pathway to better and more accessible care, especially for people in rural areas.

Ultimately, the greatest impact will be realized when providers can convince their patients and the community at large of the benefits of virtual care—to do things like engage a specialist or simply ensure on-demand access no matter how far a patient may be from a provider.

Here are four best practices to consider when developing a rural telehealth strategy.

1. **Put patient engagement first**
   When the health system Avera sought to implement a telehealth solution, it hoped to provide support for multiple use cases beyond urgent care and enable patient access via multiple end-points (e.g., mobile, web, kiosk) to ensure a high-quality online care experience—one that would encourage patient participation and engagement.

   Putting the patient experience first through telehealth enabled Avera to grow. Since launching AveraNow in the summer of 2015, Avera has seen patient enrollments and visits increase.

2. **Tailor telehealth to patient preferences**
   The best way to secure buy-in from patients is to design a telehealth program that caters to their specific needs. For example, 67 percent of patients ages 55 and older are willing to try virtual care for chronic care visits, according to American Well’s Telehealth Index: 2019 Consumer Survey. Practices that see a high number of seniors, therefore, need their telehealth platform to support chronic care management.

   For middle-aged patients, on the other hand, emphasizing the ability of telehealth to support prescription renewals is key, given the fact that 42 percent of consumers ages 45 to 54 who use mobile health apps rely on pharmaceutical apps, according to the same survey.

3. **Don’t feel you have to do it alone**
   If cost is a barrier to implementing telehealth, look for opportunities to partner with health plans that are already using telehealth. More and more health plans are investing in telehealth and encouraging their provider partners to collaborate and use telehealth as part of value-based contracts.

   When health systems are willing to partner and bring concrete success metrics to demonstrate ROI, health plans are eager to collaborate. Working directly with a health plan’s telehealth solution also gives providers the opportunity to test the waters before investing in their own technology.

4. **Collaborate with specialists**
   Patients requiring care from a variety of providers are greatly challenged in rural areas, especially when providers are not located near one another.

   Collaborating with specialists to streamline healthcare by offering consultations through a single platform ensures patients get the care they need in a timely, efficient manner while dramatically expanding the breadth of services available for in rural areas.

The future is bright
Historically, limited access to high-speed internet has been a barrier to telehealth implementation in rural communities. But access to high-speed broadband Internet is growing. As rural healthcare organizations embrace telehealth, now is the time to consider what is needed to create a value proposition for rural residents and physicians that improves quality, stretches limited resources and elevates care across the continuum. 

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**Mike Baird** is president, customer solutions, American Well and former CEO, Avizia. **Deanna Larson** is CEO, Avera eCARE. Send your tech questions to medec@mmhgroup.com.
Increasing value when negotiating with payers

by JORDAN ROSENFIELD Contributing author

Increasingly, payers are adopting a take it or leave it approach in contracts with physicians in the value-based marketplace, putting physicians in a tough spot. What can physicians do to show their value and increase their power in negotiations?

Experts say physicians will have to get creative, by partnering with health plans to achieve common goals, and finding ways to grow market share—and leverage.

“It helps if you can position yourself as a partner versus a vendor,” says Joe Caruncho, JD, CEO of Genuine Health Group in Miami, Fla., a management company that helps physicians make the transition to value-based care.

BECOMING A PARTNER

Caruncho says that physicians can achieve that partner status and increase their value by figuring out what the health plan’s strategic initiatives and focus are, and by offering to help the health plan achieve some goals in exchange for a better rate or shared profits.

“These days they’re competing on quality measures,” Caruncho says. “It’s not about [which payer] can provide the cheapest, it’s about who can increase their four-and-a-half-star plan in the market and get the best reputation. That’s how they compete for membership.”

Then, he says, the physician and the payer can work together to share in either cost savings or added revenues that result because the physician helped the plan increase its ratings, and as a result, its physicians may be getting more money from Medicare and/or more patients.

Caruncho describes this idea of treating the physician payer partnership as “a paradigm shift” from simply expecting payers to pay money for services to one of joining forces with the payer to achieve better results, higher quality, and reduced costs.

“Having a relationship with a health plan where you share in the profits is a lot more lucrative while also practicing great medicine.”

Joe Wagner, director of BRG’s Healthcare Performance Improvement practice, in San Francisco, Calif. agrees. “One thing physicians can do is to demonstrate the ability to improve or work on quality measures that are important either to a commercial payer or to the government,” he says.

Wagner says this can be done through such
means as analytics that identify through their care experience patients that are important for outreach, and patient navigation hubs that direct patients to the right services.

"Patient navigation hubs allow the provider to do outreach with identified patients, where the physician dedicates resources to the important quality measures, schedules appointments based on those measures the program deems are important to quality care of patients and then conducts those services so you actually improve the overall care that’s been delivered,” Wagner explains.

TAP EXISTING LEVERAGE
There are other scenarios where physicians may already have greater leverage than they realize or could build leverage through redesigning their practices.

“Plans need to be compelling to their purchasers, namely individuals and employers. If a health plan is missing a provider that makes it [not] compelling, it may not be very viable in the marketplace,” says Adam Powell, Ph.D, president of Payer+Provider Syndicate, a management advisory and operational consulting firm in Boston, Mass.

In some instances a provider may have one of several advantages. First, he says, the provider may be so highly regarded in a community that it would be difficult for the payer to attract patients to their plan without that provider network.

More negotiation tips

by Melissa Lucarelli, MD
Contributing author

Do your homework
Before I notified a payer that I wanted to renegotiate, I gathered meaningful data, including how much they were paying us as a percentage of our charges and how that compared to our other commercial payers. Sharing this data with them gave me powerful ammunition, and the confidence to call their bluff.

Tell them what makes your practice special
To a giant commercial insurer, your small practice is just one of many they contract with. They are not going to know what makes you special—and why they should pay you more—unless you show them.

I told this payer about their sponsored quality initiatives in which we participate. I emphasized the specific recognitions we had received for quality care from their organization and the fact that we are the only family practice in a 15-mile radius that is an in-network provider for their product.

In addition, I took what may have been perceived as negotiating weaknesses—our size and location—and tried to turn them into advantages. I pointed out that small, rural practices like mine are important to employers outside of major metropolitan areas, and these employers often have strong loyalty to their community and local physician practices. Treating my clinic well creates a favorable impression among those employers and increases business for the payer.

Don’t be afraid to ask for what you need, or want
In my experience, most physicians are willing just to “go with the flow.” They want their professional relationships to be simple and non-confrontational. So when a payer presents them with a contract and tells them nothing in it is negotiable, they sign. This is a big mistake.

I recall a talk from a contract lawyer during the practice management part of my residency. He said there’s no such thing as a non-negotiable contract. You can always do an addendum or rider. It never hurts to ask. The worst they can say is no.

Be open to trade-offs
A payer may not be able to negotiate some items due to corporate policy or regulatory restrictions, but they might be able to make a change in another part of the contract that will make up for it. A negotiated agreement is seldom going to end up exactly the way you want it to. The trick is to know when it’s good enough, and how much the time spent in additional negotiation is worth to you.

Have a backup plan
Negotiating major payer contracts can be very anxiety-provoking. At times, I have felt that if I lost a contract my entire practice could fail. But there is nearly always an alternative, and if you haven’t discovered what it is, then you shouldn’t be negotiating yet.

It’s just business
I’m not friends with the provider network person I negotiated with, but our relationship was cordial and business-like. Negotiating shouldn’t be emotional, but removing emotion from the process takes practice.

Melissa Lucarelli, MD, is a family physician, medical director and owner of Randolph Community Clinic, a rural primary care clinic in South Central Wisconsin. She is a member of the Medical Economics Editorial Advisory Board.
He cites the example of Tufts Medical Center in Boston, which is so well regarded an insurer would have trouble selling its plans without keeping Tufts in network.

Second, a provider may have what Powell calls a “local monopoly,” which often happens in rural communities where there aren’t as many options, or a provider who is one of a very few offering a specialized service within a certain area.

In that case, Powell says, a health plan is likely to be compelled to contract with the provider because the payer needs to have access to their services in the domains with the monopolies.

“Substantial market share gives the provider leverage, Powell says, because if that organization leaves the network due to failed negotiations with the payer, “then all those members are going to have to change their family physicians, internists or PCPs and they’re not going to be happy,” he says.

Since not all physician practices are going to meet either of these criteria, he says, another option is to merge with another provider organization in order to obtain a larger market share.

He says that many of the small physician practices that haven’t gone out of business as a result of such pressures have been absorbed by larger entities, though the downsides are real, including loss of control over how medicine is practiced.

“If you have people merging their practices into group practices, there’s better coverage,” Powell says. “Probably more modest incomes, but also more modest expectations.”

SIDE HUSTLE

Lower reimbursement amounts and tough negotiations with payers are pushing more physicians to practice differently in general, says Andria Jacobs, chief operating officer at PCG Software, which develops healthcare applications focused on cost containment, fraud and abuse detection, based in Las Vegas, Nev.

“It’s a tough environment for physicians,” she says, based on polling done by such groups as the Medical Group Management Association. “Now we have so few payers it’s an oligopoly, and the health plans have all the power. Physicians are really unhappy.”

They’re also unhappy with the demands of managed care, from the authorization process to quality improvement measures and frustrations with their electronic health records.

As a result, she’s seeing physicians either retiring or selling their practices to group practices, or having to get creative.

“My OB/GYN now offers additional services not covered by insurance to make ends meet because she wants to be in solo practice,” Jacobs says. Simply taking what insurers pay is no longer enough.

Other doctors are moving more toward direct pay and concierge options. Jacobs’ own physician has a membership program that ranges from $500 to $1500 per year that gives patients quicker and more consistent access to him.

“Otherwise he can’t stay in business,” she says. “You can’t run your practice like you did in the past where there was always enough money coming in,” Jacobs says.

INCREASING DIRECT PAY SERVICES

If negotiations with payers stall or remain unsatisfying, the best option is to offer direct pay services to patients, either on the side or as part of a direct pay practice, says Paula Muto, MD, a surgeon in private practice outside Boston. Muto founded UBERDOC, a direct pay, direct access healthcare platform.

“Doctors should realize who the payer actually is. It is no longer the employer as the burden of payment has dramatically shifted to the patient because of high deductible plans. The patient is the payer,” she says.

With patients facing increasingly higher deductibles they often don’t meet in a given year, she sympathizes with their frustration at also receiving bills from their physicians. She believes that price transparency will bring an alternative to the system especially for lower cost routine care, leaving insurance for bigger, more catastrophic services.

“We need to think differently,” Muto says. “I’m very excited about bringing the doctor and the patient back together.”
FINANCIAL STRATEGIES

Rein in hidden billing costs

In physician practices, there are multiple billing pitfalls that threaten practice revenue. For every 10 physicians who provide care in the United States, nearly seven people provide billing support. Nationally, providers spend $282 billion per year on billing and insurance-related costs—and half of these costs are considered excessive, a recent study found.

But too often, practice leaders fail to spot these revenue traps. The result: low cash collections, higher-than-necessary billing costs, and threats to patient satisfaction.

Where do hidden billing costs typically exist—and how can practice leaders more effectively rein them in? Here are four common blind spots.

Benefits and eligibility verification
This is the starting point for billing support, and it’s rife with inefficiency. Manual transactions take 10 minutes to perform, on average, and some last as long as 23 minutes. Yet while most providers have adopted electronic eligibility and benefits verification, this billing process remains the single biggest savings opportunity for medical providers to reduce administrative costs, at $3.4 billion.

Making the switch to electronic eligibility and benefits verification is about more than administrative efficiency. It can also reduce denials rework—especially when eligibility checks are run again prior to claim submissions to ensure patients’ coverage is still active. Registration and eligibility errors are the root cause of one-third of denials.

Claim status inquiries
Manual claim status inquiries are the costliest of any administrative billing expense tracked by the Council for Affordable Quality Healthcare (CAQH). Why? Manual inquiries require 14 minutes of staff time, on average, to complete, according to the 2018 CAQH Index. Electronic claim status inquiries, on the other hand, take just five minutes to complete. As a result, the savings opportunity in moving from manual to electronic status inquiries totals $2.6 billion among medical providers.

Out-of-pocket estimates
Given the impact out-of-pocket estimates have on practices’ ability to engage patients in the cost of their care, practice leaders should consider:

- Investing in tools that calculate patients’ out-of-pocket costs at the point of registration
- Training front-end staff to have financial discussions with patients prior to the point of service
- Publishing prices for common procedures
- Equipping physicians with cost information so they may engage in cost discussions with patients

Cash posting
For physician practices, cash posting is tedious, highly manual, and delegated to entry-level staff. It takes staff significantly longer to process paper-based check payments than electronic payments, according to an Association for Finance Professionals report. Paper checks also are five times more expensive to receive than e-payments. But the inefficiencies associated with manual payment posting result in more than lost productivity and higher transaction costs. They also threaten practice revenue—especially when errors in posting strangle a practice’s ability to follow up on underpayments.

Patient loyalty also is put at risk, such as when errors in manual posting prompt staff to pursue higher balances than necessary.

These are just some of the reasons why automating cash posting makes financial sense for medical practices. It’s an approach that also provides real-time visibility into payments, streamlines remittance advice management, more quickly identifies opportunities to better manage denials, and reduces the costs associated with medical billing. One specialty practice saved 13 hours per day by automating its cash-posting processes, increasing productivity and freeing up staff to focus on more value-added activities.

Dan Richards is chief growth officer of Revenue IQ, which specializes in automated remittance and status transactions for healthcare organizations. Send your financial questions to medec@mmhgroup.com

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- **Prevented exacerbations**
  - 51% reduction in AER\(^8\) (0.74) compared to placebo + SOC (1.52) in Trial 1 (48 weeks)\(^1\)
    - FASENRA (n=267), placebo (n=267) (P<0.0001)\(^2\)
  - FASENRA (0.73) reduced AER by 28% compared to placebo + SOC (1.01) in Trial 2 (56 weeks)\(^1\)
    - FASENRA (n=239), placebo (n=248) (P=0.019)\(^3\)

- **Reduced or eliminated OCS use**
  - 75% reduction in median OCS dose compared to 25% reduction with placebo + SOC in Trial 3 (28 weeks)\(^1\)
    - FASENRA (n=73), placebo (n=75) (P<0.001)\(^7\)
  - 52% of patients who were controlled on doses ≤12.5 mg eliminated OCS use compared to placebo + SOC (19%) in Trial 3 (28 weeks)\(^1,7\)
    - FASENRA (n=42), placebo (n=42)\(^1,7\)

In Trials 1 and 2, FASENRA and placebo were administered with high-dose ICS/LABA (inhaled corticosteroids/long-acting β\(_2\) agonist) with or without other controllers, including systemic steroids.\(^2,3\) In Trial 3, FASENRA and placebo were administered in addition to daily OCS (7.5 to 40 mg) plus SOC, which is defined as high-dose ICS/LABA with or without other controllers.\(^7\)

The most common adverse reactions (≥3%) from Trials 1 and 2 in patients who received FASENRA Q8W (n=822) or placebo (n=847) included headache (8% vs 6%); pyrexia (3% vs 2%); pharyngitis\(^*\) (5% vs 3%); and hypersensitivity reactions\(^*\) (3% vs 3%).\(^1\)

Adverse reactions from Trial 3 with 28 weeks of treatment with FASENRA (n=73) or placebo (n=75) in which the incidence was more common in FASENRA than placebo include headache (8.2% compared to 5.3%, respectively) and pyrexia (2.7% compared to 1.3%, respectively). The frequencies for the remaining adverse reactions with FASENRA were similar to placebo.\(^1\)

**IMPORTANT SAFETY INFORMATION (cont’d)**

**Parasitic (Helminth) Infection**

It is unknown if FASENRA will influence a patient’s response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with FASENRA. If patients become infected while receiving FASENRA and do not respond to anti-helminth treatment, discontinue FASENRA until infection resolves.

**ADVERSE REACTIONS**

The most common adverse reactions (incidence ≥ 5%) include headache and pharyngitis.

Injection site reactions (eg, pain, erythema, pruritus, papule) occurred at a rate of 2.2% in patients treated with FASENRA compared to 1.9% in patients treated with placebo.

Please see additional Important Safety Information throughout and accompanying Brief Summary of full Prescribing Information.

Scan this code to visit FASENRAhcp.com
STUDY DESIGNS

Trials 1 and 2
Trial 1 (48-week) and Trial 2 (56-week) were 2 randomized, double-blind, parallel-group, placebo-controlled, multicenter studies comparing FASENRA 30 mg SC Q4W for the first 3 doses, then Q8W thereafter; benralizumab 30 mg SC Q4W, and placebo SC. A total of 1204 (Trial 1) and 1306 (Trial 2) patients aged 12-75 years old with severe asthma uncontrolled on high-dose ICS (Trial 1) and medium- to high-dose ICS (Trial 2) plus LABA with or without additional controllers were included. Patients had a history of ≥2 exacerbations requiring systemic corticosteroids or temporary increase in usual dosing in the previous year. Patients were stratified by geography, age, and blood eosinophil counts (≥300 cells/µL and <300 cells/µL). The primary endpoint was annual exacerbation rate ratio vs placebo in patients with blood eosinophil counts of ≥300 cells/µL on high-dose ICS and LABA. Exacerbations were defined as a worsening of asthma that led to use of systemic corticosteroids for ≥3 days, temporary increase in a stable OCS background dose for ≥3 days, emergency/urgent care visit because of asthma that needed systemic corticosteroids, or inpatient hospital stay of ≥24 hours because of asthma. Key secondary endpoints were pre-bronchodilator FEV1, and total asthma symptom score at Week 48 (Trial 1) and Week 56 (Trial 2) in the same population.2,3

Trial 3
A 28-week, randomized, double-blind, parallel-group, placebo-controlled, multicenter OCS reduction study comparing the efficacy and safety of FASENRA (30 mg SC) Q4W for the first 3 doses, then Q8W thereafter; benralizumab (30 mg SC) Q4W, and placebo (SC) Q4W. A total of 220 adult (18-75 years old) patients with severe asthma on high-dose ICS plus LABA and daily OCS (7.5 to 40 mg/day), blood eosinophil counts of ≥150 cells/µL, and a history of ≥1 exacerbation in the previous year were included. The primary endpoint was the median percent reduction from baseline in the final daily OCS dose while maintaining asthma control.7

REFERENCES

FASENRA® (benralizumab) injection, for subcutaneous use

Initial U.S. Approval: 2017

Brief Summary of Prescribing Information. For complete prescribing information consult official package insert.

INDICATIONS AND USAGE

FASENRA is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype [see Clinical Studies (14) in the full Prescribing Information].

Limitations of use:

- FASENRA is not indicated for treatment of other eosinophilic conditions.
- FASENRA is not indicated for the relief of acute bronchospasm or status asthmaticus.

DOSEAGE AND ADMINISTRATION

Recommended Dose

FASENRA is for subcutaneous use only.

The recommended dose of FASENRA is 30 mg administered once every 4 weeks for the first 3 doses, and then every 8 weeks thereafter by subcutaneous injection into the upper arm, thigh, or abdomen.

General Administration Instructions

FASENRA is intended for use under the guidance of a healthcare provider. In line with clinical practice, monitoring of patients after administration of biologic agents is recommended [see Warnings and Precautions (5.1) in the full Prescribing Information].

Administer FASENRA into the thigh or abdomen. The upper arm can also be used if a healthcare provider or caregiver administers the injection. Prior to administration, warm FASENRA by leaving carton at room temperature for about 30 minutes. Visually inspect FASENRA for particulate matter and discoloration prior to administration. FASENRA is clear to opalescent, colorless to slightly yellow, and may contain a few translucent or white to off-white particles. Do not use FASENRA if the liquid is cloudy, discolored, or if it contains large particles or foreign particulate matter.

Prefilled Syringe

The prefilled syringe is for administration by a healthcare provider.

Autoinjector (FASENRA PEN™)

FASENRA PEN is intended for administration by patients/caregivers. Patients/caregivers may inject after proper training in subcutaneous injection technique, and after the healthcare provider determines it is appropriate.

Instructions for Administration of FASENRA Prefilled Syringe (Healthcare Providers)

Refer to Figure 1 to identify the prefilled syringe components for use in the administration steps.

Figure 1

1. Grasp the syringe body, not the plunger, to remove prefilled syringe from the tray. Check the expiration date on the syringe. The syringe may contain small air bubbles; this is normal. Do not expel the air bubbles prior to administration.

2. Do not remove needle cover until ready to inject. Hold the syringe body and remove the needle cover by pulling straight off. Do not hold the plunger or plunger head while removing the needle cover or the plunger may move. If the prefilled syringe is damaged or contaminated (for example, dropped without needle cover in place), discard and use a new prefilled syringe.

3. Gently pinch the skin and insert the needle at the recommended injection site (i.e., upper arm, thigh, or abdomen).

4. Inject all of the medication by pushing in the plunger all the way until the plunger head is completely between the needle guard activation clips. This is necessary to activate the needle guard.

5. After injection, maintain pressure on the plunger head and remove the needle from the skin. Release pressure on the plunger head to allow the needle guard to cover the needle. Do not re-cap the prefilled syringe.

6. Discard the used syringe into a sharps container.

Instructions for Administration of FASENRA PEN

Refer to the FASENRA PEN ‘Instructions for Use’ for more detailed instructions on the preparation and administration of FASENRA PEN [See Instructions for Use in the full Prescribing Information]. A patient may self-inject or the patient caregiver may self-inject FASENRA subcutaneously after the healthcare provider determines it is appropriate.

CONTRAINICATIONS

FASENRA is contraindicated in patients who have known hypersensitivity to benralizumab or any of its excipients [see Warnings and Precautions (5.1) in the full Prescribing Information].

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, rash) have occurred following administration of FASENRA. These reactions generally occur within hours of administration, but in some instances have a delayed onset (i.e., days). In the event of a hypersensitivity reaction, FASENRA should be discontinued [see Contraindications (4) in the full Prescribing Information].

Acute Asthma Symptoms or Deteriorating Disease

FASENRA should not be used to treat acute asthma symptoms or acute exacerbations. Do not use FASENRA to treat acute bronchospasm or status asthmaticus. Patients should seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with FASENRA.

Reduction of Corticosteroid Dosage

Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with FASENRA. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helmintic) Infection

Eosinophils may be involved in the immunological response to some helminth infections. Patients with known helminth infections were excluded from participation in clinical trials. It is unknown if FASENRA will influence a patient’s response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with FASENRA. If patients become infected while receiving treatment with FASENRA and do not respond to anti-helmintic treatment, discontinue treatment with FASENRA until infection resolves.

ADVERSE REACTIONS

The following adverse reactions are described in greater detail in other sections:

- Hypersensitivity Reactions [see Warnings and Precautions (5.1) in the full Prescribing Information]

Clinical Trials Experience

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

Across Trials 1, 2, and 3, 1,808 patients received at least 1 dose of FASENRA [see Clinical Studies (14) in the full Prescribing Information]. The data described below reflect exposure to FASENRA in 1,863 patients, including 1,559 exposed for at least 24 weeks and 1,367 exposed for at least 48 weeks. The safety exposure for FASENRA is derived from two Phase 3 placebo-controlled studies (Trials 1 and 2) from 48 weeks duration [FASENRA every 4 weeks (n=841), FASENRA every 4 weeks for 3 doses, then every 8 weeks (n=822), and placebo (n=847)]. While a dosing regimen of FASENRA every 4 weeks was included in clinical trials, FASENRA administered every 4 weeks for 3 doses, then every 8 weeks thereafter is the recommended dose [see Dosage and Administration (2.1) in the full Prescribing Information]. The population studied was 12 to 75 years of age, of which 64% were female and 79% were white.

Adverse reactions that occurred at greater than or equal to 3% incidence are shown in Table 1. Table 1. Adverse Reactions with FASENRA with Greater than or Equal to 3% Incidence in Patients with Asthma (Trials 1 and 2)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>FASENRA (N=842)</th>
<th>Placebo (N=847)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Hypersensitivity reactions†</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

†Pharyngitis was defined by the following terms: ‘Pharyngitis’, ‘Pharyngitis bacterial’, Viral pharyngitis, ‘Pharyngitis streptococcal’.

† Hypersensitivity Reactions were defined by the following terms: ‘Urticaria’, ‘Urticaria papular’, and ‘Rash’ [see Warnings and Precautions (5.1) in the full Prescribing Information].

Do not re-cap the prefilled syringe.
Risk Summary

There is no information regarding the presence of benralizumab in human or animal milk, and the effects of benralizumab on the breast fed infant and on milk production are not known. However, benralizumab is a humanized monoclonal antibody (IgG1/c-class), and immunoglobulin G (IgG) is present in human milk in small amounts. If benralizumab is transferred into human milk, the effects of local exposure in the gastrointestinal tract and potential limited systemic exposure in the infant to benralizumab are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for benralizumab and any potential adverse effects on the breast-fed child from benralizumab or from the underlying maternal condition.

Pediatric Use

There were 108 adolescents aged 12 to 17 with asthma enrolled in the Phase 3 exacerbation trials (Trial 1: n=53, Trial 2: n=55). Of these, 46 received placebo. 40 received FASENRA every 4 weeks for 3 doses, followed by every 8 weeks thereafter, and 22 received FASENRA every 4 weeks. Patients were required to have a history of 2 or more asthma exacerbations requiring oral or systemic corticosteroid treatment in the past 12 months and reduced lung function at baseline (pre-bronchodilator FEV1, <80%) despite regular treatment with medium or high dose ICS and LABA with or without OCS or other controller therapy. The pharmacokinetics of benralizumab in adolescents 12 to 17 years of age were consistent with adults based on population pharmacokinetic analysis and the reduction in blood eosinophil counts was similar to that observed in adults following the same FASENRA treatment. The adverse event profile in adolescents was generally similar to the overall population in the Phase 3 studies (see Adverse Reactions (6.1) in the full Prescribing Information). The safety and efficacy in patients younger than 12 years of age has not been established.

Geriatric Use

Of the total number of patients in clinical trials of benralizumab, 13% (n=320) were 65 and over, while 0.4% (n=9) were 75 and over. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

OVERDOSAGE

Doses up to 200 mg were administered subcutaneously in clinical trials to patients with eosinophilic disease without evidence of dose-related toxicities. There is no specific treatment for an overdose with benralizumab. If overdose occurs, the patient should be treated supportive with appropriate monitoring as necessary.

PATIENT COUNSELING INFORMATION

Advise the patients and/or caregivers to read the FDA-approved patient labeling (Patient Information and Instructions for Use for FASENRA PEN) before the patient starts using FASENRA, and each time the prescription is renewed so that there may be new information they need to know.

Provide proper training to patients and/or caregivers on proper subcutaneous injection technique using the FASENRA PEN, including aseptic technique, and the preparation and administration of FASENRA PEN prior to use. Advise patients to follow sharps disposal recommendations (see Instructions for Use in the full Prescribing Information).

Hypersensitivity Reactions

Inform patients that hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, rash) have occurred after administration of FASENRA. These reactions generally occurred within hours of FASENRA administration, but in some instances had a delayed onset (i.e., days). Inform patients to contact their healthcare provider if they experience symptoms of an allergic reaction (see Warnings and Precautions (5.1) in the full Prescribing Information).

Not for Acute Symptoms or Deteriorating Disease

Inform patients that FASENRA does not treat acute asthma symptoms or acute exacerbations. Inform patients to seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with FASENRA (see Warnings and Precautions (5.2) in the full Prescribing Information).

Reduction of Corticosteroid Dosage

Inform patients to not discontinue systemic or inhaled corticosteroids except under the direct supervision of a physician. Inform patients that reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy (see Warnings and Precautions (5.3) in the full Prescribing Information).

Pregnancy Exposure Registry

Inform women there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to FASENRA during pregnancy. Healthcare providers can enroll patients or encourage patients or partners to enroll themselves by calling 1-877-311-8972 or visiting motherthrobaby.org/Fasenra.

Risk Summary

Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to FASENRA during pregnancy. Healthcare providers can enroll patients or encourage patients or partners to enroll themselves by calling 1-877-311-8972 or visiting motherthrobaby.org/Fasenra.

Risk Summary

The data on pregnancy exposure from the clinical trials are insufficient to inform on drug-associated risk. Monoclonal antibodies such as benralizumab are associated with increased clearance of benralizumab and increased blood eosinophil levels in patients with high anti-drug antibody titers compared to antibody negative patients. No evidence of an association of anti-drug antibodies with efficacy or safety was observed.

The data reflect the percentage of patients whose test results were positive for antibodies to benralizumab in specific assays.

Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following adverse reactions have been identified during post approval use of FASENRA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These events have been chosen for inclusion due to either their seriousness, frequency of reporting, or causal connection to FASENRA or a combination of these factors.

Immune System Disorders: Hypersensitivity reactions, including anaphylaxis.

DRUG INTERACTIONS

No formal drug interaction studies have been conducted.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to FASENRA during pregnancy. Healthcare providers can enroll patients or encourage patients or partners to enroll themselves by calling 1-877-311-8972 or visiting motherthrobaby.org/Fasenra.

Risk Summary

The data on pregnancy exposure from the clinical trials are insufficient to inform on drug-associated risk. Monoclonal antibodies such as benralizumab are transported across the placenta during the third trimester of pregnancy; therefore, potential effects on a fetus are likely to be greatest during the third trimester of pregnancy. In a prenatal and postnatal development study conducted in cynomolgous monkeys, there was no evidence of fetal harm with IV administration of benralizumab throughout pregnancy at doses that produced exposures up to approximately 310 times the exposure at the maximum recommended human dose (MRHD) of 30 mg SC (see Data).

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-associated maternal and/or embryo/fetal risk:

In women with poorly or moderately controlled asthma, evidence demonstrates that there is an increased risk of preeclampsia in the mother and prematurity, low birth weight, and small for gestational age in the neonate. The level of asthma control should be closely monitored in pregnant women and treatment adjusted as necessary to maintain optimal control.

Data

Animal Data

In a prenatal and postnatal development study; pregnant cynomolgous monkeys received benralizumab from beginning on G20 to G22 (dependent on pregnancy determination), on G23, and once every 14 days thereafter throughout the gestation period and 1-month postpartum (maximum 14 doses) at doses that produced exposures up to approximately 310 times that achieved with the MRHD (on an AUC basis with maternal IV doses up to 30 mg/kg once every 2 weeks). Benralizumab did not elicit adverse effects on fetal or neonatal development (including organ function) up to 6.5 months after birth. There was no evidence of treatment-related external, visceral, or skeletal malformations. Benralizumab was not teratogenic in cynomolgous monkeys. Benralizumab crossed the placenta in cynomolgous monkeys. Benralizumab concentrations were approximately equal in mothers and infants on postpartum day 7, but were lower in infants at later time points. Eosinophil counts were suppressed in infant monkeys with gradual recovery by 6 months postpartum; however, recovery of eosinophil counts was not observed for one infant monkey during this period.
The electronic health record (EHR) has become the third wheel in the exam room, often getting in the way of physicians making meaningful connections with their patients.

“Both as a physician and on the receiving end as a patient, I have found that EHRs absolutely can cause certain barriers,” says Johnny Dias, DO, an internist with the Medical Group of the Carolinas in Spartanburg, South Carolina. “By starting to type in the computer, you can feel the disengagement from the patient.”

Payer documentation mandates have forced doctors to rely too much on the computer during exams, says Jack Ende, MD, MACP, an internist in Philadelphia, Pennsylvania and former president of the American College of Physicians. “We are in an age now where we are being required to over-document so we can demonstrate we’ve done things so we can get paid for them, and that’s all part of the problem,” Ende says.

But while finding the right balance between thorough documentation and a successful patient encounter may be difficult, it’s not impossible, physicians say. It requires understanding the doctor’s own style of conducting visits and the quirks of their software and exam rooms, not to mention a good dose of pre-planning and staff support.

THE PHYSICIAN LEADS
While everyone these days can become absorbed in their electronic devices, in a patient exam it’s up to physicians to control the dynamic. A 2015 study in the International Journal of Medical Informatics that tracked the eye movements of doctors and patients during exams found that patient gaze and eye contact followed cues from the physician. In other words, physicians must establish eye contact and create an inviting, engaging atmosphere for the patient.

Each physician needs to learn their best way of managing the EHR during patient visits. Ende, for example, says he never types on a computer during patient examinations and instead jots a few notes while focusing on the patient. “I will take a history for a new patient the old-fashioned way: with a pad of paper on my lap, making good eye contact and being able to appreciate the patient’s body language,” he says.
3 future changes to make EHRs more ideal for doctors

The EHR of the future can become less of a barrier to physician-patient interactions if vendors can design more physician-focused products. Three physicians weigh in on what EHR systems can do to reduce the friction.

Make software more intuitive
“Eliminate the number of clicks. It’s too many. You have to log in repeatedly after a few moments of inactivity, you have to enter the orders in a very specific way otherwise the computer will not accept them. It’s enormously complicated. Compare that to going onto Amazon. In three clicks I’ve bought a book.” —Jack Ende, MD

Promote usable data
“We don’t always have discrete data. What I mean by that is we don’t have interfaces with all the players yet. We have direct interface with one regional lab, while others send virtual faxes (PDFs), but to make that useful we need to go in and type them in the boxes to be trendable. There needs to be an electronic patient data home at the level of the patient, not at the level of the healthcare organization.” —Melissa Lucarelli, MD

Explore artificial intelligence
“Where I see things going is the benefit of some type of AI system where it’s basically translating all of the verbal communication directly onto an electronic record, so you’re not physically spending time documenting. In the next couple of years, I hope to see some models of this practice. That will completely change the dynamic.” —Johnny Dias, DO

He enters lab orders, billing information and other such data into the computer, but typically dictates the narrative portion of the patient note to a staff member. Ende, who is also professor and assistant dean at the Perelman School of Medicine at the University of Pennsylvania, admits that’s a rare method for today’s physicians but says it’s the way he feels he can best connect with the patient.

Melissa Lucarelli, MD, a solo family physician in Randolph, Wisconsin, says that before she walks into the exam room she studies the patient’s data and history to make sure she has the basic knowledge she needs to avoid relying on the computer. Also, she will copy-and-paste patient history information in her EHR to get a head start on the note before the upcoming encounter.

“Ideally, your EHR would become invisible, but what I’ve set for myself as the sort of gold standard for the computer in the room, is to make it as unobtrusive as a paper chart,” says Lucarelli, a member of the Medical Economics editorial advisory board.

Lucarelli uses laptops on carts in her practice, which lets her position herself to look the patient in the eye regardless of the layout of the exam room.

Dias works in a similar way, doing as much prep work as possible before walking into the room so that he can focus on connecting with the patient. He studies the patient’s history, including what preventive care screenings the patient needs and what lab orders or tests are likely, based on the patient’s conditions.

“You are essentially walking into the appointment with some good background knowledge and really already knowing what you want to do,” he says.

Building bridges with technology
The EHR need not be a barrier: It’s also a tool to potentially increase patient engagement.

“The 2015 study found that when physicians look at the computer, the patient’s gaze usually follows. The study’s authors describe this moment as a chance to use the EHR as a ‘shared artifact,’ meaning a way to gain the patient’s attention. What happens next in such instances can either be a missed opportunity or a way to gain the patient’s trust.

“When physicians share information visually from the EHR monitor, patient satisfaction and patients’ involvement in the decision-making process improves,” the authors write.

Lucarelli says she uses data and charts in almost every visit to show trend lines for weight, hemoglobin A1C and other types of discrete and trackable data. In other words, it uses technology to bring the patient into the encounter.

“I’ll show it on the computer and say: ‘Good job, your weight is down.’ I used to be flipping back and forth, looking at their weight at the last appointment. Now we can look at the trend for the last year. That’s the sort of thing the EHR does well,” she says.

Ende typically uses charts and graphs on his EHR near the end of the patient appointment, and says it’s an excellent teaching tool that shows the potential of technology for patient-centered care.

Those instances when you can bring the patient into the medical record are very helpful,” he says. “The availability of the data right there has been a real plus.”
PRACTICAL MATTERS

5 ways to build a better medical team

Medicine is a team sport—the collective is often much greater than the individual when it comes to patient care, innovative ideas, productivity, and efficiencies. Even more important is that effective teamwork leads to fewer medical errors.

Bearing in mind that not all teams are created equal, below are some strategies worth considering to get the most from your team.

1 Develop a team mission.
When people all agree on a common purpose and feel that they are all working towards that purpose, there is a greater sense of camaraderie and teamwork. Reminding people of that common purpose (i.e. patient care and comfort) helps them feel a sense of meaning and significance and helps break down and/or avoid silos. It is critical for teams to understand that success is best defined by achieving your purpose. In other words, it is more about team success than individual success.

2 Develop team agreements.
One of the most common traits of successful teams, is that they have established norms by which they agree to operate under. Here are some questions I typically use when helping teams develop their agreements:
- What are the behaviors we need from each other to develop greater trust?
- How do we want to make team decisions?
- How do we ensure that everyone’s voice is heard?

3 Clarify team roles.
When team members clearly understand each other’s roles and responsibilities, they can then find opportunities to help each other out. I often ask healthcare teams how they define success at the end of their day. My objective is for them to see that their work is all about the best interest of patient care, and that includes helping out our colleagues when needed. Establishing a common set of metrics helps to define success and ensure that the team is able to measure their progress. The ability to achieve goals not only boosts team morale and reinforces the team mission, it also helps the team to identify factors that contributed to their success. When goals are not achieved, it allows the team to discuss strategies that might be more effective.

4 Learn from mistakes and failures.
Teams that learn together, bond together. It is critical, especially in a health-care setting, that mistakes are seen as an opportunity to learn and improve, versus an opportunity to shame and blame. The team agreements should address this issue. You want people to openly discuss errors and near misses so that they can continually improve patient care and safety. A culture of continuous improvement among a team means that everyone knows that mistakes are bound to happen and that the best thing that can come from them is learning.

5 Provide opportunities for the team to get to know each other on a more personal level.
One great way to do this is through a personality workshop. It is a perfect opportunity to learn about people’s different styles, preferences, communication behaviors, and ways they might be misunderstood. It can lay the foundation for ongoing sharing, a key element for teams to develop psychological safety.

Catherine Hambley, PhD, is CEO of Brain-Based Strategies Consulting, where she specializes in executive coaching, leadership and team development and organizational transformation. Send your practice management questions to medec@mmhgroup.com.
A mid speculation that malpractice insurance rates will rise, maintaining an air-tight risk management plan should be on doctors’ agenda this year.

Malpractice insurance rates declined over the last decade as tort reform and industry safety measures led to fewer claims, but the size of the largest claims is growing. This could lead to higher rates in the future, experts say.

“It’s not widespread, but we’re finally beginning to see some upward pressure on [malpractice insurance] rates,” says Chad Karls, FCAS, principal and consulting actuary for Milliman, a Brookfield, Wis.-based actuarial and consulting firm. The examples are spotty geographically, but primary care practices are among those at higher risk, he says.

A 2017 study of hospital professional liability by consulting firm Aon and the American Society for Healthcare Risk Management projects no increase in the number of claims below $2 million for 2018, but a 2 percent rise in claim severity. The study also noted “early signs” of a rise in the number of claims above $5 million, but the data weren’t conclusive enough to quantify the increase.

Also on the rise, the report found, are so-called batch claims, or multiple claims resulting from a repeated behavior. One example: improperly sterilized equipment.

Karls still expects liability insurance rates to stay favorable for another couple of years, but there are some signs of changes ahead. Increasing demand for more electronic records and safeguarding patient privacy could spur a rise in the number of claims.

Internists, in particular, could see higher rates as claims centered on failure to diagnose rise, Karls says. These types of claims often can take a long time to surface as more is learned about how a disease progressed, so he urges doctors to be sure they are working with a highly-rated carrier.

Beyond taking care when choosing a carrier, practice owners should stay vigilant in maintaining their risk mitigation strategies, he says. And that involves protecting a doctor’s personal finances from excess professional liability as well as those of the practice.

“Large hospital systems today have whole risk management teams to do investigations and implement policies,” says Craig Brodsky,
JD, a partner with law firm Goodell DeVries in Baltimore, Md. “The question is how to put that type of system in place at a smaller practice without breaking the bank.”

**PHYSICIAN, AUDIT THYSELF**

Physicians should start by taking advantage of the built-in resources available through vendors, Brodsky says. Liability insurers typically offer some risk mitigation reviews as part of their contracts or provide more comprehensive services for a fee, and many offer discounts if physicians attend risk-mitigation seminars.

Primary care doctors, in particular, need to be aware of some newer types of risks, he says. Mandatory use of EHRs increases their exposure to possible security and data breaches. Greater use of telemedicine raises the possibility of more diagnostic errors. Practice mergers and rising numbers of non-physician practitioners can chip away at the close personal relationship doctors used to have with their patients, and studies show patients are more likely to sue providers they don’t know well.

The renewed focus on sexual harassment in the workplace also poses a risk that a practice’s attorney should address through written policies and procedures, says Brodsky.

Fees for these services vary depending on the size and scope of the practice. Another route to explore, particularly if budgets are tight, is to see whether a practice’s admitting hospitals offer risk-management audits or similar services to affiliated physicians.

**MANAGE CONFLICTS**

Physicians should be aware that those hospital affiliations, along with other agreements, can lead to certain conflicts of interest, experts say. Doctors in a small group practice, for example, often have contractual arrangements with other entities for providing care or procuring services. These arrangements can leave a practice, or an individual physician, exposed from a liability standpoint.

In the Aon study, 61 percent of hospital providers were moderately or extremely concerned about vicarious liability from non-employed physicians, and 73 percent said they require those physicians to carry between $1 million and $2 million in coverage.

As more primary care physicians have become employed by or affiliated with hospitals, a possible outcome could be more large claims, as plaintiffs’ attorneys seek deeper pockets, says Erik Johnson, regional director for Aon Global Risk Consulting and author of the report.

As a result, it’s essential to understand the professional liability implications of the arrangements, experts say. Often, a large network will move to settle claims quickly, for example, when an individual doctor might be better off disputing the claim to clear their professional record.

“Doctors still have an individual interest and they need to be aware that a business entity is not going to look out for their interests,” says John Lyddane, JD, a partner with law firm Dorf & Nelson LLP in New York. Negotiating an independent attorney or liability insurer as part of an employment agreement is the best way to avoid those conflicts ahead of time, he says.

Frequently, joint practice agreements will spell out how legal claims will be handled, and the arrangements typically are meant to serve the organization, not necessarily to get the best outcome for an individual doctor. “In a sense, [physicians] really can’t just go hire their own representation because the contract itself says you are agreeing to their risk management system,” Lyddane says.

If a group decides to settle a malpractice case instead of going to trial, for example, the physician named in the suit has to live with the repercussions of having his or her name and the incident (plus any monetary settlement) in the National Practitioner Data Bank. This, in turn, can lead to denials for participation in certain healthcare plans, Lyddane says. It could also affect a physician’s employability and likelihood of receiving hospital admitting privileges.

**GO BEYOND THE CHART**

Practice consultants routinely chide physicians for not documenting courses of action that they recommend to patients. This lack of documentation can be problematic in lawsuits, but limiting it to a chart entry isn’t always sufficient, either.

If a primary care physician, for example, refers a patient to a specialist but the patient doesn’t go, the physician can be held responsible in a lawsuit if there was no follow-up with the patient or the specialist, Lyddane says.

Lyddane often recommends that referring physicians follow-up directly with the spe-
cialist to confirm that a patient was actually seen and the results of the visit were added to the primary care physician's record.

And physicians must remember to incorporate phone and email conversations into the record as well, Lyddane says. An electronic message trail is better than no trail at all to document a physician's orders, but if the order never makes it into the official record, it can be a problem, he says.

Copying and pasting previous notes in the EHR when seeing a patient with a recurring problem is another mistake from a liability standpoint, he says, as any inaccurate information in those passages then gets repeated in newly-created notes. For each visit, physicians should make a new electronic record, he says.

CONSIDER THE WHOLE TEAM

The use of ancillary services, physician assistants, and nurse practitioners is another factor to consider in risk management, experts say.

Vicarious liability, or the responsibility of a physician for the actions of subordinate providers, is an important part of assessing a practice's overall risk profile, says Ingrid Hubbard Reidy, vice president of risk management for ISMIE Mutual Insurance Company, a Chicago-based medical liability insurer.

Some states require written collaborative practice agreements covering the scope of work performed by non-physicians, she says, and all providers should have documentation of staff members' credentials and continuing training. And be aware that state laws covering these arrangements are changing frequently, she adds.

Even among physicians, other types of documentation are crucial, she says. For example, when practices don't have access to their patients' data from admitting hospitals, it creates a significant liability risk.

Many physicians today are so accustomed to EHRs that they don't think about picking up a phone to inform a colleague about a patient, she says. So if a specialist is not connected to the primary care provider via the EHR, the primary physician can be left completely unaware of a patient's progress.

Care coordination poses another potential risk, particularly for primary care physicians, Reidy says.

"It’s in the handoffs of care that we’re missing a lot of things," she says. "Many of the large health systems are doing a good job within the confines of their own system with this, but it’s a real challenge for [doctors] not in the system. Sometimes, [primary care providers] don’t even know their patient is in the hospital. They’re really struggling with that and it provides a lot of risk for them" because they don’t know to ask questions about their patients’ most recent medical encounters.

Sometimes, simply asking a patient if they’ve seen other physicians since their last office visit is an effective way of catching errors of omission in the information trail, she says.

Another risk mitigation tool is the human element. As medical groups get bigger and more corporate, the deep personal relationships formed between patients and doctors are under siege, Reidy says.

One way providers can counter this trend is by sharpening their communication skills. Be very clear with patients about the diagnosis and treatment plan at hand, she says. Making sure to educate patients and then having them acknowledge that they understand what they need to do to comply with the plan is crucial, she says.

SHIELDING PERSONAL SAVINGS

While relatively few malpractice awards exceed physicians’ insurance limits, it’s important to consider personal assets when thinking about protection against liability claims.

Employer-sponsored retirement accounts generally are protected from claims and a 401(k) or 403(b) plan carries the most protection of all from creditors because they are protected by federal labor law.

Individual Retirement Accounts (IRAs) have fewer protections than employer plans in non-bankruptcy liability cases, though state laws vary.

Some states offer strong protections for IRAs against creditor claims, says Richard Naegele, JD, an employee benefits attorney with Wickens, Herzer, Panza, Cook & Batis ta Co. in Avon, Ohio. California, on the other hand, leaves wide discretion to judges as to how much money within an IRA can be included in a malpractice award.

And in some states, SEP-IRAs (designed for the self-employed) are not protected from claims, he says. Physicians with funds in these accounts should discuss it with their financial adviser.
Am I liable if the patient wasn’t mine?

Dr. Wrong has recently been sued in a most disturbing case. Three years ago, an independent nurse practitioner (NP) he supervises by employment contract, saw a young woman with a pigmented lesion, took a photo of it, and showed it to Dr. Wrong. He saw nothing atypical and conveyed this to the nurse practitioner. Unfortunately, the patient died two years later from metastatic melanoma. The estate ultimately sued both the NP and the physician. He does not understand. He tells his lawyer that since he never saw the patient, he never established a patient-physician relationship; therefore, should have no liability. Is he right?

A recently decided case in Minnesota, Warren v. Dinter took a good look at this situation. This case analyzed the essential law underpinning a medical negligence claim – that a doctor-patient relationship must exist for a plaintiff to prevail. Generally, a physician owes no duty to a patient without a physician-patient relationship; therefore, should have no liability. Is he right?

David J. Goldberg, MD, JD, is a dermatologist and healthcare attorney. Send your legal questions to: medec@mmhgroup.com.
**FLUZONE® HIGH-DOSE QUADRIVALENT (INFLUENZA VACCINE) CONSISTENT REAL-WORLD EVIDENCE SINCE LAUNCH**

**FIRST LICENSED IN 2009.** Fluzone High-Dose has been proven in a randomized controlled trial to prevent 24% more cases of influenza versus Fluzone® (Influenza Vaccine), a standard-dose comparator, in adults 65+. In a randomized controlled trial for immunogenicity and safety, the most common local and systemic adverse reactions to Fluzone High-Dose vaccine include pain at the injection site, myalgia, malaise and headache.

Primary endpoint of the study was the occurrence of laboratory-confirmed, protocol-defined, influenza-like illness caused by viral strains regardless of their antigenic similarity to vaccine components.

These results were demonstrated in large-scale retrospective observational studies within the following influenza seasons.

The efficacy of Fluzone High-Dose (trivalent formulation) is relevant to Fluzone High-Dose Quadrivalent since both vaccines are manufactured according to the same process and have overlapping compositions.

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010-2011</td>
<td>17%</td>
<td>(95% CI: 9-24) fewer cardiorespiratory hospitalizations</td>
</tr>
<tr>
<td>2011-2012</td>
<td>17%</td>
<td>(95% CI: 10-23) fewer cardiorespiratory hospitalizations</td>
</tr>
<tr>
<td>2012-2013</td>
<td>19%</td>
<td>(95% CI: 10-26) fewer cardiorespiratory hospitalizations</td>
</tr>
<tr>
<td>2013-2014</td>
<td>19%</td>
<td>(95% CI: 11-26) fewer cardiorespiratory hospitalizations</td>
</tr>
<tr>
<td>2014-2015</td>
<td>18%</td>
<td>(95% CI: 12-23) fewer cardiorespiratory hospitalizations</td>
</tr>
<tr>
<td>2015-2016</td>
<td>25%</td>
<td>(95% CI: 2-43) fewer influenza &amp; pneumonia hospitalizations</td>
</tr>
<tr>
<td>2016-2017</td>
<td>31%</td>
<td>(95% CI: 8-48) fewer influenza-related hospitalizations</td>
</tr>
<tr>
<td>2017-2018</td>
<td>9%</td>
<td>(95% CI: 7-11) fewer influenza-related hospital encounters</td>
</tr>
</tbody>
</table>

~3.6M 65+ person-influenza seasons from Veterans Health Administration (VHA) and Medicare.

Endpoints included All-Cause, Cardiorespiratory, and Pneumonia & Influenza Hospitalizations. Across all 5 seasons, the 3 endpoints were statistically significant. However, every endpoint was not statistically significant every season.

~74,000 adults 65+ from VHA.

Primary outcome was any hospitalization from pneumonia or influenza. Exploratory endpoints, which included outpatient visits from pneumonia or influenza, laboratory-confirmed influenza, all-cause outpatient visits, and all-cause hospitalizations, were consistently positive, even if not always statistically significant.

~24,000 adults 65+ from Oregon’s Immunization Database.

~13M Medicare beneficiaries.

Fluzone High-Dose was significantly better compared to standard-dose influenza vaccine and adjuvanted comparators, and similar to cell-based comparator for influenza-related hospital encounters.
Fluzone High-Dose Quadrivalent is a vaccine indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. Fluzone High-Dose Quadrivalent is approved for use in persons 65 years of age and older.

**IMPORTANT SAFETY INFORMATION FOR FLUZONE HIGH-DOSE QUADRIVALENT VACCINE**

Fluzone High-Dose Quadrivalent should not be administered to anyone who has had a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein, or after previous dose of any influenza vaccine.

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

If Guillain-Barré syndrome has occurred within 6 weeks following previous influenza vaccination, the decision to give Fluzone High-Dose Quadrivalent should be based on careful consideration of the potential benefits and risks.

If Fluzone High-Dose Quadrivalent is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be lower than expected.

Vaccination with Fluzone High-Dose Quadrivalent may not protect all recipients.

For Fluzone High-Dose Quadrivalent, in adults 65 years of age and older, the most common injection-site reaction was pain; the most common solicited systemic adverse reactions were myalgia, headache, and malaise. Other adverse reactions may occur.

Please see brief summary of the full Prescribing Information on the following page.

2010-2011 through 2014-2015 Study Limitations: VHA has a 98% male population, which tends to have greater disease burden than the general population. No diagnosis codes, whether parts of medical billing records, could capture conditions that are difficult to measure or are unmeasured.

2015-2016 Study Limitations: VHA has a 98% male population, and the PERR method could not be applied to the baseline period because the outcome was not observed here, possibly resulting in an underestimation of VE of Fluzone High-Dose.

2016-2017 Study Limitations: Results may be biased as the measures for exposure and risk (such as frailty) were not comprehensive. Some influenza-related hospitalizations, particularly non-respiratory hospitalizations, may not have been tested and detected as local area hospitals did not have uniform policies.

2017-2018 Study Limitations: Outcomes may not represent laboratory-confirmed influenza infections.

To order Fluzone High-Dose Quadrivalent, go to VaccineShoppe.com® or call 1-800-VACCINE (1-800-822-2463).

Fluzone High-Dose Quadrivalent is manufactured and distributed by Sanofi Pasteur Inc.

Fluzone High-Dose Quadrivalent (CPT® code 90662) is a covered benefit under Medicare Part B.

CPT (Current Procedural Terminology) is a registered trademark of the American Medical Association.

**References:**
5. Fluzone High-Dose Quadrivalent (Prescribing Information). Swiftwater, PA: Sanofi Pasteur Inc.
Fluzone® High-Dose Quadrivalent
Rx Only
(Influenza Vaccine), Suspension, for intramuscular injection
2018-2019 Formula

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE
Fluzone® High-Dose Quadrivalent is a vaccine indicated for active immunization for the prevention of influenza caused by influenza A subtype viruses and type B viruses contained in the vaccine.
Fluzone High-Dose Quadrivalent is indicated for use in persons 65 years of age and older.

2 DOSAGE AND ADMINISTRATION
For intramuscular use only

2.1 Dose and Schedule
Fluzone High-Dose Quadrivalent should be administered as a single 0.7 mL injection by the intramuscular route in adults 65 years of age and older.

2.2 Administration
Inspect Fluzone High-Dose Quadrivalent visually for particulate matter and/or discoloration prior to administration. If either of these conditions exists the vaccine should not be administered. Before administering a dose of vaccine, shake the prefilled syringe.
The preferred site for intramuscular injection is the deltoid muscle. The vaccine should not be injected into the gluteal area or areas where there may be a major nerve trunk.

3 CONTRAINDICATIONS
A severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine [see Description (11) in the full prescribing information], including egg protein, or to a previous dose of any influenza vaccine is a contraindication to administration of Fluzone High-Dose Quadrivalent.

5 WARNINGS AND PRECAUTIONS
5.1 Guillain-Barré Syndrome
If Guillain-Barré syndrome (GBS) has occurred within 6 weeks following any previous influenza vaccination, the decision to give Fluzone High-Dose Quadrivalent should be based on careful consideration of the potential benefits and risks. The 1976 swine influenza vaccine was associated with an elevated risk of GBS. Evidence for a causal relation of GBS with other influenza vaccines is inconclusive; if an excess risk exists, it is probably slightly more than 1 additional case per 1 million persons vaccinated. GBS has also been temporally associated with influenza disease. (See references 1 and 2 in the full prescribing information.)

5.2 Preventing and Managing Allergic Reactions
Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

5.3 Altered Immunocompetence
If Fluzone High-Dose Quadrivalent is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be lower than expected.

5.4 Limitations of Vaccine Effectiveness
Vaccination with Fluzone High-Dose Quadrivalent may not protect all recipients.

6 ADVERSE REACTIONS
6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse event rates observed in the clinical trial(s) of a vaccine cannot be directly compared to rates in the clinical trial(s) of another vaccine and may not reflect the rates observed in practice. One clinical study has evaluated the safety of Fluzone High-Dose Quadrivalent.

Study 1 (NCT03282240, see https://clinicaltrials.gov) was a randomized, active-controlled, modified double-blind pre-licensure trial conducted in the U.S. The study compared the safety and immunogenicity of Fluzone High-Dose Quadrivalent to those of Fluzone High-Dose (trivalent formulation). The safety analysis set included 1777 Fluzone High-Dose Quadrivalent recipients, 443 Fluzone High-Dose recipients, and 450 investigational Fluzone High-Dose containing the alternate B influenza strain recipients.
The most common reactions occurring after Fluzone High-Dose Quadrivalent administration were injection-site pain (41.3%), myalgia (22.7%), headache (14.4%), and malaise (13.2%). Onset usually occurred within the first 3 days after vaccination.

Table 1 displays solicited adverse reactions for Fluzone High-Dose Quadrivalent compared to Fluzone High-Dose reported within 7 days after vaccination and collected using standardized diary cards.

Table 1: Study 1: Frequency of Solicited Injection-Site Reactions and Systemic Adverse Events within 7 Days after Vaccination with Fluzone High-Dose Quadrivalent or Fluzone High-Dose, Adults 65 Years of Age and Older

<table>
<thead>
<tr>
<th>Event</th>
<th>Fluzone High-Dose Quadrivalent (N=1761-1768)</th>
<th>Fluzone High-Dose (N=885-889)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Reactions</td>
<td>Percentage</td>
<td>Percentage</td>
</tr>
<tr>
<td>Injection Site Pain</td>
<td>41.3</td>
<td>36.4</td>
</tr>
<tr>
<td>Injection Site Erythema</td>
<td>6.2</td>
<td>5.7</td>
</tr>
<tr>
<td>Injection Site Swelling</td>
<td>4.9</td>
<td>4.7</td>
</tr>
<tr>
<td>Injection Site Induration</td>
<td>3.7</td>
<td>3.5</td>
</tr>
<tr>
<td>Injection Site Bruising</td>
<td>1.3</td>
<td>1.1</td>
</tr>
<tr>
<td>Systemic Reactions</td>
<td>Percentage</td>
<td>Percentage</td>
</tr>
<tr>
<td>Myalgia</td>
<td>22.7</td>
<td>18.9</td>
</tr>
<tr>
<td>Headache</td>
<td>14.4</td>
<td>13.6</td>
</tr>
<tr>
<td>Malaise</td>
<td>13.2</td>
<td>13.4</td>
</tr>
<tr>
<td>Shivering</td>
<td>5.4</td>
<td>4.7</td>
</tr>
<tr>
<td>Fever</td>
<td>0.4</td>
<td>0.9</td>
</tr>
</tbody>
</table>

NCT03282240

5.4.1 Postmarketing Experience
Fluzone High-Dose Quadrivalent: Based on data from Fluzone High-Dose, solicited injection site reactions and systemic adverse reactions were slightly more frequent after vaccination with Fluzone High-Dose compared to a standard-dose vaccine.

Unsolicited non-serious adverse events were reported in 279 (15.7%) recipients in the Fluzone High-Dose Quadrivalent group and 140 (15.7%) recipients in the Fluzone High-Dose group. The most commonly reported unsolicited adverse event was cough.

Within 180 days post-vaccination, 80 (4.5%) Fluzone High-Dose Quadrivalent recipients and 48 (5.4%) Fluzone High-Dose recipients experienced a serious adverse event (SAE). None of the SAEs were assessed as related to the study vaccines.

6.2 Postmarketing Experience
The following additional adverse events have been spontaneously reported during the postmarketing use of Fluzone High-Dose, Fluzone, or Fluzone Quadrivalent and may occur in people receiving Fluzone High-Dose Quadrivalent. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

- **Blood and Lymphatic System Disorders**: Thrombocytopenia, lymphadenopathy
- **Immune System Disorders**: Anaphylaxis, other allergic/hypersensitivity reactions (including urticaria, angioedema)
- **Eye Disorders**: Ocular hyperemia
- **Nervous System Disorders**: Guillain-Barré syndrome (GBS), convulsions, febrile convulsions, myelitis (including encephalomyelitis and transverse myelitis), facial palsy (Bell’s palsy), optic neuritis/neuropathy, brachial neuritis, syncope (shortly after vaccination), dizziness, paresthesia
- **Vascular Disorders**: Vasculitis, vasodilation
- **Respiratory, Thoracic and Mediastinal Disorders**: Dyspnea, cough, wheezing, throat tightness, oropharyngeal pain, and rhinorrhea
- **Gastrointestinal Disorders**: Vomiting
- **Skin and Subcutaneous Tissue Disorders**: Stevens-Johnson syndrome
- **General Disorders and Administration Site Conditions**: pruritus, asthenia, fatigue, chest pain, chills
8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Fluzone High-Dose Quadrivalent is not approved for use in persons <65 years of age. There are limited human data on Fluzone High-Dose and no animal data available on Fluzone High-Dose Quadrivalent to establish whether there is a vaccine-associated risk with use of Fluzone High-Dose Quadrivalent in pregnancy.

8.2 Lactation
Fluzone High-Dose Quadrivalent is not approved for use in persons <65 years of age. No human or animal data are available to assess the effects of Fluzone High-Dose Quadrivalent on the breastfed infant or on milk production/excretion.

8.4 Pediatric Use
Safety and effectiveness of Fluzone High-Dose Quadrivalent in children younger than 18 years of age have not been established.

8.5 Geriatric Use
Safety, immunogenicity, and efficacy of Fluzone High-Dose Quadrivalent have been evaluated in adults 65 years of age and older [see Adverse Reactions (6.1) and Clinical Studies (14) in the full prescribing information].

Manufactured by:
Sanofi Pasteur Inc.
Swiftwater PA 18370 USA

INHDQ-BPLR-SL-NOV19 Revised: November 2019
As the opioid crisis continues, physicians need the most appropriate tools to combat the opioid crisis, including medication-assisted treatment (MAT).

But do they have access to them? And are there enough of these front-line caregivers with the tools they need to help people suffering from an opioid addiction?

**ACCESS IS A CHALLENGE**
Medication-assisted treatment, or MAT, involves the use of certain medications, along with counseling and other behavioral therapies to treat addiction. Buprenorphine is one of the three FDA-approved medications used in MAT, according to the Substance Abuse and Mental Health Services Administration (SAMHSA).

Currently, access to this kind of treatment is a challenge for patients across the country, says Mohammad Zare, MD, associate professor and vice chair of community services in the department of family and community medicine at McGovern Medical School at The University of Texas Health Science Center at Houston (UTHealth) and the chief of staff of ambulatory care services in the Harris Health System. That includes Houston, where the methadone clinics can’t handle the volume of patients with an opioid use disorder.

In fact, improving access to treatment and recovery services and promoting the use of overdose-reversing drugs are two of the U.S. Department of Health and Human Services’ five top priorities in responding to the ongoing opioid crisis.

But clinicians can’t just prescribe buprenorphine whenever they want to. They must have a special waiver, certifying that they’ve completed a relevant training course.

The federal Drug Addiction Treatment Act of 2000 requires healthcare practitioners to apply for a waiver in order to prescribe or dispense buprenorphine as a treatment for an opioid use disorder. They have to start by conveying their intent to apply for a waiver to the SAMHSA Center for Substance Abuse Treatment.

Currently, physician applicants must provide proof that they’ve completed an eight-hour training course, plus their DEA...
Physicians increasingly avoid prescribing opioids for pain patients, survey finds

**by Keith A. Reynolds** associate editor

Doctors are increasingly hesitant to prescribe opioids for their patients even when the drugs are warranted, and despite government warnings about the negative effects of sudden discontinuation and tapering, according to a recent report from Quest Diagnostics and the Center on Addiction.

The survey found that 81 percent of responding physicians are reluctant to take on new patients currently prescribed opioids, even though 83 percent of physicians admit that the ongoing opioid crisis has made it increasingly difficult to treat patients suffering from chronic pain.

This reticence is in line with a 2016 CDC guideline for prescribing opioids for chronic pain that warned of the risks of opioid use. The guideline said that no evidence showed a long-term benefit of opioids in improving pain and function compared to treatment without the drugs.

On the other hand, extensive evidence existed for the possible harms of opioids and the benefits of non-opioid treatments for chronic pain, according to the CDC.

The guideline was a response to a growing crisis, which as of early 2019 saw 130 people dying each day of opioid overdoses and is thought to be partly responsible for an overall drop in life expectancy. Some of the blame for the crisis has been directed at pharmaceutical companies, many of which had marketed opioids as safe and non-addictive since the late 1990s, leading to an explosion of prescriptions, according to drugabuse.gov.

But there’s evidence that physicians have pulled back on prescribing opioids and as a result may be causing harm to some patients, leading health officials to clarify guidance about the 2016 CDC guidelines.

In April, 2019, the CDC and FDA clarified the guidelines by acknowledging the harm that can result from abruptly ceasing or rapidly tapering opioid treatment for chronic pain.

“These practices can result in severe opioid withdrawal symptoms including pain and psychological distress, and some patients might seek other sources of opioids,” the CDC clarification says.

“In addition, policies that mandate hard limits conflict with the Guideline’s emphasis on individualized assessment of the benefits and risks of opioids given the specific circumstances and unique needs of each patient.”

The CDC clarification also includes advice to physicians with patients receiving long-term high-dosage opioid regimens. This includes:

- Maximizing non-opioid treatment,
- Empathetically reviewing risks associated with the regimens,
- Collaborating with patients who agree to taper their doses,
- Tapering slowly enough to minimize withdrawal symptoms
- Individualizing the pace of tapering, and
- Closely monitoring and mitigating overdose risk for patients who continue the regimen.

These clarifications were followed in October by new guidance from HHS on appropriate tapering or discontinuing long-term opioid use. The guidance emphasizes that once a patient is on an opioid regimen for an extended period of time any change can put the patient at risk for harm.

“In certain situations, a reduced opioid dosage may be indicated, in joint consultation with the care team and the patient,” the new guide says. “HHS does not recommend opioids be tapered rapidly or discontinued suddenly due to the significant risks of opioid withdrawal, unless there is a life-threatening issue confronting the individual patient.”

The physicians Quest surveyed say they believe their peers will increasingly use non-opioid treatments for chronic pain, including 85% who say physicians will be more likely to use non-pharmacological treatments such as acupuncture, massage and physical therapy, and 58% who say physicians will use marijuana products.
study, a clinical trial designed to examine which strategies can increase buprenorphine prescription rates in primary care settings.

Zare’s team is testing out a collaborative care approach called the Massachusetts Model. They’re comparing one clinic with a clinical nurse manager to support three waiver-trained primary care providers against a control clinic without that additional support. They hope to find out if that support can expand the number of patients they’re able to see and treat in a primary care setting.

The goal: to find an approach that reaches more people who need MAT so they can experience long-term success. “They become more functional. They go back to work again. They start having a job and going back to their families,” says Zare.

“Do you want an orthopedist delivering your baby? You want somebody who’s trained. Treating addiction isn’t something that we can just make up as we go along. Our training and medical education needs to catch up to the problem.”

—DEBRA FURR-HOLDEN, PHD, ASSOCIATE DEAN FOR PUBLIC HEALTH INTEGRATION, MICHIGAN STATE UNIVERSITY; DIRECTOR, FLINT CENTER FOR HEALTH EQUITY SOLUTIONS

IS THE WAIVER REQUIREMENT A BARRIER?

Some suggest that the waiver requirement is a barrier to having more front-line clinicians prepared to provide MAT. But how much of a barrier does the requirement present?

The waiver does set limits on the number of patients for whom a provider can prescribe buprenorphine. But the training course is free, and can be completed at the student’s leisure, notes psychiatrist Michael Mancino, MD, program director of The Psychiatric Research Institute’s Center for Addiction Services and Treatment at the University of Arkansas for Medical Sciences. “That is not a significant barrier,” he says.

Nurse practitioners and physician assistants are eligible for waivers, too. They must complete 24 hours of training, or they can take the same eight-hour training as physicians, plus an additional 16 hours of training from SAMHSA.

In Arkansas, the number of providers with waivers has grown from 85 to more than 300 over the past few years, according to Mancino. But he says the waiver isn’t the biggest hurdle standing in the way of people gaining access to more waiver-trained clinicians. “The number one barrier in Arkansas is stigma,” says Mancino.

He explains that some clinicians don’t believe that addiction is an illness—and thus should not be treated as such. Instead, some still view addiction as a moral failure or the result of a lack of willpower. Zare agrees that the mindset needs to shift. “Substance use disorder is a chronic disease,” he says. “We don’t stigmatize someone who has hypertension. We manage it chronically. We need to take patients with substance use disorder and treat them the same way.”

WHAT ELSE IS NEEDED?

A recent study in the journal Drug and Alcohol Dependence examined the disparity between opioid overdose deaths and available treatment services in Flint, Michigan. The researchers found that opioid treatment centers were rarely located in the areas where the most overdose deaths occurred.

That’s critical information because it shows where the greatest need lies and illustrates a geographic barrier for people who may want treatment but can’t access it, according to researcher and epidemiologist Debra Furr-Holden, PhD, associate dean for public health integration at Michigan State University and director of the Flint Center for Health Equity Solutions.

The study also illustrates the need for more healthcare professionals who are specialists in addiction medicine, says Furr-Holden. A generalist with waiver training can be helpful, but having an adequate number of experts with the specialized training and experience is really critical.

“Do you want an orthopedist delivering your baby?” Furr-Holden says. “You want somebody who’s trained. Treating addiction isn’t something that we can just make up as we go along. Our training and medical education needs to catch up to the problem.”
Primary care is in a bad place. Physicians feel undervalued. Cumber-
some technology, administrative burdens and payer hassles mean
physicians are unable to spend the time they want with their patients.
At the same time, patients have
never had more choices for where
to get primary care. Hospital systems and
private equity are gobbling up practices.
Drug store chains are opening clinics,
where patients can see a non-physician
provider for basic care.

Does this mean the traditional physi-
cian-patient relationship is dead?
Timothy Hoff, Ph.D., professor of man-
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argues that both physicians and patients
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Timothy Hoff, Ph.D., professor of man-
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still want a long-term relationship, but
modern healthcare, with all its complex-
ity and focus on value is preventing both
parties from forging the caring relation-
ships they would prefer.

This is the case that Hoff makes in his
book, *Next in Line: Lowered Care Expecta-
tions in the Age of Retail- and Value-Based
Health*, published in 2018 by Oxford Uni-
versity Press.

Hoff sat down with *Medical Economics*
to discuss the state of the physician-pa-
tient relationship and what can be done
to fix it. This interview has been edited for
length and clarity.

**Q:** *Medical Economics:* There is this ideal
of the doctor-patient relationship that physicians
and patients hold on to. Has it ever really existed?

**Hoff:** That’s a fair question. It’s something
that we’ve romanticized over time. But I
think it’s real, it’s been real, and you can
see evidence for it in our own healthcare
history, as well as even some of the trends
that you see going on right now.

There was a time where we had these
doctors called general prac-
titioners, the forerunners of
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When my BPH symptoms became unbearable I really didn’t want to undergo invasive surgery and I’m not a personal fan of BPH medications. Relief can be inadequate and temporary and they have a whole host of side effects.1

Peter J. Walter, M.D., F.A.C.S. Western New York Urology Associates and UROLIFT® SYSTEM PATIENT

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1. AUA Guidelines 2003, 2010
2. Speakman et al. 2014 BJUI International
3. Roehrborn | Urol 2013 LIFT Study
4. Shore, Can J Urol 2014 Local Study
5. AUA BPH Guidelines 2003

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family doctors, when we did have much more relational medicine. That was in part because we didn't have as much technology to rely on and we didn't have so many specialists. Back then, many people did have long-standing ongoing relationships with a single doctor, particularly in the primary care area. Those doctors tended to practice in the same communities, they stayed fairly stable over time within a practice.

So those relationships were definitely there. I think it's definitely been real. I think we do romanticize it for a reason because there's elements of it that are very real that many people have experienced over time and feel very strongly about.

Q: ME: How has being a primary care physician changed over the years?

Hoff: Primary care has changed an awful lot. I would focus, and the book talks about this, on three major reasons. One is the continued specialization in American medicine, this idea that no one doctor can do it all. And so, increasingly, primary care physicians have had their scope of practice whittled down. For example, they stopped doing hospital care, and were replaced by hospitalists. They stopped delivering babies. So one of the ways it's changed is the scope of practice continues to get more and more narrow.

Another way it's changed, and my book really takes aim at this, is primary care is the first brand of medicine that's really been fully corporatized, and corporatized with this idea I call "metric fever," which is what I call trying to standardize medicine as much as possible, which has the effect of making it more transactional. That makes it less focused on the squishy or relational elements like the doctor getting credit for talking to the patient. You can't measure that precisely, so increasingly those things aren't being valued.

And finally, as healthcare is being consolidated, more primary care doctors now work for large entities with hospitals at the center of them. And hospitals think about primary care very differently than the traditional primary care practice used to. So I think that those are the major ways primary care has changed: narrow scope of practice, standardization and cook-booking of primary care, and doctors who are largely employees of large systems.

Q: ME: One of the things we hear about a lot is the consumerization of healthcare, that patients are looking at healthcare more like they're looking at other things that they purchase and consume in their lives. Do you think it's true patients are looking at healthcare this way?

Hoff: Most doctors will tell you that most of their patients still desire the same things from their care and from their interactions with the system as they did 20 or 30 or 40 years ago. Patients want someone who's an expert, who's going to listen to them. They want someone who's going
to help them solve the problems they have, they don’t want to feel blown off and they want someone who shows a degree of empathy towards them.

I think a lot of consumerization is being concocted by an industry that’s not being controlled by doctors right now. For big organizations that want to streamline care, the view of the patient as consumer is really the best view to take.

Do patients want more consumer convenience? That’s true. They don’t want to wait three months to see a doctor. They don’t want to have to be put through tons of inconvenience for a primary care visit.

But the expectations of patients are being taken advantage of. This consumer rhetoric comes along that says, ‘Oh, I know your needs are not being met, and we can meet them, and here’s how we’re going to do it.’ But, you know, a lot of that, in my opinion, is snake oil.

Q: ME: What are your thoughts on the emergence of quick convenient care settings?

Hoff: There’s a real concerted effort among big healthcare companies and even non-healthcare companies like Amazon, Apple, and Google, to turn the primary care part of healthcare into a cheaper, more transactional form of care delivery—a fast food kind of model. Fast food with the use of technology: that’s the way I would put it. I think it’s a tsunami threatening to disrupt all primary care. There’s government acceptance of this new way of looking at it, there is venture capital acceptance of this new way of looking at it. But I don’t think patient acceptance is there. I think we’re being led to believe it is, but it’s not. But I do worry that, if something doesn’t change soon, you’re going to see a primary care system that looks extraordinarily different from the one we had even 10 years ago, a sort of pop-up franchise, drive-thru kind of system, aided by the use of technology.

Q: ME: What is the impact of these trends on actual patient outcomes? Are these changes leading to improvement in outcomes for, say, patients with chronic conditions?

Hoff: The data is underwhelming, let’s put it that way. We’ve invested a ton of money in the use of metrics and the use of measurements, the use of EHRs to document and collect data on patients. And yet the studies that are out there show the quality gains are negligible, particularly given the amount of investment. In other words, we haven’t had this dramatic improvement in outcomes. So, from a quality perspective, none of these new ways of looking at primary care have done the job, and from a cost perspective, the jury’s still out.

“There’s a real concerted effort among big healthcare companies . . . to turn the primary care part of healthcare into a cheaper, more transactional form of care delivery—a fast food kind of model.”

Q: ME: For primary care physicians who feel the deck is stacked against them, what should they do? How can they fight back against these trends?

Hoff: When it comes to primary care, it’s important to stress the relational side of medicine, the interpersonal connections that really make the difference. And so we have to pay for that. Doctors have been saying this for years, and I agree with them, that you’ve got to value those aspects more. And we’ve got to acknowledge the fact that to many policymakers and payers, that sort of care looks inefficient. So we do need to invest more in this relational care.

The medical profession itself is going to need to come to a decision about how much primary care doctors matter. I think doctors of all kinds now need to think about new forms of collective mobilization. I don’t use the term unions. They’ve got to find ways to band together—not in the way that they are banding together now. It’s very reactive now. They need to come together to assert their economic power and to advocate for specific things that are going to bring more value to the work that they do.
Fixing the problems with primary care

A core problem with primary care today is a schedule that does not allow the physician to be effective. The primary care physician lacks the time to heal.

The work of primary care became expansive starting in the 1970s when chronic illness management, preventive medicine and the biopsychosocial model were developed. Before the 1970s, in general, people only went to the doctor when they were sick. The physician had one problem to deal with. Now the work is much more complicated but no one changed the schedule! The number of patients a primary care physician is expected to manage stayed largely the same. Physicians are the only professionals in society that try to do complex work during brief visits. Lawyers, accountants, psychologists, interior decorators, landscape architects—no one else does. Without the necessary time, primary care physicians are not fulfilled and frequently burn out.

I started as a semi-rural physician out of residency in 1978. I had a 10-minute appointment schedule and saw about 30 patients a day. My patients convinced me to take longer with them so I went to 15 minute appointments. I would often drive home reflecting on the patients who really needed me that day that I wish I had more time for but I was too busy servicing the needs of the rest.

Fast forward to 1996, when I went to a university practice. The clinic was so dysfunctional at the front desk that they could only schedule me for 8 patients a half day clinic. I complained to no avail. So I just went with it and took more time with the patients I saw. Magic started to happen. I knew my patients narrative. They told me I learned things they never told another doctor. They loved me in a much different way. I was more effective.

I now practice in hybrid direct primary care model with 30 and 60 minute appointments. My group has had the highest patient satisfaction in our entire health system every quarter for the past 10 years. We now have 12,000 patients, 18 physicians and a handful of PAs/NPs in the practice. No one has ever burned out.

“Physicians are the only professionals in society that try to do complex work during brief visits.”

The economics of reduced panel sizes and fewer visits work by reducing healthcare costs when primary care is improved. Unfortunately, fee-for-service medicine still dominates and health systems bring in revenue from high revenue healthcare. We need to transition to a health industry from a wealth industry. Only then will we be able to re-engineer primary care to be attractive and effective.

Joseph E Scherger, MD, MPH, is a Primary Care 365 Physician and core faculty in the family medicine residency program at Eisenhower Health in La Quinta, Calif. He is also a member of the Medical Economics Editorial Advisory Board.
4 WAYS TO START IMMEDIATELY INCREASING REVENUE

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