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—Internist Ann Cordum, MD

CUT COSTS ON EMPLOYEE BENEFITS
**STATISTICALLY SIGNIFICANT REDUCTIONS IN A1C WHEN ADDED**

**Primary end point:** A1C change from baseline at week 26

![Graph showing LS mean change from baseline A1C, %]

<table>
<thead>
<tr>
<th></th>
<th>N=152; BL=8.0%</th>
<th>N=155; BL=8.1%</th>
<th>N=152; BL=8.0%</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIFFERENCE FROM PLACEBO, %</td>
<td>-0.5 ($P&lt;0.001$)</td>
<td>-0.6 ($P&lt;0.001$)</td>
<td></td>
</tr>
</tbody>
</table>

* N includes all randomized and treated patients with a baseline measurement of the outcome variable. At week 26, the primary A1C end point was missing for 10%, 11%, and 7% of patients, and during the trial, rescue medication was initiated by 16%, 1%, and 2% of patients randomized to placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively. Missing week 26 measurements were imputed using multiple imputation with a mean equal to the baseline value of the patient. Results include measurements collected after initiation of rescue medication. For those patients who did not receive rescue medication and had values measured at 26 weeks, the mean changes from baseline for A1C were -0.2%, -0.8%, and -0.9% for placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively.

b Intent-to-treat analysis using ANCOVA adjusted for baseline value, prior antihyperglycemic medication, and baseline estimated glomerular filtration rate (eGFR).

BL=baseline; LS=least squares.
**Study design:** 463 adults with type 2 diabetes, inadequately controlled (A1C between 7% and 10.5%) on metformin (≥1500 mg/day for ≥8 weeks) and sitagliptin 100 mg once daily participated in a randomized, double-blind, multicenter, 26-week, placebo-controlled study to evaluate the efficacy and safety of STEGLATRO. Study subjects were randomized to STEGLATRO 5 mg, STEGLATRO 15 mg, or placebo administered once daily in addition to continuation of background metformin and sitagliptin therapy. The primary efficacy endpoint was the change from baseline in A1C at week 26.

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

**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).

Additional Selected Safety Information on next page.
SELECTED SAFETY INFORMATION (continued)

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.

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.

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

- Severe renal impairment, end-stage renal disease (ESRD), or dialysis
- Active bladder neck obstruction or prostatic hypertrophy
- Hypersensitivity to STEGLATRO

**WARNINGS AND PRECAUTIONS**

- Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues.

**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 seven Phase 3 clinical trials in the STEGLATRO development program, non-traumatic lower limb amputations were reported in 1 (0.1%) patient in the comparator group, 3 (0.2%) patients in the STEGLATRO 5 mg group, and 8 (0.5%) patients in the STEGLATRO 15 mg group. A causal association between STEGLATRO and lower limb amputation has not been definitively established.

- **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.

- **Genital Mycotic Infections.** STEGLATRO increases the risk of genital mycotic infections. Patients who have a history of genital mycotic infections or who are uncontrolled 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.

**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 and dialysis in patients receiving SGLT2 inhibitors.

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

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

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

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

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

**Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues.** Insulin and insulin secretagogues (e.g., 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.

**Genital Mycotic Infections.** STEGLATRO increases the risk of genital mycotic infections. Patients who have a history of genital mycotic infections or who are uncontrolled 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.
Ketoacidosis. Across the clinical program, ketoacidosis was identified in 3 of 3,409 (0.1%). Laboratory findings were observed to reverse after treatment discontinuation.

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

Volume Depletion. STEGLATRO causes an osmotic diuresis, which may lead to intravascular volume contraction and adverse reactions related to volume depletion, particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m²). In patients with moderate renal impairment, adverse reactions related to volume depletion (e.g., dehydration, dizziness postural, presyncope, syncope, hypertension, and orthostatic hypotension) were reported in 0%, 4.4%, and 1.9% of ertugliflozin-treated patients and 0.0% of comparator-treated 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>Reaction</th>
<th>Placebo 611</th>
<th>STEGLATRO 5 mg N=619</th>
<th>STEGLATRO 15 mg N=610</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female genital mycotic infections†</td>
<td>3.0%</td>
<td>9.1%</td>
<td>12.2%</td>
</tr>
<tr>
<td>Male genital mycotic infections§</td>
<td>0.4%</td>
<td>3.7%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Urinary tract infections§</td>
<td>3.9%</td>
<td>4.0%</td>
<td>4.1%</td>
</tr>
<tr>
<td>Headache</td>
<td>2.3%</td>
<td>3.5%</td>
<td>2.9%</td>
</tr>
<tr>
<td>Vaginal pruritus¶</td>
<td>0.4%</td>
<td>2.8%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Increased urination†</td>
<td>1.0%</td>
<td>2.7%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>2.3%</td>
<td>2.5%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Back pain</td>
<td>2.3%</td>
<td>1.7%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Weight decreased</td>
<td>1.0%</td>
<td>1.2%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Thrast</td>
<td>0.6%</td>
<td>2.7%</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

* The three placebo-controlled studies included one monotherapy trial and two add-on combination trials with metformin or with metformin and sitagliptin.
† Includes: genital candidiasis, genital infection fungal, vaginal infection, vulvitis, vulvovaginal candidiasis, vulvovaginal mycotic infection, and vulvovaginitis.
§ Includes: cystitis, dysuria, streptococcal urinary tract infection, urethral, urinary tract infection.
¶ Includes: vulvovaginal pruritus and pruritus genital.
# Includes: pollakiuria, micturition urgency, polyuria, urine output increased, and nocturia.
†† Includes: vulvovaginal candidiasis, vulvovaginal mycotic infection, vaginal infection, vulvitis, vulvovaginitis.
‡‡ Includes: balanitis candida, balanoposthitis, genital infection, and genital infection fungal.
¶¶ Includes: genital candidiasis, genital infection fungal, vaginal infection, vulvitis, vulvovaginitis.

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

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

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

<table>
<thead>
<tr>
<th>Study</th>
<th>Placebo 154</th>
<th>STEGLATRO 5 mg N=158</th>
<th>STEGLATRO 15 mg N=155</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline Overall Hypoglycemia (N (%))</td>
<td>9 (4.3)</td>
<td>15 (7.8)</td>
<td>16 (10.3)</td>
</tr>
<tr>
<td>Severe Hypoglycemia (N (%))</td>
<td>1 (0.5)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Week 6 Change Overall Hypoglycemia (N (%))</td>
<td>1 (0.6)</td>
<td>1 (0.6)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Severe Hypoglycemia (N (%))</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

Renaal-related adverse reactions (e.g., acute kidney injury, renal impairment, acute prenial 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 was used as monotherapy and in combination with other antihyperglycemic agents, non-traumatic lower limb amputations occurred in 0.0%, 0.1%, 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>Study</th>
<th>Placebo 153</th>
<th>STEGLATRO 5 mg N=156</th>
<th>STEGLATRO 15 mg N=152</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Hypoglycemia (N (%))</td>
<td>1 (0.7)</td>
<td>4 (2.6)</td>
<td>4 (2.6)</td>
</tr>
<tr>
<td>Severe Hypoglycemia (N (%))</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Week 6 Change Overall Hypoglycemia (N (%))</td>
<td>1 (0.5)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Severe Hypoglycemia (N (%))</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</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., balanitis candida, balanoposthitis, genital infection, vulvitis, vulvo vaginal candidiasis, vulvovaginal mycotic infection, vulvovaginitis) occurred in 3%, 9.1%, and 12.2% of females treated with placebo, STEGLATRO™ (ertugliflozin) 5 mg, and STEGLATRO 15 mg, respectively (see Table 1). In females, discontinuation due to genital mycotic infections occurred in 0% and 0.6% of patients treated with placebo and STEGLATRO, respectively.

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

Laboratory Tests.

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

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

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

DRUG INTERACTIONS

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

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

Interference with 1,5-anhydroglucitol (1,5-AG) Assay. Monitoring glycermic control with 1,5AG assay is not recommended as measurements of 1,5AG are unreliable in assessing glycermic control in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycermic control.

USE IN SPECIFIC POPULATIONS

Pregnancy.

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

In animal studies, adverse renal changes were observed in rats when ertugliflozin was administered during a period of renal development corresponding to the late second and third trimesters of human pregnancy. Doses approximately 13 times the maximum clinical dose caused renal pelvic and tubule dilatations and renal mineralization that were not fully reversible. There was no evidence of fetal harm in rats or rabbits at exposures of ertugliflozin approximately 300 times higher than the maximal clinical dose of 15 mg/day when administered during organogenesis (see Data). The estimated background risk of major birth defects is 6-10% in women with pre-gestational diabetes with a HbA1c >7 and has been reported to be as high as 20-25% in women with HbA1c >10. The estimated background risk of miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Clinical Considerations.

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For more detailed information, please read the Prescribing Information. usp1m8835-r17172-000

Revised 12/2017

DIAB-1251861-0003 06/18
The war against physician burnout starts with a strong plan of attack

“It is OK to ask for help. The stigma around physician burnout—that it is ‘part of the job’ or only happens to weaker individuals—is one of the biggest obstacles to improvement.”

It is a common refrain I heard at a national internal medicine conference addressing the stress today’s physicians face:

“You can’t yoga your way out of burnout.”

I agree. Yoga, meditation, and mindfulness are helpful, but more is required to restore the joy of practicing medicine. These are just some of the ways. There are many more.

The fact is, there is no one-size-fits-all answer to an issue as large as physician burnout. As the stressors vary—from time in front of an EHR vs. face-to-face with a patient to battling payers over the best treatment—so do the means to relieve that tension. But that doesn’t mean it is too much to overcome.

Physicians have numerous allies in this battle, most importantly, their peers. Find strength in their path and their advice.

In this issue, you’ll find examples of numerous doctors who are overcoming and/or preventing burnout from interrupting their core mission of treating patients. And we’d be foolish to believe that readers use this as a handbook, following step-by-step the path of another doctor and expecting the same outcome. But, what we believe we’ve provided are sound strategies to piece together the initial path to improving physician wellness and truly restoring the joy of medicine.

And the other thing we hope becomes clear after reading about peers is that it is OK to ask for help. The stigma around physician burnout—that it is “part of the job” or only happens to weaker individuals—is one of the biggest obstacles to improvement.

Ask for help. Ask a peer how they get back to the heart of treating patients without added, and unnecessary, obstacles. Learn from and listen to one another.

Use this issue as a starting point, as a small step toward taking back a little more of each day to help those who truly need you—whether patients or family and friends. Fight back.

Relief could come in the form of opening a direct primary care practice. Perhaps some simple workflow adjustments free up additional time. It might even be reaching out for some peer-to-peer support and guidance. The solutions are out there, and they are numerous.

And yes, you might even consider a little yoga as well.

Keith L. Martin is editorial director of Medical Economics. How are you beating burnout? Tell us at medec@ubm.com.
To solve U.S. healthcare crisis, think small, not big

American healthcare, with all its included industries and administrative bloat, is more expensive than ever. From hospital charge master pricing to prescription medications to government-mandated insurance; all parties agree that costs are way out of hand. To fix the problem, we must examine human behavior, history, and cost drivers, at least in brief.

We have seen individuals shifting their health responsibilities to these bureaucracy-laden behemoths with disastrous results. Rates of lifestyle-caused diseases like obesity, diabetes, coronary artery disease, and cancer have all increased despite technology and advances in screening and medical treatment.

The fatal flaw? The bureaucracy cannot change an individual’s behavior. This is one of the myriad reasons population health fails. What then is the big solution? How about thinking small, not big? “Small” as on the individual level taking human motivation and action into consideration.

Individuals have their own value system based on their ethics, morals, motivations, preferences, risk tolerance, experience, etc. And since this is America after all, individuals must be free to exercise their individual liberty and choose what benefits to pursue and risks to take.

History proves that for the best outcomes and use of resources, we must allow individuals to make individual choices. This will work in healthcare too if allowed. Let patients decide on their own whether or not to pursue and buy insurance, preventive care, and other healthcare services, and bear the consequences of the decisions.

“Let patients decide on their own whether or not to pursue and buy insurance, preventive care, and other healthcare services, and bear the consequences of the decisions.”

Here are the steps to get us there:

1. Don’t use government-controlled and designed EHRs.
2. Don’t take insurance assignment. Empower patients to file their own claims.
3. Don’t take Medicare. See Medicare patients outside the system.
4. Don’t take Medicaid. Treat these patients at a price they can afford to create mutual respect.
5. Utilize inexpensive direct care or direct primary care with pretax Health Savings Accounts.
6. Work directly for patients in all possible areas, cutting out middlemen and government.
7. Opt out of ACA, MACRA, and all the counter-productive acronym alphabet soup programs.
8. Foster true inexpensive high-deductible plans or health sharing plans for catastrophic injuries with an HSA for doctor visits.
9. These steps will make patients and physician happy and healthy.
10. But most importantly will maximize the health and happiness of American patients.

― Craig M. Wax, DO
MULLICA, HILL, NJ.
Beat burnout
How to have fun practicing medicine again

Coding for venipuncture
Why proper documentation is key to correct reimbursement

Workflow as stress relief
Learn to delegate responsibility to ease physician burdens

Artificial intelligence
How future technology will finally make data useful

Direct primary care
An internist explains how transitioning his practice saved his career

Reduce patient debt
How to take a proactive approach to payment plans

Employee benefits
What perks to offer employees and how to reduce costs

A helping hand
How physicians are helping their peers take on burnout

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The AGA recommends PEG laxatives (like MiraLAX) as a first-line constipation treatment\(^1\)

- 96% patient satisfaction rate*
- #1 GI-recommended laxative for over 10 years

Start with MiraLAX for proven relief of occasional constipation.
Create your own medical technology

Physicians who use medical devices for diagnosis and therapeutic patient care in day-to-day practice often notice unmet patient care needs that could be filled with new devices or technology.

There are many steps between having an idea and creating a viable product. Some physicians have made the leap and have developed their own medical technology, rather than waiting for products to appear on the market. Often, doctors whose work is heavily procedural are the ones who develop devices, but primary care physicians have created their own devices as well.

The process is not easy, nor is it impossible. Important steps for physicians who are planning to develop medical devices include securing funding, making prototypes and templates, testing the technology, getting a patent, obtaining regulatory approval, and marketing the product.

While ideas are plentiful, a physician may not have a strong sense of the true size of the market or whether there are similar products already available or in development.

New York City-based internist Jennifer Meller, MD, co-founded Navimize, a digital health company focused on reducing patient wait times. She surveyed patients to get feedback about the demand and value of her product.

“Lots of doctors have great ideas, but not every great idea is something that other people are willing to pay for,” she explains. And getting input from seasoned professionals played an important role right from the beginning.

Sam Slishman, MD, an emergency care physician in San Luis Obispo, Calif., developed the Slishman Traction Splint which he started working on in 1999 during his residency. He says getting started requires research to see whether your concept for a device is truly original and whether there is a need.

“You really have to soul search and Google search to know whether your idea merits a patent and whether you are willing to do what it takes,” he advises.

As physicians, we can start to change the market by remaining independent, by referring only to other independent doctors and free-standing outpatient centers, and by educating patients about why they, too, must only go to independent doctors.”

— Marni Jameson Carey, executive director of the Association of Independent Doctors, on avoiding healthcare “consolidation Kool-Aid”

“It stands to reason that the best way to deal with unaffordable healthcare isn’t to take a second mortgage out on the house, but to make healthcare more affordable.”

— Anish Koka, MD, a Philadelphia-based cardiologist on making free markets work in medicine
PROGRESS TOWARD VALUE-BASED CARE HAS STALLED

A survey of physicians and health plan executives published by Quest Diagnostics in July found that a majority in both camps believe that the United States is not making progress towards value-based care. More troubling, a majority believe physicians do not have the tools they need to succeed.

**Fee-for-service still dominates the reimbursement landscape**

2017, 63% believe the U.S. is still primarily a fee-for-service system in 2018, 67% felt the same way

2 out 3 of physicians and health plan executives say value-based care will stall under the Trump administration

**Physicians do not have what they need to succeed**

57% of health plan executives say physicians need better tools to make value-based care work (up from 45% in 2017)

72% of those surveyed say physicians need more data about their patients to succeed

**Physicians on value of quality metrics**

“Quality measures are useful in improving care.”

68% of physicians agree

“Progress has been made toward aligning the goals of payers and providers.”

41% of physicians agree

**Physicians not sold on consumer-based healthcare**

“Putting more emphasis on a consumer-based approach to healthcare will advance value-based care.”

55% of physicians agree

“It’s clear that health plan executives and physicians need to better align around a shared vision of how technology and data can improve patient care.”

—L. Patrick James, MD, chief clinical officer, Quest Diagnostics

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“It’s clear that health plan executives and physicians need to better align around a shared vision of how technology and data can improve patient care.”

—L. Patrick James, MD, chief clinical officer, Quest Diagnostics
INTERNIST ANN CORDUM, MD, belongs to a seemingly endangered species of primary care doctors—those who enjoy their work and look forward to coming to the office every day.

It hasn’t always been that way for Cordum. She spent the first quarter century of her career in clinical and administrative positions with large healthcare systems, where she found herself growing increasingly frustrated with bureaucracy, too-short patient visits, and answering to managers who were MBAs rather than MDs.

So in 2015, Cordum decided to strike out on her own. She and another internist opened a direct primary care practice in Boise, Idaho, with the goal, she says, of “having no intermediary between myself and the patient.”

The result has been exactly what she hoped for in terms of her approach to practicing medicine. “Now it really is joyful,” she says. “I like going to work and even when I’m not at work, I’m always available. I feel like it’s my pleasure to help the patients with their needs.”

BURNOUT, ALIENATION INCREASE

Doctors’ use of terms like “joyful” and “pleasure” when talking about medical practice has grown increasingly rare in the last decade or so. Studies and surveys consistently show rising levels of burnout and alienation within the medical profession. For example,
in the Physicians Foundation’s 2016 Survey of American Physicians, 54 percent of respondents rated their morale as “somewhat or very negative,” and 49 percent said they “often or always experience feelings of burnout.” Only 37 percent said they harbored positive feelings about the future of the medical profession.

The reasons behind these feelings have been well documented. They range from frustration with EHRs and time spent obtaining prior authorizations to anger over government mandates and payers’ “take it or leave it” attitude in contract negotiations.

CARVING OUT MORE PATIENT TIME
And yet, in spite of all the obstacles, it is still possible for doctors to enjoy their work. The key, according to practice consultants, psychologists, and physicians, is spending more time doing what doctors are trained to do and gives them pleasure: treating patients.

While that sounds obvious, the challenge lies in finding the time for it. To start with, many doctors—particularly those working for hospitals and hospital systems—usually have little control over their schedule or working conditions and often must wrestle with the system’s bureaucracy to get patients the care they need.

But even doctors in independent practice often find it difficult to carve out more time for patients, given the range of administrative tasks and quantity of paperwork pulling them away from the exam room.

“A lot of what’s driving doctor unhappiness is that more and more is being expected of them than in the past, and this has compressed the amount of time they have to spend with patients, while the documentation burden has gone up,” says Cynthia “Daisy” Smith, MD, FACP, vice president of clinical programs for the American College of Physicians and part of the ACP’s Physician Well-being and Professional Satisfaction initiative.

Smith cites a 2016 study in *Annals of Internal Medicine* that found that for every hour doctors spend in face-to-face clinical time with patients, they spend nearly two hours on “EHR and desk work in the office,” according to the authors, and another one to two hours of personal time on computer and clerical work.

RETHINKING APPROACHES TO MEDICAL PRACTICE
But the barriers to finding, or rediscovering, joy in medicine aren’t all external, experts say. Sometimes it requires physicians to re-think how they approach their work, says Gail Gazelle, MD, FACP, a former hospice physician who now coaches doctors on issues of professional satisfaction and work-life balance.

Gazelle notes, for example, that many physicians are perfectionists, a personality attribute that is important for success in medical education and training but can contribute to frustration and anxiety as a practitioner. “If you spend hours [on patient notes]...
Fighting back against burnout

because you believe that every note has to be perfect, but you only have so many hours in a day, you can see how the math doesn’t add up, and helps to explain why so many physicians struggle to keep up with documentation demands,” Gazelle says.

That drive for perfectionism, Gazelle adds, goes hand-in-hand with how many

Physician tell their burnout stories

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ACP TRIES PEER COUNSELING TO REDUCE BURNOUT  By Jeffrey Bendix

In January, the American College of Physicians launched a “Physician Well-being & Professional Satisfaction initiative,” with the goal of increasing professional satisfaction among its members. [For more information, visit bit.ly/ACP-champions]

One of the components included in the initiative is the “Well-being Champion” program, which the college began in 2015 as a way for individual ACP members to support other members and chapters in their efforts to combat burnout. Among the first cohort of champions is Louis Snitkoff, MD, FACP, a former practicing internist and now chief medical officer of Community Care Physicians, a multi-specialty practice in the Albany, N.Y. region.

“I saw the toll that medical practice was taking on physicians in my group who were friends and colleagues,” Snitkoff says, in explaining why he volunteered for the program. The initial, two-day training session focused largely on the organizational and institutional factors behind doctors’ unhappiness with their work. That was in marked contrast to his previous thinking about burnout.

“The earlier approach was to see what could be done to make the individual physician more resilient,” he says. “It’s like saying to someone in an abusive relationship, ‘just toughen up and you’ll be fine.’ There are dynamics that occur within a work setting, and in the larger environment of the American healthcare system, that can’t be solved just on the individual level.”

Snitkoff adds that he witnesses those dynamics in the talks he gives at local and state ACP chapters and other venues, such as hospital grand rounds. The most common complaint he hears from doctors is the administrative burdens they face. That is followed by frustrations over battles with insurance companies and prior authorizations.

“It’s like every single thing needs a signature these days,” he says. If a patient says his wheelchair needs repair you need to verify that. We’re doctors, not mechanics.”

Many of the hospital-employed clinicians he encounters say the use of relative value units to measure their productivity is demoralizing. “It creates a factory sort of environment where you’re judged by how many people come through as opposed to what you’re really doing to help patients,” he says.

Getting doctors to open up

One of the biggest problems Snitkoff and his fellow champions face is simply persuading physicians to open up about their feelings of depression and alienation, and to seek help for overcoming them. That’s due in part, he says, to medical school and residency training where doctors receive the message that they must be “invincible,” although in recent years there’s been more emphasis on physician well-being, he adds.

But reluctance to seek help goes beyond training, Snitkoff says. “Physicians have a concern, that is not unfounded, that having to disclose that you sought mental health assistance could have an adverse effect on credentialing and licensure,” he says. That’s because virtually all applications for these include questions about the doctor’s mental and physical health.

No ‘one size fits all’ solution

When it comes to solutions for restoring enjoyment in practice and fighting burnout, “There’s no one size fits all,” Snitkoff says. “They have to be specific and tailored to the environment and organization where people are working.”

But that doesn’t mean the solutions have to be complicated or expensive. For example, he says, hospitals “quiet rooms,” where doctors can go to decompress are known to be effective at improving physician morale. He also cites the example of a well-known hospital system that arranges and pays for small groups of doctors to have meals together. “It creates a sense of community and allows them a space where they know it’s safe to talk about problems without fearing negative repercussions,” he says.

Snitkoff adds that he’s been able to apply some of what he’s learned as a champion to his own practice. For example, Community Care has formed a committee to study ways of making EHRs more efficient and reducing the quantity of documentation they create. “Having physicians and staff understand that we’re focused on their professional experience as much as we focus on the patient experience has been a helpful thing,” he says.
Coding Insights

How to properly document and bill for venipuncture

What is the correct way to code venipuncture? Does the billing change if the procedure is performed by a medical assistant (MA) instead of a physician?

If your physician has seen the patient prior to the MA performing the venipuncture (on the same day or a previous date) and instructs the MA to perform the venipuncture, the billing is the same regardless of whether the physician or MA actually performs the service, based on incident-to guidelines. Just make sure that the physician’s order and the performance of the venipuncture are documented. Here are some coding tips:

1. Select the right code. Venipuncture coding is described using CPT 36415 (collection of venous blood by venipuncture).

2. Don’t append modifier -63. Modifier -63 describes a procedure performed on an infant less than 4 kg. CPT instructs us that use of modifier -63 with 36415 is inappropriate.

3. Report a single unit of 36415, per episode of care, regardless of how many times venipuncture is performed. This instruction comes from the 2018 National Correct Coding Initiative (NCCI) Policy Manual, Chapter V: Respiratory, Cardiovascular, Hemic and Lymphatic Systems CPT Codes 30000-39999. The Policy Manual stipulates:

CPT code 36415 describes collection of venous blood by venipuncture. Each unit of service (UOS) of this code includes all collections of venous blood by venipuncture during a single episode of care regardless of the number of times venipuncture is performed to collect venous blood specimens. Two or more collections of venous blood by venipuncture during the same episode of care are not reportable as additional UOS [Units of Service].

Per the Policy Manual, “An episode of care begins when a patient arrives at a facility for treatment and terminates when the patient leaves the facility.” Medicare will not reimburse for routine venipuncture, and neither will many private payers.

CPT includes codes to report venipuncture requiring a physician’s skill, which are chosen according to the patient’s age and, for those patients younger than 3 years old, by the vein accessed:

- **36410** Venipuncture, age 3 years or older, necessitating physician skill (separate procedure), for diagnostic or therapeutic purposes (not to be used for routine venipuncture; femoral or jugular vein

   - **36405** scalp vein

   - **36406** other vein

Renee Dowling is a billing and coding consultant with VEI Consulting in Indianapolis, Ind. Send your coding and billing questions to medec@ubm.com.
Manage practice workflow to reduce burnout

Learn to delegate responsibly to help ease pressure on physicians

C. Nicole Swiner, MD, has worked hard to create a better work-life balance for herself. She transitioned from a hospital-owned clinic to private practice eight years ago and now is one of two physicians at Durham Family Medicine in Durham, N.C. She knows that devising best practices and strategies before they’re needed can go a long way toward keeping the “flow” in “workflow.”

Here’s how to strengthen organizational workflow within a practice to make sure everything isn’t always the physician’s responsibility—a surefire set-up for burnout.

Maximize staff capabilities

The best thing she’s done to improve her sanity is to hire someone who functions like a scribe, says Swiner. “I should have done it sooner. Now I focus less on note-taking and finishing and more on being able to listen to my patients instead of staring at the computer.”

She knows time is money. “Now it takes me 15 minutes to do 15 to 20 notes,” she says. “Paying a premed or grad student to scribe gives me time to see two to three extra patients in a day. They gain knowledge by working with me, and we both win.”

Ideally, everyone works to maximal capabilities and training, says Swiner, who also works with her LPNs and medical assistants so they understand her organizational structure and can support her at “full capacity,” meaning they can rise to the ever-changing list of tasks that occur in the practice every day. “The fewer phone calls and less paperwork I have, the better my life is,” she says.

Her ingenuity helps keep burnout at bay. Leading contributors to the pervasive problem include increasing administrative and documentation burdens, and the pressure to do more with fewer resources, says Nisha Mehta, MD, a radiologist based in Charlotte, N.C., who writes and speaks about physician burnout.

“To address this, practices need to take a sincere look at workflow, identify areas where other members of the healthcare team or staff can help, and then devote resources and training to make this possible,” Mehta says.

Collaborate with the practice manager

“The first thing physicians sometimes need to understand is how to ask for help,” says Kenneth T. Hertz, FACMPE, principal consultant for the Medical Group Management Association Health Care Consulting Group. “Remember, too, that there isn’t always one solution, i.e., ‘If you do this, everything will be fine.’”

Enter the practice manager, who can help build teams “to pull people together to solve problems,” says Hertz. “This requires collaborative effort, knowing you can’t solve everything by yourself. Practice managers really can help when we’re able to analyze things from the outside, without being in the middle of them.”

Create a positive culture

Remember to recognize good work, says Hertz. “You can do this when you praise your staff. It’s especially powerful from expectations very clear, up front, Hertz says. “For example, say to your trusted nurse, ‘When I come into the exam room, please have this and this laid out for me. And check the chart to make sure lab and X-ray results are back.’”

In addition to the nurse, the receptionist is just one staff member who may see patients before the physician and should process them quickly, says Hertz. Checking them in and obtaining their medical files, confirming current insurance, address, phone, and emergency contact efficiently prepares them for the next steps.

“Then [the patient is] ready to be seen so the doctor can walk into the exam room and do his or her job. Everyone needs to accept responsibility for their little piece and to know that everyone succeeds or fails as a team,” he says.

Be clear about expectations

Make work performance
the doctor, who might say, 'Thank you, it was a great day today.' The employee on the receiving end walks on air for the next two weeks and now wants to continue to rise to the occasion on the job.

Be patient with staff, since sometimes, practices can be quick to let valued staff members go for reasons that aren’t so well thought out, says Mehta. She suggests that maybe it’s ultimately beneficial not to focus on the “small stuff,” but to appreciate the broader contributions a seasoned staff member makes to the practice workflow.

“Focus on the retention and satisfaction of valuable, well-trained staff so that you’re not wasting time, money, and effort on recruitment and training of new members,” Mehta says. Think about creating efficiency in the practice—then preserving it.

### Define workflows

Every clinical and non-clinical staff member should have well-defined roles in the workflow, Turton said. This allows the physician to devise protocols that staff members should adhere to. “This is about taking decision making out of doctor’s hands, and placing it in the hands of a protocol,” Turton said.

### Avoid batching

Turton defined “batching” as all of the things that need to get done that get stacked and put off until later: unfinished charting, unanswered messages, lab values, imaging results, mail, the phone queue, and appointment queue. “When you stack something, you reduce quality and increase the costs,” Turton said.

### Delegate to your team

Delegation is about ensuring that the physician can work at the top of their license. Turton said it’s about “allowing the least trained—but still qualified—person do the work.” There are a few ways to do this. First, practices should have a prescription refill protocol, under which refill inquiries are routed to a certified staff member and most refills are authorized without the physician. Second, Turton said his practice in Atlanta, Ga., improved adherence to diabetes markers by having medical assistants conduct the basic interview with the patients and perform A1c tests and foot exams based on a protocol designed by the physician. That has allowed the practice to improve greatly on hitting its diabetes markers, he said.

### Say goodbye to difficult patients

Workflow is also better without problematic patients, so don’t hesitate to make necessary changes, says Swiner. “Taking that action is appropriate when patients are late, cancelling or no-showing, not taking medications correctly, or being belligerent with staff. You have every right to ask them to find someone who suits them better,” she says.

This tactic can result in immediate benefits, says Swiner, for both doctor and patient. “I’m much less stressed when I look at the schedule and don’t see as many patients that give me heartburn. And it may be healthier for both of you,” she says.
Artificial intelligence in primary care

The evolution of cognitive technology has the potential to transform the way physicians work

by MARY K. PRATT Contributing author

Physicians could have new assistants in the future: artificial intelligence (AI). AI could be capable of screening patients, offering diagnoses, and suggesting optimal treatments as well as triaging patient inquiries and processing patient claims.

AI is a technology that mimics human thought processes by finding patterns, then using what it finds to make decisions. AI is also defined by its ability to learn as it processes more data over time.

AI, in fact, promises to impact nearly every aspect of primary care, according to health IT experts.

Those knowledgeable about the technology say AI-enabled computer applications will collect and synthesize disparate patient data and present it to physicians alongside insights into the patient’s medical needs.

It will help physicians better identify patients who need more attention and provide personalized recommendations on what protocols would work best for each individual.

And AI will even help diagnose patients by analyzing quantities of information that would be too difficult for any human to assess.

“There are very high hopes for AI to improve the lives of physicians as well as the lives of their patients,” says Anil Jain, MD, FACP, an internist who is vice president and chief health information officer for Watson Health at IBM in Armonk, N.Y. “As a primary care doctor, I’m encouraged by this because it could make my life easier.”

AI IS GEARING UP

Several factors have come together recently to support the quickening pace of AI developments for healthcare and, more specifically, for primary care.

Leading the way is the amount of healthcare data collected in recent years. The high level of computing power now available to process large data sets, the ubiquity of computer systems and EHRs, and overall advances in computer technologies also have fueled AI’s advancements in medicine, according to experts.

Still, AI in healthcare is in its early stages, says Teresa Zayas Cabán, Ph.D., chief scientist at the Office of the National Coordinator for Health Information, which funded the 2017 report “Artificial Intelligence for Health and Health Care.”

Zayas Cabán says technology vendors, medical institutions, and other health organizations are working to identify the tasks that would be suitable for AI to handle and bring together the right data needed to develop.

HIGHLIGHTS

- AI is expected to enable primary care physicians to engage in precision medicine, where care protocols culled from large-scale studies are tailored to the individual patient.

- Experts see a future that involves physicians leveraging AI for clinical and administrative tasks but not one where physicians are actually replaced by technology.
or “train,” AI to handle those tasks.

**ANTICIPATED USES**

Even though AI is in its early stages, experts say it’s poised to impact both clinical care and administrative tasks in primary care practices and thereby allow more physicians to practice to the top of their license, says Erik Louie, MD, chief medical officer at HealthBox, a healthcare innovation consulting and fund management services firm in Chicago, Ill.

Louie and others envision a variety of different uses. AI could screen patient data from physician notes, tests results, and other data sources and combine that with information from protocols, clinical studies, and recommendations to identify a patient’s condition, which follow-up tests are needed, and which medicines work best. In other words, AI will be significantly more sophisticated versions of today’s clinical decision tools.

Meanwhile, AI could collect and analyze patient data as it is generated from multiple sources, including fitness trackers and at-home monitors, thus aiding physicians as they monitor patients’ health in ways that time and resources without AI don’t allow. “AI lets us look at data and help think about the patient’s total picture. In the future, it will help [physicians] to get insights, rather than just data,” Jain says.

Moreover, AI is expected to enable primary care physicians to engage in precision medicine, where care protocols culled from large-scale studies are tailored to the individual patient based on analysis of his or her own conditions, genetic makeup, and even social circumstances. It’s a level of analysis that no human could do, Jain says.

Experts predict physicians will use AI to help them more accurately identify patients who need specialty care. They also expect physicians will use it to better manage patients by directing those who need higher-level care to specialists while being able to more accurately monitor at-risk patients in their own practice—a critical benefit as the U.S. healthcare system moves more patients to value-based care models.

As an example, Louie points to an AI application to screen for diabetic retinopathy as a tool for primary care physicians. The federal Food and Drug Administration in April approved IDx, a diagnostic system that uses AI to detect diabetic retinopathy. IDx does not require a specialist to interpret the images or results, making it the first such system cleared for use by the FDA.

Physicians and their care teams, even those not normally involved in eye care, can use the technology to screen their patients for the condition during routine office visits.

In addition, physicians soon could have AI take their notes, analyze their discussions with patients, and enter required information directly into their EHR systems. Physicians might even use AI to analyze indicators that they can’t, such as patients’ voices to detect anxiety or depression.

IT forecasters predict that this emerging technology will also improve many front- and back-office functions. For example, AI will guide patients through intake forms that it tailors based on responses, and AI will analyze patient records to determine how to most accurately submit claims for timely reimbursements with less chance of denials.

**NUMEROUS BENEFITS EXPECTED**

AI has the potential to positively impact healthcare in several ways, all delivering real returns, health IT leaders say. Consider, for instance, that research shows that clinicians have an average of 15 minutes with each patient but spend nine of those minutes entering data in their EHRs, says R “Ray” Wang, MPH, principal analyst and
founder of Constellation Research Inc. of Monta Vista, Calif. Imagine, he says, how much more a clinician can discuss with the patient if AI takes over those mundane data-entry tasks.

Wang also notes that AI can access and learn new research at a volume and speed impossible for any human to match. That means a physician using AI can expand his or her breadth of knowledge and ensure his or her decisions draw on the latest research as well.

“AI will be going through information—the patient’s genome, history, current medications, all the things the physician doesn’t have the time to be on top of and infor-

Can AI help physician burnout?

By Jordan Rosenfeld
Contributing author

So much of a physician’s workload includes repetitive, tedious tasks involved in researching diagnoses and analyzing patient data and imaging. Combined with increasingly demanding administrative and regulatory burdens and EHR hassles, it’s no wonder physicians are burning out in record numbers.

Experts in artificial intelligence (AI)—a form of machine learning in which computers can be trained to recognize patterns in large quantities of data—are hopeful that AI will be a key part of reducing physicians burdens and saving them time and energy.

“We live in an age where a lot more data can be generated than a physician can really analyze,” says Mark Lambrecht, PhD, director of the global health and life sciences department at SAS, a North Carolina-based analytics company that works with healthcare providers and payers.

He believes that AI can step in to help. “Studies have shown that AI can help physicians reduce the time they have their hands on the keyboard,” Lambrecht says. “They do this by capturing the data automatically, making sense of it, providing content, and making sure the data is put in the right field.”

Lambrecht gives another example of how AI can help physicians who have patients with type 1 diabetes. “There are pens that can measure glucose values every minute. Lots of physicians are not able to interpret that data, so we have techniques in AI to help that interpretation, to see if a patient is stable or unstable.”

AI is already improving workflow for radiologists, according to Tarik Alkasab, MD, PhD, service chief for informatics, IT and operations at Massachusetts General Hospital in Boston.

Before AI, in order for a radiologist to interpret an X-ray, they’d have to flip through a book containing hundreds of images and manually find the best match for their image. Now, with AI, he says, Mass General is incorporating a system that automatically detects the best match, then shows that to the radiologist along with some neighboring ones. “The tedious task of finding the book and flipping through it to find the right information is not something the radiologist has to do anymore.”

Alkasab feels that two of the reasons for physician burnout are related to “hunt and search” tasks and the documentation process, both of which can be improved by AI. “[Physicians] will do less of the searching, describing and measuring kinds of tasks, and more of the analyzing, synthesizing, evaluating, and planning kinds of tasks. AI is going to be a lot more rewarding and less tedious.”

In addition to reducing hassles and repetitive tasks for physicians, AI has the potential to save more lives. Lambrecht knows of a hospital where AI is helping to predict whether liver cancer patients need chemotherapy or surgery.

“Physicians will become convinced that it is really a new tool in their toolbox, a very powerful one, that will help them make better decisions for their patients,” Lambrecht says.

Some organizations are also using AI-based scheduling programs, particularly where there are a large number of physicians and ancillary staff to keep on a tight schedule. As the technology evolves, Lambrecht is sure the uses for AI will only expand.

For those physicians who are nervous that AI could one day replace them, Lambrecht says that it is highly unlikely. “What AI will do is take out a little bit of that variability that exists in medicine.”
John Huffman, chief scientific officer of data science and AI at Philips, a Dutch company whose portfolio of integrated health tech products includes AI-enabled platforms.

**AI AT WORK TODAY**
Numerous initiatives and technology vendors are introducing more AI products into a variety of healthcare disciplines, including primary care.

“**There are very high hopes for AI to improve the lives of physicians as well as the lives of their patients. As a primary care doctor, I’m encouraged by this because it could make my life easier.”**

—ANIL JAIN, MD, FACP, INTERNIST, VICE PRESIDENT AND CHIEF HEALTH INFORMATION OFFICER FOR WATSON HEALTH, IBM, ARMONK, N.Y.

One example of AI at work in primary healthcare is the nonprofit Human Diagnosis Project, or Human Dx, which uses machine learning algorithms to analyze patient conditions.

This is how it works: a physician inputs his or her patient’s background and medical findings into the Human Dx system, which then invites other physicians to review the case and enter their recommended tests and diagnosis. The system uses AI to combine and analyze the information from the contributing physicians along with the patient’s medical records; it also factors in what it has learned from other cases analyzed on the Human Dx system.

In the future, Human Dx will also incorporate genomics, epigenomics, proteomics, published medical research, and health outcomes data. Already, though, thousands of physicians around the world are using Human Dx to gain insight on their patient cases, according to a spokesperson with Human Dx.

Robin Healthcare, a Berkeley, Calif.-based technology company, has developed a voice-enabled AI device that drafts clinical notes for clinicians as they speak and enters them directly into their EHRs. A spokesman says the company is currently serving only orthopedists but plans to expand to other outpatient specialists and eventually primary care physicians.

IBM Watson Health also uses AI to help physicians and researchers derive insights from vast data sets to support cancer care in more than 230 hospitals and health organizations worldwide, according to IBM.

Healthcare organizations, particularly some of the larger institutions, also have implemented AI for administrative needs, such as using chatbots to answer and direct patient inquiries and to handle financial tasks, says Kaveh Safavi, MD, JD, senior managing director for the global health practice at Accenture, a global management consulting firm.

Safavi says EHR vendors and technology giants like Apple and Google as well as numerous startups around the globe are exploring ways that they can develop AI-powered products for the healthcare industry.

Patients seem comfortable interacting with a computer instead of a doctor. Global consulting firm PwC, in its 2017 report, “What doctor? Why AI and robotics will define new health,” found that 54 percent of the 12,003 respondents in Europe, the Middle East, and Africa said they’re willing to engage with AI and robotics for their healthcare needs, while 38 percent said they’re unwilling to do so. (Some 7 percent said they were neither willing nor unwilling.)

**BARRIERS TO WIDESPREAD USE**
EHRs and other computerized medical systems have created vast quantities of data over the past few decades, but not all that data is ready to be used to teach AI systems, Zayas Cabán says.

For AI to work, the data and the algorithms that process it need to be perfect, with no “biases,” meaning algorithms producing skewed results due to either being trained with faulty data or developed in ways that incorporate...
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“We never thought an AI agent would get good enough to replace the judgment of a well-trained physician. What I would say is we expect the technology to take the simpler and more routine tasks away.”

—KAVEH SAFAVI, MD, JD, SENIOR MANAGING DIRECTOR FOR THE GLOBAL HEALTH PRACTICE, ACCENTURE

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the developers’ own human misconceptions. She says technology vendors, medical institutions, and other health organizations are still working to “train” AI applications to handle certain tasks by “feeding” systems the large data sets they’ve gathered in recent years.

That work takes time, so health IT experts say physicians shouldn’t expect a plethora of additional AI applications to arrive soon.

Moreover, they predict that AI will work its way into EHRs and other applications gradually, with vendors building AI into existing systems or offering AI functions as add-on components one or two functions at a time. “You won’t go to the AI system; there isn’t going to be an AI product. AI will always be embedded in some operational system,” Huffman says.

Even if AI functions are embedded in EHRs and other applications that physicians already use, health IT leaders say that’s no guarantee physicians will quickly adopt them. They say vendors will have to develop AI applications that integrate well into physicians’ workflow and that are easy to use.

More important, AI vendors will have to demonstrate to physicians and even to their patients—who may eventually interact with the AI applications directly—that the systems are based on solid science and produce consistently accurate results.

Regulators and medical leaders will want to test AI functions and ensure they’re safe, secure, and reliable—requirements that could slow AI’s move into the exam room. “The algorithms have to be transparent, and they have to be explainable,” Wang says.

Furthermore, given how most physicians struggled for many years with EHRs and other health IT components without seeing real benefits, physicians will need to know that AI will help them be better, more efficient clinicians and not become another mundane computer function that they feel obligated to use, says Scott Shipman, MD, MPH, director of primary care initiatives and workforce analysis at the Association of American Medical Colleges.

ARTIFICIAL INTELLIGENCE VS. AUGMENTED INTELLIGENCE

Already, however, examples exist of AI stepping into the role of primary care physician.

London-based Your.MD offers a free service that employs AI to help users find health information. Ada Health of Berlin, Germany, similarly uses AI alongside physicians for its app that helps consumers manage their health, an application that also includes some diagnostic capabilities.

Still, health IT experts see a future that involves physicians leveraging AI for clinical and administrative tasks but not one where physicians are actually replaced by AI. As such, Jain says AI should be thought of as augmented intelligence.

Safavi has similar thoughts, saying that AI won’t ever get good enough to replace a physician’s capabilities for higher-level decision-making—even as it starts to help the clinician with his or her job.

“We never thought an AI agent would get good enough to replace the judgment of a well-trained physician,” he adds. “What I would say is we expect the technology to take the simpler and more routine tasks away.”
Take a proactive approach to bad debt

Making a cultural shift in terms of patient payments and bad debt isn’t easy, but it helps both those giving and receiving care

Changes to the way many Americans select insurance—and the plans they ultimately choose—have introduced a number of new factors to the payment equation making the issue of bad debt ever more pervasive for medical practices. In an AArete survey, over 90 percent of hospital chief financial officers report selling debt to multiple collection agencies, recouping only a portion of what is rightfully owed to them.

The rise of high deductibles

More Americans are turning to high-deductible plans through both employer-provided and Affordable Care Act coverage. Consumer Reports said two-thirds of eligible U.S. residents purchased low-premium, high-deductible plans through ACA exchanges in 2016; a study from administrative software developer Benefitfocus found 34 percent buy high-deductible plans from employers when given the choice.

This means more healthcare costs fall directly on patients—and this is happening on a significant scale across the country. Of the financial executives AArete surveyed, only one-tenth said patients feel they have coverage that can meet their health needs, while nearly half reported patients still have to pay out of pocket for the majority of their services. For physicians, that kind of shift means a new patient population, the under-insured, is now accumulating additional bad debt. This is a situation that must be addressed head-on to avoid serious financial pitfalls.

The avoidance perspective

Given the right tools and institutional mindset, practices can adopt a strategy and goals to move past the current back-end-focused approach to bad debt, and more reliably collect the money they are owed. While acquiring the technology—tools to establish payment plans, financially clear patients, and perform other tasks—is relatively straightforward, creating the necessary organization-wide cultural shift in attitude toward bad debt isn’t. It’s critical for practice leaders to understand why this attitudinal change is so vital, and what benefits it can bring.

The difficult conversation

As Medicare moves to a value-based care reimbursement model where payments are tied to patient satisfaction, a positive patient experience has a direct impact on physicians’ bottom line. Executive teams are investing heavily in improving the patient experience to both protect their branding strategies and meet the challenges of patients as consumers. And since a patient’s final interaction with the clinician will be the financial settlement of what they owe, their entire perception of the quality of care, and their experience will be largely influenced by the aftercare settlement. We have found that engaging up front with the patient, in an honest and transparent manner that avoids financial surprises, is one successful strategy to shape a positive patient experience.

This potentially difficult conversation should occur when patients are following up with their primary care physician and specialists, scheduling elective procedures, or even as soon as they are stable in the emergency department.

The ability to pay

Only one-fifth of surveyed hospital executives report that financial clearance—a practice that ensures patients’ ability to pay before they arrive for an exam or procedure—is part of their facility’s operations. This process guarantees patients have access to funds, sometimes beyond insurance and direct payment, to compensate the hospital. Financial clearance can mean having your facility’s financial counselors work with patients to find alternative resources such as charity and community sponsorships, low- or no-interest loan options from the facility, or simply setting up a payment plan.

For independent medical practices, it can mean developing programmatic or manual processes to
Financial Strategies

screen for a patient’s ability to pay, and verify insurance prior to scheduling visits and rendering care. Proactive bad debt avoidance is especially critical here as it is likely more difficult to track bad debt as an expense for medical practices.

Financial clearance is thus focused on ensuring that the right payment information and resources are presented in a way that helps both the facility and the patient—an attitudinal shift that moves beyond collection to education.

While adopting this financial clearance process won’t mean that 100 percent of what’s owed is paid as soon as care is provided, it goes a long way toward helping facilities recoup payment, and not letting their debt turn bad or get old.

Historically, there have always been patients who regularly avoid payment, and choose facilities based on the strength (or weakness) of their collection efforts. Considering this, facilities that make a strategic change in their approach to payments also benefit by keeping a financially risky group of patients at bay.

Make the cultural shift

Making a cultural shift in terms of patient payments and bad debt isn’t easy. Many staff members have strong opinions and established methods for dealing with this concern. However, from a top-down perspective, a change that ensures a significantly higher degree of revenue capture while still giving patients options is better for everyone involved, facility, patient, and individual staff member.

Bad debt is an unfortunate constant for healthcare providers. All practices, large and small, constantly contend with patients who won’t or simply can’t settle their bills.

The issue of bad debt will never go away in the current U.S. healthcare model, but that by no means indicates there aren’t strategies and tactics to tackle bad debt head on, reduce the financial liability, better connect with patients, and realize better outcomes.

FRONT DESK SCRIPT

Consider creating a script for front desk staff to address high deductibles and related issues that include questions, such as:

Q “Do you know whether your insurance plan covers this test before we order it?”
This reminds patients that they are ultimately responsible for understanding their own benefits. Provide the patient with the specific name of the test as well as the reason for the test so they can call their insurance company to obtain more information.

Q “Can we provide you with a range for the cost of this visit?”
Tell the patient the practice wants to help them budget accordingly. Staff can also ask to collect a certain amount so that the bill does not hit them all at once. Up-front collections ensure that physicians are paid at least a portion of the bill.

Q “Do you have an HSA? If so, did you know you could pay for today’s services using that money?”
HSAs help patients budget for medical services, increasing the likelihood that they can pay for the service.

Q “Do you understand that the purpose of today’s visit is for an annual physical only?”
Inform the patient that if they have other health problems, to up a separate appointment. This helps maintain a smooth patient flow throughout the practice, and it subtly reminds patients with a high-deductible plan that they can’t address all ailments during the annual physical.

—Lisa A. Eramo, Contributing author

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MedicalEconomics.com
Benefits review: How to better your practice

An annual review of employee benefits might save a lot of money, according to experts

by JORDAN ROSENFELD Contributing author

Offering benefits to employees is a necessary part of staying competitive and encouraging employee retention.

A 2017 report on employee benefits by the Society for Human Resources Management (SHRM) found that the number one reason employees leave a workplace after seeking better pay, is for better benefits. Additionally, the individual market for health insurance since the passage of the Affordable Care Act has become “a field of land mines,” says Adam Hyers, owner and president of Hyers and Associates, Inc., a Columbus, Ohio-based independent insurance agency that works with numerous healthcare providers across the country.

“It’s a fool’s errand to send your employees out on the individual market where the networks are very restrictive and the costs are very high,” he says.

However, every practice has to find the right balance of offered benefits to keep a healthy margin. The 2017 Kaiser Family Foundation Employer Health Benefits Survey showed that on average, organizations offering health benefits paid as much as $5,900 per year per individual covered, and $13,400 for family coverage. These costs add up in practices with numerous employees.

Experts suggest practices review their benefits annually and survey employees before making any major changes, but to also be proactive in seeking opportunities for cost savings.

COST SAVING OPTIONS

In the current health insurance landscape, in which the Trump administration has been seeking legal workarounds to the ACA in lieu of a failed repeal, it may be especially useful to review benefits more than once a year, says Arthur Tacchino, JD, chief innovation officer at Sync Stream Solutions, a New Orleans, La.-based consulting firm that helps employers understand and manage health benefits.

“Things are always changing, so re-evaluating benefits is a really good idea because a better option might have come along or have been created that [employers] might not be aware of,” he says.

However, physicians and practice administrators need to be aware that some new options may not be as good as advertised. One such area, billed as cheaper for employers and individuals, are short-term or “mini” medical plans, which might only cover an individual for three months to 12 months, Tacchino explains.
Jonathan Gruber, PhD, professor of economics at MIT, in Cambridge, Mass., who has expertise in employee benefits, calls these plans “terrible.”

“They’re not real insurance,” he warns. “Some people are going to be fooled into thinking they have insurance when they don’t, and it will pull healthy people out of the pool and raise the premiums for everyone else.”

Additionally, while not new, multiple employer welfare arrangements, which allow smaller practices to band together and buy health insurance as a larger group, are becoming more popular in the face of the high cost of steeper health insurance costs, according to Tyler Reid, director of worksite benefits with the O’Neill Group, an insurance broker of employee benefits, in Wadsworth, Ohio.

“Smaller practices are starting to contract healthcare in the way much larger organizations do through risk sharing agreements,” Reid explains.

Gruber feels the most effective way physicians can save money is to be “more aggressive in shopping across insurers.” He sees employers saving a lot of money by narrowing the networks of the plans they offer to their employees. “Employers don’t need to cut benefits, just cut out high-priced providers that aren’t much better than any other providers,” he says.

He says it’s common for physicians to see a name they’re familiar with, such as Blue Cross, and sign up purely because of the name recognition, “but they don’t shop around or realize there are better options out there. It’s worth a day and a half to sit down and shop the options,” he insists.

FORECAST YOUR FINANCIAL COSTS
Whether a practice is engaging in an annual review of benefits, or financial concerns drive a need for a change, it should attempt to forecast the costs of offering different levels of benefits packages, either through available tools, such as online analysis toolkits or with the help of a financial adviser who can run the numbers under multiple scenarios.

THE BENEFIT MENU BEYOND HEALTH INSURANCE

By Elizabeth Woodcock, MBA, FACMPE, CPC Contributing author

Take the time to review your benefits package to ensure that it complements, rather than sabotages, your staffing strategy.

Below are a number of key benefit options to provide your employees beyond health insurance. Remember to consult with an attorney familiar with human resources’ regulations and laws before introducing any benefit.

1/ Time off plans
Typically, paid vacation time increases with seniority. A common arrangement is to offer employees two weeks (10 days) of vacation during their first through fifth years of service, then bumping it up another week to 15 days after five years on the job. Start with five, and try gradually increasing the time-off-with-pay annually by offering, for example, an additional day of vacation each year.

The employee still reaches 15 days of paid time off in year five, but you avoid taking a sudden hit from that large jump in paid leave.

Rather than hashing out what category of leave is appropriate, consider converting your program to paid time off (PTO), a step a majority of companies have taken.

PTO programs offer flexibility and privacy and allow employees to make their own choices about absences. Payouts for unused days work the same way as sick and vacation leave; you have to establish your policy and manage it appropriately.

Most practices provide sick leave because you don’t want ailing workers to come in contact with patients, other employees, and you with their illnesses.

Furthermore, there is a cost associated with “presenteeism”—the lost productivity that occurs when staff are present for work but execute their job duties below expectations because they are sick. Provide leave, while encouraging employees to avoid using sick leave inappropriately, by allowing them to carry over unused leave days, or a portion of them, to the following year.

Other options would be to extend the opportunity to convert un-
Forecasting costs helps a practice come up with benefits options, such as tiers of coverage based on employee classifications, says Tacchino. The higher the tier, the more expensive the premium is likely to be, for the employee, but there may be fewer out-of-pocket expenses.

Another area of cost savings could come from changing the percentage the employer pays for the plan. If a practice is already paying 80 percent of benefits, dropping that contribution to 60 percent, for example, could result in significant savings, Tacchino recommends.

Of course, this must be done with a clear understanding of the legal and regulatory considerations about how much an employee is allowed to pay for the benefits a practice offers.

“If the plan you’re offering is not affordable, you may be subject to penalties under the law,” Tacchino says. And it could also affect morale among employees.

He strongly recommends having a financial adviser or human resources expert who understands the legal particulars about employee benefits weigh in as providers make decisions about changing benefits.

Additionally, Hyers recommends keeping an eye on employees who might be eligible for Medicare in the near future.

“Even if they’re not retiring, you want them to be investigating their Medicare options, with or without a broker,” he says.

used sick leave days into vacation time at a 50 percent ratio; that is, one day of unused sick leave becomes a half-day of vacation. Some practices offer a day or two of personal leave as well per year—just to enable employees to take a break.

Regardless of your choice of leave packages, be sure that your practice has policies in place for handling family medical leave, jury duty, military leave, and any other types of leave that your state may require.

2/ Attendance bonuses
Instead of cash, try offering an extra one or two days of leave to those with perfect attendance (no sick days taken) during the year. To reduce disruptions, require that attendance bonuses be used on slow days, such as Friday afternoons.

3/ Education and training
Your practice will benefit from extending training incentives to employees in good standing.

Higher education costs can be considerable, but you can keep a lid on this type of benefit by limiting its use to practice-specific training, such as coding recognition for business office staff, phlebotomy certification for medical assistants, technology training for administrative staff, continuing medical education for nurses, and so on. Typical packages include reimbursement for tuition and books.

Make sure to budget for these costs and limit both overall spending and per-employee, so that one or two employees seeking specialized skills don’t gobble up the entire allocation for training. Add a written clause for any assistance towards a certification or degree, so that the employee is required to reimburse you if, for example, he or she leaves within two years of the training’s conclusion.

4/ Additional benefits
In addition, practices can consider:

- Retirement plans and insurance
- Uniforms or uniform allowances
- Health club memberships

Elizabeth Woodcock, MBA, FACCME, CPC, is a consultant, speaker, trainer, and author with Woodcock & Associates in Atlanta.
“Smaller practices are starting to contract healthcare in the way much larger organizations do through risk sharing agreements.”

—TYLER REID, DIRECTOR OF WORKSITE BENEFITS, O’NEILL GROUP, WADSWORTH, OHIO.

“A lot of people can mess up their Medicare enrollment by not understanding the deadlines and rules.”

Reid says it’s also important for practices to keep in mind that the average employee’s literacy about their own benefits tends to be low.

“Medical practices are focusing on the employee experience. Rather than potentially adding or dropping certain benefits, the focus has shifted to improving the way they are communicated,” he explains.

Practices are turning to concierge services, coaching, and decision-making support tools such as apps for smartphones or tablets, such as PolicyGenius, which helps consumers understand the ins and outs of health insurance, defines terms, and the details of their specific plans to help employees find the best and most efficient ways to receive care.

“After all, benefits are only as valuable as what you get out of them,” Reid says. “So it’s becoming less about which benefits to offer, and more about using the ones they have more effectively.”

**ENGAGE A SURVEY**

Many practices opt to survey their employees to make sure that the benefits are covering the things that employees actually want, according to Hyers.

“Sometimes you can get pretty good tips as to what’s bothering people, he says. “There’s competition out there for employees and you’ll see a lot of people leave groups out of frustration from poor benefits.”

However, he cautions that survey questions must be carefully crafted so as not to get employees’ hopes up for benefits a practice does not intend to offer.

The SHRM employee benefits report echoes this, stating, “Be mindful that conducting a survey will set up employee expectations that benefits may change or be improved. Therefore an organization should have a clear purpose and a plan of action based on the survey results.”

And when rolling out new benefits packages, Joe Weinlick, chief marketing officer of Nexxt, a workforce recruiting company, encourages providers to be as transparent as possible about reasons for the change.

“With premiums rising in recent years it’s very hard to convey to employees that the reason they may have to pay more, or that benefits are getting worse, is external to the company,” Weinlick says.

If a practice has done its homework, surveying employees and forecasting costs, and picked a new set of benefits to unroll, Weinlick urges thoughtfulness in laying this out for employees. Changes to benefits can be stressful and often require provider changes.

Just rolling out changes, particularly if costs are going up for employees, without much warning, “leaves a bad taste in employees’ mouths,” Weinlick says.

**OFFER OTHER KINDS OF BENEFITS**

Weinlick says results of a 2018 internal survey from Nexxt’s database of 2,403 employees in the healthcare industry the survey revealed that “medical and dental was critical,” followed by vision.

Retirement plans are often popular, Weinlick says, but not always an option for employers–due to costs–so he sees employers offering professional and career development resources, as well as “wellness benefits,” in the form of resources and information.

The SHRM employee benefits report shows that employers were most likely to have increased wellness benefits over any others in 2016, as a way of making up for gaps in medical, dental, and vision benefits.

The number one benefit after medical coverage that employees want is schedule flexibility, Weinlick shares. This may be a way to keep employees happy without offering too wide a panel of benefits.”

People want the ability to be able to fit their private life into their work life,” he says, to take time off for family time and even their own medical appointments.

This could come in the form of vacation days off, or other forms of paid time off, as well as allowing an employee to work part-time hours. He’s even heard of companies that offer loan reimbursement programs for employees with student loans, as an incentive for younger employees who might not need as comprehensive health benefits, or for older employees who are trying to increase their education.

In trying to strike the right balance between retaining employees and keeping a happy bottom line, the expert consensus is to review benefits annually with an open mind toward change.

“A once a year review of benefits can save you a lot of money,” Gruber says.
Medicaid is funded by federal and state governments, and administered by the states. However, because of dramatic increases in the population covered—2 percent at inception to today’s 22 percent (>74 million participants)—and ever-increasing expenditures per patient, there is agreement that with huge increases in cost, it cannot survive in its present form.

Budget limitations have created lower reimbursement rates for physicians and hospitals. This limits physician access (varying by state), resulting in continued use of expensive emergency departments for otherwise routine care. Low reimbursements have led hospitals to cover losses by negotiating higher reimbursements from private insurance. In many poorer rural areas this has not been possible, leading to hospital closures.

Many studies have consistently demonstrated a lack of health outcome benefits for Medicaid patients. Recently, the Government Accountability Office claimed not enough is being done to eliminate fraud. Faced with unsustainable costs, many states are applying for federal waivers to explore a variety of options, such as Medicaid managed care, work requirements (recently negated by a federal court), direct primary care, health savings accounts, and premium assistance.

“With deep philosophical differences between our two political parties, is there a solution to saving Medicaid? Yes.”

With deep philosophical differences between our two political parties, is there a solution to saving Medicaid? Yes. There is a uniquely American solution. Let individuals decide between the present Medicaid and a proven successful plan that provides better care at far less cost. This alternative could be modeled after Indiana’s successful Medicaid pilot program (2007-2012).

The idea behind this plan was relatively simple: With the proper financial arrangements the poor would wisely manage the money and develop healthy behaviors. A health account was set up for each participant, a $1,100 deposit (would need adjustment) into the individual’s account paying for routine care, coupled with nationally available insurance solely for bigger ticket items. Contributions by federal/state governments and the individual would be on a means-tested sliding scale. This insurance would be in the individual’s name, thus immune from cancellation due to developing a chronic illness. Funding for hospital care would be at private insurance levels greatly helping rural institutions. For the recipients to receive funding for the following year they had to obtain preventative care. This plan avoids “middle men” between patients and care.

The results were impressive: 96 percent had positive feelings about this plan. It was proven that Medicaid recipients managed their healthcare dollars in a proper manner, their use of EDs declined, as did their medical costs. They reported improved health.

Medicaid now is spending more than $7,000 per person; this alternative would cost significantly less, conserve government funds, and allow for personal choice. This should appeal to conservatives. It would also improve care of our most vulnerable and be available to more Americans. This should appeal to liberals. Importantly more resources could then be devoted to the future of our nation, which should appeal to everyone.

Kenneth A. Fisher, MD, is an internist/nephrologist, teacher, author, and co-founder of Michigan Chapter of the Free Market Medicine Association.

We must save Medicaid through bipartisan effort
There is no question physician burnout is high as some estimates put it at more than 50 percent of the current practicing population in the United States. This is troubling as burned-out physicians retire early, reduce the time they devote to clinical work, or leave medicine entirely. As a result, patients have longer waits to see their doctor or, worse yet, are losing their trusted physician forever. Additionally, burnout can lead to serious emotional and physical health consequences for physicians themselves.

Here are some programs that enable physicians to help themselves and their peers overcome burnout.

**AMERICAN MEDICAL ASSOCIATION'S STEPS FORWARD**
[www.stepsforward.org]

The AMA’s immediate past president, David O. Barbe, MD, MHA, says “an energized, engaged, and resilient physician workforce is essential to achieving national health goals. Yet burnout is more common among physicians than other U.S. workers, and that gap is widening as the bureaucracy of modern medicine inflicts a mounting toll on physicians.”

As part of AMA’s commitment to help physicians, it has created STEPS Forward, an interactive practice transformation series that provides proven, physician-developed strategies for confronting common challenges in busy medical practices, allowing physicians to devote more time to caring for patients.

Barbe says the AMA is striving to help physicians navigate and succeed in a continually evolving healthcare environment and it is imperative to promote engagement and combat the issues leading to burnout.

“Evidence suggests that improvement is possible, investment is justified, and return on investment measurable,” he says.

This training program promotes peer-to-peer burnout solutions through seven components. These include establishing wellness as a quality indicator for the practice; organizing a wellness committee; distributing a yearly wellness survey; holding regular meetings with practice leaders or staff to talk about data and interventions to promote wellness; initiating selected interventions; repeating the survey over the course of the year to evaluate progress; and looking for answers within the data, refining the interventions, and working to continually make improvements.

“Analysis has shown that engagement levels with STEPS Forward’s practice transformation modules have been high, with 86 percent of participants indicating their likelihood to implement their learnings,” Barbe
“What’s even more encouraging is the feedback we’re getting from physicians saying they can finally get back to spending time with their patients, and how good that feels.”

CENTURA HEALTH PHYSICIAN GROUP
[www.centura.org]

The executive and physician leadership at Centura Health Physician Group, which includes more than 900 providers and 6,000 physician partners in Colorado and Kansas, has recognized the need to develop a comprehensive program to address physician well-being. The program is being developed with the goal of a system-wide comprehensive approach for its members to prevent burnout.

“Our goal is to address as many areas as possible which contribute to decreased physician well-being,” says Lief Sorensen, MD, specialty medical director with Centura Health. “As our program progresses, we hope to offer support groups, mentoring options for new physicians, a provider-specific on-boarding process, options for collaboration and socializing with other physicians, and more.”

Moreover, the fact that such a high percentage of physicians are experiencing symptoms of burnout has begun to shift the focus on how this issue is being addressed among the entire healthcare population. Previous efforts focused mostly on resiliency and coping strategies. While these efforts continue to be very valuable, Sorensen notes there is now increasing attention toward addressing the environments where physicians are working.

“Physicians understand the pressures other physicians are under better than anyone,” he says. “Historically, physicians are very poor at admitting we are having concerns. We often just internalize our stresses and fears and are scared to discuss with others. One of the most valuable things I see happening, as more physicians are aware of these issues and start talking about them, is simply the understanding that we are not alone.”

NORTH CAROLINA PHYSICIANS HEALTH PROGRAM (NCPHP)
[www.ncphp.org]

The NCPHP, based in Raleigh, N.C., assists more than 3,000 physicians and other licensees of the North Carolina Medical Board with burnout and other problems that may affect their ability to deliver high-quality care and services to their patients.

Clark Gaither, MD, medical director of the NCPHP, notes the program was created to assist physicians with issues that would put their own health or the safety of their patients at risk. “Over the years, in addition to alcoholism, drug addiction, and mental health issues, we have seen a rise in the number of participants with job-related burnout,” he says. A full third of the health issues the NCPHP sees can be directly tied to burnout and another third is indirectly associated with burnout.

The program is designed to give providers a compassionate, caring, and confidential pathway to get the help they need. If needed, it facilitates professional assessments, therapies, treatment, and ongoing follow-up. Sometimes monitoring is also employed to give physicians the support they need early in their recovery.

Study: Physician burnout spurs medical errors

New research indicates what many doctors may already know: significant professional burnout can lead to medical errors. Published in Mayo Clinic Proceedings, the study surveyed 6,695 U.S. physicians of varying specialties in active practice about the last three months of work.

Among the findings:

- 54.3% reported symptoms of burnout
- 32.8% reported excessive fatigue
- 6.5% reported suicidal thoughts
- 3.9% reported a poor or failing patient safety grade at their practice
- 10.5% reported making a major medical error

Of the doctors reporting a major medical error:

- 77.6% reported symptoms of burnout
- 46.6% reported excessive fatigue
- 12.7% reported suicidal thoughts

MedicalEconomics.com
How to defeat physician burnout

Physician Essay: Burnout led to my retirement

By William M. Gilkison, MD

After 40 years of practicing family medicine, I had had enough. Years of progressively increasing obstacles in the path of good medical care that stalled my economic livelihood led me to decide to retire. They won! They beat me down! Who’s “they”? Well, they are Medicare, commercial insurers, HMOs, Medicaid, HIPAA, Clinical Laboratory Improvement Amendments (CLIA), nurse practitioners, physician assistants, prior authorizations, pre-certifications, retail clinics, healthcare economists, and the assassin-in-chief, Meaningful Use (MU); that’s who! They all did their part to emasculate physicians and make the business of medicine nearly impossible. If I were paranoid, I would think there was a concerted effort to devalue physician importance, control and reduce our financial well-being, and relegate us (at least those in primary care) to employee status.

“I got tired of taking an annual pay cut when I should be at the peak of my earning years, interrupting patient visits to talk to an unknown person on the phone to justify a test I ordered.”

Every day was met with new challenges, new policies, or denial of payment. When they did pay, it was pennies on the dollar. The threat of fines and disenrollment in payer contracts by these entities scared me into submission. I was tired. Becoming an employee of a large multi-specialty group for my last seven years eased the burden some, but then MU came along, and I was done. It was the final insult. My productivity plummeted. My frustration and anger grew, and there was no solution other than backing away from clinical practice.

Being a physician used to command respect and prestige, but now that only exists in the hearts of loyal, long-term patients. It is healthcare economists, hospital administrators, insurance company executives, CMS, et al., who now call the shots.

“I got tired of taking an annual pay cut when I should be at the peak of my earning years, interrupting patient visits to talk to an unknown person on the phone to justify a test I ordered.”

Getting back to basics

So how can doctors find more time to spend with patients, and thereby find—or rediscover—the joy of practicing medicine? For Cordum and her partner, the solution has been to remove as many barriers as possible between themselves and their patients, starting with insurance companies, which is why they have chosen the direct primary care model for their practice.

“If you are on an insurance panel, your contract is with the insurance company.
not with the patient, and that’s a conflict of interest for me. It goes against my oath to work for the patient and not someone else,” she says. Besides, she adds, “I get intimidated with all the third parties and contracts and 1-800 numbers, and it takes away from having meaningful time with my patients.”

Not accepting third-party payments has brought the additional benefit of not being required to use an EHR. Instead, Cordum uses a Microsoft Word-based system to record her notes and other pertinent information. “It’s perfectly adequate [and] costs me nothing so I can keep costs down,” she says.

Using the DPC model also allows her to keep her patient panel between 400 and 500 patients. “We know our patients, and we know what’s important to each of them, their goals and their values,” Cordum says. “Also, we don’t have intermediaries and barriers to patients’ ability to reach us and spend time with us. When the patient calls our office, we call them back ourselves.”

“A lot of what’s driving doctor unhappiness is that more is being expected of them than in the past, and this has compressed the amount of time they have to spend with patients, while the documentation burden has gone up.”

—CYNTHIA “DAISY” SMITH, MD, FACP, VICE PRESIDENT OF CLINICAL PROGRAMS, ACP

William Gilkison, MD, is a 1969 graduate of Indiana University School of Medicine and completed his residency at the University of Colorado School of Medicine in 1974. He practiced family medicine in Indianapolis for 40 years; 23 of those years as a solo practitioner. His practice experience includes adult and pediatric outpatient and inpatient care, nursing home care, and for the first part of his career, obstetrics. He retired Dec. 31, 2013, and now resides outside Phoenix.
Cordum notes that the DPC model hasn’t freed her entirely from the administrative hassles of medical practice. Some of her patients have health insurance, which means she must still get prior authorizations for some drugs she prescribes and prepare bills for these patients to submit for reimbursement. But the amount of work and time required for these tasks is far less than what her colleagues with insurance contracts contend with.

“When I decided on this model, it was for simplicity and removing anything onerous or complex and bringing it back to the patient and the doctor,” she says. “And I’m having fun with medicine again. I get to do house calls, I get to do walking visits with my patients. And if something isn’t working,
Fighting back against burnout

I don’t have to go through three committees. I just change it and make it better.”

TEAMWORK AND SCHEDULING CONTROL
Of course, most independent practices have payer contracts and thus operate under more constraints than Cordum. But even under those circumstances, doctors can take steps to increase their patient time and reduce their frustration level, experts say. Among these are: streamlining practice workflow, strengthening collaboration among practice staff, and reassigning tasks not requiring an MD to other providers or staff members.

The ACP’s Smith recommends that practices hold regular staff huddles, establish protocols and standing orders wherever grassroots campaigns, leadership in our institutions and professional societies, and political engagement.

To begin, share your story. We had all heard the report that half of residents in our program are burned out. But our panel transformed burnout from an abstract banality to a living discussion with faces and feelings. Patient stories bring color and meaning to disease. The same is true of our own accounts of burnout. Your story is your scalpel. Dissect away.

Rich Joseph, MD, MBA, is currently a resident within the Primary Care Residency Program at Brigham & Women’s Hospital. This training program is a collaboration between the internal medicine residency at Brigham & Women’s Hospital, Harvard Vanguard Medical Associates at Atrius Health, the Department of Population Medicine at Harvard Medical School, and the Harvard Pilgrim Health Care Institute.

This will require radical honesty about the ways in which medical training sets the stage for burnout. Medical school incentivizes perfectionism, which breeds competition and impedes our ability to work collectively.

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“The earlier approach was to see what could be done to make the individual physician more resilient. It’s like saying to someone in an abusive relationship, ‘just toughen up and you’ll be fine.’”

—LOUIS SNITKOFF, MD, FACP, CHIEF MEDICAL OFFICER, COMMUNITY CARE PHYSICIANS, ALBANY, N.Y.

Appropriate, and utilize pre-visit planning. “Have someone from the staff look at the patient’s chart and anticipate what needs and questions that patient is going to have,” she says. “Some practices even go so far as to order labs ahead of time so all the administrative needs are addressed before the patient comes in and the doctor can focus all his attention on the patient.”

At Community Care Physicians, improving physician satisfaction took the form of negotiating an agreement with one of the practice’s major payers, with whom it is in a shared-savings arrangement, to eliminate prior authorizations for complex imaging procedures. “Even though it’s not all our payers, it’s still a huge thing for morale, and has really helped reduce the burden on our physicians and staff,” says Snitkoff.

Allowing doctors some say in patient scheduling can also help to increase their satisfaction, particularly when it comes to who they see at the beginning and end of the day. “We’ve found the bookends of the day can be some of the most stressful for physicians, particularly those who are juggling competing demands at home and at work,” Smith says. For example, a parent needing to pick up a child at daycare will feel less stress knowing the last appointment of the day is for something minor and straightforward, like a urinary tract infection.

“If you can give clinicians some flexibility over that first and last slot of the day, that really seems to ease anxiety and makes people feel like they have more control,” she says.

Allowing primary care doctors more flexibility in their schedules and time with patients was the goal of an experimental program at Virginia Mason Medical Center, a Seattle, Wash.-based hospital system. Launched in 2016, the program increased patient appointment lengths for some physicians and nurse practitioners in outpatient settings to a uniform 30 minutes, rather than Virginia Mason’s standard 15- or 20-minute allotments.

“Some of that [the reason for the pilot] was to try and give us back time with our patients,” explains Carrie Horwitch, MD, FACP, who oversaw the pilot program. “It also simplified our scheduling, so that the provider didn’t have to figure out if that patient needed a longer or shorter appointment.

Part of what enabled Virginia Mason to free up time for longer visits, Horwitch explains, is its long-standing emphasis on team-based care and handing off tasks that don’t require a physician to other staff members. For example, patients who come in for opioid prescriptions first meet with a pharmacist, who provides information about the medication, ascertains that the patient is using it correctly, and checks the patient’s record in the state’s prescription monitoring program database.

“That sets up the appointment for the clinician so that we can really spend time with the patient, answer their questions, and see how they’re doing,” she says.

Horwitch notes that the program led to greater feelings of satisfaction among the participating clinicians, leading Virginia Mason to expand the option of uniform 30-minute appointments to all its primary care providers. Its success, she adds, confirms her belief that much of what makes doctors unhappy is due to not having the time necessary to provide quality care to their patients.

“It’s why we’re in this profession and we stay in it,” she says. "To be healers and helpers of people."
o, how’s life in your concierge practice?”
I didn’t correct him; people don’t know the difference. Five years ago, I left “normal” fee-for-service medicine to start a direct primary care practice. Most people have no idea what that means, and my colleague obviously didn’t know either.

“Great,” I said honestly. “Life is really so much better, and the care I give is so much better than it used to be. I’ve got time with people.” I normally try not to get too enthusiastic when talking to colleagues, as it sounds either too good to be true or like I’m rubbing in how good my life is now. But for some reason I added, “Even after five years I’m not busy; I saw just two patients this morning.”

There was a brief silence on the other end of the line. “Two patients?” He asked, sounding stunned. Then he added quietly, as if talking to himself, “I just can’t imagine that.”

I was struck by just what a gulf lay between my life and his, and between my life now and the one I had just five years ago. I had loved being a primary care doctor and had built a thriving (and very busy) practice. But over the last few years, my joy in practice had been hacked away by the increasing requirements of the government, computerized records, data submission, insurance harassment, and shrinking time with each person. By my last year, I was becoming increasingly aware of my ineffectiveness as a doctor. I didn’t feel like I was able to give truly good care to anyone.

I was burning out.

So it was a blessing when friction with my partners ended up in an all-out break up. I could hit the reset button and do things right. Things had to change, or I’d have to find another profession.

There was one solution that seemed right to me: direct primary care. This practice model has two main differences from fee-for-service care:

- Payment is from the patient (no insurance or other third-party payments accepted); and
- Patients pay only a low monthly fee (usually around $50 per month for each patient) which covers all care.

Despite having few examples to learn from (there were around 100 practices in the U.S. using this model when I started), I opened my practice in February 2013 and have not regretted the decision since. My practice now has over 750 patients, and I still have room for growth.

My income now equals that which I had when I left my old practice. Most importantly, I love the medicine I practice now and feel like I am giving truly good care to all of my patients.

I truly believe this not only is best for doctors and patients, but perhaps an idea that could rescue a system that is dying at the hands of others.

Rob Lamberts, MD, is a board-certified internist and pediatrician who runs Dr. Rob Lamberts, LLC, a direct primary care practice in Augusta, Ga. He also recently gave a TED talk on the DPC model (bit.ly/DPC-TED-talk). Have questions about DPC? Email medec@ubm.com.
What are you currently binge watching?

Maria Young Chandler, MD, MBA  
Business of Medicine / Pediatrics  
Irvine, Calif.  
“The news (but it is so depressing).”

George G. Ellis, Jr., MD  
Internal Medicine  
Boardman, Ohio  
“NCIS.”

Antonio Gamboa, MD, MBA  
Internal Medicine / Hospice and Palliative Care  
Austin, Texas  
“Master of None’ and ‘Game of Thrones.’”

Jeffrey M. Kagan, MD  
Internal Medicine / Hospice  
Newington, Conn.  
“Law and Order SVU.”

Melissa E. Lucarelli MD, FAAFP  
Family Medicine  
Randolph, Wis.  
“Doctor Who,’ ‘Quantico,’ and late-night comedy shows.”

Joseph E. Scherger, MD  
Family Medicine  
La Quinta, Calif.  
“HGTV (to escape depressing news shows).”

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

The board members that contribute expertise and analysis to help shape content of Medical Economics.
“A lot of what’s driving doctor unhappiness is that more is being expected of them than in the past.”

—ANIL JAIN, MD, FACP, INTERNIST, VICE PRESIDENT FOR WATSON HEALTH, IBM

"There are very high hopes for AI to improve the lives of physicians."

—ANIL JAIN, MD, FACP, INTERNIST, VICE PRESIDENT FOR WATSON HEALTH, IBM

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