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SELECTED SAFETY INFORMATION

Contraindications: STEGLATRO is contraindicated in patients with severe renal impairment, end-stage renal disease, or on dialysis, and/or a history of a serious hypersensitivity reaction to ertugliflozin.

Hypotension: STEGLATRO causes intravascular volume contraction. Symptomatic hypotension may occur after initiating STEGLATRO, particularly in patients with impaired renal function (estimated glomerular filtration rate (eGFR) less than 60 mL/min/1.73 m²), elderly patients (≥65 years), patients with low systolic blood pressure, or patients on diuretics. Before initiating STEGLATRO, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms after initiating therapy.

Ketoacidosis: Ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, has been reported in patients with type 1 and type 2 diabetes receiving sodium glucose co-transporter 2 (SGLT2) inhibitors, including STEGLATRO. Some cases were fatal. Assess patients with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If ketoacidosis is suspected, STEGLATRO should be discontinued, patients should be evaluated, and prompt treatment should be instituted. Before initiating STEGLATRO, consider risk factors for ketoacidosis, including pancreatic insulin deficiency from any cause, caloric restriction, and alcohol abuse. In patients treated with STEGLATRO, consider monitoring for ketoacidosis and temporarily discontinuing STEGLATRO in clinical situations known to predispose to ketoacidosis (e.g., prolonged fasting due to acute illness or surgery).

Acute Kidney Injury and Impairment in Renal Function: STEGLATRO causes intravascular volume contraction and can cause renal impairment. There have been postmarketing reports of acute kidney injury, some requiring hospitalization and dialysis, in patients receiving SGLT2 inhibitors. Before initiating STEGLATRO, consider factors that may predispose patients to acute kidney injury. Consider temporarily discontinuing STEGLATRO in any setting of reduced oral intake or fluid losses; monitor patients for signs and symptoms of acute kidney injury. If acute kidney injury occurs, discontinue STEGLATRO promptly and institute treatment.

STEGLATRO increases serum creatinine and decreases eGFR. Patients with moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m²) may be more susceptible to these changes. Renal function abnormalities can occur after initiating STEGLATRO. Renal function should be evaluated prior to initiating STEGLATRO and periodically thereafter. Use of STEGLATRO is not recommended when eGFR is persistently between 30 and less than 60 mL/min/1.73 m² and is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m².

Urosepsis and Pyelonephritis: There have been postmarketing reports of serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization in patients receiving SGLT2 inhibitors. Cases of pyelonephritis also have been reported in patients treated with STEGLATRO in clinical trials. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated.
SELECTED SAFETY INFORMATION (continued)

**Lower Limb Amputations:** An increased risk for lower limb amputation has been observed in clinical studies with another SGLT2 inhibitor. Across seven Phase 3 clinical trials with STEGLATRO, nontraumatic lower limb amputations were reported in 1 (0.1%) patient in the comparator group, 3 (0.2%) patients in the STEGLATRO 5-mg group, and 8 (0.5%) patients in the STEGLATRO 15-mg group. A causal association between STEGLATRO and lower limb amputation has not been definitively established. Before initiating STEGLATRO, consider factors that may predispose patients to the need for amputations. Monitor patients and discontinue STEGLATRO if complications occur. Counsel patients about the importance of routine preventative foot care.

**Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues:** Insulin and insulin secretagogues (eg, sulfonylurea) are known to cause hypoglycemia. STEGLATRO may increase the risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with STEGLATRO.

**Necrotizing Fasciitis of the Perineum (Fournier’s Gangrene):** A rare but serious and life-threatening necrotizing infection requiring urgent surgical intervention has been reported in post-marketing surveillance in females and males with diabetes mellitus receiving SGLT2 inhibitors. Serious outcomes have included hospitalization, multiple surgeries, and death. Patients treated with STEGLATRO presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise, should be assessed for necrotizing fasciitis. If suspected, start treatment immediately with broad-spectrum antibiotics and, if necessary, surgical debridement. Discontinue STEGLATRO, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control.

**Genital Mycotic Infections:** STEGLATRO increases the risk of genital mycotic infections. Patients who have a history of genital mycotic infections or who are uncircumcised are more likely to develop genital mycotic infections. Monitor and treat appropriately.

**Increases in Low-Density Lipoprotein Cholesterol (LDL-C):** Dose-related increases in LDL-C can occur with STEGLATRO. Monitor and treat as appropriate.

**Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with STEGLATRO.

The most common adverse reactions associated with STEGLATRO (≥5%) were female genital mycotic infections.

**INDICATION**

STEGLATRO is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. STEGLATRO is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

Please read the adjacent Brief Summary of the Prescribing Information.
Brief Summary of the Prescribing Information

**STEGLATRO™ (ertugliflozin) 5 mg, 15 mg tablets**

**INDICATIONS AND USAGE**

STEGLATRO™ is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

**Limitations of Use**

- STEGLATRO is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

**DOSAGE AND ADMINISTRATION**

**Recommended Dosage.** The recommended starting dose of STEGLATRO is 5 mg once daily, taken in the morning, with or without food. In patients tolerating STEGLATRO 5 mg once daily, the dose may be increased to a maximum recommended dose of 15 mg once daily if additional glycemic control is needed. In patients with volume depletion, correct this condition prior to initiation of STEGLATRO (see Warnings and Precautions).

**Patients with Renal Impairment.** Assess renal function prior to initiation of STEGLATRO and periodically thereafter (see Warnings and Precautions). Use of STEGLATRO is contraindicated in patients with an eGFR less than 30 mL/minute/1.73 m² [see Contraindications]. Initiation of STEGLATRO is not recommended in patients with an eGFR of 30 mL/minute/1.73 m² to less than 60 mL/minute/1.73 m² [see Warnings and Precautions and Use in Specific Populations]. Continued use of STEGLATRO is not recommended when eGFR is persistently between 30 and less than 60 mL/minute/1.73 m². No dose adjustment is needed in patients with mild renal impairment.

**CONTRAINDICATIONS**

- Severe renal impairment, end-stage renal disease (ESRD), or dialysis (see Warnings and Precautions and Use in Specific Populations).
- History of a serious hypersensitivity reaction to STEGLATRO.

**WARNINGS AND PRECAUTIONS**

**Hypotension.** STEGLATRO causes intravascular volume contraction. Therefore, symptomatic hypotension may occur after initiating STEGLATRO (see Adverse Reactions) particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m²) [see Contraindications]. Initiation of STEGLATRO is not recommended in patients with an eGFR of 30 mL/minute/1.73 m² to less than 60 mL/minute/1.73 m² [see Warnings and Precautions and Use in Specific Populations]. Continued use of STEGLATRO is not recommended when eGFR is persistently between 30 and less than 60 mL/minute/1.73 m². No dose adjustment is needed in patients with mild renal impairment.

**Ketoacidosis.** Reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, have been identified in clinical trials and postmarketing surveillance in patients with type 1 and type 2 diabetes mellitus receiving sodium glucose co-transporter-2 (SGLT2) inhibitors and cases have been reported in STEGLATRO-treated patients in clinical trials. Across the clinical program, ketoacidosis was identified in 3 of 3,409 (0.1%) of STEGLATRO-treated patients and 0% of comparator-treated patients. Fatal cases of ketoacidosis have been reported in patients taking SGLT2 inhibitors. STEGLATRO is not indicated for the treatment of patients with type 1 diabetes mellitus (see Indications and Usage).

Patients treated with STEGLATRO who present with signs and symptoms consistent with severe metabolic acidosis should be assessed for ketoacidosis regardless of presenting blood glucose levels, as ketoacidosis associated with STEGLATRO may be present even if blood glucose levels are less than 250 mg/dL. If ketoacidosis is suspected, STEGLATRO should be discontinued, patient should be evaluated, and prompt treatment should be instituted. Treatment of ketoacidosis may require insulin, fluid and carbohydrate replacement.

In many of the reported cases, and particularly in patients with type 1 diabetes, the presence of ketoacidosis was not immediately recognized and institution of treatment was delayed because presenting blood glucose levels were below those typically expected for diabetic ketoacidosis (often less than 250 mg/dL). Signs and symptoms at presentation were consistent with dehydration and severe metabolic acidosis and included nausea, vomiting, abdominal pain, generalized malaise, and shortness of breath. In some but not all cases, factors predisposing to ketoacidosis such as insulin dose reduction, acute febrile illness, reduced caloric intake due to illness or surgery, pancreatic disorders suggesting insulin deficiency (e.g., type 1 diabetes, history of pancreatitis or pancreatic surgery), and alcohol abuse were identified.

Before initiating STEGLATRO, consider factors in the patient history that may predispose to ketoacidosis, including pancreatic insulin deficiency from any cause, caloric restriction, and alcohol abuse. In patients treated with STEGLATRO consider monitoring for ketoacidosis and temporarily discontinuing STEGLATRO in clinical situations known to predispose to ketoacidosis (e.g., prolonged fasting due to acute illness or surgery).

**Acute Kidney Injury and Impairment in Renal Function.** STEGLATRO causes intravascular volume contraction and can cause renal impairment (see Adverse Reactions). There have been postmarketing reports of acute kidney injury some requiring hospitalization and dialysis in patients receiving SGLT2 inhibitors.

Before initiating STEGLATRO, consider factors that may predispose patients to acute kidney injury including hypovolemia, chronic renal insufficiency, congestive heart failure and concomitant medications (diuretics, ACE inhibitors, ARBs, NSAIDs). Consider temporarily discontinuing STEGLATRO in any setting of reduced oral intake (such as acute illness or fasting) or fluid losses (such as gastrointestinal illness or excessive heat exposure); monitor patients for signs and symptoms of acute kidney injury. If acute kidney injury occurs, discontinue STEGLATRO promptly and institute treatment.

STEGLATRO increases serum creatinine and decreases eGFR. Patients with moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m²) may be more susceptible to these changes. Renal function abnormalities can occur after initiating STEGLATRO (see Adverse Reactions). Renal function should be evaluated prior to initiating STEGLATRO and periodically thereafter. Use of STEGLATRO is not recommended when eGFR is persistently between 30 and less than 60 mL/min/1.73 m² and is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m² [see Dosage and Administration, Contraindications, and Use in Specific Populations].

**Urosepsis and Pyelonephritis.** There have been postmarketing reports of serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization in patients receiving SGLT2 inhibitors. Cases of pyelonephritis also have been reported in STEGLATRO-treated patients in clinical trials. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated (see Adverse Reactions).

**Lower Limb Amputation.** An increased risk for lower limb amputation (primarily of the toes) has been observed in clinical studies with another SGLT2 inhibitor. Across seven Phase 3 clinical trials in the STEGLATRO development program, non-traumatic lower limb amputations were reported in 1 (0.1%) patient in the comparator group, 3 (0.2%) patients in the STEGLATRO 5 mg group, and 8 (0.5%) patients in the STEGLATRO 15 mg group. A causal association between STEGLATRO and lower limb amputation has not been definitively established.

Before initiating STEGLATRO, consider factors in the patient history that may predispose them to the need for amputations, such as a history of prior amputation, peripheral vascular disease, neuropathy and diabetic foot ulcers. Counsel patients about the importance of routine preventative foot care. Monitor patients receiving STEGLATRO for signs and symptoms of infection (including osteomyelitis), new pain or tenderness, sores or ulcers involving the lower limbs, and discontinue STEGLATRO if these complications occur.

**Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues.** Insulin and insulin secretagogues (e.g., sulfonylurea) are known to cause hypoglycemia. STEGLATRO may increase the risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue (see Adverse Reactions). Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with STEGLATRO.

**Necrotizing Fasciitis of the Perineum (Fournier’s Gangrene).** Reports of necrotizing fasciitis of the perineum (Fournier’s gangrene), a rare but serious and life-threatening necrotizing infection requiring urgent surgical intervention, have been identified in postmarketing surveillance in patients with diabetes mellitus receiving SGLT2 inhibitors. Cases have been reported in females and males. Serious outcomes have included hospitalization, multiple surgeries, and death.

Patients treated with STEGLATRO presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise, should be assessed for necrotizing fasciitis. If suspected, start treatment immediately with broad-spectrum antibiotics and, if necessary, surgical debridement. Discontinue STEGLATRO, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control.
Genital Mycotic Infections. STEGLATRO increases the risk of genital mycotic infections. Patients who have a history of genital mycotic infections or who are uncircumcised are more likely to develop genital mycotic infections [see Adverse Reactions]. Monitor and treat appropriately.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C). Dose-related increases in LDL-C can occur with STEGLATRO [see Adverse Reactions]. Monitor and treat as appropriate.

Macrovascular Outcomes. There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with STEGLATRO.

ADVERSE REACTIONS

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

Pool of Placebo-Controlled Trials Evaluating STEGLATRO 5 and 15 mg. The data in Table 1 are derived from a pool of three 26-week, placebo-controlled trials. STEGLATRO was used as monotherapy in one trial and as add-on therapy in two trials. These data reflect exposure of 1,029 patients to STEGLATRO with a mean exposure duration of approximately 25 weeks. Patients received STEGLATRO 5 mg (N=519), STEGLATRO 15 mg (N=510), or placebo (N=515) once daily. The mean age of the population was 57 years and 2% were older than 75 years of age. Fifty-three percent (53%) of the population was male and 73% were Caucasian, 15% were Asian, and 7% were Black or African American. At baseline the population had diabetes for an average of 7.5 years, had a mean HbA1c of 8.1%, and 19.4% had established microvascular complications of diabetes. Baseline renal function (mean eGFR 88.9 mL/min/1.73 m²) was normal or mildly impaired in 97% of patients and moderately impaired in 3% of patients.

Table 1 shows common adverse reactions associated with the use of STEGLATRO™ (ertugliflozin). These adverse reactions were not present at baseline, occurred more commonly on STEGLATRO than on placebo, and occurred in at least 2% of patients treated with either STEGLATRO 5 mg or STEGLATRO 15 mg.

Table 1: Adverse Reactions Reported in ≥2% of Patients with Type 2 Diabetes Mellitus Treated with STEGLATRO* and Greater than Placebo in Pooled Placebo-Controlled Clinical Studies of STEGLATRO Monotherapy or Combination Therapy

<table>
<thead>
<tr>
<th>Number (%) of Patients</th>
<th>Placebo N = 515</th>
<th>STEGLATRO 5 mg N = 519</th>
<th>STEGLATRO 15 mg N = 510</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female genital mycotic infections†</td>
<td>3.0%</td>
<td>9.1%</td>
<td>12.2%</td>
</tr>
<tr>
<td>Male genital mycotic infections†</td>
<td>0.4%</td>
<td>3.7%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Urinary tract infections‡</td>
<td>3.9%</td>
<td>4.0%</td>
<td>4.1%</td>
</tr>
<tr>
<td>Headache</td>
<td>2.3%</td>
<td>3.5%</td>
<td>2.9%</td>
</tr>
<tr>
<td>Vaginal pruritus§</td>
<td>0.4%</td>
<td>2.8%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Increased urination¶</td>
<td>1.0%</td>
<td>2.7%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>2.3%</td>
<td>2.5%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Back pain</td>
<td>2.3%</td>
<td>1.7%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Weight decreased</td>
<td>1.0%</td>
<td>1.2%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Thirst¶</td>
<td>0.6%</td>
<td>2.7%</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

† The three placebo controlled studies included one monotherapy trial and two add-on combination trials with metformin or with metformin and sitagliptin.

‡ Includes: genital candidiasis, genital infection fungal, vaginal infection, vulvitis, vulvovaginal candidiasis, vulvovaginal mycotic infection, and vulvovaginitis. Percentages calculated with the number of female patients in each group as denominator: placebo (N=235), STEGLATRO 5 mg (N=252), STEGLATRO 15 mg (N=245).

§ Includes: cystitis, dysuria, streptococcal urinary tract infection, urethritis, urinary tract infection.

¶ Includes: balanitis candida, balanoposthitis, genital infection, and genital infection fungal. Percentages calculated with the number of male patients in each group as denominator: placebo (N=280), STEGLATRO 5 mg (N=267), STEGLATRO 15 mg (N=265).

RENAL-RELATED ADVERSE REACTIONS

Volume Depletion. STEGLATRO causes an osmotic diuresis, which may lead to intravascular volume contraction and adverse reactions related to volume depletion, particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m²). In patients with moderate renal impairment, adverse reactions related to volume depletion (e.g., dehydration, dizziness postural, presyncope, syncope, hypotension, and orthostatic hypotension) were reported in 0%, 4.4%, and 1.9% of patients treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively. STEGLATRO may also increase the risk of hypotension in other patients at risk for volume contraction [see Use in Specific Populations].

Ketoadiposis. Across the clinical program, ketoadiposis was identified in 3 of 3,409 (0.1%) ertugliflozin-treated patients and 0.0% of comparator-treated patients [see Warnings and Precautions].

Impairment in Renal Function. Treatment with STEGLATRO was associated with increases in serum creatinine and decreases in eGFR (see Table 2). Patients with moderate renal impairment at baseline had larger mean changes. In a study in patients with moderate renal impairment, these abnormal laboratory findings were observed to reverse after treatment discontinuation [see Use in Specific Populations].

Table 2: Changes from Baseline in Serum Creatinine and eGFR in the Pool of Three 26-Week Placebo-Controlled Studies, and a 26-Week Moderate Renal Impairment Study in Patients with Type 2 Diabetes Mellitus

<table>
<thead>
<tr>
<th>Pool of 26-Week Placebo-Controlled Studies</th>
<th>Placebo N=515</th>
<th>STEGLATRO 5 mg N=519</th>
<th>STEGLATRO 15 mg N=510</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline Mean</td>
<td>Creatinine (mg/dL)</td>
<td>0.83</td>
<td>0.82</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>89.5</td>
<td>88.2</td>
<td>89.0</td>
</tr>
<tr>
<td>Week 6 Change</td>
<td>Creatinine (mg/dL)</td>
<td>0.00</td>
<td>0.03</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>-0.3</td>
<td>-2.7</td>
<td>-3.1</td>
</tr>
<tr>
<td>Week 26 Change</td>
<td>Creatinine (mg/dL)</td>
<td>-0.01</td>
<td>0.00</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>0.7</td>
<td>0.5</td>
<td>-0.6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Moderate Renal Impairment Study</th>
<th>Placebo N=154</th>
<th>STEGLATRO 5 mg N=158</th>
<th>STEGLATRO 15 mg N=155</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>Creatinine (mg/dL)</td>
<td>1.39</td>
<td>1.38</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>46.0</td>
<td>46.8</td>
<td>46.9</td>
</tr>
<tr>
<td>Week 6 Change</td>
<td>Creatinine (mg/dL)</td>
<td>-0.02</td>
<td>0.11</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>0.6</td>
<td>-3.2</td>
<td>-4.1</td>
</tr>
<tr>
<td>Week 26 Change</td>
<td>Creatinine (mg/dL)</td>
<td>0.02</td>
<td>0.08</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>0.0</td>
<td>-2.7</td>
<td>-2.6</td>
</tr>
</tbody>
</table>

Rena-related adverse reactions (e.g., acute kidney injury, renal impairment, acute prerenal failure) may occur in patients treated with STEGLATRO, particularly in patients with moderate renal impairment where the incidence of renally related adverse reactions was 0.6%, 2.5%, and 1.3% in patients treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively.
Lower Limb Amputation. Across seven Phase 3 clinical trials in which STEGLATRO™ (ertugliflozin) was studied as monotherapy and in combination with other antihyperglycemic agents, non-traumatic lower limb amputations occurred in 1 of 1,450 (0.1%) in the non-STEGLATRO group, 3 of 1,716 (0.2%) in the STEGLATRO 5 mg group, and 8 of 1,693 (0.5%) in the STEGLATRO 15 mg group.

Hypoglycemia. The incidence of hypoglycemia by study is shown in Table 3.

Table 3: Incidence of Overall* and Severe† Hypoglycemia in Placebo-Controlled Clinical Studies in Patients with Type 2 Diabetes Mellitus

<table>
<thead>
<tr>
<th>Monotherapy (26 weeks)</th>
<th>Placebo (N = 153)</th>
<th>STEGLATRO 5 mg (N = 156)</th>
<th>STEGLATRO 15 mg (N = 152)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall [N (%)]</td>
<td>1 (0.7)</td>
<td>4 (2.6)</td>
<td>4 (2.6)</td>
</tr>
<tr>
<td>Severe [N (%)]</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>2 (1.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Add-on Combination Therapy with Metformin (26 weeks)</th>
<th>Placebo (N = 209)</th>
<th>STEGLATRO 5 mg (N = 207)</th>
<th>STEGLATRO 15 mg (N = 205)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall [N (%)]</td>
<td>9 (4.3)</td>
<td>15 (7.2)</td>
<td>16 (7.8)</td>
</tr>
<tr>
<td>Severe [N (%)]</td>
<td>1 (0.5)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Add-on Combination Therapy with Metformin and Sitagliptin (26 weeks)</th>
<th>Placebo (N = 153)</th>
<th>STEGLATRO 5 mg (N = 156)</th>
<th>STEGLATRO 15 mg (N = 153)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall [N (%)]</td>
<td>5 (3.3)</td>
<td>7 (4.5)</td>
<td>3 (2.0)</td>
</tr>
<tr>
<td>Severe [N (%)]</td>
<td>1 (0.7)</td>
<td>1 (0.6)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In Combination with Insulin and/or an Insulin Secretagogue in Patients with Moderate Renal Impairment</th>
<th>Placebo (N = 133)</th>
<th>STEGLATRO 5 mg (N = 148)</th>
<th>STEGLATRO 15 mg (N = 143)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall [N (%)]</td>
<td>48 (36.1)</td>
<td>53 (35.8)</td>
<td>39 (27.3)</td>
</tr>
<tr>
<td>Severe [N (%)]</td>
<td>3 (2.3)</td>
<td>5 (3.4)</td>
<td>3 (2.1)</td>
</tr>
</tbody>
</table>

* Overall hypoglycemic events: plasma or capillary glucose of less than or equal to 70 mg/dL.
† Severe hypoglycemic events: required assistance, lost consciousness, or experienced a seizure regardless of blood glucose.

Genital Mycotic Infections. In the pool of three placebo-controlled clinical trials, the incidence of female genital mycotic infections (e.g., genital candidiasis, genital infection fungal, vaginitis, vulvovaginal candidiasis, vulvovaginal mycotic infection, vulvovaginitis) occurred in 3%, 9.1%, and 12.2% of females treated with placebo, STEGLATRO™ (ertugliflozin) 5 mg, and STEGLATRO 15 mg, respectively (see Table 1). In females, discontinuation due to genital mycotic infections occurred in 0% and 0.6% of patients treated with placebo and STEGLATRO, respectively.

In the same pool, male genital mycotic infections (e.g., balanitis candida, balanoposthitis, genital infection, genital infection fungal) occurred in 0.4%, 3.7%, and 4.2% of males treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively (see Table 1). Male genital mycotic infections occurred more commonly in uncircumcised males. In males, discontinuations due to genital mycotic infections occurred in 0% and 0.2% of patients treated with placebo and STEGLATRO, respectively. Phimosis was reported in 8 of 1729 (0.5%) male ertugliflozin-treated patients, of which four required circumcision.

Laboratory Tests.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C). In the pool of three placebo-controlled trials, dose-related increases in LDL-C were observed in patients treated with STEGLATRO. Mean percent changes from baseline to Week 26 in LDL-C relative to placebo were 2.6% and 5.4% with STEGLATRO 5 mg and STEGLATRO 15 mg, respectively. The range of mean baseline LDL-C was 96.6 to 97.7 mg/dL across treatment groups [see Warnings and Precautions].

Increases in Hemoglobin. In the pool of three placebo-controlled trials, mean changes (percent changes) from baseline to Week 26 in hemoglobin were 0.21 g/dL (1.4%) with placebo, 0.46 g/dL (3.5%) with STEGLATRO 5 mg, and 0.48 g/dL (3.5%) with STEGLATRO 15 mg. The range of mean baseline hemoglobin was 13.90 to 14.00 g/dL across treatment groups. At the end of treatment, 0.0%, 0.2%, and 0.4% of patients treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively, had a hemoglobin increase greater than 2 g/dL and above the upper limit of normal.

Increases in Serum Phosphate. In the pool of three placebo-controlled trials, mean changes (percent changes) from baseline in serum phosphate were 0.04 mg/dL (1.9%) with placebo, 0.21 mg/dL (6.8%) with STEGLATRO 5 mg, and 0.26 mg/dL (8.5%) with STEGLATRO 15 mg. The range of mean baseline serum phosphate was 3.53 to 3.54 mg/dL across treatment groups. In a clinical trial of patients with moderate renal impairment, mean changes (percent changes) from baseline at Week 26 in serum phosphate were 0.01 mg/dL (0.8%) with placebo, 0.29 mg/dL (9.7%) with STEGLATRO 5 mg, and 0.24 mg/dL (7.8%) with STEGLATRO 15 mg.

DRUG INTERACTIONS

Concomitant Use with Insulin and Insulin Secretagogues. STEGLATRO may increase the risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue [see Adverse Reactions]. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with STEGLATRO [see Warnings and Precautions].

Positive Urine Glucose Test. Monitoring glycemic control with urine glucose tests is not recommended in patients taking SGLT2 inhibitors as SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose tests. Use alternative methods to monitor glycemic control.

Interference with 1,5-anhydroglucitol (1,5-AG) Assay. Monitoring glycemic control with 1,5-AG assay is not recommended as measurements of 1,5-AG are unreliable to monitor glycemic control.

USE IN SPECIFIC POPULATIONS

Pregnancy.

Risk Summary. Based on animal data showing adverse renal effects, STEGLATRO is not recommended during the second and third trimesters of pregnancy. The limited available data with STEGLATRO in pregnant women are not sufficient to determine a drug-associated risk of adverse developmental outcomes. There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy (see Clinical Considerations).

In animal studies, adverse renal changes were observed in rats when ertugliflozin was administered during a period of renal development corresponding to the late second and third trimesters of human pregnancy. Doses approximately 13 times the maximum clinical dose caused renal pelvic and tubule dilatations and renal mineralization that were not fully reversible. There was no evidence of fetal harm in rats or rabbits at exposures of ertugliflozin approximately 300 times higher than the maximal clinical dose of 15 mg/kg/day when administered during organogenesis (see Data).

The estimated background risk of major birth defects is 6-10% in women with pre-gestational diabetes with an HbA1c >7 and has been reported to be as high as 20-25% in women with HbA1c >10. The estimated background risk of miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Clinical Considerations.

Disease-Associated Maternal and/or Embryo/Fetal Risk. Poorly-controlled diabetes in pregnancy increases the maternal risk for diabetic ketoacidosis, pre-eclampsia, spontaneous abortions, preterm delivery, stillbirth, and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia related morbidity.
Animal Data. When ertugliflozin was orally administered to juvenile rats from PND 21 to PND 90, increased kidney weight, renal tubule and renal pelvis dilatation, and renal mineralization occurred at doses greater than or equal to 5 mg/kg (13-fold human exposures, based on AUC). These effects occurred with drug exposure during periods of renal development in rats that correspond to the late second and third trimester of human renal development, and did not fully reverse within a 1-month recovery period.

In embryo-fetal development studies, ertugliflozin (50, 100 and 250 mg/kg/day) was administered orally to rats on gestation days 6 to 17 and to rabbits on gestation days 7 to 19. Ertugliflozin did not adversely affect developmental outcomes in rats and rabbits at maternal exposures that were approximately 300 times the human exposure at the maximum clinical dose of 15 mg/day, based on AUC. A maternally toxic dose (250 mg/kg/day) in rats (707 times the clinical dose), was associated with reduced fetal viability, and a higher incidence of a visceral malformation (membranous ventricular septal defect). In the pre- and postnatal development study in pregnant rats, ertugliflozin was administered to the dams from gestation day 6 through lactation day 21 (weaning). Decreased postnatal growth (weight gain) was observed at maternal doses ≥100 mg/kg/day (greater than or equal to 331 times the human exposure at the maximum clinical dose of 15 mg/day, based on AUC).

Lactation.

Risk Summary. There is no information regarding the presence of STEGLATRO in human milk, the effects on the breastfed infant, or the effects on milk production. Ertugliflozin is present in the milk of lactating rats (see Data). Since human kidney maturation occurs in utero and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing human kidney. Because of the potential for serious adverse reactions in a breastfed infant, advise women that the use of STEGLATRO is not recommended while breastfeeding.

Data.

The lacteal excretion of radiolabeled ertugliflozin in lactating rats was evaluated 10 to 12 days after parturition. Ertugliflozin derived radioactivity exposure in milk and plasma were similar, with a milk/plasma ratio of 1.07, based on AUC. Juvenile rats directly exposed to STEGLATRO during a developmental period corresponding to human kidney maturation were associated with a risk to the developing kidney (persistent increased organ weight, renal mineralization, and renal pelvic and tubular dilatations).

Pediatric Use. Safety and effectiveness of STEGLATRO in pediatric patients under 18 years of age have not been established.

Geriatric Use. No dosage adjustment of STEGLATRO is recommended based on age. Across the clinical program, a total of 876 (25.7%) patients treated with STEGLATRO were 65 years and older, and 152 (4.5%) patients treated with STEGLATRO were 75 years and older. Patients 65 years and older had a higher incidence of adverse reactions related to volume depletion compared to younger patients; events were reported in 1.1%, 2.2%, and 2.6% of patients treated with comparator, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively [see Warnings and Precautions and Adverse Reactions]. STEGLATRO is expected to have diminished efficacy in elderly patients with renal impairment [see Use in Specific Populations].

Renal Impairment. The safety and efficacy of STEGLATRO have not been established in patients with type 2 diabetes mellitus and moderate renal impairment. Compared to placebo-treated patients, patients with moderate renal impairment treated with STEGLATRO did not have improvement in glycemic control, and had increased risks for renal impairment, renal-related adverse reactions and volume depletion adverse reactions [see Dosage and Administration, Warnings and Precautions and Adverse Reactions]. Therefore, STEGLATRO is not recommended in this population. STEGLATRO is contraindicated in patients with severe renal impairment, ESRD, or receiving dialysis. STEGLATRO is not expected to be effective in these patient populations [see Contraindications]. No dosage adjustment or increased monitoring is needed in patients with mild renal impairment.

Hepatic Impairment. No dosage adjustment of STEGLATRO is necessary in patients with mild or moderate hepatic impairment. Ertugliflozin has not been studied in patients with severe hepatic impairment and is not recommended for use in this patient population.

OVERDOSAGE

In the event of an overdose with STEGLATRO, contact the Poison Control Center. Employ the usual supportive measures as dictated by the patient’s clinical status. Removal of ertugliflozin by hemodialysis has not been studied.

For more detailed information, please read the Prescribing Information.

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How to lose a malpractice suit

By Eric Postal, MD

I’ve heard more than a few tales of docs who proceeded to do precisely the wrong things when they found themselves in the clutches of ambulance-chasers. I thought I might offer some pointers as to how to lose a malpractice suit.

1 Blame yourself. You might have heard that a lot of docs get sued (approaching 50%, over the course of a career.) And that the majority of cases are dropped, dismissed, or withdrawn. Forget all that—decide that you’re the only one this has ever happened to, and also that you probably deserve it. Be sure to wear your heart on your sleeve, so everyone knows you’re guilty of Crimes Against Humanity. This is especially important during depositions and courtroom appearances: Avoid eye contact and mumble.

2 Expect a speedy resolution. You might have heard at some point that one of your basic rights is to a “speedy trial.” So, obviously, if things are going well, you should be done with the malpractice process in a few weeks, maybe months at most. If it takes longer—certainly if things drag on for years before there’s even talk of a court date—chances are it’s going poorly. Be sure to let this permeate all other aspects of your life and eat away at you.

3 Fix the records. Write extra notes in the patient’s chart, make addenda to your diagnostic reports, and adjust stuff you previously documented if you can. Provide commentary about things that happened weeks, months, or years ago. Write up your own “personal” accounting of how events transpired. Nobody will ever know you did this after the fact, right?

4 Tell everyone all about your situation. Maybe you want to know other folks’ opinions, maybe you just want to commiserate. “A burden shared is a burden halved,” right? Thank God for social media; look how many more people you can broadcast your every random thought to! Don’t let scary legal concepts like discoverability make you bottle everything up.

5 Clam up, or self-contradict, around your legal team. Now that you’re freely expressing yourself to everyone else under the sun, be sure to give the attorney(s) and experts defending your case as little to work with as possible. They’re getting paid the big bucks to save your hide, right? Why should you lift a finger to help? Besides, remember that you were a lousy doctor and brought all of this on yourself in the first place, so what could you possibly have to contribute?

6 Point fingers. Just because your other behavior is screaming “I’m guilty of everything!” doesn’t mean that you can’t drag other people down with you, whether they deserve it or not. Hey, if some of them have deeper pockets (or more generous coverage), maybe the plaintiffs will go after one of those bigger fish and you’ll get off easier. Come up with ways that everyone involved in the case contributed to bad outcomes. Best yet, offer up ideas about how policies, procedures, and inefficiencies of the healthcare facility itself caused the whole mess.

Eric Postal, MD, is a practicing radiologist in Waynesburg, Penn.
Physician groups: Streamline prior auths now

More than 370 physician associations wrote a letter to Congress urging members to support legislation that would simplify and streamline prior authorizations for Medicare Advantage patients.

The physician groups—which include groups that represent primary care physicians such as the American College of Physicians, the American Academy of Family Physicians, the American Osteopathic Association and more—are pushing Congress to support the Improving Seniors’ Timely Access to Care Act of 2019, which has been introduced by a bipartisan group of representatives.

“This bipartisan legislation would help protect patients from unnecessary delays in care by streamlining and standardizing prior authorization under the Medicare Advantage program, providing much-needed oversight and transparency of health insurance for America’s seniors,” the letter reads. “We urge you to join your colleagues in supporting this important legislation.”

The bill has five key provisions. According to the letter, it would:

- create an electronic prior authorization program, including the electronic transmission of prior authorization requests and responses and a real-time process for items and services that are routinely approved;
- improve transparency by requiring plans to report to CMS on the extent of their use of prior authorization and the rate of approvals or denials;
- require plans to adopt transparent prior authorization programs that are reviewed annually, adhere to evidence-based medical guidelines, and include continuity of care for individuals transitioning between coverage policies to minimize any disruption in care;
- hold plans accountable for making timely prior authorization determinations and to provide rationales for denials; and
- prohibit additional prior authorization for medically necessary services performed during a surgical or invasive.

Streamlining prior authorizations for Medicare Advantage patients could be a major relief to physician practices and the health system, the physicians groups argue.

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“‘There is an insidious misunderstanding of primary care. Most people, including all too many physicians and medical school faculty, think of primary care as treating only the ‘simple stuff.’”

—Stephen C. Schimpff, MD

“HIPAA has also made it much harder for physicians and patients to work with innovators to advance healthcare technology.”

—Kim-Lien Nguyen, MD
Master your finances
Tips for tackling debt, investing and retirement

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Why medical leaders must pay attention to physician frustration, dissatisfaction

Simon G. Talbot, MD, and Wendy Dean, MD, in “Beyond Burnout: Moral injury is the real problem” (August 25, 2019 issue) are to be congratulated by all physicians for their courageous statements on physician burnout.

Every paragraph of their article is truthful and speaks to the dissatisfaction, the demoralization, the anxiety and the frustration that most doctors feel in our over-regulated and exploited profession.

As they said, “we doctors have ‘...taken on the job of data entry clerks, insurance go-betweens...coders/billers...[that]...we are pulled in too many directions...’”

Their comments that we are not taught or encouraged or empowered to set boundaries must be read by our medical leaders in our state and county medical societies; and in our specialty societies and the American Medical Association.

Their most telling comment was that physicians can free themselves from the exploitive constraints that sicken them like a malignant virus by saying ‘no’ to the unfair demands asked of us.

Here is my personal example of frustration and dissatisfaction. I know that other physicians have experienced the same:

I recently was informed by Medicare that I must re-validate my enrollment with PECOS (Provider Enrollment Chain and Ownership System). I spent over 6 hours navigating the labyrinth of prompts and finally (so I thought) completed this needlessly complicated task.

A few days later I received an email stating that my submission was rejected because it was ‘unsolicted’, meaning I think not needed.

I followed all the prompts to clarify the issue but after several hours of frustration I gave up and sent Medicare a letter (at the cost of $25) explaining the problem and my lack of success with their user-unfriendly electronic system. No answer yet.

I even contacted my state medical society and was told that other doctors had the same problem; and that the society had someone who could walk me through the submission form.

That my medical society could walk me or any colleague through the submission process is good, but I have been practicing primary care for 44 years and in good standing with Medicare; and that I or any colleague needs help to fill a Medicare re-validation form is nonsensical.

I replied that the real problem here is physicians’ fears of not bringing this to Medicare’s attention— and to our lawmakers and representatives. Not doing it just prolongs the problem and enforces Medicare’s impression that physicians are a pliable, easily manipulated group.

The time is way overdue for physicians to say “no” and not to hold back any harsh words against those who for one reason or another are the cause of our dissatisfaction and demoralization. The problems with the Medicare re-validation form is a good place to start.

Edward Volpintesta, MD
BETHEL, CONN.
While the number of women in medicine has been steadily increasing, respect and equality for women in the profession continue to lag. The medical staffing company CompHealth recently surveyed more than 700 physicians on a range of workplace issues and found that women are far more likely to experience and witness instances of harassment, discrimination and even violence than are men. Here are some of the key findings:

Gender inequality in the medical workplace

Men and women have widely differing perceptions of respect and gender equality where they work.

- **21%** of women think men are more respected than women.
- **63%** of men think both genders are respected at their organization.
- **54%** of men think both genders are respected at their organization.
- **27%** of women think both genders are respected at their organization.

Women are far more likely than men to witness negative treatment of women in the workplace.

- **49%** of women have witnessed discrimination very often/often.
- **16%** of men have witnessed discrimination very often/often.

More women than men experience sexual harassment.

- **77%** of women were subjected to sexual remarks compared to **48%** of men.
- **37%** of women were subjected to unwanted touching compared to **20%** of men.
- **29%** of women have witnessed sexual harassment of women very often/often compared to **13%** of men.

Women physicians reported lower levels of annual income compared to men.

- **28%** of men earn $0-$199,999.
- **45%** of women earn $0-$199,999.
- **52%** of men earn $200,000-$399,999.
- **45%** of women earn $200,000-$399,999.

Women are more likely to make career sacrifices for family/child care.

- **46%** of women have reduced work hours.
- **29%** of men have reduced work hours.
Over the course of their careers, physicians face several major financial decisions that can have a lasting impact on their financial well-being. Here’s a look at some of these key decisions and advice physicians should consider when making them.

WHEN TO REFINANCE YOUR STUDENT DEBT
According to the Association of American Medical Colleges, three-fourths of medical students carry education debt (including college and medical school), with the median debt level hitting $200,000 in 2018. A 2018 Medical Economics survey of
physician readers found that 30 percent of respondents had student loans upwards of $200,000.

Whether physicians should refinance their debt hinges on the types of loans they have, says Carolyn McClanahan, MD, CFP, director of financial planning at Life Planning Partners, Inc., in Jacksonville, Fla. Her advice: If physicians have loans with high interest rates that aren’t available for forgiveness, they should shop around for better rates.

“You could save a lot of money over a long period of time just by decreasing the interest rate by 1 percent or more,” she says. In fact, physicians should consider refinancing their private loans as early as the first year of residency, according to Andrew Musbach, CFP, co-founder and financial advisor with MD Wealth Management, LLC, in Chelsea, Mich. However, those with federal loans may already have low effective interest rates or may be pursuing public service loan forgiveness, so refinancing may not be beneficial, he says.

Roozehra Khan, DO, assistant professor of clinical medicine at Western University of Health Sciences in Pomona, Calif., paid off $289,000 in student loans in three years without refinancing. She started by whittling down her government loans with 7 to 8 percent interest rates and then moved on to loans with 2 percent interest rates.

As a single professional, she was able to keep her rent and other expenses low while paying down debt. “I continued to live like a fellow when I was an attending—I put almost all of my paycheck toward my loan repayment every month,” says Khan. She made sure to direct the additional payments toward reducing the loan’s principal balance, not the interest.

“I want young people to know this is completely possible,” she says. “When you are able to take financial control, it creates a mental freedom that allows you to be the doctor you want to be.”

BUYING LIFE AND DISABILITY INSURANCE

Many physicians make the mistake of relying solely on the life and disability insurance they receive from their employers when they should also have their own individual coverage, McClanahan says. “I tell everyone, especially young physicians who may be thinking about having children, to get a cheap term life insurance policy right out of the gate that you own and that goes with you if you leave your job,” she says.

Another mistake is purchasing whole life insurance rather than a term policy, Musbach says. While term life insurance provides coverage for a fixed amount of time (often 10 to 30 years), whole life provides permanent coverage along with a savings and investment component. “On the surface, it sounds like a good idea. But in the end, it’s just expensive insurance coverage with mediocre investment returns,” he explains.

“I want young people to know [paying off medical school debt] is completely possible. When you are able to take financial control, it creates a mental freedom that allows you to be the doctor you want to be.”

—ROOZEHRA KHAN, DO, ASSISTANT PROFESSOR OF CLINICAL MEDICINE, WESTERN UNIVERSITY OF HEALTH SCIENCES, POMONA, CALIF.
Financial mastery

another lengthy medical underwriting process when they are older and may no longer be as healthy, he says.

ESTATE PLANNING
According to McClanahan, many young physicians are behind when it comes to estate planning. At a minimum, every physician should have documents designating a healthcare surrogate and a power of attorney, she says.

As soon as they have children, physicians also should draw up wills or trusts that allow them to name guardians for their children and dictate what happens to their estate after their death, Musbach says. “Having an estate plan is going to help your kids save a lot of headaches and also minimize the potential for family conflict,” he adds.

“Having an estate plan is going to help your kids save a lot of headaches and also minimize the potential for family conflict.”

— ANDREW MUSBACH, CFP, CO-FOUNDER AND FINANCIAL ADVISOR, MD WEALTH MANAGEMENT, LLC, CHELSEA, MICH.

SAVING FOR COLLEGE AND RETIREMENT
Many young physicians have difficulty prioritizing their money goals once they begin practice and see their salary jump, experts say. Physicians likely still have student loans and are many years behind their peers in other professions who required less education and training, Musbach says. At the same time, they may have a family and want to save for college or a home.

John Cullen, MD, FAAFP, a family physician practicing in Valdez, Alaska, recalls such struggles early in his career. Nearly 30 years ago, Cullen and his wife, who was earning her teaching degree, had their first of three children while he was in medical school and their second during his residency. The young couple had accumulated about $130,000 in student debt, which they consolidated into one low-rate loan.

Even though both of their incomes were modest, they made it a priority to start investing for retirement right away. To save for college, they took advantage of state-sponsored 529 college savings plans soon after their first child was born.

Comparing his experience with young physicians today, he recognizes that many have a tough time getting an early start on investing while balancing other financial priorities.

“Medical students and residents don’t get nearly enough education on investment strategies for retirement,” says Cullen, who hopes to promote greater financial education in his role as president of the American Academy of Family Physicians.

Last year he and his wife, both in their mid-50s, paid off all of their consolidated debt for their house, a sailboat, and loans, so they are able to put away even more money for retirement.

Getting an early start on retirement savings is one of the best money moves physicians can make, experts say. In fact, financial advisors have a mantra: You can borrow for college, but you can’t borrow for retirement. That is why McClanahan and Musbach recommend that physicians save as much as they can in qualified retirement plans like 401k’s and 403b’s, which provide tax benefits and are protected from creditors.

For those in training, contributing post-tax dollars to Roth accounts can provide additional tax diversification before their jump in income makes traditional 401k or 403b contributions (which are made with pre-tax dollars) more beneficial, Musbach adds.

INVESTMENT STRATEGIES BEYOND THE 401K OR 403B
If physicians have maximized their 401k or 403b contributions, they can explore
other savings vehicles that may offer tax advantages, Musbach says. Depending on their situation, practice owners may want to consider cash-balance plans, a type of qualified retirement plan that allows them to save considerably more on a pre-tax basis than 401k plan contributions. And for certain physicians who also work in a locum tenens role, a simplified employee pension IRA or 401k may provide an additional tax-advantaged vehicle to save some of their independent contracting income, he adds.

Given their high incomes, there is no need for physicians to take on the additional risk—and hassles—of investing

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**Debt: How much is too much?**

_by Debra A. Shute _Contributing author

_F_ or many physicians, living with debt is an integral part of their training; but few learn how to manage it once their “real” paychecks begin rolling in.

In fact, many physicians continue to dig themselves deeper into debt as their careers progress, says Cory S. Fawcett, MD, a personal finance coach and author. “As can happen to anyone, physicians often just become totally numb to the consequences of debt,” says Fawcett.

“We end up feeling like it’s Monopoly money,” agrees James M. Dahle, MD, editor and founder of the White Coat Investor LLC. “We owe so much money, what’s a little bit more?” Here are four signs that a physician may already owe too much:

1. **Not knowing how much is owed**
   “You would be surprised by how many physicians there are who have not sat down and written out what they owe altogether—because it’s terrifying,” Dahle says. “But you can’t formulate a plan until you know what you’re up against.”

   Once a physician musters the courage to analyze his or her problem, he or she can create a budget and work toward resolving the debt.

   “The word ‘budget’ can be difficult for some people,” Fawcett says. “But you have a limited amount of income. You already have a restriction on the amount you want to spend. So why not be in charge of the restriction by being proactive—not reactive—about what you want to spend?”

2. **Living paycheck to paycheck**

   As a result of a mentality in which debt is the norm, it’s not unusual for established physicians to live paycheck to paycheck—albeit with larger checks than the average American, says Fawcett.

   “Just because your income jumped to $260,000 a year doesn’t mean you have to spend it all this month,” he says. For new residents coming out of training, he recommends they live on roughly $60,000 a year until their finances catch up.

   A key danger of depending on one’s entire income every month, he adds, is that there is no cushion to protect against loss of income due to job loss, illness, or maternity leave.

3. **Paying with plastic**

   Physicians’ financial problems can be compounded by a societal expectation that equates practicing medicine with wealth.

   Thus, physicians can easily fall prey to misconceptions such as, “I’m a doctor. I can afford it,” or “I work hard. I deserve a nice car and vacations,” says Gail L. Clifford, MD, an internist in Phoenix, Ariz.

   In reality, these purchases are premature if they need to be bought with credit cards.

   “Physicians are just like everybody else, and we all want to have stuff before we can actually afford to do it,” says Dahle, who recommends that physicians avoid taking on any debt besides student loans and a mortgage.

4. **Unclear goals**

   When physicians are fuzzy on what they owe or what standard of living they can afford, it’s nearly impossible to plan for the future. Specific, individual financial goals can help physicians ascend from a rut, says Fawcett.

   Whether that goal is to buy a new home, retire at a certain age, or live debt-free, you can make a plan to get there. “Once you see where you are and where you want to go, you can plot out a map to get there. Following it isn’t as hard as you’d think,” he says.
Financial mastery

in startups, private deals, or rental real estate to meet their financial objectives, Musbach says. “The goal isn’t to chase the highest return every year, but rather to make sure the way you are investing is aligned with your goals,” he says.

If physicians do invest in a startup or another risky investment, they should use their “play money,” McClanahan advises. But they should shy away from making “friend of a friend” investments in what’s billed as the next big thing, she says.

“Private placements lack transparency, and because of this physicians are often hoodwinked,” she notes.

WHEN TO RETIRE
AAFP’s Cullen has no plans to stop seeing patients, although he thinks he could do so while maintaining his financial independence.

Becoming financially independent for life transitions, rather than focusing on retirement, should be every physician’s goal, says McClanahan.

She believes the biggest determinant of when physicians can reach financial independence is how much they spend, not how much they save. “If you develop an expensive lifestyle that you become locked into, it’s going to be hard to achieve financial independence or retirement at a young age,” she says.

Physicians shouldn’t count on the sale of their practice as their nest egg, she adds. Smart investing and modest spending over the long run will likely bring greater returns.

Musbach urges physicians to aim for a state of financial independence where work is optional, not required. As a general rule, retirees can safely withdraw 4 percent from their portfolio each year, he says. That means a doctor looking to draw $100,000 each year would need to save about $2.5 million. Reaching that goal requires saving at least 15 to 20 percent each year, he says.

HIRING AND CHANGING FINANCIAL ADVISORS
There is no set moment, such as when physicians reach a certain savings target or income bracket, when they should consider working with an investment professional, says Gerri Walsh, senior vice president for investor education at FINRA, the Washington, D.C.-based organization that licenses and registers all brokers in the United States. Rather, physicians should contact an advisor whenever they want guidance on managing their money.

When selecting an advisor, Walsh recommends visiting FINRA’s BrokerCheck, a free tool for researching investment professionals that provides information on brokers’ licensing, experience, and history of customer complaints.

When might physicians want to switch advisors? One cause is when they suspect the advisor of engaging in problematic behavior, such as making unauthorized trades, Walsh says. If physicians are not satisfied with their advisor’s explanation, they can contact the firm’s branch manager and visit FINRA’s investor complaint center for more guidance.

Another cause for switching would be if the physician does not believe the advisor is offering unbiased advice. As Walsh says, “If you ever feel discomfort with the products, services, and strategies that are being recommended to you, that is an important point to pause and reflect on the relationship—especially if the products, services, and strategies don’t align with your goals.”

“Medical students and residents don’t get nearly enough education on investment strategies for retirement.”

— JOHN CULLEN, MD, FAAFP, FAMILY PHYSICIAN, VALDEZ, ALASKA

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Malpractice insurance costs: Which direction are rates headed?

Medical Economics spoke with an industry expert to gain insight into how consolidation is changing the market and how rates might be affected.

by TODD SHRYOCK Managing editor

Malpractice costs have been relatively stable in recent years, but the healthcare industry is changing. Consolidation among hospitals, health plans and provider groups has left insurers fighting for fewer customers, while juries have handed out some increasingly large malpractice verdicts.

Bill Fleming, MBA, is the chief operating officer for The Doctors Company and oversees all claims, underwriting and risk management for the nation’s largest physician-owned medical malpractice insurer.

Medical Economics spoke with Fleming about how these changes in healthcare are going to affect malpractice premiums. The transcript below has been edited for length and clarity.

Q: Medical Economics: What impact has consolidation had on malpractice rates and why?

Bill Fleming: A lot of the consolidation in healthcare, whether it’s payers, practices or hospitals, has been more about pulling organizations together and less about integrating them. We insure physician practices from one to thousands of physicians in a single practice and sometimes the roll up is a larger group of doctors and sometimes it’s actually more like an enterprise or organization, so it’s really quite variable.

In terms of the effect on medical liability coverage, I’ll take it two ways. One, there is this sort of traditional business view that if you are a larger organization, you have more leverage over those organizations that provide services to you. If you are a
Malpractice rates

fleet buyer of cars, that’s different than if you or I go out and buy a car. There’s that pressure, and I think some of the stagnation in rates has been about that.

Two, it’s also about enterprises that want to get into the medical liability world for the first time. If you want to build premium volume quickly, that part of the market is the part where you can grow faster. There’s an old saying in insurance of don’t let the aroma of the premium overcome the stench of the losses. The premiums come now, the losses come later, and in our business they come years later.

“From a carrier perspective, you can have the same number of companies chasing a smaller market. That creates a competitive pressure and if you are the buyer, that pressure could benefit you at least in the near term.”

think that era maybe is starting to come to a close.

I would guess over the next five or certainly 10 years that we would see more healthcare organizations choosing to take more of their own risk and having less of a need to protect their balance sheet by buying insurance at least down to a level they have today or over the last five or eight years.

Q: ME: Are you seeing as healthcare organizations get larger an interest in self-insuring?

BF: When we were in our 20s, we bought an auto policy with the lowest possible deductible because that’s all we could afford if we had a loss. But as our personal balance sheet grows, you increase your deductible because you can lower your premium and you can afford that once-in-a-while claim. Same thing happens in liability insurance in healthcare.

So there has been some movement toward self-insurance over the last 15 years. Moderating against that is the lower than historical trends in medical liability—the cost isn’t going up at a marked rate every year, so there is less of an incentive relative to say prior decades to self-insure. I

Q: ME: For the smaller practice, is there any drawback to that? Will it mean less choices on the market? How will it impact them, if at all?

BF: It has a couple of impacts. From a carrier perspective, you can have the same number of companies chasing a smaller market. That creates a competitive pressure and if you are the buyer, that pressure could benefit you at least in the near term. In the long term, that could mean and probably will mean that some of the smaller carriers need to find a home with a larger organization, because it’s a little bit difficult to lay off insurance risk onto an organization that is smaller than the customer.

There is a level of financial protection that you need that if your insurance company is smaller than you are, there is a mismatch there. We have not seen that constraint in terms of fewer companies in the market yet, but over time, that certainly could come.

Q: ME: If consolidation in healthcare continues, what’s going to happen to the malpractice insurance market? Will it result in fewer insurers?

BF: In the long term, that would likely be the case and traditional business theory in a market where there are fewer customers or customers choosing to get their services in a different way, typically the companies serving that market are going to roll up. We saw some of that from 2005 to 2012-13 and there’s been a bit of a pause there.

Continued on page 20
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The nation’s largest physician-owned insurer is now expanding in New York.
As we sit here today, we have companies with plenty of balance sheet, but a shrinking income statement if you will. Their revenue year over year is flat to shrinking because the physicians and book of business have chosen to self-insure or joined a healthcare organization that is self-insured or is taking on more risks themselves and laying out more on their insurance company.

**Q:** ME: Are all specialties seeing the same price trends across the market?

**BF:** Generally, that is the case. The tide has changed for all specialties, but there are a couple of outliers, but I think most of them, the decrease in the number of claims has been fairly even. But I don’t think there is a particular specialty that has benefitted more or less. There are certainly specialties that the market is still developing.

The movement toward hospitalists, where you have internists or OBs or critical care specialist, who is on site and available at the hospital rather than the traditional admitting physician who follows own patient into the hospital. Those specialties are still in the development phase, so I think the risk there are becoming more understood over time.

Same thing with advanced practice nurses. That’s an area the industry has been watching, because PAs, NPs and nurse midwives, nurse anesthetists, as they take on more responsibility and relieve some of the pressure from the doctor shortage, the question is, will the liability exposure of the nurse practitioner start to look more like the doctor that they work with rather than the traditional nurse practitioner from a decade ago?

**Q:** ME: Is there any one big change that could lead to price increases for doctors, whether it’s a major insurer leaving the business or some other event?

**BF:** If you look at history, a change of capacity is what usually drives a market shift. Back in 2002-2003, when St. Paul fire and Marine pulled out of the line, that was part of an era when the market stiffened up and prices went up. But behind that, the move by that particular company was a change in losses. Seeing some of that in the last couple of years, if you look at some of the public companies in our space and at their analysts calls and their public filings, there is a concern that the loss picture is becoming worse or more severe, and higher losses tend to take capital out of the industry, which can result in higher prices.

I think there have been some larger companies, ours included, who have said that the combined ratios that we currently see, even though we are a member-owned organization, we are mission focused, but can’t pursue your mission long term if there is no margin. If you are not around, you can’t deliver on your mission.

And so companies like ours have been taking increases in prices where it is necessary, whether it’s part of the market be-
cause of size of group or type of group or by venue. Some states, where we see rates that are flat, there is not a need for a rate increase, but we see a lot of markets where there is a need for a rate increase and we're implementing those.

Part of our strategy and goal there is to not be disruptive. But if we don’t raise rates a little bit when it’s necessary, that builds up pressure that eventually results in a large increase, which is very disruptive from a customer perspective. Our hope and expectation is that a small increase is more tolerable over time than a single large increase that is disruptive to a budget.

There a term—frequency of severity—that is an issue the industry is watching, where you see large verdicts in some places. There are some counties around the country where a very large seven or eight-figure verdict is not surprising. We know where those places are. It’s not pleasant for the defendant and maybe not economically sustainable, but it’s not a surprise.

But we’re seeing, as an industry, more large verdicts in places that have never had one like that. It’s introduced a sort of randomness to large verdicts. That’s a challenge for the industry, a challenge for smaller companies that aren’t accustomed to that size of a loss and maybe don’t have the backstops in place to cover up to the level of verdict they are seeing. We are not seeing it have an overall statistical effect on losses, it’s just one $10 million verdict for example, but it is a trend we are watching. The question is, is it a trend of social inflation that’s going to be seen more broadly over the next few years?

“Part of our strategy and goal there is to not be disruptive. But if we don’t raise rates a little bit when it’s necessary, that builds up pressure that eventually results in a large increase, which is very disruptive.”

Q: ultimately, what do you see happening with rates in the next few years?

BF: I think we will see single digit rate increases most places over the next several years to get the industry to a place where the rates are more at a sustainable level. Some of the combined ratio we see in the industry today are not compatible with life, if you will. I think the industry needs to find a way to take reasonable increases that can be absorbed into practices and health systems rather than continue to defer the need to a time when you have no choice but to take a very large increase that’s disruptive not just to the marketplace, but to practices all over the country.

My forecast is you’ll see increases where it is necessary and there are various hurdles to that. One is market place adoption, one is regulatory—regulators have their own needs and pressures that they have on them, and we have to work with them to get a rate that keeps their market stable and keeps coverage available.

A: According to CPT guidelines, only the physician or non-physician practitioner (NPP) placing the patient in observation status (and subsequently discharging the patient) may report the appropriate initial observation code (99218, 99219, 99220). This refers to the initiation of observation status and the supervision of the care plan for observation. Encounters by physicians/NPPs other than the supervising (admitting) physician for same day services may be reported with outpatient consultations codes (99241-99245) or subsequent observation codes (99224-99226), as appropriate.

Be sure to check with your payers to verify that they follow CPT guidelines. Some Medicare contractors and other payers may instruct to bill outpatient office visit codes (99201-99215) to report all subsequent observation care, regardless of whether the provider is the “admitting” physician or not.

Q: If a patient is admitted to observation status (99218-99220) and remains for two days before being admitted as an inpatient, is it appropriate to report the initial hospital care codes (99221-99223)?

A: If a patient is admitted to the hospital on a date subsequent to the date of observation placement, the hospital admission may be reported with the appropriate initial hospital care code (99221-99223). The initial hospital care level of service reported should include all evaluation and management (E/M) services provided to that patient in conjunction with that admission on the same date by the admitting physician. This means that an observation discharge should not be billed on the same date that the initial hospital care code is billed.

Q: Does code 99226 require medical decision making of high complexity?

A: Not if both of the other two components (history and exam) in the code are performed. When subsequent observation care is reported, at least two of the three key components must meet or exceed the stated requirements to qualify for a particular level of E/M service, as stated in the descriptor of code:

99226: Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components:

- A detailed interval history;
- A detailed examination;
- Medical decision making of high complexity.

High complexity means counseling and/or coordination of care with other physicians, other qualified healthcare professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs. Usually, the patient is unstable, has developed a significant complication, or a significant new problem. Typically, 35 minutes are spent at the bedside.

Two of the three key components must be met or exceeded for the level of service selected. Time may be used to select the level of service when counseling and coordination of care are documented as at least half of the time spent face-to-face with the patient.

Check with payers regarding specific reporting and payment policies.

Renee Dowling, CPC, is a billing and coding consultant with VEI Consulting in Indianapolis, Ind. Send your billing and coding questions to medec@mhhgroup.com.
The importance of Hepatitis C screening

Why primary care physicians should be setting up a screening program

by KEITH LORIA  Contributing author

An estimated 2.4 million people in the United States are living with hepatitis C, and in 2016, the Centers for Disease Controls and Prevention (CDC) reported approximately 18,000 U.S. deaths were the result of the hepatitis C virus (HCV) as an underlying or contributing cause. And the CDC believes that number is a low estimation of what the true figure is.

The problem is, a majority of those living with the virus don’t even know they have it. That’s why the CDC recommends one-time screening for hepatitis C for Baby Boomers (those born between 1945 and 1965), regardless of apparent risk factors. Yet despite the recommended guidelines, only a small fraction of this segment has actually been screened. For that reason, it’s vital that primary care physicians play a more active role.
Alexea M. Gaffney, MD, an internist in Stony Brook, N.Y., says hepatitis C screening is so important because the vast majority of individuals with the infection will have no symptoms or will have symptoms that physicians describe as "extra-hepatic" outside of the liver.

"Without screening, we miss the opportunity to treat and cure this infection before patients or infected individuals become symptomatic or progress to irreversible liver disease or scarring such as cirrhosis or develop cancer of the liver," she says. "We also miss the opportunity to prevent liver failure and the need for liver transplants in significant numbers of patients."

Janette Nesheiwat, MD, a family doctor and the medical director at City MD, which operates more than 100 urgent care centers, says some routes of transmission include sexual activity, intravenous drug use, mother to child during pregnancy, a needlestick injury or blood transfusions.

"Early detection and screening is important because there is a better success rate and outcome if the disease is caught early before severe symptoms and complications occur. Early detection lowers the risk of worsening complications, such as a need for liver transplant, or cancer formation and death," she says. "This is why doctors urge screening."

Mark Shaffer, MD, a family physician and clinical assistant professor of family & preventive medicine at the University of South Carolina, says the simplest approach to set up hep C screening in the primary care office is to integrate it in the same ordering and tracking mechanism used for mammograms, colonoscopies and other preventive care services at the adult health maintenance exam.

"Most electronic medical records have a mechanism for this," he says. "One challenge, however, is that many providers seeing patients feel too far removed from
the people actually programming their EHR, especially in large systems, to drive effective changes. Another challenge is that many patients do not attend an annual health maintenance exam, which is currently the only dedicated moment for a provider to review their record and preventive care needs.

This has led to a lot of direct to patient advertising for other preventive care measures, like mammograms, and Shaffer suspects the same is needed to improve hep C screening as well.

**COMMUNICATION MATTERS**

Gaffney says providers need to inform Baby Boomers that they account for three out of four patients infected with HCV, explaining that they received healthcare before universal precautions became standard for medical care.

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**Hepatitis C screening remains low among baby boomers**

*By Mark L. Fuerst Contributing author*

Screening for hepatitis C virus (HCV) among baby boomers has increased only slightly over time, according to a new study.

Data from 2015 indicates that less than 13 percent of individuals born between 1945 and 1965, are estimated to have undergone HCV screening.

The researchers published the results on March 27, 2018 in Cancer Epidemiology, Biomarkers & Prevention.

More than three-quarters of HCV-positive Americans were born between 1945 and 1965. That’s why both the Centers for Disease Control and Prevention and the U.S. Preventive Services Task Force now recommend that baby boomers get screened for the virus.

“Hepatitis C is an interesting virus because people who develop a chronic infection remain asymptomatic for decades and don’t know they’re infected. Most of the baby boomers who screen positive for HCV infection were infected over 30 years ago, before the virus was identified,” said lead author Monica Kasting, PhD, post-doctoral fellow, Division of Population Science, at the Moffitt Cancer Center in Tampa, Fla.

Data from the 2013 National Health Interview Survey (NHIS), an annual weighted survey of the U.S. civilian noninstitutionalized population, indicated that only 12 percent of baby boomers had been screened for HCV.

Kasting and colleagues studied whether HCV screening rates had increased following the FDA approval of several well-tolerated, effective direct-acting antiviral treatments for HCV infection.


A multivariable analysis showed that females were screened less often than males in every age cohort. Additionally, among baby boomers and those born between 1966 and 1985, HCV screening rates were lower among Hispanics and non-Hispanic Blacks. “This is concerning because these groups have higher rates of HCV infection and higher rates of advanced liver disease. This may reflect a potential health disparity in access to screening, and therefore treatment, for a highly curable infection,” said Kasting.

HCV screening only increased minimally in the baby boomer population. Among baby boomers, HCV screening rates ranged from 11.9 percent in 2013 to 12.8 percent in 2015. Regardless of the federal screening recommendations, less than 20 percent of baby boomers reported that the reason for their screening was due to their age. HCV screening was also significantly associated with age, gender, and race/ethnicity in baby boomers.

The researchers acknowledge that self-reported data is a limitation of the study. “Another limitation is that this is secondary data and we didn’t collect it ourselves. There are several questions we would have liked to ask about behavioral risk factors, such as drug use, that weren’t utilized on this survey,” said Kasting.

The researchers believe that interventions are needed to increase HCV screening with special focus on groups demonstrating significantly lower screening rates, such as Hispanics and females.
Study: Universal screening for Hep C is cost-effective

By Mark L. Fuerst Contributing author

One-time universal screening of all adults for chronic hepatitis C virus (HCV) infection is now cost-effective, according to a new study. A growing number of younger patients are testing positive for HCV, fueled largely by the opioid crisis impacting communities around the country. Current guideline-based strategy suggests one-time screening of baby boomers, the 73 million U.S. adults born between 1945 and 1965. But the large increase in HCV infections, along with more effective, tolerable drug regimens for HCV, have led researchers to suggest earlier diagnosis and treatment of hepatitis C infection to prevent development of progressive liver disease and reduce the long-term risks of cirrhosis, liver cancer and other HCV-associated health problems.

Researchers led by Mark Eckman, MD, professor of clinical medicine at the University of Cincinnati, estimated the impact of one-time universal screening of adults 18 years of age and older compared either with no screening at all or birth cohort-based screening alone.

They measured effectiveness with quality-adjusted life years (QALY) and costs with 2017 U.S. dollars. Based on the model, one-time universal screening of U.S. residents would cost less than $50,000/QALY compared with a strategy of no screening.

“Most health economists consider anything less than $50,000 per QALY to be highly cost-effective,” said Eckman.

The researchers published their results online September 8 in Clinical Gastroenterology and Hepatology.

Compared with one-time birth cohort screening, one-time universal screening and treatment cost $11,378/QALY gained. Universal screening was cost-effective compared with birth cohort screening when the prevalence of HCV antibody positivity was greater than 0.07% among adults not in the cohort born from 1945 through 1965.

The face and treatment of hepatitis C has changed, making it reasonable to screen a wider population for HCV. “The incidence of hepatitis C among younger drug-injecting patients is skyrocketing so we have a blip in HCV cases that’s no longer isolated to the baby boomer cohort,” Eckman said. “We are also now in an era of HCV treatments that is more effective than even five or six years ago. Furthermore, these new regimens are easier to tolerate, have fewer severe side effects and require a short period of treatment.”

“All these factors coming together are what drove the model to show that screening a broader population than just the baby boomer cohort is effective,” he added.

The baby boomer generation came of age during a time of drug experimentation. Many who may have tried injectable drugs never thought they had a problem, but may be infected with HCV.

The costs to treat HCV range from $9,000 to $30,000 per month, depending on the medications being used. Many health insurance plans, including Medicare Part D and most Medicaid plans, cover the costs of treatment.

The U.S. Preventive Services Task Force is reviewing guidelines for HCV and may broaden the screening recommendations. □

This is not always as easy as it sounds, however.

“Sometimes physicians do not want to risk making patients feel ‘judged’ by them, so they may not ask appropriate questions to assess for hep C risk,” she says. “They also may not understand that patients can be asymptomatic and have a normal exam and lab analysis and still have hepatitis C infection.”

Additionally, patients will sometimes decline tests when they do not understand their risk factors for a disease process, especially a transmissible infection.

“It’s a challenge for many due to busy hectic lifestyles and the misunderstanding that, ‘It can’t happen to me,’” Nesheiwat says. “Well, all it takes is one encounter to acquire hep C.”

Aaron Eli Glatt, MD, chair of medicine at South Nassau Communities Hospital in Oceanside, N.Y., and a spokesperson for the Infectious Disease Society of America, says while screening is essential for Baby Boomers, hepatitis C can impact all sorts of different populations, especially those younger generations that were involved in substance abuse. He says physicians should be talking about the dangers of HCV with all of their patients.

He explains that often the virus will go unrecognized until there are symptoms, and while it can still be cured easily, some complications that develop might not be so easily fixed, which is why screening needs to be done before the virus kicks in.

Glatt believes the reason more people don’t get screened comes down to apathy.

“For most people, and I think this is especially true of the Baby Boomer population, if they aren’t sick, they feel they don’t have the time to be screened and it’s not a priority,” Glatt says. “PCPs just need to stress the importance of this screening and their patients have to agree to have the screening done. That could solve so many problems.”

Glatt says that a simple blood test can be an indicator if screening is necessary and no patients should be scared off from that.

“There’s a 98 percent cure rate, and there are very few diseases with those kind of numbers,” he says. “It’s expensive, but insurance usually covers it. A simple pill once a day for eight weeks can cure it. If someone is in the Baby Boomer range, it makes all the sense in the world to be screened.” □
Medical board complaints: What physicians need to know

Physicians plan and insure against the possibility of a medical malpractice suit. However, they often overlook another serious threat to their livelihood: a medical board complaint.

While most doctors are primarily concerned about a medical malpractice suit, a medical board complaint on its own can significantly disrupt your income — and even end a career. Complaints can result in fines, reputational damage, license suspension or limitations and even complete license revocation. Medical board complaint legal defense costs are not always covered by your medical malpractice insurance.

Unlike a medical malpractice suit, a patient can file a board complaint at little or no cost. The Federation of State Medical Boards (FSMB) provides significant guidance to physicians and medical boards in all 50 states. It also provides some very specific guidance to patients on when, and how, to file complaints against physicians. Here’s what physicians need to know about these complaints.

Causes of medical board complaints

Some common causes of medical board complaints include:

- Failure to diagnose.
- Incorrectly prescribing medication, including opioids and other controlled substances.
- Actionable violations of physician-patient confidentiality.
- Inappropriate behavior that interferes with patient care.
- Failure to provide appropriate postoperative care.

What the complaint process looks like

This can be a complex process. How long a case takes depends on how many of the following steps are required to resolve it.

1. The complaint is assessed for jurisdiction.
2. The case is prioritized, and the investigation begins. Any indication of risk to patients may allow the board to immediately suspend or otherwise limit the physician out of concern for patient safety.
3. The state medical board identifies individuals and institutions with relevant information. Individuals involved in the case are asked to provide statements.
4. The complainant receives formal notification. The physician also receives formal notice of the complaint as well as any record requests.
5. The board conducts a medical review to determine if a patient’s medical care has been impacted as a result of the complaint. Some specialty experts may be called to comment on the standard of care provided.
6. The board rules. Minor or inaccurate complaints may be resolved at this level with the board providing sanctions or conditions.
7. If not settled by the board ruling, the case is set for an informal hearing. It may be settled at this stage. If not, the matter proceeds to a formal hearing.
8. Cases go to a full hearing for adjudication, similar to a civil lawsuit. This is a formal proceeding, with presentation of evidence and witnesses. The board rules on the evidence presented.
9. Any disciplinary action imposed by the board is entered into the public record. It is then part of the physician’s permanent professional record and is available nationally through the FSMB Physician Data Center.

Check your policy

Physicians should make sure they know, at a minimum, the following important details about their coverage:

- If they are covered for board complaint defense.
- The dollar limits of that coverage. It may be a rider that only covers $50,000, for example.
- If they have stand-alone coverage or if that coverage shares limits with another policy, thereby potentially reducing the coverage available for a resulting medical malpractice claim.

Ike Devji, JD, has practiced law exclusively in the areas of asset protection, risk management, and wealth preservation for the last 16 years. Send your legal questions to: medec@mmhgroup.com
More than half of patients diagnosed with cancer have comorbid conditions. Yet once cancer treatment begins, patients sense that they don’t need to see their primary care physician, and that the oncologist should treat everything, says Jacqueline Winfield Fincher, MD, MACP, an internist in Thomson, Ga., and the ACP president-elect. “Everything health-related comes down to this one thing, which is a natural response,” she says. “You don’t want to survive cancer just to have a major stroke or heart attack because you did not continue to address and treat your cardiovascular risk factors.”

Primary care physicians (PCPs) have important roles during cancer care, though not all realize it. Once cancer is diagnosed, there’s a tendency for patients to be transferred to oncology rather than referred there, says Amy E. Shaw, MD, a family physician specializing in oncology care at St. Joseph Health Medical Group in Santa Rosa, Calif. “I think this is a holdout from the days when most cancer was fatal,” she says.

Instead, oncologists and PCPs need to work together to address all the patient’s medical needs, and therefore PCPs need to stay in touch with the patient during active treatment.

Primary care’s role in cancer care
Regular contact with patients is vital for successful treatment
ProAssurance has been monitoring risk and protecting healthcare industry professionals for more than 40 years, with key specialists on duty to diagnose complex risk exposures.

Work with a team that understands the importance of delivering flexible healthcare professional liability solutions.
The role of primary care in cancer diagnosis and patient survivorship

by Daniel R. Verdon

Diagnosis, screening, risk reduction, managing comorbidities, helping to coordinate specialty care, long-term toxicities, palliative care, survivorship, and vaccination are just a few of the roles for primary care physicians related to the diagnosis and care of cancer patients.

The message, delivered in May during a panel discussion at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, sought to address the myriad of challenges faced when coordinating care after a person is first diagnosed with cancer, during treatment, after care, and in survivorship.

“We are on the front lines for diagnosing cancer, coordinating treatment phases leading to survivorship, and end-of-life care,” says Larissa Nekhlyudov, MD, MPH, an internist and survivorship care provider at Dana-Farber/Brigham and Women’s Hospital in Boston.

Piyush Srivastava, MD, an oncologist for Kaiser Permanente in Walnut Creek, Calif., says survivorship studies have shown that Stage I and Stage II cancer patients are more likely to die from hypertension or modifiable risks like cigarette smoking than cancer. Who would you prefer to manage high blood pressure, diabetes, or other chronic diseases? “The answer is that the primary care physician needs to be an active member of the cancer-care team,” he says.

Consider that every 10 additional primary care physicians per 100,000 of population are associated with 51.5 days of additional life expectancy, versus 19.2 days for additional life expectancy with specialists.

Every 10 additional primary care providers per 100,000 of population are also associated with reduced cardiovascular, cancer and respiratory mortality.

As oncologic therapies advance, it signals a need to adopt a more collaborative approach to patient care, during treatment and when a patient enters remission.

Trevor Jolly, MBBS, a medical oncologist at the University of North Carolina at Chapel Hill, adds that the primary care physician should serve as the medical quarterback. He encourages primary care physicians and oncologists to communicate about cases and better collaborate on treatment decisions, especially for those patients undergoing chemotherapy or radiation.

“During treatment, patients tend to rely on the specialist,” Jolly says. “But in my office, we are referring back to the primary care physician.”

Elizabeth Shiff, a cancer survivor and patient advocate at the University of Cincinnati, says that when a patient is diagnosed with cancer, he or she is only thinking about next steps in the treatment plan. “It is important to stress to the patient that his or her care will be like a triangle—between the oncologist, primary care physician, and patient,” Shiff says.

“Empower your patients with communication about the treatment plan and the role of providers,” she adds.

Jolly agrees. “I think we need to have a more collaborative approach where treatment decisions are shared, especially with comorbidities and when hypertension or diabetes is uncontrolled.”

As cancer therapies advance, survivorship numbers have been climbing as well. Consider that 1.7 million new cases of cancer are diagnosed each year, but there are 16.9 million survivors. It signals a growing need for improved collaboration between oncologists and primary care physicians.
Primary care and cancer patients

Practice Management

Shaw. She also hears how disappointed patients are when they don’t hear from their PCP, and that the patient may not want to return to their care as a result.

“Patients know you’re not an expert in cancer. When they’re going through something terrible, at least acknowledge what they’re going through,” she says.

Shaw recommends calling the patient to say something like, “I’m sorry you are going through this. Is there anything I can do to help?” The best times to call are at transition points, when the patient is starting or finishing a treatment. “I know doctors have 2,000 patients, and you’re not going to call every time someone breaks a leg or gets a sore throat. But cancer is uniquely terrifying.”

Sometimes the patient may have difficulty getting a specialist appointment, and the PCP can make a phone call to help. Shaw also recommends giving priority to calls from a patient undergoing cancer treatment. “We have this sign posted in our office for staff and doctors: ‘Just because we see it commonly, does not mean it is common for the patient,’” she says.

Shaw sometimes hears from patients that their PCP immediately refers them back to their oncologist when they call the PCP’s office with a medical problem during cancer treatment. Even if the PCP doesn’t have oncology expertise, they should find out a patient’s issue before referring them back to the oncologist.

“If I haven’t personally spoken with the patient to determine that they are having a problem that only the oncologist can address, then I shouldn’t be telling them to go elsewhere for care,” Shaw says.

WAYS TO STAY INVOLVED

Both the PCP and oncologist should encourage patients undergoing cancer treatment to see their PCP for existing health issues, especially as cancer treatment can impact these conditions. “We know that high blood pressure, heart disease, heart failure, and diabetes are profoundly affected by cancer treatment, particularly chemotherapy and steroids that sometimes accompanies chemo,” says Fincher.

For example, she says, she might need to increase a patient’s diabetes medications due to steroid use, or decrease blood pressure medications if they’re losing weight and their blood pressure is dropping, or if they have significant treatment-related fluid losses or gains. Oncology treatment can be delayed if the patient’s glucose levels or blood pressure aren’t controlled.

“Patients know you’re not an expert in cancer. When they’re going through something terrible, at least acknowledge what they’re going through.”

—AMY E. SHAW, MD, FAMILY PHYSICIAN SPECIALIZING IN ONCOLOGY CARE, ST. JOSEPH HEALTH MEDICAL GROUP, SANTA ROSA, CALIF.

Shaw has seen many oncologists renew a patient’s blood pressure or diabetes prescription because the patient hasn’t seen their PCP in years. “This is understandable, but renewing a prescription is not the same as managing the condition,” Shaw says.

For patients without comorbid conditions, PCPs can help with treatment decisions, care coordination, and managing treatment side effects. Shaw has helped patients understand each clinician’s role on the team, and get treatment authorizations and referrals. “Not every (oncology practice) has a patient navigator. The primary care doctor sometimes has to help,” Shaw says.

Especially in rural communities, PCPs can take control of drains and manage general side effects. It’s best when the oncologist communicates this with the PCP, which isn’t always done well, says Eben Rosenthal, MD, director of Stanford Cancer Center in Palo Alto, Calif.

As a PCP in a rural town, Fincher says her patients are usually at least 45 minutes away from their oncologists. Patients come to her for issues that develop between chemotherapy treatments. And while not all PCPs have oncology expertise, patients still may want their opinion on recommended treatments.

“There’s a level of trust,” Fincher says. The patient often has an ongoing relationship with the PCP, while only seeing the cancer specialist for a short time. “Our patients come back to us and say, ‘this is what the doctor recommended, what do
you think?” “That’s common. A 2016 study in the Journal of Clinical Oncology showed that 35.4 percent of women with newly diagnosed breast cancer consulted their PCPs about treatment options.

Shaw says she’s talked with patients who didn’t want a recommended treatment because of the side effects. She discusses the patient’s personal goals, how potential side effects would be treated, and why it was recommended to give a more thorough perspective for making a decision.

COMMUNICATION WITH SPECIALISTS

While experts say that it’s the specialist’s responsibility to share updates with the PCPs, the PCP plays a role as well. PCPs often complain that oncologists don’t send their notes, says Shaw, but PCPs also don’t always send their notes to the oncologist, forcing patients to act as the messengers between various doctors. Giving the patient access to their notes via a patient portal makes communication easier.

“Cancer providers should be reminded to send office notes to PCPs at a minimum, or better yet, have the EHR automatically route office notes to the PCP.”

—G VAN LONDEN, MD, ONCOLOGIST, UPMC HILLMAN CANCER CENTER

Of course this isn’t practical for most PCPs, but there are other ways to develop relationships. Stanford’s Rosenthal recommends that PCPs attend courses about oncology care, and visit facilities where they refer patients.

This can help PCPs understand which cancer treatment-related symptoms to expect, screen for, and manage. Communication also helps eliminate duplication of efforts, says van Londen, and decreases the risk of the bystander effect, where everyone thinks someone else is tackling the problem.

“We travel and have dinners (with PCPs), do grand rounds at community hospitals about treatments, and talk about what to expect,” Rosenthal says. “It’s old fashioned communication.”

Ideally, specialists would also refer patients back to their PCP to manage quality of life issues such as anxiety, depression, sleep disturbances, and treatment-related pain, Fincher says, adding that primary care physicians are in a better position to treat patients’ pain.

Given the problems caused by opioid addiction, PCPs knowing the patients and the community give better context to treatment options, and PCPs also treat the patient holistically, rather than treating just the cancer.

For example, Fincher recalls one patient who had intense pain from bone metastases, and the oncologist was not responsive to the patient or Fincher when approached about the issue several times. The patient maxed out on her pain medication but was still in severe pain. Fincher referred the patient to a radiation oncologist, who began radiating the area. Within a week, the patient’s pain decreased, she was sleeping and feeling better.

Patients expect that PCPs will be available to help them when there’s a serious medical issue, including cancer, says Shaw.

“We stay closely involved when there are other medical crises like a CVA, car accident, myocardial infarction, Parkinson’s, or dementia. But for partly historical reasons, we treat a cancer diagnosis differently,” Shaw says. “Most of our patients now survive their cancer and these patients will return to our practices, so it’s best to stay in contact with them so a gap doesn’t open up.”
Financial Strategies

How much money do you need for retirement?

Although every person’s situation is completely different, there are five universal considerations when determining how much you need to save for retirement. The impact of underestimating any of these factors could be catastrophic, so this is not the time to be overly optimistic about your retirement readiness. This is the time to be clear-eyed about setting your goals and expectations.

Q1 WHAT WILL YOUR HEALTHCARE NEEDS BE?
A related note to longevity is healthcare costs. According to a 2019 study by Fidelity, the average American retiring at age 65 will need $285,000 to cover their medical expenses through retirement. That puts a big dent in your retirement nest egg! Healthcare costs have been outstripping inflation for many years and are highly unpredictable. That is why medical bills are the No. 1 cause of bankruptcy in the U.S.

Q2 HOW MUCH MONEY WILL YOU SPEND WHEN YOU RETIRE?
No one likes to compile a budget, so try to avoid using that word and think instead about how you spend your money. There are many online tools that can help you get to this number fairly easily without pulling out a pencil and paper and spending tedious hours poring over bank statements. Do not assume that you will spend less at retirement. In fact, many spend more (at least initially) on travel, entertainment and the like. Determine the lifestyle you want and then calculate what kind of monthly income that will require.

Q3 WHEN WILL YOU RETIRE?
Again, be realistic about this. The study from the Employee Benefit Research Institute also showed that 34 percent of workers expect to work until at least age 70 although only 4 percent actually do. Other things tend to get in the way of working longer, such as unexpected health problems of the worker or a family member and corporate downsizing. Make sure to build in a cushion for this. Look at working until age 70 as a luxury that you may be able to accomplish but build in a contingency for potentially retiring earlier. Regardless of the reason, if you retire earlier, you will need to have more money saved because you will have less time to contribute to your nest egg.

Q4 HOW LONG WILL YOU LIVE?
It is important to not underestimate your lifespan. Consider your own health as well as your family history. According to AARP, the fastest growing segment of the U.S. population are those over age 85 and the second fastest growing segment are those over 100. In our own firm, we assume a longevity of 95 years for everyone.

Q5 WHAT WILL BE THE IMPACT OF INFLATION?
Although inflation has been hovering around 2 percent for the last 10 years, over the last 50 years it has averaged 3.67 percent. That may not seem like a big difference, but it does have a big impact on retirement. An inflation rate of 3.67 percent means that your cost of living will double approximately every 20 years. And that does not take into account things such as healthcare expenses, which are increasing at a faster rate.

All of this is to say that retirement planning is not really about a one-size-fits-all number. It is being realistic about your own goals and expectations while determining what will give you peace of mind.

Julianne F. Andrews, MBA, CFP, is a principal and co-founder of Atlanta Financial Associates. Send your financial questions to medec@mmhgroup.com.
Why patient experience matters more than ever

by TODD SHRYOCK Managing Editor

Thomas H. Lee, MD, has been Press Ganey’s chief medical officer since 2013, and is an internist and cardiologist, practicing primary care at Brigham and Women’s Hospital in Boston. As chief medical officer, he is responsible for developing clinical and operational strategies to help providers across the nation measure and improve the patient experience, with an overarching goal of reducing the suffering of patients as they undergo care, and improving the value of that care. He has more than three decades of experience in healthcare performance improvement as a practicing physician, a leader in provider organizations, researcher, and health policy expert.

Medical Economics spoke to Lee about the growing importance of the patient experience and how it can affect care outcomes. The conversation has been edited for length and clarity.

Q: Medical Economics: How important is the patient experience in today’s healthcare environment?

Lee: I think it’s huge. There’s lots of change in healthcare as you know well and I think it’s changed for the better overall. But as we deal with the effects of tremendous medical progress, aging of our population and economic challenges, we have a perfect storm of good
things that create pressure for change. It means we have to ask: what are we trying to do in healthcare?

Clearly because of all the frailty of our aging population and the incredible amount of things we can do and limited resources, that question of what are we trying to do has become something that has to be addressed. We just can’t keep doing more and more and more and assuming it’s all good. We’re trying to meet patients’ needs, and among their needs is peace of mind that things are as good as they can be.

Among their needs is to minimize the fear that they have, minimize the anguish that they have, preventable anguish from confusion and chaos. Patient experience defines what we’re trying to accomplish.

Q: ME: How does the patient experience impact patient outcomes?

Lee: Patients want a good experience. It’s not about parking, it’s not about something as simple as waiting time. It’s about how they feel. Do they feel peace of mind? Do they feel like everyone is doing all they can for them and working well together? These are the big drivers of patient’s likelihood to recommend. Do patients feel the teamwork is good, the communication is good, the empathy is real?

The reason I go into this is because these are outcomes. I mean obviously, mortality is the most important outcome if you’re about to have cardiac surgery. But the truth is, mortality has really limited value as an outcome measure in healthcare for two reasons. Number one, none of us are going to live forever so that not preventing mortality doesn’t necessarily mean failure of healthcare. And the second reason is that a whole lot of healthcare, we do things not to prevent death but to try to help people feel better.

In life there are all these conditions like ALS, you know Parkinson’s Disease—we’re never going to restore patients to perfect health, but we want to give them peace of mind that they are as healthy as they can be given the cards that they’ve been dealt. So that peace of mind is in fact an outcome.

The key thing I would emphasize is that physicians have this suspicion that there’s conflict between patient experience and the performance measures they think of as real quality. And I think business people in healthcare sometimes have a concern that there is a tension between patient experience and financial performance.

“There is a generational change afoot and the younger people are ... looking online and reading about the doctors where they are getting care and even after they pick the doctor, they keep going back and reading the doctor’s comments.”

We’ve looked at a ton of data at Press Ganey, and there is actually alignment that organizations that have better patient experience also have better technical quality, they have better safety records, and they also have better engagement of data from their doctors, nurses, and other employees. By engagement I mean how they feel about working where they work. Are they happy there? Will they stay there?

You know regardless of where you are, if you are getting better, that is good business and it’s also good for patient care.

Q: ME: If a doctor or health organization wants to improve their patient experience, how can they do that? Where do they start?

Lee: If you measure things you’ve got a chance at improving them, and if you don’t measure things, there’s a very good chance that they won’t improve. I think that we’re moving into a world where it’s
not about quality assurance, it’s about quality improvement. Quality assurance is you just want to make sure that something terrible is not going on. Quality improvement is where no matter where you are, you’re trying to get better. And if you’re trying to get better, then you don’t just measure samples of patients, you try to get data from everyone. That takes you down a road where you start sampling electronically rather than using telephone or paper, because it’s just too expensive.

But then what do you do with the data and which data are most useful? The comments are really even more compelling than the numbers. Using transparency, put the comments out there on the internet. Like if you Google me, and if you scroll down that page you’ll see all the comments from my patients. There was a new comment up there from someone who went into great detail about the things I do that the patient likes. That was good for me in that it makes me realize I should do those things all the time.

But that’s like a more tactical aspect of the bigger thing that I would bring up, which is the real goal has to be culture change—trying to be highly reliable about delivering care the way we think it should be delivered.

“The real goal has to be culture change—trying to be highly reliable about delivering care the way we think it should be delivered.”

But then, I actually think the more important thing is their own morale, their own burnout issues. What lifts doctors and nurses and others in the long run is feeling proud of their work and feeling like they’re really meeting patients’

cinally excellent. Increasingly, my colleagues and I are realizing these things are integrated. Patient experience isn’t just one thing. It’s part of a package that organizations have to pursue.

Q: ME: What happens if a practice or an organization doesn’t embrace the changes that are sweeping through healthcare? What are the consequences?

Lee: On a very short-term basis, they may feel like, “Well, at least we don’t have to disrupt ourselves. We can come to work and we know what we’re going to do and we know how we’re going to do it.” So there’s a sort of peace of mind on a very short-term basis. There’s probably nervousness, “Am I missing the boat?”

But, you know, on a medium-term basis—and I don’t think we’re talking about a decade—there is a real risk of business performance suffering because patients are going to move to get care where their needs are being met. I mean there is a generational change afoot and the younger people are not as loyal to brand as older people are. Younger people tend to be healthier, so they’re not dominating and filling the office yet. They’re not behaving like their parents. They are looking online and reading about the doctors where they are getting care and even after they pick the doctor, they keep going back and reading the doctor’s comments. That’s one of the interesting insights is that patients aren’t just using data to pick physicians, but they’re looking online; it’s like a relationship-management tool, something akin to Facebook more than Yelp. Physicians ought to be worried about the business implications. But then, I actually think the more important thing is their own morale, their own burnout issues. What lifts doctors and nurses and others in the long run is feeling proud of their work and feeling like they’re really meeting patients’
needs and that’s what sustains them. When I look at the comments from patients about me, it also helps me understand, OK, these are things I should be darn sure I do reliably. And this is the kind of thing that keeps you from getting burned out. It’s feedback and if you do a good job, it’s positive feedback.

**Q:** In the past, physicians may have felt like being a great doctor is all they needed to do. But you are saying there is more to it now, and doctors that aren’t cognizant of that are going to lose patients and possibly go out of business.

**Lee:** That is the way that I look at it. Plunging in is a smarter thing to do than pushing back. I have a sense of your readers and I know a lot of them are in practices for whom these changes are very disruptive and threatens their current business models.

But you know, helping them listen to their better angels and see a path forward that they might have their best shot at medium and long-term business success as well as pride is the best thing to do. You know the morale issue, the engagement stuff, the burnout stuff—that’s the case that I would make to them. I talk a lot to physicians and a lot of them are in a bad mood. But I actually find that they respond to imperative and the opportunity to give patients peace of mind even more than financial issues.

Whenever you ask physicians and other healthcare providers about instances where the care made you proud, you never get them bringing up instances where it was because they did something that was really, really new in the way of treatment techniques. The technical advances, the new drugs, new procedures, I think that stuff is cool, but they never bring that up. What they always bring up is old fashioned stuff about they work together, they’re really timely and they really met a patient’s psychological needs.

The values that come out are really old school values. But then how do you deliver old school values in the world we live in with very complex care with many people involved? That’s a lot of the real work that we have to do in healthcare.

**Q:** Is there anything else that primary care doctors need to know about the patient experience or how things are changing?

**Lee:** You know on this transparency issue, they really should plunge in. They should do it because of the way people make choices today. In the old days, someone would say, “Who should I go see?” and they would get a recommendation and they would go to that doctor. Today, they get three or four names and they go to the internet and they see what they can read about them. When they look if they’ve got comments, they read the comments, and if there are no comments, that’s not a good thing.

For example, when people look on Amazon, if a book’s got four reviews and they’re superb but another book’s got 50 reviews and it’s like two-thirds good, one-third bad, they buy the book that’s got 50 reviews because this is a well-documented phenomenon.

“Primary care physicians should recognize that consumers are going to look online for information about them and they should be responsive to that and recognize that plunging in will make them better.”

The same thing is true how consumers respond to the data that’s online. Primary care physicians should recognize that consumers are going to look online for information about them and they should be responsive to that and recognize that plunging in will make them better, and it will make them reliably be at their best.
Artificial intelligence (AI) has largely dominated conversations about the future of healthcare. From improving diagnoses to analyzing EHR data, AI is often touted as the cure for many of healthcare’s technological woes. But there are currently huge barriers to that future.

That’s according to an editorial written in *Nature* partner journal *Digital Medicine*, which seeks to temper expectations about AI.

The titular truth in “The ‘inconvenient truth’ about AI in healthcare,” is “that at present the algorithms that feature prominently in research literature are in fact not, for the most part, executable at the frontlines of clinical practice.”

The authors say that while AI has the potential to help fix many of healthcare’s biggest problems, the hype of AI is just that—at least in the current state of healthcare.

“We are so far away from artificial intelligence becoming a tool to improve the way we deliver care despite all the sensational research publications,” says Leo Anthony Celi, MD, the article’s co-author. Celi is an internist and critical care physician at Beth Israel Deaconess Medical Center.
Public discourse and policy intervention, the authors say, are necessary to help answer those questions and move the state of healthcare data forward. Before AI can begin to revolutionize healthcare, healthcare data must be in a state where it can be shared—and controlled—in a way that the public and government sectors approve of.

The authors point to two possible solutions. The first would involve the creation of “generalized data infrastructure by building on existing impactful successes in the research domain,” citing examples like the STRIDES initiative from the National Institutes of Health or MIMIC from the MIT Laboratory for Computational Physiology. Another, more radical solution would be for the government to require all healthcare organizations to store their data in commercially-available clouds.

Even those solutions, the authors admit, would require solving several complex problems, from how to protect confidentiality to how to handle consent of data.

“The potential of AI is well described,” the authors conclude, “however in reality health systems are faced with a choice: to significantly downgrade the enthusiasm regarding the potential of AI in everyday clinical practice, or to resolve issues of data ownership and trust and invest in the data infrastructure to realize it.”

For healthcare executives, Celi says the biggest takeaway from the editorial should be a cautionary tale, that before AI can succeed, the challenges to its adoption must be fully grasped and dealt with, saying that “most healthcare executives have no grasp of what is entailed and what investments are necessary to realize the promise of AI in medicine.” Only when those challenges are met can the true promise of AI be realized.
A remedy for burnout: Have time to listen

One of the problems I’ve had writing about direct primary care (DPC) is that I end up sounding like an infomercial. I sound like I’m saying that my practice is better than others, and that I’m smarter than other people. This goes against the modesty that was so strongly preached to me as I grew up, and the biblical call to “consider others better than yourself.” But this is basically the truth.

OK, I guess I’m just a conceited SOB. Sorry.

I was struck by the difference between my care and that of the rest of the system as I cared for a patient recently. She was complaining of a strange pulsating noise in her ear that had started a few weeks before. We chatted for a while, as I asked about any sinus symptoms, if she’d ever had anything else like this, what other significant symptoms she was having (headache, other sensory changes), and just general medical questions.

The diagnosis remained a mystery as I went to examine her. The exam was not really helpful. She had no foreign bodies in her ear canal (something I was guessing I’d find), no fluid behind her eardrum, and basically a negative exam.

“My decision to practice this way has saved my career, has healed my heart, has saved money for my patients, and has given me the time to listen, and the time to care for them.”

The diagnosis was “pulsatile tinnitus,” which is basically a description of her symptoms: a loud whooshing symptom in her ear. I’ve said in the past that one of the best tricks a doctor can do to bullshit patients is to use fancy words to describe exactly what the patient says to you.

So when a person has a rash, you call it “dermatitis.” When they have a loose cough, you call it “bronchitis.” And when they hear their heartbeat as a “whooshing” in an ear, you call it “pulsatile tinnitus.” It offers absolutely no help to the patient, but it perhaps impresses them with your grasp of medical jargon and distracts them from the fact that you don’t know what is going on with them.

Not satisfied, I chatted with her some more, talking about tinnitus, something that I’ve had for the past 15-plus years. It came on suddenly in my 40s and was associated with the sudden inability to hear words in a crowded room. This is one of the few bad things I’ve inherited from my now 92-year-old dad. I talked to her about the frustration of this condition and how certain
things make it worse. One of the main things is when other people mention the ringing in their ears. It makes me so aware that the volume of my tinnitus is turned up to “high” (it is very loud as I type these words). Another thing that makes tinnitus worse, I mentioned, is aspirin therapy.

She interrupted my rambling. “Wait. Aspirin makes it worse? I just started on aspirin therapy for my knee a couple of weeks ago.” And that is pretty much when her pulsatile tinnitus began.

This was about 20 minutes into my time in the room with her. Let me clarify: she had spent 25 minutes in my office, 20 of which was spent discussing her situation with me. She didn’t wait to see me, and I didn’t spend my time staring at a computer screen making her answer questions to satisfy data quality measures. I just talked to her, and this fact came out at minute 20 of that discussion. That’s a moment in the exam room that doesn’t happen often: after 20 minutes of discussion.

This is one of the reasons I believe the DPC practice model is clearly superior to “care as usual” with the assembly line/hamster wheel care that is performed by most primary care doctors. I have time. I can listen. I can chat with people until important information emerges.

In many, if not most, primary care practices, this patient would’ve been referred to ENT for a workup that may have resulted in lab testing and likely CT scans or other testing.

Having the time to listen was superior to an ENT consult, labs, or a CT scan. Time is something I have for patients, even after growing my practice to 800 patients. I give them 30 minutes of my time for normal visits, and 60 for complex care or new patient visits. Often the time I spend is shorter, but that time is available. This is exactly the opposite of what happens in most primary care settings. I used to have only 15 minutes set aside for people, much of which was devoted to documentation, and had to stretch that out to 30 or more minutes to get in the basics of care for complex problems.

With so much attention to physician burnout and the high cost of care, the discussion spends far too little time talking about the lack of time most primary care docs have for their patients. Before I left my old practice (nearly seven years ago!), I was increasingly burdened by the fact that I was being robbed of the time necessary to provide good care. I was spending too much time dealing with red tape from the insurance companies and from the rules from the government aimed at “improving care.”

Since leaving, I’ve yet to see more than 15 patients in any given day, and am often reminded how much my patients appreciate the time I can spend with them.

It doesn’t matter to me how we accomplish it—whether by the direct care model or another—but we must fix this problem. Primary care just had its worst year in matching residents from medical school, this at a time when we need more primary care doctors and less specialists.

My decision to practice this way has saved my career, has healed my heart, has saved money for my patients, and has given me the time to listen, and the time to care for them.

Rob Lamberts, MD, is a board-certified internist and pediatrician who runs Dr. Rob Lamberts, LLC, a direct primary care practice in Augusta, Ga. He also recently gave a TED talk on the DPC model. Have questions about DPC? Email medec@mmhgroup.com.
What is your guilty pleasure food?

Maria Young Chandler, MD, MBA
Business of Medicine / Pediatrics
Irvine, Calif.

“Lobster.”

George G. Ellis, Jr., MD
Internal Medicine
Boardman, Ohio

“Barbeque ribs.”

Antonio Gamboa, MD, MBA
Internal Medicine / Hospice and Palliative Care
Austin, Texas

“Any carbs basically, but pizza from Home Slice is the ultimate.”

Jeffrey M. Kagan, MD
Internal Medicine / Hospice
Newington, Conn.

“Chocolate.”

Melissa E. Lucarelli MD, FAAFP
Family Medicine
Randolph, Wis.

“Haribo gummy bears.”

Joseph E. Scherger, MD
Family Medicine
La Quinta, Calif.

“Dark chocolate.”

Salvatore Volpe, MD
Pediatrics/Internal Medicine / Pediatrics
Staten Island, N.Y.

“Chocolate.”

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