Chronic Care Management SUCCESS

How to overcome tech limitations

- Building care plan templates
- Documenting non-visit care
- Coordinating referrals

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CHRONIC CARE MANAGEMENT SUCCESS

STARTS ON PAGE 32

How to overcome tech and electronic health record limitations.

Building care plan templates
Documenting non-visit care
Managing care transitions

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THERE'S A REASON DR. STIEFEL IS SO SUCCESSFUL. HE'S GOT 3,500 PEOPLE WORKING FOR HIM.

When we work as one, staying independent is a healthy option. Work as one
Two recent studies published in the *Journal of the American Medical Association* are raising questions over the effectiveness of maintenance of certification (MOC) requirements for physicians. The studies found little difference in outcomes among patients cared for by internists grandfathered out of the American Board of Internal Medicine’s recertification requirements and those who had to recertify. Read full details at [ow.ly/GlTVF](http://ow.ly/GlTVF).
The physician should be the one who decides to terminate the physician-patient relationship.”
—Eve Green Koopersmith, JD ATTORNEY

ask us
Have a question for our advisers? Email your question to medec@advanstar.com.
When they record doctors’ every diagnosis and medication and procedure and imaging study, electronic records intrude into doctors’ lives in a way that has never been seen before. For any value that electronic records may have, insurance companies neutralize it when they use them to exploit physicians.

Edward Volpintesta, MD, BETHEL, CONNECTICUT

CRITIQUE OF MEANINGFUL USE IS OVERDUE

I would like to say it is about time you finally spent a little bit of time critiquing Meaningful Use. (“MU2: Mission Impossible” January 25, 2015). Or as I prefer to call it, “Meaningless Use.” No one has been able to explain to me (besides possibly being an effort to limit doctors reimbursement) what exactly is the purpose of MU.

What totally boggles my mind is this acceptance of the idea that we should be treating patients (with great liability and no reimbursement) by Internet and e-mail. It is mindless. Am I missing something?

In addition, would everyone prefer that physicians spend whatever “extra” time they have in follow-up patient care and expanding their knowledge base rather than doing MU “homework?”

If CMS wants data from doctors why can’t this be coordinated with the software providers? Why does the physician have to be responsible for collecting and submitting this stuff? Coordinate this with CMS and the software people.

Please leave the doctors out of this mess-unless of course the whole idea from the beginning has more to do with finding a reason to cut doctors’ reimbursements.

William DeStefano, MD
NEW YORK, NEW YORK

EHRs ARE INTRUSION INTO DOCTORS’ LIVES

In his letter of December 10, “ACA not reducing number of uninsured,” Dennis Martin, MD was right to criticize how electronic health records [EHRs] are used to control physicians.

When they record doctors’ every diagnosis and medication and procedure and imaging study, electronic records intrude into doctors’ lives in a way that has never been seen before. For any value that electronic records may have, insurance companies neutralize it when they use them to exploit physicians.

Until the day that doctors have unions to break the stranglehold that insurance companies with impunity and great success have placed on them doctors will continue to wallow in the malaise that awaits them every day.

Edward Volpintesta, MD
BETHEL, CONNECTICUT

ONLY PRIVATE SECTOR CAN INNOVATE IN HEALTHCARE

Electronic health records (EHRs) are a complex technological way of recording physician and patient data from the office or hospital level, for the purposes of medical care delivery, archiving, and reimbursement from third party and government payers. Prior to the early 2000s, EHRs were in use in few
private office- and hospital-based implementations for use only by physicians, nurses and hospital administrators for patient care purposes.

By 2000, the federal government had decided that their expenditures for healthcare through Medicare and Medicaid were unsustainable. From the federal government’s perspective, the only way to control costs for these outdated and poorly implemented programs was to store and control all healthcare information for the purposes of reducing healthcare payments and ultimately rationing care.

In 2004-5, the Bush administration, with financial pressure from the technology and insurance lobbies, gave each state money to send consultants to hospitals and private office to assess “readiness” to adopt EHRs. Although there was little or no research or formal trials on the subject, the government was moving forward in its quest to manage healthcare data to control costs.

The “Health Information Technology for Economic and Clinical Health” (HITECH) Act was signed into law on February 17, 2009 to promote the adoption and meaningful use of health information technology.

Thus “meaningful use,” (MU) was born and the rush for all sectors of healthcare delivery to adopt EHRs as virtually mandated by the government for reimbursement for care from Medicare and Medicaid. CMS promised each eligible provider thousands of dollars over five years to help defray the costs of implementation, security, and support. This temporary revenue stream was in return for healthcare entities meeting federal criteria for three stages of MU.

Government and insurance reimbursement was determined to change healthcare payment from a procedure and office visit repayment to a “value-based,” model yet to be developed. This was the rationale for meaningful use as the basis for “value-based care.”

The Centers for Medicare and Medicaid Services mandated the use of EHRs without considering the risk to physicians, hospitals, and patients, while punishing them with fines for each violation due to use of unsafe and unsecured EHRs. In this example, we see the bipolarity of the government lobbied by special interests to force immediate adoption of expensive insecure technology as the new standard, and yet fine healthcare entities and physicians for the problem and privacy violations that arise due to government mandate.

True healthcare innovation can only come from physicians and private healthcare entities that seek the best patient care and efficiency after tireless experimentation. Centralized government mandates to control costs are destined to fail. The free market will provide excellent care at competitive prices through independent individual health freedom.
OBAMA BUDGET ASKS FOR HIGHER ONC FUNDING

The budget proposal from the White House is looking to boost funding for the Office of the National Coordinator for Health Information Technology (ONC) substantially to make strides on improving interoperability between electronic health record (EHR) systems and preparing for meaningful use.

The budget asks for $92 million in 2016, an increase of more than $30 million over the 2015 budget.

“The Administration is working to create transparency of cost and quality information and to bring electronic health information to the point of care—enabling patients and providers to make the right decisions at the right time to improve health and care,” said U.S. Health and Human Services Secretary Sylvia Burwell during February testimony before a U.S. House of Representatives subcommittee.

The increased funding is part of the government’s push to increase how capable health IT is of exchanging patient records.

REPORT: ACA WILL BOOST PRIMARY CARE VISITS BY 3.8%

A new report from the Commonwealth Fund finds that the Affordable Care Act (ACA) will have only “modest effects” on the demand for healthcare services in the United States and is unlikely to strain the existing supply of physicians and other providers.

According to the report, the estimated 30 million previously uninsured patients who have entered the healthcare market because of the ACA projects to an additional 1.34 office visits per week for primary care physicians, an increase of 3.8%. Hospital outpatient departments are expected to see a larger per week jump in visits, from 1.2 to 11, an increase of 2.6% nationwide.

“Increases of the magnitude likely to be generated by the Affordable Care Act will have modest effects on the demand for health services, and the existing supply of providers should be sufficient to accommodate this increased demand,” the report reads.
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LATEST ICD-10 TESTING DATA RELEASED

The Centers for Medicare & Medicaid Services (CMS) accepted more than 8 out of 10 ICD-10 claims submitted during the latest testing week, the agency announced.

The latest testing period, which ran from late January to early February, included more than 600 providers, billing companies and clearinghouses submitting roughly 15,000 claims using the new ICD-10 codes, which are scheduled to be rolled out for use on October 1, 2015.

“This successful week of testing continues to put us on course for successful implementation of this important initiative that better reflects modern practice of medicine by Oct. 1,” said CMS Administrator Marilyn Tavenner in a blog post about the testing results. “CMS is ready for ICD-10.”

The federal government is seeking to roll out ICD-10 later this year after required use of the new coding system was delayed last spring by congressional action. Whether physician advocacy groups and other stakeholders will seek further delay of ICD-10 is yet to be seen. Last year’s delay occurred as part of sustainable growth rate negotiations in March 2014.

WITH MEDICARE

and commercial insurers increasingly tying physicians’ reimbursement to their ability to report on—and meet—outcome measurements, the question logically arises, is it working? Is the growing emphasis on quality and value having an impact on patient health, and/or healthcare spending?

The short answer is, it’s too soon to tell. Still, intriguing—if scattered—evidence is beginning to emerge that it might be. For example:

—Medicare spending for 2014 was projected to be about $1,200 less per beneficiary than had been forecast in 2010, the year the Affordable Care Act was passed, according to a Kaiser Family Foundation study. The slowdown in spending is partially attributable to “cancellations in provider payment updates and Medicare Advantage payments” as well as cuts resulting from the 2013 budget sequester, the authors say, while adding that “providers may be tightening their belts and looking to deliver care more efficiently in response to financial incentives included in the ACA, and it is possible that these changes are having a bigger effect than expected.”

—The National Council of Quality Assurance found improvements in 46% of the 139 Healthcare Effectiveness Data and Information Set performance measures it tracked over the previous three to five years, performance declines in 8%, and mixed results or no trend in 46%.

—Medicare’s evaluation of the first year of its Comprehensive Primary Care (CPC) initiative concluded that “CPC appears to have reduce total monthly Medicare Part A and B expenditures per beneficiary...by $14, or 2 percent. The reductions appear to be due to the favorable impacts on hospitalizations and emergency department visits (total and outpatient).” The evaluation also found a four percent reduction in unplanned 30-day hospital readmissions, a decline it calls “sizable but not quite statistically significant.”

“Moving away from pure fee-for-service to a more value-based reimbursement system is the direction we want to move in. But we’re not sure yet if we are moving the needle in terms of whether patients overall are getting a higher quality of care.”

—Nitin Damle, MD, FACP

Do quality metrics actually improve medical care?

“...the needle in terms of whether patients overall are getting a higher quality of care.”

—Nitin Damle, MD, FACP

The Vitals is continued on page 17
In the treatment of type 2 diabetes, help INSPIRE PATIENTS TO GO FURTHER

*Data on file. Based on TRx data sourced from IMS NPA Database, weekly data through 11/21/14.

The recommended starting dose of INVOKAN® (canagliflozin) is 100 mg once daily. INVOKAN® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. INVOKAN® is not recommended in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS
- History of a serious hypersensitivity reaction to INVOKAN®
- Severe renal impairment (eGFR <30 mL/min/1.73 m²), end-stage renal disease, or patients on dialysis

Please see additional Important Safety Information and brief summary of full Prescribing Information on the following pages.
In the treatment of type 2 diabetes, help

INSPIRE PATIENTS TO GO FURTHER

INVOKANA® (canagliflozin) starting dose: 100 mg once daily. In patients tolerating the starting dose who have an eGFR ≥60 mL/min/1.73 m² and require additional glycemic control, the dose can be increased to 300 mg once daily.2

IMPORTANT SAFETY INFORMATION (cont’d)

WARNINGS and PRECAUTIONS

» Hypotension: INVOKANA® causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA®, particularly in patients with impaired renal function (eGFR <60 mL/min/1.73 m²), elderly patients, patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system, or patients with low systolic blood pressure. Before initiating in patients with ≥1 of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating.

» Impairment in Renal Function: INVOKANA® increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiation. More frequent renal function monitoring is recommended in patients with an eGFR <60 mL/min/1.73 m².
**GREATER REDUCTIONS in A1C**

**INVOKANA® 300 mg demonstrated greater reductions in A1C vs Januvia® 100 mg**

at 52 weeks in patients inadequately controlled on metformin + a sulfonylurea

<table>
<thead>
<tr>
<th>Mean baseline</th>
<th>Adjusted Mean Change in A1C From Baseline (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.13%</td>
<td>-0.66</td>
</tr>
<tr>
<td>8.12%</td>
<td>-1.03</td>
</tr>
</tbody>
</table>

Mean baseline: 8.13% 8.12%

*95% CI: –0.50, –0.25; P < 0.05.

**Adjusted Mean Change in A1C From Baseline (%)**

| Januvia® (sitagliptin) 100 mg + metformin and a sulfonylurea (n=378) | INVOKANA® 300 mg + metformin and a sulfonylurea (n=377) |
|====================================================================|==================================================================|
| –0.66                                                              | –1.03                                                            |

Secondary endpoint: **GREATER REDUCTIONS in body weight**

Difference from Januvia® 100 mg: –2.8%; P<0.001

**Incidence of hypoglycemia**

INVOKANA® 300 mg: 43.2%; Januvia® 100 mg: 40.7%

The incidence of hypoglycemia increases when used in combination with insulin or an insulin secretagogue.

INVOKANA® is not indicated for weight loss or as an antihypertensive treatment.

*Adjusted mean change from baseline.

Indicated trademarks are registered trademarks of their respective owners.

A randomized, double-blind, active-controlled, 52-week study of patients with type 2 diabetes inadequately controlled on maximally or near-maximally effective doses of metformin (≥2000 mg/day, or ≥1500 mg/day if higher dose not tolerated) and a sulfonylurea.

**Adverse events (AEs)**

Incidences of AEs were similar between groups except for:

- Male/female genital mycotic infection, INVOKANA® 300 mg: 9.2%/15.3%; Januvia® 100 mg: 0.5%/4.3%
- Increased urine frequency/volume, INVOKANA® 300 mg: 1.6%/0.8%; Januvia® 100 mg: 1.3%/0%

Learn more and register for updates at INVOKANAhcp.com

**GREATER REDUCTIONS in systolic blood pressure**

Difference from Januvia® 100 mg: –5.9 mm Hg; P<0.001

**Greater reductions in body weight**

**GREATER REDUCTIONS in body weight**

Difference from Januvia® 100 mg: –2.8%; P<0.001

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Learn more and register for updates at INVOKANAhcp.com

**Hyperkalemia:** INVOKANA® can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia. Monitor serum potassium levels periodically in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions.

**Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues:** INVOKANA® can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA®

**Genital Mycotic Infections:** INVOKANA® increases risk of genital mycotic infections. Patients with history of these infections and uncircumcised males were more likely to develop these infections. Monitor and treat appropriately.

**Hypersensitivity Reactions:** Hypersensitivity reactions (eg, generalized urticaria), some serious, were reported with INVOKANA®; these reactions generally occurred within hours to days after initiation. If reactions occur, discontinue INVOKANA®, treat per standard of care, and monitor until signs and symptoms resolve.

Please see additional Important Safety Information and brief summary of full Prescribing Information on the following pages.
**IMPORTANT SAFETY INFORMATION (cont’d)**

- **Increases in Low-Density Lipoprotein (LDL-C):** Dose-related increases in LDL-C can occur with INVOKANA® (canagliflozin). Monitor LDL-C and treat per standard of care after initiating.

- **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKANA® or any other antidiabetic drug.

**DRUG INTERACTIONS**

- **UGT Enzyme Inducers:** Rifampin: Coadministration of INVOKANA® with rifampin decreased INVOKANA® area under the curve (AUC) by 51% and therefore may decrease efficacy. If an inducer of UGT enzymes must be coadministered with INVOKANA®, consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA® 100 mg once daily, have an eGFR ≥60 mL/min/1.73 m², and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR <60 mL/min/1.73 m² who require additional glycemic control.

- **Digoxin:** There was an increase in the AUC and mean peak drug concentration of digoxin (20% and 36%, respectively) when coadministered with INVOKANA® 300 mg. Monitor appropriately.

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

- **Interference With 1,5-Anhydroglucitol (1,5-AG) Assay:** Monitoring glycemic control with 1,5-AG assay is not recommended in patients taking SGLT2 inhibitors as SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose test results. Use alternative methods to monitor glycemic control.

**USE IN SPECIFIC POPULATIONS**

- **Pregnancy Category C:** There are no adequate and well-controlled studies of INVOKANA® in pregnant women. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters.

- **Nursing Mothers:** It is not known if INVOKANA® is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants, discontinue INVOKANA®.

- **Pediatric Use:** Safety and effectiveness in patients <18 years of age have not been established.

- **Geriatric Use:** 2034 patients ≥65 years and 345 patients ≥75 years were exposed to INVOKANA® in 9 clinical studies. Patients ≥65 years had a higher incidence of adverse reactions related to reduced intravascular volume (eg, hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300-mg dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were ≥75 years. Smaller reductions in HbA1c relative to placebo were seen in patients ≥65 years (−0.61% with INVOKANA® 100 mg and −0.74% with INVOKANA® 300 mg) compared to younger patients (−0.72% with INVOKANA® 100 mg and −0.87% with INVOKANA® 300 mg).

- **Renal Impairment:** Efficacy and safety were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to <50 mL/min/1.73 m²). These patients had less overall glycemic efficacy and a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR ≥60 mL/min/1.73 m²); patients treated with 300 mg were more likely to experience increases in potassium. INVOKANA® is not recommended in patients with severe renal impairment (eGFR <30 mL/min/1.73 m²), with end-stage renal disease, or receiving dialysis.

- **Hepatic Impairment:** INVOKANA® has not been studied in patients with severe hepatic impairment and is not recommended in this population.

**OVERDOSAGE**

- In the event of an overdose, contact the Poison Control Center and employ the usual supportive measures, eg, remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment as needed.

**ADVERSE REACTIONS**

- The most common adverse reactions associated with INVOKANA® (5% or greater incidence) were female genital mycotic infections, urinary tract infections, and increased urination.

Please see brief summary of full Prescribing Information on the following pages.

**References:**


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**Invokana®

canagliflozin tablets

Janssen Pharmaceuticals, Inc.
Canagliflozin is licensed from Mitsubishi Tanabe Pharma Corporation.
CONTRAINDICATIONS

Limitation of Use: INVOKANA is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

INDICATIONS AND USAGE

INVOKANA™ [see Clinical Studies (14) in full Prescribing Information]

Table of Placebo-Controlled Trials: The occurrence of adverse reactions was also evaluated in a larger pool of patients participating in placebo- and active-controlled trials. The data combined eight clinical trials [see Clinical Studies (14) in full Prescribing Information] and reflect exposure of 1,177 patients to INVOKANA. The mean duration of exposure to INVOKANA was 38 weeks with 1832 individuals exposed to INVOKANA for greater than 50 weeks. Patients received INVOKANA 100 mg (N=3992), INVOKANA 300 mg (N=3085) or comparator (N=3262) once daily. The mean age of the population was 60 years and 5% were older than 75 years of age. Fifty-eight percent (58%) of the population was male and 73% were Caucasian, 16% were Asian, and 4% were Black or African American. At baseline the population had diabetes for an average of 7.3 years, had a mean HbA1C of 8.0% and 20% had established microvascular complications of diabetes. Baseline renal function was normal or mildly impaired (mean eGFR 88 mL/min/1.73 m²).

Table 1 shows common adverse reactions associated with the use of INVOKANA. These adverse reactions were not present at baseline, occurred more commonly on INVOKANA than on placebo, and occurred in at least 2% of patients treated with either INVOKANA 100 mg or INVOKANA 300 mg.

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo</th>
<th>INVOKANA 100 mg</th>
<th>INVOKANA 300 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female genital mycotic infections</td>
<td>0.6%</td>
<td>4.0%</td>
<td>3.2%</td>
</tr>
<tr>
<td>Urinary tract infections</td>
<td>0.8%</td>
<td>5.9%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Increased urination</td>
<td>0.6%</td>
<td>5.3%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Male genital mycotic infections</td>
<td>0.0%</td>
<td>4.2%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Vulvovaginal pruritus</td>
<td>0.0%</td>
<td>1.6%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Thirst*</td>
<td>0.2%</td>
<td>2.8%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Constipation</td>
<td>0.9%</td>
<td>1.8%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Nausea</td>
<td>1.5%</td>
<td>2.2%</td>
<td>2.3%</td>
</tr>
</tbody>
</table>

* The four placebo-controlled trials included one monotherapy trial and three add-on combination trials with metformin, metformin and sulfonylurea, or metformin and pioglitazone.

† Female genital mycotic infections include the following adverse reactions: Vulvovaginal candidiasis, Vulvovaginal vaginitis, Vaginal infection, Vulvitis, and Genital infection fungal. Percentages calculated with the number of female subjects in each group as denominator: placebo (N=312), INVOKANA 100 mg (N=425), and INVOKANA 300 mg (N=430).

‡ Urinary tract infections include the following adverse reactions: Urinary tract infection, Cystitis, Kidney infection, and Urosepsis.

§ Increased urination includes the following adverse reactions: Polyuria, Polydipsia.

¶ Male genital mycotic infections include the following adverse reactions: Balanitis or Balanoposthitis, Balanitis candida, and Genital infection fungal. Percentages calculated with the number of male subjects in each group as denominator: placebo (N=334), INVOKANA 100 mg (N=408), and INVOKANA 300 mg (N=404).

In clinical studies, the incidence of bone fractures was evaluated, comparing fractures occurring in patients treated with INVOKANA to both comparator groups. Patients received INVOKANA (300 mg) for at least 24 weeks and were included in the analyses if they had a baseline HbA1C of 7.5% or more, were not on other antidiabetic agents, and continued to receive the study drug. The percentages of patients with bone fractures were 6.8% for INVOKANA 300 mg (N=833) versus 2.3% for placebo (N=846) and 1.8% for comparator (N=834). These data reflect exposure to INVOKANA (68 weeks), the incidence rate of bone fracture was 14.2, 18.7, and 20.0 per 1000 patient-years of exposure to comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Upper extremity fractures occurred more commonly on INVOKANA than comparator.
**INVO Kann™ (canagliflozin) tablets**

In the pool of eight clinical trials, hypersensitivity-related adverse reactions (including erythema, rash, pruritus, urticaria, and angioedema) occurred in 3.0%, 3.8%, and 4.2% of patients receiving comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Five patients experienced serious adverse reactions of hypersensitivity with INVOKANA, which included 4 patients with urticaria and 1 patient with a diffuse rash and urticaria occurring within hours of exposure to INVOKANA. Among these patients, 2 patients discontinued INVOKANA. One patient with urticaria had recurrence when INVOKANA was re-initiated.

Photosensitivity-related adverse reactions (including photosensitivity reaction, photomycotic light eruption, and sunburn) occurred in 0.1%, 0.2%, and 0.2% of patients receiving comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

Other adverse reactions occurring more frequently on INVOKANA than on comparator were:

**Volume Depletion-Related Adverse Reactions:** INVOKANA results in an osmotic diuresis, which may lead to reductions in intravascular volume. In clinical studies, treatment with INVOKANA was associated with a dose-dependent increase in the incidence of volume depletion-related adverse reactions (e.g., hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration). An increased incidence was observed in patients on the 300 mg dose. The three factors associated with the largest increase in volume depletion-related adverse reactions were the use of loop diuretics, moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m²), and age 75 years and older (Table 2). [See Dosage and Administration (2.2) in full Prescribing Information, Warnings and Precautions, and Use in Specific Populations].

**Other adverse reactions occurring more frequently on INVOKANA than on comparator were:**

**Female patients who developed genital mycotic infections on INVOKANA were more likely to experience recurrence and require treatment with oral or topical antifungal agents and anti-microbial agents [see Warnings and Precautions].**

**Hypoglycemia:** In all clinical trials, hypoglycemia was defined as any event regardless of symptoms, where biochemical hypoglycemia was documented (any glucose value below or equal to 70 mg/dL). Severe hypoglycemia was defined as an event consistent with hypoglycemia where the patient required the assistance of another person to recover, lost consciousness, or experienced a seizure (regardless of whether biochemical documentation of a low glucose value was obtained). In individual clinical trials [see Clinical Studies (14.4) in full Prescribing Information], episodes of hypoglycemia occurred at a higher rate when INVOKANA was co-administered with insulin or sulfonylureas (Table 4). [See Warnings and Precautions].

### Table 2: Proportion of Patients With at Least One Volume Depletion-Related Adverse Reaction (Pooled Results From 8 Clinical Trials)

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>Comparator Group</th>
<th>INVOKANA 100 mg</th>
<th>INVOKANA 300 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td><strong>Overall population</strong></td>
<td>1.5%</td>
<td>2.3%</td>
<td>3.4%</td>
</tr>
<tr>
<td><strong>75 years of age and older</strong></td>
<td>2.6%</td>
<td>4.9%</td>
<td>8.7%</td>
</tr>
<tr>
<td>eGFR less than 60 mL/min/1.73 m²</td>
<td>2.5%</td>
<td>4.7%</td>
<td>8.1%</td>
</tr>
<tr>
<td>Use of loop diuretic†</td>
<td>4.7%</td>
<td>3.2%</td>
<td>8.8%</td>
</tr>
</tbody>
</table>

* Includes placebo and active-comparator groups

**Impairment in Renal Function:** INVOKANA is associated with a dose-dependent increase in serum creatinine and a concomitant fall in estimated glomerular filtration rate (eGFR). Patients with moderate renal impairment at baseline had larger mean changes.

### Table 3: Changes in Serum Creatinine and eGFR Associated with INVOKANA in the Pool of Four Placebo-Controlled Trials and Moderate Renal Impairment Trial

<table>
<thead>
<tr>
<th>Pool of Four Placebo-Controlled Trials</th>
<th>Placebo N=646</th>
<th>INVOKANA 100 mg N=90</th>
<th>INVOKANA 300 mg N=834</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline Creatinine (mg/dL)</td>
<td>0.84</td>
<td>0.62</td>
<td>0.82</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>87.0</td>
<td>88.3</td>
<td>88.8</td>
</tr>
<tr>
<td>Week 6 Creatinine (mg/dL)</td>
<td>0.01</td>
<td>0.03</td>
<td>0.05</td>
</tr>
<tr>
<td>End of Treatment Creatinine (mg/dL)</td>
<td>0.01</td>
<td>0.02</td>
<td>0.03</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>-1.6</td>
<td>-2.3</td>
<td>-3.4</td>
</tr>
</tbody>
</table>

* Week 26 in mITT LOCF population

In the pool of four placebo-controlled trials where patients had normal or mildly impaired baseline renal function, the proportion of patients who experienced at least one event of significant renal function decline, defined as an eGFR below 60 mL/min/1.73 m² and 30% lower than baseline, was 2.1% with placebo, 2.0% with INVOKANA 100 mg, and 4.1% with INVOKANA 300 mg. At the end of treatment with INVOKANA 100 mg, 0.7% with INVOKANA 100 mg, and 1.4% with INVOKANA 300 mg had a significant renal function decline.

In a trial carried out in patients with moderate renal impairment with a baseline eGFR of 30 to less than 50 mL/min/1.73 m² (mean baseline eGFR 39 mL/min/1.73 m²), see Clinical Studies (14.3) in full Prescribing Information, the proportion of patients who experienced at least one event of significant renal function decline, defined as an eGFR 30% lower than baseline, was 6.9% with placebo, 18% with INVOKANA 100 mg, and 22.5% with INVOKANA 300 mg. At the end of treatment, 4.8% with placebo, 3.4% with INVOKANA 100 mg, and 3.4% with INVOKANA 300 mg had a significant renal function decline.

In a pooled population of patients with moderate renal impairment (N=1085) with baseline eGFR of 30 to less than 60 mL/min/1.73 m² (mean baseline eGFR 37 mL/min/1.73 m²), the overall incidence of these events was lower than in the dedicated trial but a dose-dependent increase in incident episodes of significant renal function decline compared to placebo was still observed.

Use of INVOKANA was associated with an increased incidence of renal-related adverse reactions (e.g., increased blood creatinine, decreased glomerular filtration rate, renal impairment, and acute renal failure), particularly in patients with moderate renal impairment.

In the pooled analysis of patients with moderate renal impairment, the incidence of renal-related adverse reactions was 3.7% with placebo, 8.9% with INVOKANA 100 mg, and 9.3% with INVOKANA 300 mg. Discontinuations due to renal-related adverse events occurred in 1.0% with placebo, 1.2% with INVOKANA 100 mg, and 1.6% with INVOKANA 300 mg [see Warnings and Precautions].

### Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies

<table>
<thead>
<tr>
<th>Treatment*</th>
<th>Placebo (N=482)</th>
<th>INVOKANA 100 mg (N=192)</th>
<th>INVOKANA 300 mg (N=197)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe (%)</td>
<td>4 (0.8)</td>
<td>1 (0.5)</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Moderate (%)</td>
<td>15 (3.1)</td>
<td>2 (1.0)</td>
<td>3 (1.5)</td>
</tr>
</tbody>
</table>

* Includes patients with hypoglycemia with symptoms and those with biochemical hypoglycemia who were asymptomatic

**Adverse Events**: The most common events with INVOKANA were male genital mycotic infections. Male genital mycotic infections occurring more commonly in uncircumcised males and in males with a prior history of balanitis or balanoposthitis. Male patients who developed genital mycotic infections on INVOKANA were more likely to experience recurrent infections (22% on INVOKANA versus none on placebo), and require treatment with oral or topical antifungal agents and anti-microbial agents than patients on comparators. In the pooled analysis of 8 controlled trials, phimosis was reported in 0.3% of uncircumcised male patients treated with INVOKANA and 0.2% required circumcision to treat the phimosis [see Warnings and Precautions].
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Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies (continued)

<table>
<thead>
<tr>
<th>In Combination with Metformin + Pioglitazone (26 weeks)</th>
<th>Placebo (N=550)</th>
<th>INVOKANA 100 mg (N=113)</th>
<th>INVOKANA 300 mg + Metformin + Pioglitazone (N=114)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (%)</td>
<td>3 (2.6)</td>
<td>3 (2.7)</td>
<td>6 (5.3)</td>
</tr>
<tr>
<td>Severe (%)</td>
<td>14 (2.5)</td>
<td>10 (1.8)</td>
<td>16 (2.7)</td>
</tr>
</tbody>
</table>

* Number of patients experiencing at least one event of hypoglycemia based on either biochemically documented episodes or severe hypoglycemic events in the intent-to-treat population

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antihyperglycemic therapy in patients with an eGFR of 45 to less than 60 mL/min/1.73 m² receiving concurrent therapy with a UGT inducer and require additional glycemic control [see Dosage and Administration (2.3) and Nonclinical Toxicology (13.2) in full Prescribing Information].

Digoxin: There was an increase in the AUC and mean peak drug concentration (Cmax) of digoxin (20% and 36%, respectively) when co-administered with INVOKANA 300 mg [see Clinical Pharmacology (12.3) in full Prescribing Information]. Patients taking INVOKANA with concomitant digoxin should be monitored appropriately.

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

Interference with 1,5-anhydroglucitol (1,5-AG) Assay: Monitoring glycemic control with 1,5-anhydroglucitol (1,5-AG) assay is not recommended as 1,5-AG assays used for monitoring glycemic control are unreliable in assessing glycemic control in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycemic control.

USE IN SPECIFIC POPULATIONS

Pregnancy: Teratogenic Effects: Pregnancy Category C: There are no adequate and well-controlled studies of INVOKANA in pregnant women. Based on results from rat studies, canagliflozin may affect renal development and maturation. In a juvenile rat study, increased kidney weights and renal pelvic and tubular dilatation were evident at greater than or equal to 0.5 times clinical exposure from a 300 mg dose [see Nonclinical Toxicology (13.2) in full Prescribing Information]. These outcomes occurred with drug exposure during periods of animal development that correspond to the late second and third trimester of human development. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters. INVOKANA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known if INVOKANA is excreted in human milk. INVOKANA is secreted in the milk of lactating rats reaching levels 1.4 times higher than that in maternal plasma. Data in juvenile rats directly exposed to INVOKANA showed risk to the developing kidney (renal pelvic and tubular dilatation) during maturation. Since human kidney maturation occurs in utero and during the first 2 years of life, when lactational exposure may occur, there may be risk to the developing human kidney. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from INVOKANA, a decision should be made whether to discontinue nursing or to discontinue INVOKANA, taking into account the importance of the drug to the mother.

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

Geriatric Use: Two thousand thirty-four (2034) patients 65 years and older, and 345 patients 75 years and older were exposed to INVOKANA in nine clinical studies of INVOKANA [see Clinical Studies (14.3) in full Prescribing Information]. Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume, such as hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration, particularly with the 300 mg daily dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were 75 years and older [see Dosage and Administration (2.1) in full Prescribing Information and Adverse Reactions]. Smaller reductions in HbA1C with INVOKANA relative to placebo were seen in older (65 years and older; -0.61% with INVOKANA 100 mg and -0.74% with INVOKANA 300 mg relative to placebo) compared to younger patients (-0.72% with INVOKANA 100 mg and -0.87% with INVOKANA 300 mg relative to placebo).

Renal Impairment: The efficacy and safety of INVOKANA were evaluated in a study involving patients with moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m²) [see Clinical Studies (14.3) in full Prescribing Information]. These patients had lesser overall glycaemic efficacy and had a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR greater than or equal to 60 mL/min/1.73 m²); patients treated with INVOKANA 300 mg were more likely to experience increases in potassium [see Dosage and Administration (2.2) in full Prescribing Information, Warnings and Precautions and Adverse Reactions]. The efficacy and safety of INVOKANA have not been established in patients with severe renal impairment (eGFR less than 30 mL/min/1.73 m²), with ESRD, or receiving dialysis. INVOKANA is not expected to be effective in these patient populations [see Contraindications and Clinical Pharmacology (12.3) in full Prescribing Information].

Drug Interactions

UGT Enzyme Inducers: Rifampin: Co-administration of canagliflozin with rifampin, a nonselective inducer of several UGT enzymes, including UGT1A9, UGT2B4, decreased canagliflozin area under the curve (AUC) by 51%. This decrease in exposure to canagliflozin may decrease efficacy. If an inducer of these UGTs (e.g., rifampin, phenytoin, phenobarbital, rifabutin) must be co-administered, with canagliflozin, if increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA 100 mg once daily, have an eGFR greater than 60 mL/min/1.73 m², and require additional glycemic control. Consider other
INVOKANA™ (canagliflozin) tablets

OVERDOSAGE
There were no reports of overdose during the clinical development program of INVOKANA (canagliflozin).

In the event of an overdose, contact the Poison Control Center. It is also reasonable to employ the usual supportive measures, e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment as dictated by the patient’s clinical status. Canagliflozin was negligibly removed during a 4-hour hemodialysis session. Canagliflozin is not expected to be dialyzable by peritoneal dialysis.

PATIENT COUNSELING INFORMATION
See FDA-approved patient labeling (Medication Guide).

Instructions: Instruct patients to read the Medication Guide before starting INVOKANA (canagliflozin) therapy and to reread it each time the prescription is renewed.

Inform patients of the potential risks and benefits of INVOKANA and of alternative modes of therapy. Also inform patients about the importance of adherence to dietary instructions, regular physical activity, periodic blood glucose monitoring and HbA1C testing, recognition and management of hypoglycemia and hyperglycemia, and assessment for diabetes complications. Advise patients to seek medical advice promptly during periods of stress such as fever, trauma, infection, or surgery, as medication requirements may change.

Instruct patients to take INVOKANA only as prescribed. If a dose is missed, advise patients to take it as soon as it is remembered unless it is almost time for the next dose, in which case patients should skip the missed dose and take the medicine at the next regularly scheduled time. Advise patients not to take two doses of INVOKANA at the same time.

Inform patients that the most common adverse reactions associated with INVOKANA are genital mycotic infection, urinary tract infection, and increased urination.

Inform female patients of child bearing age that the use of INVOKANA during pregnancy has not been studied in humans, and that INVOKANA should only be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Instruct patients to report pregnancies to their physicians as soon as possible.

Inform nursing mothers to discontinue INVOKANA or nursing, taking into account the importance of drug to the mother.

Laboratory Tests: Due to its mechanism of action, patients taking INVOKANA will test positive for glucose in their urine.

Hypotension: Inform patients that symptomatic hypotension may occur with INVOKANA and advise them to contact their doctor if they experience such symptoms [see Warnings and Precautions]. Inform patients that dehydration may increase the risk for hypotension, and to have adequate fluid intake.

Genital Mycotic Infections in Females (e.g., Vulvovaginitis): Inform female patients that vaginal yeast infection may occur and provide them with information on the signs and symptoms of vaginal yeast infection. Advise them of treatment options and when to seek medical advice [see Warnings and Precautions].

Genital Mycotic Infections in Males (e.g., Balanitis or Balanoposthitis): Inform male patients that yeast infection of penis (e.g., balanitis or balanoposthitis) may occur, especially in uncircumcised males and patients with prior history. Provide them with information on the signs and symptoms of balanitis and balanoposthitis (rash or redness of the glans or foreskin of the penis). Advise them of treatment options and when to seek medical advice [see Warnings and Precautions].

Hypersensitivity Reactions: Inform patients that serious hypersensitivity reactions such as urticaria and rash have been reported with INVOKANA. Advise patients to report immediately any signs or symptoms suggesting allergic reaction or angioedema, and to take no more drug until they have consulted prescribing physicians.

Urinary Tract Infections: Inform patients of the potential for urinary tract infections. Provide them with information on the symptoms of urinary tract infections. Advise them to seek medical advice if such symptoms occur.

Active ingredient made in Belgium
Manufactured for:
Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560
Finished product manufactured by:
Janssen Ortho, LLC
Gurabo, PR 00778
Licensed from Mitsubishi Tanabe Pharma Corporation
© 2013 Janssen Pharmaceuticals, Inc.
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020588-140827
Medication therapy for smoking can increase long-term quitting success

A STUDY OF more than 1,500 cigarette smokers who were not ready to quit smoking but were willing to cut back on cigarette consumption and combine their approach with varenicline (Chantix, Pfizer) increased their long-term success of quitting smoking, according to a study published in the February issue of the Journal of the American Medical Association.

Jon O. Ebbert, MD, MSc, professor of medicine, Mayo Clinic, and colleagues, reported the effects of the prescription medication varenicline for increasing smoking abstinence rates among smokers who wanted to reduce the number of cigarettes they smoked before trying to quit completely.

Ebbert and colleagues enrolled smokers who had no intention of quitting in the next month but who were willing to reduce the number of cigarettes they smoked while working toward a quit attempt in the next 3 months, and randomly assigned them to 6 months of varenicline or placebo along with behavioral strategies for smoking reduction. Their continuous smoking abstinence rates were evaluated at 6 and 12 months.

In the a multinational study, researchers found that 760 participants receiving varenicline were greater than 4 times more likely to quit than the 750 participants receiving placebo at 6 months (32.1% vs. 6.9%) and more than 2 times more likely to quit than participants receiving a placebo at 12 months (27.0% vs. 9.9%).

“Among smokers who were not willing or able to quit in the next 30 days but willing to reduce their smoking rate and make a quit attempt by 3 months, varenicline significantly increased long-term smoking cessation rates compared to placebo,” said Dr Ebbert, who also is associate director for research in the Mayo Clinic Nicotine Dependence Center.

“The results tell us that varenicline works to help people quit smoking completely long-term through a gradual reduction in the number of cigarettes they smoke.”

This study is important because this opens the door to treatment for approximately 14 million smokers who have no intention of quitting in the next 30 days but are willing to reduce their smoking rate while working toward a quit attempt, according to the authors.

In the past, these smokers may have not received medication therapy, Ebbert said.

Varenicline costs about $250 per month.

“Not all insurance companies require that a quit date be set before covering medication,” he said. “This data would suggest that among patients who want to work toward a quit date in 3 months through gradual smoking reduction, varenicline will increase long-term smoking cessation compared to placebo.”

“This research was funded by Pfizer.

SURVEY: PRACTICES LAG ON HIPAA COMPLIANCE

Medical practices are required to understand and comply with the U.S. Health Insurance Portability and Accountability Act (HIPAA), but many are either not aware of the specific requirements or do not have a plan in place, according to a recent survey.

The survey, conducted by NueMD, a software vendor, asked questions about HIPAA compliance to physicians across the country, and received more than 1,000 responses.

The results found that 36% of medical practices surveyed were unaware of the HIPAA “omnibus” rule and the changes the rule required to their HIPAA policies, including updates to patient rights, sliding scale penalties for violations, and requirements about breach notification and information use and disclosure.

In addition, only 58% of respondents said they had a HIPAA compliance plan in place, while another 19% said they were not sure. A HIPAA plan is required to be in compliance with the law. HIPAA compliance has received new levels of scrutiny since news broke in February of a massive customer data breach at Anthem.
We asked for your stories on connecting care, and you delivered.

When editors at Medical Economics decided on the theme of “connecting care” for the 2015 Physician Writing Contest, we hoped our readers would share with us “real-life stories that can move, teach, and inspire other physicians.”

That’s exactly what we received, in spades. You sent us more than 300 entries brimming with the wisdom and insight that comes from physicians who connect with patients and their families on a daily basis. Collectively, these essays show that the passion for medicine is still alive and well in today’s physicians, despite the numerous challenges you face.

In our next three issues, Medical Economics will unveil the contest winners. We believe these essays exemplify what connecting with patients is truly about, and demonstrate the levels of heart, determination, and empathy you strive to bring into every exam room, every day. Thanks for reading.

**First place**
Daniel Taylor, DO
“Jeremy”

**Second place**
Ken Moon, MD
“To care always”

**Third place**
Rashmee Patil, MD
“From the other side”
Millions of people are now taking OTC acid control to the Nexium Level

Those are numbers that let you recommend with confidence

Order samples now at PreviewNexium24HR.com

*Based on eligibility.

Jeremy had lived his whole life in a desert when I first met him for his annual checkup at St. Christopher’s Hospital for Children. Fifteen formative years of this life and their effects on Jeremy have been toxic. As I reviewed his chart I was heartbroken reading over his past medical history trying to imagine what he had endured, yet not surprised by the predictability of his diagnoses rooted in a life lived in a desert.


Age eleven. Groin pain. Radiograph shows slipped capital femoral epiphysis, ICD code 732.2. Open surgery on hip with metal pins placed for fixation. Age thirteen: diagnosed with hypercholesterolemia, vitamin D deficiency and pre-hypertension. The ICD codes kept stacking up like grains of sand falling from an hourglass inevitably shortening Jeremy’s life.

FOOD DESERTS AND POVERTY

The desert that Jeremy lives in is not that of the glamour and excitement of T.E. Lawrence’s Arabia, but one that continues to damage tens of millions of children in the United States, and one that contributes to the unconscionable possibility that the present generation of children in the U.S. might live shorter, sicker lives than their parents for the first time in recorded history.

Jeremy’s home and school reside in Pennsylvania’s First Congressional district, a few blocks from our hospital. This district is the third-most-impoverished for children in America. It is the second-most food insecure, with almost half of all families running out of food, or having to make the unimaginable choice of heating their home or eating.

Jeremy lives in a food desert. A desert where fresh, affordable food is out of his reach. Something that is taught about in health class, but at home, he finds only calorie-dense, inexpensive processed foods.

In the food deserts of Philadelphia, in the most concentrated areas of poverty, childhood overweight and obesity rates exceed 50%. Jeremy at fifteen weighed 240 pounds and like many in his family was on a predictable course for the development of diabetes and it’s crippling consequences.

Jeremy told me he was scared. His grandfather had his leg removed from diabetes and his mother had recently been started on insulin. Jeremy did not like shots. He tearfully discussed with me the powerlessness he felt dealing with his weight. He saw the inevitability of a diabetic future that many in his family sensed.

He did not want this to happen to him. He wanted help. He wanted to stop the sands of time, and live a healthier life. The grains of sand had buried too many in his family already.

A PRESCRIPTION FOR FOOD

Social determinants of health, (where people are born, grow up, live, work, and play), are now thought to contribute up to 80% of health in the United States. It’s well known that your zip code is a more important factor in health than your genetic code. No other health condition is more evidence of this than obesity.

One of the tenets of motivational interviewing is assessing a patient’s readiness. Jeremy was ready, engaged, and was old and insightful enough to be able to take matters into his own hands, with some help.

Obesity, like many chronic illnesses, is multifactorial, but can be broken down to the basic equation of more calories in than out. Unfortunately, this equation is stacked against children like Jeremy who live in pov-
erty. Children who can’t find a safe place to play stay inside, snacking, their faces reflected on computer and video game screens. Their parents may have to take two buses to the nearest grocery store, past dozens of more convenient corner stores, just to get fresh fruits and vegetables.

The cost of obesity in America is estimated at $93 billion annually and more than 20 million Americans suffer from diabetes, a four-fold increase since 1980. The emotional cost to Jeremy was immeasurable.

I could not write a prescription for Jeremy to lose weight, or could I? Could I put together a treatment plan for Jeremy, using resources both in our community and inside our own hospital’s walls? It started with a prescription for food.

Since 2011, in response to the food insecurity that our families face, our hospital has collaborated with an organization that brings low-cost, farm-fresh foods into our office weekly coupled with a demonstration kitchen to introduce families to foods that may be foreign to them.

Kale, cabbage and beets overflow the “Farm to Families” boxes, surrounded by the more familiar eggs and cheese. Jeremy and his family became Farm to Families regulars but this wasn’t enough.

Using his cell phone, I helped Jeremy connect with the USDA’s choosemyplate.gov website that helps teens plan, analyze and track their diet and personal physical activity goals. Jeremy was eager to embrace these changes, and help his family members do the same, but he needed one more intervention that had eluded him most of his life. A safe place to be more active.

Health insurers are well aware of the cost of childhood obesity to society and their bottom line and many have become allies in this battle. A quick check of Jeremy’s insurance, as well as his zip code, and I was able to find a YMCA close to his home that he could join free of charge. He had walked by this YMCA for years, staring at the modern exercise equipment, but never thought that his family could afford a membership.

We had several follow-up visits and his weight slowly came off, and then, discouragingly, I didn’t see him for over a year.

When I saw that he was finally back on my panel after a year’s absence, I was worried that all the connections that we worked so hard to make may have been broken, and that he, like many other children lost to follow-up, had put back on the weight that he worked so hard to lose. I was quite wrong.

‘I DID IT FOR ME’

Now seventeen years old, Jeremy looked at me expressively with pride: 185 pounds. He was in great shape and that brooding adolescent that I first encountered morphed into a confident young adult teeming with life.

“Where you been?” I asked trying to discover why he hadn’t come to his follow-up visits. “You know, school, working”, he answered. “I got my mom to come to the Y as well. She’s doing better.” He had become her health coach as well. “How did you do it?” I asked pointing to his flattened abdomen. “I did what we agreed to do, I did it for me, for my mom,” his maturity surprised me and his drive to combat a disease that had crippled so many in his family members and neighbors was palpable.

Jeremy’s trek through the obstacles to good health brought him to a personal oasis that eludes far too many children and adults in the United States. Through coordinated care and connecting with each patient, we can slow down the sands of time and help each Jeremy find a path to a healthier life.

Through coordinated care and connecting with each patient, we can slow down the sands of time and help each patient, each neighborhood, and help each Jeremy find a path to a healthier life.”
HEART FAILURE SHATTERS MILLIONS OF LIVES

HEART FAILURE PATIENTS: “STABLE” OR SILENTLY PROGRESSING?
Heart failure is a progressive disease that is characterized by frequent hospital admissions and high mortality rates:

>1 MILLION HEART FAILURE HOSPITALIZATIONS OCCUR EVERY YEAR¹

and rehospitalization continues to be an issue²

≥24% OF HEART FAILURE PATIENTS DIE WITHIN 1 YEAR OF DIAGNOSIS³

this increases to ~50% within 5 years³⁴

The neurohormonal imbalance associated with chronic heart failure is a major contributing factor to the progression of the disease. Sustained overactivation of the RAAS and SNS, with dysfunction of the normal counterregulatory effects of the NPS and other compensatory mediators,* lead to impairment in heart function and cardiac remodeling.⁵⁻⁸

LET’S WORK TOGETHER TO CHANGE THAT

Learn more at InsideHeartFailure.com: your dedicated heart failure resource.

*Additional counterregulatory mediators include adrenomedullin, prostaglandin E, bradykinin, etc.⁵

NPS = natriuretic peptide system; RAAS = renin-angiotensin-aldosterone system; SNS = sympathetic nervous system.

An estimated 50 to 70 million adults have some form of sleep or wakefulness disorder, based on reports from the United States Centers for Disease Control and Prevention. Insomnia effects approximately 30% of adults in the United States, according to estimates from the American Academy of Sleep Medicine. About 10% of these patients have insomnia symptoms severe enough to cause daytime consequences. Insomnia is more common in women, and the prevalence of insomnia increases with advancing age.

Adults who sleep less than the recommended 7 to 9 hours per night are more likely to report difficulty performing daily tasks. Additionally, patients with insomnia are more likely to have chronic diseases such as depression, diabetes, hypertension, and obesity. They may also suffer from increased mortality, reduced productivity, and poor quality of life.

Insomnia also carries heavy economic costs. According to the America Insomnia Survey, the estimated annual cost for lost work performance at an individual level was $2,280. When generalized to the total national workforce, this represented a population-level estimate of $63.2 billion.

Because the disorder can be impacted by a variety of biological, psychological, and social factors, and because most patients who have insomnia do not report their symptoms to their clinician, diagnosis and management can be challenging when a patient presents in the primary-care setting. Screening for insomnia in at-risk populations and at the occurrence of various presenting symptoms is essential to diagnose the disorder expeditiously. Furthermore, effective physician-patient communication, appropriate selection of diagnostic testing, and referral to specialty practitioners when necessary are important components of successful insomnia diagnosis and management.

Continued on page 25
PATIENT MANAGEMENT TIPS

Understand patient concerns. Typically, insomnia is defined simply by a patient’s report of difficulty with sleep. Most patients with insomnia tend to report nonrestorative sleep, difficulty initiating sleep, frequent waking during the night, and waking too early. Insomnia can be precipitated by a range of factors, and many symptoms are subjective.

Because the poor sleep of insomnia can leave patients stressed and anxious, it is important to help them clearly articulate their main concerns during the office visit. In addition to taking a careful medical, substance, and psychiatric history, asking questions like, “Do you have trouble falling or staying asleep?” and “How often do you wake during the night?” can help guide the discussion.

Educate patients on sleep hygiene and available treatments. The stress associated with insomnia can cause patients to experience anxiety that undermines their ability to self-manage their sleep lifestyle.

Patients may worry about the inability to sleep and the daytime consequences of poor sleep, develop maladaptive efforts to accommodate to the condition, and spend excessive time awake in bed. This last behavior can be particularly damaging because it often exacerbates anxiety and creates a pattern of wakefulness. Encourage patients to make lifestyle changes that support good sleep, including:

- keep a regular sleep schedule that offers sufficient sleep time and starts and ends at the same time every day, even non-working days,
- include regular daytime exercise and a healthy diet,
- maintain a bedroom environment that is conducive to good sleep: dimly lit room; no TV, computer, or smart phones for a few hours before bedtime,
- avoid napping, caffeine, other stimulants, nicotine, alcohol, excessive fluids, and stimulating activities before bedtime, and
- limit time spent awake in bed.

While sleep hygiene is a critical aspect of insomnia self-management, this education alone may be insufficient for the treatment of chronic insomnia. Patients may also require stimulus control, relaxation training, sleep restriction, cognitive-behavioral therapy (CBT) or medications.

Select diagnostics and treatments carefully. The American Board of Internal Medicine Foundation and the American Academy of Sleep Medicine have partnered to develop a list of common tests and treatments that may not necessarily be appropriate under the following circumstances when treating patients with insomnia:

- Avoid polysomnography in chronic insomnia patients unless symptoms suggest a comorbid sleep disorder. Polysomnography in patients with insomnia is only indicated in specific circumstances: when sleep apnea or sleep-related movement disorders are suspected, the initial diagnosis is uncertain, behavioral or pharmacologic treatment fails, or sudden arousals occur with violent or injurious behavior.
- Avoid use of hypnotics for chronic insomnia in adults as initial therapy if possible; instead offer CBT, and reserve medication for adjunctive treatment when necessary. In clinical trials, CBT is generally as or more effective than prescription medications at improving sleep.
- Don’t use polysomnography to diagnose restless legs syndrome, except in instances when the clinical history is ambiguous and periodic leg movements need to be ruled out. Restless legs syndrome can typically be diagnosed based on a patient’s description of symptoms and their clinical history. Periodic leg movements occur while the patient is asleep, and has no awareness of its presence.
- Insomnia occurs in nearly 50% of patients with obstructive sleep apnea. However, there is no need to perform re-titration studies in asymptomatic, adherent sleep apnea patients with stable weight. Re-titration of positive airway pressure is not indicated for adult obstructive sleep apnea patients with stable weight whose symptoms are well controlled.

Refer when appropriate. CBT can be particularly effective in helping patients reframe worries about insomnia and its daytime consequences and feel more empowered in their self-management skills. Referral to a specialist for CBT may be very effective. Psychologists and other clinicians with general training in CBT may have varying degrees of experience in behavioral sleep treatment, and ideally this treatment is delivered by a behavioral sleep medicine specialist. CBT is now also offered on certain websites and in group therapies.

However, there is a current shortage of trained sleep specialists, and this level of care may not be available to all patients. For the clinician interested in providing more in-depth insomnia treatment in the primary-care office, several strategies can be put into place. These might include on-site staff training and alternative methods of treatment and follow-up, such as telephone or email consultations to review patient-completed sleep logs or questionnaires. Such options may offer better access to treatment for patients who are unable to receive care from a specialist.

—Written by Nicole Klemas, ELS
—Reviewed by Paul P. Doghramji, Sr., MD, Collegeville, Pennsylvania

Continued on page 24

PATIENT EDUCATION RESOURCES

American Academy of Sleep Medicine
http://bit.ly/1vyyM6y

National Institutes of Health
http://1.usa.gov/1psnPf9

National Sleep Foundation
http://bit.ly/2XRB1Q

restless legs syndrome, except in instances when the clinical history is ambiguous and periodic leg movements need to be ruled out. Restless legs syndrome can typically be diagnosed based on a patient’s description of symptoms and their clinical history. Periodic leg movements occur while the patient is asleep, and has no awareness of its presence.

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### Key Coding Considerations

#### Common Insomnia ICD-9 codes

<table>
<thead>
<tr>
<th>ICD-9 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>V69.4</td>
<td>Lack of adequate sleep (sleep deprivation)</td>
</tr>
<tr>
<td>V69.5</td>
<td>Behavioral insomnia of childhood</td>
</tr>
<tr>
<td>291.82</td>
<td>Alcohol induced sleep disorders (Alcohol induced insomnia)</td>
</tr>
<tr>
<td>292.85</td>
<td>Drug induced sleep disorders (Drug induced insomnia)</td>
</tr>
<tr>
<td>307.42</td>
<td>Persistent disorder of initiating or maintaining sleep</td>
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<tr>
<td>307.41</td>
<td>Transient disorder of initiating or maintaining sleep</td>
</tr>
<tr>
<td>307.46</td>
<td>Sleep arousal disorder</td>
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<tr>
<td>307.49</td>
<td>Other specific disorder of sleep of nonorganic origin</td>
</tr>
<tr>
<td>327.00</td>
<td>Organic insomnia, unspecified</td>
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<tr>
<td>327.01</td>
<td>Insomnia due to medical condition classified elsewhere</td>
</tr>
<tr>
<td>327.02</td>
<td>Insomnia due to mental disorder</td>
</tr>
<tr>
<td>327.09</td>
<td>Other organic insomnia</td>
</tr>
<tr>
<td>780.52</td>
<td>Insomnia, unspecified</td>
</tr>
<tr>
<td>780.51</td>
<td>Insomnia with sleep apnea, unspecified</td>
</tr>
<tr>
<td>780.55</td>
<td>Disruption of 24 hour sleep wake cycle, unspecified</td>
</tr>
<tr>
<td>780.59</td>
<td>Other sleep disturbances</td>
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</tbody>
</table>

#### Symptoms and Common Causes of Insomnia

<table>
<thead>
<tr>
<th>ICD-9 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>291.82</td>
<td>Alcohol induced sleep disorders</td>
</tr>
<tr>
<td>292.85</td>
<td>Drug induced sleep disorders</td>
</tr>
<tr>
<td>296.24</td>
<td>Major depressive disorder, single episode, severe, specified as with psychotic behavior</td>
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<tr>
<td>300.00</td>
<td>Anxiety state, unspecified</td>
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<tr>
<td>300.02</td>
<td>Generalized anxiety disorder</td>
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<tr>
<td>305.1</td>
<td>Nondependent tobacco use disorder</td>
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<tr>
<td>307.81</td>
<td>Tension headache</td>
</tr>
<tr>
<td>311</td>
<td>Depressive disorder, not elsewhere classified</td>
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<tr>
<td>339.10</td>
<td>Tension type headache, unspecified</td>
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<tr>
<td>339.11</td>
<td>Episodic tension type headache</td>
</tr>
<tr>
<td>339.12</td>
<td>Chronic tension type headache</td>
</tr>
<tr>
<td>780.79</td>
<td>Other malaise and fatigue</td>
</tr>
<tr>
<td>780.91</td>
<td>Fussy infant (baby)</td>
</tr>
<tr>
<td>799.52</td>
<td>Irritability</td>
</tr>
<tr>
<td>995.20</td>
<td>Unspecified adverse effect of unspecified drug, medicinal and biological substance</td>
</tr>
</tbody>
</table>

### Sources


To see ICD-10 codes for treating insomnia, visit this story on MedicalEconomics.com: http://www.modernmedicine.com/tag/clinical-economics
Chronic Care Management SUCCESS

How to overcome tech limitations

by KEN TERRY Contributing editor

HIGHLIGHTS

01 EHRs aren’t designed to create the kind of care plan required by chronic care management, but the templates in their assessment and plan section can be modified to accommodate the requirements.

AT FIRST GLANCE, Medicare’s new chronic care management (CCM) billing code, which became available January 1, looks like a major opportunity for primary care practices. But many practices will find it difficult to meet the requirements for billing the code, and a major reason is the limitations of today’s electronic health record (EHR) systems. The Centers for Medicare and Medicaid Services (CMS) will pay physicians roughly $40 per patient per month to provide enhanced care management and care coordination to fee-for-service Medicare beneficiaries with two or more chronic conditions. Patient-centered medical homes (PCMHs) are in a good position to take advantage of this offer, experts say, because they have already changed their workflows to improve care coordination.

However, practices must use certified EHRs to bill the CCM code (CPT code 99490) and the latest systems include features that can support chronic care management. But EHRs are not designed for non-visit care or for collaboration among providers caring for the same patient. Moreover, they lack the data analysis and automation functions that practices need to deliver chronic disease care efficiently.

So even if your practice is PCMH-recognized by the National Committee on Quality Assurance (NCQA), you’ll probably need to do some EHR workarounds and customization, and you may require some additional software to bill CCM. If your practice has not achieved
Ivermectin: A New Player in the Rosacea Game

By Scott Kober, MBA, CCMEP

In the most recent issue of this publication, we provided an overview of current classifications and grading systems that define rosacea, along with information on traditional therapeutic approaches for the management of inflammatory papules and pustules. In this issue, we’ll focus on ivermectin 1%, the newest addition to the rosacea armamentarium, by reviewing its mechanism of action and exploring data that supported its recent approval by the FDA for the once-daily topical treatment of inflammatory lesions, or bumps and pimples associated with rosacea.

Mechanism of action

Ivermectin has been reported to have both anti-inflammatory and antiparasitic activities. It has been used orally as an antiparasitic for more than 25 years to treat conditions such as onchocerciasis, pediculosis, and scabies. A topical formulation is also FDA-approved to treat head lice.

Ivermectin’s antiparasitic effects in rosacea are thought to be associated with its ability to decrease the density of mites called Demodex folliculorum. Although the exact cause of rosacea remains unclear, one emerging theory concerns the impact of Demodex mites on the exacerbation of the condition.1 In clinical trials, Demodex density has been shown to be 5.7 times higher in the skin of patients with rosacea compared to healthy controls.2 Approximately 35% to 50% of patients with rosacea have an increased load of Demodex.2

Oral ivermectin has been shown to reduce the number of Demodex mites in patients with blepharitis and demodicidosis. It is postulated that topical ivermectin is efficacious in reducing the inflammatory response in patients with rosacea in part due to its ability to directly eliminate these Demodex mites. This hypothesis, however, needs to be studied further in clinical trials.

Ivermectin has also been shown to have anti-inflammatory effects due to its ability to inhibit lipopolysaccharide-induced production of inflammatory cytokines, including tumor necrosis factor (TNF)-α and interleukin (IL)-1β, while upregulating the anti-inflammatory cytokine IL-10 (see Figure 1 for visual representation of this process). It is important to note that ivermectin’s exact mechanism of action in the treatment of rosacea is still unclear. Figure 2 includes information on readers’ overall familiarity with ivermectin’s primary effects in rosacea.4

Efficacy data

As noted in the initial article in this 2-part series, agents currently utilized to control the proliferation of inflammatory papules and pustules in patients with rosacea include topical metronidazole (twice-daily 0.75% gel, cream, or lotion), azelaic acid (AZA) twice-daily 15% gel, and modified-release doxycycline 40 mg once daily.5,6 Although each of these agents has demonstrated efficacy in patients with rosacea, patients can expect only partial clearance without proven duration of remission. For many patients with rosacea, 50% or even 75% improvement isn’t good enough—to be able to truly overcome the emotional and psychological toll of rosacea, they want to be completely clear of inflammatory lesions.

Three phase 3 clinical trials were conducted to compare the safety and efficacy of ivermectin 1% against the approved topical agents, AZA 15% gel and metronidazole.7,8

In the initial 12-week components of these studies, 38.4% and 40.1% of patients treated with ivermectin were deemed “clear” or “almost clear” according to Investigator’s Global Assessment compared to 11.6% and 18.8% in the vehicle arms (P<.001 in both studies).7 In the 40-week extension trials, 71.1% and 76.0% of patients treated with ivermectin were deemed “clear” or “almost clear” at the end of 1 year.8

Only 59.4% and 57.9% of patients treated with AZA met these criteria, although direct comparisons between the 2 groups cannot be made because patients in the control arm received 12 fewer weeks of active AZA treatment.8

It is also important to note that approximately 11% of patients in the ivermectin arm of these studies saw resolution or near resolution of their papules and pustules at week 4.7

The third phase 3 trial compared once-daily ivermectin to twice-daily metronidazole 0.75% cream. Patients in this trial completed 16 weeks of treatment. (Data from a 36-week extension trial have not yet been published.) At 16 weeks, 84.9% of patients in the ivermectin group were deemed “clear” or “almost clear” versus 75.4% in the metronidazole group (P<.001). Patients with severe rosacea at baseline saw nearly...
Ivermectin: A New Player in the Rosacea Game

The therapeutic effect of topical ivermectin is thought to be tied to:

- Dermatology Times
- Contemporary OB/GYN
- Medical Economics
- Drug Topics

Figure 2: In a recent multidisciplinary Pulse Poll survey of readers, only Dermatology Times readers were mostly able to correctly identify that ivermectin is effective in rosacea largely due to its anti-inflammatory effects.

Published as a promotional supplement to Medical Economics | © 2015 March/2015

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Equivalent levels of improvement as patients with moderate rosacea.

Safety data
Tolerability is of critical importance in any topical treatment of rosacea. In fact, in the phase 3 trial that compared ivermectin to a vehicle cream derived from Cetaphil, there were fewer local side effects in the ivermectin than vehicle arm (4.2% vs. 7.2%).

In all 3 of the phase 3 trials, less than 2% of all patients experienced a dermatologic adverse event related to ivermectin, whereas approximately 10% to 15% of patients reported local intolerance, including stinging/burning, dryness, and itching. Rates of local intolerance for the comparator agents (AZA or metronidazole) were slightly higher in each of the studies.

Combination therapy
Although ivermectin has demonstrated efficacy in reducing papules and pustules associated with rosacea, it has limited, if any, effect on background erythema. Although it has not been studied in clinical trials in combination with an alpha agonist such as brimonidine, this may be an approach to consider.

Combination therapy in patients with papulopustular rosacea that includes both a topical agent (metronidazole or AZA) along with doxycycline is often a popular approach. Although this again may be a consideration, there are no published data involving ivermectin to support such a regimen.

Drug holidays in rosacea
Rosacea is a lifelong condition, with an often unpredictable course. For many patients, continuous treatment is necessary. There are many patients whose condition clears up in the short term, but who then stop taking their prescribed topical or systemic therapy only to return to their previous baseline a few weeks later.

It is important from a quality-of-life standpoint to continue exploring options for drug-free holidays. A handful of recent studies have looked either at tapering or at discontinuing therapy after initial resolution of papulopustular rosacea.

One study explored a strategy of tapering from a combination of twice-daily AZA and doxycycline to once-daily AZA alone in patients who achieved ≥75% inflammatory lesion count reduction after 12 weeks on the twice-daily regimen. After 6 months of this maintenance regimen, 75% of patients remained in remission. (Loss of remission was defined as either 50% deterioration in the lesion count improvement from the initial phase of the study, increase in erythema intolerable to the subject, or maintenance therapy failure as judged by the investigator and/or the subject.)

The phase 3 ivermectin study detailed earlier in this article that compared a 16-week regimen of ivermectin to metronidazole looked at a more rigid cutoff. In that study, patients who were deemed “clear” or “almost clear” stopped treatment entirely after 16 weeks. The study’s primary endpoint is time to relapse after treatment cutoff. Data from this trial are expected to be presented later in 2015.

Conclusion
Once-daily ivermectin 1% provides clinicians with new opportunities to successfully improve the overall appearance and quality of life for patients with inflammatory papules and pustules associated with rosacea. Its overall efficacy, safety, and once-daily dosing offer significant improvements over currently available options that should be attractive to patients with rosacea.

References
Chronic care management

medical home recognition, you’ll face the same technical problems and will have to re-engineer your work processes to take advantage of the code. Only you and your colleagues can decide if doing so is worthwhile.

CCM BASICS

CMS will pay eligible providers—who include primary care physicians, some specialists, nurse practitioners and physician assistants—an average of $41.92 per month for each eligible patient for whom they provide the required services. But 20% of that is a copayment that practices must collect from patients.

To be eligible for CCM billing, a patient must have multiple chronic conditions expected to last for at least 12 months. Physicians and other providers must obtain written consent from the patient to be his or her CCM provider, including authorization for sharing data with other providers. Only one eligible provider can bill CMS for CCM services provided to an individual patient in any given month.

Any certified healthcare professional can provide CCM services, and services are expected to be provided by teams. Direct physician supervision of clinicians is not needed for this program.

The required CCM services include non-face-to-face care management and care coordination with other providers. Care teams must spend a total of at least 20 minutes per patient per month on these activities, and each team member must document what they did and for how long.

Specifically, practices must provide:

- continuity of care with a particular provider or care team member,
- enhanced ability for patients and caregivers to communicate with providers,
- 24/7 access to care management services
- care management that includes an assessment of the patient’s medical, functional, and psychosocial needs; preventive care, medication reconciliation, and oversight of the patient’s medication self-management,
- a comprehensive, patient-centered care plan,
- electronic capture and sharing of care plan information, and
- management of care transitions, including referrals and follow-up after hospital discharges and ER visits.

CARE PLANS

The comprehensive care plan for CCM must include an assessment of the physical, mental, cognitive, psychosocial, functional and environmental needs of the patient. It must contain a record of preventive care services, medication reconciliation, a review of adherence and potential drug interactions, and oversight of patient self-management of medications. In addition, it must list the clinicians and the community resources involved in the patient’s care and explain how the care will be coordinated.

The care plan must be available at all times to care team members and to treating providers in other practices.

EHRs aren’t designed to create this kind of care plan, but the templates in their assessment and plan section can be modified to accommodate CMS’ requirements. If your practice doesn’t have the technical expertise needed to do this, you can create a form outside of the EHR or use one provided by the American Academy of Family Physicians (AAFP), which can be accessed by AAFP members. The American College of Physicians also has a CCM tool kit that provides resources for physicians. But you must store the care plan in the EHR to share it among your care team members.

Sharing the plan with outside providers is going to be a bigger challenge. Practices will have to cope with the same lack of interoperability that impedes the exchange of care summaries for Meaningful Use. Direct messaging is fine where it’s available; but many providers don’t yet accept Direct, so the care plans may have to be faxed.

Edward Gold, MD, an internist with a 59-physician group based in Emerson, New Jersey, said his group is modifying its EHR to create CCM care plans. As part of the practice’s preparation to become a NCQA-recognized level 3 PCMH, he adds, it built additional care plan templates for such things as patients’ compliance and understanding of their conditions, he said.

As for sharing the care plan with specialists, he’ll include it in the visit notes he sends as part of referrals.

DOCUMENTING NON-VISIT CARE

Of course, that isn’t the same as having a care plan that’s available to all providers at all times. The idea of a longitudinal care plan that goes across care settings is still more of
How to implement chronic care management (CCM) codes

1. Identify patients

Physicians can bill for CCM codes for Medicare patients diagnosed with two or more chronic conditions that will last at least a year. The first step, then, is to identify the patients in your practice who qualify. This can be done by searching your EHR records.

2. Invite patients to participate

Physicians must obtain an eligible patient’s written consent to participate in CCM, along with authorization to share the patient’s records electronically with other providers. The physician should explain how the program works, the patient’s obligations for payment and how to terminate the arrangement.

3. Build a care plan

A care plan must be created for each patient that includes an assessment of the patient’s medical, functional and psychosocial needs, consistent with the patient’s choices and values.

4. Document

All of the above information, from patient consent through the care plan, must be documented in the patient’s electronic health record. When in doubt, document it.

5. Termination considerations

Patients can only participate in CCM with one primary care provider, and they can opt out at any time. Physicians must document patients who cancel CCM services.

a vision than a reality, noted a recent study in the *Journal of the American Medical Informatics Association*. In fact, EHRs have only a limited ability to support the work of care teams within practices, another study found.

EHRs replicate the visit-oriented model of paper records, in which a provider has to document everything that can be used to justify billing, points out Steve Waldren, MD, director of the AAFP’s Alliance for eHealth Innovation. The EHR vendors did not build the systems to document care team activities, he notes. “They were building it for a single physician to do everything.”

That makes it problematic to document the care coordination and non-visit care required by CCM.

“Most of that is being done in the messaging section of these EHRs taking the telephone message, which is a non-visit encounter, and letting the docs enter the information in a particular area,” Waldren points out. “It’s mostly how you document it from a medico-legal standpoint, not how do you support and facilitate that type of collaboration [among care team members].”

Internist Kenneth Kubitschek, MD, belongs to a nine-doctor group in Asheville, N.C. that encourages non-visit encounters with patients, both as a recognized PCMH and as part of its use of Medicare’s Transitional Care Management (TCM) billing codes.

In most cases, he says, these non-visit encounters are documented as free text messages. However, the EHR allows the practice to keep care management messages separate from other phone or email messages.

Gold’s group also uses the messaging function of its EHR to document and respond to non-visit care. The practice is already using care coordinators hired by the accountable care organization (ACO) it belongs to. When one of these nurses needs to alert a physician about something concerning a patient, says Gold, she sends a “task” to the doctor in the EHR’s messaging system, and the physician has to respond to the care coordinator and/or take some other action.

After the practice begins providing care billed under the CCM code, these care “navigators” also will document their activities in the EHR, he notes.

TRANSITIONS OF CARE

Given the fragmentation of healthcare, the CCM criteria for transitions of care are among the hardest to meet. Your EHR might be able to help you here, but it depends on what kind of EHR you have.

Referral modules, for example, can list the referrals that were sent out, but they can’t tell you whether the patient made an appointment with the specialist, notes Margalit Gur-Arie, a founder and health IT consultant with BizMed Solutions. “The best referral modules will list referrals, when they were sent out,
and a time period in which you expect the visit to the specialist to be made,” she says. “If you don’t get anything back in that time, it pings someone on the staff, who can call the specialist to find out what happened. But it’s still a largely manual process.”

Gold’s practice gets information on hospital admissions, discharges and transfers and emergency department visits from the ACO, which has a connection with its main hospital’s admission, discharge and transfer (ADT) system. When one of Gold’s patients is admitted or discharged, an ACO care coordinator sends him a message about that event in the “tasks” section of his EHR.

This direct link to a hospital ADT system is unusual. But Kubitschek’s group has worked out its own arrangement with its hospital, which notifies the practice of admissions and discharges via fax.

To meet the TCM requirements, the practice has its nurses call the patients to make office appointments within 48 hours after their discharge. They use a customized EHR template to document their interactions.

Some nursing homes are better than others about communicating with patients’ primary care physicians, Kubitschek says. Getting information from these facilities and from home health providers is more about relationships than about technology at this point, because few post-acute-care providers are online with ambulatory care clinics.

TIMEKEEPING

EHRs are not designed to track the time that providers or other care team members spend on particular tasks. While people can free-text that information when they document a non-visit encounter, for example, there is no way to locate the various amounts of time recorded so that a practice can determine whether they add up to 20 minutes of CCM activity, notes Gur-Arie.

One solution to this problem, she suggests, is to develop a spreadsheet that shows a list of CCM patients, what was done for each patient, and how long it took. The AAFP provides a free Excel spreadsheet for this purpose.

Spreadsheets make sense for documenting time, says Mark Anderson, a health IT consultant in Montgomery, Texas. The drawback is that the spreadsheet won’t be integrated with the EHR, which means it requires manual data entry. And, unlike sophisticated registry programs, spreadsheets can’t be used for care management, he says.

Practices can also adapt time management software of the kind used by attorneys and consultants, notes Gur-Arie. This can’t be integrated with EHRs, either, but at least it’s designed for recording the time spent on tasks.

CARE COORDINATION SOFTWARE

In the context of meeting CCM billing requirements, Waldren says, the biggest drawback of EHRs is their lack of robust registries that can be used to manage population health within the clinical workflow.

Registries, which show problems, lab results, and when patients last received recommended services, are used for everything from stratifying patients by their health risks to identifying care gaps to helping care managers prioritize their case loads. They can be used to support chronically ill patients between visits and to ensure these patients receive the services they need.

Because EHRs are deficient in this area, many groups have purchased outside population health management software. This kind of software, which can interface with EHRs, typically includes a registry and a range of applications designed for such functions as point-of-care reminders, patient outreach and education, and care management of high-risk patients.

All of this would seem tailor-made for
CCM, except for one thing: It’s too expensive for most small practices. A 40-doctor group for whom Anderson consults paid between $75,000 and $100,000 to install population health management software and “pull the data together,” he points out. No practice of fewer than 20 doctors, in his opinion, could afford this type of IT solution.

Gold says that not even his fairly large group can afford population health management software on its own. Its ACO spent approximately $1 million to buy and implement such a solution on a large scale, he points out. The organization is now considering whether to offer its analytic services to non-member practices for a fee.

Kubitschek, too, knows that his practice can’t justify purchasing this kind of system. In fact, the group’s physicians doubt that it makes financial sense to hire a full-time care coordinator so that they can pursue CCM. They’re waiting to see what a brand-new ACO that the group belongs to might be able to offer its members, he says. For now, the group has not decided to take on CCM.

CONCLUSION
Observers are divided on how advanced or how large a practice must be to take advantage of CCM. Gur-Arie maintains that nearly any level 3 PCMH could take it on with a little guts and ingenuity. Anderson believes CCM is suitable only for groups of 20 or more physicians, although some smaller PCMHs might consider tackling it.

Waldren points out that PCMHs already are doing most of what CCM requires. And many practices that haven’t gone the medical home route have at least implemented an EHR and met the Meaningful Use criteria.

“Maybe now they can use the CCM program to get further into population health management and care management and move toward becoming a medical home,” he says.

Has your practice or healthcare organization found an intuitive way to perform CCM services using your EHR?

Tell us at: medec@advanstar.com.

**EHRs and chronic care management**

**QUESTIONS TO ASK YOUR VENDOR**

Most electronic health record (EHR) systems will not support the requirements of the new chronic care management CPT code without modifications or additions to the basic system. So before you start billing for chronic care management services here are 5 important questions to ask your EHR vendor:

- **Q**: Is the EHR system certified to 2011 or later standards (a requirement for billing the code)?

- **Q**: Does the EHR support documentation of team care and/or care outside of an office visit? If not, what add-ons and modifications would be needed, and how much would they cost?

- **Q**: Does the EHR include a referral module, and if so, what elements are included in it (date referral was made, alert when report comes from the specialist, etc.)? If not, how much would it cost to add a referral module?

- **Q**: Does the EHR enable providers to document the time spent on each patient encounter and track that time on a monthly basis?

- **Q**: Does the EHR system include capabilities for developing and a plan of care for patients with chronic diseases or conditions, and sharing the plan with other providers and the patient? If not, what add-ons or modifications would be needed, and how much would they cost?
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Mining EHR data for quality improvement

How physicians can provide better care and adhere to quality metrics, and why its important to start now

by KEN TERRY Contributing editor

M any physicians doubt that electronic health records (EHRs) improve the quality of care. But relatively few practices are mining their EHR data to see how well they’re doing or to update their care delivery processes. Most are collecting data mainly for external reporting purposes, usually with the help of automated EHR features.

According to a recent study in Health Affairs, between 2007 and 2013 the percentage of large practices that collected data on quality measures nearly doubled; that activity increased even more in small and medium-sized practices between 2009 and 2013. But the use of electronic registries to identify patient care gaps and the feedback of performance data to physicians remained confined to a small percentage of practices.

There are several possible reasons for the low interest in mining data for quality improvement. Most physicians believe they’re already doing a good job, and they may feel they’re too busy to devote time to running reports and looking at data. Especially if they’re working in small practices, they may feel intimidated by the technical requirements of data mining. It’s also difficult for providers to enter data consistently in the right EHR fields so that they have enough data to yield solid information on individual patients or populations.

With the growing use of value-based reimbursement, however, practices find themselves under increased pressure to prove that they are providing high-quality care to patients. At the same time, payers’ are emphasizing population health management, which requires practices to identify care gaps and reach out to those who need care, regardless of whether they’ve been seen recently.

Experts and doctors interviewed by Medical Economics say data mining is vital to helping practices meet those objectives. Each practice must find an approach that fits its needs and goals; but whatever that is, the sooner you get started, the better off you’ll be in the long run.

DATA MINING OPTIONS

Health IT experts advise practices to take a close look at their EHR’s capabilities before thinking about using outside solutions or outsourcing. In many products, these capabilities include health maintenance alerts and report writers.

Health maintenance alerts, which are reminders about preventive or
chronic care services that are recommended for a particular patient, pop up whenever an electronic chart is opened. While their use may not be considered data mining, when you create a new health maintenance alert, you are, in effect, mining your EHR data for a purpose.

It’s difficult to program new health maintenance alerts in most EHRs, says Ernie Hood, senior director, research and insights, for the Advisory Board Co. But Jen Brull, MD, says that her nine-provider family practice in Plainville, Kansas, customized several alerts without any trouble. The real problem with prompts, she says, is that they can be overwhelming. “If you turn on everything all at once, you don’t pay attention to anything.”

Another method of data mining is to run the reports available in the EHR or to write the reports you want and then run them. This is an area where EHRs differ widely. Brull, for example, says that her EHR includes prebuilt reports for all of the quality measures in the Meaningful Use incentive program and the Physician Quality Reporting System (PQRS). However, her practice cannot modify these reports because they’re written to meet EHR certification requirements. To produce custom reports, the practice’s IT staff developed a special web-based application that queries the EHR database.

In contrast, Michelle Holmes, MBA, a Seattle-based principal with ECG Management Consultants, says the problem with many EHRs is that they don’t offer enough prebuilt reports. Instead, they supply a “sandbox” and a variety of tools that practitioners can use to write their own reports.

“They provide a blank slate where you can identify the criteria or parameters of the report; you can identify the frequency with which you want to run the report, identify the target population, and so on,” she says. The vendors do this, she notes, so everyone can create the reports they want. “But there’s still a lot of setup that you have to do, and many people never get to it. So even though a lot of EHRs offer this functionality, it’s underutilized.”

Rosemarie Nelson, a Syracuse, New York-based consultant with the Medical Group Management Association (MGMA), agrees that EHR report writers are underutilized. Noting that some of these applications are not hard to use, she suggests that practices ask their vendors for advice setting up the reporting modules. They can also attend user group meetings or webinars. A report that shows how many and which diabetic patients in the practice are overdue for an HbA1c test, she says, can be written by a nontechnical person with the right training.

**DRAWBACKS OF EHR REPORTS**

If your EHR provides prebuilt reports related to Meaningful Use and/or PQRS measures, they might be programmed for a particular reporting period. When you run those reports, they will omit data on patients who have not sought care or have missed appointments during that period. You can lengthen the period for which the report searches the EHR database to a year or two, Brull notes. But some patients on your panel will still be left out—a significant challenge if you’re trying to manage the health of your entire patient population.

Another problem is that someone has to run EHR reports—whether prebuilt or customized—to extract the latest data from them. They’re not running in the background and updated every time you see a patient or want to see how you’re doing on a particular quality measure. Consequently, they’re not integrated into the workflow at the point of care, notes Bruce Bagley, MD, president and CEO of TransforMED, the patient-centered medical home subsidiary of the American Academy of Family Physicians (AAFP). He sees this as a serious deficiency of EHR-based reports, because the reports can’t be used to inform medical decisions.

The current way of gathering information for medical decision-making, he says, is to scroll through the chart until you have what you need. “The new way would be to have it all presented on a single screen that shows you the care gaps you can focus on. That can make the visit more efficient and effective.”

**STANDALONE REGISTRIES**

Third party registry software interfaced with EHRs can provide automated reports that are available to physicians when they’re providing of patients. In addition, a good registry can give you up-to-date information on all of your patients, whether or not you’ve seen them recently. And in some cases, this software can connect with your patient portal or an automated messaging application, allowing your practice to automatically reach out to patients who have care gaps.
The purpose of registries, Bagley explains, is to manage chronic and preventive care and keep track of high-risk patients. The more sophisticated registries are designed to:

- provide lists of subpopulations, such as patients with hypertension and diabetes,
- identify patients with care gaps, based on evidence-based guidelines,
- support outreach to patients who have care gaps,
- provide feedback on how each physician is doing on particular types of care, such as the percentage of their diabetic patients who have their HbA1c levels or blood pressure under control, and
- generate quality reports for the practice.

Brull's practice uses outside registry software with its EHR. The program includes a dashboard that she looks at when she sees patients. This dashboard shows data from six chronic care suites and 11 preventive care suites that are applied to each patient for whom they are appropriate. For example, if a patient is a female over 50 with diabetes, she should have colon cancer screening and mammography, and everything in the diabetes suite applies to her. The registry generates a sheet that tells Brull whether she is meeting the goals for that patient's care.

REGISTRIES IN ACTION

Brull and her colleagues look at the registry data for the whole group once a quarter and use it to design quality improvement initiatives. Recently, they examined their data on patients with hypertension and metabolic syndrome. After comparing the data with past information on these patients, they decided to focus on patients who had hypertension and moderate renal insufficiency and were not taking an ACE inhibitor. Lists of patients in that category were provided to physicians, who could decide if this medication was appropriate.

Yul Ejnes, MD, MACP, a former American College of Physicians board chairman who practices in an 80-provider medical group in Providence, Rhode Island, says his practice uses third-party software attached to its EHR. The group has an IT department that mines and analyzes the data and sends reports on patient care gaps to physicians.

While Ejnes finds this information helpful, he notes that he receives the reports only once a month or quarterly, depending on their areas of focus. That can make them less useful when he sees patients toward the end of a reporting period. But the data is far more timely than health plan claims data.

The group also uses the registry software to generate performance reports that compare Ejnes and his colleagues to each other. If the group reports the data to a health plan, they may also be compared with providers in other groups that contract with the same plan. In cases where the contract involves pay for performance, this exercise can be economically worthwhile, he notes.

HIGH COST FOR SMALL PRACTICES

Experts agree that sophisticated registry software can be cost-prohibitive, especially for smaller practices. An insurance company paid for the application that Brull's group uses as part of a statewide patient-centered medical home program. Otherwise, it would have cost her practice a lot, she says. But she adds that it's so valuable to the group that they probably would have bought it anyway.

Very basic registry applications, which are available online, can be fairly inexpensive and easy to implement, says Holmes. But Hood notes that these programs require some technical expertise to generate useful reports. The less costly the tool, the more technical knowledge needed to make it work.

Small practices can consider outsourcing data mining and analysis to their EHR vendor or one of its technology partners. Some vendors, such as Epic, Cerner, Meditech, and athenahealth, are incorporating analytics into their EHRs and will do the work for you in the cloud, Hood says.

Nelson says this can be affordable for practices of any size, depending on the cost-benefit ratio. If a group considers buying a less costly product, its leaders should ask themselves whether the practice has the technical expertise to build it out. “You’re going to pay one way or the other,” she says.

You should also look at how data mining fits into your business plan. If you're creating a patient-centered medical home or are participating in an accountable care organization, it might make sense to invest in registry software or outsourcing, because you have financial incentives that could recoup your investment in time. Bagley believes that the use of registries...
to collect and analyze data can help practices reap care management fees and other incentives. Even a simple do-it-yourself registry based on a spreadsheet can spur a practice “to build the workflows that are required to ensure that data is used at the point of care. Eventually, you’ll have it integrated into the EHR. But you’ll have the workflow in place already.”

**GETTING THE DATA YOU NEED**

Regardless of whether you rely on your EHR report module or outside resources, you need good data to obtain actionable results. This is a big challenge for most practices.

To start with, lab results may not be available in structured form, depending on whether the EHR interfaces with a particular lab. Ejnes’ practice, for example, doesn’t have interfaces with all of the labs it uses, so employees must enter some faxed lab results manually into the EHR.

Ejnes also underlines the problem of getting all of the group’s physicians and nurse practitioners to enter data in structured fields, rather than as free text. The group has medical assistants inputting some of this data. “There’s a lot of front-end work involved in getting data in there so miners have something to mine,” he says.

Even when providers enter the data in structured fields, Ejnes notes, the EHR allows them to put it in any of several places—a feature that many vendors have built into their products, says Nelson. “They design it for maximum flexibility, but all that flexibility can create havoc.”

Nelson says the solution is to train staff members to enter data in agreed-upon fields. But that’s difficult if a practice tackles 15 or 20 quality improvement areas all at once. Holmes suggests focusing on just one area, such as breast cancer screening. This ensures the organization receives accurate data to change provider and patient behavior.

**UNCOVER YOUR EHR’S LIMITATIONS**

10 questions for your vendor

**Q:** Does the EHR have a built-in patient registry that I can use for quality measure reporting?

**Q:** Is the registry standard or is there an extra fee for the feature?

**Q:** Does the system give me a way to measure my performance on quality measures?

**Q:** Can I create customized reports or am I limited to reports provided off the shelf?

**Q:** Can I query the EHR to identify certain patients, such as those with a particular condition or who use certain medication?

**Q:** Will my staff be able to generate queries to identify patient cohorts with certain conditions and/or risk factors?

**Q:** Does the system flag overdue health maintenance items?

**Q:** Does the EHR come with preconfigured health maintenance alerts?

**Q:** Can the EHR system automatically generate reminders for follow-up based on specified criteria?

**Q:** Does the EHR notify me of abnormal lab results when they are received?

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The electronic health record (EHR) continues to be a tool for both evil and good. One of my roles in my healthcare organization is helping fellow physicians with workflow and efficiency. Observing other physicians' struggles and having challenges of my own with the EHR compels me to consider ways to incorporate the computer into the patient-physician encounter in a manner that supports rather than detracts from the work that I love to do.

**THE FOLLOWING** strategies and considerations can help any physician better navigate the use of EHRs for patient care and efficiency.

**Beware the illusion of anonymity**

We’ve all made the fatal error of sending a poorly-worded, emotionally-laced email. It’s a terrible feeling but the behavior is so quick and easy to replicate. The EHR offers the same illusion of protected communication. But be cautious with how you word communications to your nursing staff or what you choose to immortalize forever in an electronic record.

While many of us are careful with the office visit notes we write or dictate, we may be less careful in how we word comments in the patient’s chart or in electronic communication with our staff members.

**Educate your staff**

One of the best things I ever did was take ten minutes and educate my medical assistant about the new cervical cancer screening guidelines. Armed with the information and my preferences, she is now able to determine if a patient needs a pap smear 90% percent of the time. This allows her to educate my patient before I enter the room and to enter the correct orders electronically for me.

The more you can share with your medical assistant or nursing staff about your preferences and processes, the more they can do to help you with the growing pile of electronic work.

**Find opportunities to standardize**

Do you tell your patients with bronchitis or low back pain or toenail fungus the same thing every time? If you have (as most of us do) patient information that you use routinely, standardize that by using the tools available in your EHR to build custom text.

Look for these opportunities wherever you can find them. It will improve your documentation because the information will be complete and well thought out. It will also save time because you will be able to short-cut the typing. Any time you can do a better job in less time is a win.

**One-piece flow**

Our organization models lean manufacturing principles. Therefore, one piece flow figures high on our list of model behaviors.

Like many physicians, I tend to batch work. I look at all my results over lunch or finish up all my charts at the end of the day. This is a definite no-no in the manufacturing world and, for the sake of safety, quality, and sanity, should become a no-no in medicine as well. This is a definite no-no in the manufacturing world and, for the sake of safety, quality, and sanity, should become a no-no in medicine as well. Think about how hard it is to remember which of your six patients with pharyngitis had tonsillar exudate at the end of the day or which of your patient’s ears was infected.

Attending a recent professional practice seminar, I vowed to incorporate one piece flow into my clinic day. This
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WHEN YOU SEE THE RESULT, ADDRESS IT AND FINISH IT.

Rule of 3s
Despite my admonition to avoid batching work, inevitably it will happen. So when work does pile up, think of the rule of threes. It is daunting to sort through 50 results, but you could sort through three. Do the work in little chunks throughout your day and the job becomes more manageable.

Set small goals
Sometimes I run into the note that I really don’t want to finish. Usually it involves a complex patient with multiple social and medical issues that ran over by a good 20 minutes. Sometimes I haven’t been able to type anything in the exam room because my attention needed to be fully on the patient for the entire visit. Trying to reconstruct a complicated 45-minute office visit in your notes can be painful. This might be a situation you need to break into chunks and tackle just one part of the note throughout the day. Avoid the temptation to put this off because the task will become more onerous as the day (or days) pass.

Touch it once
If you’re like me, you probably look at certain lab results and can instantly and easily address them with a couple of clicks. Other lab results require you to review the chart, calculate the 10 year cardiovascular risk score, or consult a reference.

While our natural inclination is to put aside the more complicated work, don’t do it. When you see the result, address it and finish it. Otherwise it will take up electronic space, space in your brain, and will probably be a result (or refill request or patient call) that you click on repeatedly, waiting hours or days to finally reach a conclusion.

Use your own templates
Previously I used the standard templates provided by our organization, especially for acute complaints. This gave the illusion of efficiency, except that I didn’t necessarily conduct my visit according to the template, nor did I ask all of the same questions. This translated into formulaic notes that failed to convey the story of the patient and which required a lot of editing.

So, I moved to my own templates and narrowed it down significantly.

Jennifer Frank, MD, is a family physician practicing in Neenah, Wisconsin. Send your practice management questions to medec@advanstar.com.
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Understanding risk-based payer contracts

An exploration of emerging payment models for patient-centered medical homes, accountable care organizations, and episode-based care

by ALICE G. GOSFIELD, JD  Contributing author

Physicians across the country are witnessing the advent of new payment models such as patient-centered medical homes, bundled payments, accountable care organizations, and other risk models. What do physicians need to know to incorporate—and succeed with—these payment models?

In the mid-late 1990s, and even into the early 2000s, the physician-targeted literature was replete with articles about how to evaluate a managed care contract offered by a payer, typically a health maintenance organization (HMO) or a preferred provider organization (PPO). Most of these contracts are very similar and contain provisions that establish the services the physician is contracting to provide, the payment rates (capitation or fee-for-service), not charging for covered services and required in-network referrals. In fact, many physicians’ current contracts have not been significantly updated in some years.

Unless a physician is part of a large group, in today’s world there is very little negotiation with the payer. The rates are the rates. The
appeals mechanisms are established. There are some variations in termination clauses – e.g. none allowed for the physician until the initial term has expired and thereafter on 60 days notice, or only 60 days before the renewal term.

Requirements to comply with medical management programs (e.g., utilization review, prior authorizations, quality measurement programs) and patient grievance processes are similar, although the content of the programs may vary.

From the beginning of the heyday of managed care contracting, physicians had complaints about how health plans interacted with them. In the late 1990s many states enacted laws to control some of the more egregious plan practices, including establishing prompt pay requirements and banishing gag clauses that restricted how physicians could describe treatment options to their patients. These requirements now are reflected in many health plan contracts.

Similarly, class action litigation around the country has changed certain aspects of how health plans manage data over the course of the participation agreement, how they narrow their networks and based on what data. Against this evolution of health plan contracting, we see now the advent of new payment models such as patient-centered medical homes, bundled payments, accountable care organizations, and other risk models. Because they are new, they may be part of a pilot project, with some evaluation of results later.

In virtually every instance these new payments, if addressed contractually at all, are set forth in amendments to the basic physician or group participation agreement. But these amendments bear special scrutiny as well.

1/ PCMH payment
Here, the plan typically requires some form of recognition by the National Committee for Quality Assurance of which there are three levels. Some plans only pay for Level 3 practices. Others tier the enhancement for all 3 levels.

The typical payment is an enhanced capitation rate to recognize the increased care

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coordination activities and infrastructure necessary to deliver what the PCMH standards require. Leading primary care physician societies have called for a three-part payment model to include a monthly care coordination fee, an enhanced visit fee and a performance bonus based on achieving quality targets. But most plans do not take such an approach. Some merely make payment if the NCQA recognition is met.

If there is an amendment to the physician participation agreement, in many instances it states a term—typically a year, but sometimes longer—and when payment will be made (e.g., for the succeeding month or for the preceding month).

If additional bonus payments are available for meeting targets, the amendment also addresses what those targets are, and when they are measured and paid.

Because these are amendments to the basic participation agreement, however, an issue that frequently gets overlooked is how the practice can challenge the data on which the payment determinations are made. The basic agreement sets forth the typical appeal process for denial of claims or termination from the plan.

But whether an opportunity to challenge data is available, and then in what forum or to what body, is rarely addressed, but should be.

2/ **Bundled payment**

Most bundled payment programs are modeled on a gainsharing basis so that physicians are paid in the ordinary course of business and then, depending on the savings achieved against the specific case rate for the targeted condition, a predetermined portion from a pool of dollars (e.g., 50% of net savings) is also paid.

The most critical issue is whether one party (a hospital, network or physician group) will hold the money for others. If that is the case, then there will be an amendment to that entity’s payer contract.

If, instead, the program uses a bundled budget, but can pay separately, as in "PRO-METHEUS Payment," then each participating provider will have an amendment. The amendment typically addresses when gainsharing reconciliation.

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**4 ingredients of successful payment models**

There are four aspects any payment model must have to successfully provide physicians with enough income and improve patient outcomes through accountability and quality measures.

1. **Flexibility**
   - In many of today’s payment models, physicians don’t have the flexibility to adapt their practice in ways that match what the payer requires in terms of outcomes and cost savings. Giving physicians the flexibility to build a program that makes economic and clinical sense is key.

2. **Accountability**
   - Holding physicians accountable is the flip side of flexibility. If physicians are going to have leeway to adapt their methods to achieve outcomes, then they must be judged on whether their methods are effective.

3. **Adequacy**
   - Physicians must be paid enough to achieve the outcomes that the health plan seeks.

4. **Adjustment**
   - Payments must be adjustable to reflect the real differences in patient needs. Sicker patients require more resources, and physicians should not be put at risk financially for treating sicker patients.

Source: Harold D. Miller, executive director, Center for Healthcare Quality and Payment Reform
ension occurs, using what data, and when payments take place. If administrative costs are deducted from the savings pool before allocation to the providers, clear definitions of those costs can be important.

Some bundled payment models merely offer shared savings over a predetermined amount, such as total payments for cardiac services in the previous year, without using episode or case rates. While amendments are also necessary for using this approach, the contractual issues are simpler than where episode payments are used.

The most critical issues in episode or case rate amendments are clarity on what triggers the episode, how long the episode lasts, what ‘breaks’ the episode (e.g., the patient develops comorbidities which overtake the primary reason for the original bundle) and when the episode expires. Definitive statements as to the data on which these judgments are made is also important.

In addition, however, because these agreements, unlike PCMH amendments, are often negotiated, it is important to look at the basic provider participation agreement and ensure that the typical utilization management, prior authorization, and post payment review processes don’t get in the way of the new approach. Those issues that are subject to appeal (e.g., anything that turns on the application of data to payment decisions) and those which are not (e.g., the budget in the episode, when an episode is triggered or terminated) should be addressed.

Again, a different appeals process may be necessary since the issues under these agreements are quite different from the medical necessity or absence of prior authorization issues that are addressed in the typical provider participation agreement.

In cases where the bundled payment is made to an entity other than the physician group, then the contract that is the basis for the payment will be with another provider (e.g., a hospital or health system), or a network which contracts for payment.

Any bundled payment that is not made to the physician group has all the contracting issues that arise in an ACO.

3/ ACOs

Most ACOs have formed networks that accept bundled payments or the hospital is the lead contracting entity. In some of the Medicare shared savings ACOs, physician organizations will receive the payments. Almost all ACOs, even those devoted to a single service line (e.g., orthopedics, cardiology) use some bundled payment using gain-sharing payments at the conclusion of some predefined period. Others use global capitation rates (e.g., percent of premium, or true capitation).

If a physician group contracts to receive the bundled payment and then pay the other providers including the hospital, then the physicians hold the risk of having to pay the others.

When a physician group is offered the opportunity to participate in an ACO, it will include a contract governing how payment will be made, grounds for termination, and other basic aspects of payment. For primary care physicians, the participation sometimes must be exclusive. This is true in the Medicare shared savings ACO.

When physicians may terminate is an essential issue. Often the required time commitment is longer than for a typical managed care contract, because the gainsharing opportunity may come far later than the regular payments. Dispute resolution also is important because whether physicians have qualified for bonus payments, whether they must share in downside risk, and whether the data on which these judgments are made are accurate all can be subject to dispute.

What happens when more than one clinician claims to be eligible for a bonus for the same patient? Unless the rules are very clear in the contract or supporting materials the ability to obtain the additional monies, which is the reason for participating, may be speculative.

While there are common contracting concerns in new payment models, the amendment to the provider participation agreement can be widely variable in specificity and impact. Good legal advice can help in negotiating clear language.

Alice G. Gosfield, JD, is a healthcare attorney with Alice G. Gosfield and Associates in Philadelphia, Pennsylvania, and a Medical Economics editorial consultant.
CONSIDERATIONS WHEN REMOVING A PATIENT FROM YOUR PRACTICE

by EVE GREEN KOOPERSMITH, JD, and SAMANTHA N. TOMEY, JD Contributing authors

While a doctor may discharge a patient for any nondiscriminatory reason, termination is not without pitfalls. Physicians should follow a careful process so as to avoid claims of patient abandonment.

A MYRIAD OF situations might bring about a doctor’s discharge of a patient and termination of the physician-patient relationship. The physician might move, leave the insurance network, or determine that the patient needs the care of a different specialist. The physician also might want to end the relationship due to inappropriate patient conduct such as disruptive or violent behavior; repeatedly missing appointments and/or nonadherence to treatment plans; or refusal to pay for medical services.

Avoid discrimination
Physicians must avoid discriminatory practices that are prohibited by law, including refusing to treat or discharge of a patient based upon the patient’s race, nationality, religion, age, sex or sexual orientation.

What defines patient abandonment?
Patient abandonment generally is defined as the unilateral severance by the physician of the physician-patient relationship, without giving the patient sufficient advance notice to obtain the services of another practitioner, and at a time when the patient still requires medical attention.

While individual states have their own definitions of patient abandonment, the concept of reasonable notice is common to most jurisdictions. In New York, for example, the following is considered professional misconduct: “Abandoning or neglecting a patient under and in need of immediate professional care, without making reasonable arrangements for the continuation of such care, or abandoning a professional employment by a group practice, hospital clinic or other healthcare facility, without reasonable notice and under circumstances which seriously impair the delivery of professional care to patients or clients.”

Significant liability, fines and/or restrictions or loss of the physician’s professional license can result. In states such as California, Texas and Washington, D.C., patient abandonment is addressed in the medical malpractice laws, and significant liability may result if the physician abandons a patient without sufficient notice in advance of termination and injury results.

While some jurisdictions require a specific amount of time for providing notice to the patient, others simply allude to “reasonable” notice. In the absence of a specific legal notice period, 30 days generally is considered a reasonable amount of time to provide adequate notice to the patient in advance of termination.

The physician also should check his or her managed care contracts, which may include specific requirements concerning the termination of covered patients.

Most importantly, during the “notice” period, the physician must continue treating the patient and remain available for office visits.

Practical tips
The following strategies can help protect physicians from liability and accusations of patient abandonment:

Provide written notice
The physician should issue a written termination letter to the patient prior to the effective date of termination.
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The letter should clearly state a termination date (we suggest 30 days in advance) and the reason for termination.

Include a list of suitable alternative providers

We suggest that the letter also contain a list of alternative healthcare providers in the area and if appropriate, referral to the patient’s insurance network.

In addition, physicians can provide the patient with contact information from the local and state medical societies, which can be resources for finding a provider that fits their needs.

Time the termination properly

Avoid withdrawing from treating the patient when the patient is in medical crisis, unless the patient requires the services of a different specialist and arrangements are made for transferring the patient’s care to such specialist.

Continue providing effective treatment during the intermediate period following issuance of the termination letter and prior to the effective date of termination. Advise your office staff members that the patient is still welcome to schedule an office visit and/or arrange for services before the effective date of termination.

Examine managed care contracts and communicate with health plans

If you are a participating provider in a managed care network in which the patient is covered, review the managed care agreement for specifications concerning termination of the physician-patient relationship. Some managed care contracts contain language requiring suitable justification for termination as well as specific notice requirements.

The best strategy is to contact the payer, explain the situation, and ensure everything is done properly per the contract to prevent problems later.

Provide access to medical records

Offer to send a copy of the discharged patient’s medical records to the patient’s new doctor. Numerous states have laws which require that records not be withheld solely because of a patient’s inability or refusal to pay.

Communicate with everyone else in the practice

Be sure to apprise all physicians and office staff members of the termination to avoid inadvertent reestablishment of the physician-patient relationship.

For example, a receptionist or appointment scheduler who is unaware that a patient has been issued a withdrawal letter might schedule a new appointment for that patient following the termination date. In some jurisdictions, this has been construed as renewing the physician-patient relationship, regardless of whether such a result was intended.

Finally, the treating physician should always be the one who makes the determination to terminate the physician-patient relationship rather than another staff member.

By remaining personally involved, the physician can ensure that all of the above concerns are addressed appropriately.

Eve Green Koopersmith, JD, is a partner, and Samantha N. Tomey, JD, is an associate with Garfunkel Wild, PC, in Great Neck, New York. Send your legal questions to medec@advanstar.com.
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PILOT PROGRAM WILL EXPLORE GIVING PATIENT ACCESS TO EHR RECORDS

by RACHAEL ZIMLICH Contributing author

Five primary care facilities will test a new initiative that will allow patients to view and add to their physicians' visit notes in their electronic health records (EHR) systems.

THE INITIATIVE is being made possible by a $450,000 grant from The Commonwealth Fund to develop the OurNotes platform, which is an extension of the OpenNotes program to offer patients greater access to their electronic health information.

“The health centers involved in the pilot include the Israel Deaconess Medical Center (BIDMC) in Boston, as well as original OpenNotes study partners Geisinger Health System in Danville, Pa. and Harborview Medical Center in Seattle, Wash., and more recent OpenNotes participants Group Health Cooperative in Seattle and Mosaic Life Care in St. Joseph, Mo.

“We know that increasing patient engagement is a critical component of improving health care, and we hope to build on BIDMC’s well-established work in this area,” says Anne-Marie Audet, MD, vice president at The Commonwealth Fund.

“This research will explore the potential for OurNotes to help improve care among the most medically complex patients—those with multiple chronic health conditions.”

According to BIDMC, more than 5 million patients nationwide can now read their medical notes online—an effort spearheaded by a 2012 study at BIDMC that involved more than 100 PCPs and 20,000 patients.

“This is really building for the future. We envision the potential capability of OurNotes to range from allowing patients to, for example, add a list of topics or questions they’d like to cover during an upcoming visit, creating efficiency in that visit, to inviting patient to review and sign off on notes after a visit as way to ensure that patients and clinicians are on the same page,” says principal investigator, Jan Walker, RN, MBA, of the division of general medicine and primary care at BIDMC and assistant professor of medicine at Harvard Medical School.

“Our research has shown—and feedback from patients continues to confirm—that patients benefit from reading their visit notes. For example, patients say they have better recall of the treatment plan, feel more in control of their health care, and report improved adherence to medications,” Walker adds.

“We believe that OurNotes, which will enable patients to contribute to their own medical records, has the potential to further enhance communication and engage patients in managing illness more effectively and efficiently, leading to improved patient safety and quality of care and potentially, to lower health care costs.”

The program will focus initially on primary care and involved not only patients and physicians, but also industry experts, who will all work together to develop a user-centered design.

“During this phase we’ll be asking clinicians questions about what kinds of information they think would be helpful to receive from patients. Likewise, we’ll be talking to patients to find out what kinds of information they would like to contribute to their records and their notes,” Walker says.

Prototypes will be developed and phased into pilot programs at each site with the hope that they will result in formal clinical trials of the initiative, according to BIDMC.

“We envision OurNotes as a therapeutic intervention that will prove effective over time for a wide range of patients, especially those struggling with chronic health concerns,” adds co-investigator Jonathan Darer, MD MPH, chief innovation officer at Geisinger Health System. “We expect this process to enlighten our understanding of patient and family engagement and its role in reducing healthcare costs, increased shared accountability, improving the health of those with chronic illness and multiple comorbidities and, most importantly, enhancing the overall patient experience of care.”

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