NEW MALPRACTICE RISKS
How the pandemic will affect costs & liability

PRACTICE MANAGEMENT
How to set up a drive-thru vaccine clinic

MONEY
Major E/M coding changes: What you need to know

LEGAL
Tips to navigate a government audit

CHRONIC CONDITIONS
Obesity management: New implications for doctors

TECHNOLOGY
Why are cyberattacks on the rise?

MedicalEconomics.com
Indication
SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older. SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

Important Safety Information
• SHINGRIX is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX
• Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX
• Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%)
• Solicited general adverse reactions in subjects aged 50 years and older were myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%)

Not an actual patient.
ARE YOU OVERLOOKING PATIENTS LIKE JENNIFER, AGE 52?

PATIENT STORY:

Who’s in Jennifer’s Life?
- Her husband and two kids in high school
- The employees in her flower shop
- Her running buddies

Lifestyle:
She eats healthy, walks every day, and runs a few times a week

Medical History:
No current medical issues

Interaction with HCP:
Diligent about annual physicals and is proactive in discussing lifestyle changes to ensure she stays healthy

Recommendation Opportunity:
When discussing prevention during her annual exam

Recommend SHINGRIX Because¹:
She is always proactive about her healthcare

NO MATTER HOW HEALTHY SHE MAY FEEL, JENNIFER’S AT RISK FOR SHINGLES¹-⁴

She’s 52 years old and never felt healthier. But she’s still a candidate for SHINGRIX, a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older. Consider the patients in your office: Are you overlooking patients like Jennifer?

Important Safety Information (cont’d)
- SHINGRIX was not studied in pregnant or lactating women, and it is unknown if it is excreted in human milk. Therefore, it cannot be established whether there is vaccine-associated risk with SHINGRIX in pregnant women or if there are effects on breastfed infants or milk production/excretion
- Vaccination with SHINGRIX may not result in protection of all vaccine recipients

Please see Brief Summary of Prescribing Information for SHINGRIX on the following pages.


See more patient profiles at ProfilesSHINGRIX.com

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BRIEF SUMMARY

SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)

The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE

SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older.

Limitations of Use:

SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

2 DOSAGE AND ADMINISTRATION

2.2 Administration Instructions

For intramuscular injection only.

After reconstitution, administer SHINGRIX immediately or store refrigerated between 2°C and 8°C (36° and 46°F) and use within 6 hours. Discard reconstituted vaccine if not used within 6 hours.

2.3 Dose and Schedule

Two doses (0.5 mL each) administered intramuscularly according to the following schedule: A first dose at Month 0 followed by a second dose administered anytime between 2 and 6 months later.

4 CONTRAINDICATIONS

Do not administer SHINGRIX to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX [see Description (11) of full prescribing information].

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

Prior to administration, the healthcare provider should review the immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. There is the possibility that broad use of SHINGRIX could reveal adverse reactions not observed in clinical trials.

Overall, 17,041 adults aged 50 years and older received at least one dose of SHINGRIX in 17 clinical studies.

The safety of SHINGRIX was evaluated by pooling data from 2 placebo-controlled clinical studies (Studies 1 and 2) involving 29,305 subjects aged 50 years and older who received at least one dose of SHINGRIX (n = 14,643) or saline placebo (n = 14,660) administered according to a 0- and 2-month schedule. At the time of vaccination, the mean age of the population was 69 years; 7,286 (24.3%) subjects were aged 50 to 59 years, 4,486 (15.3%) subjects were aged 60 to 69 years, and 17,531 (59.8%) subjects were aged 70 years and older. Both studies were conducted in North America, Latin America, Europe, Asia, and Australia. In the overall population, the majority of subjects were white (74.3%), followed by Asian (18.3%), black (1.4%), and other racial/ethnic groups (6.0%); 58% were female.

Solicited Adverse Events

In Studies 1 and 2, data on solicited local and general adverse events were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., day of vaccination and the next 6 days) in a subset of subjects (n = 4,886 receiving SHINGRIX, n = 4,881 receiving placebo with at least 1 documented dose). Across both studies, the percentages of subjects aged 50 years and older reporting each solicited local adverse reaction and each solicited general adverse event following administration of SHINGRIX (both doses combined) were pain (78.0%), redness (38.1%), and swelling (25.9%); and myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%), respectively.

The reported frequencies of specific solicited local adverse reactions and general adverse events (overall per subject), by age group, from the 2 studies are presented in Table 1.

Table 1. Percentage of Subjects with Solicited Local Adverse Reactions and General Adverse Events within 7 Days of Vaccination in Adults Aged 50 to 59 Years, 60 to 69 Years, and 70 Years and Older (Total Vaccinated Cohort with 7-Day Diary Card)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>SHINGRIX %</th>
<th>Placebo %</th>
<th>SHINGRIX %</th>
<th>Placebo %</th>
<th>SHINGRIX %</th>
<th>Placebo %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aged 50-59 Years</td>
<td>n = 1,315</td>
<td>n = 1,312</td>
<td>n = 1,311</td>
<td>n = 1,305</td>
<td>n = 2,258</td>
<td>n = 2,263</td>
</tr>
<tr>
<td>Pain</td>
<td>88.4</td>
<td>14.4</td>
<td>82.8</td>
<td>11.1</td>
<td>69.2</td>
<td>8.8</td>
</tr>
<tr>
<td>Pain, Grade 3</td>
<td>10.3</td>
<td>0.5</td>
<td>6.9</td>
<td>0.5</td>
<td>4.0</td>
<td>0.2</td>
</tr>
<tr>
<td>Redness</td>
<td>38.7</td>
<td>1.2</td>
<td>38.4</td>
<td>1.6</td>
<td>37.7</td>
<td>1.2</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>2.8</td>
<td>0.0</td>
<td>2.6</td>
<td>0.0</td>
<td>3.1</td>
<td>0.0</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>30.5</td>
<td>0.8</td>
<td>26.5</td>
<td>1.0</td>
<td>23.0</td>
<td>1.1</td>
</tr>
<tr>
<td>General Events</td>
<td>n = 1,315</td>
<td>n = 1,312</td>
<td>n = 1,309</td>
<td>n = 1,305</td>
<td>n = 2,252</td>
<td>n = 2,264</td>
</tr>
<tr>
<td>Myalgia</td>
<td>56.9</td>
<td>15.2</td>
<td>49.0</td>
<td>11.2</td>
<td>35.1</td>
<td>9.9</td>
</tr>
<tr>
<td>Myalgia, Grade 3</td>
<td>8.9</td>
<td>0.9</td>
<td>5.3</td>
<td>0.8</td>
<td>2.8</td>
<td>0.4</td>
</tr>
<tr>
<td>Fatigue</td>
<td>57.0</td>
<td>19.8</td>
<td>45.7</td>
<td>16.8</td>
<td>36.6</td>
<td>14.4</td>
</tr>
<tr>
<td>Fatigue, Grade 3</td>
<td>8.5</td>
<td>1.8</td>
<td>5.0</td>
<td>0.8</td>
<td>3.5</td>
<td>0.8</td>
</tr>
<tr>
<td>Headache</td>
<td>50.6</td>
<td>21.6</td>
<td>39.6</td>
<td>15.6</td>
<td>29.0</td>
<td>11.8</td>
</tr>
<tr>
<td>Headache, Grade 3</td>
<td>6.0</td>
<td>1.7</td>
<td>3.7</td>
<td>0.2</td>
<td>1.5</td>
<td>0.4</td>
</tr>
<tr>
<td>Shivering</td>
<td>35.8</td>
<td>7.4</td>
<td>30.3</td>
<td>5.7</td>
<td>19.5</td>
<td>4.9</td>
</tr>
<tr>
<td>Shivering, Grade 3</td>
<td>6.8</td>
<td>0.2</td>
<td>4.5</td>
<td>0.3</td>
<td>2.2</td>
<td>0.3</td>
</tr>
<tr>
<td>Fever</td>
<td>27.8</td>
<td>3.0</td>
<td>23.9</td>
<td>3.4</td>
<td>14.3</td>
<td>2.7</td>
</tr>
<tr>
<td>Fever, Grade 3</td>
<td>0.4</td>
<td>0.2</td>
<td>0.5</td>
<td>0.2</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>GI</td>
<td>24.3</td>
<td>10.7</td>
<td>16.7</td>
<td>8.7</td>
<td>13.5</td>
<td>7.6</td>
</tr>
<tr>
<td>GI, Grade 3</td>
<td>2.1</td>
<td>0.7</td>
<td>0.9</td>
<td>0.6</td>
<td>1.2</td>
<td>0.4</td>
</tr>
</tbody>
</table>

Total vaccinated cohort for safety included all subjects with at least 1 documented dose (n).

a 7 days included day of vaccination and the subsequent 6 days.

b Data for subjects aged 50 to 59 years and 60 to 69 years are based on Study 1. Data for subjects 70 years and older are based on pooled data from Study 1: NCT01165177 and Study 2: NCT01165229.

c Placebo was a saline solution.

d Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.

f Grade 3 myalgia, fatigue, headache, shivering, GI: Defined as preventing normal activity.

i Fever defined as ≥37.5°C/99.5°F for oral, axillary, or tympanic route, or ≥38°C/100.4°F for rectal route; Grade 3 fever defined as ≥39°C/102.2°F.

Gl = Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

(continued on next page)
The incidence of solicited local and general symptoms was lower in subjects aged 70 years and older compared with those aged 50 to 69 years.

The majority of solicited local adverse reactions and general adverse events seen with SHINGRIX had a median duration of 2 to 3 days.

There were no differences in the proportions of subjects reporting any or Grade 3 solicited local reactions between Dose 1 and Dose 2. Headache and shivering were reported more frequently by subjects after Dose 2 (28.2% and 21.4%, respectively) compared with Dose 1 (24.4% and 13.8%, respectively). Grade 3 solicited general adverse events (headache, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3.1%, 3.6%, and 3.5%, respectively) compared with Dose 1 (1.4%, 1.4%, 2.3%, and 2.4%, respectively).

Unsolicited Adverse Events

Unsolicited adverse events that occurred within 30 days following each vaccination (Day 0 to 29) were recorded on a diary card by all subjects. In the 2 studies, unsolicited adverse events occurring within 30 days of vaccination were reported in 50.5% and 32.0% of subjects who received SHINGRIX (n = 14,645) and placebo (n = 14,660), respectively (Total Vaccinated Cohort). Unsolicited adverse events that occurred in ≥1% of recipients of SHINGRIX and at a rate at least 1.5-fold higher than placebo included chills (3.5% versus 0.2%), injection site pruritus (2.2% versus 0.2%), malaise (1.7% versus 0.3%), arthralgia (1.7% versus 1.2%), nausea (1.4% versus 0.5%), and dizziness (1.2% versus 0.8%).

Gout (including gouty arthritis) was reported by 0.18% (n = 27) versus 0.05% (n = 8) of subjects who received SHINGRIX and placebo, respectively, within 30 days of vaccination. Available information is insufficient to determine a causal relationship with SHINGRIX.

Serious Adverse Events (SAEs)

In the 2 studies, SAEs were reported at similar rates in subjects who received SHINGRIX (2.3%) and placebo (2.2%) from the first administered dose up to 30 days post last vaccination. SAEs were reported for 10.1% of subjects who received SHINGRIX and for 10.4% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. One subject (<0.01%) reported lymphadenitis and 1 subject (<0.01%) reported fever greater than 39°C; there was a basis for a causal relationship with SHINGRIX.

Optic ischemic neuropathy was reported in 3 subjects (0.02%) who received SHINGRIX (all within 50 days after vaccination) and 0 subjects who received placebo; available information is insufficient to determine a causal relationship with SHINGRIX.

Deaths

From the first administered dose up to 30 days post last vaccination, deaths were reported for 0.04% of subjects who received SHINGRIX and 0.05% of subjects who received placebo in the 2 studies. From the first administered dose up to 1 year post last vaccination, deaths were reported for 0.8% of subjects who received SHINGRIX and for 0.9% of subjects who received placebo. Causes of death among subjects were consistent with those generally reported in adult and elderly populations.

Potential Immune-Mediated Diseases

In the 2 studies, new onset potential immune-mediated diseases (pIMDs) or exacerbation of existing pIMDs were reported for 0.6% of subjects who received SHINGRIX and 0.7% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. The most frequent pIMD occurred with comparable frequencies in the group receiving SHINGRIX and the placebo group.

Dosing Schedule

In an open-label clinical study, 238 subjects 50 years and older received SHINGRIX as a 0- and 2-month or 0- and 6-month schedule. The safety profile of SHINGRIX was similar when administered according to a 0- and 2-month or 0- and 6-month schedule and was consistent with that observed in Studies 1 and 2.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of SHINGRIX. 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 the vaccine.

General Disorders and Administration Site Conditions

Decreased mobility of the injected arm which may persist for 1 or more weeks.

Immune System Disorders

Hypersensitivity reactions, including angioedema, rash, and urticaria.

7 DRUG INTERACTIONS

7.1 Concomitant Vaccine Administration

For concomitant administration of SHINGRIX with inactivated influenza vaccine [see Clinical Studies (14.5) of full prescribing information].

7.2 Immunosuppressive Therapies

Immunosuppressive therapies may reduce the effectiveness of SHINGRIX.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There are no available human data to establish whether there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1) of full prescribing information].

8.2 Lactation

It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfed infant or on milk production/excretion [see Use in Specific Populations (8.2) of full prescribing information].

8.5 Geriatric Use

Of the total number of subjects who received at least 1 dose of SHINGRIX in the 2 efficacy trials (n = 14,645), 2,243 (15.3%) were aged 60 to 69 years, 6,837 (46.7%) were aged 70 to 79 years, and 1,921 (13.1%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups or between these subjects and younger subjects [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information].

The frequencies of solicited local and general adverse events in subjects aged 70 years and older were lower than in younger adults (aged 50 through 69 years) [see Adverse Reactions (6.1)].

17 PATIENT COUNSELING INFORMATION

• Inform patients of the potential benefits and risks of immunization with SHINGRIX and of the importance of completing the 2-dose immunization series according to the schedule.

• Inform patients about the potential for adverse reactions that have been temporally associated with administration of SHINGRIX.

• Provide the Vaccine Information Statements, which are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

Storage:

Store vials of Lyophilized gE Antigen and Adjuvant Suspension Components refrigerated between 2° and 8°C (36° and 46°F). Protect vials from light. Do not freeze. Discard if the vials have been frozen.

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Malpractice risk trends

COVID-19 has changed the world, including nearly every aspect of health care. One change that physicians are in the midst of — and where there remains considerable uncertainty — is what effect the pandemic will have on physician malpractice risk.

Medical Economics® editors have asked malpractice experts about what they think is coming, and whether COVID-19, increased reliance on telehealth and patients avoiding care because of justified fears of the coronavirus will mean an increase in lawsuits. Some say they think the goodwill that physicians have earned during the pandemic will mean fewer lawsuits. Others call malpractice risk a “lagging indicator” from the pandemic, and that physicians need to prepare for rising costs and potential increased risk. Check out our cover story, which breaks all of this down in a useful way and provides tips for physicians to weather this uncertainty.

Malpractice is not the only risk we cover in this issue. Would you be surprised to learn that the risk of your practice being hacked remains on the rise? Our editors sat down with a cybersecurity expert, who broke down for us why risks are increasing and what practice and other health care organizations can do protect themselves.

I also want to highlight the fact that flu season is here, and that this year will likely be challenging as physicians and patients grapple with flu while still managing COVID-19. One thing many physicians are doing is figuring out creative ways to administer vaccines in a way that make physicians feel safe. Terry Brenneman, M.D., has created a drive-thru vaccine clinic at his practice and he wrote a very helpful article explaining step-by-step how he did it. Check it out inside.

As always, please let us know how we’re doing by emailing our editors at medec@mjhlifesciences.com. Our goal is to provide you, our physician audience, with the practical content you need to help manage the myriad challenges facing physicians today. We need your ideas, your questions and your thoughts to make this publication the best it can be!

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Exacerbations are frequently not reported by patients \(^2\)

After one exacerbation, a patient's lung function may never recover \(^1\)

Exacerbations may increase the risk of death \(^5,6\)

References:

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Although the danger may be hidden, COPD EXACERBATIONS CAN STRIKE ANYTIME \(^1,4\)

- Exacerbations are frequently not reported by patients \(^2\)
- After one exacerbation*, a patient's lung function may never recover \(^1\)
- Exacerbations may increase the risk of death \(^5,6\)

You can't predict, so protect \(^3,4,7\): HiddenDangers.com
COVID-19 COVERAGE CENTRAL

Medical Economics® editors are covering what you need to know during the ongoing novel coronavirus (COVID-19) pandemic. Our ongoing coverage of COVID-19 includes:

- Breaking news on the latest developments.
- Tips for physicians to extend the life of N95 respirators.
- Mental health tips for doctors and other providers.
- How physicians can protect themselves from COVID-19.
- Strategies for using telehealth.

To read all of our ongoing coverage, go to MedicalEconomics.com

Perfect your telehealth program

Tabassum Salam, M.D., the ACP’s vice president of medical education, discusses what physicians need to know to get started with telehealth right away.

Watch this video and others at: bit.ly/MedEcVideo

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BETWEEN COVID-19 AND A HARDENING MARKET, MEDICAL MALPRACTICE INSURANCE HAS UNDERGONE A SEISMIC SHIFT.
Now, more than ever, you need coverage options that give you **peace of mind**.
ISMIE continues to provide innovative solutions to ensure physicians are protected in any market.
How COVID-19 will affect costs & liability

COVID-19 has changed the world, including nearly every aspect of health care, including legal risks. Physicians will need to stay vigilant to ensure they can appropriately manage potential risks from increased telehealth, patients delaying care and much more.
Malpractice trends

What’s happening with cost and claims in the wake of COVID-19

by Jeffrey Bendix Senior Editor

Doctors have enjoyed more than a decade of relatively affordable medical malpractice premiums. But for many, those good times are ending.

The turnaround is documented in a white paper published earlier this year by the investment management firm Conning. The company found that after peaking in 2006, premiums dropped 20% between 2007 and 2013, then remained fairly steady before increasing by 5% in 2019.

Similarly, Medical Liability Monitor, in its 2019 annual rate survey, found that more than 25% of medical professional liability premium rates increased during the preceding year, the first time that has happened since 2006.

“2018 marked the year in which premiums were the lowest we’ve seen in this century,” says Robert E. White Jr., executive vice president for medical professional liability at The Doctors Company, a malpractice insurance provider. “But in the last year or two we’ve seen the market become firmer.”

Still unknown is how the COVID-19 pandemic will affect the medical malpractice market. The

Continues on Page 12 >>
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• Up to a 15% premium discount for participation by eligible policyholders in our Managing Risk Partnership Program
• Resources during COVID-19 such as our Wellness Center and Reopening Your Practice Risk Management guidance

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LEGAL / MALPRACTICE TRENDS

Continued from Page 10

answer to that question won’t become clear for several years, White says, because most malpractice suits aren’t filed until several years after the incident on which they are based, and then take more years to move through the judicial system.

Matt Gracey, CEO of Danna-Gracey, a malpractice insurance broker headquartered in Delray Beach, Florida, says rate increases in the 5% range actually are on the lower end of the scale he has seen, and are generally limited to smaller practices. Some large multispecialty groups his company works with have seen their rates go up by as much as 100% over the last 18 months, he adds.

Gracey says premiums were held down in the years prior to 2019 because of a combination of factors, including new competitors entering the market and a decline in the number and severity of malpractice suits around the country. The latter development was due in part to a wave of tort reform legislation prior to 2006 in which states placed caps on the dollar amounts of damage awards in malpractice cases and/or made it more difficult for plaintiffs to sue physicians and hospitals.

But those drivers of lower premiums have ended or reversed over the past few years. White notes that there is less competition in the market, with about 100 companies writing policies today compared with approximately 130 four or five years ago. Meanwhile, states such as Texas, Florida and Oregon have seen their caps on damage awards either struck down by the courts or modified by their legislatures.

The result, says Gracey, is that “every A-rated carrier specializing in malpractice insurance now is running a combined loss ratio of over 100%, meaning that for every dollar of premium they bring in they’re paying out more than a dollar, which means they have to raise their rates.”

To be sure, not all doctors have seen increases in their malpractice premiums. Melissa Lucarelli, M.D., a family practitioner in Randolph, Wisconsin, and member of the Medical Economics editorial advisory board, is paying $10,288 in premiums. Melissa Lucarelli, M.D., a family practitioner in Randolph, Wisconsin, and member of the Medical Economics editorial advisory board, is paying $10,288 in 2020, a slight decrease from the $10,357 she paid in 2015. Similarly, Damon Raskin, M.D., an internist in Pacific Palisades, California, says his malpractice premiums have changed “hardly at all” over the past five years.

That there are exceptions to the overall trend doesn’t surprise White. “The fact is, there are 50 different states and 50 different markets in the MPL (medical professional liability) business, and when the market starts to change it trends slowly,” he says. And although an insurance carrier may be experiencing an overall loss in a state, “there may be specialties in that state where no increase is indicated.”

As for the legal risks to doctors posed by COVID-19, experts say these could take several forms. One stems from the prohibitions on elective surgeries most states imposed at the start of the pandemic. “If a doctor deemed something to be nonemergent during the elective surgery ban and (it) turned out they were wrong, they could be sued,” White says.

A second category of risks is from patients claiming they contracted COVID-19 at a physician’s office. Some practices are trying to protect themselves by requiring patients to sign an “exculpatory clause” agreement, limiting the patient’s ability to sue if they experience any harm while being treated. But White warns that relying on exculpatory clauses for protection is dangerous.

“We tell these physicians upfront that an exculpatory clause probably won’t provide the protection they’re looking for because they generally aren’t viewed with favor by the courts,” he says.

“Probably the best they can hope for in that regard is some form of state or federal legal immunity for physicians.”

Doctors can also take heart from the difficulty inherent in proving that a person contracted COVID-19 in a particular place, says Frederick M. Cummings, J.D., a health law attorney with Dickinson Wright in Phoenix, Arizona.

“Exposure could come from a myriad of places,” Cummings notes. “If I were a plaintiff’s lawyer, I wouldn’t take that case because there’s still so much community spread.”

White urges practices to follow the CDC’s COVID-19 safety guidelines as a way of defending themselves in the event of a patient lawsuit. “We followed the standard of care, what else could we have done?” That will be the best defense,” he says.

Probably the greatest potential danger, however, comes from the exponential growth in the number of Legal - Malpractice Trends
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thedoctors.com/COVID
Tips for buying the right coverage
by Keith Loria Contributing Author

1 Talk to colleagues
Daniel Cavanaugh, vice president of membership development for malpractice insurer Cooperative of American Physicians Inc., says young physicians going into private practice generally search the internet for information and coverage options or ask a colleague for a carrier or broker recommendation. Both of these, he notes, are a good start. Meanwhile, midcareer and older physicians are often more familiar with the insurance market and will gravitate toward carriers that have been in the marketplace for many years.

Older physicians are also more likely to seek coverage through an intermediary such as an insurance broker or financial adviser.

Diane Robben, JD, an attorney with Sandberg Phoenix’s medical malpractice group, advises physicians to pay attention to the laws for whatever jurisdiction they practice in. Talking to colleagues can help with this as well.

2 Check the insurer’s rating
Bill Fleming, chief operating officer for The Doctors Company, says independent physicians should choose a carrier with an A.M. Best rating in the “A” range and be aware of the class size from I to XV, as the smaller the number, the smaller the company. Even with a rating in the “A” range, if the carrier is very small, a few large losses can have a devastating effect on its financial security.

“You’ll want a carrier with history and experience in your state and specialty,” he says. “Medical professional liability insurance has an industry reputation of producing more volatile results, so you’ll want an insurer that has weathered the cyclical conditions of this market.”

3 Remember, if it’s too good to be true …
Fleming also advises physicians to be wary of policies that offer numerous one-year discounts, because prices will almost always increase substantially and physicians will often be stuck paying more than what they were first led to believe.

Also, if a practice is multi-state or might become multi-state in the future, it’s important to choose a company that is licensed in the states where a physician might practice, including telemedicine visits.

Before finalizing a policy, a physician should read the entire document, including all addendums and exclusions and be proactive if there is something that is excluded that they thought was covered before it becomes an issue.

“Know the scope of what is not included in the coverage such as HIPAA liability or cyber insurance coverage,” Robben says. “Also pay attention to whether the policy provides coverage for defense of licensure board complaints, or governmental investigations. Having a trusted and experienced lawyer to guide you through those scary and complex proceedings can help ease your fears and anxiety, and knowing there is coverage for the expenses is important.”

A physician who does it the right way compares policies, including commercial carriers and risk retention groups, which are liability insurance companies owned by the people it insures. This will help physicians determine which offer the best protections and provide the ability to consent and/or select counsel of his/her choosing, says Christopher J. Kutner, J.D., MBA, of Rivkin Radler LLP’s Health Services Practice Group.

4 Be upfront early
When buying malpractice insurance, Fleming says, be candid with the underwriter. The more accurate and comprehensive the application is, the better.

“It is best to deal with issues like prior claims, changes in practice locations, negative news or social media, at the beginning,” he says. “That way you have established that you are open and candid in your relationship with the carrier.”

5 When to re-evaluate
Even if physicians are happy with their malpractice insurance, they shouldn’t ignore it. It should be evaluated yearly and kept up to date.

“Whenever you change in size, add or drop practitioners, or have a significant change in the scope of practice, you should evaluate your medical malpractice insurance needs,” Robben says. “At a minimum, I would recommend calendaring to review your malpractice insurance on an annual basis. You want to be sure there are no gaps in coverage and that you have coverage from term to term.”

And don’t wait until the last minute to make a change. It’s important to leave enough time before the expiration of one term to be able to evaluate other options and test the market.
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“It’s more important than ever to make sure that whatever information they get on calls from patients they’re no longer seeing regularly is documented.”

—Frederick M. Cummings, J.D. health law attorney, Dickinson Wright, Phoenix, Arizona.

“Remote examinations have inherent limitations when it comes to diagnosing,” White notes. “That means doctors have to make sure their antennae are out for those symptoms that require a patient to be seen in person in order to ascertain a potentially life-threatening condition.”

He points to the decline in emergency department visits for strokes and heart attacks since the pandemic began (20% and 23%, respectively, from mid-March through May, according to the CDC) as cause for concern. Symptoms of both conditions often are first detected by a patient’s primary care doctor, and speedy treatment is crucial to good outcomes for both. “Failure to pick up on the need to get these patients seen right away, that’s where most of the exposure comes from in these cases,” he says.

Cummings points out that many doctors already have experience in deciding when a patient requires an in-person diagnosis. “I don’t see it as any different than when a patient called you on the phone and said, ‘I’m having these symptoms,’ and the doctor judging whether they should come in,” he says. “But it does require some previous knowledge of the patient (and) things like their history and comorbidities.”

But despite doctors’ best efforts at remote diagnosing, Cummings notes, the number of deaths from causes other than COVID-19 unexplained causes increased substantially after the pandemic started. (According to results from a July study in JAMA Internal Medicine, there were approximately 122,000 more deaths between March 1 and May 30 than would normally be expected during those months, which was 28% higher than the number of COVID-19-related deaths.) He speculates that many of those unexplained deaths were due to the disease’s exacerbating underlying conditions in patients.

“The big issue for many of my clients is not whether they recognized COVID(-19), it’s whether they paid attention to any of the other health issues that were lurking in those patients,” he says.

Cummings adds that doctors can defend themselves in a lawsuit stemming from a remote diagnosis by thoroughly documenting the encounter. This is especially the case for patients who have missed in-person visits because of concerns over COVID-19.

“It’s more important than ever to make sure that whatever information they get on calls from patients they’re no longer seeing regularly is documented and whatever their thought process was at the time is reflected in the note,” he says.

In the end, experts say, a doctor’s best defense against a malpractice suit is to prevent it from occurring. And that requires building a trusting relationship with patients, fostered by honesty and good communication.

Gracey points out that one of the most common malpractice charges primary care doctors face is failure to diagnose. “But when you drill into those claims, you find a lot of what’s really behind them are communication issues,” he says. And although occasional miscommunications in relationships are inevitable, “if we have terrible relationships with each other, those miscommunications get blown out of proportion, and in the case of doctors and patients, they end up before judges and juries.”
What are the risks associated with telemedicine?
We’re barely making payroll, what if we can’t make a payment?
I’m a retired doc that wants to help, will I be covered?
Will my premium be lower while I’m closed or not doing certain surgeries?
What do you do to help burned out physicians serving on the frontline?
Am I covered if I get infected?
How do we keep our practice safe?

Visit the ProAssurance COVID-19 Information Center to find frequently updated information gathered to support your medical professional liability coverage decisions.

You’ll find helpful risk guidelines, policy updates, and crisis support at ProAssurance.com/COVID-19.

For ProAssurance policyholder information and resources. ProAssurance.com/COVID-19
The ongoing pandemic and resulting public health emergency (PHE) has brought about massive and quick changes in the health care industry, notably the temporary suspension of Medicare Fee-For-Service (FFS) audits. The Centers for Medicare & Medicaid Services (CMS) suspended most audits on March 30, 2020, and this change was nearly universally welcomed by the health care industry.

Although the PHE continues, the hiatus of audits was short-lived. CMS announced the end of exercising audit enforcement action during late July, and it resumed program integrity audits effective August 3, 2020. The agency acknowledged the continuing PHE, but determined the importance of and need to resume medical review activities.

If your organization is selected for an audit, remember that you have options. CMS recognizes that staffing and resources to respond to audits may be limited. Providers may contact Recovery Audit Contractors (RAC) to explain any COVID-19 related hardships they are experiencing that may impact response time.

Many assumed that payers would not audit claims adjudicated during the PHE, especially because of the associated waivers issued by CMS. The agency communicated it would audit for potential fraud or abuse during the PHE. This guidance was somewhat confusing to the industry, with many assuming CMS and commercial payers would audit claims adjudicated during the PHE.

CMS published its last approved RAC audit in February 2020. On August 3, 2020, the agency published five new RAC focus areas including ambulance services, hospital inpatient, hospital outpatient, ambulatory surgical centers, and professional services. This audit downtime has enabled payers to shift their focus to data-mining claims. This is why medical records requests and overpayment demand letters from RAC contractors and commercial payers will likely resume during the next few weeks.

Audits, disruptive during the best of times, become even more so when fewer staff are available to process record requests and otherwise respond. A timely response is imperative. Third-party medical record release vendors have gained appeal among practices. Vendors can handle all third-party record requests without administrative or financial burden to an organization. The resources and expenses are left to the vendor. Outsourcing record requests is one part of the equation. There will be overpayment letters which flow from all payer audits.

Heed every overpayment and audit letter, whether from a government or commercial payer. The rules applicable to telehealth, supervision, inpatient rehabilitation facilities and nursing homes changed rapidly at the onset of the PHE. This increased the likelihood of audit errors, misapplication of rules, and application of rules and regulations to inapplicable dates of service.

Nearly all health care providers have experienced a financial hit. Avoid prematurely and unnecessarily returning any overpayment by confirming all overpayments before you accept audit findings. Qualified staff or third-party vendors should re-audit records identified as having overpayments. Parameters of the confirmation process must include all appropriate regulations and/or payer policies that were applicable on the date of service.

Claims adjudicated during the PHE, and particularly within the first 60 days of the PHE, may ultimately be subject to several different rule changes that varied from day to day. This is why these audits are at a higher risk of errors having occurred. Generally, audits reflect a specific date range and auditors apply appropriate payer rules. The appropriate guideline or regulation may not be applied correctly or to the applicable timeframe, which could reveal an erroneous overpayment. Numerous executive orders at the state and federal levels have further complicated audits during the PHE.

The uptick of audits will continue to approach previously unseen levels. Providers need to understand how to efficiently handle this and have a well-designed process in responding to the audits. Prevention is always the best practice.

Joe Rivet, Esq., CPC, is a reimbursement attorney and founder of Rivet Health Law, PLC. Send your legal questions to medec@mjhlifesciences.com.
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Physician employment contracts: What to know before you sign

by Jeffrey Bendix Senior Editor

Physician contracting is becoming extremely important today, as more physicians are working for hospitals, large health systems and multiphysician practices in non-ownership roles.

Medical Economics® recently sat down with Richard Roberts, M.D., J.D., a professor emeritus of family medicine at the University of Wisconsin School of Medicine and Public Health. Roberts was an attorney and has counseled numerous young doctors on employment matters and contracts. He believes it is very important for doctors to investigate the core culture of a potential employer before signing a contract with them. The below transcript of this interview was edited for length and clarity.

**Medical Economics®**: Why is it important for doctors to learn about the culture of a particular institution or practice before going to work for them?

**Roberts**: The typical physician will spend more awake hours at work than with his or her family and friends. ...The sense of your feeling welcomed and supported, and the sense of professional growth, those are all the things that make a workplace a good or bad place for you to be. And so, if you don’t get that, it really doesn’t matter what the contract says because you’re going to be miserable.

**ME**: Are there areas of flexibility where doctors can negotiate in a contract, and what are some typical examples?

**Roberts**: Absolutely, there are all kinds of areas to negotiate. But when hospital people say to me or to a young doc, ‘Well, we try to treat everybody the same,’ my immediate answer is, ‘Does that mean the custodial staff is getting paid the same and has the same benefits as a CEO?’

The reality is, nobody is exactly the same as anybody else, because people have unique needs. You may have a young mom who’s got scheduling needs that don’t match what the typical young male physician may feel is a good schedule for him. If the contract doesn’t reflect that, it has not done a good job...
of really identifying and addressing the priorities of the individual. It’s in the organization’s best interest to try to make you happy. Yeah, you do take up more of their time. Yeah, you do generate more legal fees for them as these things have to be reviewed by their lawyers. But hey, it’s your life.

In an ideal world, at the end of the day, when both you and the organization are prepared to sign, you can both look at that set of papers and say, ‘This is pretty good. This meets our needs but isn’t perfect.’

………..

ME: Can you talk about the concepts of must-haves and deal breakers?

Roberts: The example that I’ll often turn to is the group at Harvard called the Harvard Negotiation Project (cofounded) by professors Roger D. Fisher and William L. Ury. Their book called Getting to Yes lays out some basic ideas on what they call “principled negotiation,” because their view is that if a contract …or an agreement unfairly gives one the advantage over the other party, it’s in the end not going to succeed.

I usually say to people to identify two to three things. One thing might be having the ability to do certain kinds of procedures. And if that’s something that’s really, really important to you, put it in the agreement. On the other hand, there may be certain things that you’re being asked to perform, a certain task or service, and you absolutely cannot deal with that or don’t want to do that. So, it should say, basically, in the agreement that you don’t have to do them. But it’s not an infinite list, because then you’ll never manage to get through the contracting process. It’s a list that really highlights the few things both that you must have and that are deal breakers.

Now, the thing to be careful about in all of this is that language is important and the tone that we set is important. I think, as a physician, you always want to be professional, you want to be polite. You want to assume good intentions on the other party’s part. But you also need to ask good, hard questions and not be afraid to push gently but persistently.

………..

ME: Can you provide a step-by-step guide for thinking through a job offer?

Roberts: Well, just like planning for a procedure or visit with a patient in the office, I think the first step is (that) you want to think ahead. And that means planning and prioritizing and developing an overall game plan with a pretty clear sense of the things that you really need to have to be a happy, successful physician and the things that you really must avoid or must not have. Now, you may only be able to identify one or two, that’s fine, or you may identify 10. That’s not so good. But you want to make sure that whatever you’ve identified as key issues for you and for those who are important to you in your life are reflected in the document.

Don’t ever be afraid to speak up for yourself. I think many times, we physicians are so used to deferring gratification and putting the needs of others before ourselves that we feel a little embarrassed asking for this or asking for that, especially when you go from kind of minimum wage jobs as a college student to pretty substantial salary offers. When the recruiter or whoever you’re talking with from the organization says to you, ‘Well, this is the same agreement that everybody signs,’ my advice is that your first response should be, ‘I’m not everybody.’ And I tell people, when you get the first draft of the contract — because it’s always written by the system’s lawyer not by your lawyer — change something, even if it’s the date, because under the law, the two bargaining parties have equal rights until you sign on the bottom line.

Because what you do when you sign a contract is you give away certain rights to the employer. So, you want to be sure that your rights are protected sufficiently around the things that you care the most about.

And the third thing that I would say is you need to always be thinking ahead and reflecting on this whole process as your career plays out, because what you find is that most people today, especially professional people, usually have several careers. And not only in terms of where we might work, but the particular kinds of duties or jobs. And so, as a young physician, I’m going to find myself constantly going through this prioritization and identifying what I must and must not have, in terms of my list, the standard of living that I’m trying to fund, the investments I’m trying to make for my children’s future — all the things that we all have to think about. And always doing that on a regular basis puts you in a better position when something comes up that feels more pressured or all of a sudden.

It’s the planning ahead that keeps you out of trouble. »
The physiology of obesity: Implications for primary care

by Ted Kyle

Twenty-two years ago, the National Institutes of Health published the first ever evidence-based guidelines for identification and treatment of obesity. This 262-page report was an important milestone, but at the time, the authors stated that the “understanding of how and why obesity develops is incomplete.” Today, we know much more. And because of that knowledge, obesity care has changed radically in twenty years.

Today we know that obesity is an altered physiologic state.

The drivers of obesity

Obesity researchers know that obesity results from the effects of environmental triggers on genetically susceptible individuals. These triggers are many but may be grouped into four categories:

- **Alterations to the food supply are most cited** – the composition of food, its quantity, and its promotion to consumers. Research has identified many dimensions of the food supply that may contribute.
- **A physical and technological environment** that makes routine physical exertion less common.
- **Stress and distress in many forms** can promote a state of obesity.
- **Finally, drugs and chemicals** can act as endocrine disruptors with the effect of promoting obesity.

Implications for primary care

Perhaps the most important change in understanding the physiology of obesity comes from a 2011 study in the *New England Journal of Medicine*. Sumithran et al. demonstrated that weight loss causes changes in metabolic hormones that serve to return the body to its prior level of adiposity. Simply stated, the authors documented how the body acts to protect fat mass in subjects with overweight or obesity.

In other words, they documented that the physiology of obesity makes weight loss, by itself, unlikely to be an effective treatment for the chronic disease of obesity. It requires chronic treatment — just like dyslipidemia, hypertension, or diabetes.

The meaning of these insights for primary care is straightforward. When obesity is a clinical concern, simply advising a patient to lose weight will have a negligible benefit. The physiology of this disease state will make long-term clinical improvement very unlikely – even though many patients might lose weight in the short term.

The emerging standard of care is to use a range of treatments to help a patient reach and maintain a better state of health. These include dietary interventions, physical activity, behavioral therapy, pharmacotherapy, and metabolic surgery. Most often, a combination of these will yield the best outcomes, tailored to the needs of the patient.

A growing number of primary care physicians are seeking certification in obesity medicine to equip themselves to provide such treatment. Others might instead refer to an obesity medicine specialist. Either way, the patient will benefit from evidence-based care for this complex, chronic disease.

Ted Kyle is a pharmacist and health innovator living in Pittsburgh.
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*Dr. Walter is a UroLift System faculty and a paid consultant for NeoTract|Teleflex
**Management estimate based on product sales and average units per procedure


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Coding case studies

Dementia

by Renee Dowling, CPC Contributing Author

Getting paid requires accurate documentation and selecting the correct codes. In our Coding Case Studies, we will explore the correct coding for a specific condition based on a hypothetical clinical scenario. This scenario involves a patient presenting with symptoms of dementia; see if you can choose the correct codes.

Clinical Scenario

Chief complaint
Resident is followed for Dementia, Hypertension, HLD, anxiety, insomnia, and debility. Meds reviewed and updated. Resident continues to be in long term care at facility. Labs reviewed and will be ordered as clinically indicated. Res denies c/o pain.

Review of Systems

Constitutional: Positive for activity change.
HENT: Positive for trouble swallowing.
Eyes: Negative.
Respiratory: Positive for cough and shortness of breath. Aspiration PNA
Cardiovascular: Negative for leg swelling. HTN
GI: Positive for constipation.
Endocrine: Negative.
Genitourinary: Negative.
Musculoskeletal: Positive for back pain and gait problem.
Skin: Negative.
Allergic/Immunologic: Negative.
Neurological: Positive for weakness.
Psychiatric/Behavioral: Positive for confusion and sleep disturbance.

Social History
Smoking status: Quit 5 years ago
Types: Cigarettes
No known allergies

Encounter Medications
- Acetaminophen (Tylenol) 325 mg tablet, Take 650 mg by mouth 3 (three) times daily
- Maximum dose of acetaminophen is 4,000 mg from all sources in 24 hr
- ARIPiprazole (Abilify) 2 mg tablet, Take 4 mg by mouth daily
- Donepezil (Aricept) 10 mg tablet, Take 10 mg by mouth, Nightly
- Hydrocortisone 0.5 % cream, Apply topically 2 (two) times daily, Apply to rash
- Lorazepam (Ativan) 0.5 mg tablet, Take one tablet (0.5 mg total) by mouth daily, 30 tablet
- Magnesium hydroxide (Milk of Magnesia) 400 mg/5 mL suspension, Take 30 mLs by mouth nightly as needed for constipation
- Trazadone 50 mg tablet. Take 100 mg by mouth nightly.

Physical Exam

Constitutional: He appears well-developed.
Head: Normocephalic and atraumatic.
Eyes: EOM are normal. Pupils are equal, round, and reactive to light.
Cardiovascular: Normal rate, regular rhythm and intact distal pulses.
Pulmonary/Chest: Effort normal and breath sounds normal. o2 sats 95%
Abdominal: Soft. Bowel sounds are normal.
Musculoskeletal: He exhibits no edema, Moves all extremities independently
Neurological: He is alert, Oriented x1, Able to follow simple commands
Skin: Skin is warm and dry, Noted right ankle warguard intact
Psychiatric: Cognition and memory are impaired.
Nursing note and vitals reviewed.

Assessment and Plan
- Late onset Alzheimer’s disease without behavioral disturbance
- Malaise
- Generalized anxiety disorder
- Insomnia, unspecified type
- Weakness generalized

Continue meds and therapy as ordered
Meds reviewed and updated
Resident to continue to be in long term care at facility
### Documentation Coding Requirements
When documenting dementia, include the following:

- With or without behavior disturbance
- Alcohol-induced
- Sedative, hypnotic or anxiolytic-induced
- Inhalant-induced

### ICD-10 Codes for Dementia

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>F01.51</td>
<td>Vascular dementia with behavioral disturbance</td>
</tr>
<tr>
<td>F01.50</td>
<td>Vascular dementia without behavioral disturbance</td>
</tr>
<tr>
<td>F02.80</td>
<td>Dementia in other diseases classified elsewhere without</td>
</tr>
<tr>
<td></td>
<td>behavioral disturbance</td>
</tr>
<tr>
<td>F03.90</td>
<td>Unspecified dementia without behavioral disturbance</td>
</tr>
<tr>
<td>F03.91</td>
<td>Unspecified dementia with behavioral disturbance</td>
</tr>
<tr>
<td>F10.27</td>
<td>Alcohol dependence with alcohol-induced persisting dementia</td>
</tr>
<tr>
<td>F10.97</td>
<td>Alcohol use, unspecified with alcohol-induced persisting dementia</td>
</tr>
<tr>
<td>F13.27</td>
<td>Sedative, hypnotic or anxiolytic dependence with</td>
</tr>
<tr>
<td></td>
<td>sedative, hypnotic or anxiolytic-induced persisting dementia</td>
</tr>
<tr>
<td>F13.97</td>
<td>Sedative, hypnotic or anxiolytic use, unspecified with</td>
</tr>
<tr>
<td></td>
<td>sedative, hypnotic or anxiolytic-induced persisting dementia</td>
</tr>
<tr>
<td>F18.17</td>
<td>Inhalant abuse with inhalant-induced dementia</td>
</tr>
<tr>
<td>F18.27</td>
<td>Inhalant dependence with inhalant-induced dementia</td>
</tr>
<tr>
<td>F18.97</td>
<td>Inhalant use, unspecified with inhalant-induced persisting dementia</td>
</tr>
<tr>
<td>F19.17</td>
<td>Other psychoactive substance abuse with psychoactive substance-induced persisting dementia</td>
</tr>
<tr>
<td>F19.27</td>
<td>Other psychoactive substance dependence with psychoactive substance-induced persisting dementia</td>
</tr>
<tr>
<td>F19.97</td>
<td>Other psychoactive substance use, unspecified with</td>
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<tr>
<td></td>
<td>psychoactive substance-induced persisting dementia</td>
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<tr>
<td>G31.09</td>
<td>Other frontotemporal dementia</td>
</tr>
<tr>
<td>G31.83</td>
<td>Dementia with Lewy bodies</td>
</tr>
</tbody>
</table>

### Coding notes

- Code first the underlying physiological condition or sequelae of cerebrovascular disease.
- Code first the underlying physiological condition, such as:
  - Alzheimer’s (G30.-), cerebral lipidosis (E75.4), Creutzfeldt-Jakob disease (A81.0-), dementia with Lewy bodies (G31.83), dementia with Parkinsonism (G31.83), epilepsy and recurrent seizures (G40-G40.B19), frontotemporal dementia (G31.09), hepatolenticular degeneration (E83.01), human immunodeficiency virus [HIV] disease (B20), Huntington’s disease (G10), hypercalcemia (E81.52), hypothyroidism, acquired (E01-E03.9), intoxications (T36-T65.94XS), Jakob-Creutzfeldt disease (A81.0-), multiple sclerosis (G35), neurosyphilis (A52.17), niacin deficiency [pellagra] (E52), Parkinson’s disease (G20), Pick’s disease (G31.01), polyarteritis nodosa (M30.0), prion disease (A81.9), systemic lupus erythematosus (M32-M32.9), traumatic brain injury (S06.-), trypanosomiasis (B56-B56.9, B57-B57.5.), vitamin B deficiency (E53.8)
- Use additional code, if applicable, to identify wandering in dementia in conditions classified elsewhere (Z91.83)
- Use additional code for blood alcohol level, if applicable (Y90.-)
- Use additional code to identify dementia with behavioral disturbance (F02.81), dementia without behavioral disturbance (F02.80)

### Diagnosis Code

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<tr>
<th>Code</th>
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<tr>
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<td>Alzheimer’s disease with late onset</td>
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<tr>
<td>F02.80</td>
<td>Dementia in other diseases classified elsewhere without behavioral disturbance</td>
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<tr>
<td>F41.1</td>
<td>Generalized anxiety disorder</td>
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<tr>
<td>G47.00</td>
<td>Insomnia, unspecified</td>
</tr>
<tr>
<td>R53.1</td>
<td>Weakness</td>
</tr>
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</table>

Reenee Dowling is a billing and coding consultant with VEI Consulting in Indianapolis, Indianapolis. Send your diagnosis coding questions to medec@mjhlifesciences.com

Medical Economics.com
DO YOUR ADULT PATIENTS HAVE A GAP IN IMMUNIZATIONS?

HELP PROTECT YOUR ADULT PATIENTS. TAKE THE SIMPLE STEP OF ADDING Tdap TO YOUR VACCINATION PROTOCOL.

Help close the Tdap gap

• CDC recommends that all adults 19 years of age and older who have not previously been vaccinated with Tdap receive a dose of Tdap\(^1\)

• However, only 31.7\% of eligible adults in this age group are vaccinated with Tdap as of 2017\(^2\)
  – By comparison, the rate for adult influenza vaccination for the 2016-2017 season was 45.4\%\(^2\)
  – As of 2017, pneumococcal vaccination coverage in adults 65 years of age and older was 69.0\%\(^2\)

\(^{1}\) For vaccine age indications and coadministration information, please visit www.cdc.gov.


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Help close the Tdap gap

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BOOJRNA200001 July 2020
Produced in USA.

For vaccine age indications and coadministration information, please visit www.cdc.gov.

Tdap = Tetanus, diphtheria, and acellular pertussis


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DIY: Time to try a drive-thru flu shot clinic?

by Terry Brenneman, MD Contributing Author

The COVID-19 pandemic has added a wrinkle to my pediatric office’s plans to administer more than one thousand influenza vaccines to our patients and their parents.

In previous years we would put families in an exam room, administer the shot or live nasal vaccine, and send everyone back out through the waiting room packed with other families awaiting their turn. We did this both during regular office hours and also during some after-hours times in the evening and on weekends.

This traditional approach will not work this year for several reasons:

- The requirement for social distancing means we can’t have several families waiting in the reception area for their turn in an exam room.
- Time between each family would now need to be built in, drastically reducing the number of persons we could vaccinate per hour.
- Cleaning all the surfaces in a room between each family’s use — something not required previously — would also add time and expense.

So, here in Raleigh, North Carolina, we have come up with a plan.

We have all seen pictures on TV of long lines of cars with people waiting their turn for a COVID-19 test or picking up some free groceries for the unemployed. Why would this drive-through approach not work for your office in giving vaccines?

---

**Step 1 Find an empty parking lot**
If your office is in a commercial building, check with your landlord or fellow tenants to see whether you could commandeer the parking lot for a Sunday morning or afternoon or both. A school parking lot on a weekend morning or a large church’s parking area during the week are also options, but you would need to obtain permission.

**Step 2 Pick a date with a backup plan for inclement weather**
You may want to have some tents for your staff and proceed even if it rains. Or, have an alternate date and time. We intend to set our date up on a Saturday afternoon with a plan to move it back 24 hours to Sunday afternoon should it rain.

**Step 3 Get the word out**
to your patients about your plan for a drive-through vaccination clinic. Social media, your website, your on-hold phone message, signs in your office, and e-mail blasts to all your patients are some options to consider. A press release to your local paper or TV station might lead to some free publicity at the risk of having nonpatients show up on the day of the clinic.

**Step 4 Offer appointment times**
to avoid traffic jams and ensure you have enough supplies on hand on the day. I would suggest one car every five minutes. Some cars will have a single person wanting a vaccine and some may have four or five. For our office I think the average will be between three and four people per car.
We will be offering either the shot or the nasal vaccine. Both take about the same amount of time to administer to a cooperative patient. Children will be left in their car seats. A parent may be required to hold their arms, and car doors may need to be opened.

**Step 5** Have your front office staff print out the appointment log for next day’s staff the day before the clinic. We plan to have a preprinted sheet for each car with lines for each scheduled patient or parent and a few empty spaces in case of an unexpected extra. As the administration site of the vaccine is supposed to be recorded, four choices for the nurse to circle will be present next to each name — left arm, right arm, left leg and right leg — which cover the four extremity choices in pediatrics. Adult patients require just two, right arm and left arm.

Each preprinted sheet will have the initials of all staff administering the vaccines because that information also must be recorded. Additionally, the sheet must have a list of the vaccines being offered. As we won’t need any vaccines for patients older than age 65, we will simply list the shot or live attenuated influenza vaccine as options for the nurse to circle. The administering provider will circle their initials, the vaccine given, and the location of administration.

**Step 6** Get your supplies together

You will need PPE for your staff, alcohol wipes, Band-Aids, antiseptic hand gel for use between cars for staff, sharps containers, an emergency medical kit with epinephrine available, tables and chairs for staff, and proper storage gear for the vaccines. We will be using prefilled syringes to save time. A laptop on site will allow you to remotely access electronic medical records if required. The CDC has guidelines for off-site vaccine clinics and proper storage requirements at this link: https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/.

**Step 7** Set up two stations in the parking lot, one for check-in and one for administration, on your clinic day.

At the check-in station, a staff member will confirm who in the car is receiving vaccinations. Your preprinted sheet will have the names already listed, but you will have to expect some no-shows and also be ready to add someone extra. Names of no-shows will be crossed out and an extra person’s name can be added to the sheet, which will eventually be required for billing.

Vaccine Information Statement sheets should be available here and offered. If you have standard screening questions, this is the place and time to ask them. When check-in is complete, the staff member will hand the driver the preprinted sheet and direct them to the administration station ahead.

**Step 8** Have the nurse collect the preprinted sheet at the administration station, ask if any other questions need to be answered, and vaccinate those patients who are on the sheet. If the driver is receiving a vaccine, you may want to suggest they pull over into a parking space for 15 minutes to cover yourself from a medical-legal point of view in case of syncope. Someone from your office will need to monitor those spaces. The vaccine administrator then circles the initials, the vaccine given, and the site and saves the sheet for later when information is entered into the medical record and billing. You may wish to have some preprinted sheets available for those patients requesting a copy of what they received (eg., as proof for an employer).

Our office is planning to do a trial run with 12 cars the week before we have our mass clinic(s). Most likely, we will need to modify some things. In pediatrics, we always have a few resistant, uncooperative school-aged children dragged to the office by their parents. In previous years we would leave such families alone in the exam room for that parent-child discussion that can sometimes take 15 minutes. When this happens this year, we will give the vaccine to everyone willing in the car, then the family will be required to get out of line and go back through the check-in line when they think their child is ready.

COVID-19 has caused a lot of changes in our lives. We have all had to think outside of the box and make changes to long-established routines. Some of those changes may end up being for the better (eg., an elbow bump instead of a handshake).

Hopefully, we will find that this drive-through clinic works out better than our old way of doing things. »

Terry Brenneman, MD, is a pediatrician and the founder of Pediatrics Partners in Raleigh, North Carolina.
Practicing with, and without, payers

Stay in network or out? Accept Medicare or don’t? What’s better for physicians or more appealing to patients?

For physicians changing to a membership medicine model, these are some of the most pivotal questions to consider. Under the membership medicine umbrella, concierge models usually accept insurance while direct primary care (DPC) generally does not. The lines, however, are not solidly drawn, and in certain situations and markets, concierge physicians have launched thriving payer-free practices in an effort to simplify payment arrangements for themselves and their patients.

The majority of physicians in our concierge medicine network do choose to participate in both Medicare and remain in-network with commercial insurance, which is a decision fueled by patient preference. From the patient’s perspective, the ability to use Medicare, a program they’ve paid into for decades, is a valued benefit. It’s also important to note that the entire insurance submission process is not as unwieldy or time-intensive for physicians caring for between 300 and 600 members in our concierge model versus nearly 2,000 patients in traditional fee-for-service practices.

But our model is tailored to reflect each doctor’s individual vision while ensuring optimal care and convenience for their patients. We have successfully partnered with doctors who prefer to practice outside of insurance networks and be freed of the need to file or submit claims, enter insurance data into the EHR or comply with insurance oversight and restrictions.”

For Chicago-based internist and endocrinologist Robert Sobel, M.D., who changed to concierge medicine with the help of Specialdocs in 2016, the decision to practice without payers was carefully considered but seemed almost inevitable.

“The direction of reimbursement payments continued to go south over the last two decades, and cost controls and increased regulations for professional services were becoming unmanageable for our practice,” Sobel explains. “In my opinion, more bureaucracy seldom means better care. Our healthcare system is evolving with increasing complexity as more advanced diagnostic and therapeutic tools are introduced, and it’s vital that we use only the best clinical decision-making to incorporate and implement these into our practice.”

Sobel stresses that being out of insurance networks does not eliminate interaction with their systems and processes.

“We are still intimately involved in advocating for our patients’ treatments and medications, and in providing referral entities with essential information,” says Sobel. “However, practicing in this model allows me to focus on making the right clinical decisions for my patients as well as the time and resources to fight through bureaucratic tangles to help them get what they need.”

Family medicine physician Larry Leibowitz, M.D., who hasn’t participated in any type of insurance network since establishing his Connecticut-based Matrix Personalized Medicine practice with Specialdocs’ support in 2017, says he’s never regretted his decision.

“There’s really no advantage to patients by my accepting insurance or Medicare,” he says. “If I were in-network, patients would be responsible for copays and would incur out-of-pocket costs for office visits and other procedures until they met their deductibles, on top of my annual membership fees. In my model, they’re responsible for none of that.”

Once he clarifies for prospective patients that all services beyond the ones he renders will continue to be covered by insurance, patients rarely object to the arrangement. In fact, Leibowitz says he has never had a prospective patient opt not to enroll as a member of his practice because of insurance concerns.

“Keep in mind the potential downside of not accepting insurance.”
“On a personal and professional level, I couldn’t have anticipated how much more unfettered I feel over the course of the day,” he says. “While I still need to obtain prior authorizations for medications and imaging studies for my patients, I no longer have to please insurance companies or Medicare or meet the proper metrics for reimbursement.”

The decision to stay in-network or remain outside of it is a personal one for physicians, not based on finances, but on their perception of how they can make it easier for their patients to receive care. The concierge medicine model is not sustained by insurance reimbursement but by membership fees. On average, 87% of a concierge physician’s revenues come from members paying an annual fee, while only 13% of revenues are realized through insurance reimbursement.

Leibowitz acknowledges that he’s leaving a relatively small amount of money on the table by not filing for reimbursements, but says the resulting independence is worth every penny. “I’m able to care for patients without the daunting administrative burdens that most participating providers face. And the personal and spiritual freedom I’ve gained in this model has been priceless to me.”

He adds: “I’m also able to modify my fee schedule as I please in order to accommodate a patient who has fallen on hard times. I can simply say ‘I’ve known you for years... so let’s make this work for you’ without concerns about insurance backlash.”

My advice for physicians weighing whether to accept insurance as they make the change to a personalized practice model is keep in mind the potential downside of not accepting insurance in terms of practice growth. Insurance coverage remains the top-ranked factor influencing American consumer decisions about where and with whom to seek medical treatment. Other surveys show that patients typically first evaluate potential providers by posing just one question: Do they take my insurance? And if you do feel strongly that remaining outside of insurance networks is the right choice for you? Here are some tips:

■ Consider your patient panel carefully. Doctors who successfully practice without accepting insurance have exceptionally loyal patients who stay with them because of the value placed on their relationship.

■ Thoroughly understand your community’s demographics. Price your services in a manner that both sustains your practice and is affordable for current and future patients.

■ Work with a partner who is flexible in considering your best options when making the change to a concierge medicine practice with or without payers, and has the experience and compassion to support your decision. Our approach has always been to manage the business for our physician clients according to their values and preferences, and enable them to focus solely on the business of caring for their patients.

Terry Bauer is CEO of Specialdocs, a leading concierge medicine transition and practice management company.
E/M changes take effect January 2021:
Is your practice ready?

by Lisa A. Eramo, M.A., Contributing Author

Good news for physicians tired of counting bullet points to assign an evaluation and management (E/M) level for an outpatient office visit: Per new AMA guidelines, it’s going to be a whole lot simpler. As of January 1, 2021, physicians will select an E/M code based on total time spent on the date of the encounter or medical decision making (MDM)—whichever is most financially advantageous. An added bonus? Medicare payments for almost every E/M level will increase if proposed payment rates become final.

History and exam
Today, the three key components of an E/M level are history, exam, and MDM. In 2021, the history and exam must simply be medically appropriate. They aren’t factored directly into the E/M level, nor must they adhere to a specific type (i.e., problem-focused, expanded problem-focused, detailed or comprehensive) says Cheryl Cyrus, RHIT, CPMA, quality assurance auditor at ConforceHealth, a health care business consulting company. This means streamlined documentation, fewer cumbersome requirements to remember and potentially more time spent on direct patient care, she adds.

“We’re shifting back to the patient-provider relationship,” says James P. Fee, M.D., CCS, CEO of Enjoin, a clinical documentation integrity company. These changes also reflect the AMA’s desire to reduce physician burnout, a major component of which is documentation, he adds.

Still, physician documentation must accurately depict what occurred during the encounter, says Dreama Sloan-Kelly, M.D., CCS, president of Dr. Sloan-Kelly Consulting, a medical coding consulting company. “You still need to be covered in the event of a lawsuit or post-payment recoupment,” she adds.

Although January 1 is several months away, experts say physicians must prepare now to ensure they understand precisely what is changing.

MDM
Current E/M guidelines require physicians to document one of the following four types of MDM: Straightforward, low complexity, moderate complexity, or high complexity. Each of these types is driven by a complicated point system derived from the number of diagnoses or treatment options, the amount and/or complexity of data reviewed, and the risk of complications and/or morbidity and mortality.

In 2021, these four types and drivers remain; however, physicians will use a “new and improved” MDM table that includes easy-to-understand requirements for each E/M level.

Other good news? Physicians get credit for the following:
- Reviewing prior external notes from each unique source.
- Reviewing the results of each unique
test, including imaging, lab, psychometric or physiologic data.
- Ordering each unique test.
- Performing an assessment requiring an independent historian, defined by the AMA as an individual who supplements information provided by a patient who is unable to provide a complete or reliable history (e.g., due to developmental stage, dementia or psychosis) or because a confirmatory history is deemed necessary. Examples include a parent, guardian, surrogate, spouse or witness.
- Independently interpreting a test performed by another physician or other qualified health care professional (QHP). Note that physicians and QHPs can only count this toward the MDM when they cannot report the service using another CPT code.
- Discussing patient management or test interpretation with an external physician or other QHP (i.e., someone who is not in the same group or who is in a different specialty or subspecialty, a licensed professional practicing independently, a hospital, nursing facility or home health care agency), or another appropriate source (e.g., lawyer, parole officer, case manager or teacher). It does not include discussion with family or informal caregivers.
- Note that physicians and QHPs can only count this toward the MDM when they cannot report the service using another CPT code.

Fee provides this example of the new MDM table in action:
An established 69-year-old female patient presents to the office with her daughter. The patient has had stable depression for the last three years and a new onset of mild amnesia. She reports increased frustration in losing objects over the past few months. Her daughter confirms this and also says the patient frequently forgets names and isn’t able to remember certain words during conversations. The patient denies any stressors, headaches, dizziness or problems with sleep or anger. The physician reviews recent TSH, CMP, and B12 labs; orders an MRI scan; and renews her anti-depression medication. The total duration of the visit is 25 minutes. This maps to a 99214 code based on the 2021 MDM table.

Physicians will be happy to hear that the new MDM table compensates them for complex MDM regardless of the time spent, as long as documentation supports medically necessary services, says Joe Rivet, Esq., CEMC, health care reimbursement attorney and coding compliance and audit expert. Currently, physicians are only compensated for a complex MDM when they also document a higher-level history or exam, he adds.

Time-based billing
Current E/M guidelines permit physicians to select an E/M level based on time only when they spend more than 50% of the visit counseling and/or coordinating care. In 2021, this requirement no longer applies. Instead, physicians can count the total time on the date of the encounter that may or may not include counseling and care coordination. Eligible time includes both the face-to-face and non-face-to-face time that the physician personally spends before, during and after the visit on that same day. Specific examples include:
- Care coordination (when not separately reportable).
- Counseling and educating the patient, family and/or caregiver.
- Documenting clinical information in the electronic or other health record.
- Independently interpreting results (when not separately reportable) and communicating results to the patient, family and/or caregiver.
- Getting and/or reviewing separately obtained history.
- Ordering medications, tests or procedures.
- Performing a medically appropriate exam and/or evaluation.
- Preparing to see the patient (e.g., reviewing tests).
- Referring the patient to and communicating with other health care professionals (when not separately reportable).

“My fear is that physicians...
MONEY / E/M CHANGES

would forget to count some of this, so they need to make sure they review this list,” says Kim Huey, MJ, CPC, independent coding and reimbursement consultant. For example, physicians will be able to count the time they spend reviewing their state’s prescription drug monitoring program database when prescribing opioids.

7 E/M tips for 2021
Experts provide these seven tips to maintain compliance:

- **Avoid generic documentation**
  For example, if a physician obtains and reviews medical records, they should document what specific records, from whom, and for which treatment dates, says Jessica Miller, CPC, CPC-P, manager of professional coding at Ciox Health, a coding outsource company.

- **Describe diagnosis management**
  Simply selecting a diagnosis from a drop-down menu won’t be sufficient, says Huey. To get credit for diagnosis management in the new MDM table, physicians need to link each diagnosis with some type of action—a prescription, test, counseling or some other type of workup. Stating that the diagnosis is managed by another provider doesn’t count.

- **Tell the truth**
  Physicians aren’t required to itemize their time; however, their documentation must be an accurate depiction of services rendered, says Rivet. “I think itemizing starts to dilute the benefit of these new guidelines.” It could also open physicians up to scrutiny, he adds. For example, an auditor may question why it took 12 minutes to review a complete blood count.

  However, be mindful of total time spent, says Rivet. For example, a physician sees 20 patients a day and documents that they spend 35 minutes per patient, totaling approximately 12 hours. This exceeds a typical eight-hour workday and could be a red flag for a payer, says Rivet.

- **Pay attention to when services are rendered**
  For example, a physician reviews lab results two days after an

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### E/M payments: 2020 vs. 2021

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<tr>
<th>CPT CODE</th>
<th>2020 NATIONAL AVERAGE MEDICARE PAYMENT</th>
<th>2021 NATIONAL AVERAGE MEDICARE PAYMENT</th>
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*Rates will be finalized in the calendar year 2021 Physician Fee Schedule Final Rule.*
encounter. They can't count this time toward the E/M level for the previous visit to which the labs pertain, says Rivet.

However, they may be able to report CPT codes 99358 and 99359 for prolonged services on a date other than the date of a face-to-face encounter, says Huey. The code description for 99358 states that it requires at least 60 minutes of services; however, per CPT rules, physicians may bill it once they have reached the midpoint (30 minutes). The code description for 99359 is for each additional 30 minutes, but physicians may bill it once they have reached 15 minutes. These codes must pertain to a face-to-face encounter that has occurred or will occur related to ongoing patient treatment, she adds.

There is also a new code that physicians may be able to report when they personally render prolonged services when billing 99205 and 99215 based on time: 99XXX. Physicians can report this code only when they spend at least 15 minutes of additional time on the date of the encounter with or without direct patient contact, says Huey. For 99205, this means more than 75 minutes. For 99215, it means more than 55 minutes.

Don't count services that are separately reportable
For example, if a physician performs an ECG interpretation and report, they can't apply that toward the E/M level because separate CPT codes exist (93000, 93005 and 93010), says Rivet.

Focus on social determinants of health (SDOH)
Capturing SDOH via ICD-10-CM diagnosis codes (e.g., Z59.0 for homelessness or Z59.5 for extreme poverty) may help support a more complex MDM and thus a higher-level E/M code, says Huey.

Always remember medical necessity
“You're not going to be able to justify 50 minutes on a patient with strep throat,” says Sloan-Kelly.

Coding based on time or MDM—that is the question
Although optimal code assignment depends on the clinical circumstances of each scenario, Fee provides three important questions to consider when determining whether it is more advantageous to bill based on time or MDM:

- Did the physician spend a considerable amount of time collecting the history or performing the exam? If so, it may be more advantageous to bill based on time.
- Did the physician order several tests, speak with other physicians, or review complex data? If so, it may be more advantageous to bill based on MDM.
- Is the patient medically complex (and do they support a level five E/M) but the physician went beyond the time threshold associated with the code? If so, it may be more advantageous to bill based on time because then the physician can also bill for prolonged services.

Five tips to prepare now
Do you want to prepare for the upcoming E/M changes, but are not sure how? Experts provide the following five tips:

Find a coding champion
Identify someone within the practice (e.g., a coder or practice manager) to champion the education effort, says Courtney Davenport, CCS, CCS-P, lead educator at Aquity Solutions, a coding outsource company. This person can attend webinars or take online courses and provide staff members with need-to-know education.

Contact payers
Ask whether they will adopt Medicare’s changes. Some payers may continue to require code selection based on history, exam and MDM—or they may have specific requirements for individual codes, says Davenport.

Contact your EHR vendor
Ask what the vendor is doing to incorporate Medicare’s changes. In particular, how will the EHR’s code calculator incorporate time and MDM? How will the algorithm distinguish between outpatient office visits and other types of E/M services to which the 2021 changes don’t apply?

Create an edit in your practice management system for 99XXX
Flag this code for manual review to ensure documentation supports services lasting 75 minutes or longer for new patients and 55 minutes or longer for established patients, says Miller.

Look at your current documentation
Does it support total time spent with patients as well as complex MDM? How does your current documentation map to various E/M levels using the new AMA guidelines? Now is the time to start documentation improvement efforts, if needed, says Huey.

“Remember that if it’s not documented, it didn’t happen,” says Sloan-Kelly. “We went to school for a long time to get paid for what goes on in our minds.”

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Medical Economics.com
Strategy checklist for medical practice acquisitions

With the ever-changing health care landscape and the increasing competitiveness among physician practices and hospitals, many physicians are looking at acquiring other practices and bringing them into the fold. Unfortunately, I have often seen physicians who would like to jump to the valuations or due diligence of a medical practice without having first established their own strategy as it relates to potential acquisitions.

If your practice doesn’t already have a strategic growth plan, make one. Growing for growth’s sake really doesn’t make sense for you or for the potential target. Instead, think about practices that might be interesting to acquire, geographies that might be important, capacity that might enhance operations, or perhaps even technology that could be transformational.

You should consider what you need before looking at opportunities, because after the acquisition the integration follows, and that can be an extremely difficult process if there was no strategy beforehand. The discipline of articulating a strategy will guide you in finding and assessing acquisition targets.

Nick Hernandez, MBA, FACHE, is the CEO and founder of ABISA, a consultancy specializing in strategic health care initiatives for physician practices. His firm helps devise and implement strategies that will allow practices to remain competitive and solvent. Send your financial questions to medec@mjhlifesciences.com

Getting started

What is your vision for where you want your practice to go? In developing your acquisition strategy, you should consider your goals (What is it that you want to do?) as well as your experience (What have you already demonstrated the capability to succeed at?). It is imperative that you fully study these two areas and write down your thoughts before you proceed.

As a physician-owner, you need to know what strategic outcomes you ultimately want from engaging in acquisitions and consider the implications to both you, as the buyer, and the practices that may want to sell. Developing an acquisition strategy requires knowing what makes your practice successful now and what a potential acquisition can add to make your business even better in the future. This strategy will help you clearly define the value proposition for both buyer and seller, as well as the value drivers that should guide acquisition decisions. In this instance, the value drivers are essentially capabilities that add worth to the practice.

Practices are continually bought and sold as a result of an opportunity being made available or because of a strategic plan. As the buyer, you are acquiring an established practice that is hopefully making money and has patients and employees already in place. You also know that if you buy a good practice, you have the opportunity to make it a better one. From time to time, things come your way that are more opportunistic. Ask yourself, is the downside (risk) significantly less than the realistic upside (opportunity)? Are the seller’s goals aligned with what you want to do? Look at the fit. Will integration require a fundamental change in either practice? Unfortunately, the answers are rarely black and white, hence the importance of having an underlying acquisition strategy.
Defining the practice you want to buy

When your desires and experience intersect with a good acquisition strategy, you have the foundation for your plan. It is now time to look at opportunities, by first defining the parameters of the practice you want to acquire. What are the characteristics of the medical practice you propose to buy? Items such as practice size, location, price range and patient catchment area are just some of the key areas to initially think about.

What is your plan to grow the new, combined business? You should include both top- and bottom-line growth in your discussion. Are you looking for a troubled practice where you can create value or a practice that is already on a fast-growth trajectory? Do you foresee additional acquisitions? If so, what are the attributes of the prospective add-on practices. What will the new business look like as your plan moves forward?

Targeting a practice

Once this exercise is complete, you will be in a position to start targeting the right practice. There are two ways of doing this: find a practice already listed for sale, or approach the physician-owner of a practice that is not for sale and make an offer. Some key questions you should keep in the forefront of your mind include the following:

- How does the target make you, the buyer, better?
- How do you make the target better? Most often, you are buying the producer (the physician), so alignment with his or her personal goals is absolutely critical.
- What are the risks that could impact the future success of the business? What is your plan to deal with them?

The process of buying a medical practice can be narrowed down to one very simple question: Is the practice you’re buying actually the business that you think you’re buying? Some purchases are more straightforward than others. If you have a thorough understanding of what you are buying, then the process will be smoother. It is extremely important to remember that when you encounter an opportunity that does not align perfectly with your original strategy, return to the key questions that defined it. Local market dynamics may change your own practice and, thus, there may be a need to alter your acquisition strategy. There is nothing wrong with that. In fact, I am a firm believer that strategy should be fluid and ever-evolving. Just make sure that as your acquisition strategy changes over time, the practices you acquire still make your business better and more valuable.

Final thoughts

Essentially, your strategy will become the roadmap for your acquisition initiatives and will serve you well at every stage. Thoughtful development of an acquisition strategy should tell you as much about the medical practices you should not pursue as those you should. You can use your refined strategy to help locate medical practices, seek investors and lenders, assess the value of practices, and structure deals. Most importantly, as you get caught up in the heat of the chase, it will help you to assess whether the deal you are working on is really going to be right for you.

The challenge is to stay true to your strategic direction, not allowing yourself to be distracted by acquisitions that don’t keep you on the intended path. Physician-owners often make mistakes here. All the work you do to meet and evaluate practices, only to walk away, is not wasted. It’s part of staying true to the thesis and testing and achieving your long-term vision for your business.
Select Important Safety Information

Flublok Quadrivalent and 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 for Fluzone High-Dose Quadrivalent) or after previous dose of the respective vaccine. In addition, Fluzone High-Dose Quadrivalent should not be administered to anyone who has had a severe allergic reaction after previous dose of any influenza vaccine.

Don’t let influenza spread like wildfire.

Help contain it with better protection.

Flublok Quadrivalent and Fluzone High-Dose Quadrivalent are vaccines indicated for active immunization against disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. Flublok Quadrivalent is approved for use in persons 18 years of age and older. Fluzone High-Dose Quadrivalent is approved for use in persons 65 years of age and older.
Don’t let influenza spread like wildfire. Help contain it with better protection.

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**Select Important Safety Information**
Flublok Quadrivalent and 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 for Fluzone High-Dose Quadrivalent) or after previous dose of the respective vaccine. In addition, Fluzone High-Dose Quadrivalent should not be administered to anyone who has had a severe allergic reaction after previous dose of any influenza vaccine.

Please see Brief Summary of Prescribing Information for Flublok Quadrivalent on the third spread, and for Fluzone High-Dose Quadrivalent please see the fourth spread.
Only 2 influenza vaccines have been proven to prevent more cases of influenza versus standard-dose vaccine comparators in older adults\textsuperscript{1-4}

**Fluzone® High-Dose Quadrivalent (Influenza Vaccine)**

With 4-strain protection, Fluzone High-Dose Quadrivalent builds on the legacy of the trivalent formulation, which was proven to provide

\[ \text{24\% BETTER PROTECTION AGAINST INFLUENZA} \]

(95\% CI: 10-37)

due to any lab-confirmed circulating strain compared with standard-dose Fluzone (Influenza Vaccine) in patients 65+.\textsuperscript{1,3}

Based on data from the trivalent formulation, solicited injection site reactions and systemic adverse reactions were slightly more frequent after vaccination with the trivalent formulation compared with a standard-dose vaccine.\textsuperscript{1}

**Flublok® Quadrivalent (Influenza Vaccine)**

According to a head-to-head randomized controlled efficacy trial among adults 50+, Flublok Quadrivalent was proven to provide

\[ \text{30\% BETTER PROTECTION AGAINST INFLUENZA} \]

(95\% CI: 10-47)

due to any PCR\textsuperscript{a}-confirmed circulating strain versus a standard-dose quadrivalent inactivated influenza vaccine.\textsuperscript{2,4}

In this randomized controlled trial, the most common local and systemic adverse reactions to Flublok Quadrivalent included pain at the injection site, headache, and fatigue.\textsuperscript{2}

Learn more at sanofiflu.com
Important Safety Information for Flublok Quadrivalent and Fluzone High-Dose Quadrivalent

Flublok Quadrivalent and 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 for Fluzone High-Dose Quadrivalent) or after previous dose of the respective vaccine. In addition, Fluzone High-Dose Quadrivalent should not be administered to anyone who has had a severe allergic reaction 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 Flublok Quadrivalent and Fluzone High-Dose Quadrivalent should be based on careful consideration of the potential benefits and risks.

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

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

For Flublok Quadrivalent, in adults 18 through 49 years of age, the most common injection-site reactions were tenderness and pain; the most common solicited systemic adverse reactions were headache, fatigue, myalgia, and arthralgia. In adults 50 years of age and older, the most common injection-site reactions were tenderness and pain; the most common solicited systemic adverse reactions were headache, and fatigue.

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.

For Flublok Quadrivalent and Fluzone High-Dose Quadrivalent, other adverse reactions may occur.

Please see Brief Summary of Prescribing Information for Flublok Quadrivalent on the third spread, and for Fluzone High-Dose Quadrivalent please see the fourth spread.

To order Fluzone High-Dose Quadrivalent or Flublok Quadrivalent vaccine, 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.
Flublok Quadrivalent is manufactured by Protein Sciences Corporation, a Sanofi company, and distributed by Sanofi Pasteur Inc.
Flublok Quadrivalent (CPT code 90682) is a covered benefit under Medicare Part B.

a PCR = Polymerase chain reaction.
b CPT (Current Procedural Terminology) is a registered trademark of the American Medical Association.

Flublok® Quadrivalent Rx Only
(Trivalent Influenza Vaccine), Sterile Solution for Intramuscular Injection
2020-2021 Formula

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE
Flublok Quadrivalent is a vaccine indicated for active immunization against disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. Flublok Quadrivalent is approved for use in persons 18 years of age and older. [see Clinical Studies (14) in the full prescribing information].

2 DOSAGE AND ADMINISTRATION
For intramuscular injection only.

2.1 Dosage
Administer Flublok Quadrivalent as a single 0.5 mL dose.

2.2 Administration
Invert the prefilled syringe containing Flublok Quadrivalent gently prior to affixing the appropriate size needle for intramuscular administration. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered. The preferred site for injection is the deltoid muscle. Flublok Quadrivalent should not be mixed in the same syringe with any other vaccine.

4 CONTRAINdications
Flublok Quadrivalent is contraindicated in individuals with known severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine [see Postmarket Experience (6.2) and Description (11) in the full prescribing information].

5 WARNINGS AND PRECAUTIONS
5.1 Managing Allergic Reactions
Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

5.2 Guillain Barré Syndrome
The 1976 swine influenza vaccine was associated with an increased frequency of Guillain-Barré Syndrome (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 one additional case per million persons vaccinated. If GBS has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give Flublok should be based on careful consideration of the potential benefits and risks.

5.3 Altered Immunocompetence
If Flublok Quadrivalent is administered to immunocompromised individuals, including persons receiving immunosuppressive therapy, the immune response may be diminished.

5.4 Limitations of Vaccine Effectiveness
Vaccination with Flublok Quadrivalent may not protect all vaccine recipients.

6 ADVERSE REACTIONS
In adults 18 through 49 years of age, the most common (≥10%) injection-site reactions were tenderness (48%) and pain (37%); the most common (>10%) solicited systemic adverse reactions were headache (20%), fatigue (17%), myalgia (13%), and arthralgia (10%) [see Clinical Trials Experience (6.1)]. In adults 50 years of age and older, the most common (>10%) injection site reactions were tenderness (34%) and pain (19%); the most common (≥10%) solicited systemic adverse reactions were headache (13%) and fatigue (12%) [see Clinical Trials Experience (6.1)].

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

Flublok Quadrivalent

Flublok Quadrivalent has been administered to and safety data collected from 998 adults 18-49 years of age (Study 1) and 4328 adults 50 years of age and older (Study 2).

In Studies 1 and 2, local (injection site) and systemic adverse reactions were solicited with the use of a memory aid for 7 days following vaccination, unsolicited adverse events were collected for ~28 days post-vaccination, and serious adverse events (SAEs) were collected for 6 months post-vaccination via clinic visit or remote contact.

Study 1 included 1330 subjects 18 through 49 years of age for safety analysis, randomized to receive Flublok Quadrivalent (n=998) or a comparator inactivated influenza vaccine (Pharzix® Quadrivalent, manufactured by GlaxoSmithKline) (n=332) [see Clinical Studies (14) in the full prescribing information]. The mean age of participants was 33.5 years. Overall, 95% of subjects were female, 59% white/Caucasian, 37% black/African American, 1.0% Native Hawaiian/Pacific Islander, 0.6% American Indian/Alaskan Native, 0.5% Asian, 1.4% other racial groups, and 16% of Hispanic/Latino ethnicity. Table 1 summarizes the incidence of solicited local and systemic adverse reactions reported within seven days of vaccination with Flublok Quadrivalent or the comparator vaccine.

<table>
<thead>
<tr>
<th>Reactogenicity Term</th>
<th>Flublok Quadrivalent N=996 (%)</th>
<th>Comparator N=332 (%)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>52</td>
</tr>
<tr>
<td>Grade 3</td>
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</tr>
<tr>
<td>Grade 4</td>
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<td>0</td>
</tr>
<tr>
<td>Subjects with &gt;1 injection site reaction</td>
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<td>25</td>
</tr>
<tr>
<td>Local Tenderness</td>
<td>48</td>
<td>47</td>
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<tr>
<td>Local Pain</td>
<td>37</td>
<td>36</td>
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<td>3</td>
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<tr>
<td>Redness</td>
<td>4</td>
<td>0</td>
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<td>Subjects with &gt;1 systemic reaction</td>
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<td>36</td>
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<tr>
<td>Headache</td>
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<td>21</td>
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<tr>
<td>Fatigue</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>Muscle Pain</td>
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<td>12</td>
</tr>
<tr>
<td>Joint Pain</td>
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<td>Nausea</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Shivering / Chills</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Fever</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 1: Frequency of Solicited Local Injection Site Reactions and Systemic Adverse Reactions within 7 Days of Administration of Flublok Quadrivalent or Comparator in Adults 18-49 Years of Age, Study 1 (Reactogenicity Populations)

<table>
<thead>
<tr>
<th>Reactogenicity Term</th>
<th>Flublok Quadrivalent N=6312 (%)</th>
<th>Comparator N=3272 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Grade 1</td>
<td>38</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Grade 3</td>
<td>&lt;1</td>
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<tr>
<td>Grade 4</td>
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<td>&lt;1</td>
</tr>
<tr>
<td>Subjects with &gt;1 injection site reaction</td>
<td>38</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

Table 2: Frequency of Solicited Local Injection Site Reactions and Systemic Adverse Reactions within 7 Days of Administration of Flublok Quadrivalent or Comparator in Adults 50 Years of Age and Older, Study 2 (Reactogenicity Populations)

*Comparator = U.S.-licensed comparator quadrivalent inactivated influenza vaccine manufactured by GlaxoSmithKline.
†Study 1 is registered as NCT02290509 under the National Clinical Trials registry.
‡Denominators for systemic reactions: Flublok Quadrivalent n = 4306, Comparator n = 4319.
§38
¶Denominators for injection site reactions: Flublok Quadrivalent n = 996, Comparator n = 332.
\*Comparator = U.S.-licensed comparator quadrivalent inactivated influenza vaccine manufactured by GlaxoSmithKline.
†Study 2 included 18672 subjects 50 years of age and older for safety analysis, randomized to receive Flublok Quadrivalent (n=4328) or Comparator (Fluarix Quadrivalent, manufactured by GlaxoSmithKline) as an active control (n=4344) [see Clinical Studies (14) in the full prescribing information]. The mean age of participants was 62.7 years. Overall, 56% of subjects were female, 80% white/Caucasian, 18% black/African American, 0.9% American Indian/Alaskan Native, 0.4% Asian, 0.2% Native Hawaiian/Pacific Islander, 0.7% other racial groups, and 5% of Hispanic/Latino ethnicity. Table 2 summarizes the incidence of solicited local and systemic adverse reactions reported within seven days of vaccination with Flublok Quadrivalent or Comparator.

<table>
<thead>
<tr>
<th>Reactogenicity Term</th>
<th>Flublok Quadrivalent N=6312 (%)</th>
<th>Comparator N=3272 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Grade 1</td>
<td>38</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Grade 3</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Grade 4</td>
<td>40</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Subjects with &gt;1 injection site reaction</td>
<td>38</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>
Flublok® Quadrivalent (Influenza Vaccine), Sterile Solution for Intramuscular Injection

2020-2021 Formula

Study 4 included 602 subjects 50 through 64 years of age for safety analysis, randomized to receive Flublok (n=300) or another U.S.-licensed trivalent influenza vaccine (Fluzone, manufactured by Sanofi Pasteur, Inc.) as an active control (n=302).

Study 5 included 869 subjects aged 65 years and older for safety analysis, randomized to receive Flublok (n=436) or another U.S.-licensed trivalent influenza vaccine (Fluzone) as an active control (n=433).

Study 6 included 2627 subjects aged 50 years and older for safety analysis, randomized to receive Flublok (n=1314) or another U.S.-licensed trivalent influenza vaccine (Afluria, manufactured by Seqirus Pty Ltd.) as an active control (n=1313). Among subjects 50 through 64 years of age, 972 received Flublok and 655 received Afluria. Among subjects aged 65 years and older, 646 received Flublok and 648 received Afluria.

Study 7 was a Phase 2 dose-finding trial conducted in adults 18 through 49 years of age, 153 of whom received Flublok 135 mcg, the licensed trivalent formulation.

Serious Adverse Events

Among 2497 adults 18-49 years of age (Studies 3 and 7 pooled), through 6 months post-vaccination, two deaths were reported, one in a Flublok recipient and one in a placebo recipient. Both deaths occurred more than 28 days following vaccination and neither was considered vaccine-related. SAEs were reported by 36 Flublok recipients and 35 placebo recipients. One SAE (pleuropneumonia) in a Flublok recipient was assessed as possibly related to the vaccine.

Among 972 adults 50-64 years of age (Studies 4 and 6 pooled), through up to 6 months post-vaccination, 4 deaths occurred, 2 in Flublok recipients and 2 in Comparator recipients. None were considered related to the study vaccines. SAEs were reported by 80 subjects (37 Flublok recipients, 43 Comparator recipients). None were considered related to the study vaccines.

Among 1314 adults 50 years of age and older (Study 7) for whom the incidence of rash, urticaria, swelling, non-pitting edema, or other potential hypersensitivity reactions were actively solicited for 30 days following vaccination, a total of 2.4% of Flublok recipients and 1.6% of Comparator recipients reported such events over the 30 day follow-up period. A total of 1.3% and 0.9% of Flublok and Comparator recipients, respectively, reported these events in the 7 days following vaccination.

Of these solicited events, rash was most frequently reported (Flublok 1.3%, Comparator 0.8%) over the 30 day follow-up period.

D.2 Postmarketing Experience

The following events have been spontaneously reported during post-approval use of Flublok Quadrivalent. They are described because of the temporal relationship, the biologic plausibility of a causal relationship to Flublok Quadrivalent, and their potential seriousness. 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. Immune system disorders: anaphylaxis, allergic reactions, and other forms of hypersensitivity (including urticaria).

7. DRUG INTERACTIONS

Data evaluating the concomitant administration of Flublok Quadrivalent with other vaccines are not available.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure

Pregnancy outcomes in women who have been exposed to Flublok Quadrivalent during pregnancy are being monitored. Sanofi Pasteur Inc. is maintaining a prospective pregnancy exposure registry to collect data on pregnancy outcomes and newborn health status following vaccination with Flublok Quadrivalent during pregnancy. Healthcare providers are encouraged to enroll women who receive Flublok Quadrivalent during pregnancy in Sanofi Pasteur Inc’s vaccination pregnancy registry by calling 1-800-622-2463.

Risk Summary

Adults with a history of birth defects, loss, or other adverse outcomes. In the U.S. general population, the estimated background risks of major birth defects and miscarriage in clinically recognized pregnancies are 2% to 4% and 15% to 20%, respectively. Available data on Flublok Quadrivalent and Flublok (trivalent formulation) administered to pregnant women are insufficient to inform vaccine-associated risks in pregnant women.

There were no developmental studies of Flublok Quadrivalent formulation performed in animals. The developmental effects of Flublok Quadrivalent formulation are relevant to Flublok Quadrivalent because both vaccines are manufactured using the same process and have overlapping compositions. A developmental study of Flublok (trivalent formulation) has been performed in rats administered 0.5 mL divided of Flublok (trivalent formulation) prior to mating and during gestation. This study revealed no evidence of harm to the fetus due to Flublok (trivalent formulation) [see Data].

Table 2: Frequency of Solicited Local Injection Site Reactions and Systemic Adverse Reactions within 7 Days of Administration of Flublok Quadrivalent or Comparator in Adults 50 Years of Age and Older; Study 2 (Reactivity Populations) 1, 2 (continued)

<table>
<thead>
<tr>
<th>Reactogenicity Term</th>
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<th>Comparator N=4237</th>
<th>%</th>
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<th>Grade 1</th>
<th>Grade 2</th>
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<tr>
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</tr>
<tr>
<td>Redness</td>
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<td>2</td>
<td>2</td>
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<td>1</td>
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<tr>
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</table>

*Denominators for injection site reactions: Flublok Quadrivalent n = 4307, Comparator n = 4319.
†Denominators for systemic reactions: Flublok Quadrivalent n = 4306, Comparator n = 4318.
‡Denominators for fever: Flublok Quadrivalent n = 4262, Comparator n = 4282.

Note: Data based on the most severe response reported by subjects. Results ≥1% reported to nearest whole percent; results >0 but <1% reported as <1%.

Flublok® Quadrivalent is approved for use in persons 18 years of age and older in persons receiving immunosuppressive therapy, the immune response may be impaired.

If Flublok Quadrivalent is administered to immunocompromised individuals, including those with impaired immune responses, the immune response may be impaired.

Invert the prefilled syringe containing Flublok Quadrivalent gently prior to affixing the needle. Flublok Quadrivalent is approved for use in persons 18 years of age and older in persons receiving immunosuppressive therapy, the immune response may be impaired.

If Flublok Quadrivalent is administered to immunocompromised individuals, including those with impaired immune responses, the immune response may be impaired.
Please continue reading to see Brief Summary of Prescribing Information for Fluzone High-Dose Quadrivalent (Influenza Vaccine).
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 breastfeeding infant or on milk production/excretion.

8.4 Pediatric Use
Safety and effectiveness of Fluzone High-Dose Quadrivalent 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-SPLR-SL-JUL20 Revised: July 2020

### 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>Local Reactions</th>
<th>Fluzone High-Dose Quadrivalent (N=1761-1768) Percentage</th>
<th>Fluzone High-Dose³ (N=885-889) Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any</td>
<td>Grade 3</td>
</tr>
<tr>
<td>Injection Site Pain&lt;sup&gt;4&lt;/sup&gt;</td>
<td>41.3</td>
<td>0.7</td>
</tr>
<tr>
<td>Injection Site Erythema&lt;sup&gt;4&lt;/sup&gt;</td>
<td>6.2</td>
<td>0.6</td>
</tr>
<tr>
<td>Injection Site Swelling&lt;sup&gt;4&lt;/sup&gt;</td>
<td>4.9</td>
<td>0.2</td>
</tr>
<tr>
<td>Injection Site Induration&lt;sup&gt;4&lt;/sup&gt;</td>
<td>3.7</td>
<td>0.2</td>
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<tr>
<td>Injection Site Bruising&lt;sup&gt;4&lt;/sup&gt;</td>
<td>1.3</td>
<td>0.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Systemic Reactions</th>
<th>Fluzone High-Dose Quadrivalent (N=1761-1768) Percentage</th>
<th>Fluzone High-Dose³ (N=885-889) Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any</td>
<td>Grade 3</td>
</tr>
<tr>
<td>Myalgia&lt;sup&gt;4&lt;/sup&gt;</td>
<td>22.7</td>
<td>0.9</td>
</tr>
<tr>
<td>Headache&lt;sup&gt;4&lt;/sup&gt;</td>
<td>14.4</td>
<td>0.6</td>
</tr>
<tr>
<td>Malaise&lt;sup&gt;4&lt;/sup&gt;</td>
<td>13.2</td>
<td>0.7</td>
</tr>
<tr>
<td>Shivering&lt;sup&gt;4&lt;/sup&gt;</td>
<td>5.4</td>
<td>0.3</td>
</tr>
<tr>
<td>Fever&lt;sup&gt;4&lt;/sup&gt;</td>
<td>0.4</td>
<td>0.2</td>
</tr>
</tbody>
</table>

<sup>†</sup>N is the number of vaccinated participants with available data for the events listed
<sup>‡</sup>Safety results for the Fluzone High-Dose and investigational Fluzone High-Dose containing the alternate B influenza strain recipients were pooled for the analysis.
<sup>§</sup>Grade 3: A type of AE that interrupts usual activities of daily living, or significantly affects clinical status, or may require intensive therapeutic intervention.
<sup>¶</sup>Grade 3: > 100 mm
<sup>⁄</sup>Grade 3: ≥ 102.1°F (39.0°C)

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. Adverse events were included based on one or more of the following factors: severity, frequency of reporting, or strength of evidence for a causal relationship to Fluzone High-Dose, Fluzone, or Fluzone Quadrivalent.

- 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, vasodilatation
- 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

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Q&A

Cyberattack threats on the rise

by Todd Shryock Managing Editor

With much of the nation’s health care infrastructure focused on COVID-19, the world’s hackers sense an opportunity. Cyberattacks are increasing, forcing hospitals and health care providers to divert precious resources to boosting security.

Medical Economics® spoke with Matt Gyde, CEO of NTT Ltd. Security Division, to discuss cybersecurity in health care and how cybercriminals are using the pandemic to go after vulnerable facilities. The transcript has been edited for clarity and brevity.

Medical Economics®: Why has there been a recent increase in the number of cyberattacks directed at health care institutions?

Gyde: Different parts of the world have reacted differently to COVID-19, but a lot of what we saw was a result of people starting to work from home. Many organizations globally had work-from-home policies, but not for the whole organization. What we saw in the medical profession was an uptick in terms of the attacks against hospitals and facilities. And I think one of the main reasons for that, is that COVID-19 has brought a lot of pressure onto the health care infrastructure as a whole. When there’s pressure and it is focused on other areas, it’s generally an opportunity for the cyber bad people out there.

Now more and more of the devices in our environment are connected to the internet. That also opened a huge opportunity for the cybercriminals. We published our global threat intelligence report in May, and one of the key points is that the internet of things is being weaponized. So, we’re really seeing that as we’re making our lives easier by having everything connected, we’re also opening up to the abilities of the cybercriminals.

ME: Is there a particular size or type of health care target that strongly attracts the most attention from these hackers?

Gyde: We’ve seen one of everything, essentially, if not more. It’s a bit scary out there. There is no “You’re a big facility, we’ll go after you,” or “You’re a small one.” We operate on a global basis, so we’re present in 58 countries, and we’ve seen small hospitals with maybe 10 beds being attractive, right up to the top end with the large health care facilities being under attack. So there’s been no delineation, no focus on a particular segment. I think that’s part of what we see with this cybercriminal community. There are obviously nation states involved, then it goes to the next level where...
people are looking to make money, right down to individuals who are just trying to test out their skill with hacker tool sets. There has been no specific focus, though, on large or small institutions.

ME: It sounds as if these hackers are anything from large organized crime groups down to just individuals. Who are they and what are they ultimately after?

Gyde: Each group is after something different. A lot of research is going on at the moment trying to find a solution to COVID-19, how we immunize against it or if there is a piece of medicine that can help solve the problem. Obviously, some groups are going after intellectual property, to see if they can get a step ahead without having to do the work. A lot of the cybercriminals are going after money right now. So, if you’ve got a critical piece of infrastructure within your hospital, maybe an X-ray machine or an MRI, that they can get hold of and put some ransomware on, the facility can’t use it any longer and could potentially be in a position where they either scrap the machine or pay a ransom. Then you get down to the individuals who are just trying to test out their skills. What we’ve seen is a lot of variants in terms of how they use information, so the more you are having to do and review, the more room there is where they either scrap the machine or pay a ransom. Then you get down to the individuals who are just trying to test out their skills. What we’ve seen is a lot of variants in terms of how they use information, so the more you are having to do and review, the more room there is for making human mistakes.

I would say the threat is no more than it was previously, but that they have to be much more rigorous in terms of how they use information, email, and various content pieces.

ME: How are hackers getting into health care systems? What are their favorite tactics?

Gyde: It’s still sending an email to an individual and that person clicking the link. Then (the hackers) put a piece of malware on the infrastructure.

Now, the interesting thing about malware, and going back to that global threat intelligence report, is we’re actually seeing a lot more use of machine learning and artificial intelligence. So essentially, when you get a piece of malware on your infrastructure, it needs to call back to a central computer or some sort of infrastructure to get instructions in terms of ‘What do you want me to do next?’ We’re seeing a lot more of that. It used to be the human that would have to then say, ‘OK, move this way, or do this or that, attack that machine.’ But now what we’re seeing is a lot of those decisions are being made by algorithms—so, essentially, machine learning. The sophistication behind it is incredible.

If you look at a lot of this infrastructure that gets built, it’s short term. So they’ll spin things up and turn them off when they need to. But a lot of it’s being done by machines. It’s like having a corporate infrastructure only for the cybercriminals. Now they can go onto the dark web, acquire a piece of malware, and they can actually call a phone number in many cases and get technical support in terms of how to use that piece of malware. It’s a bit scary.

They’re running a business, essentially.

ME: What can be done to stop these attacks, especially if an organization lacks funding for extra IT help?

Gyde: You have people and process as the key things and technology is the third component. In terms of people, it’s absolutely essential that you’re continuously updating them, giving them information that they can consume. Now, it’s up to the individual to read that information,
but education about cyberspace is absolutely critical right now. And it’s incumbent on every employee that they’re aware of what they’re doing and what they’re clicking on. Just because you get a special email that’s personalized doesn’t mean that you’re going to get what it promises. So, education is number one.

For me, process is probably the second-most important thing. There’s a whole bunch of different security frameworks and depending on what environment you’re operating in, how you want to align the framework is so critical in terms of how you’re going to secure it and align it to whatever’s best for your industry.

Then the technology piece is ensuring that your technology is patched. We are 30 or 35 years into having technology and we’ve still got systems that are unpatched. The main reason patches get released is to upgrade the security and the performance of that particular device. So it’s absolutely essential that we keep what we’ve got patched.

And the other piece I would add in there is that an incident is going to happen. You can have the most expensive technology, processes, and people on the planet, but people are still going to find ways through as technology is complex. Be in a position where you’ve either partnered with someone or you’ve got the resources internally to respond to an incident. We have many health care facilities, for instance, that run fire drills. This is how we evacuate everybody, this is where we expect them to go. The question I would ask is whether they do that with technology in that environment? And the majority of the answers would be ‘No, we don’t, because we haven’t been in a position to.’ But doing fire drills around your technology gives people the understanding that if they are breached, this is the reaction they need to take. ‘These are the three steps that many companies are putting in place behind this to say, ‘If this does happen, this will be our reaction to it, but secondly, this is how we’ll approach it.’ My view is that you should immediately notify authorities. It’s important that your local government bodies — from the police to the federal government-type institutions — are notified because they have plans in place and more often than not have seen these things before and can give you short-term advice. It’s a bit of an insurance model, in terms of having a retainer in place for a third party to come in and help you. There are many companies like NTT that do that, for instance.

Generally, those sorts of contracts have a time frame around them — whether it’s minutes, hours, days — in terms of response time. A lot of the response to ransomware incidents right now can be done remotely. So, my strong piece of advice is to have a third party that specializes in this area and can respond in a very short time frame and help you through that process. Obviously, having done a fire drill makes it easier, right? It’s not panic. It’s ‘OK, we knew this was going to happen. These are the three steps that we’ve got to take.’ Having that documented would be absolutely critical as well.

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ME: For ransomware, if hackers already have your files, should you pay the ransom?

Gyde: Ransomware is generally going to lock a device down so you can’t access it. My view on it is, no, you shouldn’t pay the ransom. I think that just encourages people to try again and potentially get some more money. But that’s from me in a noncritical situation. We’ll go back to that comment I made earlier about an MRI. If you’ve got a critical patient that needs to get an MRI and suddenly your MRI machine is locked down and you can’t access it, you’re going to be in a very different situation.

I think what we are seeing is that many companies are putting policies in place behind this to say, ‘If this does happen, this will be our reaction to it, but secondly, this is how we’ll approach it.’ My view is that you should inform the authorities immediately. It’s very dependent on the situation. We are seeing more ransoms being paid in order for companies to get control back of their machines that they previously had, but that doesn’t necessarily mean that I agree with it.

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Check out Medical Economics pulse. This interview was transcribed from a video interview that was recorded as part of Medical Economics® Pulse video program. Check out more video interviews with experts at bit.ly/MedEcVideo.
“Family physicians topped the list of Merritt Hawkin’s 20 most-requested recruiting engagements, underscoring continued demand for primary care,” according to a report by the national recruiter. Internal Medicine, General Practice, and Cardiologists rank in the top 20 most requested searches as the growing volume for recruiting activity is shifting toward medical specialties.*

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Joanna Shippoli
Account Executive
JShippoli@mjhlifesciences.com
440-891-2615

Who profits from medical records?

Medical records, which most patients think are private and protected, are in reality lucrative commodities in a multi-billion-dollar industry. As hospitals and health networks assemble these records, they routinely strip away names and other identifiers and sell millions of HIPAA-compliant files to massive aggregator corporations. Aggregators in turn profit from integrating, analyzing and selling access to data on a massive scale. For example, Truven Health Analytics, part of IBM Watson Health, brought 215 million patient records to IBM when it was purchased in 2016, raising IBM’s total to about 300 million records. Access to these records is sold to pharmaceutical companies, insurers, health systems and government entities for research purposes.

Medical data reside with other owners, as well. Since the development of modern pharma, it has been axiomatic that clinical trial data belong to the companies that gather that data. When participants join a clinical trial, they typically agree that, aside from test entries into their medical records, the data they generate become the property of the sponsor. It makes sense: A typical phase 3 clinical trial costs about $40 million, and pharma companies want the sole right to profit from the data they’ve spent millions to collect.

Other collectors of medical data have taken a more consumer-facing route. 23andMe and Ancestry.com have built massive genetic testing databases. They acquire data by selling DNA test kits for genealogy purposes and using that money to cover testing costs. Consumers get a genealogy report, and 23andMe and Ancestry.com then sell access to the identity-striped analyses of genetic data on millions of people similar to the way large aggregators such as Truven share medical records.

An investigator can pay 23andMe to identify 250,000 people distributed across multiple genetic groups, launch an Institutional Review Board-approved voluntary email survey to those people and deliver the research results. This business model is by no means clear to consumers who want to trace their family trees, but it is legal and thriving. More concerning still is that analysts have found ways to break anonymity, marry records from multiple sources (including search engines and social media) and sell these amalgamated records to a variety of for-profit enterprises.

These data owners also sell access to medical and genetic data for many beneficial uses. For example, if investigators want to know the long-term adverse effects of a drug, they can access 10 years of data for 20 million people and check how often adverse effects or dangerous drug interactions occurred.

It’s critical to understand that patients generally do not have exclusive rights to their data. Once a patient shares their data, they have little or no say in how it is used. Most do not even know their data are being sold and never see any direct profit from the sale. But that could change. In an age where consumers know that Facebook, Google, Amazon and others are exploiting their electronic data for profit, the models for medical data ownership soon may be ripe for overhaul. Governments in Europe and elsewhere already are legislating limits on these data uses.

Fueled in part by European Union’s General Data Protection Regulation, which reflects a growing societal consensus that each of us should own the biomedical data we generate, new ideas are taking shape. These new European rules are leading many to ask: Is it possible to create a transparent model where patients own their medical data and share in any profits derived from it? Will the future of data ownership remain exclusively with large corporations who aggregate that data, or will a more patient-centered approach emerge?

One area where one might imagine change in the near term is pharma. Big Pharma has, in recent years, been making its approach to study participants increasingly patient-centric. More broadly, the health care industry has been developing new ways to regulate and share data in interoperable formats. With emerging standards such as the Fast Healthcare Interoperability Resources, a format that makes patient records compatible across platforms, transactions in which data are sold or loaned at the level of individual patients are becoming feasible. Clinical trial data gathered in a drug study could even be transferred back into patients’ medical records.

HIPAA presents another
opportunity for change. When Congress passed the Health Insurance Portability and Accountability Act of 1996, medical records were still kept on paper in file rooms. The law has been amended in the past, but it is becoming increasingly clear that, in our fully digital medical landscape, it will need to be revised again. When patients sign a HIPAA form in a hospital waiting room, they authorize providers to strip away 18 pieces of potentially identifying information and then empower their health care provider to sell their data without compensating them. A new HIPAA could not only retain a patient’s right to access their data, it could also give them ownership and even some measure of control.

When patients own their medical data in a more exclusive way, the data’s intrinsic value remains with them. They could opt to keep the data completely private and not sell it to any corporation. But with companies willing to pay for access, the potential for profit exists. How can patients share their medical data and reap the profits? One possibility is a medical data “bank.” Patients could elect to store and pool their medical records at the bank in exchange for a slice of the profits. Instead of data ownership residing with private companies, medical data would be aggregated in a patient-centered model where drug companies and others gain access for a fee, and patients receive a share of the profits. It would work much like a savings account, where thousands of account holders deposit their money, the bank makes loans at 7% interest and the bank returns 3% interest to the savings accounts. Patients who participate in clinical trials would be making their medical records more valuable and thus earn a larger return. This may sound far-fetched, but many people are advocating for a model such as this on an ethical level, and it is now being explored commercially by several startups.

Led by regulators in the European Union and California, parts of the U.S. government are actively exploring changes to data ownership that could significantly alter the contemporary landscape. As our society develops new positions with regard to data privacy, ownership and profit, patients and consumer organizations are likely to join insightful health care leaders in building a new medical data system with transparency, privacy and patient control.

Paul W. Glimcher, Ph.D., is a neuroscientist, psychologist, economist and entrepreneur who holds the Julius Silver Professorship at New York University. At NYU, he is also a professor of neuroscience and physiology, NYU Grossman School of Medicine professor of psychology and economics, and codirector of the Institute for the Study of Decision Making. In addition, Glimcher is chairman and chief science officer of Datacubed Health, developer of new platform-as-a-service (PaaS) technologies for health care and biomedical/behavioral research.

“A new HIPAA could not only retain a patient’s right to access their data, it could also give them ownership and even some measure of control.”
Things You Should Know About Patient-Centered Asthma Care

Sandhya Khurana, MD
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Director, Mary Parkes Center for Asthma, Allergy and Pulmonary Care
University of Rochester School of Medicine and Dentistry
Rochester, NY

This activity was written by PER® editorial staff under faculty guidance and review.

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Disclosures (Dr. Sandhya Khurana): Grant/Research Support: GlaxoSmithKline, Sanofi.

The staff of PER® have no relevant financial relationships with commercial interests to disclose.

Learning Objectives
Upon successful completion of this activity, you should be better prepared to:
• Discuss the role of eosinophils in the spectrum of eosinophilic asthma phenotypes
• Develop strategies for shared decision-making and asthma action plans with patients affected by eosinophilic asthma

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3. Answer the evaluation questions.
4. Request credit using the drop-down menu.
You may immediately download your certificate.
Federal statistics show that nearly 62% of adults with asthma have uncontrolled disease. Features of uncontrolled asthma include poor symptom control and/or frequent exacerbations that require oral corticosteroids (OCS) or hospitalization, according to the Global Initiative for Asthma (GINA). Some of these patients have severe asthma that remains uncontrolled despite high-intensity therapy.

Improving asthma control requires understanding the phenotype of patients’ disease, their ability to adhere to planned treatments and the role of comorbidities. Here are 3 important things you need to know about better asthma control.

1. In severe uncontrolled asthma, pay attention to the blood eosinophils.

In the majority of patients with severe asthma, T-helper cell (Th) type 2 responses drive the disease. In these cases of type 2-high asthma, eosinophils play a central role. Eosinophils promote airway hyperresponsiveness, mucus overproduction and airway remodeling. Certain Th2 cytokines that contribute to eosinophil development or mediate their activities—IL-4, IL-5 and IL-13—are targets for biologic therapies in severe asthma.

Recent guidelines discuss the eosinophil count threshold that should prompt consideration of add-on biologic therapy in patients with severe asthma. The 2020 European Respiratory Society/American Thoracic Society guidelines provide these conditional recommendations for use of eosinophil counts:

<table>
<thead>
<tr>
<th>BLOOD EOSINOPHIL COUNT CUTOFF</th>
<th>RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥150 cells/µL</td>
<td>For guiding anti-IL-5 biologic initiation in adult patients with severe asthma and history of exacerbations.</td>
</tr>
<tr>
<td>≥260 cells/µL</td>
<td>For identifying adolescents or adults with severe allergic asthma who are more likely to benefit from anti-IgE biologic therapy.</td>
</tr>
</tbody>
</table>

The 2020 GINA asthma management strategy notes that higher blood eosinophil counts are strongly predictive of response to anti–IL-5, anti–IL-5 receptor and anti–IL-4 receptor therapy. Analysis of data from randomized controlled trials of omalizumab also found a larger decrease in asthma exacerbations in patients with blood eosinophil counts of 260 per µL or higher. Blood eosinophil counts can vary and they are affected by treatment, so blood eosinophil measurements should be repeated if they’re low in the first assay, and they should be assessed before the patient begins OCS therapy or when the patient is using the lowest possible OCS dose.

Five biologics are available for treating severe asthma: mepolizumab and reslizumab bind to circulating IL-5; benralizumab binds to the IL-5 receptor α; omalizumab binds to IgE; and dupilumab binds to the IL-4 receptor α to block IL-4 and IL-13 signaling.

2. Verify that your patients are using their inhalers correctly.

Up to 80% of patients with asthma do not use their inhalers correctly, resulting in poor asthma control and increased risk of exacerbations. Correct inhaler technique requires learning and maintaining specific skills, which may diminish over time. In addition, physical limitations related to arthritis, poor vision, hand weakness or poor inspiratory flow may also interfere with proper inhaler use.

GINA recommends that clinicians ask patients to demonstrate how they use their inhaler at each follow-up visit. If patients continue to have symptoms or exacerbations despite treatment with medium-dose inhaled corticosteroids and long-acting β₂ agonist or they require maintenance OCS, evaluating their inhaler technique and investigating their degree of adherence is especially important.

In order to help patients use their inhalers correctly, clinicians should also:

- Ensure that they can demonstrate proper inhaler technique for each type of device they prescribe to patients.
- Ask patients to demonstrate their knowledge via “teach-back” following the clinician demonstration.
- Consider patients’ functional ability and any potential barriers before prescribing a device.
- Avoid prescribing multiple types of inhaler devices when possible.
Involve patients in their asthma treatment decisions.

Another key factor for improving patients’ asthma control is involving them in decisions regarding their asthma medications, which supports better adherence and outcomes.7

Medication adherence has been found to be particularly low in pulmonary disease compared with many other chronic conditions. A systematic review of 29 randomized controlled trials found only 47% to 57% adherence to inhaled corticosteroids among patients with asthma.9 Patients may be intentionally nonadherent due to a sense of exclusion from the decision-making process, discordant beliefs about therapy or fear of side effects or medication dependence. Alternatively, their nonadherence may be unintentional, due to difficulty following a complicated regimen or poor understanding of asthma control.9,10

“Self-report tends to underestimate nonadherence, so it’s important to objectively confirm adherence by other means, such as confirming with their pharmacy that the patient is filling their prescription regularly.”

—Dr Sandhya Khurana

Shared decision-making takes into consideration patients’ characteristics that may affect their use of therapies, as well as their goals, treatment preferences, beliefs (including those influenced by patients’ culture) and concerns about their disease.9,10 Factors to discuss with patients during decision-making include:

Cost of medication options
Expected outcomes of the treatment options
Risk factors that may affect their outcomes, such as smoking

Also consider directing patients toward up-to-date and user-friendly decision aids, which can help drive conversations in the clinic, or allow patients to use them on their own. These tools can provide information on evaluating the benefit versus risk of treatment options and possible outcomes if the patient defers treatment, as well as guidance on how to reach a decision.11

Shared decision-making tools and patient education guides are available from several organizations, including the CHEST Foundation, the American College of Allergy, Asthma, and Immunology and GINA.12,13

KEY REFERENCES


For a full list of references go to: gotoper.com/go/asthma2020print
CME POST-TEST QUESTIONS

1. Earl, a 52-year-old male patient, presents for a follow-up visit after having four asthma exacerbations in the past 12 months. He has required 20 mg prednisone daily in the past month for symptom control. All of the following are appropriate steps at this stage according to GINA guidelines EXCEPT:
   A. Assessing the patient’s blood eosinophil count
   B. Asking the patient about his feelings regarding injectable therapies
   C. Relying on the patient’s report that he is using his inhalers regularly and with good technique
   D. Reviewing the patient’s refill history to assess his adherence

2. Recent guidelines make which of the following statements regarding elevated blood eosinophil counts?
   They are:
   A. Associated with lower risk of exacerbations
   B. Associated with good response to several types of biologics, including anti–IL-5s
   C. Less clinically valuable than sputum eosinophil counts
   D. Not affected by oral corticosteroid use

To learn more about this topic, including information on guidelines and recommendations for management of severe asthma, go to gotoper.com/online-cme-activities/cpc/cpc-asthma2020
Three Things You Should Know About Asthma, COPD and the Overlap Between the Two

Learning Objectives
Upon successful completion of this activity, you should be better prepared to:
• Discuss the diagnostic criteria that provide an accurate diagnosis of asthma-chronic obstructive pulmonary disease overlap (ACO) in light of asthma and chronic obstructive pulmonary disease (COPD)
• Evaluate evidence-based therapy for the management of ACO in contrast to the management of asthma and COPD

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1. Read this activity in its entirety.
2. Go to gotoper.com/activity/aco2020print to access and complete the post-test.
3. Answer the evaluation questions.
4. Request credit using the drop-down menu.
You may immediately download your certificate.
An estimated 19 million American adults have asthma and 16 million adults have chronic obstructive pulmonary disease (COPD), which are the most common chronic respiratory conditions worldwide. Typically, the clinical presentations of these two conditions are easily differentiated. However, up to 30% of patients with asthma or COPD have features of both conditions, currently called asthma-COPD overlap (ACO). Although evidence shows that patients with features of asthma and COPD have more exacerbations, a faster decline in lung function and poorer quality of life than individuals with either condition alone, the optimal approach to ACO treatment is still evolving. Here are 3 important things you need to know about identifying and managing ACO in your practice.

1 The definition of ACO is a work in progress.

Experts have yet to reach a consensus on the definition of ACO, which is sometimes referred to as ACO syndrome, or ACOS. The Global Initiative for Asthma (GINA) and Global Initiative for Chronic Obstructive Lung Disease (GOLD) jointly described it as being “characterized by persistent airflow limitation with several features usually associated with asthma and several features usually associated with COPD; (it) is therefore identified in clinical practice by the features that it shares with both asthma and COPD.” However, in its most recent COPD strategy report, GOLD stopped using the term ACO, instead positioning asthma and COPD as different disorders that may share clinical features. Another definition, published by an international panel, requires the presence of three major criteria and at least one minor criterion:

<table>
<thead>
<tr>
<th><strong>MAJOR CRITERIA</strong></th>
<th><strong>MINOR CRITERIA</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-bronchodilator FEV1/FVC &lt;0.70 or lower limit of normal in individuals aged ≥40 y</td>
<td>Documented history of atopy or allergic rhinitis</td>
</tr>
<tr>
<td>≥10 pack-years of tobacco smoking OR exposure to equivalent indoor or outdoor air pollution</td>
<td>Bronchodilator response of FEV1, ≥200 mL and 12% from baseline values on ≥2 visits</td>
</tr>
<tr>
<td>Documented history of asthma before age 40 y OR bronchodilator response of &gt;400 mL in FEV1</td>
<td>Peripheral blood eosinophil count of ≥300 cells/μL</td>
</tr>
</tbody>
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FEV1/FVC, forced expiratory volume in 1 second/forced vital capacity ratio.

2 Key factors differentiate the 3 conditions.

GINA’s 2020 strategy for asthma management provides a clinical guide to help diagnose patients with chronic respiratory symptoms based on the following factors:

**Highly likely to be asthma**
- Sx vary in frequency and intensity over short time periods
- Triggers may include allergens, exercise and aspirin
- Onset before age 40
- Sx improve on own or rapidly with bronchodilators or ICS
- Current or childhood asthma dx

**Features of asthma and COPD**
- Sx are intermittent or episodically worse on top of chronic level
- Sx may have started before or after age 40
- May have hx of smoking or other toxic exposures, respiratory illness such as tuberculosis, or low birth weight
- May have asthma features from above

** Likely COPD**
- Dyspnea present most days
- Onset after age 40
- Limitation of physical activity, usually progressive
- Chronic cough/sputum may be initial sx
- Bronchodilator provides limited relief
- Hx of smoking, toxic exposure, respiratory illness or low birth weight
- No current or past confirmed asthma dx

In addition, a patient with variable expiratory airflow limitation is highly likely to have asthma. A patient with persistent expiratory airflow limitation, with or without bronchodilator reversibility, is likely to have COPD, but could have features of COPD and asthma.

3 When patients have features of both, treat like asthma and COPD.

The initial treatment for patients with overlapping features of asthma and COPD includes low- or medium-dose inhaled cortico-
steroids (ICS). These patients will also typically require additional treatment with a long-acting β₂ agonist (LABA), a long-acting muscarinic antagonist (LAMA), or both. GINA notes that ICS may lower the risk of mortality in patients with moderate or severe COPD and even mild asthma symptoms.

In addition, patients with an asthma diagnosis and newly diagnosed COPD were shown to have a lower risk of COPD-related hospitalizations and death if they used ICS and a LABA versus LABA alone.

An algorithm published in 2019 recommended the use of ICS, plus LABA if needed, as the initial therapy for patients with ACO. Patients with a more severe course may require triple therapy with ICS, a LABA and a LAMA, which has been shown to improve lung function and reduce rates of exacerbation in patients with COPD.

For patients who continue to have uncontrolled symptoms or frequent exacerbations, the authors recommend evaluating their levels of IgE and blood eosinophils to test for type 2 inflammation, which is marked by increased eosinophil levels. Patients with positive results may be candidates for biologic asthma therapies such as the anti-IgE omalizumab or the anti-interleukin (IL)-5 treatments benralizumab or mepolizumab. In patients without evidence of type 2 inflammation, treatment with the phosphodiesterase-4 inhibitor roflumilast or chronic macrolide therapy may be appropriate.

Finally, patients with ACO require advice about smoking cessation, if they smoke; treatment of comorbidities such as rhinosinusitis or gastroesophageal reflux; appropriate adult vaccines; and in most cases, pulmonary rehabilitation.

“Trying to decide if one of your patients has ACO is not easy (since) the definition is really not clear. It’s like asking how to decide that this is a good piece of artwork. It’s based on assessment and opinion.”

—Barbara Yawn, MD, MSc

KEY REFERENCES


For a full list of references go to: gotoper.com/activity/aco2020print
CME POST-TEST QUESTIONS

1. Which of the following is a major diagnostic criterion for ACO according to an international panel's consensus definition?
   A. Current tobacco smoking status
   B. Post-bronchodilator FEV₁/FVC less than 0.70 or lower limit of normal in a patient 40 years of age or older
   C. Childhood diagnosis of asthma
   D. Peripheral serum eosinophils at least 150/µL

2. A 65-year-old woman with a working diagnosis of ACO presents with worsening symptoms on ICS plus a LABA. She has no chronic sputum production. Her FEV₁ is 35% predicted and her oxygen saturation on room air is 96%. Prior history includes 3 hospitalizations in the past year for exacerbations. Current labs include blood eosinophils at 550/µL.
   Which of the following is the most appropriate next step in therapy?
   A. Continue with ICS + LABA and add pulmonary rehab 1 to 2 times per week
   B. Continue with ICS + LABA but add supplemental oxygen
   C. Maintain ICS + LABA and add roflumilast
   D. Maintain ICS + LABA and add an anti-IL5 or anti-IL5 receptor α biologic

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- Provides a 1 page summary report
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- **HEMODYNAMIC DRIVERS**
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  - High intraglomerular pressure

- **INFLAMMATORY AND FIBROTIC DRIVERS⁵⁻⁶**
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  - Fibrotic proteins

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