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Fluzone High-Dose Quadrivalent vaccine is approved for use in persons 65 years of age and older.

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.

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 vaccine is manufactured and distributed by Sanofi Pasteur Inc. Fluzone High-Dose Quadrivalent vaccine (CPT® code 90662) is a covered benefit under Medicare Part B.

Flublok Quadrivalent vaccine is manufactured by Protein Sciences Corporation, a Sanofi company, and distributed by Sanofi Pasteur Inc. Flublok Quadrivalent vaccine (CPT® code 90682) is a covered benefit under Medicare Part B.

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

References: 1. Fluzone High-Dose Quadrivalent vaccine [Prescribing Information]. Swiftwater, PA: Sanofi Pasteur Inc.
2. Flublok Quadrivalent [Prescribing Information]. Meriden, CT : Protein Sciences Corporation.
Flublok Quadrivalent and Fluzone High-Dose Quadrivalent are vaccines indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and influenza 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.

**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.

**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 vaccine is manufactured and distributed by Sanofi Pasteur Inc. Fluzone High-Dose Quadrivalent vaccine (CPT® code 90662) is a covered benefit under Medicare Part B.

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

**References:**

1 INDICTIONS AND USAGE

Flublok® Quadrivalent (Influenza Vaccine), Rx Only
Sterile Solution for Intramuscular Injection

2019-2020 Formula

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

For Intramuscular Injection only.

2.1 Dosage

Administer Flublok Quadrivalent as a single 0.5 mL dose.

2.2 Administration

Invert the pre-filled syringe containing Flublok Quadrivalent gently prior to afferring 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.

3 CONTRAINDICATIONS

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

4 WARNINGS AND PRECAUTIONS

5.1 Managing Allergic Reactions

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

5.2 Guillain Barre Syndrome

The 1976 swine influenza vaccine was associated with an increased frequency of Guillain-Barre 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 Immunocompetence

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

5.4 Limitations of Vaccine Effectiveness

Vaccination with Flublok Quadrivalent may not protect all vaccine recipients.

6 ADVERSE REACTIONS

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

In adults 50 years of age and older, the most common (≥10%) injection site reactions were tenderness (34%) and pain (19%); the most common (≥10%) solicited systemic adverse reactions were headache (13%) and fatigue (12%) (see Clinical Trials Experience [6.1]).

6.1 Clinical Trials Experience

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

Flublok Quadrivalent has been administered to and safety data collected from 988 adults 18-49 years of age (Study 1) and 4328 adults 50 years of age and older (Study 2).

In Studies 1 and 2, local (injection site) and systemic adverse reactions were solicited with the use of a memory aid for 7 days following vaccination, unsolicited adverse events were collected for 28 days post-vaccination, and serious adverse events (SAEs) were collected for 6 months post-vaccination via clinic visit or remote contact. Study 1 included 1330 subjects 18 through 49 years of age for safety analysis, randomized to receive Flublok Quadrivalent (n=938) or Comparator (Fluarix Quadrivalent, manufactured by GlaxoSmithKline) as a placebo control (n=392) (see Clinical Studies [14] in the full prescribing information).

The mean age of participants was 33.5 years. Overall, 65% of subjects were white, 5% black/African American, 4% Asian, 4% Hispanic/Latino, 2% other racial groups, and 1% 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 1: Frequency of Solicited Local Injection Site Reactions and Systemic Adverse Reactions within 7 Days of Administration of Flublok Quadrivalent or Comparator in Adults 18-49 Years of Age, Study 1 (Reactivity Concentrations) 1-3

<table>
<thead>
<tr>
<th>Reactogenicity Term</th>
<th>Flublok Quadrivalent N=938 %</th>
<th>Comparator N=392 %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any Grade</td>
<td>Grade 3</td>
</tr>
<tr>
<td>Subjects with ≥1 injection site reaction</td>
<td>51</td>
<td>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>
</tbody>
</table>

Study 2 included 8672 subjects 50 years of age and older for safety analysis, randomized to receive Flublok Quadrivalent (n=4328) or Comparator (Fluarix Quadrivalent, manufactured by GlaxoSmithKline) as an active control (n=4344) (see Clinical Studies [14] in the full prescribing information).

The mean age of participants was 62.7 years. Overall, 56% of subjects were female, 80% white/Caucasian, 18% black/African American, 0.9% American Indian/Alaskan Native, 0.4% Asian, 0.2% Native Hawaiian/Pacific Islander, 0.7% other racial groups, and 5% of Hispanic/Latino ethnicity. Table 2 summarizes the incidence of solicited local and systemic adverse reactions reported within seven days of vaccination with Flublok Quadrivalent or Comparator.

Table 2: Frequency of Solicited Local Injection Site Reactions and Systemic Adverse Reactions within 7 Days of Administration of Flublok Quadrivalent or Comparator in Adults 50 Years of Age and Older, Study 2 (Reactivity Concentrations) 1-3

<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>Subjects with ≥1 injection site reaction</td>
<td>38</td>
<td>&lt;1</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>
<tr>
<td>Subjects with ≥1 systemic reactogenicity event</td>
<td>25</td>
<td>1</td>
</tr>
<tr>
<td>Headache</td>
<td>13</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Fatigue</td>
<td>12</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Muscle Pain</td>
<td>9</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Joint Pain</td>
<td>8</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>
Table 2: Frequency of Solicited Local Injection Site Reactions and Systemic Adverse Reactions within 7 Days of Administration of Flublok Quadrivalent in Adults 50 Years of Age and Older, Study 2 (Reactogenicity Populations) *(continued)*

<table>
<thead>
<tr>
<th>Reactogenicity Term</th>
<th>Flublok Quadrivalent n=4327</th>
<th>Comparator n=4327</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any Grade</td>
<td>Grade 3</td>
</tr>
<tr>
<td>Nausea</td>
<td>5</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Shivering / Chills</td>
<td>5</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Fever*</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

*Comparative vaccine = U.S.-licensed comparator quadrivalent inactivated influenza vaccine, Fluarix Quadrivalent, manufactured by GlaxoSmithKline.
*A placebo (saline) injection was given.
†Recovery from the vaccine injection site was considered sufficient for the injection site reactogenicity term.
‡Comparative = U.S.-licensed comparator quadrivalent inactivated influenza vaccine, Fluarix Quadrivalent, manufactured by GlaxoSmithKline.

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

<table>
<thead>
<tr>
<th>Reactogenicity Term</th>
<th>Flublok Quadrivalent n=4327</th>
<th>Comparator n=4327</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any Grade</td>
<td>Grade 3</td>
</tr>
<tr>
<td>Headache</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td>Fatigue</td>
<td>12</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Injection site reaction</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>Local reactions</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>Systemic reactions</td>
<td>10</td>
<td>9</td>
</tr>
</tbody>
</table>

*Comparative vaccine = U.S.-licensed comparator quadrivalent inactivated influenza vaccine, Fluarix Quadrivalent, manufactured by GlaxoSmithKline.
*A placebo (saline) injection was given.
†Recovery from the vaccine injection site was considered sufficient for the injection site reactogenicity term.
‡Comparative = U.S.-licensed comparator quadrivalent inactivated influenza vaccine, Fluarix Quadrivalent, manufactured by GlaxoSmithKline.

**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%.
*Comparative = U.S.-licensed comparator quadrivalent inactivated influenza vaccine, Fluarix Quadrivalent, manufactured by GlaxoSmithKline.
†Study 2 is registered as NCT02695998 under the National Clinical Trials registry.
‡Reactivity 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 mm (small), Grade 2=51 to <100 mm (medium), Grade 3=100 mm (large). Grade 4=neoncrosis or autoclave denaturation.
§Denominators for injection site reactions: Flublok Quadrivalent n = 4307, Comparator n = 4319.
‖Denominators for systemic reactions: Flublok Quadrivalent n = 4306, Comparator n = 4318.
‡Denominators for fever: Flublok Quadrivalent n = 4282, Comparator n = 4282.
*Fever defined as ≥100.4°F (99°F/90°F). Grade 1 (≥100°F to <101.1°F); Grade 2 (101.1°F to ≤102.2°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% (1/10) Flublok Quadrivalent recipients and 2 (0.6%) Comparator recipients. No SAESs 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. SAESs were reported by 145 (3.4%) Flublok Quadrivalent recipients and 152 (3%) Comparator recipients. No SAESs were considered related to study vaccine.

In the 28 days following vaccination, one or more unsolicited 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 Description [7] in the full prescribing information).

Flublok (trivalent formulation) has been administered to and safety data collected from a total of 13,077 subjects in clinical trials (Studies 3-7): 2497 adults 18 through 49 years, 972 adults 50 through 84 years, and 1078 adults 65 years and older. In Studies 3-5 and 7, SAESs were collected for 6 months post-vaccination. Study 6 collected SAESs through 30 days following receipt of vaccine. In Study 6, 18% of Flublok Quadrivalent recipients and 17% of Comparator recipients reported at least one adverse event. Most events were mild to moderate in severity.

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. SAESs were reported by 145 (3.4%) Flublok Quadrivalent recipients and 152 (3%) Comparator recipients. No SAESs were considered related to study vaccine.

In the 28 days following vaccination, one or more unsolicited 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 Quadrivalent (Influenza Vaccine), Sterile Solution for Intramuscular Injection 2019-2020 Formula

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 1.9% 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.

6.2 Postmarketing Experience
There is no post-marketing experience with Flublok Quadrivalent.

The following events have been spontaneously reported during post-approval use of Flublok (trivalent formulation). They are described because of the temporal relationship, the biologic plausibility of a causal relationship to Flublok (trivalent formulation), and their potential seriousness. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Immunologic disorders: anaphylaxis, anaphylactoid reactions, allergic reactions, and other forms of hypersensitvity.

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. Santor 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 Santor Pasteur Inc.'s vaccination pregnancy registry by calling 1-800-822-5663.

8.2 Lactation
Risk Summary
If it is 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 milk production/secretion.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Flublok (trivalent formulation) and any potential adverse effects on the breastfed child from Flublok Quadrivalent or from the underlying maternal condition. For precautionary vaccines, the underlying condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use
Data from a randomized, controlled trial demonstrated that children 6 months to less than 3 years of age had diminished hemagglutinin inhibition (HI) responses to Flublok (trivalent formulation) as compared to a U.S.-licensed influenza vaccine approved for use in this population, strongly suggesting that Flublok (trivalent formulation) would not be effective in children younger than 3 years of age. Safety and effectiveness of Flublok Quadrivalent have not been established in children 3 years to less than 18 years of age.

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 [6.4] in the full prescribing information).

Manufactured by Protein Sciences Corporation (Meriden, CT.)

US license 1795.

Distributed by Santor Pasteur Inc.

Flublok is a registered trademark of Protein Sciences Corporation.
Fluzone® High-Dose Quadrivalent

(1996-2016 Formula)

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

For intramuscular use only

2.1 Dose and Schedule

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

2.2 Administration

Inspect Fluzone High-Dose Quadrivalent visually for particulate matter and/or discoloration prior to administration. If either of these conditions exists the vaccine should not be administered.

Before administering a dose of vaccine, shake the prefilled syringe.

The preferred site for intramuscular injection is the deltoid muscle. The vaccine should not be injected into the gluteal area or areas where there may be a major nerve trunk. Do not administer this product intravenously.

Fluzone High-Dose Quadrivalent should not be combined through reconstitution or mixed with any other vaccine.

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

5.1 Guillain-Barré Syndrome

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

5.2 Preventing and Managing Allergic Reactions

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

5.3 Altered Immunocompetence

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

5.4 Limitations of Vaccine Effectiveness

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

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

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

Study 1 (NCT03282240, see https://clinicaltrials.gov) was a randomized, active-controlled, modified double-blind pre-licensure trial conducted in the U.S. The study compared the safety and immunogenicity of Fluzone High-Dose Quadrivalent to those of Fluzone High-Dose (trivalent formulation). The safety analysis set included 1777 Fluzone High-Dose Quadrivalent recipients, 443 Fluzone High-Dose recipients, and 451 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 3 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.

### 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>Injection Site Pain</th>
<th>Injection Site Erythema</th>
<th>Injection Site Swelling</th>
<th>Injection Site Induration</th>
<th>Injection Site Bruising</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluzone High-Dose Quadrivalent</td>
<td>Fluzone High-Dose</td>
<td>Fluzone High-Dose Quadrivalent</td>
<td>Fluzone High-Dose</td>
<td>Fluzone High-Dose Quadrivalent</td>
</tr>
<tr>
<td>Any</td>
<td>Grade 3</td>
<td>Any</td>
<td>Grade 3</td>
<td>Any</td>
</tr>
<tr>
<td>41.3%</td>
<td>0.7%</td>
<td>36.4%</td>
<td>0.2%</td>
<td></td>
</tr>
<tr>
<td>6.2%</td>
<td>0.6%</td>
<td>5.7%</td>
<td>0.2%</td>
<td></td>
</tr>
<tr>
<td>4.9%</td>
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Based on data from Fluzone High-Dose, solicited injection site reactions and systemic adverse reactions were slightly more frequent after vaccination with Fluzone High-Dose compared to a standard-dose vaccine.

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

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

6.2 Postmarketing Experience

The following additional adverse events have been spontaneously reported during the postmarketing use of Fluzone High-Dose, Fluzone, or Fluzone Quadrivalent and may occur in people receiving Fluzone High-Dose Quadrivalent. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. Adverse events were included based on one or more of the following factors: severity, frequency of reporting, or strength of evidence for a causal relationship to Fluzone High-Dose, Fluzone, or Fluzone Quadrivalent.

- **Blood and Lymphatic System Disorders**: Thrombocytopenia, lymphadenopathy
- **Immune System Disorders**: Anaphylaxis, other allergic/hypersensitivity reactions (including urticaria, angioedema)
- **Eye Disorders**: Ocular hypermia
- **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
- **Respiratory, Thoracic and Mediastinal Disorders**: Dyspnea, cough, wheezing, throat tightness, oropharyngeal pain, and rhinorrhea
- **Gastrointestinal Disorders**: Vomiting
- **Skin and Subcutaneous Tissue Disorders**: Stevens-Johnson syndrome
- **General Disorders and Administration Site Conditions**: pruritus, asthenia/ fatigue, chest pain, chills
8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

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

8.2 Lactation

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

8.4 Pediatric Use

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

8.5 Geriatric Use

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

Manufactured by:
Sanofi Pasteur Inc.
Swiftwater PA 18370 USA

INHDQ-BPLR-SL-NOV19 Revised: November 2019
very physician worries about getting sued for malpractice. The bad news is that it is a realistic worry.

Fred Cummings, JD, a malpractice defense attorney, told us that getting sued is not inevitable, but is a common outcome of practicing medicine. He says that one-third to one-half of all physicians can reasonably anticipate facing a lawsuit during their career. And of those physicians that are sued, about half can expect to be sued again.

So, what should you do if it actually happens?

Step one: Don’t panic. How a physician behaves after they have been served with a lawsuit can go a long way to determining the outcome of a case. One mistake can lead to disaster. But how do you know what you should—and shouldn’t—do while the case works its way through the legal system?

For our cover story in this issue, we talked with experts who provided us with solid, practical strategies physicians should use after they are served with a lawsuit.

In addition, our weekly video show features a recent interview with Cummings, where he talks about ways to avoid getting sued in the first place. It offers great tips physicians can use today to protect themselves.

You can find that interview, and episodes on a variety of other topics, at http://bit.ly/MedEcVideo.

In addition, this issue features articles on:

- How women are changing the medical profession, and the persistent challenges they face;
- Why making a budget is crucial to growing your practice;
- Tips to navigate sensitive and difficult conversations with patients about the costs of treatment; and
- A deep dive into the role that social determinants of health play in treatment of patients with chronic conditions such as diabetes, COPD and more.

As always, we welcome your feedback. If you have opinions on our content, article ideas, or would like to contribute to Medical Economics, please reach out to us at medec@mmhgroup.com.

Mike Hennessy, Sr.
Chairman and Founder
of MJH Life Sciences
Despite growing interest in the use of mobile health (mHealth) apps, doctors face significant hurdles both in evaluating these apps' effectiveness and using them to improve the health of their patients, a new study finds.

According to the study, more than 50 million people around the world use apps to determine if they need to see a doctor about a medical issue, while 26 percent of U.S. doctors have been asked about mHealth by a patient. Worldwide, 2.5 billion people own a mobile phone, creating enormous potential for accessing clinical diagnostics and treatment advice from physicians.

The challenge for healthcare professionals is finding evidence of effective clinical use of mHealth apps. The authors report that while a PubMed database search of “mHealth” returned more than 30,000 hits, “our analysis identified only a handful of clinical scenarios where use of mHealth apps is supported by the highest levels of evidence.” Few studies of mHealth apps are registered on clinicaltrials.gov, and many of the apps used in the studies they identified are not available in the Apple or Android app stores.

The absence of useful clinical evidence, the authors say, may be due to mHealth developers lacking the resources to fund large trials before releasing their apps, along with pressure from their investors to quickly demonstrate product growth. Consequently, many studies of app effectiveness rely on retrospective analyses of data from existing apps.

The results of these are difficult for doctors to apply in clinical settings, since app users generally are self-selected, and their outcomes might not apply to larger patient populations.
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A physician’s guide to surviving a malpractice case  PAGE 10

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How physicians behave after learning that they’re being sued for medical malpractice can determine the outcome of the case, regardless of its legal and medical merits. That’s why it’s important for physicians to know how to act upon being served notice of a lawsuit. Medical Economics spoke to malpractice defense attorneys and insurers to determine the do’s and don’ts to follow. The experts are:

**Ericka Adler**, a malpractice defense attorney with Roetzel & Andress in Chicago

**Richard Cahill, JD**, vice president and associate general counsel, The Doctors Company, a medical malpractice insurer

**Sam Rosenberg**, a malpractice defense attorney with Rosenberg Jacobs Heller & Fleming, P.C. in Morris Plains, N.J.
**THE DO’S**

- **NOTIFY YOUR INSURER AS SOON AS YOU’RE SERVED.**
  Not only does that get your insurer working on your behalf as soon as possible, it also means you’ll have legal representation faster, and that provides a protective shield for some conversations, says Adler. If doctors learn of a likely lawsuit before it’s filed, they should alert the insurer, she says.
  Employed physicians should notify their employers immediately as well.

- **LEARN ABOUT ATTORNEY-CLIENT PRIVILEGE.**
  This protects conversations between legal counsel and their clients from disclosure in lawsuits. However, it only applies once a client has retained or had counsel appointed, and only in conversations regarding the case. Defendants should talk about the case only when their attorney is present and only with those people who are relevant to the case, says Rosenberg, who adds, “Everything you say can be used against you.”

- **STUDY YOUR INSURANCE POLICY.**
  Doctors should review their malpractice policy to know exactly what is covered, the amount of coverage and what rights and responsibilities they have. Employed physicians should examine their contracts to determine their own and their employer’s responsibilities. While many policies give the physician final say in whether a suit is settled, many employment contracts give the employer that discretion.

- **ASK QUESTIONS.**
  It’s natural upon being sued for physicians to have multiple questions for their attorneys. Physicians should ask their attorney about how long the process will take, the steps involved, and any other questions they have.

- **TALK TO A MENTAL HEALTH PROFESSIONAL, IF NECESSARY.**
  Being sued for malpractice is a mental and emotional blow, and not being able to talk to friends and colleagues about it can place enormous stress on the physician. “To have an adverse event is bad enough; when it results in a lawsuit that’s even worse,” Cahill says. Conversations with mental health professionals are, of course, privileged.

**Who gets sued?**

According to the American Medical Association 2016 Benchmark Survey, 34 percent of physicians have a claim filed against them at some point in their careers and 16.8 percent have been sued twice or more.

Internists and family physicians were right at the national average in lawsuit frequency. General surgeons and ob/gyns had the highest rate of claims, while psychiatrists and pediatricians had the lowest.

The good news is that the frequency of malpractice lawsuits is declining. According to a 2019 study from medical insurer CRICO, the frequency of malpractice claims and suits per physician fell 27 percent over the past decade. However, the same study found that the volume of high-indemnity payments ($3 million to $11 million) resulting from those suits increased by 7 percent annually.

- **BE CAREFUL ABOUT TREATING THE PLAINTIFF.**
  Rosenberg estimates that 10 percent of defendants continue to treat the patients who are suing them. In those cases, they should treat them only for conditions unrelated to the lawsuit. Dropping the patient can be seen as an admission of guilt, he warns.

- **FOLLOW THROUGH.**
  Malpractice settlements and adverse judgments are reported to the National Practitioner Data Bank (NPDB) and state medical boards. This information follows physicians throughout their careers. Adler says she tries, when negotiating employment contracts with hospitals, to give doctors the right of approval for the language in the NPDB report. Doctors can appeal notification wording to the NPDB if they feel it’s unfair or inaccurate.

**THE DON’TS**

- **DON’T PANIC.**
  Being sued is common and the odds are in your favor. A 2012 study published in the Archives of Internal Medicine found that about 55 percent of claims resulted in a lawsuit. Of those litigated claims, more than half were dismissed by the court. Of the rest, most were settled before a verdict; less than 5 percent were decided by a trial verdict. And the verdict was in favor of the doctor 80 percent of the time.
Malpractice suits by state

The rate of malpractice suits varies widely by state, according to a study based on data from the National Practitioner Data Bank. Using data from 2015, the study found Louisiana to be the most medically litigious state with 44.1 malpractice suits per 100,000 residents. Hawaii was at the other extreme, with only 4.9 suits per 100,000 residents.

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"Physicians with electronic health records should exercise similar care," he says. "Changes to electronic entries should not be made without a clear notation that it is an addendum or a late entry—those should be made only on rare occasion, should be objective and not self-serving and should never attempt to falsely contradict prior entries."

DON'T INVESTIGATE.
The natural impulse upon being sued is to go back and review the case, looking for errors, incomplete records, the involvement or liability of other providers, etc. This could involve talking to colleagues, staff and others involved in the case, which can be seen as an effort to block the investigation or cover up wrongdoing.

DON'T TALK TO THE PLAINTIFF’S ATTORNEY.
It’s not uncommon for a plaintiff’s attorney to call or email the office of the defendant doctor with a request for records or other information, says Rosenberg. Do not respond to such requests or talk to anyone on the plaintiff’s side, because the conversation can be used against you, he says. Let your attorney handle all records requests. And, of course, don’t offer a settlement.

DON'T USE YOUR PERSONAL ATTORNEY.
Unless a doctor has been sued so often that his or her personal attorney is a malpractice specialist, it’s safer to be represented by an attorney appointed by the insurer or employer. They’re experts in malpractice law and are familiar with the tactics used by plaintiff’s attorneys. "Using your own attorney is like going to a podiatrist to treat your heart disease," says Rosenberg.

DON'T TAKE A SETTLEMENT PERSONALLY.
Most malpractice cases are settled out of court, often with no admission of wrongdoing. These settlements usually are driven by the insurer’s decision that it’s easier and less expensive to settle than to go to trial, Adler says. "For anyone to have to settle something when they’ve done nothing wrong is hard," she says. "A lot of it is really about money. It’s a business decision and not about whether the doctor is good or bad."
Biometric data: Another HIPAA risk to address

The Illinois Biometric Information Privacy Act (BIPA) of 2008 was the first state law in the country to regulate biometric data use. For physicians, the intersection of laws such as BIPA and the federal HIPAA law cannot be overlooked.

Let’s begin with the term “biometric.” Since various components of personally identifiable information (PII) are inherent in the definition of Protected Health Information (PHI), the HIPAA Privacy Rule applies to the de-identification of PHI. The HIPAA Privacy Rule sets forth two acceptable de-identification methods:

- expert determination (an expert is utilized to ascertain that an individual could not be identified); and
- safe harbor (no actual knowledge that PII, including biometrics, can identify an individual).

Satisfying either method demonstrates that the regulation has been met and that the likelihood of exposure is slim. HIPAA includes certain exceptions, such as for law enforcement purposes and the protections afforded to whistleblowers and workforce member crime victims.

It is important to realize that because a biometric falls under the category of PHI, entities must adhere to the Security Rule to ensure that adequate technical, administrative, and physical safeguards are in place to protect the confidentiality, integrity, and availability of the data.

BIPA also requires adequate technical, administrative and physical safeguards. And it applies to a variety of industries, ranging from healthcare to retail to hospitality to any employer who uses fingerprint technology for time keeping purposes.

As with PHI in relation to HIPAA, BIPA, in most instances, requires providing notice that the biometric information is being collected and stored, giving written notice of the specific purpose and length of time for which that biometric information will be used and stored; and obtaining written consent.

Healthcare is a bit different than simply using a biometric to log in to record hours worked, because the 6-7-year period of record retention serves another purpose—ensuring the continuity of patient care and treatment.

One key distinction between BIPA and HIPAA is that BIPA allows a private cause of action to be brought by individuals, without showing that actual harm occurred in order to recover damages.

There is no private cause of action expressly stated in HIPAA; rather, individuals typically sue under a common law negligence theory and use HIPAA as the standard to satisfy the elements of duty and breach. Causation and damages are items that still need to be proven in order to recover under a negligence case.

Compliance with HIPAA and any state privacy laws has never been more important. I’m still amazed at the number of practices that have not done a risk analysis in years or ever. This one item, a proper annual risk analysis, can prevent significant financial, legal, and reputational damage.

What’s PII?

Federal regulations define Protected Personally Identifiable Information (PII) as follows: an individual’s first name or first initial and last name in combination with any one or more of types of information, including, but not limited to,

- social security number
- passport number
- credit card numbers
- clearances
- bank numbers
- biometrics
- date and place of birth
- mother’s maiden name
- criminal, medical, and financial records
- educational transcripts

Rachel V. Rose, JD, MBA, advises clients on compliance and transactions in healthcare, cybersecurity, corporate and securities law. Send your legal questions to medec@mmhgroup.com.
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*Dr. Walter is UroLift System faculty and a paid consultant for NeoTract|Teleflex
1. AUA Guidelines 2003, 2010
2. Speakman et al. 2014 BJUI International
3. Roehrborn J Urol 2013 LIFT Study
4. Shore, Can | Urol 2014 Local Study
5. AUA BPH Guidelines 2003

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Budgeting for practice excellence

by TODD SHRYOCK Managing Editor

For many small practices, creating a budget is an annual exercise that culminates in a binder that sits on the shelf and collects dust for the remainder of the year. But experts say practices that don’t develop and regularly review a budget are missing out on a tool that can provide warning signs of financial trouble and fraud, and help make large purchases less disruptive to cash flow.

“If you think of a practice as a living body, the budget is like a vaccine,” says Rick Gundling, CMA, senior vice president for healthcare financial practices for the Healthcare Financial Management Association. “Having one doesn’t mean your practice’s health won’t go off track, but the risks are minimized. And when you check in on a periodic basis, that’s like your financial stethoscope.”

A solid, regularly reviewed budget sparks conversations between the physician and staff about potential trouble spots in the practice. “It keeps you informed instead of surprised and lets you take action before something becomes a problem,” Gundling says.

Janet Burns, business manager for University Family Medicine Center, a two-physician primary care practice in Orlando, says the importance of budgeting and watching overhead is not always obvious to physicians, because they don’t understand the value they can get from it.

“By looking at monthly numbers, I am able to find things that are happening that I otherwise would not be aware of,” she says.

CREATING A BETTER BUDGET

An effective budget does not have to be complicated, but should match the management style of the physician, or else it won’t be effective experts say.

Doctors who prefer high-level overviews with minimal details of the business should work from budgets with those same traits. Doctors who are detail-oriented may be interested in a budget with more line items that show expenses in greater detail, says Cindy Nyberg, CPA, CMPE, chief financial officer and strategic planning consultant for Fulcrum
Strategies, a physician consulting firm in Raleigh, North Carolina.

For example, medical supplies could be one broad category, or broken down into specific subcategories for greater detail.

Melissa Lucarelli, MD, a primary care physician in Randolph, Wisconsin, tried a detailed annual budgeting process but didn’t see any return on the time and cost of creating it. “For a small practice like mine, I don’t have the luxury of saying, ‘We’ll go into the red this month and make it up next month.’”

What works for her practice is a simpler accounting review of monthly expenses compared to what the practice has spent in the past. “We are just looking at how much do we have, how much are we getting in and how much do we need to pay each month,” says Lucarelli, a member of the Medical Economics editorial advisory board. “To me, it feels more agile and less stressful.”

“I always caution physicians to keep it as simple as possible,” says Nick Fabrizio, Ph.D., FACMPE, principal at the Medical Group Management Association. “Come up with a simple process you can use that monitors revenue and expenses. It’s OK to forget things when you start. It’s better to do that than to create an elaborate budget with 50 line items that is too difficult to understand and becomes this big, scary thing that no one wants to touch.” Detail may be great, but keep in mind that more detail also requires more staff time to track, he adds.

Lucarelli’s strategy for budgeting exemplifies the best approach—find what works, experts say. “There’s not one model you must use,” says Nyberg. “The budget has to serve the business.”

The first step in creating a budget is to look at revenue and payer mix, Nyberg says. This will not only establish a starting point, but offer insight into creating growth. “You can’t just say you’re going to increase revenue 10% next year,” she says. “If you are 50% Medicare, revenue is pretty much flat.”

Once revenue is established in the budget, Nyberg suggests organizing and dividing expenses into categories like staff compensation and benefits, occupancy expenses, furniture and equipment, medical expenses, miscellaneous expenses, midlevel provider expense and physicians expense. These broad categories make a budget much easier to understand, and if variances occur, practices can gather information to provide more detail and get a better idea of what is causing the changes.

3 quick budget tips

Monitor regularly
Review the budget at least monthly, and make sure the staff knows it is being monitored. Doing so can reduce the risk of embezzlement.

Make a copy
Print out the budget for anyone in the practice reviewing it so that it doesn’t become just another email that gets lost in the inbox.

Adapt with growth
Change the structure of the budget as needed to reflect practice growth. The budget used today won’t necessarily be the one that works five years from now.
“If you aren’t making financial decisions off every office and medical supply purchase, then put them together,” says Gundling. “If you need to go deeper, then do it.”

Communicate to the staff which expenses go in each category, because they may not always be obvious, Nyberg says. Some staff members may be involved in the budget-creation process, but who is included is largely a level of job function and physician comfort with sharing financial details.

“Getting input is great, but it depends on how much the owners want to share with the staff,” says Nyberg. “Eventually though, someone will be held responsible for trying to move the needle on budget goals and they should have some input into the creation process.”

USING A BUDGET TO IMPROVE THE PRACTICE
Once the budget is finalized, it must be reviewed at least monthly to be useful, experts say.

Gundling says physicians should look for trends—compare the current month’s numbers to the prior month and to the same month from the year prior. If a particular category is much higher or lower than it was previously, start asking questions.

“Once you understand the variance, then you can start formulating what to do,” says Gundling. “The budget causes you to ask the ‘what’ and the ‘why’ questions. It gives you more impetus to dig deep.”

If, for example, supplies are costing more than in the past, maybe a contract or supplier review is in order. If nothing can be done about the increase, then maybe money needs to be taken elsewhere from the budget to make up the difference and protect cash flow, says Gundling.

“Work with your staff to be very attuned to those variances to try to understand whether it’s a one-time thing or an ongoing problem,” he adds.

Fabrizio recommends looking at actual dollar amounts and not just percentage increases or decreases when reviewing. “Two percent in one category may be $100 while in others it might be $1,000,” he says. “If that extra $1,000 expense goes on for 10 months, you might have paid out $10,000 before you realize it.”

Burns explains that her practice’s budget functions as a guide on where to focus cost-cutting efforts. It can also be used to forecast returns on larger investments.

For example, Nyberg worked with a practice that was sending patients out for MRIs. “The physicians thought getting their own MRI machine would be a good investment so as to keep the money in-house, but a budget analysis showed that with 53% of their payer mix in Medicare and with the correspondingly small reimbursements, the machine would never pay for itself.

When a budget is done correctly and regularly reviewed, it can offer many beneficial insights into the financial health—present and future—of a practice.

“It’s one of those necessary things, but I think physicians look at budgeting like they look at having a tooth pulled,” Gundling says. “But budgeting really does help in having an ongoing conversation about the practice and minimizes surprises and maximizes cash flow. A budget allows you to stay on top of your practice.”
FINANCIAL STRATEGIES

Employee risk management: Three tips to avoid trouble

Proactively managing risk and avoiding harm is almost always cheaper and more predictable than managing any actual crisis.

Asset protection has three layers: a culture of compliance that helps avoid the most common risks; a well-developed insurance program to help cover any mistakes or accidents; and legal tools that separate risks and assets to back up anything not covered by the first two.

In this article we address one of the major risks physicians experience that does not involve patients: Risks from exposures related to your employees.

Employment law exposures are among the most common risks American business owners face and medical practices are no exception. In addition to the traditional claims related to wages and labor law, employers now must manage less tangible, more subjective issues.

Our socially- and politically-charged climate, including the #MeToo movement, requires attention and physician leadership. Businesses are up to five times more likely to be sued over an employment issue than for any other reason. In addition, employees are winning more often and the average sexual harassment lawsuit verdict is roughly $500,000.

Fortunately, this risk can be effectively managed in three simple steps:

1. Be adequately insured for both employment law related liability with EPLI (employment practices liability coverage) insurance and general liability and other specialty commercial insurance that protects the business from the vicarious liability of being an employer. For doctors, common exposures might include HIPAA employee breaches that reveal confidential patient information including photos or other identifying patient data or social media related liability for making defamatory statements or claims.

   Having these basics in place will put many medical practices ahead of their peers and not just help defend against such a claim, but ideally avoid ever facing one in the first place.

2. Create a culture of respect, compliance, and authority.

   Every workplace has its own “vibe,” some are formal and all business, others are more casual, fun and familiar. Either may be effective, but both need to start with a culture that observes and uniformly enforces good conduct among physicians, executives, and other staff. This means a willingness to be (or delegating someone to be) the adult in the room and address issues and set standards.

3. Have an enforced, custom drafted, state-law specific employment manual. Failing to do so means that many rules polices will be open to interpretation by your employees, and worse, the courts. I routinely find that many practices have no manual or have one they got off the internet or cobbled together themselves that may not be up to date or legally compliant.

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Between ever-changing regulatory requirements, more time spent interacting with electronic health records systems than with patients, and a lack of work/life balance, physicians are burning out at an unprecedented rate. Yet there is hope that the next generation of women physicians can address many of the systemic issues that currently plague the field of medicine.

But the question remains: will they be given the opportunity to do so?

When Diane Birnbaumer, MD, FACEP, emeritus professor in the department of emergency medicine at Harbor-UCLA Medical Center, was training to be a physician more than 30 years ago, she did a clinical rotation in otolaryngology with an older, well-established male surgeon. When she finished the rotation, the surgeon complimented Birnbaumer on her abilities, but also told her he wasn’t going to give her a good evaluation.

“I immediately asked, ‘Why?’” she says. “He told me, ‘Women will ruin medicine. All you want to do is come into medicine and make it part-time. Women want other things. Medicine just isn’t your passion the same way it is for [male physicians].’”

It would be easy to say that such a conversation is a relic of a time long gone, when men dominated the field of medicine and women were fighting just for the opportunity to show what they might bring to the examining room. After all, today about one-third of practicing physicians are women. And most of those, like Birnbaumer, have worked hard to advance in their careers.

And more and more women are entering the field. Per the Association of American Medical Colleges, women today not only make up the majority of medical school applicants but are enrolling and graduating from medical school at a rate slightly higher than their male counterparts.

Despite those growing numbers, Roberta Gebhard, DO, president of the American
Medical Women’s Association, says that women still face significant challenges as they pursue their careers. While they may not experience discrimination quite as blatant as Birnbaumer did when she was a trainee, there are still significant hurdles they must overcome.

“Even though we are seeing parity in the numbers, and we have for a couple years now, what we are not seeing is parity in pay for women or in the opportunities to advance in their careers,” she explains. “And it’s the kind of stuff that, over the course of a career, can really hold someone back from reaching their true potential.”

With so many women entering the field—and looming fears of physician shortages—many observers hope that women will help to transform medicine for the better. Women today constitute the majority of physicians in countries with highly effective healthcare services. But how can healthcare fulfill the promise of women in medicine when women continue to face the same systemic obstacles as previous generations?

**THE PROMISE — AND BARRIERS**

There is good reason why so many see women physicians as integral to solving many of medicine’s problems. Research studies suggest that women physicians spend more time with patients, on average, than men—and focus more on discussions about preventative medicine.

Female physicians are more likely to closely follow evidence-based clinical guidelines for care. And patients who see a female physician are less likely to be re-hospitalized within 30 days or succumb to their illnesses.

While many of these studies are small, the collective results suggest that, especially as medicine moves to value-based models of care, women doctors are a valuable asset to healthcare, says Susan Hingle, MD, MACP, a professor of medicine at Southern Illinois University School of Medicine and former chair of the American College of Physicians’ Board of Regents.

“These are very targeted studies, but in multiple situations and in multiple specialties, we see that women physicians are showing better outcomes than male physicians,” says Hingle, who co-authored a position paper regarding improving gender pay equity.

But studies also show the challenges women working in medicine commonly face. Timothy Hoff, Ph.D., a professor of management, healthcare systems, and health policy at Northeastern University, has been studying such barriers for decades. And despite the growing number of female physicians, many of those issues have not improved over time.

Hoff noted in a recent Medical Economics blog post that women are more likely to experience work-family conflicts, less likely to be promoted or selected for leadership positions, and still experience high rates of sexual harassment. On the whole, they also make significantly less money than similarly qualified male physicians.

“We have a fairly pervasive situation where physicians who are doing the same job are getting less money just because they happen to be women,” says Hoff. “That’s a problem. And these issues are deep-rooted and long-standing trends in this particular field that need to be addressed.”

**MOVING TOWARD CHANGE?**

Many physicians, even women physicians, say medicine is close to or has already achieved gender parity, says Gebhard. These physicians refer to their own personal successes, the growing number of female doctors and medical students, and the fact that high-profile leadership positions, including the presidency of the American Medical Association, are now being occupied by women. At times, Hoff says, it is difficult to see the discrepancies.

“Doctors are some of the most successful people in the country,” says Hoff. “They work and sacrifice an awful lot to get where they are. In some respects it’s difficult for people—once they reach what they think is the

“I want every single person in medicine to see women as leaders. I want them to see women taking on more demanding roles ... and succeeding, whether they have a family or not.”

—LATASHA SELIBY PERKINS, MD, FAMILY PHYSICIAN, WASHINGTON, D.C.
pinnacle of what they see as their own hard work and perseverance—to understand they are not being treated the same ways as their peers.”

At times, those very discrepancies can be used to make the case that medicine has become more female-friendly. In a recent *New York Times* article, three female physicians discuss how they make time for their growing families while continuing to work in medicine. One switched to a less demanding (and less lucrative) specialty where she could better control her hours. Another took a position as a hospitalist where she works predictable shifts. The third is working remotely, doing radiology scans from home.

“The possibility that the establishment might allow these women to stay in competitive, highly successful, and lucrative careers was never mentioned in this piece,” says Gebhard. “Men manage to have families and stay in those kinds of careers without a problem. But here, these women had to make sacrifices. They had to give up potential earnings and leadership positions. Is that really such a big improvement?”

While Birnbaumer acknowledges Gebhard’s point—and notes that these issues are not unique to medicine—she thinks the article shows that things are improving, albeit slowly, for women. And for male physicians, too.

“Thirty years ago, women had to choose between family and career. There was no middle ground,” says Birnbaumer. “But having women in the field has changed how medicine is practiced and just what is possible. Today, there are options so you can have a better work-life balance. Women drove that.

“And the male residents I work with are just as interested in options that allow them to have more time with their families,” she adds. “As more women enter the field, I think we’ll see more changes in the way medicine is practiced that will benefit everyone.”

**THE FUTURE IS FEMALE**

Experts agree that the medical profession is at least starting to recognize that it needs to change so that women can achieve greater parity, both in terms of opportunities for advancement as well as remuneration. Hoff suggests that addressing the myriad challenges that women face, including implicit biases about abilities and sexual harassment, as early as medical school will help to change them in the future.

“If medical schools and residency programs start addressing these issues during training—because that’s when they start—and challenge the way that women have historically been viewed and treated, it’s an important start,” he says. “We also need as many strong female role models as we can get into leadership positions so we can change those implicit biases people have about women.”

LaTasha Seliby Perkins, MD, a family physician in Washington, D.C., and a board member of the American Academy of Family Physicians, agrees. It’s one reason why she decided to take on a leadership position in the organization, even while experiencing a high-risk pregnancy.

“I want every single person in medicine to see women as leaders,” she says. “I want them to see women taking on more demanding roles in more demanding specialties and succeeding, whether they have a family or not. I want more women to apply for challenging jobs, to ask for more money, and know that they have earned their place at the table. That kind of visibility is vital not only to our success as women, but to the success of medicine as a whole.”

Krystal Savice, a third-year medical student at the Touro College of Osteopathic Medicine, has already taken on a leadership position as a student with the Student National Medical Association, and is set on becoming a residency director in the future. She intends to be the change she wants to see in the field.

“We women have made a lot of strides in medicine and are demonstrating just what is possible,” she explains. “We will become the leaders we need.”

**“We have a fairly pervasive situation where physicians who are doing the same job are getting less money just because they happen to be women. That’s a problem.”**

—TIMOTHY HOFF, PH.D., HEALTH POLICY PROFESSOR, NORTHEASTERN UNIVERSITY
A recent survey conducted by InstaMed, an online healthcare payments service, revealed that 93 percent of patients were surprised by their medical bill, including 61 percent who received a bill for more than expected and 50 percent who received an unexpected bill.

“This surprise and confusion stems all too often from a lack of communication between medical practices and their patients,” says Deirdre Ruttle, senior vice president of strategy and communications for InstaMed. “Patients are not usually aware of their responsibility until after a visit, which is unlike many other payment experiences where there is a clear price tag and an understanding of how to pay.”

But medical practices can remove the uncertainty in healthcare payments by communicating early with patients, setting expectations, and offering payment convenience. This includes talking about payment responsibility, insurance coverage and cost estimates, offering multiple payment options including online payments and automated payment plans, and enhancing patient convenience through electronic statements, email notifications and text notifications, experts say.

THE COST CONVERSATION

David Belk, MD, an internist in Alameda, Calif., says there was a time when most discussions about medical costs centered around questions like “Will insurance cover this?” or “How can we get insurance to cover this?”

“As nightmarish as those conversations were thought to be, such questions do seem rather quaint and simplistic by today’s standards,” he says, citing discussions today of questions like, “What does covered even mean?” “Can I afford this test or procedure even if it is covered?” and “Would I be better off not even using my insurance and just paying for the medical test or procedure myself?”

Brian P. Sanders, MD, a family physician at About You Family Medicine in Atlanta, Ga., says he’s finding that fewer people are shy about discussing cost of care.

“For folks that live paycheck to paycheck, the discussion involves how to save up to afford a more expensive but necessary evaluation or treatment or procedure,” he says. “Without these discussions, many patients would oftentimes not get any medical care or allow the problem to fester until it becomes a more expensive emergency.”

Troy Russell, MD, a family doctor in Lynn, Mass., notes that for about half the medications he prescribes, patients will ask wheth-
er it is covered by insurance. He’s also asked routinely whether all the medications they take are absolutely necessary.

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“Patients are often most concerned about costs of specialty medications like insulin, Remicade, and Xarelto,” he says. “My response is usually that we try to use generic medications first, try to use coupon programs like GoodRx and if that doesn’t work, we pursue prior authorization through insurance.”

Katarina Lindley, DO, FACOFP, a direct primary care family physician in Brock, Texas, says she discusses pricing and affordability with patients almost daily. For example, when she orders labs or imaging for patients, she helps them decide where to have them done.

Some patients prefer to pay directly rather than going through insurance because deductibles are so high.

“An example is, I can get labs for an annual physical for about $20, but with insurance it can be $150-500 if the patient has not reached their deductible,” she says.

The same is true with medications. Before prescribing, Lindley discusses with her patients if they can afford them. Such discussions are important, she says, because patients sometimes are embarrassed to say they cannot pay for meds and won’t get them filled.

“My job as their doctor is not only to help them recover from or control an illness but also to look at their overall health and at times that means financial needs as well,” she says. “All physicians should have these discussions with patients, because they may not be compliant and their blood pressure is still high because they could not pay for that third medication.”

Jeffrey Gold, MD, a pediatrician in Marblehead, Mass., notes that a typical discussion will find him showing a patient what lab test pricing is compared to what a typical hospital charges, using websites such as mymedicalshopper.com and healthcarebluebook.com.

“I once saved a patient $2,000 for a cardiac stress test by sending him to Derry, New Hampshire, versus our local hospital,” he says. “Obviously, this was a low probability test and non-urgent, and it took him two weeks to get a reply from his insurer as to what his out-of-pocket payment would be. But it was something that was greatly appreciated.”

NAVIGATING THE DISCUSSION

Russell routinely has his medical assistant screen for financial or social economic barriers to care so he’s prepared for where the conversation will go.

“Some patients are not interested in telling me these issues unless it is really bothering them,” he says. “Since my medical assistant staff are native Spanish speakers and culturally able to connect better with some patients, they are able to elicit this information a little easier.” They do this, he says, simply by asking if the patient has any questions or concerns.

Gold says physicians need to be open and honest, and not just say what the patient wants to hear. “Most people still don’t even understand what coinsurance, deductibles or networks are, and the conversations are still not as prevalent as I would like them to be, but definitely more common,” he says. “If you’re honest with them about their options, it can drive the relationship even further.”

RECOMMENDING RESOURCES

One of the most common questions patients ask physicians is where they can find help in reducing their out-of-pocket costs. Doctors say prescription drugs often are a good place to start.

“Most people believe that they’re getting a good deal from their insurance if they’re only paying a $5-$10 monthly copay for a generic medication,” Belk says. “They’re usually wrong about that.”
PRACTICAL MATTERS

5 tips for growing your medical practice

1 EVALUATE WHERE YOU STAND.
Make sure you have a firm grasp of the current state of your business. Assess your revenue, costs, budget, and staff productivity on a recurring basis. Celebrate your strengths and current successes, but also make an honest evaluation of your biggest weaknesses and needs as a business. And don’t forget the last step: document the assessment to ensure follow-up and execution.

It may seem obvious on the front end, but starting—and maintaining—a routine of self-monitoring and assessment is an essential first step for scaling and fostering long-term success at your practice.

2 DREAM—THEN SET REALISTIC EXPECTATIONS.
Are you looking to expand your services? Have you had your eye on some new equipment or exciting technology? Wish you could move into a larger, sleeker office space? That’s great—as the office entrepreneur, give yourself permission to be creative and think big.

But chances are you can’t do everything you want in the near term.

Try to determine what can realistically be done in one, three, and five years given your patient panel, prospective revenue, and responsibilities. By embarking on this exercise, you’ll find that you’re less likely to get overwhelmed trying to achieve all of your goals. Creating a documented plan to manage the change will keep you on track.

3 DETERMINE WHAT KIND OF FINANCING IS BEST FOR YOU.
Expanding your footprint can be exciting—but price barriers can get in the way. Practice startup costs alone run upwards of $100,000. So if you’re looking to grow your practice, you’ll need to evaluate what borrowing options will work best for you.

Remember, interest rates don’t tell the whole story—there are account fees, premiums, and other closing costs to consider. Always scrutinize the details and entirety of the lending relationship before making a decision.

A key consideration is the term of your loan. Cash-flow is extremely important, and while you may want to do a quick payoff, that can create a cash flow crunch. Most loans will allow you to pay down the debt quicker if things are going well.

SBA loans can be especially helpful for doctors who are looking to open, acquire, or expand a practice because of a federal guarantee of up to 85%. That means there’s less risk for the lender and easier access for the borrower.

When you’ve figured out what type of financing works best for you, don’t just let the banks interview you—interview them as well. You’ll find that some have expertise and experience dealing with certain types of businesses—including medical practices. Often, the business savvy they bring is every bit as important as the financing itself. Do your research and ask questions.

4 FORMALIZE YOUR THOUGHTS IN A BUSINESS STRATEGY.
Once you’ve arrived at a strategy, put pen to paper. Your bank or lender of choice can assist with developing your business plan, setting financial goals and parameters, and weighing financial gain against your interests and passions as a physician.

From there, it’s time to go shopping—but stick to your plan and your budget. Any smart lender will make sure you do so. It’s mutually beneficial.

5 CAREFULLY BUILD YOUR TEAM.
Human capital is your most important growth area, and it’s where you’ll be investing the majority of your money.

Whether you’re adding a partner, hiring a non-physician provider, or bringing on an office manager to help with the administrative load, you’ll want to take extra care to choose team members that will be the right fit for your practice in the long run. Unlike a big company, each employee represents a significant chunk of your business.

Resist the temptation to hire quickly because of immediate demands or pressures. This is where the best plans are often ruined. Focus instead on curating a high-quality staff for sustainable growth.

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Small medical practices must perform many information technology (IT) functions—EHR system management, cybersecurity, imaging, billing, and controlling and keeping tabs on infrastructure operations, among others—to achieve the clinical and financial outcomes necessary for their success.

While most such offices don’t have in-house IT staff, some do, whether they train existing personnel to perform these functions or hire dedicated staff who already have these skills.

This article looks at both approaches, examining the pros and cons of each, and when, or if, it makes sense to combine them.

Before a practice decides who will oversee its IT functions, it must know which functions are essential to clinical and financial success. EHRs are a given, but so is a practice management system that integrates patient data with health records and creates a workflow that expedites patient appointments.

To accomplish this, the EHR must have an API (Application Programming Interface) that has easy back-and-forth communication with the management system, and both components must be HIPAA-compliant. While not mandatory, it’s certainly desirable to have a patient portal that lets patients access their appointment schedules and records online.

**COST & RISK**

The tradeoffs of hiring IT staff versus outsourcing the function is that a practice has greater operational control over employed staff, but assumes higher costs and risks, says Graham Caparulo, principal consultant with Diligex, a New York City-based provider of outsourced IT services to small and medium-sized medical practices.

“On the risk side, if you have your own staff and a data breach, there’s no one to point the finger at except yourself,” Caparulo says. (Under the HIPAA Omnibus Rule, if a contractor has signed a HIPAA Business Associate agreement with the practice to comply with HIPAA privacy, security and breach notification requirements, it is liable for any HIPAA infractions it commits.)
Contracting out IT lets a practice focus on its core business of providing healthcare. Moreover, the practice may get a broad base of contract employees with a wide variety of technical competencies, and it’s not left exposed if the in-house IT staffer gets sick, goes on vacation, or leaves the practice.

“The average tenure of an IT person is about two or three years,” says Caparulo, “so do you want to go through this every couple of years or shift that over to somebody else?”

Before hiring outside contractors, the practice needs to conduct a thorough internal inventory to determine what the staff members and doctors already know about the existing IT system, identify their IT product and service needs, then develop a Request for Proposals based on those precise needs.

‘SUPER-USERS’

At some point, however, it usually makes sense for a small practice to hire someone for what Caparulo calls “level one or front-end triage issues,” such as if a front-desk staffer can’t log in to the EHR, access e-mail, or print out a medical record. In those instances, it’s better to have a more technically adept practice employee on hand to solve the problem. “They’ll likely get things resolved quicker than if they go through an outsourced provider,” says Caparulo.

A practice that doesn’t outsource its IT functions might train its own employees—even if they have little or no IT experience—instead of hiring someone. While this approach certainly costs less than hiring a full-time, dedicated IT employee, the question becomes: is it worth the time to train a tech neophyte currently on the practice’s staff, and will the growth in size and complexity of an IT structure be too much for that staffer to manage in the future? It might be easier to choose this path if the practice’s IT vendor makes training and system support part of the services it provides.

On the other hand, many people today are increasingly comfortable with sophisticated digital technology, says Ken Hertz, FACMPE, a principal with MGMA Health Care Consulting Group, in Englewood, Colo. These staffers can learn the workings of the EHR and perform certain IT functions in a practice, potentially removing the need for a full-time IT employee.

These “super users” can be and are highly trained in software, and in understanding and problem-solving with the EHR or practice management software. A vendor can furnish that training.

“Now, they’re not going to solve your network problems and things like that,” Hertz cautions, while noting that super-users who develop more experience handling software can sometimes help with networking and hardware problems as well.

But the more complex services, such as interoperability and telemedicine, ought to be left to contract experts, Hertz says. “You want somebody who knows all about HIPAA issues, cybersecurity issues, encoding messages and so forth.”

SUBCONTRACTING

For some small practices—like that of Karen Smith, MD, a family physician in rural Raeford, N.C.—hiring new or training existing in-house staff isn’t an option. First, the cost is prohibitive—about $30,000 per year, according to practice administrator Michael Hendricks. That would be an operations budget-buster for Smith.

Second, it’s more practical to use a sub-contractor from nearby Ft. Bragg to provide IT support. “Even if we had an IT specialist to come in and train us it’s out of our purview because we would literally have to study that technology and know what the upgrades are,” explains Smith.

Each service the practice installs incurs training costs. It’s also highly important that the contractor have an industry-specific knowledge base.

“Subcontract with someone who stays up to date with technology and who understands healthcare,” Smith says. “You really need an IT person who understands the nuances of medicine.”

Practices also should understand how IT pricing works. More labor-intensive functions, such as a help desk, are likely to be costly, Hertz says. But vendors may charge a lower monthly fee for certain standard services, such as security, anti-virus security, back-up, monitoring alerts, and hardware support.

Finally, Hertz says, a vendor contract should address response time for dealing with technical issues or downtime. “They may say, ‘Yeah, we said we’d be onsite, but didn’t you read the part of the contract where we said we’d probably be there within three days?’”

“On the risk side, if you have your own staff and a data breach, there’s no one to point the finger at except yourself.”

— GRAHAM CAPARULO, PRINCIPAL CONSULTANT, DILIGEX, NEW YORK CITY
At Northwest Permanente, a Portland, Ore.-based medical group of more than 1,400 physicians, a 15-year-old female patient, “Jennifer,” visited the Kaiser Permanente Emergency Department 34 times in an 18-month period. Diagnosed with Type 1 diabetes, the girl had developed major depression. Suicide attempts took her to the ED twice, and her other visits were due to symptoms of uncontrolled sugars.

Rather than simply treating the diabetes and depression, the medical team began digging deeper into Jennifer’s life. She had been missing school regularly. She lived with her brother and her mother, who speaks only Spanish and works two jobs, keeping her away from home most of the time. Their apartment had holes in the floor, and mold and mildew in many corners, says Imelda Dacones, MD, president and CEO at Northwest Permanente, P.C.

Northwest Permanente connected Jennifer with a social worker who linked her and her family with a Latina community health worker. Through that community health worker, the family found better, more affordable housing and applied for financial assistance. With increased financial stability, Jennifer’s mom no longer needed to be away from home all the time.

After building trust with authorities, Jennifer agreed to start seeing a mental health therapist and to follow up more frequently with her physicians.
regularly with her doctor. She got control of her diabetes and mental health, and graduated from high school. Now Jennifer is in college and is thinking about a job in healthcare.

“Jennifer’s main issues were not her depression and diabetes,” Dacones says. “Her medical diagnoses—just as for all of us—do not define who she is. Screening for and helping to address the things most important to our lives empower us, ultimately, to own our total health. If we had only addressed her diabetes and depression through a ‘medical lens,’ I don’t know where she’d be today.”

Jennifer’s story exemplifies the importance of social determinants of health (SDOH), and how doctors can help improve health outcomes by taking note of the non-medical factors that may be affecting patients’ health.

Up to 90 percent of health outcomes are a result of social, behavioral and economic factors, according to recently-published data in *JAMA Open Network*. And research shows that screening for the five leading SDOH—food security, housing access, transportation issues, utility needs and interpersonal violence—can greatly improve patient outcomes.

However, 33 percent of physician practices do not screen for any SDOH and just 16 percent screen for all five of the leading SDOH. Without the first four, patients may not be able to purchase, store or take needed medications, or they may experience high levels of stress, anxiety and fear, making them less likely to pay attention to other health concerns.

Physician practices are primarily focused on clinical care, but their clinical work will be more successful if they start paying attention to patients’ needs beyond medicine.

“We should be managing the entire patient, not just the medical portions of their care,” says Nupur Mehta, MD, associate senior medical officer at CareMore Health, a physician-led integrated care delivery system. “Considering not just the medical needs, but also the entire spectrum of things that a patient may benefit from has been invaluable in achieving the outcomes that we have attained. Not to mention, it’s the right thing to do.”

**INCORPORATING SCREENING**

Physician practices can help patients attain their clinical care goals and take control of their overall health by incorporating SDOH screening into their check-in procedures. For instance, at CareMore, office staff screen for SDOH with Healthy Start, a comprehensive assessment intended to gain more insight into the patient’s medical, social and behavioral needs and to appropriately triage them into disease management programs and services to support their care.

In addition, any time a clinician is concerned about a patient’s needs, they are trained to ask about access to core needs such as food, housing, and transportation.

Northwest Permanente includes questions about SDOH with other data that is entered into each patient’s electronic health record upon arrival, “much like you input vital signs and other information about the patient,” Dacones says. “Having the form for this information in the EHR in front of you prompts one to collect the data in the first place.”

Atrius Health, a group of 36 medical practices in Massachusetts, screens for nine SDOH every time a child comes in for an annual pediatric checkup. The group uses a questionnaire, which screens for a family’s access to permanent housing, employment, ability to pay utilities, and access to food, transportation, childcare, and mental health resources.

“This annual check-in sees what’s happening outside of the clinic that can affect this child’s health for the rest of their life,” says Stephen Parodi, MD, chairman of the Council for Accountable Physician Practices (CAPP) which represents Atrius Health and other large physician-led and ACO-focused medical groups.

**COMPLETING THE LOOP**

Uncovering non-clinical needs that affect patients’ health isn’t the final step. When a practice finds that patients are hungry or lacking secure housing, they have a responsibility to take the next step and assist in helping find a solution. Various practices handle this responsibility in different ways.

Kaiser Permanente has added a specific staff role to support this work, called patient navigators. “Navigators
Chronic Conditions

are front-line public health workers and non-clinically licensed staff who are extensions of the clinical care team,” Dacones says. “They are there to help address the social and non-medical needs of our members by building trusting relationships with patients, helping them to connect with resources in their communities, and to activate individual patients’ care plans.”

For some patients, navigators provide resources and information that patients use to get their needs met on their own. For those needing more help—such as those with a language barrier or without a strong support system—a social worker or other staff member may help them apply for housing or other community resources.

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HARNESSING TECHNOLOGY

But even when physician practices screen for SDOH, disconnect between their offices, other care providers, and various community and social agencies can prevent patients from getting the help they need to improve their health outcomes. But some practices and regional groups are finding ways to use technology to simplify the process and ensure that patients get help when needed.

Kaiser Permanente, for example, is launching Thrive Local, a new social care network that will connect member practices and patients to community-based social services providers. Because the cloud-based network will be available to staff throughout the system, as well as to community agencies, it will be easier to refer patients to the help they need and follow up to make sure they received that help.

“The goal is to create a more holistic connection between the medical and social sectors to address total health, moving beyond screening and one-way referrals to a bi-directional, closed loop referral system with a robust network of social care providers.”

—IMELDA DACONES, MD, PRESIDENT AND CEO, NORTHWEST PERMANENTE, P.C.

At CareMore, patients who screen positive for an SDOH question are referred to an in-house team of case management and community health workers. Working alongside clinicians, the case management team helps connect patients with resources to address their social and medical needs, Mehta says.

And at Arius, the provider reviews a patient’s answers from the screening to understand any potential needs. “Physicians then help connect patients with the resources to help,” Parodi says. “They also have case managers and social workers on staff, and a care facilitator will connect patients with other resources in the community.”

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And at Arius, the provider reviews a patient’s answers from the screening to understand any potential needs. “Physicians then help connect patients with the resources to help,” Parodi says. “They also have case managers and social workers on staff, and a care facilitator will connect patients with other resources in the community.”

“The goal is to create a more holistic connection between the medical and social sectors to address total health, moving beyond screening and one-way referrals to a bi-directional, closed loop referral system with a robust network of social care providers.”

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