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Discover STEGLATRO™ (ertugliflozin): the 4th SGLT2i to market

YES, WE’RE #4

As an adjunct to diet and exercise for appropriate adults with type 2 diabetes. STEGLATRO is not for the treatment of type 1 diabetes or diabetic ketoacidosis.

SGLT2i: sodium glucose co-transporter 2 inhibitor.

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 (eg, 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.

See 4 yourself what STEGLATRO could do 4 your appropriate patients with type 2 diabetes by requesting samples today at: >>> DiscoverSteglatro.com

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Limitations of Use

- STEGLATRO is not recommended in patients with type 2 diabetes mellitus or for the treatment of diabetic ketoacidosis.

Dosage and Administration

Recommended Dose: 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.

Patients with Renal Impairment: Access 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/min/1.73 m² (see Contraindications). Initiation of STEGLATRO is not recommended in patients with an eGFR of 30 mL/min/1.73 m² to less than 60 mL/min/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/min/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 < 60 mL/min/1.73 m²) (see Use in Specific Populations). Elderly patients (>65 years), in patients with low systolic blood pressure, and in patients on diuretics. Before initiating STEGLATRO, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms of hypotension after initiating therapy.

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 5,109 (0.06%) 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 in 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 or intake (such as acute illness requiring 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 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 toe) has been observed in clinical studies with another SGLT2 inhibitor. Across several 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 6 (0.3%) 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., sulfonylureas) 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>Nausea</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: cystitis, dysuria, streptococcal urinary tract infection, urethritis, urinary tract infection.
‡ Includes: vulvovaginal pruritus and pruritus genital. 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: balanitis candid, 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=245).

Pool of 26-Week Placebo-Controlled Studies

<table>
<thead>
<tr>
<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) 0.83</td>
<td>0.82</td>
</tr>
<tr>
<td></td>
<td>eGFR (mL/min/1.73 m²) 89.5</td>
<td>88.2</td>
</tr>
<tr>
<td>Week 6 Change</td>
<td>Creatinine (mg/dL) 0.00</td>
<td>0.03</td>
</tr>
<tr>
<td></td>
<td>eGFR (mL/min/1.73 m²) -0.3</td>
<td>-2.7</td>
</tr>
<tr>
<td>Week 26 Change</td>
<td>Creatinine (mg/dL) -0.01</td>
<td>0.00</td>
</tr>
<tr>
<td></td>
<td>eGFR (mL/min/1.73 m²) 0.7</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Moderate Renal Impairment Study

<table>
<thead>
<tr>
<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) 1.39</td>
<td>1.38</td>
</tr>
<tr>
<td></td>
<td>eGFR (mL/min/1.73 m²) 46.0</td>
<td>46.8</td>
</tr>
<tr>
<td>Week 6 Change</td>
<td>Creatinine (mg/dL) -0.02</td>
<td>0.11</td>
</tr>
<tr>
<td></td>
<td>eGFR (mL/min/1.73 m²) 0.6</td>
<td>-3.2</td>
</tr>
<tr>
<td>Week 26 Change</td>
<td>Creatinine (mg/dL) 0.02</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>eGFR (mL/min/1.73 m²) 0.0</td>
<td>-2.7</td>
</tr>
</tbody>
</table>

Renal-related adverse reactions (e.g., acute kidney injury, renal impairment, acute renal failure) may occur in patients treated with STEGLATRO, particularly in patients with moderate renal impairment where the incidence of renal-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>
<tr>
<td>Add-on Combination Therapy with Metformin (26 weeks)</td>
<td>Placebo (N = 209)</td>
<td>STEGLATRO 5 mg (N = 207)</td>
<td>STEGLATRO 15 mg (N = 205)</td>
</tr>
<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>
<tr>
<td>Add-on Combination Therapy with Metformin and Sitagliptin (26 weeks)</td>
<td>Placebo (N = 153)</td>
<td>STEGLATRO 5 mg (N = 156)</td>
<td>STEGLATRO 15 mg (N = 152)</td>
</tr>
<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>
<tr>
<td>In Combination with Insulin and/or an Insulin Secretagogue in Patients with Moderate Renal Impairment</td>
<td>Placebo (N = 153)</td>
<td>STEGLATRO 5 mg (N = 148)</td>
<td>STEGLATRO 15 mg (N = 143)</td>
</tr>
<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., candidiasis, infection fungal, vaginal infection, vulitis, vulvo vaginal candidiasis, vulvovaginal mycotic infection, vulvovaginitis) occurred in 3%, 9.1%, and 12.2% of females treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively (see Table 1). Male genital mycotic infections occurred more commonly in patients treated with STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively (see Table 1). Male genital mycotic infections occurred in 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 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, discontinuation due to genital mycotic infections occurred in 0% and 0.6% of patients treated with placebo and STEGLATRO, respectively.

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/day when administered during organogenesis (see Data).

The estimated background risk of major birth defects is 6-10% in women who are not pregnant at the time of conception. In women who are pregnant at the time of conception, the risk of having a baby with a major birth defect is increased by 2-4% and 15-20%, respectively.

Diabetes-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. 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 post-natal development study in pregnant rats, ertugliflozin was administered to the dams from gestation day 6 through lactation day 21 (weaning). Increased post-natal 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.

Animal 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 192 (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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US-STE-00293 04/19
Connecting with patients

What is implicit bias?

Every person has biases that affect the way they interact with the people and the world around them, and physicians are no different. That’s what implicit bias is: “unconscious attitudes or stereotypes that affect our understanding, actions and decisions,” according to a 2016 report from The Joint Commission.

There has been a great deal of research in recent years exploring how implicit biases in healthcare affect diagnoses, patient outcomes and the physician-patient relationship. While research is still developing, one fact is clear: The implicit biases that physicians and other healthcare providers hold has a real impact on the care their patients received.

But there’s the rub: If these biases are unconscious, then how can physicians recognize and address them? For our cover story in this issue, we talked with physicians, experts and researchers into implicit bias.

One of the areas primary care physicians find themselves treating on a more frequent basis are patient behavioral health conditions, including depression, anxiety and many others. We have in-depth feature in this issue discussing how practices can integrate behavioral health services—and use proper coding and documentation to get paid for it.

In addition, we have: a look at precision medicine, and what practices need to do to get started; a legal piece on what to do if a patient posts a defamatory online review about you or your practice; and our second place winner in our 2019 Physician Writing Contest essay, titled “The Hope of Living Better” by Scarlett Hao, MD.

Enjoy the issue! ☞

Mike Hennessy, Sr.
Chairman and Founder
COVER STORY

Overcome bias
Tips for connecting with all patients

OPINION

Tackle chronic conditions
Our healthcare system is in dire need of addressing the chronic diseases that plague patients, writes Julia Hu

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Get started in your practice
MS has issued the final rule for Medicare’s 2020 Physician Fee Schedule (PFS), and it’s a win for primary care doctors. Under the rule, doctors in the coming years will see higher reimbursements for evaluation and management (E/M)-related services as well as simplified requirements for billing and coding these services. Both have been long-standing goals of primary care doctors.

"Historic simplifications to billing requirements mean that clinicians will be able to focus on recording the information that’s most important to keeping a patient healthy," Alex Azar, secretary of the U.S. Department of Health and Human Services, said in a statement. "As we move toward a system that pays more and more providers for outcomes rather than procedures, we look forward to freeing clinicians from even more of these burdens."

Beginning Jan. 1, 2020, CMS will increase the PFS conversion factor—part of the formula used to translate relative value units (RVUs) into actual payments—to $36.09 from $36.04. Beginning Jan. 1, 2021, it will increase payments for office and outpatient E/M visits and provide enhanced payments for visits with payments with greater needs and multiple medical conditions.

CMS says the higher reimbursements will result from its decision to use the American Medical Association (AMA) Relative Value Scale Update Committees’ recommended values for office and outpatient E/M codes for 2021 and a new add-on CPT code for prolonged service time.

E/M changes includes reduce from five to four the number of levels for office/outpatient E/M visits for new patients.
Frequent heartburn affects
UP TO 75% of sufferers
at night¹

PUT THE BEAST TO SLEEP

PROTECTION THAT LASTS | ALL DAY & ALL NIGHT*

UP TO 10x as many patients achieved complete resolution of nighttime heartburn after just 1 week of treatment²†‡

Time to first resolution of frequent heartburn-related sleep disturbances for most patients was on their first night²†


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James Ellzy, MD, FAAFP, is a board-certified family physician, an assistant professor at the Uniformed Services University of the Health Sciences and served for 22 years in the U.S. Navy, where he attained the rank of captain. In spite of his sterling credentials, Ellzy, who is also a board member of the American Academy of Family Physicians (AAFP), says he frequently encounters double-takes the first time he meets with patients at his clinical practice at the Fort Belvoir Family Medicine Residency in Virginia. In part, he says, the response is due to looking younger than his 49 years. But mostly it’s because he is African-American, while many of his patients are white.
It’s not that these patients are overtly racist or even aware of holding any biases against African-Americans. Still, he adds, “I notice the look on their face when I first meet them that says, ‘this isn’t who I was expecting to see.’”

The “this isn’t who I was expecting to see” reaction is an example of what psychologists and others who study human behavior call “implicit bias”: the unconscious, usually negative assumptions humans make about others they perceive as being in some way different from themselves.

While implicit (or “unintended”) bias affects nearly everyone, its consequences are especially significant in medicine. Since the majority of physicians are white and male, the unconscious assumptions they may hold about patients who are neither white nor male can lead to inappropriate treatment decisions, and on a larger scale, worsen disparities in health outcomes.

The good news is that as understanding of implicit bias grows, so do techniques for combating it. Increasing numbers of healthcare institutions, physicians organizations, and medical schools are developing training programs to help doctors recognize unintended bias and prevent it from affecting their medical decision-making.

THE ROOTS OF IMPLICIT BIAS

By itself, experts say, implicit bias is neither good nor bad. Rather, it is a result of the brain performing one of its primary evolutionary functions—absorbing and organizing the information constantly bombarding it and guiding our actions based on that information.

“It’s our brains trying to function at maximum capacity by finding patterns among information or events or groups of individuals as a way of enabling us to make decisions without really thinking about it,” explains Kierra S. Barnett, MPH, a doctoral candidate in public health at the Kirwan Institute for the study of Race and Ethnicity at Ohio State University in Columbus.

While this form of information processing is highly efficient—and indeed vital to humans’ ability to function on a day-to-day level—psychologists note that it comes with a significant drawback: some of the information it takes in produces, or reinforces, negative stereotypes about others based on attributes such as their race, gender, ethnicity, and sexual orientation.

Michelle van Ryn, Ph.D., MPH, a professor at the Oregon Health and Sciences University School of Nursing who has studied and written extensively about stereotypes and implicit bias, cites the example of an experiment where two groups of white people were given an account of the same crime, except that in one account the criminal had a name usually associated with African-Americans.

“The people in the group reading that account were more likely to recall the violent aspects of the crime than was the group who assumed the criminal was white, which in turn reflects the pervasive images of African-Americans as violent criminals in the news and entertainment media, she says.

“So implicit biases are basically this [learning] system applying whatever information it’s learned, even if it’s negative and inaccurate, to whole groups of people,” she explains. Moreover, unless the process is interrupted, the brain will engage in confirmation bias by focusing on events or actions affirming what we think we already know about those groups, van Ryn says.

“Doctors have been molded throughout medical school and all our training to be non-prejudiced when it comes to treating patients. It’s not only asked of us, it’s demanded of us, so many physicians would like to think they have no biases.

But it’s not true. All human beings have biases.”

—JAMES ALLEN, MD, PULMONOLOGIST AND MEDICAL DIRECTOR, UNIVERSITY HOSPITAL EAST, OHIO STATE UNIVERSITY’S WEXNER MEDICAL CENTER.
UNEQUAL TREATMENT, UNEQUAL OUTCOMES
The impact of unintended bias, both in individual physician-patient encounters and outcome disparities, has been well-documented in research studies, most notably in an influential 2003 Institute of Medicine report on racial and ethnic disparities in healthcare.

The report found evidence that "stereotyping, biases and uncertainty on the part of healthcare providers can all contribute to unequal treatment." Moreover, even white clinicians who don’t believe they are prejudiced "typically demonstrate unconscious implicit negative racial attitudes and stereotypes."

More recently, a 2016 study published in the *Journal of Clinical Oncology* examined interactions between black patients and white oncologists who had been administered a test for their levels of implicit bias. (See sidebar, "Measuring Implicit Bias").

It found that oncologists who rated higher in implicit racial bias had shorter interactions with their patients, and their patients rated the interactions as "less patient-centered and supportive" than those with less implicit bias.

The study also found links between a physician’s bias level and their patients’ confidence in recommended treatments, and more perceived difficulty in completing them.

"One of the effects we and other researchers have demonstrated in a variety of medical contexts is that if the doctor is high in implicit bias, the patient leaves the interaction with the feeling the doctor doesn’t really care about them, they don’t trust the doctor, and the treatment may not work," he says.

In the case of cancer treatment, with its expense and unpleasant side effects, the result may be high rates of non-adherence or sometimes stopping treatment entirely—outcomes which can, in turn, shape doctors’ treatment decisions.

"What happens in a lot of cases is, black patients are underdosed and the rationale many physicians give is, ‘the patient’s probably not going to do the treatment anyway, so why should I make him that sick?’" Penner explains.

ACCEPTING THE REALITY OF IMPLICIT BIAS
While many people have difficulty acknowledging that their actions are influenced by unconscious biases, the concept is particularly troubling for doctors, who have been trained to view—and treat—patients equally, and the vast majority of whom sincerely believe that they do.

"Doctors have been molded throughout medical school and all our training to be non-prejudiced when it comes to treating patients," says James Allen, MD, a pulmonologist and medical director of University Hospital East, part of Ohio State University’s Wexner Medical Center.

"It’s not only asked of us, it’s demanded of us, so many physicians would like to think they have no biases. But it’s not true. All human beings have biases."

"Among physicians, there’s a stigma attached to any suggestion of racial bias," adds Penner. "And were a person to be identified that way, there could be very severe consequences in terms of their career prospects or even maintaining their license."

Ironically, as Penner and others point out, the conditions under which most doctors practice today—high levels of stress, frequent distractions, and brief visits that allow little time to get to know patients—are the ones most likely to heighten their vulnerability to unintentional biases.

Louis Penner, Ph.D., professor emeritus in the oncology department at Wayne State University School of Medicine in Detroit and lead author of the study, notes that the results highlight another harmful result of implicit bias: patients are able to recognize their physician’s attitude and, as a result, become less likely to adhere to treatment recommendations.

"I notice the look on their face when I first meet them that says, ‘this isn’t who I was expecting to see.’"

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"A doctor under time pressure from a backlog of overdue charting and whatever else they’re dealing with will have a harder time treating all patients with the same level of empathy and concern," van Ryn says.

**LEARNING TO MINIMIZE THE IMPACT**

So what can physicians and healthcare organizations do to address these biases? Since the process that produces them is "hardwired," eliminating them is next to impossible, experts say. Instead, the focus should be on reducing their impact on doctor-patient interactions and medical decision-making. And that process begins by just recognizing that they exist, says Preshuslee Thompson, a training and development specialist at the Kirwan Institute.

"Once you become aware of your biases, you can kind of bring them to your conscious mind and be able to say, 'I know I have this bias, so I'll keep it in mind while I'm working with this patient, or I know that some circumstances make me more susceptible to my implicit biases so I'll try to avoid those when I'm making decisions about my patients," she says.

Conversely, according to Barnett, "If you're not going to acknowledge those biases, then you're going to continue to allow your brain to work on autopilot and be influenced by them."

Equally important is finding each patient’s unique qualities or features, thereby making it easier to see them as an individual rather than part of a faceless group. Penner cites the example of a white physician’s initial encounter with a patient who’s African-American.

“If that doctor views the patient simply as a black woman, the possibility that the doctor’s implicit bias will be activated is much greater than if she’s seen as Mrs. Brown, a retired school teacher and mother of four children. So he’s not looking at a social category, he’s looking at an individual,” Penner says.

**“NO ONE IS IMMUNE TO THIS”**

People who have conducted training in identifying and addressing implicit bias also find it helpful to emphasize its pervasiveness. "No one is immune to this.

**When it comes to bias in healthcare, patients are by no means always on the receiving end. Doctors, too, face prejudice from patients, especially if they are African-American, female, or foreign-born.** And while doctors are trained, and strive, to treat all patients with courtesy and respect, patients themselves are under no such constraints in their encounters with physicians and other clinicians.

Two recent analyses document the extent and impact of prejudiced behavior directed at physicians. In a 2017 survey of more than 800 doctors conducted by WebMD/Medscape in collaboration with the website STAT, 59 percent of respondents had heard offensive remarks in the previous five years about a personal characteristic, usually tied to age, race, or ethnic background.

In addition, 31 percent had a patient request a different doctor because of the survey respondent’s personal characteristics, and 27 percent had a patient ask to be referred to someone other than who the survey respondent recommended.

These types of encounters can be profoundly demoralizing, as evidenced by a 2019 study in *JAMA Internal Medicine*. The authors conducted focus groups with a diverse group of hospitalists, residents, and medical students at two San Francisco healthcare facilities, asking participants to talk about their experiences with patient bias.

“Incidents of biased patient behavior described by participants ranged from outright rejection of care and racist, sexist, or homophobic epithets to inappropriate compliments, flirtatious remarks, and jokes reflecting ethnic stereotypes,” they write. Less extreme examples of patient bias included assuming that women were nurses or that doctors from minority groups were support staff.

Participants’ responses to these incidents, according to the authors, were feelings of anger, fear, and confusion. “Most notable were the negative effects on learning and clinical practice,” they add, citing a first-year woman resident who said, “Biased interactions take away from your ability to focus on learning or training or developing into a better clinician.”

To help doctors navigate encounters with biased patients, the authors recommend incorporating training into medical curricula. Such training, they add, should focus on individual as well as team responses and include “setting limits, appropriate deflection, team plans, debriefings, and support for the offended physician or trainee.”

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Bias in medicine is a two-way street

by Jeffrey Bendix, senior editor

When it comes to bias in healthcare, patients are by no means always on the receiving end. Doctors, too, face prejudice from patients, especially if they are African-American, female, or foreign-born. And while doctors are trained, and strive, to treat all patients with courtesy and respect, patients themselves are under no such constraints in their encounters with physicians and other clinicians.

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even those of us with the most egalitarian goals of fairness and equality,” says Danielle Jones, MPH, manager of the AAFP’s Center for Diversity and Health Equity. “When you frame it from that perspective, I think it makes people a lot less defensive and more open to having a conversation around, ‘what are my biases, and what can I do to address them’?”

That was true for Ohio State’s Allen, who earlier this year participated in a university-sponsored training session on implicit bias, an event he approached with some trepidation.

“I had this fear there were these dark sides of me that I was not aware of and that the training would make me discover that I’m a bad person without realizing it,” he recalls. So he was pleasantly surprised to find that wasn’t the goal of the training, but rather to explore different forms of bias and how to overcome them.

Allen attended the training to learn how to work better with his colleagues, who hail from a wide variety of ethnic, national, and religious backgrounds. But he found that it also changed how he relates to patients.

“I think it has resulted in my taking more of a shared decision-making approach in caring for my patients, rather than paternalistically dictating what the patient has to do,” he says. “Now, I’m more sensitive to personalizing care plans depending on whether the patient wants to be more aggressive or less in their treatment.”

Another useful technique for lessening the impact of unintentional bias is by undermining stereotypes. For example, in her group training sessions, Jones might present a case study about an African-American patient who’s frequently late to appointments and ask participants to discuss factors that might account for the patient’s behavior, such as difficulty finding reliable transportation.

“The goal is to find additional information or context to minimize that immediate reaction of assuming that the stereotype is true,” Jones says.

Similarly, Jones encourages doctors to practice mindfulness as a way of counteracting the bias that can result from not being able to spend much time with patients. The situation may unwittingly lead to assumptions—what Jones calls “mental shortcuts”—about patients.

“These mental shortcuts are where bias kind of sneaks in,” she explains. “So when we talk about mindfulness we’re trying to make doctors aware this could be happening, and get them to maybe consider alternatives in their clinical decision-making and patient interactions.” Doing so, she adds, can also help physicians develop empathy for, and build relationships with, their patients.

While not attributing it to mindfulness, Allen says that as a result of his training he now makes a point of chatting with patients about what’s going on in their lives, such as what they did on vacation or how their children are doing. Such conversations usually add no more than a minute or two the visit, and Allen feels it is time well spent.

“It allows me to build those ties that come from showing my interest in them as unique people,” he says. “And hopefully it lets them see that I care about them as a person and not a bunch of skin and bones that happens to have a disease.”
Get your practice ready for 2020

Don’t leave the management and growth of your practice up to chance. Now is the right time to think about what you want to achieve in 2020. Here’s how to prepare.

Reflect on the year
What has gotten done, what is still in process, and which high priority projects would you like to complete by the end of 2019? Review your calendar and your to-do lists and ask the staff involved in the discussion to do the same.

Consider that, although you’ve got a few months to address priority items before year-end, the holidays will be here soon, and that productivity may wane a bit given employee time off and schedule. Be realistic about what you can achieve by December 31; some projects may need to be moved to next year.

Set a vision for the practice’s future
A good plan starts with a vision of what you want from your practice. What do you want for your practice in the next one to three years? For example, do you want to improve physician time flexibility by transitioning to a concierge model or adding telemedicine services? Add new services by opening a physical therapy department or recruiting a subspecialty partner? Increase revenue by partnering with the hospital in a new surgery center? Get your ideas out on the table, and refine them into a list of no more than three objectives.

More than that can splinter your focus. Put the finalized list in writing.

Identify the business problems
Do you have old technologies that need updating? Is the practice experiencing growth that requires additional managers or staff? Are the days in A/R through the roof? These are examples of business problems that could be solved next year. Walk through each area of the practice and discuss which problems need to be addressed. For instance:

- Hiring/Workforce Planning
- Coding and Revenue Cycle
- Technology
- Financial Management
- Growth/Marketing
- Strategy

List the issues in each area and identify the highest 1-2 priorities in each. Set goals for how you will address and achieve them. If you can, add a few details - such as a likely project lead for technology selection and implementation, or the type of roles you’ll need to hire for if say, you are planning to develop and open a second office site.

Ask probing questions
If done well, planning discussions should foster rigorous discussion and questions about the direction of the practice. Don’t see disagreement as negative but rather as a way to get to a better quality result.

For the goals and objectives in the plan you might ask the team:

- "What do we have to make sure we do right in order to achieve this goal?"
- "What tools/staff need to be in place to get this project done?"
- "If we choose to pursue this goal in 2020, what are we going to have to decide not to do?"

Put goals in writing
Putting the plan in writing makes it real. It does not have to be lengthy or complicated. Several pages or a short slide deck will do. Document your vision for 2020, the three objectives you chose, and the specific goals for solving key business problems. Distribute it to your team so everyone knows what to expect.

Karen Zupko is president of Karen Zupko & Associates, Inc., a healthcare consulting and education firm. Send your practice management questions to medec@mmhgroup.com.
Sound accounts receivable (A/R) management is integral to the financial health of a medical practice. The ability to maximize collections and profitability depends on it. Thus, it’s important that practices know what processes they can implement to ensure a smooth-running A/R operation.

David Norris, MD, MBA, an anesthesiologist in Wichita, Kan., and author of *The Financially Intelligent Physician: What They Didn’t Teach You in Medical School*, pays his practice’s employees every two weeks, but has an average A/R cycle of 45 days, meaning it takes about three pay periods for him to earn what he’s already paid out to his staff. So having an efficient A/R process makes possible the cash flow that, in turn, lets him pay his employees on time. “You want a system that is very accurate and gets as much of the money into the practice as quickly as possible,” he says.
Accounts receivable

START WITH VERIFYING DATA
Obtaining and verifying current insurance information, including any recent changes in coverage—preferably before the patient arrives—is essential to that accuracy and efficient income stream. So is properly coding patient visits, entering the correct data into the billing system, billing insurance on that basis and posting and adjusting the resulting payment.

“That’s where the breakdown happens, because providers don’t invest the time up front to make sure the patient knows what their responsibilities are,” says David Zetter, CHBC, founder of Zetter Healthcare, a healthcare practice management consulting firm in Mechanicsburg, Pa. “And that’s why they’ve been chasing money for years.”

To prevent that breakdown, the practice should verbally inform all its patients what their payment expectations are, have them sign an agreement containing that information, and ensure that back-office staff know about and support that agreement. This is a financial policy that clearly spells out what’s expected of both patients and staff.

To minimize the possibility of any misunderstandings, the staff should discuss the policy’s main points with the patients. As well, the policy must be enforced uniformly (e.g., the practice will collect a copay at the time of service; it will request some kind of payment if a high-deductible plan applies.)

“The biggest challenge there, if you have more than one owner, is making sure the owners buy into their own process,” says Zetter, alluding to practices where doctors waive copays for friends—a behavior that, if repeated, means the practice has breached its contract with its commercial insurers and likely violated Federal law (because it’s probably seeing Medicare and/or Medicaid patients). If it bills the insurance company while waiving the copay, the practice has committed fraud.

Unfortunately, few practices have what Zetter insists must be in that policy: a clear-cut assignment of benefits that gives practices the right to bill and be paid by patients’ insurance. Indeed, Zetter estimates that “probably 90 percent” of practices “do not have a legally binding, worded contract of assignment of benefits that their patients are signing.

“If an auditor sees that an assignment of benefits is worded incorrectly, and truly doesn’t provide them the right to bill, then the payer can ask for every single dime back,” he says.

Zetter is adamant that sending out patient statements and doing follow-up calls to retrieve tardy payments doesn’t work any longer. “It’s an archaic process...
that’s been going on since the days of Marcus Welby,” he says, adding that it’s better to establish processes to guarantee the money up front, including keeping a credit or debit card on file. “Then, when the balance falls to the patient account, the practice already has approval from the patient because it has communicated this information, and it can start billing that balance and get paid immediately.

“Are claims being denied for certain things for which they haven’t been denied before? If you see that, I would get on the phone with that carrier to see if I could come to a resolution.”

—DAVID NORRIS, MD, MBA, AUTHOR, THE FINANCIALLY INTELLIGENT PHYSICIAN: WHAT THEY DIDN’T TEACH YOU IN MEDICAL SCHOOL

**KEEPING TABS ON Payers AND PROBLEMS**

Monitoring and managing your payers to see how much they have in the A/R pipeline is a vital task, according to Norris. His practice’s staff generates a monthly report, broken into 30-, 60-, 90- and 120-day A/R cycles, showing who owes them how much money, how many of those dollars are still uncollected, and if that number is rising. Then he tracks denials—what’s being denied and, just as important, why.

“Are they playing games? Is it something on our end like we’re not coding things right? Are people making certain the claim is ready to be submitted as a clean claim or are we just trying to get as many bills out the door as fast as possible, where we’re just missing things that wind up costing us money as we try to reprocess that claim?” he says.

With denials, spotting trends is crucial in discovering where the problem lies. “Are claims being denied for certain things for which they haven’t been denied before?” asks Norris. “If you see that, I would get on the phone with that carrier to see if I could come to a resolution.”

Practices can’t afford to leave money on the table or be slow in collecting it. For Williams, staff training is essential in preventing that. “Process breakdowns could be any number of things, including that staff, when they’re working on insurance and patient balances, may be writing off things that are collectible,” she says. “And they need to know at what point do you escalate problems with insurance companies that aren’t paying properly.”

It’s A/R staff’s responsibility to identify any breakdowns that delay payments, including technical problems such as computer or clearinghouse glitches. “But if you’ve got an astute staff that are running regular reports and know what they should be looking for, then they should be able to stay on top of collections,” says Williams.

Patients sometimes dread talking with A/R departments, which is why adopting a payments policy that’s consistently applied, and coupling it with a flexibility to work with patients on a payment plan can make that conversation easier on both ends. So it helps if A/R can tell patients with a financial hardship upfront that the practice is willing to work out an installment plan with them. Kagan suggests what a hypothetical deal might look like: “If you’ve got a deductible of $3,000 and you owe me $800, I’d be thrilled if you gave me $100 a month,” he says.

“Having a smooth patient portal where you can store credit card information can help you engage with the patient, too,” says Norris. So can having a human touch, which the practice can encourage by training staff members how to politely but firmly ask for payment on the day of the visit.

Finally, practices must ensure that their statements are more patient-friendly than the typical physician’s handwritten prescription in the pre-digital days. Otherwise, the patient may be forced to call the billing staff and ask them to interpret something that makes no sense to them—something nobody enjoys doing.

“It’s often necessary to work with your process vendor to make sure that the statements are easily understood,” says Williams.

Ultimately, successful A/R is about two basic, but not necessarily simple, tasks: keeping close tabs on the accounts, every day, and getting timely payments. “Those are going to be your main challenges: figuring out who owes you and then when you can collect it,” Norris says.
6 tips to boost billing and collections

If your practice is like most other practices, then one area where you could use some work is billing and collections.

Here are six resolutions that can improve your billing and collections in 2020.

1. Educate your patients.
   - Insurance is complex and is getting more so. Patients could use a bit of schooling. Copays, deductibles, and other medical billing terminology can be a bit of a mystery to most people.
   - Consider printing a simple flyer that explains billing basics that can apply to any insurance plan. Direct patients toward the customer service number on the back of their insurance cards for more detailed questions.
   - Educating patients on where to get more information can also help improve patient relationships. Patients often blame the doctor when billing problems are really between patients and their insurance provider.

2. Talk to your patients in an effective way.
   - Make sure your staff knows how to communicate with patients about their bills. Never ask patients whether they want to pay their bill now.
   - Instead, offer a choice of two options for paying. Assume that they’re going to pay and ask them if they prefer to pay by check or credit card.

3. Stay on top of claims.
   - This is one of the most important things you can do to improve your bottom line.
   - File claims on time, daily if possible, and have a routine system for checking open claims.
   - Be sure to file amended claims when necessary and never miss a resubmission deadline.

4. Verify insurance.
   - Do this on the phone before and at every patient visit.
   - When you verify insurance, be sure to also confirm the patient’s contact information. People change jobs, switch email accounts, ditch landlines and move across town but don’t always remember to notify their physicians.
   - Regardless of how you send bills, be sure to avoid sending statements to the wrong address.

5. Review your contracts.
   - Take a little time at the first of the year to review your contracts with payers.
   - Make sure you are aware of any changes from the prior year, especially if those changes require a change in workflow, process or staff retraining.
   - Note all filing deadlines for the year ahead.
   - This is also a good time to make a chart of when your contracts come due, so you can plan ahead for any renegotiations.

6. Designate a go-to person for billing.
   - Make sure you have one person on your staff who is thoroughly trained and experienced in all things billing.
   - Refer any staff and patient questions or issues to this person.
   - Spend the time and money training your go-to person, too, as your revenue depends on her capabilities. It’s also wise to cross-train in case your billing pro has to miss work for a lengthy period.

Avery Hurt is a contributing author. Send your financial questions to medec@mmhgroup.com
I met Mr. AR for the first time in September of my intern year. He was a 70-year-old gentleman admitted to the hospital with nausea, vomiting, and abdominal pain. CT scans revealed an obstructing mass in the head of his pancreas. The rest of the workup yielded a frightening diagnosis of pancreatic cancer, prompting his primary medical team to consult us—the surgical oncology service. Although another resident had already seen him the day before, the patient’s daughter had only just arrived today, having traveled over 300 miles to be with her father. Mr. AR knew only that he needed to have surgery, so his daughter asked the nurse to page the surgery team, asking for someone to explain the proposed procedure.

I felt my heart pounding as I listened to the nurse relaying the request. I was barely three months out from graduating medical school, but my senior residents were operating (and so was the attending physician), so there was no one but me to walk to the north wing of the hospital, frantically studying diagrams on my phone as I made my way over. I made silent promises to myself that it would be okay to say, “I don’t know,” because I truly didn’t know. How long would he have to stay postoperatively? When could he eat normal food? What activity could he do afterward? Would he be cured? Would he still need chemotherapy? These were questions I’d ask if I were the patient, and yet I had none of the answers.

Up until that day, I had decided that I hated surgical oncology. The patients were ill to begin with, having spent some time fighting a malignancy prior to presentation, then some of them would be weakened by neoadjuvant chemotherapy, sustaining neither nourishment nor exercise, and then we would throw them into the gauntlet of a major surgical resection. Much of a surgical intern’s time is spent on the inpatient floor following postoperative patients, and I felt a crushing gloom entering the ward every day looking in on how sickly the patients seemed to be. Watching them die was even worse. The promise of more time to live, however long, didn’t seem worth it, and I struggled to care about these patients when everything seemed so futile to me.

Despondent, I knocked gently and pushed the door open, peering in. Mr. AR and his daughter looked up
from their conversation, smiling brightly and asking if I was the surgery person. I stumbled over my greeting, taken aback by the sunny atmosphere. They were so glad that someone had come. He looked nothing like my patients: no temporal wasting, no ribs showing through his side, no exhaustion in his eyes. I drew pictures of the anatomy that would be altered during the procedure in order to remove the cancer. I apologized where I had no answer and reassured them that the attending surgeon would be by to fill in the gaps.

I also found out that he and his daughter came from my hometown, and by the time we were done chatting about more than just his diagnosis, an hour of my afternoon had drifted by. They thanked me for the information that I could give, and as I left the room, I couldn’t hide my own smile at having shared a positive connection with another human being.

The next time I saw him, Mr. AR had undergone his surgery and relocated to our surgical postoperative floor. His recovery was not without complications. He endured a prolonged course of ileus, a string of electrolyte derangements, and an infection requiring antibiotics. Despite that, he greeted me cheerily every morning, even if I came to bother him at five or six o’clock. When I caught him pushing a rolling walker in the halls, he wanted to show off his dance moves, weak as he was. The optimistic attitude he and his daughter shared was contagious, and it motivated me to continue working hard to get him better after every setback. By the time he left the hospital, he looked more like the cancer patients I was used to seeing, frail and thin, but he didn’t stop smiling.

Months later, a stranger tapped me on the shoulder. I almost didn’t recognize him. He was a far cry from the last I’d seen him: normal clothing, filled out cheekbones, standing on his own. Apparently he was there following up with his oncologist and was doing very well on his adjuvant chemotherapy. He thanked me for the care he had received and expressed that I must continue doing so for others. I left that encounter with a renewed sense of purpose: the care I was providing no longer seemed futile.

Though progress was slow, I began to see how Mr. AR had changed me. As an intern, I had focused on the nitty-gritty details: the diagnosis, the pathophysiology, the workup, the treatment, the answers to difficult questions from the attending, the right orders to input into the computer. As a second-year resident, I found that the knowledge and workflow were now second nature, and I began to really see the patients for who they were. I saw new patients, anxious about their symptoms, fearful of the “c” word.

I saw survivors, racking up years free of cancer, eating well and living normal lives. I saw beyond the details of the treatments and began realizing the principles and patterns guiding the care of cancer patients. I assisted in surgeries big and small, where some patients were cured with a small excision and others like Mr. AR had to face the gauntlet. For these latter patients, I could now picture where they would be a few months following their surgery, strolling down to the hospital cafeteria for a snack after their infusion.

But they wouldn’t get there on their own. Motivated by their stories, I challenged myself to take ownership of their care, to read as much as I could, to be able to answer their questions where I couldn’t answer before. I presented patients I had seen at the multidisciplinary tumor board. I took notes on my clinic patients the night before so that I could spend more time with them in person and less with the computer. I stayed past shift changes to struggle through difficult cases with my attending. So imagine the surprise when third year rolled around, and I said with certainty, “I want to go into surgical oncology.”

Mr. AR is still alive today, and the lesson I learned from our shared experience is still with me as well. He showed me a different perspective of caring for cancer patients. Where I had once viewed it as a process of dying and merely delaying the inevitable, now I view it through his lens, as a process of living for the hope of living better, no matter what length of time we can give them. He had the strength to face every day with joy and positivity, and now I can do the same for my patients who don’t have that strength themselves. This is what has helped me become a better doctor.

Scarlett Hao, MD, is an Asian-American resident physician in general surgery at the East Carolina Brody School of Medicine. She received her medical degree from the University of Maryland School of Medicine and speaks multiple languages, including Spanish and Mandarin. She is happily married and enjoys board games, Marvel movies, and trying new restaurants. Her hope is to become an academic surgeon in the field of surgical oncology.
**Behavioral health**

How to generate revenue, improve patient care

*by LISA A. ERAMO, MA Contributing author*

Physicians understand the connection between mental and physical health, yet many don’t feel equipped to address patients’ behavioral health problems. They also don’t have the time, says Bonnie T. Jortberg, Ph.D., RD, associate professor of the department of family medicine at the University of Colorado School of Medicine. “Severe depression and anxiety isn’t something you can address effectively during a 15-minute visit,” she adds.

Yet talking about behavioral health is critical—particularly when physicians are increasingly held accountable for patient outcomes under value-based care models. For example, screening for depression, evaluating risk of opioid misuse, and screening for unhealthy alcohol use—all of which are billable—can help physicians increase reimbursement under the Merit-based Incentive Payment System.

Providing behavioral health-related services can also help providers hit quality benchmarks, bill for new and/or higher-level services, and even address social determinants of health such as food insecurity, housing instability, and health literacy.

Behavioral health integration care management, another billable service that focuses on care coordination between a care manager and behavioral health specialist, pays approximately $49 for 20 minutes of services each calendar month.

Aside from the revenue implications, incorporating behavioral health into a primary care practice also can help patients achieve better outcomes—both physical and mental.

“This isn’t just about someone’s mood—it’s about addressing physiologic problems that affect patients’ health,” says Allen Y. Tien, MD, MHS, president and chief science officer at mdlogix, a software company that develops cloud-based solutions to help practices streamline behavioral health screening, care coordination, and outcomes reporting.

In some cases, a mental health problem is the root cause of the physical ailment, says Tien. Depression fueling diabetes is one example. If physicians don’t treat the depression, they likely won’t improve the diabetes, he adds.
**CREATING A ONE-STOP SHOP FOR ADDRESSING PATIENTS’ NEEDS**

Experts agree that embedding a behavioral health specialist in the practice can potentially boost revenue and take pressure off physicians by serving as a resource for patients. Doing so makes sense because primary care physicians already have a rapport with patients, making it more likely that patients will follow through with behavioral health referrals, says Coley Bennett, CMM, CHA, practice manager at A Plus Medical, P.C., an independent primary care practice in Tacoma Park, Md.

Earlier this year, A Plus Medical hired a certified registered nurse practitioner to focus on billable mental health services such as smoking cessation counseling and intensive behavioral therapy. As in many communities, there’s a growing need for these services because many providers don’t accept Medicaid, and there aren’t enough outpatient mental health centers to accommodate timely appointments.

In addition, Takoma Park is a culturally diverse city with many undocumented immigrants. Trust plays a large role in whether patients ultimately decide to seek any kind of treatment and particularly behavioral health services for which there continues to be a stigma, says Bennett. Once they find a provider they trust, they tend to want to stay within the practice for as many services as possible, she adds.

Last year, Matthews-Vu Medical Group, a multi-specialty group in Colorado Springs, Colo. integrated an adult psychiatrist, a pediatric psychiatrist, and five licensed clinical social workers (LCSWs) after physicians had difficulty finding providers who would accept Medicaid patients, says Debbie Chandler, MBA, CMPE, chief executive officer at the practice. Even with these providers, Chandler says, there’s frequently a waiting list for patients requesting services.

**REVENUE CONSIDERATIONS**

Despite the benefits of behavioral health integration, experts agree that hiring a specialist requires a financial risk that isn’t easy for small independent practices to take.

“The model that typically works best is the primary care physician employs an LCSW or team of LCSWs that internally handle the majority of behavioral health care and then contracts with a psychiatric consultant for services that require advanced expertise,” says Toni M. Elhoms, CCS, CPC, consultant at Alpha Coding Experts LLC in Orlando, Fla. “LCSWs are a lot more affordable than psychologists and psychiatrists.”

According to Payscale.com, the average national salary for an LCSW is approximately $57,000, whereas a psychologist earns about $76,000, and a psychiatrist earns approximately $202,000. Local and regional salaries may vary.

Physicians need to determine what services the behavioral health specialist will perform and whether revenue from those services will pay for that provider’s salary, says Chandler.

For example, if physicians don’t routinely screen for anxiety and depression, these should be among the most common services the behavioral health professional renders, says Tien. Many of these screenings can be completed electronically on a tablet while patients wait to see the physician in a fraction of the time it takes to administer them face-to-face, he adds.

However, specialists can also focus on more intensive therapies (e.g., for obesity) and generally spend more time with patients discussing advanced care planning, smoking cessation, and other mental health concerns.

A behavioral health specialist can also perform and bill for general behavioral health integration care management for patients with a behavioral health condition (including substance abuse) who require at least 20 minutes of face-to-face or non-face-to-face services each calendar month, says Elhoms. This service is appropriate for patients who require ongoing care coordination similar to chronic care management, though the documentation requirements are not nearly as onerous, she adds.

Behavioral health specialists can also bill for this service during the same calendar month as the patient receives chronic care management, creating more revenue for the practice while helping patients with chronic conditions obtain
Chronic Conditions

Behavioral health

the added layer of behavioral health services when needed, she says.

Another consideration is how much additional revenue the primary care physician can generate as a result of increased productivity. For example, a planned 10-minute visit could easily become a 45-minute encounter when a physician tries to manage the patient’s anxiety or depression.

By saving 35 minutes, physicians could potentially see an additional three patients. The SAMHSA-HRSA Center for Integrated Health Solutions has published a guide, The Business Case for Behavioral Health Care, that can help physicians calculate a more specific return on investment.

If employing a full-time specialist isn’t realistic, another option is to hire one on a contractual basis with a financial split. The CRNP at A Plus Medical, for example, is a contractor who receives a percentage of each fee-for-service amount billed. Under this model, there’s less financial risk for the practice because the specialist is paid based only on the revenue she generates, says Bennett.

However, “Bringing the behavioral health specialist on as an employee changes the financial game,” she adds. “It means their schedule must be full, and you’re also going to need to actively market those be-

Behavioral health integration: Common billable services

When primary care physicians integrate behavioral health professionals into their practices, they may be able to provide and bill for new and/or higher-level services that can generate additional revenue, says Toni M. Elhoms, CCS, CPC. Elhoms provides details below. Note that CPT codes listed with an * are approved for telemedicine, meaning the behavioral health specialist could work from a remote location.

<table>
<thead>
<tr>
<th>Medicare CPT code</th>
<th>Description</th>
<th>Medicare reimbursement</th>
<th>Documentation, coding tips</th>
</tr>
</thead>
<tbody>
<tr>
<td>99484</td>
<td>Behavioral health integration care management services, 20 minutes per calendar month</td>
<td>$48.65</td>
<td>Document total time spent on care management services each calendar month; initial assessment or follow-up monitoring (including the use of applicable validated rating scales); behavioral healthcare planning and revisions for patients who are not progressing or whose status has changed; and care coordination efforts for psychotherapy, pharmacotherapy, counseling, and/or psychiatric consultation.</td>
</tr>
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</table>

Other common billable services that a behavioral health specialist can perform

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>G0442*</td>
<td>Alcohol misuse screening</td>
<td>$18.38</td>
<td>Document the validated screening tool used, the findings of the screening, total time spent screening for alcohol misuse, the development of a patient-specific plan, and that the patient was competent and alert at the time of the screening.</td>
</tr>
<tr>
<td>G0443*</td>
<td>Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes</td>
<td>$26.67</td>
<td>Document total time spent counseling the patient and what was discussed.</td>
</tr>
<tr>
<td>G0444*</td>
<td>Annual depression screening, 15 minutes</td>
<td>$18.38</td>
<td>Document the validated screening tool used, the findings of the screening, total time spent screening for depression, the development of a patient-specific plan, and that the patient was competent and alert at the time of the screening.</td>
</tr>
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</table>
Behavioral health services as if you’re building a business from the ground up. If neither of these are feasible, practices could consider co-locating a behavioral health specialist in the practice, says Chandler. The primary care physician could refer patients to the specialist, who rents space within the office—but there are no financial ties or formal care coordination.

This arrangement gives physicians an option when behavioral health issues arise, but it doesn’t offer the full suite of benefits that comes with truly integrated care, including the ability to bill for their services, she adds.

**OPERATIONAL CONSIDERATIONS**
Consider these six tips to ensure a successful integration of behavioral health and primary care:

1. **Use a “warm handoff.”**
   At A Plus Medical, for example, patients complete relevant screenings, then, depending on the results, there’s a “warm handoff” between the physician and CRNP. During these handoffs, Bennett says, physicians tell patients they reviewed the screening and feel the patient could benefit from talking with someone else in the practice.
Five reasons to integrate behavioral health services into primary care

1. Boost value-based payments by hitting quality benchmarks
2. Decrease costs by preventing ED visits and hospitalizations
3. Identify and address social determinants of health (e.g., food insecurity, housing instability, and health literacy)
4. Increase patient satisfaction by providing convenient care options
5. Generate additional revenue

Matthews-Vu follows a similar workflow; however, it also has a process in place for crisis management. If a patient presents in crisis, or a crisis develops during a medical appointment, a behavioral health specialist is always available to speak with that individual.

Practices may want to consider using a daily huddle to identify patients who might benefit from behavioral health services, says Jortberg. For example, have any patients been on depression medication long-term? Do any patients have a history of substance abuse? Flag these patients in the EHR for a warm handoff to the specialist for a brief check-in after meeting with the physician, she adds.

Hire a behavioral health specialist with diverse experience. Depression and anxiety are common; however, behavioral health providers may have varying degrees of experience with trauma, post-traumatic stress disorder, eating disorders, substance abuse, post-partum depression, and pain management, says Chandler. Identify specific needs within the population, and hire someone who can address those needs, she adds.

Develop a plan to address coding, billing challenges. Practices may need more specialized administrative support when hiring a behavioral health specialist, says Chandler. Matthews-Vu, for example, hired a certified medical coder with behavioral health experience to address coding and billing challenges.

Alternatively, a practice could pay for existing staff to obtain training in this field. A Plus Medical trained staff on how to obtain prior authorizations for initial assessments and subsequent visits, though Bennett says there are ongoing challenges. For example, some payers will approve psychotherapy for depression but not for anxiety.

Make sure your EHR vendor can accommodate documentation requirements. The SOAP note works well for primary care; however, behavioral health providers must also perform a mental status examination that should be included in an EHR template, says Bennett. To provide effective care, these providers also need access to comprehensive assessment tools that go beyond the standard Patient Health Questionnaire (PHQ)-2 and PHQ-9, she adds.

Invest in an e-prescribing module. A module that integrates the state’s Prescription Drug Monitoring Program (PDPM) database into the EHR streamlines the process of prescribing controlled substances, says Bennett. In Maryland, providers prescribing these medications are required to check the state’s PDPM before prescribing because many mental health drugs are controlled substances. Forty-one states have this type of mandate, though the specific requirements vary.

Require the specialist to sign a business associate agreement (BAA). This only applies if the practice intends to provide access to protected health information without employing the behavioral health specialist directly, says Tien.
It’s time to tackle chronic diseases head-on

BY JULIA HU

The U.S. healthcare system is at a crossroads. In one direction, we have the Mack truck of chronic disease barreling toward us. By next year, about 157 million Americans—nearly half the nation’s population—will be managing a chronic disease, with 81 million people managing more than one. These conditions are incredibly costly, representing 75 percent of the nation’s $3.3 trillion annual healthcare costs.

In the other direction, we have a looming physician shortage. By 2032, the U.S. could see a shortage of between 46,900 and 121,900 physicians.

Both problems are only worsening, and will accelerate more rapidly in the coming decade as our population ages. In order to avoid a massive collision, we need to move now.

The challenge is that the healthcare system was designed in an earlier era when acute and infectious diseases were the nation’s biggest health problems. We needed highly trained doctors to help the sickest people deal with urgent medical conditions. Then came industrialization, the end of polio, and the flu shot. People are living longer, our lifestyles and our diets have changed, and the new silent killer is chronic disease.

We have neglected to build a system that can help people stay healthy or manage a chronic condition effectively and in a way that prevents more serious problems from developing. To build a new healthcare system that meets the needs of all patients, we must do two things.

First, we need to make staying healthy or managing a chronic condition less burdensome. People who have a chronic disease or are at risk of developing one need highly personalized care that gives them ongoing support when they need it. That kind of care is not always complex, but it is very time consuming and life-long. Seemingly small things like helping people adhere to their medication regimen (and making sure it’s appropriate), keeping track of their blood sugar or blood pressure, helping patients make healthy food choices, and encouraging activity when possible have a huge impact on disease management and health outcomes.

Second, we need a healthcare system that can deliver care to half of the nation’s population every day. To achieve these, we need to consider conversational AI. While it is not yet developed enough to navigate most tasks highly-trained humans can perform, AI works in tightly constrained, large scale, and data-rich situations.

While it cannot replace doctors, nurses, and health coaches, it can provide the type of care needed to help people manage chronic conditions every day. The interventions are largely similar across many of the most prevalent chronic conditions—the modality should be ongoing small touch points of support that feels empathetic, compassionate, and friendly. In addition, AI can base these touch points on daily health data.

While doctors and nurses should be monitoring and coordinating care for people with chronic conditions, it does not take a health professional to provide the day-by-day, hour-by-hour support needed to help people stay healthy. Instead, we should be thinking about care that can meet people where they are—right on their smartphones that they carry with them all the time.

This use of AI in healthcare will make the healthcare system more efficient and effective, and, ultimately, will result in better health outcomes.

Julia Hu is the CEO of Lark, a chronic disease prevention and management platform that’s powered by artificial intelligence.
Maintaining a positive online presence is vital to the success of any medical practice. A recent survey from Doctor.com revealed that as many as 63 percent of respondents would choose one provider over another because of a strong online presence. Similarly, 60 percent of respondents have chosen one provider over another based on a positive online reputation.

As patients increasingly rely on the internet to determine which provider is best for them, online reviews play a critical role in the success—or failure—of modern medical practices. Unfortunately, it is often impossible for a potential patient to differentiate truthful and accurate reviews from fraudulent ones. Worse, a single disgruntled patient may leave many reviews across a number of platforms, inflicting untold harm with a few keystrokes. Thus, defamatory reviews can quickly destroy a thriving practice.

The risks posed by online reviews are especially dangerous for healthcare practices since health complications can arise or worsen even if providers have done everything properly, and reviewers may be completely misinformed regarding the standard of practice applicable to their situation.

Doctors have a right to defend their reputations and livelihoods against reviewers who spread false and damaging claims. Fortunately, there are a variety of legal options available to combat defamatory online reviews.

KNOW YOUR RIGHTS

Defamation laws vary from state to state but, generally, a person may be liable for defamation when he or she posts a review that contains demonstrably false assertions of fact (as opposed to opinion), that are damaging to the subject of the review.

This means that patients are entitled to post reviews that are statements of opinion, such as "I didn’t care for the doctor’s bedside manner" or "The office was poorly decorated." While a provider may disagree with a patient’s opinion, those disagreements are not proper bases for legal action because opinion is generally protected by the First Amendment.

Patients can also provide reviews that contain statements of fact, so long as those assertions are accurate. Like statements of opinion, truthful statements of fact are protected free speech under the First Amendment.

However, if a review contains a false assertion of fact, the reviewer may be liable...
for defamation. This may include statements such as “I was billed for procedures that were not performed” or “The doctor botched the procedure.”

**SEEK LEGAL ADVICE**
Unlike many other industries, healthcare providers operate in a highly-regulated environment. Providers should be extremely careful when confronting defamatory reviews, as they must not violate any of the ethical, legal, or regulatory guidelines, e.g., HIPAA, that govern doctor-patient relationships.

In addition to regulatory concerns, healthcare practices should keep the following steps in mind when considering whether or how to address negative online reviews:

**SEEK A LAWYER.** Consult a lawyer with experience handling defamation matters for healthcare providers. These matters are fraught with potential peril if not handled properly, so you need to work with a qualified and effective advocate. After all, your business and reputation are on the line not only because of the defamatory review but in how you respond to it.

**DETERMINE IF THE REVIEW QUALIFIES AS PURPORTED FACT.** Work with your lawyer to determine whether the statements in the negative online review qualify as statements of purported fact. To do this, you may need to parse the language carefully to determine exactly what the reviewer was communicating. Often times, statements may initially appear to be factual but after a deeper look may constitute opinion, or vice versa.

**ADDRESS THE REVIEW.** If the review contains only statements of opinion, consider alternative methods for addressing it, such as pursuing any takedown procedures or other features the review platform provides to help business owners address negative reviews.

**INCREASE POSITIVE REVIEWS.** Make a sustained effort to increase the number of positive reviews. Asking satisfied patients to post truthful online reviews can increase a provider’s overall rating and may dilute the effect of one older negative comment compared to more recent positive reviews.

**DETERMINE IF A LEGAL CLAIM IS VIABLE.** If you believe that the review is indeed defamatory, ask your lawyer about whether you have a viable legal claim. When determining whether to pursue legal action, keep in mind that:

- If a review is posted anonymously, you may be able to obtain a court order compelling the internet service provider to disclose the identity of the wrongdoer so that he or she may be taken to court.
- To prevail in court, you will need to prove that the statements in question are false. There are many different ways of establishing the falsity of the reviewer’s claims, including through the testimony of witnesses (such as office personnel), records, or other evidence.

**ASK YOURSELF IF LEGAL ACTION IS WORTHWHILE.** Consider the severity of the harm inflicted when determining whether to pursue legal action. A widespread defamatory review can lead to the loss of patients as well as significant—and often permanent—reputational harm. Pursuit of a legitimate defamation claim can result in both removal of the offending review and an award of damages to the provider to compensate for the harm suffered.

On the other hand, in cases of very minor misstatements, it may not be worth investing the time and resources required to pursue legal action, even if you may have a valid claim.

**TAKE ACTION**
Some proactive healthcare practices have begun fighting back against defamatory online reviews. Although many such cases settle outside of court, providers have been increasingly seeking court intervention where the damages are significant or when the reviewers will not cooperate.

Online reviews play a critical role in virtually all modern businesses, and healthcare providers are no exception. Although physicians operate in a highly-regulated environment, they have the right to defend their reputations and businesses when they are defamed.

If this happens, physicians should consult experienced lawyers to ensure they take appropriate legal measures that comply with HIPAA and other regulations while effectively addressing damaging and defamatory reviews.

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Countless physician groups are grappling with how best to introduce and leverage genomics in their practices. And with good reason, as precision medicine appears to be an unstoppable force that could revolutionize how physicians diagnose and treat patients.

The science of genomics has advanced at a rapid pace, with new discoveries about how these insights impact clinical decision-making circulating almost weekly. Consumer demand is rising, thanks to regulatory approval for direct-to-consumer genetic testing and resulting media coverage. In my own practice, more and more patients come to office visits with questions about how genomics could help identify their risk for disease; how this data could guide wellness, prevention, and screening activities; and if we should adjust medications and other therapies based on their genomic profile.

So, how do you get started?

THE REIMBURSEMENT LANDSCAPE

Unfortunately, reimbursement policy lags behind clinical practice when it comes to precision medicine, and payment varies wildly from state to state and test to test. Medicare coverage is advancing most rapidly, with 80 percent of carriers covering specific pharmacogenomics testing, such as behavioral health and pain panels (if appropriate ICD-10 codes are reported, supported by required documentation).

Likewise, genomics tests may be reimbursed to identify disease risk and heritable conditions (e.g., BRCA 1 and 2 or familial hypercholesterolemia). Medicaid plans also often provide coverage for specific tests and may offer the best reimbursement, especially in areas where opioid addiction and behavioral health challenges are acute.

Commercial plans are less predictable. Some offer a flat fee, while others reimburse testing on a case by case basis—with payments for the same diagnostic codes ranging from just a few dollars to thousands. The advent and spread of Molecular Diagnostic Services, intended to help health plans identify tests, determine coverage and determine reimbursement, is stabilizing payment in certain areas, although almost always at lower rates than what might have previously been paid.
SIX STEPS TO PRECISION MEDICINE

Within the context of these variables, six steps can help medical practices launch and grow a viable precision medicine program.

1. Understand your patient population. Who can benefit most from genomic testing? Do you have a large number of polypharmacy patients? Or individuals approaching the age where risk for certain conditions rises (e.g., coronary artery disease, cancer, etc.)? This information will help you understand if pharmacogenomics would deliver value, or if cancer genomics or germline testing for hereditable diseases (or both) is more appropriate.

2. Evaluate where specific populations fit into various payer contracts you have in place. Are most covered in traditional fee-for-service agreements, or are many included in ACO or shared savings plans? Consider if you can deliver not only return on investment for the patient (i.e., lower personal costs, better care, etc.) but for the practice as well. Could precision medicine afford you the opportunity to take on more risk, because you can leverage genomics to better identify patients more likely to develop disease, intervene earlier, and target therapies more effectively?

3. Use the analysis generated by steps one and two to negotiate aggressively with payers. Determine which populations you likely can impact with precision medicine and work towards contracts that increase your revenue for effectively managing those patient populations while reducing payer costs.

4. Educate physicians and medical staff about precision medicine and your strategy to integrate it as the standard of care for specific patient populations. Ensure that they understand the clinical value, as well as the business value, that genomics can deliver. In addition, develop educational materials to help patients understand how they can benefit from precision medicine and what to expect from their caregiver.

5. Begin your precision medicine program with the patients who were identified in step one as those who can realize the greatest benefit. Integrate genomics testing with diagnostic and therapeutic care incrementally, so you can realize success before expanding into other patient groups.

6. Evaluate and assess technologies and solutions that can bring genomics data directly into the EHR workflow, allowing providers to use it in real-time clinical decision-making (e.g., should I prescribe antidepressant A or antidepressant B?). Typically, genomics results are reported on paper or scanned PDFs that cannot be clinically integrated within the patient record context. And all too often, test results have not been translated into clinical vocabulary that is meaningful and actionable for providers. New platforms are emerging that bridge the gap between the science of genomics and making the data useful at the point of care.

“Could precision medicine afford you the opportunity to take on more risk, because you can leverage genomics to better identify patients more likely to develop disease?”

Industry thought leaders agree that genomics holds great potential to transform healthcare—from prevention to diagnosis to treatment. Patients are often ahead of their providers in understanding how genomics can help them stay healthier, and in highly competitive healthcare markets, providers cannot afford to be late adopters. By thinking strategically and equipping providers with critical support tools, practices can leverage the promise of precision medicine to improve current clinical practice—and begin to reap the benefits of better care and outcomes.

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