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DON’T BE OUT OF THE LOOP ON OUT-OF-POCKET COST

LET PATIENTS KNOW THE AVERAGE OUT-OF-POCKET COST MAY BE LESS THAN THEY THINK

SHINGRIX
(ZOSTER VACCINE RECOMBINANT, ADJUVANTED)

LESS THAN* $5

*Average out-of-pocket cost for commercially insured patients.

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
• In a postmarketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following vaccination with SHINGRIX
• Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope
• Solicited local adverse reactions reported in individuals aged 50 years and older were pain (78%), redness (38%), and swelling (26%)
• Solicited general adverse reactions reported in individuals aged 50 years and older were myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%)

LET PATIENTS KNOW THE AVERAGE OUT-OF-POCKET COST MAY BE LESS THAN THEY THINK
When it comes to healthcare, coverage and cost are often big concerns for patients. But as you’ll see, cost doesn’t need to be an obstacle to receiving quality care. In fact, for most commercial plans, the out-of-pocket cost to patients is usually minimal.

Nationally, payers covering 96% of commercial medical benefit enrollees cover SHINGRIX²,³

90% of privately insured patients pay no or limited out-of-pocket cost with the average cost being less than $5 per dose¹

Individual access may vary by geography and plan benefit design.

What you need to know:
Coverage, coding, cost to patient, reimbursement amount for product, and administration fee will vary by payer, plan, patient, professional setting, or services rendered and are subject to change without notice. Cost to patients may vary. Coverage and reimbursement decisions are made by individual payers following receipt of claims from providers. Providers must follow payer documentation and billing requirements.

¹SOURCE: Managed Markets Insight & Technology, LLC, Database as of June 2021. “Coverage” is formulary access without restrictions, which means reimbursement from a health plan with no accompanying step edits or prior authorizations. Veterans Affairs (VA) and Indian Health Service (IHS) lives have been omitted when calculating the percentage of lives for this geography.

Important Safety Information (cont’d)
• The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women
• 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
• Vaccination with SHINGRIX may not result in protection of all vaccine recipients

You are encouraged to report vaccine adverse events to the US Department of Health and Human Services. Visit www.vaers.hhs.gov to file a report, or call 1-800-822-7967.

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

To see additional information about cost and coverage go to CoverageSHINGRIX.com


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SGXJRNA210065 September 2021
Produced in USA.
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 (HZ) (shingles) in adults aged 50 years and older.

2 DOSAGE AND ADMINISTRATION

2.2 Administration Instructions

For intramuscular injection only.

After reconstitution, administer SHINGRIX immediately or store refrigerated between 2° 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 2 to 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.

5.2 Guillain-Barré Syndrome (GBS)

In a postmarketing observational study, an increased risk of GBS was observed during the 42 days following vaccination with SHINGRIX [see Adverse Reactions (6.2)].

5.3 Syncope

Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

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.

Adults Aged 50 Years and Older

Overall, 17,041 adults aged 50 years and older received at least 1 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 1 dose of SHINGRIX (n = 14,660) 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 (25%) subjects were aged 50 to 59 years, 4,488 (15%) subjects were aged 60 to 69 years, and 17,313 (60%) 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%), followed by Asian (18%), Black (1.4%), and other racial/ethnic groups (6%); 58% were female.

Solicited Adverse Reactions: In Studies 1 and 2, data on solicited local and general adverse reactions 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 and general adverse reaction following administration of SHINGRIX (both doses combined) were pain (78%), redness (38%), swelling (26%); and myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%).

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

Table 1. Percentage of Subjects with Solicited Local and General Adverse Reactions 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>Local Adverse Reactions</th>
<th>Aged 50-59 Years</th>
<th>Aged 60-69 Years</th>
<th>Aged ≥70 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHINGRIX</td>
<td>Placebo</td>
<td>SHINGRIX</td>
<td>Placebo</td>
</tr>
<tr>
<td>Pain</td>
<td>88</td>
<td>14</td>
<td>83</td>
</tr>
<tr>
<td>Pain, Grade 3</td>
<td>10</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Redness</td>
<td>39</td>
<td>1</td>
<td>38</td>
</tr>
<tr>
<td>Redness, &gt;100 mm</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>General Adverse Reactions</th>
<th>Aged 50-59 Years</th>
<th>Aged 60-69 Years</th>
<th>Aged ≥70 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHINGRIX</td>
<td>Placebo</td>
<td>SHINGRIX</td>
<td>Placebo</td>
</tr>
<tr>
<td>Myalgia</td>
<td>57</td>
<td>15</td>
<td>49</td>
</tr>
<tr>
<td>Myalgia, Grade 3</td>
<td>9</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Fatigue</td>
<td>57</td>
<td>20</td>
<td>46</td>
</tr>
<tr>
<td>Fatigue, Grade 3</td>
<td>9</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Headache</td>
<td>51</td>
<td>22</td>
<td>40</td>
</tr>
<tr>
<td>Headache, Grade 3</td>
<td>6</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Shivering</td>
<td>36</td>
<td>7</td>
<td>30</td>
</tr>
<tr>
<td>Shivering, Grade 3</td>
<td>7</td>
<td>0.2</td>
<td>5</td>
</tr>
<tr>
<td>Fever</td>
<td>28</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>Fever, Grade 3</td>
<td>0.4</td>
<td>0.2</td>
<td>1</td>
</tr>
<tr>
<td>GI*</td>
<td>24</td>
<td>11</td>
<td>17</td>
</tr>
<tr>
<td>GI, Grade 3*</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

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

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

† 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.

Placebo was a saline solution.

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

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

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 ≥39.0°C/102.2°F.

GI: Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

The incidence of solicited local and general reactions was lower in subjects aged 70 years and older compared with those aged 50 to 69 years.

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

(continued on next page)
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% and 21%, respectively) compared with Dose 1 (24% and 14%, respectively). Grade 3 solicited general adverse reactions (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3%, 4%, and 4%, 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 51% and 32% of subjects who received SHINGRIX (n = 14,645) or 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 (4% 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 or 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%) or placebo (2.2%) from the first administered dose 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-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 from the first administered dose up to 1 year post-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.

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 frequently reported pIMDs 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.

Nervous System Disorders

Guillain-Barré syndrome.

Postmarketing Observational Study of the Risk of Guillain-Barré Syndrome following Vaccination with SHINGRIX

The association between vaccination with SHINGRIX and GBS was evaluated among Medicare beneficiaries aged 65 years or older. Using Medicare claims data, from October 2017 through February 2020, vaccinations with SHINGRIX among beneficiaries were identified through National Drug Codes, and potential cases of hospitalized GBS among recipients of SHINGRIX were identified through International Classification of Diseases codes.

The risk of GBS following vaccination with SHINGRIX was assessed in self-controlled case series analyses using a risk window of 1 to 42 days post-vaccination and a control window of 43 to 183 days post-vaccination. The primary analysis (claims-based, all doses) found an increased risk of GBS during the 42 days following vaccination with SHINGRIX, with an estimated 3 excess cases of GBS per million doses administered to adults aged 65 years or older. In secondary analyses, an increased risk of GBS was observed during the 42 days following the first dose of SHINGRIX, with an estimated 6 excess cases of GBS per million doses administered to adults aged 65 years or older, and no increased risk of GBS was observed following the second dose of SHINGRIX. These analyses of GBS diagnoses in claims data were supported by analyses of GBS cases confirmed by medical record review. While the results of this observational study suggest a causal association of GBS with SHINGRIX, available evidence is insufficient to establish a causal relationship.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1) of full prescribing information].

8.2 Lactation

Risk Summary

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

Adults Aged 60 Years and Older

Of the total number of subjects who received at least 1 dose of SHINGRIX in Studies 1 and 2 (n = 14,645), 2,243 (15%) were aged 60 to 69 years, 6,837 (47%) were aged 70 to 79 years, and 1,921 (13%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information].

The frequencies of solicited local and general adverse reactions 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).

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Do physicians need MBAs?

There’s no question the business of medicine has gotten more complex in recent decades. From small practices to massive hospitals, every aspect of health care delivery has ratcheted up the complexity. There are myriad payment models, reimbursement schemes, payer nuances, the list goes on.

Even a solo physician has to take on more business challenges than once upon a time, when often it was enough to hang up a shingle where there weren’t so many other doctors and start accepting patients. Now that doctor must compete for patients against other physicians, pharmacy-run clinics, urgent care, and more.

It’s a common thing we hear from our audience that these challenges — the type Medical Economics® covers — are the things they “don’t teach in medical school.” No one would accuse physicians of being undertrained. Yet, we must ask the question: Do physicians need more business training?

Our cover story in this, our November issue, drills into this very question: Do doctors need business training to succeed in today’s environment? The answers we heard, not surprisingly, were mixed.

Some said the administrators and lawyers and accountants on the business side of medicine, frankly do not respect the business acumen of physicians. As Maria Chandler, M.D., MBA, told us: “I was shocked at how physicians were regarded, as if we didn’t know anything about the business side. So I decided that if I want to be a leader and fight for physicians I’d better do something about this and get an education.”

Not everyone agrees. David Zetter, a health care business consultant, says physicians with more business training can often bump heads with those administrators. “I’ve got a situation now where the practice administrator is butting heads with a doc [with an MBA] who keeps sticking his nose in.”

This debate reflects where the nonclinical side of health care is right now: complex, with lots of gray areas that are challenging for physicians to navigate.

As always, we value your feedback on our coverage, and welcome your story ideas and other thoughts. Please reach out at medec@mjhifesciences.com.

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Beware the trend of for-profit medicine

Over a century ago, most states passed laws prohibiting the corporate practice of medicine. The goal was to make sure medical decisions would be uninfluenced by the profit motive and left to the physicians caring for their patients. States were also concerned that large industries would operate their own health care services or even own their own hospitals exclusively for their employees, thereby making health care less accessible to the general population.

While still on the books in many states, these laws have been eroded and rendered unenforceable over time. Physicians who incorporated used professional corporation statutes to comply. These statutes required physician ownership but preserved the intent of the law.

The erosion of anti-corporate ownership laws started when many states exempted not-for-profit hospitals from them, leading to large-scale purchase of physician practices by health systems starting in the 1990s. Employee clinics for larger companies also became more prevalent in the 2000s.

If we fast-forward to 2021, we see that most of the goals of the laws prohibiting corporate medical practice have been lost. Medical decision making now is influenced by everyone from insurers and government policymakers to the administrators of corporate entities that employ physicians. This interference takes the shape of prior approval requirements, hospital length of stay requirements, formularies, administrative control of scope and operation of medical practices, and even includes our new value-based contracts requiring physicians to take insurance risks. No wonder physicians have signaled a deep sense of dissatisfaction with the current state of medicine and a growing disenfranchisement.

The last decade has also seen a major and accelerating shift in the basic structure of the U.S. health care system. Whether intentional or not, the opportunity for corporations to extract profits from a high cost and inefficient system is undeniable. Venture capital has entered the health care system at a historic rate. In the first half of 2021 over $21.8 billion has been invested, up from $16.8 billion for all of 2020. Some of this increase can be traced to Covid response and the new opportunities for innovation and increased investments in telemedicine technology. However, there is also increasing venture capital investment directly into the structure and provision of primary care services. This represents a marked shift, and the implications of such a change makes it worth pointing out. How will this affect the future of the US health care system?

To read the full article, go to MedicalEconomics.com
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What physicians need to know about exchange-traded funds

By Dave Gilreath, CFP

Exchange-traded funds (ETFs), investments not widely known a decade ago, are proliferating in a broadening variety, affording investors increased flexibility to shape their portfolios. The rapid growth of ETFs makes more tightly focused strategies accessible to individual investors, especially those bewildered by the often daunting task of picking stocks. Investors who can benefit include physicians managing their accumulated wealth, retirement plans, or a 401(k) rollover executed as they approach or enter retirement.

ETFs first hit the financial services mainstream in the early 1990s. Similar to index mutual funds, they have lower fees but they offer a key advantage — they can be bought and sold during the trading day, so investors aren’t forced to take the price at market close as they are with mutual funds. Despite this edge, ETFs struggled for years to gain traction. Over the past decade, however, they’ve achieved widespread acceptance as an alternative to index funds.

Until a few years ago, ETF was pretty much synonymous with passive management in which managers picked stocks rather than tracked indices. Since 2016, however, active ETFs have taken off. As of July 2021, they accounted for 66% of the more than 188 new ETFs launched thus far in 2021, bringing the total of active products to 639. Reasons for the growth include regulatory changes that make them less expensive for investment companies, and ease of purchase for investors.

Actively managed ETFs have received a boost from the rising profile of ARK Funds, a company with several active ETFs that have posted astronomical five-year returns (though they’ve ebbed over the past year or so). ARK’s success has lent legitimacy to the idea of active ETFs based on a broad concept. ARK’s funds own shares in technology companies contributing to what the company calls transformative disruption.

As more active ETFs have launched, offerings of passively managed ETFs have expanded from basic funds tracking major indices to more sophisticated products. Some of these ETFs track part of an index, whereas others offer exposure to esoteric indices stressing a particular performance metric or characteristic.

For stock investors, a wide range of available ETFs suggests myriad strategies. Here are few examples:

- Buying into narrow subsectors on broad sector dips. For example, Amplify Transformational Data Sharing (BLOK), an actively managed blockchain-oriented ETF, owns shares of various cryptocurrency mining firms and manufacturers of high-powered computer equipment for mining. If the overall tech sector takes a big hit, investors may broadly sell tech shares such as cryptocurrency/blockchain companies. This scenario would likely push down shares of BLOK, allowing investors to buy in low.
- Discovering attractive companies while considering active ETFs based on themes. For example, ARK Autonomous Tech & Robotics ETF (ARKQ), a fund focused on autonomous vehicles, casts a wide net to buy shares of companies making contributions to autonomous vehicle technology. Reviewing this fund’s holdings might alert investors enamored with this theme — including stock pickers — to companies they hadn’t known were relevant to it. The fund includes seemingly
unlikely industrial companies developing applicable technologies such as Lockheed Martin, Deere & Company and Caterpillar.

- Building a fund of funds, custom-weighted to reflect an individual’s view of the market. Suppose an investor wants exposure to the S&P 500 but disagrees with the index’s sector weightings. Instead, the investor could buy a selection of sector ETFs to build a portfolio of sector funds, each weighted as the investor chooses. SPDR offers passive ETFs of S&P 500 stocks for all 11 sectors of the index. If an investor believes energy will rise, they can weight energy ETF (XLE) more heavily than the S&P 500 currently does (2.76%), as of press time. If the investor disagrees with many analysts that rising current interest rates will eventually lead to rising interest rates, benefiting banks and financial firms, then they might want to weight SPDR’s financials/banking ETF (XLF) lighter than does the S&P 500 (11.45%).

- Getting exposure to a particular performance metric or characteristic. For example, investors seeking exposure to value stocks with strong free cash flow might choose Distillate U.S. Fundamental Stability & Value ETF (DSTL). Or value-oriented investors with ESG (environmental, social and governmental) goals might like ClearBridge Focus Value ESG ETF (CFCV). For momentum-oriented investors, ProShares NASDAQ-100 Dorsey Wright Momentum ETF (QQQA) offers this specific exposure. It owns 18 technology stocks from the NASDAQ-100, all with high relative strength, and three from other sectors — pharmaceuticals, communications and foods — that also have strong momentum characteristics. This fund is reconstituted quarterly to maintain its exposure to stocks that have moved upward during the past quarter, a sign that they may continue this ascent for a time.

- Accessing market trends while they’re still hot—especially when many investors may think they’re not. For example, iShares U.S. Home Construction ETF (ITB) is a passively managed fund that provides exposure to the current boom in single-family home construction. The Case-Shiller U.S. Home Price Index posted the highest one-year gain ever, up 19% through the end of June 2021. Many investors might now see this as a top, but that would be to discount various data indicating room for growth: historically low interest rates, a legion of demographically dominant millennials seeking homes and a dearth of new homes built during the COVID-19 pandemic. Also, housing starts are currently way below where they need to be to meet projected long-term demand.

Potential strategies are limited only by the variety of available ETFs, which is expanding daily. — Dave Sheaff Gilreath, a certified financial planner, is a 40-year veteran of the financial services industry. He is a partner and chief investment officer of Sheaff Brock Investment Advisors LLC, a portfolio management company for individual investors, and Innovative Portfolios LLC, an institutional money management firm. Based in Indianapolis, the firms manage approximately $1.4 billion in assets nationwide.

Federal Reserve: No rate hike — yet

By Todd Shroyock
Managing Editor

The Federal Reserve held benchmark interest rates near zero for now, but indicated a rate hike will be coming. The central bank also cut its economic outlook for the year. Both moves were expected by economists.

COVID-19 continues to be a major factor, with the bank stating the path of the economy continues to depend on the course of the virus. “Progress on vaccinations will likely continue to reduce the effects of the public health crisis on the economy, but risks to the economic outlook remain,” said a statement from the Federal Reserve.

The Federal Open Market Committee said it will start pulling back some of the stimulus it has been providing, but there was no indication when that will happen. Many economists predict a tapering of bond purchases to start in December.

Though even the committee voted unanimously to keep short-term rates where they are, more members now see a rate hike happening in 2022. In June, a majority indicated they thought it would be 2023.

The Fed also made changes to some of its economic forecasts, with a decrease in the growth outlook and higher inflation expectations. GDP growth has been cut to 5.9% compared to the 7% forecast in June, but 2023 growth is set at 3.8% compared to 3.3% previously.

Core inflation is projected to increase 3.7% this year, compared to the 3% June forecast, and see inflation at 2.3% for 2022 instead of the original projection of 2.2%. The bank’s preferred inflation measure – the personal consumption expenditures index less food and energy prices – increased 3.6% in July, the highest level in 30 years.

“Progress on vaccinations will likely continue to reduce the effects of the public health crisis on the economy, but risks to the economic outlook remain.”

However, Federal Reserve Chairman Jerome Powell has said he expects price pressures to subside as supply chain factors, goods shortages, and unusually high levels of demand return to pre-pandemic levels.

According to economists, markets didn’t expect much in the way of major decisions, but were worried about when the Fed would start reducing the pace of its monthly bond purchases.
Health care workers survey: Here’s the COVID-19 vaccine messaging that works

by Sydney Jennings Associate Editor

In a new survey, U.S. health care workers (HCWs) said messages that explain COVID-19 vaccine safety and efficacy were the most helpful in getting more patients vaccinated against the novel virus. “The rapid speed of COVID-19 vaccine development, utilization of novel technology, and an atmosphere of politicized misinformation have created a perfect storm for vaccine hesitancy. As early adopters of vaccination, HCWs set an example for the general population...However, comparatively little work has investigated HCWs’ attitudes toward vaccination and how these attitudes drive their recommendation behavior,” wrote study authors led by Steven Schaeffer Spires, MD, assistant professor of medicine, Duke University School of Medicine, Durham, North Carolina.

To better understand HCWs beliefs about COVID-19 vaccines and what types of messages would improve their confidence in the vaccination and in recommending vaccination to patients, Spires and colleagues randomly assigned 674 North Carolina hospital employees (84% women, 85% White) to see one of three different messages related to the vaccine and vaccination or no message (control) in Feb. 2021.

Message themes included an appeal to return to normal life (normalcy), an explanation of vaccine safety and efficacy even given the rapid development process (process safety) and signal detection theory (SDT) which compares the risk of getting vaccinated or not (risk assessment).

Out of the total cohort, 98% of HCWs had been offered the COVID-19 vaccine and 80% had already accepted the vaccine. For the 20% who had not received the COVID-19 vaccine, the top reasons cited included the speed of development and testing, as well as concerns regarding vaccine safety and effectiveness, according to the study abstract.

Survey results showed HCWs were generally very comfortable recommending the COVID-19 vaccine to patients and supported the idea of sharing the specific message they read. The process message was rated as the one HCWs felt would be the most helpful to patients and the one they would be most likely to share with them, while the SDT/risk assessment message was the one most trusted personally among HCWs. “This suggests that what is most appealing on a personal level is not necessarily what a HCW would recommend to their patients,” explained researchers.

Rating the message as trustworthy or believable was positively correlated with sharing among the HCWS (Pearson coefficient r=0.6), according to the abstract. “HCWs’ high uptake and minimal hesitancy in recommending the COVID-19 vaccine is encouraging and merits further exploration for how to increase confidence in HCW who are hesitant to discuss and recommend vaccines to patients, as several highlighted the importance of respecting patient autonomy,” concluded researchers.

Patients with HIV used fewer essential clinical services during COVID-19 pandemic

by Grace Halsey Senior Editor

Important declines in the rates of viral-load monitoring and in-person follow-up visits among virally suppressed people living with HIV (PLWH) were identified in a study that compared use of clinical services by this population before and during the COVID-19 pandemic.

As has been documented for other chronic conditions, researchers also found that the increase in use of telehealth for follow-up visits did not offset the decrease in in-person clinic visits.

Investigators led Gerald Pierone, M.D., from Whole Family Health Center, Vero Beach, Florida, accessed data from participants in the ongoing OPERA study who were 18 years of age or younger, on antiretroviral therapy (ART) and active in care in the OPERA cohort within 2 years prior to October 30, 2020.

The researchers included OPERA participants who were virally suppressed (viral load <200 copies/mL) and had switched treatment from any ART regimen to dolutegravir/lamivudine (DTG/3TC), or to a DTG- or bictegravir-based 3-drug regimen between May 1, 2019 and April 30, 2020.

They identified 4806 eligible PLWH in the pre-COVID-19 study period (May 1, 2019, to Feb. 28, 2020) and 4992 PLWH in the COVID-19 period (March 1, 2020 to October 31, 2020).

Pierone et al estimated and compared incidence rates for clinical visits (HIV-related or otherwise), viral load measurements, and regimen discontinuation (change in any component of the ART regimen) for participants during the pre-COVID-19 period and during COVID-19. In-person visits were any scheduled or walk-in outpatient, emergency or laboratory visit. Telehealth visits comprised any telephone or video encounters.

In-person visits

Investigators found that rates of in-person visits were reduced nearly 2-fold during COVID-19 and that telehealth visits increased almost 9-fold. The resulting overall reduction in any visit rates fell from 10.07 visits per person-year (95% confidence interval [CI], 9.93-10.21) pre-COVID-19 to 7.10 (95% CI, 7.01-7.19) during COVID-19.
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Thanks to 4 decades of advances in HIV research, we are more empowered to help stop the virus. In recent years, national initiatives have shifted their target from fighting the epidemic to ending it. Today’s comprehensive HIV therapies let us focus on working towards goals we never thought possible in the early days of the HIV epidemic, such as UNAIDS 90-90-90* and Ending the Epidemic: A Plan for America.1,2

Modern antiretroviral therapies (ART) help empower patients and their healthcare providers to choose the appropriate treatment for them. When selecting a treatment option, it is important to consider an individual patient’s history as well as a regimen that:

- Empowers healthcare professionals to initiate treatment ASAP
- Achieves and maintains viral suppression
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*UNAIDS goal to ensure that by 2020, 90% of all people living with HIV will know their HIV status, 90% of all people diagnosed with HIV will receive sustained ART, and 90% of all people receiving ART will have viral suppression.1


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IS AN MBA RIGHT FOR YOU?

As medicine grows increasingly corporate, doctors are finding that career advancement requires understanding the business side of the profession

by Jeffrey Bendix, senior editor

Although it’s been 30 years, pediatrician Maria Chandler, M.D., MBA, can still recall when she realized she needed to learn about the business of medicine. Soon after landing her first job, with TCC Family Health in Long Beach, California, she told the clinic’s CEO she wanted to gain some administrative experience. The CEO responded by asking Chandler to attend some committee meetings of the hospital with which the clinic was affiliated.

“I was shocked at how physicians were regarded, as if we didn’t know anything about the business side,” she recalls. “So I decided that if I want to be a leader and fight for physicians I’d better do something about this and get an education. I’m going to come to the table with the same credentials [hospital administrators] have and then they’ll have to listen to me.”

Chandler enrolled in an MBA program at Pepperdine University’s satellite campus in nearby Irvine, taking classes two nights a week while continuing to work full time. Four years later, she emerged with a degree — and a better grasp of the challenges the hospital faced.

“I realized those administrators knew what they were talking about,” she says. “At the same time, I found I was being treated with more respect at the business meetings and I have been ever since. I couldn’t be happier I got that degree.”

Moving beyond the business basics

Doctors have always known that practicing medicine includes a business component; they can’t treat patients unless they earn money. But when most physicians practiced independently or in small groups it was enough to know the basics of practice finance and hire a practice manager and/or accountant to look after the rest.

As medicine grows increasingly corporatized, however, more doctors are finding that being able to read a balance sheet or profit-and-loss statement...
is no longer enough. Whether they work for a hospital system or own an independent practice, they are realizing they need to understand the language, concepts and skills taught in MBA programs to be able to advocate for their patients, advance their careers — or just remain in business.

“You can’t do health care without the business piece, just like the business piece can’t exist without the clinical,” says Timothy Switaj, M.D., MBA, a U.S. Army colonel who oversees health care delivery for Army and Air Force personnel in the San Antonio region.

While the number of doctors with MBA degrees is unknown, several signs point to a gradual, though uneven, increase in interest among physicians in obtaining both degrees. For example, there were fewer than 30 joint M.D./MBA programs operating in 2000, according to a study in the American Journal of Managed Care®. That compares to 60 such programs now listed on the Association of M.D./MBA Programs website. In addition, 14 schools offer joint DO/MBA programs.

The Association of American Medical Colleges reports that the number of graduates from combined M.D./MBA programs rose from 61 in 2003 to 148 in 2016, a 142% increase. But after peaking at 974 in the 2017-18 academic year, enrollment in these programs dropped to 644 in 2020-21.

The paths to an MBA
Physicians generally take one of three paths to an MBA degree. The first is by enrolling in a full-time MBA program while also practicing full-time, as Chandler did. A second path is to obtain an MBA at the same time as a medical degree through a program operated jointly by a medical and business school, where students alternate between the two.

Joint-degree students at the University of Southern California (USC), for example, begin by taking two or three years of classes in the Keck School of Medicine followed by a full year of classes at USC’s Marshall Business School. The rest of their time at the university is spent completing their credit requirements for both degrees.

Independent medical schools, or those that are part of a university without a business school, sometimes will offer joint degree programs with a nearby one. Students at the Philadelphia College of Osteopathic Medicine (PCOM), for example, can take MBA classes at Saint Joseph’s University’s Haub School of Business.

The third approach to earning an MBA is through an executive program. Unlike a full-time program, executive MBA programs are geared more toward working professionals, with most classes held on weekends. That’s what appealed to internist Darren Sommer, DO, MBA, when, after five years as a hospitalist at a regional medical center in North Carolina, he enrolled in the executive MBA program at Duke University’s Fuqua School of Business. Students attended weekend-long classes at Fuqua every other weekend for two years and did coursework on their own in between.

“It was a great experience because I was directing the hospitalist program and I could come back and implement some of the things I learned in my classes right away,” he recalls. “The other good part was that I was interacting with people from all over the country who had similar backgrounds and challenges to what I was facing so we were able to learn from each other.”

Like many other professionals who return to school, Sommer found it challenging to balance the demands of coursework with job and personal life — in his case, a medical practice and a family that included three small children. “It’s kind of funny, because when you’re doing it it’s like, I never knew I could cram this much stuff into my life, but you find a way to make it work,” he says.

The pros and cons of a dual M.D./MBA degree
Each approach to obtaining a management degree at the same time as earning an M.D. or D.O., or while already in practice, has benefits and
CAREERS / PHYSICIAN MBAs

The case against doctors getting MBAs

While many doctors with MBAs say they have benefited from getting the degree, not everyone thinks it's a good idea. David Zetter, CHBC, CPC, principal of the practice consulting firm Zetter HealthCare, goes so far as to call it “a waste of money.”

“An MBA will teach you about management, but it doesn't teach you how a medical practice is run,” he says. “There are too many things that happen in a medical practice that have nothing to do with courses taught in an MBA program.”

He cites revenue cycle management as an example. “It’s the most important aspect of a medical practice but they don't teach anything about billing, collections, follow-ups, what are the best policies and procedures. None of that is ever discussed in MBA programs.”

Getting an MBA also creates the potential for conflict with practice administrators. “I’ve got a situation now where the practice administrator is butting heads with a doc [with an MBA] who keeps sticking his nose in,” he says. “It’s gotten to the point where one of his partners said, ‘Why don’t you quit being a doctor and become our administrator if you think you can do it better?’”

Zetter acknowledges his biases stemming from his own work as a practice consultant and his position as president of the National Society of Certified Healthcare Business Consultants. “I’m not saying all MBA programs are bad, but you have to do due diligence,” he says. “Ask yourself, why am I taking this program? What do I expect to do with an MBA degree? And ask other doctors with MBAs what specific aspects of their practice do they better understand because they got that degree?”

He adds that doctors, even those with an MBA, should not try to run the business side of their practice. “You’ve gone through 13-plus years of school to become a clinician and generate revenue. If you’re going to spend time also being an administrator, you cut down on the time you can generate revenue,” he says. “So do you want to see patients and generate revenue or do you want to be an administrator? Because you can’t do both.”

“A doctor should be seeing patients. They’re the ones generating revenue,” Zetter says. “So if you’re also managing the business, how are you going to have time to see patients?”

Italo Subbarao, DO, MBA, dean of the College of Osteopathic Medicine at William Carey University, says earning the degrees simultaneously (through the PCOM/Saint Joseph's joint program) enabled him to understand systemic trends in health care better than many of his colleagues when he began practicing.

“It was a time when things like managed care and hospital consolidation were coming into play, and because of my MBA I could see what was coming next and started thinking about things like value-based care and quality outcomes,” he says. “The MBA allowed me to see these things a little sooner than the people around me.”

Studying for an MBA can also better prepare medical students for residency, Subbarao says. “You look at residencies a little differently because you have a better understanding of the system you’re about to enter,” he explains. “You might find a program you’re better aligned with because of what you learned through your MBA program.”

On the other hand, getting an MBA after being in practice a few years can yield more immediate benefits, say those who've chosen that route. “I think physicians who do executive MBA programs have a much richer experience because they’re able to implement some of the concepts they learn right away,” Sommer says.

Todd Shaffer, M.D., MBA, a family practitioner at the Truman Medical Center in Kansas City, decided to get a business degree in 2004 after being named residency director for the University of Missouri-Kansas City School of Medicine, which is part of the Truman Center.

Shaffer enrolled in a program at Rockhurst University that included practicing physicians

drawbacks. One advantage of joint programs is that students usually can complete the MBA component in less than the two years required in most stand-alone MBA programs. At USC, for example, students take only 48 credits rather than the normal 63, says Evan Bouffides, assistant dean and director for MBA admissions at the Marshall School.

“In a sense, any dual-degree student cuts short the amount of time and cost by one full year compared to students who pursue the two degrees independently of each other,” he says.
and residents as well as medical students who were pursuing a joint degree. He noticed a difference between the two groups, especially in the projects students developed and worked on as part of their coursework.

“We [doctors and residents] were using our projects in our clinical settings as we were doing the course,” he recalls, “whereas the medical school students didn’t have the experience to use what they were learning, and if you don’t get to use something right when you learn it you tend not to remember it, versus if you learn something today and use it tomorrow, it’s probably going to stick with you.”

Shaffer found the program’s focus on developing leadership skills particularly useful. “We spent a lot of time figuring out what kind of leader we were. That was very useful because it helped me figure out what I’m good at and not so good at, then how to get better at some of those things,” he says.

**Reasons for getting an MBA**

While physicians and program administrators cite a variety of reasons why doctors obtain MBAs, they generally fall into three broad, often overlapping categories: to improve their management skills, to advance in an organization and to gain a better understanding of health care policy. The latter was Sommer’s motivation for seeking the degree.

“It was during the debate over the Affordable Care Act, and I had some pretty strong opinions about it,” he recalls. “But when I’d go to Washington to talk to congressmen, I quickly realized that having a medical degree wasn’t enough to participate in the debate. I needed a better business and policy understanding of health care to make my arguments more effective.”

Switaj credits the MBA and MHA degrees he earned through the Army-Baylor Graduate Program in Health and Business Administration with advancing him from chief medical officer at an Army community hospital to his current position as director of clinical operations and chief medical officer (CMO) for the Army’s San Antonio region.

“I always knew I wanted to get into a physician leadership role where I could explain the business piece to the clinicians and the clinical piece to the administrative staff,” he explains. “I was able to do that at lower levels, but when I got to the CMO level I realized I had a knowledge gap I would need to fill if I wanted to move up.”

Switaj says the skills he learned in the Army-Baylor program enabled him to better align the Army’s primary care resources in the San Antonio region with the places they were most needed. He also became proficient at using the spreadsheet program Excel to present data.

“When I have to answer questions from my superiors or explain things to my staff, the ability to organize and interpret data and create charts and tables so they could better understand the data has been a masterful tool.

“I don’t think at any level you can completely separate yourself [as a physician] from the business side,” he adds. “Having the MBA provides that ability to speak the same language and help you better understand why some decisions are made, even some you may not agree with.”

A third reason doctors obtain MBAs is to better understand the management side of their own practice. That was the goal of Nathan Granger, M.D., MBA, when he enrolled in Rockhurst’s part-time MBA program in 2005. A decade earlier, Granger had co-founded Clay Platte Family Medicine Clinic in Kansas City and realized he needed more than on-the-job training to keep up with the rapidly growing practice’s needs.

Having an MBA, he says, helped Clay Platte in a variety of ways. The human resources and organizational behavior knowledge he acquired enabled the practice to identify and hire an administrator that matched its needs, ending the churn it had experienced at that position. “Normally for a small practice to hire a high-quality administrator is very difficult,” he says.

With the financial understanding he gained, Granger was able to prepare and present monthly updates on Clay Platte’s finances, a practice he continues to this day. He now also chairs the finance committee of the clinically integrated network to which Clay Platte belongs.

But the most important takeaway from his MBA experience, Granger believes, was to broaden his perspective on what it means to be a doctor. “I came to see that physicians don’t just have a responsibility to an individual patient,” he says. “We also have obligations to the health of our communities. That’s a basic tenet of being a physician.”

Granger’s MBA helped him meet those obligations by learning to work within and lead the network of doctors, practices, hospitals, payers and other organizations behind the treatment of an individual patient. “Being able to work with all the different players in the health care system requires leadership,” he says. “And what better person to provide that than a doctor with an MBA?”

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Physicians spend most of their lives training to be the best doctors they can be. What they don’t spend a lot of time doing is understanding what they are worth.

Because of increased consolidation and a variety of other factors in health care, this problem has only worsened in the last decade. Many physicians in private practice have found themselves sitting across the table from an executive at a large hospital or health system that is looking to acquire their practice.

In a perfect world, there would be blinking red lights warning the physician to proceed with caution. The fact is, it doesn’t matter whether a physician is in their first, fifth, or 20th year of practice; in general they lack the training around salary and contract negotiations to match wits with savvy hospital executives.

The result? Physicians often wind up underpaid, relative to their colleagues, or otherwise shortchanged in their contracts.

This outcome doesn’t necessarily stem from any malicious intent on the part of the hospital. It’s more a reflection of the way the incentives are set up in American hospital-side health care. When hospital executives consider recruiting or acquiring a physician or physician group, they focus on return on investment: How much is this hire going to cost and how much revenue is that doctor going to bring in as a result?

Put another way, the hospital wants to acquire a physician at the lowest cost while generating the highest revenue and maintaining the highest clinical quality possible.

Understand your market value
This milieu can be treacherous for any physician who doesn’t have a strong understanding of their market value. A physician who’s spent four years in residency training making $55,000 a year and is suddenly offered a salary of $250,000 a year might not think to question it too much or to see if there are better offers out there. After all, they just increased their salary...
nearly fivefold – surely there’s no downside in that turn of events.

The truth, however, is that they are probably aiming too low without even knowing it. This is particularly true for Black and female physicians. They might ask other African American or female doctors in their peer network what their salary is to get a sense of the ballpark, without realizing that there’s already a 20% to 30% pay disparity for these populations.

Hyperbole? Unfortunately, not. For instance, female physicians earn about 75 cents for every dollar made by a similarly skilled male counterpart, on average. When you’re talking about physician salaries, that difference can translate to nearly $100,000.

Determine what’s important
While salary and compensation, including various bonuses and production incentives, are an important factor, they are far from the only components that matter. Another way doctors lose out in these contract negotiations is by not viewing the contract from a holistic perspective. I call it the 3 B’s: base, bonus and bennies.

BASE: the salary you get for showing up and doing your job.

BONUS: compensation you can earn by completing an action or achieving a goal (e.g., signing bonus or volume bonuses, etc.).

BENNIES: also known as benefits. These items have value but cannot be deposited into a bank account (e.g., paid time off, health insurance, etc.).

Also consider whether the ability to focus on research is important to you, or curing cancer or advancing medical education. How much vacation is optimal?

Likewise, what kind of practice support or professional development is offered? If you’re a physician who aspires to be CEO of a hospital, is the infrastructure in place to support that career path and enable progress toward that goal? A physician who is shortchanged on this aspect of their contract might be curtailing their long-term career plans.

The good news is physicians aren’t destined to lose out every time they head into salary and contract discussions. There are several things they can do to level the playing field.

Improve your position
First and foremost, they should pull the data on salaries for physicians in their geographic area with the same specialty. You can either hire a specialist with industry experience to pull the data for you and make sense of the numbers, or if you’re on a tight budget, like many residents and maybe some practicing physicians might be, you can just Google it. There are a number of resources — Doximity, Merritt Hawkins and AMGA, among others — that publish data from physician compensation surveys on an annual basis.

Second, always make sure you get more than one offer.

Don’t target just one hospital or health care system that seems like it might be a match; target five to 10 of them. Even if only three of those 10 make offers that are in line with what you’re looking for, that provides the necessary leverage to ask your first choice, “Can you meet what hospital X and hospital Y are offering me?”

Finally, always counter the first offer you receive. Of course, that’s hard to do if you have only one offer, but if you have multiple offers, you can say, “I was hoping my salary would be a bit more in line with the proposal I received from hospital X.”

The fact is hospital revenues and profit margins are growing. Physician salaries should be growing as well, not remaining flat. By taking an informed and proactive approach in contract and salary negotiations, physicians can ensure they’re getting a fair slice of the pie and not losing out on what they deserve.

Ethan Nkana is principal of RMPA (Rocky Mountain Physician Agency), which specializes in negotiating physician contracts.

“Always counter the first offer you receive.”
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• Depending on the vaccine, 79% to 85% of adult patients indicated they were likely to get vaccinated if recommended by their healthcare provider.⁵

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5 ways inflation impacts consumers and the economy

by Jeff Witz, CFP

Inflation is the concept that the cost of goods and services increases over time. What $10 can purchase today is more than $10 will be able to purchase 10 or 20 years from now. As the price of goods and services increases over time, the purchasing power of that $10 diminishes. Many interpret inflation as having a negative impact on their lives. However, inflation can actually be a healthy component in an economy’s growth.

Inflation is the increase in price of a broad basket of goods and services. For example, if the price of bananas increases, that is not considered inflation. The rest of the economy would continue mostly unaffected. Inflation refers to the increase in prices across a broad range of goods and services that impacts many areas of the economy. In the United States, the standard used to measure inflation is the Consumer Price Index (CPI). The CPI measures the weighted average of a basket of consumer goods and services. This basket of goods is intended to mimic the common products and services such as food, energy, clothing, housing, medical care, and so on. The weighted average of these goods and services produces a percentage, which is reported as the rate of inflation. Most economists agree that inflation in the 5% to 6% range and below is healthy for an economy, and inflation above the 9% to 10% range is harmful.

Investors Target Stocks
Purchasing stock in companies that benefit from receiving more money because of rising prices is one way to offset the impact of inflation. A company’s stock price will likely increase as it earns more for the products it makes. The value of an investor’s money will increase along with the stock price, which will offset some of the impact of inflation.

Many consumers feel the immediate impact of inflation and interpret it as a negative. Spending more on an item you are used to buying never feels great. However, modest inflation does serve an important role in the overall economy. Provided inflation stays within healthy ranges, it is something to take advantage of rather than fear.

Increased Spending
Because of fear that the value of their dollar will diminish, consumers and businesses attempt to spend their money before it does. If your cash is only going to lose value over time because of inflation, it is better to spend that money now on items that possibly won’t lose value. Increased spending by consumers and businesses positively impacts the economy.

Interest Rates Rise
Increased spending means more money enters the money supply, which can drive inflation even higher. To curb runaway inflation, the Fed will increase interest rates. Higher interest rates make borrowing money more expensive, resulting in higher payment amounts and less borrowing. This slows the rate of inflation.

Existing Fixed Rate Borrowers Benefit
Borrowers who already took out debt can benefit from inflation. The value of their monthly mortgage payments will decrease over time. For example, a fixed payment of $2,400 per month on a 30-year mortgage will decrease in value over the lifetime of that loan. Assuming their income is growing along with inflation, it will feel like they are paying less over time. Borrowers who are in variable debt products, however, will likely see their payments increase over time so that the value of those payments keeps up with inflation.

Reduced Purchasing Power
As we have already discussed, the purchasing power of a dollar is reduced when inflation raises prices. To purchase the same items, consumers will have to spend more money than they did before. Those impacted the most by inflation are the ones holding cash or who are on a fixed income that is not inflation-adjusted annually. Over time, their purchasing power can be significantly impacted.

Jeff Witz, CFP, welcomes readers’ questions. He can be reached at 800-883-8555 or at witz@mediqus.com.

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The first-ever *Medical Economics*® Physician Bootcamp virtual event was held Oct. 7-8. This unique event, with nine informative sessions, provided real solutions that physicians can apply in their practice right away. This special section provides highlights from the first day of sessions. Stay tuned for recaps of day two in the December issue. To view the videos of each of the sessions, use the camera app on your smartphone to scan the QR codes in this section (free registration required to access content).
Delivering the new digital patient experience

**Introduction:**
Today’s patient is a true consumer of health care who expects convenience and efficiency. COVID-19 rapidly accelerated the expectations of patients, thanks to the proliferation of telehealth and the implementation of online tools. Now that patients have seen how technology can change their health care experience for the better, practices must adapt by using the latest tools or risk losing their patients to competitors. A patient survey showed 66% prefer a telehealth appointment over a traditional in-office visit. These same patients do not want to waste time in waiting rooms filling out paper forms; they want the convenience of online notifications about scheduling and the availability of online forms to make their visit quick and easy. By looking at successful practices, it’s possible to determine a winning strategy that works with the modern consumer of health care.

**Learning objectives:**
- How to engage patients digitally: secure texting, seamless payments and more.
- How practices should market themselves.
- How to compete with care models such as convenient care clinics.

**Meet the panelists:**
Norm Schrager  
Head of Content Strategy, PatientPop
Luke Kervin  
Entrepreneur, Co-founder and Co-CEO, PatientPop

**Engaging patients digitally is a practice’s best pathway to success**
Patients are frustrated with the lack of consistency in how they connect with their physicians outside the exam room and don’t understand the best way to communicate with them. This can lead to breakdowns in care or to the patient seeking out a different doctor. The most successful practices find a way to engage with the patient at every opportunity, making it easier for them to do everything from scheduling an appointment to asking a question about their treatment.

“Health care is one of the last major industries to be transformed by technology,” says Luke Kervin, co-founder and co-CEO of PatientPop. While electronic health records are well known to practices, they are relatively invisible to patients and provide none of the consumer-oriented conveniences patients want from their doctors.

To patients and provide none of the consumer-oriented conveniences patients want from their doctors.

Today’s patients want to schedule their own appointments online and have an open line of communication with the doctor’s office via text message or email. Practices that fail to provide these conveniences risk being left behind in health care’s competitive landscape.

“The patient experience has changed for good,” says Norm Schrager, head of content strategy, PatientPop. The pandemic and the resulting shutdowns forced practices to adopt new technology like telehealth at a rapid rate, and now that patients have seen something like telehealth improved their overall health care experience, there’s no going back. “By the end of 2020, two-thirds of patients said they would prefer a telehealth visit in the future. The positive patient experience rating was going up for telehealth the more people said they had virtual visits. I think this is a clear sign of the comfort that people have with any online or digital environment.”

Schrager says patients prefer self-service and practices need it for tasks like scheduling appointments. A bonus to practices is that patients who self-schedule
When patients search for you online, what do they see?

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- **Web presence**
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- **Website**
  Your website must load quickly, be secure, and be **optimized for mobile**.

- **Reputation**
  74 percent of patients find **online reviews** very or extremely important.

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Where does your practice rank?

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are less likely to no-show, be late, or cancel and are also more likely to be engaged with their own health and their physician.

Preregistration intake forms need to be provided digitally and in advance. Automated appointment reminders need to be sent via text message or email, whatever the patient’s preference is. Practices need to set up an ongoing loop of activity and communication with each patient that starts the moment they land on your website and continues through every aspect of their care. Two-thirds of patients prefer text reminders, with another 15% opting for email. “This is an open book for patient retention, for follow-up visits. They are actually telling you, ‘Please send me a note when it’s time for me to book my next appointment,’ and they’re telling you how to send it to them,” says Kervin.

The technology benefits aren’t limited to existing patients. By adding online scheduling to its website, a practice can capture more business. According to PatientPop, when a patient lands on a website that offers online scheduling, 51% book online versus calling the practice, 66% of these appointments are with new patients and 36% of the time they are scheduled after hours when the practice is closed.

“If you use online scheduling, last-minute cancellations create open slots that become available immediately for other patients to schedule at the last minute,” says Kervin. As a result, no-show rates in the 15% range can drop to 4% to 5%.

Kervin adds that online scheduling has become a major differentiator among practices because 63% of patients are more likely to choose a provider who offers it over one who does not.

When you add a well-designed website that highlights a practice’s strengths and manage your online reputation by asking for feedback, you can not only get more digital exposure but also convert that traffic into a scheduled appointment.

“Just be consistent,” says Schrager. “Provide the patient a good, consistent experience that you know that they will respond to.”

66% percentage of people who use online appointment scheduling who are new patients for that practice

Solutions and takeaways:
- Optimize your website by focusing on services and relevant search terms.
- Take advantage of online profiles by impressing patients via Google, Yelp and WebMD.
- Offer multiple digital access points by capitalizing on texting and online functionality.
- Ask patients for feedback and monitor patient responses and online reviews.
- Send out text reminders and email campaigns that meet patient expectations and build long-term connections.

“This is an open book for patient retention.”
Luke Kervin, co-founder and co-CEO of PatientPop

MORE ONLINE:
Check out the full video and materials of this session and eight other Bootcamp sessions.
Calling for reinforcements: 
Staffing and workforce management

Introduction:
Physicians in office practice know that a professional, motivated staff is key to a practice’s success. But finding, training and retaining employees can be a significant challenge for practices. For example, in 2018 the median annual turnover rate for front office staff in primary care practices was 20%, according to a Medical Group Management Association survey.

The stress brought on by the COVID-19 pandemic has only worsened the problem, as evidenced by health care workers at all levels reporting increasing rates of burnout and depression. According to the Bureau of Labor Statistics, the quit rate among health care and social assistance employees increased from 2.1% to 2.7% between August 2020 and August 2021, while overall a record-breaking 4.3 million Americans quit their jobs in August of this year.

Fortunately, there are strategies medical practices can use to create workplace cultures that minimize staff burnout and turnover, and where employees feel empowered — and encouraged — to do their best work. But creating such an environment requires planning and the willingness to take a fresh look at all aspects of practice operations.

Learning objectives:
- Best practices in staffing, with lessons learned from COVID-19.
- Tips to improve staff retention and scheduling.
- How to enhance office efficiency, reduce patient wait times and create a better experience for all.

Meet the panelist:
Owen Dahl, LFACHE, CHBC, LSSMBB principal of Owen Dahl Consulting The Woodlands, Texas

How to hire — and keep — the right employees for your practice
Finding and retaining good employees is difficult for many independent medical practices even in the best of times, and doing so during the COVID-19 pandemic has made these tasks even harder. But according to longtime practice consultant Owen Dahl, LFACHE, CHBC, with good planning and the right strategies in place, practices of any size can overcome their staffing challenges.

Building a good staff starts with a hiring process that brings in the right people. Once candidates have been screened for their technical skills, it’s important to determine if they are a good fit for the practice’s culture. To that end, Dahl advises asking candidates plenty of open-ended questions that allow candidates to talk about themselves. He also suggests including current employees in the interviewing process.

“One of the most important things is chemistry you establish with your applicants and finding out how well they relate to your staff,” he says. “It’s much easier to train and change a skill set than it is to change a personality.”

After hiring, the next step is an effective onboarding process. This should include someone in practice leadership introducing the new employee to their colleagues, explaining the organization’s policies and procedures, reviewing benefits, familiarizing them with the technology they’ll be using, and assigning them a mentor. “You want to make that person feel like they’re part of the organization right from the start,” Dahl explains.

In terms of payroll, Dahl emphasizes the importance of looking beyond individual
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salaries and focusing instead on the employee's value to the practice. He cites the example of a medical assistant. “You may see that person just as an expense, but he could be handling your EHR, your patient communications and other things that save you enough time that you can see one more patient per day. Seeing an extra patient per day for a 99213 visit at Medicare rates generates roughly $20,000 per year, not including labs, imaging and ancillaries.

“I always like to think of an employee as a revenue generator rather than as an expense,” he adds. But hiring good people is of limited value if they lack motivation or don’t stay for long. Employee turnover is a major challenge throughout the economy, Dahl says, citing surveys in which nearly half of employed people say they are seeking other jobs or new careers.

So what can a practice do to build loyalty and make employees want to stay? Money isn’t always the answer, Dahl says, although salaries should be high enough that it isn’t a source of stress. Equally important are things like flexible scheduling and allowing emergency leave to care for child care or sick relatives — a particularly important benefit during a pandemic.

When developing benefit packages, it’s also important to focus on the differing needs of employees. “Think about the age mix of your staff, for example. For younger people, what kind of benefit package is going to enhance their retention versus someone who may have been with the practice for 20 years?”

Even when employees leave, Dahl says, a well-functioning organization should conduct exit interviews and try to learn from them. For example, multiple people leaving because of having to work too much overtime may indicate that something is amiss with employee staffing. “We have to ask, do we have the right number of employees with the right skill sets needed to move forward?” he says.

With the impact of COVID-19 still being felt, Dahl says, burnout remains a significant problem, citing Gallup polling data in which 67% of employees report feeling burned out “often” or “sometimes.”

Given those circumstances, practice owners and managers need to watch for signs of it among employees — and themselves — Dahl warns. Symptoms include declining productivity, changes in sleep habits, increased drug or alcohol use and lack of engagement with colleagues and/or patients.

“I always like to think of an employee as a revenue generator rather than as an expense.”

“The engagement aspect is really critical when we think about mental health,” Dahl says. “What kind of messages are we sending to patients and fellow employees relative to how engaged we are about being in the office?”

A good technique both for spotting burnout and improving engagement, according to Dahl, is what he calls “MBWA”: management by walking around. “It’s important to talk to your staff and listen not just to their words but the tone of voice and body language,” he says. “You can only do that by walking around.”

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**Solutions and takeaways:**

- Review hiring and interviewing procedures to ensure you’re getting candidates who are a good fit for the organization.
- Develop an onboarding process to make new employees feel welcome and smooth their entry into their position.
- Conduct exit interviews with departing employees and use information they provide to identify and address organizational problems.
- Tailor benefits to employee needs.
- Use “management by walking around” to engage with staff members and learn about their needs and concerns.

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**More online:** Check out the full video and materials of this session and eight other Bootcamp sessions.
Telehealth basic training

Introduction:
The COVID-19 pandemic has seen a sea change in the way that physicians treat their patients and nowhere is this more evident that in the near-overnight implementation of telehealth across the health care industry.

As case counts began to rise in early 2020, public health authorities across the country implemented stay-at-home orders and moratoriums on nonemergency medical services in an effort to keep health care professionals from being overwhelmed by patients with COVID-19. With no other option, many health care entities were forced to step into the telehealth space with little experience and even less training.

The use of telehealth was barely a factor among physicians in 2015, with only 5% of physicians having used video visits to see patients. That trend was on the rise by 2019, with 22%, but the pandemic accelerated it, with 80% of physicians saying they had used video visits to see their patients in 2020.

This is expected to continue even after the pandemic ends, with 92% of physicians still expecting to use video visits when it is safe to meet with patients, according to telehealth provider Amwell.

Learning Objectives

- Proper understanding of the current telehealth rules and regulations.
- Getting paid for telehealth: solutions to common mistakes.
- Tips for improving your telehealth program to boost patient satisfaction, efficiency and more.

Meet the presenter
Mia Finkelston, M.D., Senior Medical Director
Amwell Medical Group

How to be a virtual physician

While telehealth isn’t a perfect fit for every patient or service, Finkelston says some patients will ask for it because of challenges of meeting in person or just for convenience. Telehealth can be ideal for services like follow-up meetings with patients after a change in medication, wellness screenings or when going over ongoing care plans.

“When you think about medical care, so much can be done through a thoughtful conversation, a thorough history taking, an observation as to what’s going on in the background,” she says.

Before the visit begins, the physician should make sure their device is fully charged, turn off notifications, close conflicting software such as FaceTime or email, ensure the equipment is ready, test their internet speed and limit other activity on the Wi-Fi, which can consume bandwidth.

The physician should look professional, wearing a white coat and dress shirt. The camera should also be kept at the physician’s eye level, about 2 or 3 feet away. Their face should be well lit from the front and backlighting, which can make the physician appear in silhouette, should be avoided.

The biggest challenge in getting patients to embrace telehealth is technology or the lack thereof. Patients fear it won’t work or they won’t be able to see or hear their physician properly. Finkelston recommends that physicians learn some simple troubleshooting for when it appears the connection is faulty. If the physician and patient can’t connect, Finkelston says she sends the patient a text message or calls them to guide them through possible solutions to the technical issue.

When doing a video call with a patient, audio will often connect before the video feed. Finkelston recommends checking whether the patient can hear as the visit starts. She says the physician’s face should be well lit from the front and backlighting, which can make the physician appear in silhouette, should be avoided.

The COVID-19 pandemic has seen a sea change in the way that physicians treat their patients and nowhere is this more evident that in the near-overnight implementation of telehealth across the health care industry.
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The telehealth visit should start with the patient’s chief complaint. Finkelston recommends against rushing this.

When treating adults over telehealth, the physician should check the patient’s surroundings: where are they calling from, how they appear, what their environment is like and how comfortable they are. If the patient lives in a state where the physician is not licensed to practice, the patient should be encouraged to find a physician in their area to avoid any legal issues.

When treating children using telehealth, Finkelston recommends keeping toys on hand to make the exam engaging, consider seasonal decorations for the physician’s telehealth space, addressing the child directly, encouraging them to hold the device the visit is taking place on and acknowledging what the physician is doing off screen.

During telehealth visits, physicians should ensure they are in a private space, with a locked door if possible. There shouldn’t be children, pets or food in the room with the physician. The physician should maintain eye contact by looking directly into the camera and explain what they are doing when off camera, according to Finkelston.

During the visit, vitals can be collected using wearable devices, but if the patient doesn’t own one of these devices the physician should feel comfortable referring them to in-person care. When examining the patient’s mental status, the physician should evaluate their speech and mental status throughout the interview, their eye contact and whether they are understanding cause and effect. When evaluating the mental status of a patient under 18, the physician must ensure a parent or guardian is present.

At the end of the visit, the physician should take time to ask whether the patient has questions, review next steps and ensure the patient understands them and review pharmacy information.

“When you think about medical care, so much can be done through a thoughtful conversation, a thorough history taking, an observation as to what’s going on in the background.”
Deciphering the Morse code of medical malpractice

Introduction:
For many physicians, it’s not a matter of if they will be sued at some point in their career, but when it will happen. In today’s litigious society, suing a doctor for a poor health outcome is a common occurrence, even when the doctor has done nothing wrong. In fact, 50% of all doctors will be sued at some point, and 7% to 10% of cases will end up going to trial. To protect themselves, physicians need to recognize how poor business practices are increasing their liability risk and take action to minimize the chance of being named in a lawsuit. Strong documentation practices are a must, and the entire office staff needs to understand how to handle patient records. And if a legal action is filed, physicians also need to know what actions need to be taken to begin a successful defense.

Learning objectives:
- Recognize potential risk management land mines and how they can lead to increased medical professional liability.
- Summarize practical strategies for reducing risk and minimizing the likelihood of being named in a lawsuit.
- Identify actions to take — and not to take — if faced with litigation.

Meet the panelists:
Mike O’Neill, CPHRM, Assistant vice president of Risk Management Operations, ISMIE
Terese Souders, AIC, Regional claims administrator, ISMIE

Beating a malpractice suit starts with three risk management strategies
Because physicians are likely to be sued at some point, they should always be working in a way that helps mitigate their legal risks. The basic pillars of a strategy are documentation, communication, and tracking systems.

Effective documentation requires that physicians are as detailed as possible when writing patient notes, providing thought processes when appropriate. “Assuming you know what will happen may be true, and it oftentimes is, however, what happens when it’s not?” says Mike O’Neill, CPHRM, assistant vice president of Risk Management Operations, ISMIE Mutual Insurance Co. “So it’s documenting your differential diagnosis as far as what you were thinking it was, what you wanted to rule out in the event it wasn’t that, and what the next plan is going to be.”

O’Neill says it’s vital to avoid copying and pasting and moving bad information forward because other physicians may end up relying on this information. Simple mistakes like indicating the patient is male instead of female or a child instead of an adult can make the doctor look sloppy and make the case more difficult to defend.

Informed consent is a major area of emphasis. “If the informed consent form, which is maybe at a hospital or maybe in some other facility, were to disappear or didn’t exist, can your documentation support you?” O’Neill asks. “Don’t assume the hospital is going to have it or don’t assume it was scanned into the right chart. You have to make sure you are capturing that information on patient understanding.”

When a physician orders a test or a follow-up, they own that and need to be responsible for
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50% of physicians will be sued for malpractice during their career.

tracking it to close the loop. “It doesn’t always have to be the doctor that is doing all this follow-up,” O’Neill says. “Anyone from an administrative role can help that with utilization of portal messages, secure texting, secure emailing or those types of things.”

Make sure any phone calls and letters also get documented in the record. Whatever the system, it just needs to make sure patients do not get lost and that important tests get done.

No matter how diligent a physician is with documentation, a legal action might still be filed. “The most important thing is when you receive this information, you need to contact your broker or [malpractice] insurance company immediately,” says Terese Souders, AIC, regional claims administrator, ISMIE Mutual Insurance Co. They will evaluate the information to determine if it is a legal action against the physician or something else, such as a deposition notice.

But avoid going back into the medical record until you’ve talked to a defense attorney, as everything is time-stamped and it will be obvious to the plaintiff’s attorney when you were looking at it. And whatever you do, don’t alter the record in any way.

If it is a malpractice claim, she says it’s important to not panic. Once you get over the initial shock, become fully engaged in dealing with the claim. Trying to hide it or not talk about it isn’t going to help.

“The more you are invested in it, the more that you understand the process, the more that your expectations along the way are understood and met in the process, the better you are going to feel about it and the better the outcome will be,” Souders says. “Honestly, you can tell if a physician is engaged at his deposition or engaged at trial.”

“If the informed consent form were to disappear or didn’t exist, can your documentation support you?”

Mike O’Neill, assistant vice president of risk management operations, ISMIE

You need to be an expert in your own medical records so when a plaintiff’s attorney hands you a file, you know exactly what it is and can quickly explain your rationale for the actions you took. “We have had cases get dropped after a doctor gave a great deposition and defended his rationale for what he did and why he did it,” Souders says.

Solutions and takeaways:
- Document everything but be mindful of what you are adding and when.
- Use good risk-management strategies to support your clinical care.
- Communicate expectations to your team.
- Ensure patients are safe and happy, as they are less likely to sue.
- Know what steps to take if you are faced with litigation.

MORE ONLINE:
Check out the full video and materials of this session and eight other Bootcamp sessions.
**CONCIERGE**

**Tales from the trenches: A concierge medicine roundtable**

**Introduction:**
Many physicians are disenchanted with traditional practice models. Payer hassles and the fee-for-service hamster wheel often leave physicians burned out and unable to spend enough time with their patients — the reason they pursued medicine in the first place.

In response, some physicians have chosen to transform their practice into a concierge model. During this session, four physicians discussed why they left their traditional practice model behind and made the leap to offer a membership-based primary care program. The following discussion was transcribed and edited for length and clarity.

**Learning objectives:**
- Physicians who practice concierge medicine will discuss the benefits and how to overcome challenges.
- Best practices in discussing the transition with patients.
- How to select a vendor partner.

**Meet the panelists:**
- **James Jones, M.D.,** Internal Medicine
- **Mark Gomez, M.D.,** Internal Medicine
- **Bradley Hunter, D.O.,** Family Medicine
- **Gay Purcell, M.D.,** Internal Medicine
- **Derek Hill** (Moderator) MDVIP

**The breaking point: Why I switched to concierge**

**Mark Gomez, M.D.:** My breaking point was that it came down to family. I was trying to find a way to get to get home to my family faster. As physicians, we make a lot of sacrifices. And some of the sacrifices come at the cost of our own personal relationships. And I thought for me, it was more valuable. I saw more value in me being a better father, a better husband. The reason why I made the switch from traditional primary care to MDVIP was I was trying to find a way home.

**Gay Purcell, M.D.:** I am in my 22nd year of private practice, and I joined MDVIP in January of this year, so very recent. My big breaking point was I was starting to get to the point where I had such a huge patient panel that I would come in every day, and I would have 70 to 100 documents. And I started to worry that I was going to miss something; it was my biggest fear that I was going to miss something really important. And it just felt like, how do I get home to my family and still not miss anything? And I knew that there were so many things that I wanted to bring to my patients and the way that I was practicing medicine, it really wasn’t practical.

**Bradley Hunter, D.O.:** I was seeing myself lose the empathy. The burnout features were all there, I was just checking all the boxes for burnout. And so were all my colleagues. And we finally got to a point within our practice where we all said, ‘We give up!’ The entire practice folded, a practice of about 30 providers, and each of us took separate directions. And I chose to go the MDVIP way. And I can’t tell you how happy I am that I’ve done this because and every day, it’s reinforced by my patients saying, ‘Wow, this is what I was always hoping for from my doctor’s visits.’”

**James Jones, M.D.:** I was frustrated with the incompleteness of being able to do a good job, you know, seeing 30 or 40 people a day. I was at a point in my practice where I couldn’t even
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see my sick people because the schedule wouldn’t allow anybody to be put into the practice. And that was just unacceptable for me. But I haven’t looked back since. I can tell you that this was the right decision for me and it was right decision for my patients.

What were your biggest fears about the switch?

Purcell: I went into it with a lot of fears I think a lot of people would have about completely changing your traditional practice of medicine and the way that you’ve done medicine as long as you’ve done it. I think one of the things that is scary when you first start out is wondering whether or not the patients will accept this type of model, whether they’ll actually understand it — I think that is that is the biggest hurdle to overcome. ... But the wonderful thing is that so many people loved the model, and they love coming in every day, they love being able to call me on my cellphone if they need anything.

How did you determine concierge was right for you?

Jones: I was fortunate enough to have two close partners who were already practicing in the MDVIP model. So I learned through them how it exactly works, but it still took me a year or so of meetings and talking to MDVIP. I can’t emphasize how much that the analytics that they use are so accurate. We now have six practicing MDVIP physicians in our organization and they have hit the nail on the head with all of us as far as predicting how many people will join us and how big our practice would be.

How did you tell your patients?

Gomez: We certainly do tend to develop these amazing relationships with a lot of the patients that we’ve taken care of. When I went through the process, it was a very difficult decision to make, because you’re talking about having some finality to these relationships that you’ve cherished for a long time. But I had to be honest with my patients. I said, ‘Hey, I’m doing this, these are my reasons for doing it, and I hope that I can continue to be your doctor. I’m giving you the choice of choosing to stay with me.’ It’s good to give ourselves as doctors permission to take care of ourselves. And so my approach with patients was to be honest with them, and they understood.

Advice for physicians

Jones: It’s not necessarily right for every doctor, just like it’s not necessarily for every patient. But I’d also encourage people not to wait too long. If you wait till you’re 65 or 70 years old, you may have missed the boat of the real benefit of being able to practice this way.

Hunter: I’m 58. It’s about the average age of conversion. I am glad that I got in the door at this time. But I could not have gone back to becoming an employee because I think you’ll just not get out of the burnout loop that’s set up in this system. Your patients are going to be looking for personalized health care models like this, and they are out there waiting for you.
**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 (e.g., 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.
- In a postmarketing observational study, an increased risk of Guillain–Barré syndrome was observed during the 42 days following vaccination with SHINGRIX.
- Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

**Solicited local adverse reactions** reported in individuals aged 50 years and older were pain (78%), redness (38%), and swelling (26%).

**Solicited general adverse reactions** reported in individuals aged 50 years and older were myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%).

The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women.

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.

Vaccination with SHINGRIX may not result in protection of all vaccine recipients.


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SGXJRNA210047 September 2021
Produced in USA.
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 (HZ) (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° 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 2 to 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.

5.2 Guillain-Barré Syndrome (GBS)

In a postmarketing observational study, an increased risk of GBS was observed during the 42 days following vaccination with SHINGRIX [see Adverse Reactions (6.2)].

5.3 Syncope

Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

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.

Adults Aged 50 Years and Older

Adults aged 50 years and older reporting each solicited local and general adverse reaction following administration of SHINGRIX (both doses combined) were pain (79%), redness (38%), and swelling (28%); and myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%).

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

Table 1. Percentage of Subjects with Solicited Local and General Adverse Reactions 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>Adverse Reactions</th>
<th>Aged 50-59 Years</th>
<th>Aged 60-69 Years</th>
<th>Aged ≥70 Years</th>
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<tbody>
<tr>
<td></td>
<td>SHINGRIX</td>
<td>Placebo</td>
<td>SHINGRIX</td>
</tr>
<tr>
<td></td>
<td>n = 1,315 %</td>
<td>n = 1,312 %</td>
<td>n = 1,311 %</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>n = 2,258 %</td>
</tr>
<tr>
<td>Pain</td>
<td>88</td>
<td>14</td>
<td>83</td>
</tr>
<tr>
<td>Pain, Grade 3†</td>
<td>10</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Redness</td>
<td>39</td>
<td>1</td>
<td>38</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Myalgia, Grade 3*</td>
<td>9</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Fatigue, Grade 3*</td>
<td>57</td>
<td>20</td>
<td>46</td>
</tr>
<tr>
<td>Fatigue, Grade 3*</td>
<td>9</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Headache, Grade 3*</td>
<td>6</td>
<td>2</td>
<td>4</td>
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<tr>
<td>Shivering</td>
<td>36</td>
<td>7</td>
<td>30</td>
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<tr>
<td>Shivering, Grade 3*</td>
<td>7</td>
<td>0.2</td>
<td>5</td>
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<tr>
<td>Fever</td>
<td>28</td>
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<td>24</td>
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<tr>
<td>Fever, Grade 3</td>
<td>0.4</td>
<td>0.2</td>
<td>1</td>
</tr>
<tr>
<td>GI†</td>
<td>24</td>
<td>11</td>
<td>17</td>
</tr>
<tr>
<td>GI, Grade 3*</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

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

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

† 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.

‡ Placebo was a saline solution.

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

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

¶ 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 ≥39.0°C/102.2°F.

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

The incidence of solicited local and general adverse reactions was lower in adults aged 70 years and older compared with those aged 50 to 69 years. The local and general adverse reactions seen with SHINGRIX had a median duration of 2 to 3 days.

(continued on next page)
There were no differences in the proportions of subjects reporting any solicited local reactions between Dose 1 and Dose 2. Headache and shivering were reported more frequently by subjects after Dose 2 (28% and 21%, respectively) compared with Dose 1 (24% and 14%, respectively). Grade 3 solicited general adverse reactions (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3%, 4%, and 4%, 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 51% and 52% of subjects who received SHINGRIX (n = 14,645) or 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 (4% 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 or placebo, respectively, within 30 days of vaccination; available information is insufficient to determine a causal relationship with SHINGRIX.

Serious Adverse Events (SAE): In the 2 studies, SAEs were reported at similar rates in subjects who received SHINGRIX (2.3%) or 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 38°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 frequently reported pIMDs 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 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.

Nervous System Disorders

Guillain-Barré syndrome.

Postmarketing Observational Study of the Risk of Guillain-Barré Syndrome following Vaccination with SHINGRIX

The association between vaccination with SHINGRIX and GBS was evaluated among Medicare beneficiaries aged 65 years or older. Using Medicare claims data, from October 2017 through February 2020, vaccinations with SHINGRIX among beneficiaries were identified through National Drug Codes, and potential cases of hospitalized local reactions between Dose 1 and Dose 2.

The risk of GBS following vaccination with SHINGRIX was assessed in self-controlled case series analyses using a risk window of 1 to 42 days post-vaccination and a control window of 43 to 183 days post-vaccination. The primary analysis (claims-based, all doses) found an increased risk of GBS during the 42 days following vaccination with SHINGRIX, with an estimated 6 excess cases of GBS per million doses administered to adults aged 65 years or older. In secondary analyses, an increased risk of GBS was observed during the 42 days following the first dose of SHINGRIX, with an estimated 6 excess cases of GBS per million doses administered to adults aged 65 years or older, and no increased risk of GBS was observed following the second dose of SHINGRIX. These analyses of GBS diagnoses in claims data were supported by analyses of GBS cases confirmed by medical record review. While the results of this observational study suggest a causal association of GBS with SHINGRIX, available evidence is insufficient to establish a causal relationship.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1) of full prescribing information].

8.2 Lactation

Risk Summary

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

8.5 Geriatric Use

Adults Aged 60 Years and Older

Of the total number of subjects who received at least 1 dose of SHINGRIX in Studies 1 and 2 (n = 14,645), 2,243 (15%) were aged 60 to 69 years, 6,837 (47%) were aged 70 to 79 years, and 1,921 (13%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information]. The frequencies of solicited local and general adverse reactions 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).

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The right way to handle patient collections

by Todd Shryock Managing Editor

Nobody likes turning patients over to collections. But for a practice to survive, it’s imperative that a practice collect the money it is owed so it can keep the doors open and keep providing medical care to the community it serves.

For a difficult topic like collections, there are right ways and wrong ways to do it. Medical Economics® spoke with Jacob Corlyon, co-founder and CEO of Capital Collection Management, to talk about the best way to handle these difficult cases.

(Editor’s note: The transcript has been edited for length and clarity.)

Medical Economics®: What mistakes do practices make when it comes to collections?

Jacob Corlyon: It really comes down to a perspective issue. Perspective, when you look at collections in a medical practice, or at a hospital or surgery center level, is they’re not looking at it like a revenue-generating department. It’s kind of just a function that has to happen; they’re not really giving it a lot of thought and attention, which it truly does need. It does take a lot of effort and education to build a staff that can engage with empathy and can provide a very good customer experience, so that you can engage with that patient in a way to educate them on the debt that’s owed, and then work them through a solution of repayment.

It even goes down to the collection strategy and the execution of a collection strategy. I think a lot of people are missing how detailed that process has to be from a staff perspective, so that when your staff is engaging in the conversations, whether it’s in the early stage or the late stage of that collections conversation, the messaging is consistent across the board, everybody knows what to say, everybody knows the programs that are available.

Medical Economics®: What mistakes do practices make when it comes to collections?

Jacob Corlyon: From my perspective, consistency is key. Collections starts at billing. And honestly, it really starts before that, with the patient onboarding experience. You should be educating and talking about what that procedure is going to end up costing that patient out of pocket, what programs are available, and setting the expectation, whether it’s taking some sort of down payment at the time of service, or if you offer third-party financing solutions to help cover that out-of-pocket expense. Overcommunicating and educating that consumer on the front side really lends well when that account becomes in a state of collections, because they’ve received that messaging, they know what’s available to them. Everybody would go through the same process so that everybody is treated and engaged within a consistent manner.

And then when it comes to the question around who or if you should send that patient to a third-party agency, I think consistency is really key in that. You want all your patients to go through
that life cycle. It starts at creating that overall strategy, and then making sure that on a consistent basis, everybody is being treated in the same manner, so that that customer spirit experience can be measured and looked at from start to finish, and that the staff can be held accountable and the agencies that are servicing those clients can be held accountable as well.

**ME: You talk about consistency; are there ever exceptions that can be made? Or does it have to be across the board consistent with everyone?**

**JC:** I’m a firm believer in consistency. The health care provider should have a well-documented financial assistance policy. If there’s charity care or other programs that the medical practitioner offers, that should have coverage under there. It still needs to be consistently done. It’s not saying, I’m going to put 20 of these people through my billing and collections process, or send these 20 people to an outside agency if we work with them, but not send these 10. Everybody should go through that consistent process without exception.

When you’re creating this process it really takes some thought, because you want it to be people-first, you want it to be an empathetic process, but you want it to be very well thought out so it can be handled in a consistent manner from start to finish. The end goal is making that customer experience the best it can be, and providing that customer with the education and the service level they need to get that debt cleaned up and out of their minds and out of their responsibility. What we hear a lot is, outstanding debt, whether it’s from a medical provider or a bank or financial institution, whatever that might be, it does weigh a lot on that consumer’s mind. And what we see, especially in the health care side of the equation, is around surprise billing. The patient is like, OK, well, I didn’t think I owed that. And then you have the additional challenge on the health care side all of the insurance nuance.

It’s on the provider, it’s on the servicers that are working with those providers to understand it, to have a consistent, well-documented processing workflow, and then be able to educate that consumer and that patient all the way through the transaction to create that win-win solution to get them back on track or get that doctor paid.

“I’m a firm believer that everybody wants to repay.”

**ME:** It’s unfortunate that patients sometimes have to be turned over to collections. Are there tips you can share on how to collect what’s owed without creating ill will?

**JC:** When you look at collections, and when you look at what people think about when they hear debt collection, or you’re placed in collections, or in a collections department, whether it’s internal or with a servicer, it doesn’t have to be a negative experience. It can be one that’s very positive. We believe that through engaging with empathy, actively listening, being able to educate that patient on programs on how they come to owe the amount that you’re reaching out about — that’s a big thing.

So be able to understand and explain to them that debt and why they owe it, and come up with a solution, whether it’s having well-documented terms to create a repayment plan, or whether it’s offering charity care opportunities, or whether it’s offering third-party patient financing solutions. You want to arm the patient and the consumer with as much knowledge as possible, with as many opportunities as possible, to make that payment.

I’m a firm believer that everybody wants to repay, and it’s really on, whether it’s an internal collector or an external collector, to have the conversation, educate them and provide a solution so that they can repay it. And that ultimately leads to that customer experience.

**ME:** Is there a way to tell who’s making a genuine effort to pay you and who’s just trying to fool you with sad stories?

**JC:** It’s something everybody struggles with from that people side of the equation. It’s very easy to get sucked into those stories, especially if it’s always happening. If it’s always a new story, that can kind of be a little bit of a red flag. If every time you talk to somebody, there’s been something else that’s happening within their life, that may be an excuse or something that they’re trying to play, whether it’s pulling the heart-strings or just trying to extend the time in between payments.

What I think is very important as that person who’s on the phone engaging with that individual is,
more or less kind of changing your perspective in that conversation to not only actively listen in and engage with that individual, but really make it a genuine effort to connect, to build rapport, to offer that type of education, talk about the debt and really try to get them to the ultimate answer, which is to say yes to a solution that works for the provider and for that consumer. You may be getting a lot of noise, but you’re always working down the path of trying to get that yes at the end of the tunnel.

Again, being genuine in that transaction, engaging with empathy, providing that education and really talking to that person is important, and not just say, well, this call isn’t going to be successful because I’m getting another type of story. I think it’s always prudent to really engage and try to understand and then create that solution.

ME: Is there anything else you think medical practices need to be aware of when it comes to collections?

JC: From my perspective, what I like to tell medical providers is look at the collection side of your business as a revenue-generating department. So just like you’re looking at trying to acquire new patients, you want to look at how to create that great customer experience on that back side.

But again, if you look at it like a revenue-generating department, a lot of things go into that. It’s actually taking the time to peel back the onion layers and look at what’s actually happening and taking a little bit of an assessment of what’s going on today. Then it’s understanding that process and reimagining how that process works.

It does take a lot of time, but you want to put in policies, procedures, workflows, training programs, educating the people that are on the phones for you, to make sure they’re well equipped to handle those conversations, to make sure they understand the insurance side of the business and how those debts actually become due and what the back-end balance is for that out-of-pocket cost for that consumer. That’s a big question they’re going to ask and those individuals need to have the training to be able to articulate that and talk around that topic with that consumer. Then you want to start dashboarding and you want to hold those individuals accountable for their performance as you would, say, the sales team, because again, that is a part of that revenue-generating side of the practice.

The more you recover, you are saving that revenue that was already generated. So it’s vital for the medical practice, it’s vital for a hospital or center to get those funds in to continue to provide excellent patient care as well as keep a practice running efficiently.
Addressing influenza in the COVID-19 era

by Grace Halsey Senior Editor

Welcome to Around the Practice. The following transcript features three physicians discussing the upcoming influenza season and the impact of cocirculating COVID-19. This recap was edited for length and clarity, and the full video conversation is available at MedicalEconomics.com.

Our moderator is Tina Q. Tan, M.D., FAAP, FIDSA, FPIDS, professor of pediatrics at the Northwestern University Feinberg School of Medicine and a pediatric infectious disease attending physician at the Ann & Robert H. Lurie Children’s Hospital of Chicago in Illinois.

Our panelists are as follows:

John J. Russell, M.D., FAAP,
clinical professor of family and community medicine, Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia

Stephan Foster, Pharm.D.,
FAPhA, FNAP, director, professor and community pharmacist, Memphis, Tennessee

Charles (Chuck) Vega, M.D.,
FAAFP, health sciences clinical professor of family medicine, University of California, Irvine, School of Medicine

Tan: What factors contributed to the lower-than-average influenza season in 2020-21? How does this impact what we might see for the 2021-22 influenza season?

Foster: We don’t really know. We don’t have enough data on this. Everything has been evolving as we go along. We suspect that some of it has to do with the COVID-19 social distancing and other COVID-19 protections, the masking and the hand-washing, travel restrictions and the flu vaccine we received last year. All of those may have contributed to the low flu rates. There is some evidence that there might have been some viral interference, where one virus can suppress another virus mechanism. But we’re not sure. And we’re just waiting to see what will happen this year.

Vega: I think another factor that likely helped contribute to a historically lower rate of flu overall in the United States last year was school closures. I’m not a huge fan of school closures with three kids in elementary school personally. But we know that flu is passed around schools pretty readily. And then those kids come home and often infect folks at higher risk, such as grandparents. And the rates of flu vaccine last year were disappointingly low. We will have to vaccinate as many as we can this flu season.

........................................

Tan: What is the potential impact of lifting COVID-19 restrictions (for example, social distancing, face masks) in the upcoming influenza season?
**season? How will the season be impacted by the circulating Delta variant?**

**Russell:** Some people have given up wearing masks, if they ever did, and have completely gone back to other things and there are some of us who still wear masks. Personally, I’m not sure I’m ever going to see a patient sick with a viral illness without wearing a mask for the rest of my career. I can remember doing nasopharyngeal swabs on people without a mask on because it was “just the flu” and I was vaccinated.

Delta is interesting on two fronts. When you think about the infectiousness of flu, we think about how many people will an infected person get sick and it’s about one or two for influenza. For Delta, it’s up in the range of five plus — that’s comparable to the infectivity of chickenpox.

**Vega:** I think you have to watch your population locally. How are they responding to vaccines? How are they responding these nonpharmacologic measures? And you take precautions based on those factors, because it is highly variable from community to community.

### AVAILABLE INFLUENZA VACCINES — UNITED STATES, 2021-22 INFLUENZA SEASON*

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<tr>
<th>TRADE NAME/MANUFACTURER</th>
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</thead>
<tbody>
<tr>
<td>IIV4 (standard-dose, egg-based vaccines)</td>
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<tr>
<td>Afluria Quadrivalent (Seqirus)</td>
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<tr>
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<td>0.5 mL PFS ≥ 3 ys</td>
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<td></td>
<td>5.0 mL MDV ≥ 6 mos (needle/syringe)</td>
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<tr>
<td>FluLaval Quadrivalent (GlaxoSmithKline)</td>
<td>≥ 6 mos</td>
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<td>Fluzone Quadrivalent (Sanofi Pasteur)</td>
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<td>ccIIV4 (standard-dose, cell culture-based vaccine)</td>
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<td>FluMist Quadrivalent (AstraZeneca)</td>
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IIV4, inactivated influenza vaccine, quadrivalent; LAIV4, live attenuated influenza vaccine, quadrivalent; RIV4, recombinant influenza vaccine, quadrivalent.

*Please consult FDA-approved prescribing information for 2021-22 influenza vaccines for the most complete and updated information, including (but not limited to) indications, contraindications, warnings, and precautions. Scan for the available Package inserts for U.S.-licensed vaccines.
Tan: How might COVID-19 booster recommendations impact influenza vaccination rates? Can COVID-19 and influenza vaccines be administered together?

Russell: I think the people who are very interested in COVID-19 vaccines can’t wait to get a booster. For other people suddenly this has become something larger than a public health issue, that is, flu vaccine is just another part of the COVID-19 conspiracy that maybe wasn’t seen before. I think it’s going to be harder.

As for co-administration, originally there was a two-week window advised before you’d give another vaccine after a COVID-19 vaccine. But that has been changed now so someone could take a flu vaccine and a COVID-19 vaccine at the same visit. Some of the people who are working on the mRNA vaccines are hoping in future years to have a combined COVID-19/influenza vaccine, but not for this year.

Tan: What might be the scenario moving forward for COVID-19 boosters?

Vega: The guidelines as of right now are for folks who have had two doses of the Pfizer-BioNTech vaccine and had their last dose more than six months ago and then if they are aged 65 years or younger, are aged 18 years or younger with underlying conditions that put them at risk for severe disease, if they live in long-term care or another congregate setting or live and work in a high-risk setting. And it’s hard right now. I’m going through one case at a time.

In terms of the future, I don’t have a crystal ball, but I don’t think that a two- or three-dose regimen is the end of the story, but I also don’t think we’d be looking at an annual COVID-19 vaccine, although it could be possible. As long as the pandemic continues, with millions of infections around the world and the mutation rate continuing, we’ll need to think about how the vaccine is composed, including accounting for all those different variants.

Russell: I spend five minutes of every visit trying to explain what the recommendations are and which lane the patient should be in. But I think it’s something we should still be talking about. We are just figuring out what the regimen is — this may not be a booster, it’s probably just part of a series — the third dose in the mRNA series or the second in the J&J series.

Tan: How do the signs and symptoms differ between COVID-19 and influenza? How do you decide which to test for in the clinic?

Russell: The presentation can look the same. Someone who has cough and a fever — these are hallmarks of both. The anosmia happens much more with COVID-19. So I think it’s hard to figure out at point zero. But you’re more likely to have fevers and myalgias. Then your temperatures go down, about a half to 1 degree per day. And you’re going to be over that in roughly five to seven days. COVID-19 is a bit more indolent, it kind of builds up. We’ve all seen that patient who percolated along and then kind of dropped off at Day 5 to 8 and then suddenly got very sick.

Flu likes the very young and the very old. COVID-19 tends to like the very old a lot more than it likes the very young, but certainly you’ve seen teens in your hospital, you’ve seen pediatric patients with COVID-19.

Being able to do some point-of-care testing at a primary care office will be really instrumental. The test that comes back in two days doesn’t always help a lot. So I’m excited that we are entering a realm where we might have multiplex testing in the office for influenza and COVID-19, maybe respiratory syncytial virus, at the same time.

Tan: What are the potential complications of COVID-19 versus flu?

Russell: They both have pneumonia as a complication, and multiorgan failure. Influenza doesn’t really have the “long-hauler” effect; it does its damage and then moves on. Flu and COVID-19 both can cause myocarditis. We have never seen with influenza, though, the preponderance of people with clots, pulmonary embolus we have seen with COVID-19, and we never saw the numbers of people with renal failure.

Vega: Influenza is a very strong risk factor for cardiovascular events which are well documented with flu. That’s part of the way I try to convince folks to get the influenza vaccine because there is evidence that the vaccine itself can help prevent myocardial infarction and stroke.

Tan: Which patients are at higher risk for developing influenza complications?

Vega: If you have significant chronic dysfunction of any major organ — brain, heart, kidney, liver, lung — you are at high risk for complications of influenza. Some of the other important groups are pregnancy, severe obesity (BMI ≥ 40), history of heart attack or stroke. And then the large vulnerable groups that now include people of color, Black, Latinx, American Indian, Alaskan Native — they all are considered at higher risk for flu complications. These are the patients I see every day.

» Continues on Page 54
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.

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.

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.

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}

<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>Protection Against Influenza</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluzone High-Dose Quadrivalent</td>
<td>24% (95% CI: 10-37) BETTER PROTECTION AGAINST INFLUENZA compared with standard-dose Fluzone (Influenza Vaccine) in patients 65+.\textsuperscript{1,3}</td>
</tr>
<tr>
<td>Flublok Quadrivalent</td>
<td>30% (95% CI: 10-47) BETTER PROTECTION AGAINST INFLUENZA versus a standard-dose quadrivalent inactivated influenza vaccine.\textsuperscript{2,4}</td>
</tr>
</tbody>
</table>

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}

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.

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

2.2 Administration
Invent 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 Postmarketing Experience (6.2) and Description (11) in the full prescribing information].

5 WARNINGS AND PRECAUTIONS
5.1 Managing Allergic Reactions
Adequate 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 1 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 Immuneocompetence
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 (≥6 ADVERSE REACTIONS)

The following events have been spontaneously reported during post-approval use of Flublok Quadrivalent. The biologic plausibility of a causal relationship to Flublok Quadrivalent, and their significance in relation to the background frequency of similar events in the general population of uncertain size, it is not always possible to reliably estimate their incidence. Among 972 adults 50-64 years of age (Studies 4 and 6 pooled), through up to 6 months after vaccination, unsolicited adverse events were collected for 28 days post-vaccination, and serious adverse events (SAEs) were collected for 6 months post-vaccination via clinical visit or remote contact.

Study 1 included 1330 subjects 18 through 49 years of age for safety analysis, randomized to receive Flublok Quadrivalent (n=898) or a comparator inactivated influenza vaccine (Fluarix 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, 65% of subjects were female, 59% white/Caucasian, 37% black/African American, 1.6% Native Hawaiian/Pacific Islander, 0.8% American Indian/Alaskan Native, 0.5% Asian, 1% 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 2: Frequency of Solicited Systemic Adverse Reactions within 7 Days of Administration of Flublok Quadrivalent or Comparator in Adults 18-49 Years of Age, Study 1 (Reactogenicity Populations) 1

<table>
<thead>
<tr>
<th>Reactogenicity Term</th>
<th>Flublok Quadrivalent N=898</th>
<th>Comparator N=332</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any Grade 1 %</td>
<td>Grade 3 %</td>
</tr>
<tr>
<td>Subjects with ≥1 injection site reaction 1</td>
<td>8</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Local Tenderness</td>
<td>48</td>
<td>1</td>
</tr>
<tr>
<td>Local Pain</td>
<td>37</td>
<td>1</td>
</tr>
<tr>
<td>Firmness / Swelling</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Redness</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Subjects with ≥1 systemic reaction 1</td>
<td>34</td>
<td>2</td>
</tr>
<tr>
<td>Headache</td>
<td>20</td>
<td>1</td>
</tr>
<tr>
<td>Fatigue</td>
<td>17</td>
<td>1</td>
</tr>
<tr>
<td>Muscle Pain</td>
<td>13</td>
<td>1</td>
</tr>
<tr>
<td>Joint Pain</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>Nausea</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>Shivering / Chills</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Fever 1, 6</td>
<td>2</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

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%.

1 Flublok Quadrivalent or Comparator because both vaccines are manufactured using the same process.

2 Study 1 is registered as NCT02290509 under the National Clinical Trials registry.

3 Denominators for fever: Flublok Quadrivalent n = 4262, Comparator n = 4282.

4 Denominators for injection site reactions: Flublok Quadrivalent n = 4307, Comparator n = 4318.
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)\(^{1}\)\(^{1}\) (continued)

<table>
<thead>
<tr>
<th>Reactogenicity Term</th>
<th>Flublok Quadrivalent N=4312</th>
<th>Comparator N=4327</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any Grade</td>
<td>Grade 3</td>
</tr>
<tr>
<td>Local Tenderness</td>
<td>34</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Local Pain</td>
<td>19</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Firmness / Swelling</td>
<td>3</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Redness</td>
<td>3</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

Subjects with ≥1 systemic reactogenicity event\(^{1}\)\(^{1}\)\(^{2}\)

- Headache: 25 1 <1 26 1 <1
- Fatigue: 12 <1 0 12 <1 <1
- Muscle Pain: 9 <1 0 <1 <1 <1
- Joint Pain: 8 <1 0 <1 <1 <1
- Nausea: 5 <1 0 5 <1 <1
- Shivering / Chills: 5 <1 0 4 <1 <1

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%.

*Comparators = U.S.-licensed comparator quadrivalent inactivated influenza vaccine, Fluarix Quadrivalent, manufactured by GlaxoSmithKline.

†Study 2 is registered as NCT02285998 under the National Clinical Trials registry.

\(^{1}\) Reactogenicity Populations were defined as all randomized subjects who received study vaccine according to the treatment actually received and who had at least one non-missing data point for injection site, systemic or body temperature reactogenicity categories. For local pain, tenderness, and systemic reactions: Grade 1 = no interference with activity. Grade 2 = some interference with activity. Grade 3 = prevents daily activity. Grade 4 = required Er visit or hospitalization. For injection site redness and firmness/swelling: Grade 1 = 25 to ≤50 mm (small), Grade 2 = 51 to ≤100 mm (medium), Grade 3 = >100 mm (large), Grade 4 = necrosis or exfoliative dermatitis.

\(^{2}\) Denominators for injection site reactions: Flublok Quadrivalent n = 4307, Comparator n = 4319.

\(^{3}\) Denominators for systemic reactions: Flublok Quadrivalent n = 4306, Comparator n = 4318.

\(^{4}\) Denominators for fever: Flublok Quadrivalent n = 4282, Comparator n = 4282.

\(^{5}\) Fever defined as ≥100.4°F (38°C). Grade 1 = ≥100.4°F to <101.1°F; Grade 2 = 101.2°F to ≤102°F; Grade 3 = 102.1°F to ≤104°F; Grade 4 = >104°F.

Among adults 18-49 years of age (Study 1), through 6 months post-vaccination, no deaths were reported. SAEs were reported by 12 subjects, 10 (11%) Flublok Quadrivalent recipients and 2 (0.6%) Comparator recipients. No SAEs were considered related to study vaccine. Among adults 50 years of age and older (Study 2), 20 deaths occurred in the 6 months post-vaccination, including 8 Flublok Quadrivalent and 12 Comparator recipients. No deaths were considered related to study vaccine. SAEs were reported by 145 (3.4%) Flublok Quadrivalent recipients and 132 (3.0%) Comparator recipients. No SAEs were considered related to study vaccine. SAEs were reported by 145 (3.4%) Flublok Quadrivalent recipients and 132 (3.0%) Comparator recipients.

In the 30 days following vaccination, no one or more unreported treatment emergent adverse events occurred in 10.3% of Flublok Quadrivalent and 10.5% of Comparator recipients in Study 1 (adults 18-49 years of age) and in 13.9% of Flublok Quadrivalent and 14.1% of Comparator recipients in Study 2 (adults ≥50 years of age). In both studies, rates of individual events were similar between treatment groups, and most events were mild to moderate in severity.

Flublok (Trivalent Formulation)

The safety experience with Flublok is relevant to Flublok Quadrivalent because both vaccines are manufactured using the same process and have overlapping compositions [see Descriptions (11) in the full prescribing information].

Flublok (trivalent formulation) has been administered to and safety data collected from a total of 4547 subjects in five clinical trials (Studies 3-7): 2497 adults 18 through 49 years, 972 adults 50 through 64 years, and 100 adults 65 years and older. In Studies 3 - 5 and 7, SAES were collected for 6 months post-vaccination. Study 6 collected SAES through 30 days following receipt of vaccine. Study 6 also actively solicited pre-specified common hypersensitivity-type reactions through 30 days following receipt of vaccine as a primary endpoint. Study 3 included 4648 subjects 18 through 49 years of age for safety analysis, randomized to receive Flublok (n=2344) or placebo (n=2304) [see Clinical Studies (14) in the full prescribing information].

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=301) or another U.S.-licensed trivalent influenza vaccine (Fluzone, manufactured by Sanofi Pasteur, Inc.) as an active control (n=301).

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, 672 received Flublok and 665 received Afluria. Among subjects aged 65 years and older, 642 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 32 Flublok recipients and 36 placebo recipients. One SAE (pleuritic cardiitis) in a Flublok recipient was assessed as possibly related to the vaccine.

Among 872 adults 50-64 years of age (Studies 4 and 6 pooled), through up to 6 months post-vaccination, no deaths occurred, and SAEs were reported by 10 subjects, 6 Flublok recipients and 4 Comparator recipients. One of the SAEs, vasovagal syncpe following injection of Flublok, was considered related to vaccination of study vaccine.

Among 1078 adults 65 years of age and older (Studies 5 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.

Serious AEs 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.

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 1-800-822-2463.

Risk Summary

Pregnancies can have a risk of birth defect, 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 (trivalent 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 0.3 ml divided 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].
Flublok Quadrivalent
(Influenza Vaccine), Sterile Solution for Intramuscular Injection
2020-2021 Formula

Clinical Considerations

Allergy-associated Maternal and/or Embryo/Fetal Risk
Pregnant women are at increased risk of complications associated with influenza infection compared to non-pregnant women. Pregnant women with influenza may be at increased risk for adverse pregnancy outcomes, including preterm labor and delivery.

Data

Animal
In a developmental toxicity study, female rats were administered 0.5 mL divided of Flublok (trivalent formulation) by intramuscular injection twice prior to mating (35 days and 14 days prior to mating) and on gestation Day 6. No vaccine-related fetal malformations or variations and no adverse effects on pre-weaning development were observed in the study.

8.2 Lactation

Risk Summary
It is not known whether Flublok Quadrivalent is excreted in human milk. Data are not available to assess the effects of Flublok (trivalent formulation) or Flublok Quadrivalent on the breastfed infant or on milk production/excretion.

8.4 Pediatric Use

Data from a randomized, controlled trial demonstrated that children 6 months to less than 18 years of age and effectiveness of Flublok Quadrivalent have not been established in children 3 years of age or younger.

8.5 Geriatric Use

Data from an efficacy study (Study 2), which included 1759 subjects ≥65 years and 525 subjects ≥75 years who received Flublok Quadrivalent, are insufficient to determine whether elderly subjects respond differently from younger subjects (see Clinical Trials Experience (6.1) and Clinical Studies (14) in the full prescribing information).

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Distributed by Sanofi Pasteur Inc.

Flublok is a registered trademark of Protein Sciences Corporation.

INFB4-BPLR-SL-JUL20 Revised: July 2020

Table 1 displays solicited adverse reactions for Fluzone High-Dose Quadrivalent and Fluzone High-Dose (trivalent formulation).

## 5.4 Limitations of Vaccine Effectiveness

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

5.5 Altered Immune Competence

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

5.6 Limitations of Vaccine Effectiveness

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

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

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

Study 1 (NCT03282240, see https://clinicaltrials.gov) was a randomized, active-controlled, modified double-blind pre-licensure trial conducted in the U.S. The study compared the safety and immunogenicity of Fluzone High-Dose Quadrivalent to those of Fluzone High-Dose (trivalent formulation). The safety analysis set included 1777 Fluzone High-Dose Quadrivalent recipients, 443 Fluzone High-Dose recipients, and 450 investigational Fluzone High-Dose containing the alternate B influenza strain recipients.

The most common reactions occurring after Fluzone High-Dose Quadrivalent administration were injection-site pain (41.3%), myalgia (22.7%), headache (14.4%), and malaise (13.2%). Onset usually occurred within the first 3 days after vaccination. The majority of solicited reactions resolved within three days of vaccination.

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

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 breastfed infant or on milk production/excretion.

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

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

Manufactured by:
Sanofi Pasteur Inc.
Swiftwater PA 18370 USA

INHDQ-BPLR-SL-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></th>
<th>Fluzone High-Dose Quadrivalent (N=1761-1768)</th>
<th>Fluzone High-Dose(^2) (N=885-889)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any</td>
<td>Grade 3</td>
<td>Any</td>
</tr>
<tr>
<td>Injection Site Pain(^3)</td>
<td>41.3</td>
<td>0.7</td>
</tr>
<tr>
<td>Injection Site Erythema(^4)</td>
<td>6.2</td>
<td>0.6</td>
</tr>
<tr>
<td>Injection Site Swelling(^5)</td>
<td>4.9</td>
<td>0.3</td>
</tr>
<tr>
<td>Injection Site Induration(^6)</td>
<td>3.7</td>
<td>0.2</td>
</tr>
<tr>
<td>Injection Site Bruising(^7)</td>
<td>1.3</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Local Reactions

Myalgia\(^8\) | 22.7 | 0.9 | 18.9 | 0.7 |
Headache\(^9\) | 14.4 | 0.6 | 13.6 | 0.4 |
Malaise\(^10\) | 13.2 | 0.7 | 13.4 | 0.4 |
Shivering\(^11\) | 5.4  | 0.3 | 4.7  | 0.3 |
Fever\(^12\) | 0.4  | 0.2 | 0.9  | 0.2 |

Systemic Reactions

\(^1\)NCT03282240
\(^2\)Safety results for the Fluzone High-Dose and investigational Fluzone High-Dose containing the alternate B influenza strain recipients were pooled for the analysis.
\(^3\)Grade 3: A type of AE that interrupts usual activities of daily living, or significantly affects clinical status, or may require intensive therapeutic intervention.
\(^4\)Grade 3: > 100 mm
\(^5\)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 Quadrivalent 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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Tan: Would you comment on the issue of waning vaccine immunity and touch on the topic of vaccination timing?

Foster: I think it’s more likely waning vaccine efficacy. We don’t really understand what we’re seeing, and we call it waning immunity. But realistically, the studies have shown that (influenza) vaccine is still effective later in the season. The wording about vaccine timing changes every year. But this year, they came out with about the strongest recommendations that we have had on when not to give the vaccine: For most patients, do not give it in July and August because we want to make sure that it does cover throughout the rest of the season. There are certain populations, though, that should get the vaccine as early as possible — children who need two doses of vaccine, pregnant women who are going to deliver during the flu season. The other person you may want to vaccinate early is the one you don’t think you’ll get back in.

Russell: If you look at the past 12 years, one-third of seniors in the United States have not been vaccinated against flu. And even with 12 years of information at our disposal to understand why, that number is really not changing. I think we need to be strong proponents and our voice needs to be consistent. If we work with our patients, we should be able to give that vaccine even before we come into the room. Nurses in my office know they have that permission.

Vega: I want to focus on the adolescents and young adults, who have very low rates of vaccination overall. It’s ironic because some of the best studies on the public health impact of the influenza vaccine show that it’s probably greatest in terms of protecting a group of people in military barracks and in college dormitories, where things can spread really fast among healthy people. They have a low risk for complications, but they pass infection along to more vulnerable folks in their environment. That’s where we see the hospitalizations and even the associated influenza mortality go up.

Tan: What are some of the most common patient misconceptions that persist about COVID-19 vaccine and influenza vaccine?

Foster: I think every provider in the country has experienced the comments like, “Every time I get a flu shot, I get the flu,” or “I never get the flu,” or “There was no flu last year so why should I get it this year?” Just look at the COVID-19 reluctance we’ve dealt with this year; this is going to be a very difficult year for flu vaccination. Most of the people who don’t want a COVID-19 vaccine don’t want a flu vaccine either. We just need to try as hard as we can.

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Tan: What is the best way to engage patients about getting influenza, COVID-19 — any of the vaccines recommended for them?

Russell: I think it’s more likely waning vaccine efficacy. We don’t really understand what we’re seeing, and we call it waning immunity. But realistically, the studies have shown that (influenza) vaccine is still effective later in the season. The wording about vaccine timing changes every year. But this year, they came out with about the strongest recommendations that we have had on when not to give the vaccine: For most patients, do not give it in July and August because we want to make sure that it does cover throughout the rest of the season. There are certain populations, though, that should get the vaccine as early as possible — children who need two doses of vaccine, pregnant women who are going to deliver during the flu season. The other person you may want to vaccinate early is the one you don’t think you’ll get back in.

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Russell: I think the biggest misconception about influenza is “I got the flu from the flu vaccine.” And one of the ways I like to talk about that is I compare it to getting a tetanus shot and having a sore arm after. I ask, “Do you think you had tetanus?” “Well, no, I think I just had a sore arm from the vaccine.” OK.

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Below are a few handy steps for determining the ideal Accucold refrigerator size for your clinic:

**Choosing the Right Sized Unit**

Below are a few handy steps for determining the ideal Accucold refrigerator size for your clinic:

1. Estimate the maximum number of doses of public/private purchased vaccines that will be in your refrigerator.

   **Pharma-Vac Refrigerators**

<table>
<thead>
<tr>
<th>Model</th>
<th>Capacity (cu ft)</th>
<th>Height (in)</th>
<th>Width (in)</th>
<th>Depth (in)</th>
<th>Door Type</th>
<th>Price</th>
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<tbody>
<tr>
<td>ARG1PV</td>
<td>1 cu ft</td>
<td>21.25</td>
<td>17.5</td>
<td>20</td>
<td>Glass</td>
<td>$610.00</td>
</tr>
<tr>
<td>ARG1PV</td>
<td>1 cu ft</td>
<td>21.25</td>
<td>17.5</td>
<td>20</td>
<td>Glass</td>
<td>$610.00</td>
</tr>
<tr>
<td>ARG3PV</td>
<td>3 cu ft</td>
<td>33.75</td>
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<td>18.5</td>
<td>White</td>
<td>$960.00</td>
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<tr>
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<td>6 cu ft</td>
<td>32.5</td>
<td>23.5</td>
<td>23.5</td>
<td>Glass</td>
<td>$1,072.00</td>
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<tr>
<td>ARG8PV</td>
<td>8 cu ft</td>
<td>32.5</td>
<td>23.5</td>
<td>23.5</td>
<td>Glass</td>
<td>$1,204.00</td>
</tr>
<tr>
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<td>12 cu ft</td>
<td>61.75</td>
<td>23.5</td>
<td>23.5</td>
<td>Glass</td>
<td>$1,788.00</td>
</tr>
<tr>
<td>ARG15PV</td>
<td>15 cu ft</td>
<td>72</td>
<td>23.5</td>
<td>24.5</td>
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<tr>
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<td>17.5</td>
<td>20</td>
<td>Glass</td>
<td>$610.00</td>
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2. Match your maximum doses with the minimum cubic feet needed to safely store your vaccine.

   **Pharma-Lab Freezers**

<table>
<thead>
<tr>
<th>Model</th>
<th>Capacity (cu ft)</th>
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<td>Glass</td>
<td>$610.00</td>
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3. Multiply (min) inventory x 1.25. Add the number of doses on your last order form.

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  - Sreeker Audimeter: Only $875.00
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  *Touch Screen Display

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— Mark J. Nelson, MD FACC, MPH

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November 2021
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1 Neuro-Cognitive Testing
- Medicare mandates yearly cognitive assessment
- Takes 10-15 minutes to prep patient, 20 minutes to test
- Analyzes: brain health (EEG), brain processing speed (Evoke Potentials), heart health (EKG), mental health (neuropsychology)
- Reimburses using 6 CPT codes, National Average = $750 - $1000 per test
- Each test is processed into a fully-finished, clinically actionable report
- Easy to understand biomarkers facilitate more informed medical interventions, such as biofeedback

2 ANS Testing
- Can be combined with SUDOMOTOR into 1 full system
- Takes less than 10 minutes to perform, software provides verbal cues
- Tests for autonomic balance, vascular health, physical/mental stress, peripheral nerve health and other critical hidden risk factors
- Reimburses $170/test using 3 CPT codes
- Provides a 1 page summary up to a full 24 page comprehensive report

3 SudoMotor Testing
- Can be combined with ANS into 1 full system
- Takes 3 minutes to analyze a patients’ hands and feet
- Provides a 1 page summary report
- Assesses peripheral nerve health (c-fiber function) and asymmetry between each hand and foot
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