Chronic care in the digital age
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3 Ways to improve hypertension adherence
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MAY 10, 2013

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NEW HIPAA REGS

ARE YOU IN COMPLIANCE?

Because your liability just increased PAGE 14

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VOL. 90 NO. 9

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Dr Baron fears that even in the era of ACOs there will be "phantom FFS billing" that will undermine #primarycare transformation#SGIM13.

HOWARD LUKS, MD
@HJLUKS
It amazes that everyday I'm seeing patients want to choose to proceed w surg options out of fear of ACA rationing.

GOPAL YADAVALLI, MD
@DRYADAVALLI
#apdim13 #chiefsmeeting Once you lose the respect of your residents, it is very difficult to get it back. @FutureDocs

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MAY 10, 2013

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Issue 9

IN DEPTH

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NEW HIPAA REGS

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Are you in compliance? Because your liability just increased.

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- HIPAA rule violation categories and penalty amounts
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What to consider before hiring non-physician providers

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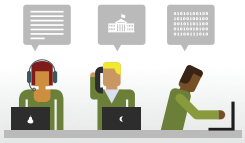

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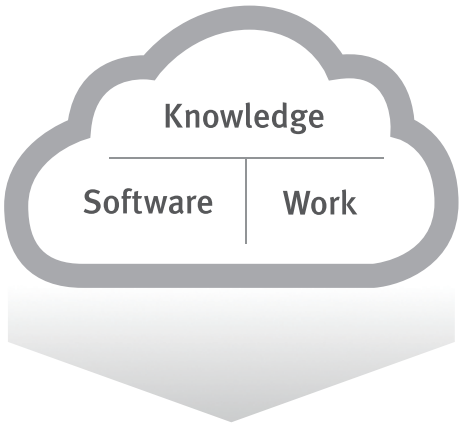

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ONLINE EXCLUSIVE

VENDOR'S MARKET DOMINANCE QUESTIONED

About 40% of Americans have their medical records stored in an Epic electronic health record (EHR) system, and the vendor counts some of the nation's leading healthcare organizations among its customers. But one critic has begun to raise questions about the company's dominance in the EHR marketplace and its lack of interoperability with other EHR systems. Find out more at **MedicalEconomics.com/Epic**

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"You're not going to want to do something that takes more work...unless there's a financial benefit."

—Joseph E. Scherger, MD, MPH

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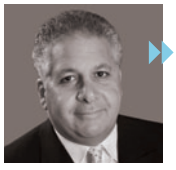

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from the Trenches

thoughts from **JEFFREY K. PEARSON, DO**

WORTH YOUR WEIGHT IN WATER

While changing the water bottles in my office, it hit me that I had been carrying the equivalent of 1.5 of these on my body all of the time. No wonder I was feeling tired and had some aching joints!

I lost 65 pounds last year and have found that a good way to help my overweight and obese patients appreciate the impact of their weight is to have them carry this 5-gallon water jug, which weighs 45 pounds.

Our skeletons are like Christmas trees: We must be very careful regarding the size of the ornaments placed; otherwise the stresses will be too great and the tree will break.

> "TO HELP ...PATIENTS APPEARCIATE THE IMPACT OF THEIR WEIGHT...HAVE THEM CARRY THIS 5-GALLON JUG."

ABOUT THE AUTHOR

The author practices family medicine in San Marcos, California.

OBESITY NOT AN 'EPIDEMIC'

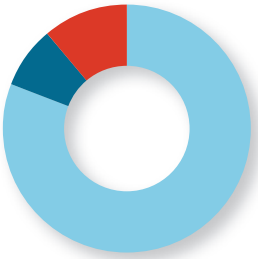
I beg to differ concerning labeling our percentage of obese citizens as an "epidemic." ("The obesity epidemic," February 25, 2013.) Because epidemic means "upon the people" and is used in medical terminology to refer to conditions that are imposed on, or introduced into, individuals, it is misleading to include obesity under that rubric.

Obesity is a state that an individual enters into of his or her own accord. That some obese people have varying needs or behaviors that incline them to overeat cannot be gainsaid. In no case, however, is the result of obesity secondary to overeating imposed on the individual by an outside, undesired source. To say that the obese are victims of advertising, or of fast foods, or of high-calorie prepackaged foods, is at odds with the fact that other individuals, exposed to the same environment, are not similarly affected.

Our "obesity epidemic" is in fact an "epidemic" of poor choices. To call it anything else is to rob the obese individual of autonomy and thus his or her sense of worth, freedom, and responsibility. Moreover, the misunderstanding of obesity as an epidemic leaves the field open to governmental and institutional legislation and policies designed to cure it. These efforts and actions will result in unintended consequences that will have further untoward effects on both obese and non-obese individuals.

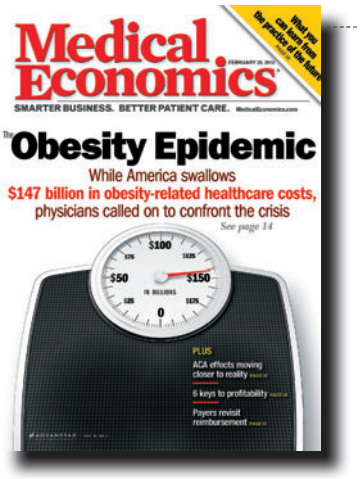
Michael G. Moffat, MD
NOME, ALASKA

Compliance with expanded HIPAA provisions begins later this year. Will you be ready?



- What expanded HIPAA provisions?
- ***Yes,*** I will be ready.
- ***No,*** I will not be ready.

Read more about the new HIPAA rules in the article beginning on page 14 of this issue.



> Does obesity, especially morbid obesity, have evitable, and even inevitable, medical consequences? Without question, the answer is yes. Should physicians discourage obesity, and offer encouragement and practical methods for losing weight to obese individuals? Again, yes. But the obese, we physicians, and the rest of society are ill-served by the ethical implications and the social and economic consequences that flow from the premise that obesity is an epidemic.
>
> **Mitchell G. Moffat, MD,** NOME, ALASKA

PATIENTS ARE ACCOUNTABLE FOR THEIR HEALTH

When are we physicians going to demand that our patients take responsibility for their healthcare? I don't accept the current thinking that I should be rewarded (or punished) based on whether my patients are controlling their chronic diseases. I address (and document) with the patient at each visit what the goals are and how to achieve them. The patients are informed of the consequences of non-adherence. Obstacles to adherence are discussed. I refuse to be put in a position where I would have a financial motivation to terminate non-adherent patients.

We physicians are all too accepting of the label of caregiver when the term babysitter is more accurate. Just like the attorneys who have made personal responsibility an archaic concept, so too now is the government telling patients that they are not responsible for being unhealthy. It is the sellers of oversized soft drinks who are the culprits in our obesity crisis. It is the doctors who are at fault and will be duly punished if our patients are not healthy enough.

If we want to have real cost control, then we must make the patient have a skin in the game. Tie the cost of health insurance to their adherence. Charge patients more for health insurance coverage if they are obese, smoke, or are not at goal for chronic disease states. Require any insurance that offers prescription drug coverage to cover a fixed percentage of the cost of all medications. Let the patient and doctor decide whether the brand-name medication is worth the extra cost.

Expanding Medicaid and mandating health insurance coverage will do nothing but exponentially expand the cost of healthcare. We need to make people more, not fewer, accountable for their health.

Keith Dinklage, MD
NEW CASTLE, INDIANA

MOC CRITICISMS TIMELY

The criticism that Dean Heller, MD, raised against the maintenance of certification (MOC) exam in "MOC exam not based on clinical practice" (Talk Back, February 28) is timely.

Along with its cost, inconvenience, and punitive nature, the little correlation with actual clinical practice that MOC has makes it deserving of criticism. Heller's voice is only one of thousands who feel the same.

Edward Volpintesta, MD
BETHEL, CONNECTICUT

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ACP POSTS CONCERNS OVER SOCIAL MEDIA USE

Although physicians should engage patients in new ways, a social media use policy paper from the American College of Physicians (ACPs) wants internists to first consider confidentiality and how it affects trust in the medical profession.

Some of the highlights of the position paper:

E-mail should be only used with patients if an established patient-physician relationship exists or with patient consent.

Keep your professional and personal lives separate.

Don't use text messaging for medical interactions with patients, or do so with extreme caution.

Do not "friend" or contact patient through personal social media.

Encourage patients to schedule office visits or go to the emergency room if they are seeking medical advice through social media.

Although communicating with patients using email offers potential benefits of "greater accessibility and immediacy or answers to non-urgent issues, it also opens up potential dangers regarding confidentiality, replacement of face-to-face or phone interaction, and ambiguity or misinterpretation of digital interactions.

WHAT'S REALLY CAUSING DECLINES IN HEALTHCARE SPENDING?

Although healthcare is growing at the slowest rate in 50 years, a new report says the trend has more to do with the sluggish economy rather than structural changes within healthcare to reduce costs.

The Henry J. Kaiser Family Foundation predicts that when the economy snaps back, so, too, will healthcare spending. How much, however, is still unknown, the report concludes.

"The vast majority (77%) of the recent decline in the health spending trend can be attributed to broader changes in the economy. At the same time, however, there are also indications that structural changes in the health system may be playing a modest role as well," the report states.

Changes coming under the Affordable Care Act could affect the trends significantly, too. "Increases in coverage will induce a modest, one-time bump of a couple percent in spending as people who were previously uninsured get insurance and gain better access to health services," according to the report.

In addition, delivery system changes through accountable care organizations and bundled payments may contain healthcare costs in the next few years.

"However, our analysis suggests that over time the economy is by far the biggest determinant of changes in health spending overall. Increases in health expenditures are likely to trend upwards over the coming decade as the economy returns to a more normal rate of growth," the authors state.

Getty Images/iStockphoto

AMA DECLARES WAR ON HYPERTENSION, DIABETES

In the next 4 years, the American Medical Association wants 10 million more Americans to have their blood pressure at goal and show measurable improvements in outcomes related to the management of diabetes.

And it's willing to spend more than $1 million over that time to do it.

In unveiling its newest "Improving Health Outcomes Initiative," the association plans to target hypertension and diabetes because they impact millions of Americans each year and cut across all medical specialties.

The initiative hopes to recruit physicians and patients to help change health habits and behaviors and forge new collaborations to help.

One new partnership is with the Armstrong Institute for Patient Safety and Quality, a research institute within Johns Hopkins Medicine, to help the U.S. Department of Health and Human Services' Million Hearts Initiative.

With diabetes, the initiative will support Centers for Disease Control and Prevention educational efforts and include a partnership with the YMCA to increase physician referrals with pre-diabetes.

Testimony calls on feds to 'reconnect' medical schools with community practices

CONGRESSIONAL FUNDING of academic programs could help solve the growing shortage of primary care physicians, says George Rust, MD, MPH, a family physician in testifying before the U.S. Senate, Health, Education, Labor, and Pensions Subcommittee on Primary Health and Aging in late April.

In speaking for the American Academy of Family Physicians at the hearing, Rust called on Congress to "reconnect academic centers with community-based practice." And that would entail funding for community-based outpatient residency programs.

In an opening statement, Sen. Bernie Sanders (I-Vermont) took it a step further, citing this country's failures as it relates to primary care.

"In the United States today, some 45,000 people unnecessarily die each year because they don't get to a doctor in time. Major reforms in primary care will save lives and save billions in healthcare costs," he said.

To solve the shortage, Sanders says lawmakers need to reform the way government subsidizes medical education and its reimbursement of physicians in higher-paying specialties.

"Only 7% of those graduates chose a primary care career. Needless to say, we must change the financial remuneration and reimbursement rates that strongly incentivize medical students with high debt-loads to go into the well-paid specialties rather than primary care. We must also address the absurdity of Medicare providing $10 billion a year to teaching hospitals—with no demands that they increase the number of primary care physicians we desperately need."

Sanders reports that U.S. is short 16,000 primary care physicians today, and that number will increase by 25,000 in 2025.

"We must also address the absurdity of Medicare providing $10 billion a year to teaching hospitals—with no demands that they increase the number of primary care physicians we desperately need."

—SEN. BERNIE SANDERS

16,000
PHYSICIANS
CURRENT SHORTAGE OF PRIMARY CARE PHYSICIANS

41,000
PHYSICIANS
EXPECTED SHORTAGE OF PRIMARY CARE PHYSICIANS BY 2025

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PART OF AN ONGOING SERIES

New HIPAA rules

Make sure you are in compliance; your liability has increased

by **JEFFREY BENDIX, MA,** *Senior Editor*

HIGHLIGHTS

01 The most important action you can take to protect your practice against penalties, experts emphasize, is to encrypt patient data, both within the practice and when they are taken outside the practice in a laptop computer, smartphone, or other portable device.

02 Your vendors are now directly responsible to the Department of Health and Human Services for securing and guarding the privacy of protected health information in the same way that practices are—and subject to the same penalties.

Healthcare providers have until September 23 to put into place internal policies and procedures needed to comply with sweeping changes coming to the Health Insurance Portability and Accountability Act (HIPAA).

IN JANUARY, the U.S. Department of Health and Human Services (HHS) released a set of rules, known collectively as the omnibus rule, designed to supplement and modify the privacy, security, breach notification, and enforcement rules governing patient health information in HIPAA. HHS has made it clear that the September 23 compliance deadline is final. Penalties can range from $100 to $1.5 million depending on the violation.

For primary care and other physicians in private practice, compliance will mean:

- conducting and documenting a risk analysis, which HHS defines as "an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability" of electronic protected health information (PHI) in your practice;
- reviewing the practice's policies and procedures for when PHI is lost or stolen or otherwise improperly disclosed, and making sure your staff members are trained in them;
- ensuring that the electronic PHI your practice holds is encrypted so that it cannot be accessed if it is lost or stolen (see "Encrypting your patients' health information");
- modifying the practice's electronic health record (EHR) system so that you can flag information a patient does not want shared with an insurance company;
- having the ability to send patients their health information in an electronic format;
- reviewing your contracts with any vendors that have access to your practice's PHI; and
- updating your practice's notice of privacy practices.

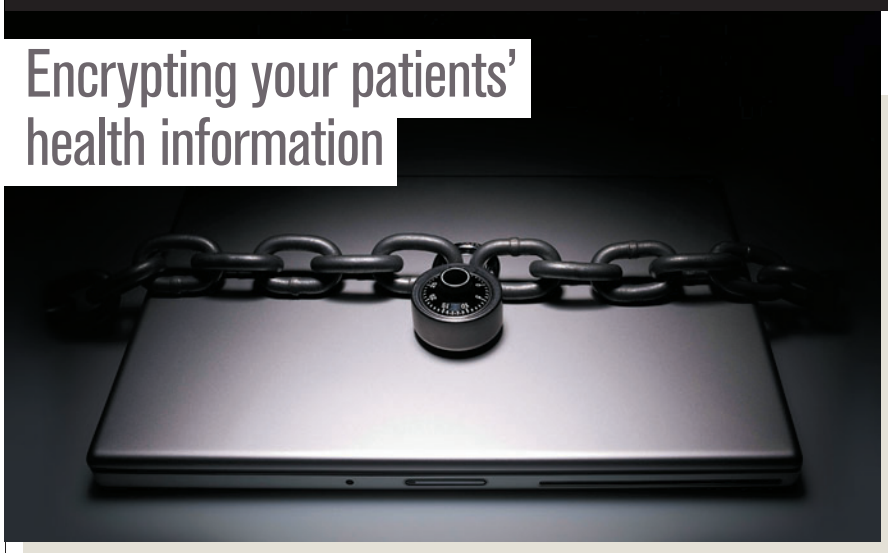
OTHER PROVISIONS

Other provisions of the omnibus rule include restrictions on selling PHI or using

it for marketing and fundraising purposes without obtaining the patient's permission and loosening some of the restrictions on sharing PHI with family members or other caregivers of deceased patients. Disclosure is only permitted, however, to the extent that the PHI is relevant to the role the family member or caregiver played in the decedent's treatment. Moreover, release is not permitted in cases in which the individual expressly stated before death that he or she did not want the PHI released.

The omnibus rule also permits doctors in states with compulsory vaccination laws to disclose a child's immunization records to schools without obtaining formal authorization from parents. Physicians now can do so with only a verbal agreement, provided they document that they obtained the permission. Lastly, the rule prohibits health plans

Encrypting your patients' health information



Although encryption has long been part of an effective data security strategy, the Health Insurance Portability and Accountability Act omnibus rule makes it more important than ever. That's because the requirements for reporting lost or stolen data that are unusable by anyone else are far less onerous than those for unencrypted data.

"IF SOMEONE STEALS MY COMPUTER, THEY'D NEED THE ENCRYPTION KEY TO ACTUALLY INTERACT WITH THE DATA."

MARK EICH, PARTNER AND DIRECTOR OF INFORMATION SECURITY, CLIFTONLARSONALLEN LLP

Mark Eich, a partner and director of information security for the accounting and consulting firm CliftonLarsonAllen LLP in Minneapolis, Minnesota, notes that numerous encryption tools are available through a Web search. He advises thinking about protected health information (PHI) in two forms: when it is "at rest" (stored) and when it is transmitted.

Start by cataloging where your PHI is at rest in the organization. "It could be servers, work stations, mobile devices, or all of them. That will tell you where you need to apply encryption, tools," he says.

On his own laptop, Eich uses Windows Bitlocker Drive Encryption software, which encrypts everything on his main drive and requires entry of a user ID and password to access.

"If someone steals my computer, they'd need the encryption key to actually interact with the data," he says. Most encryption devices automatically encrypt data when they are transferred to another device, such as a flash drive or smartphone.

Encrypting data for transmission generally requires use of a secure file server and transfer tool so that the data can only be accessed by a password or other key provided to the recipient. Eich says his firm uses a server called LeapFile to transmit PHI. After files are uploaded to the server, he sends the client credentials and a link that applies only to those data.

Although PHI also can be transmitted via standard e-mail, it is a far less secure method, and few security experts recommend it. In fact, many health systems and others dealing with PHI have blanket policies forbidding the use of e-mail to transfer it. "That's a decision you need to make right from the start," Eich advises.

"ALL THE RULES ARE WELL-INTENTIONED, BUT THEY MAY INTERACT IN WAYS THAT AREN'T UNDERSTOOD WHEN THEY ARE DEVELOPED."

JEFFREY J. CAIN, MD, FAAFP, PRESIDENT, AMERICAN ACADEMY OF FAMILY PHYSICIANS

More HIPAA guidance coming

The Web site HealthITSecurity.com reported in late April that the U.S. Department of Health and Human Services (HHS) will issue additional Health Insurance Portability and Accountability Act (HIPAA) guidance. An HHS spokesperson wrote in an e-mail to the Web site that "we will be issuing additional compliance guidance and technical assistance…that was not addressed in the preamble of the Omnibus Rule given space limitations. We hope to publish these materials…soon."

The additional guidance will appear on the Web site of the U.S. Office for Civil Rights (www.hhs.gov/ocr/office/index.html), which is responsible for enforcing HIPAA rules.

HIPAA rule violation categories and penalty amounts

The Health Insurance Portability and Accountability Act omnibus rule establishes four "tiers" of violations, based on what it terms "increasing levels of culpability," with a range of fines for each tier.

Category	Fine range
Did not know of breach	$100 to $50,000
Had reasonable cause to know	$1,000 to $50,000
Willful neglect, corrected	$10,000 to $50,000
Willful neglect, not corrected	$50,000

Violations of the same requirement or prohibition for any of the categories are limited to **$1.5 million** per calendar year.

The language of the rule states that actual dollar amounts will be based on "the nature and extent of the violation, the nature and extent of the resulting harm, and other factors…includ[ing] both the financial condition and size of the covered entity or business associate."

from using or disclosing genetic information for the purpose of insurance underwriting.

The rule also sets and describes the four categories of penalties for violating the rules and the dollar amounts for each.

The omnibus rule is the latest step in a process that began when Congress enacted the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009. Among other provisions, the HITECH Act required HHS to strengthen HIPAA's privacy and security protections for health information. HHS adopted interim rules for doing so in 2010 and finalized the rules with adoption of the omnibus rule.

GROWTH IN EHRs DRIVE CHANGES

Driving many of the changes in the omnibus rule is the proliferation of EHRs and the accompanying digitization of patient information, says Jeffrey J. Cain, MD, FAAFP, president of the American Academy of Family Physicians (AAFP).

"The [original] HIPAA legislation is 15 years old now and was enacted at a time when EHRs were nothing more than a gleam in Microsoft's eye, but now everyone's using them, and the rules were seen to be in need of tightening up," he says.

Angela Dinh Rose, director of health information management excellence for the American Health Information Management Association, says, "HITECH was a huge factor in pushing the adoption of health information technology, so along with that, Congress saw the need for improved privacy and security practices to protect patient information now that so much of it is becoming electronic."

According to a study of breaches reported on the HHS Web site by Kaufman Rossin & Co., an accounting and consulting firm based in Miami, Florida, the number of individuals affected by data breaches doubled from 2010 to 2011, even though the number of entities involved

➔ 18


Introducing a
NEW approach in
type 2 diabetes
treatment...

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

INVOKANA™ 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 INVOKANA™.
- Severe renal impairment (eGFR <30 mL/min/1.73 m^2), end stage renal disease, or patients on dialysis.

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 m^2), elderly patients, and patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system (eg, angiotensin-converting-enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs]), or patients with low systolic blood pressure. Before initiating INVOKANA™ in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating therapy.

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.

NOW AVAILABLE

In adults with type 2 diabetes,

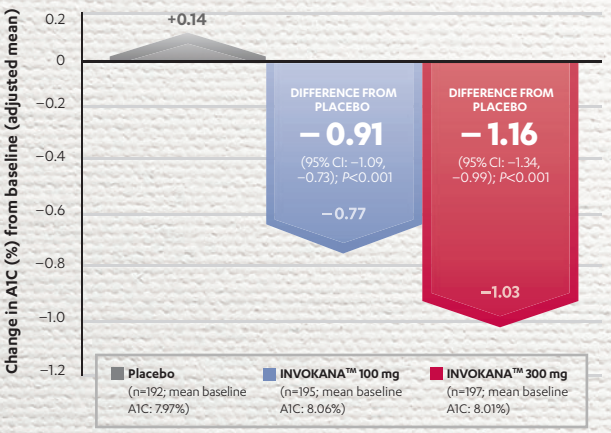
ENVISION NEW POSSIBILITIES

Introducing INVOKANA™—the first and only treatment option approved in the United States that reduces the reabsorption of glucose in the kidneys via sodium glucose co-transporter-2 (SGLT2) inhibition[1]

A1C Reductions as Monotherapy

INVOKANA™ monotherapy provided statistically significant A1C reductions vs placebo at 26 weeks[1]

A1C Change From Baseline With INVOKANA™ Monotherapy[1]



Effect on Weight*

Statistically significant weight reductions vs placebo at 26 weeks (*P*<0.001)[1]

>> Difference from placebo†:
100 mg: −2.2%; 300 mg: −3.3%

Impact on Systolic Blood Pressure (SBP)*

Statistically significant SBP lowering vs placebo at 26 weeks (*P*<0.001)[2]

>> Difference from placebo†:
100 mg: −3.7 mm Hg; 300 mg: −5.4 mm Hg

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

***Prespecified secondary endpoint.**

†Adjusted mean.

A1C Reductions vs Sitagliptin

INVOKANA™ 300 mg demonstrated greater A1C reductions vs sitagliptin 100 mg, in combination with metformin + a sulfonylurea, at 52 weeks (*P*<0.05)[1]

>> Difference from sitagliptin†: −0.37%

Incidence of Hypoglycemia

Monotherapy over 26 weeks:
100 mg: 3.6%; 300 mg: 3.0%; placebo: 2.6%[1]

With metformin and a sulfonylurea over 52 weeks:
INVOKANA™ 300 mg: 43.2%; sitagliptin 100 mg: 40.7%[1]

>> Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA™ can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue

Convenient Once-Daily Dosing[1]

>> Recommended starting dose: INVOKANA™ 100 mg

>> Dose can be increased to 300 mg in patients tolerating 100 mg, who have an eGFR of ≥60 mL/min/1.73 m^2 and require additional glycemic control

The most common (≥5%) adverse reactions were female genital mycotic infection, urinary tract infection, and increased urination.

References: 1. Invokana [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; 2013. **2.** Stenlöf K, Cefalu WT, Kim KA, et al. Efficacy and safety of canagliflozin monotherapy in subjects with type 2 diabetes mellitus inadequately controlled with diet and exercise. *Diabetes Obes Metab*. 2013;15(4):372-382.

Learn more at INVOKANAhcp.com/journal

Invokana™
canagliflozin tablets

IMPORTANT SAFETY INFORMATION *(continued from first page)*

WARNINGS and PRECAUTIONS *(cont'd)*

- **Impairment in Renal Function:** INVOKANA™ (canagliflozin) increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiating INVOKANA™. More frequent renal function monitoring is recommended in patients with an eGFR below 60 mL/min/1.73 m^2.
- **Hyperkalemia:** INVOKANA™ can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion, such as potassium-sparing diuretics, or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia. Monitor serum potassium levels periodically after initiating INVOKANA™ 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:** Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA™ can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA™.
- **Genital Mycotic Infections:** INVOKANA™ increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections and uncircumcised males were more likely to develop genital mycotic infections. Monitor and treat appropriately.
- **Hypersensitivity Reactions:** Hypersensitivity reactions (eg, generalized urticaria), some serious, were reported with INVOKANA™ treatment; these reactions generally occurred within hours to days after initiating INVOKANA™. If hypersensitivity reactions occur, discontinue use of INVOKANA™; treat per standard of care and monitor until signs and symptoms resolve.
- **Increases in Low-Density Lipoprotein (LDL-C):** Dose-related increases in LDL-C occur with INVOKANA™. Monitor LDL-C and treat per standard of care after initiating INVOKANA™.
- **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: 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 (eg, rifampin, phenytoin, phenobarbitol, ritonavir) must be co-administered with INVOKANA™ (canagliflozin), consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA™ 100 mg once daily, have an eGFR greater than 60mL/min/1.73 m^2, and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR of 45 to less than 60 mL/min/1.73 m^2 receiving concurrent therapy with a UGT inducer and requiring additional glycemic control.
- **Digoxin:** There was an increase in the area AUC and mean peak drug concentration (C_{max}) of digoxin (20% and 36%, respectively) when co-administered with INVOKANA™ 300 mg. Patients taking INVOKANA™ with concomitant digoxin should be monitored appropriately.

USE IN SPECIFIC POPULATIONS

- **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 ≥0.5 times clinical exposure from a 300-mg dose.

  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 dilatations) 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™. Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume with INVOKANA™ (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 of age. 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 that included patients with moderate renal impairment (eGFR 30 to <50 mL/min/1.73 m^2). These patients had less overall glycemic 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 ≥60 mL/min/1.73 m^2); patients treated with INVOKANA™ 300 mg were more likely to experience increases in potassium.

  The efficacy and safety of INVOKANA™ have not been established in patients with severe renal impairment (eGFR <30 mL/min/1.73 m^2), with end-stage renal disease (ESRD), or receiving dialysis. INVOKANA™ is not expected to be effective in these patient populations.

- **Hepatic Impairment:** No dosage adjustment is necessary in patients with mild or moderate hepatic impairment. The use of INVOKANA™ has not been studied in patients with severe hepatic impairment and it is therefore not recommended.

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, eg, 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.

ADVERSE REACTIONS

- The most common (≥5%) adverse reactions were female genital mycotic infections, urinary tract infections, and increased urination. Adverse reactions in ≥2% of patients were male genital mycotic infections, vulvovaginal pruritis, thirst, nausea, and constipation.

K02CAN13149

Please see Brief Summary of full Prescribing Information on the following pages.

Invokana™
canagliflozin tablets

Janssen
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Janssen Pharmaceuticals, Inc.

Canagliflozin is licensed from Mitsubishi Tanabe Pharma Corporation.

April 2013 K02CAN13075

INVOKANA™

(canagliflozin) tablets, for oral use

Brief Summary of Prescribing Information.

INDICATIONS AND USAGE

INVOKANA™ (canagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus *[see Clinical Studies (14) in full Prescribing Information]*.

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

CONTRAINDICATIONS

- History of a serious hypersensitivity reaction to INVOKANA *[see Warnings and Precautions]*.
- Severe renal impairment (eGFR less than 30 mL/min/1.73 m^2), end stage renal disease or patients on dialysis *[see Warnings and Precautions and Use in Specific Populations]*.

WARNINGS AND PRECAUTIONS

Hypotension: INVOKANA causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA *[see Adverse Reactions]* particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m^2), elderly patients, patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system (e.g., angiotensin-converting-enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs]), or patients with low systolic blood pressure. Before initiating INVOKANA in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating therapy.

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 initiating INVOKANA *[see Adverse Reactions]*. More frequent renal function monitoring is recommended in patients with an eGFR below 60 mL/min/1.73 m^2.

Hyperkalemia: INVOKANA can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion, such as potassium-sparing diuretics, or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia *[see Adverse Reactions]*.

Monitor serum potassium levels periodically after initiating INVOKANA 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: Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue *[see Adverse Reactions]*. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA.

Genital Mycotic Infections: INVOKANA increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections and uncircumcised males were more likely to develop genital mycotic infections *[see Adverse Reactions]*. Monitor and treat appropriately.

Hypersensitivity Reactions: Hypersensitivity reactions (e.g., generalized urticaria), some serious, were reported with INVOKANA treatment; these reactions generally occurred within hours to days after initiating INVOKANA. If hypersensitivity reactions occur, discontinue use of INVOKANA; treat per standard of care and monitor until signs and symptoms resolve *[see Contraindications and Adverse Reactions]*.

Increases in Low-Density Lipoprotein (LDL-C): Dose-related increases in LDL-C occur with INVOKANA *[see Adverse Reactions]*. Monitor LDL-C and treat per standard of care after initiating INVOKANA.

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

ADVERSE REACTIONS

The following important adverse reactions are described below and elsewhere in the labeling:

- Hypotension *[see Warnings and Precautions]*
- Impairment in Renal Function *[see Warnings and Precautions]*
- Hyperkalemia *[see Warnings and Precautions]*
- Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues *[see Warnings and Precautions]*
- Genital Mycotic Infections *[see Warnings and Precautions]*
- Hypersensitivity Reactions *[see Warnings and Precautions]*
- Increases in Low-Density Lipoprotein (LDL-C) *[see Warnings and Precautions]*

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

Pool of Placebo-Controlled Trials: The data in Table 1 is derived from four 26-week placebo-controlled trials. In one trial INVOKANA was used as monotherapy and in three trials INVOKANA was used as add-on therapy *[see Clinical Studies (14) in full Prescribing Information]*. These data reflect exposure of 1667 patients to INVOKANA and a mean duration of exposure to INVOKANA of 24 weeks. Patients received INVOKANA 100 mg (N=833), INVOKANA 300 mg (N=834) or placebo (N=646) once daily. The mean age of the population was 56 years and 2% were older than 75 years of age. Fifty percent (50%) of the population was male and 72% were Caucasian, 12% were Asian, and 5% 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 m^2).

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 1: Adverse Reactions From Pool of Four 26–Week Placebo-Controlled Studies Reported in ≥ 2% of INVOKANA-Treated Patients*

Adverse Reaction	Placebo N=646	INVOKANA 100 mg N=833	INVOKANA 300 mg N=834
Female genital mycotic infections†	3.2%	10.4%	11.4%
Urinary tract infections‡	4.0%	5.9%	4.3%
Increased urination§	0.8%	5.3%	4.6%
Male genital mycotic infections¶	0.6%	4.2%	3.7%
Vulvovaginal pruritus	0.0%	1.6%	3.0%
Thirst#	0.2%	2.8%	2.3%
Constipation	0.9%	1.8%	2.3%
Nausea	1.5%	2.2%	2.3%

* 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 mycotic infection, Vulvovaginitis, 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 includes the following adverse reactions: Urinary tract infection, Cystitis, Kidney infection, and Urosepsis.

§ Increased urination includes the following adverse reactions: Polyuria, Pollakiuria, Urine output increased, Micturition urgency, and Nocturia.

¶ 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).

Thirst includes the following adverse reactions: Thirst, Dry mouth, and Polydipsia.

Abdominal pain was also more commonly reported in patients taking INVOKANA 100 mg (1.8%), 300 mg (1.7%) than in patients taking placebo (0.8%).

Pool of Placebo- and Active-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 6177 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=3092), 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 11 years, had a mean HbA1C of 8.0% and 33% had established microvascular complications of diabetes. Baseline renal function was normal or mildly impaired (mean eGFR 81 mL/min/1.73 m^2).

The types and frequency of common adverse reactions observed in the pool of eight clinical trials were consistent with those listed in Table 1. In this pool, INVOKANA was also associated with the adverse reactions of fatigue (1.7% with comparator, 2.2% with INVOKANA 100 mg, and 2.0% with INVOKANA 300 mg) and loss of strength or energy (i.e., asthenia) (0.6% with comparator, 0.7% with INVOKANA 100 mg and 1.1% with INVOKANA 300 mg).

In the pool of eight clinical trials, the incidence rate of pancreatitis (acute or chronic) was 0.9, 2.7, and 0.9 per 1000 patient-years of exposure to comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

In the pool of eight clinical trials with a longer mean duration of exposure to INVOKANA (68 weeks), the incidence rate of bone fracture was 14.2, 18.7, and 17.6 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.

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, polymorphic 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 m^2) 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]*.

Table 2: Proportion of Patients With at Least one Volume Depletion-Related Adverse Reactions (Pooled Results from 8 Clinical Trials)

Baseline Characteristic	Comparator Group* %	INVOKANA 100 mg %	INVOKANA 300 mg %
Overall population	1.5%	2.3%	3.4%
75 years of age and older†	2.6%	4.9%	8.7%
eGFR less than 60 mL/min/1.73 m^2†	2.5%	4.7%	8.1%
Use of loop diuretic†	4.7%	3.2%	8.8%

***** Includes placebo and active-comparator groups

† Patients could have more than 1of the listed risk factors

Impairment in Renal Function: INVOKANA is associated with a dose-dependent increase in serum creatinine and a concomitant fall in estimated GFR (Table 3). 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

			Placebo N=646	INVOKANA 100 mg N=833	INVOKANA 300 mg N=834
Pool of Four Placebo-Controlled Trials	Baseline	Creatinine (mg/dL)	0.84	0.82	0.82
		eGFR (mL/min/1.73 m^2)	87.0	88.3	88.8
	Week 6 Change	Creatinine (mg/dL)	0.01	0.03	0.05
		eGFR (mL/min/1.73 m^2)	-1.6	-3.8	-5.0
	End of Treatment Change*	Creatinine (mg/dL)	0.01	0.02	0.03
		eGFR (mL/min/1.73 m^2)	-1.6	-2.3	-3.4
			Placebo N=90	**INVOKANA 100 mg N=90**	**INVOKANA 300 mg N=89**
Moderate Renal Impairment Trial	Baseline	Creatinine (mg/dL)	1.61	1.62	1.63
		eGFR (mL/min/1.73 m^2)	40.1	39.7	38.5
	Week 3 Change	Creatinine (mg/dL)	0.03	0.18	0.28
		eGFR (mL/min/1.73 m^2)	-0.7	-4.6	-6.2
	End of Treatment Change*	Creatinine (mg/dL)	0.07	0.16	0.18
		eGFR (mL/min/1.73 m^2)	-1.5	-3.6	-4.0

***** 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 80 mL/min/1.73 m^2 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, 0.5% with placebo, 0.7% with INVOKANA 100 mg, and 1.4% with INVOKANA 300 mg had a significant renal function decline.

INVOKANA™ (canagliflozin) tablets

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 m^2 (mean baseline eGFR 39 mL/min/1.73 m^2) *[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, 4.6% 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 m^2 (mean baseline eGFR 48 mL/min/1.73 m^2), 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]*.

Genital Mycotic Infections: In the pool of four placebo-controlled clinical trials, female genital mycotic infections (e.g., vulvovaginal mycotic infection, vulvovaginal candidiasis, and vulvovaginitis) occurred in 3.2%, 10.4%, and 11.4% of females treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Patients with a history of genital mycotic infections were more likely to develop genital mycotic infections on INVOKANA. 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]*.

In the pool of four placebo-controlled clinical trials, male genital mycotic infections (e.g., candidal balanitis, balanoposthitis) occurred in 0.6%, 4.2%, and 3.7% of males treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Male genital mycotic infections occurred 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]*.

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) 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 4: Incidence of Hypoglycemia* in Controlled Clinical Studies

Monotherapy (26 weeks)	Placebo (N=192)	INVOKANA 100 mg (N=195)	INVOKANA 300 mg (N=197)
Overall [N (%)]	5 (2.6)	7 (3.6)	6 (3.0)
In Combination with Metformin (26 weeks)	**Placebo + Metformin (N=183)**	**INVOKANA 100 mg + Metformin (N=368)**	**INVOKANA 300 mg + Metformin (N=367)**
Overall [N (%)]	3 (1.6)	16 (4.3)	17 (4.6)
Severe [N (%)]†	0 (0)	1 (0.3)	1 (0.3)
In Combination with Metformin (52 weeks)	**Glimepiride + Metformin (N=482)**	**INVOKANA 100 mg + Metformin (N=483)**	**INVOKANA 300 mg + Metformin (N=485)**
Overall [N (%)]	165 (34.2)	27 (5.6)	24 (4.9)
Severe [N (%)]†	15 (3.1)	2 (0.4)	3 (0.6)
In Combination with Sulfonylurea (18 weeks)	**Placebo + Sulfonylurea (N=69)**	**INVOKANA 100 mg + Sulfonylurea (N=74)**	**INVOKANA 300 mg + Sulfonylurea (N=72)**
Overall [N (%)]	4 (5.8)	3 (4.1)	9 (12.5)
In Combination with Metformin + Sulfonylurea (26 weeks)	**Placebo + Metformin + Sulfonylurea (N=156)**	**INVOKANA 100 mg + Metformin + Sulfonylurea (N=157)**	**INVOKANA 300 mg + Metformin + Sulfonylurea (N=156)**
Overall [N (%)]	24 (15.4)	43 (27.4)	47 (30.1)
Severe [N (%)]†	1 (0.6)	1 (0.6)	0

Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies (continued)

In Combination with Metformin + Sulfonylurea (52 weeks)	**Sitagliptin + Metformin + Sulfonylurea (N=378)**		**INVOKANA 300 mg + Metformin + Sulfonylurea (N=377)**
Overall [N (%)]	154 (40.7)		163 (43.2)
Severe [N (%)]†	13 (3.4)		15 (4.0)
In Combination with Metformin + Pioglitazone (26 weeks)	**Placebo + Metformin + Pioglitazone (N=115)**	**INVOKANA 100 mg + Metformin + Pioglitazone (N=113)**	**INVOKANA 300 mg + Metformin + Pioglitazone (N=114)**
Overall [N (%)]	3 (2.6)	3 (2.7)	6 (5.3)
In Combination with Insulin (18 weeks)	**Placebo (N=565)**	**INVOKANA 100 mg (N=566)**	**INVOKANA 300 mg (N=587)**
Overall [N (%)]	208 (36.8)	279 (49.3)	285 (48.6)
Severe [N (%)]†	14 (2.5)	10 (1.8)	16 (2.7)

* 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

† Severe episodes of hypoglycemia were defined as those 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)

Laboratory Tests: *Increases in Serum Potassium:* Dose-related, transient mean increases in serum potassium were observed early after initiation of INVOKANA (i.e., within 3 weeks) in a trial of patients with moderate renal impairment *[see Clinical Studies (14.3) in full Prescribing Information]*. In this trial, increases in serum potassium of greater than 5.4 mEq/L and 15% above baseline occurred in 16.1%, 12.4%, and 27.0% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. More severe elevations (i.e., equal or greater than 6.5 mEq/L) occurred in 1.1%, 2.2%, and 2.2% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. In patients with moderate renal impairment, increases in potassium were more commonly seen in those with elevated potassium at baseline and in those using medications that reduce potassium excretion, such as potassium-sparing diuretics, angiotensin-converting-enzyme inhibitors, and angiotensin-receptor blockers *[see Warnings and Precautions]*.

Increases in Serum Magnesium: Dose-related increases in serum magnesium were observed early after initiation of INVOKANA (within 6 weeks) and remained elevated throughout treatment. In the pool of four placebo-controlled trials, the mean change in serum magnesium levels was 8.1% and 9.3% with INVOKANA 100 mg and INVOKANA 300 mg, respectively, compared to -0.6% with placebo. In a trial of patients with moderate renal impairment *[see Clinical Studies (14.3) in full Prescribing Information]*, serum magnesium levels increased by 0.2%, 9.2%, and 14.8% with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

Increases in Serum Phosphate: Dose-related increases in serum phosphate levels were observed with INVOKANA. In the pool of four placebo controlled trials, the mean change in serum phosphate levels were 3.6% and 5.1% with INVOKANA 100 mg and INVOKANA 300 mg, respectively, compared to 1.5% with placebo. In a trial of patients with moderate renal impairment *[see Clinical Studies (14.3) in full Prescribing Information]*, the mean serum phosphate levels increased by 1.2%, 5.0%, and 9.3% with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C) and non-High-Density Lipoprotein Cholesterol (non-HDL-C): In the pool of four placebo-controlled trials, dose-related increases in LDL-C with INVOKANA were observed. Mean changes (percent changes) from baseline in LDL-C relative to placebo were 4.4 mg/dL (4.5%) and 8.2 mg/dL (8.0%) with INVOKANA 100 mg and INVOKANA 300 mg, respectively. The mean baseline LDL-C levels were 104 to 110 mg/dL across treatment groups *[see Warnings and Precautions]*.

Dose-related increases in non-HDL-C with INVOKANA were observed. Mean changes (percent changes) from baseline in non-HDL-C relative to placebo were 2.1 mg/dL (1.5%) and 5.1 mg/dL (3.6%) with INVOKANA 100 mg and 300 mg, respectively. The mean baseline non-HDL-C levels were 140 to 147 mg/dL across treatment groups.

Increases in Hemoglobin: In the pool of four placebo-controlled trials, mean changes (percent changes) from baseline in hemoglobin were -0.18 g/dL (-1.1%) with placebo, 0.47 g/dL (3.5%) with INVOKANA 100 mg, and 0.51 g/dL (3.8%) with INVOKANA 300 mg. The mean baseline hemoglobin value was approximately 14.1 g/dL across treatment groups. At the end of treatment, 0.8%, 4.0%, and 2.7% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively, had hemoglobin above the upper limit of normal.

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, ritonavir) must be co-administered with INVOKANA (canagliflozin), consider 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 m^2, and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR of 45 to less than 60 mL/min/1.73 m^2 receiving concurrent therapy with a UGT inducer and require additional glycemic control *[see Dosage and Administration (2.3) and Clinical Pharmacology (12.3) in full Prescribing Information]*.

Digoxin: There was an increase in the area AUC and mean peak drug concentration (C_{max}) 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.

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 dilatations) 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 *[see Nonclinical Toxicology (13.2) in full Prescribing Information]*.

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 with INVOKANA (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 that included patients with moderate renal impairment (eGFR 30 to less than 50 mL/min/1.73 m^2) *[see Clinical Studies (14.3) in full Prescribing Information]*. These patients had less overall glycemic 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 m^2); 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 m^2), 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]*.

Hepatic Impairment: No dosage adjustment is necessary in patients with mild or moderate hepatic impairment. The use of INVOKANA has not been studied in patients with severe hepatic impairment and is therefore not recommended *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

(Even) more MedEc

SEE WHAT YOU MAY HAVE BEEN MISSING IN OUR ENEWSLETTER

New online tool tracks health trends

A NEW online tool will make it possible for physicians to gain detailed information about community health trends.

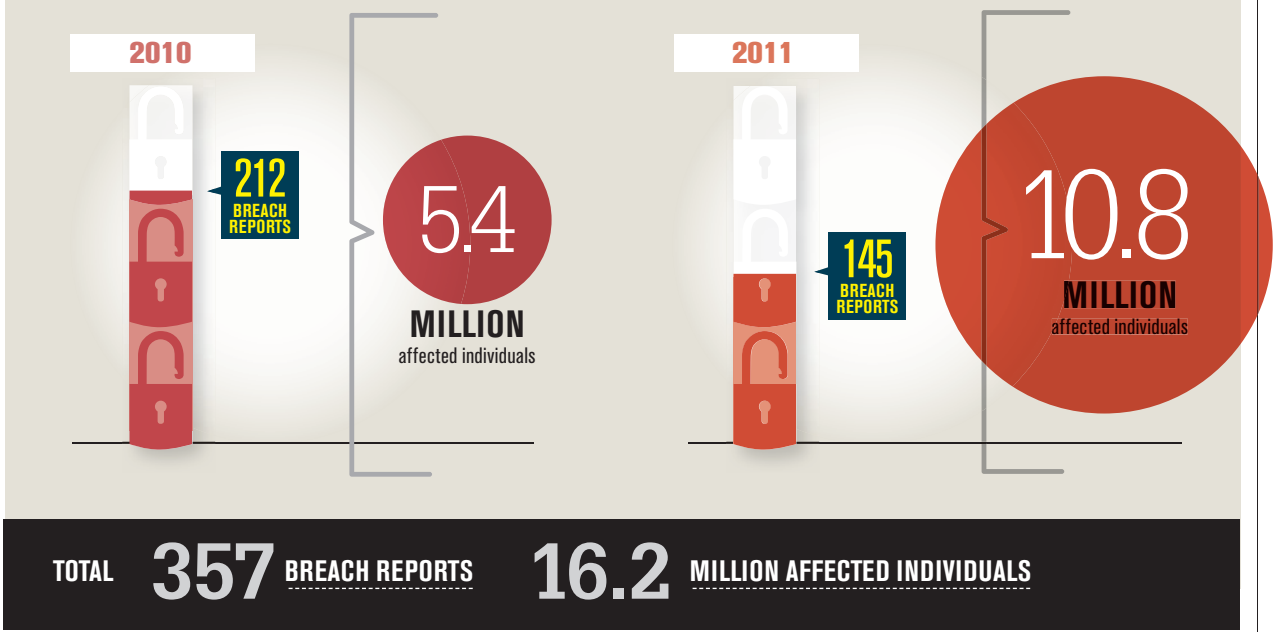
The 2013 County Health Rankings, published online by the Robert Wood Johnson Foundation and the University of Wisconsin Population Health Institute, uses a complex set of data and analysis to reveal what is making the public sick or healthy, and how health trends compare across counties.

The ranking affirms what many primary care physicians (PCPs) have long suspected—that people are healthiest in the counties with the most PCPs. In fact, residents living in healthier counties are 1.4 times more likely to have a doctor or dentist than those in the last healthy counties, according to the analysis.

The report on this year's data also shows that mortality rates and reports of poor health are higher in counties with the highest rates of smoking, teen pregnancy, physical inactivity, and preventable hospital stays.

The rankings were compiled from publically available data for each county, and can be viewed at www.countyhealthrankings.org. Data is available back to 2010.

Summary of breach information reported to HHS, 2010 to 2011



Source: Kaufman Rossin & Co.

> "The important thing for everyone to realize is that HHS has said this requirement is going into effect and you have to meet it."
>
> LISA GALLAGHER, CISM, VICE PRESIDENT OF TECHNOLOGY SOLUTIONS, HEALTHCARE INFORMATION AND MANAGEMENT SYSTEMS SOCIETY

➔16 in a breach declined (see "Summary of health breach information reported to HHS, 2010 to 2011"). The largest cause of breaches was theft (53%), followed by unauthorized access (20%) and loss (14%).

NEW RULES FOR DATA BREACHES

The changes likely to have the greatest effect on medical practices are those concerning how PHI should be secured and kept private and what practices must do in case of a breach—meaning the PHI is lost, stolen, or otherwise made available to someone who should not have it. Why? Whereas before the omnibus rule, breaches only had to be reported if they involved a "significant risk of harm," now the presumption is that virtually any unauthorized disclosure of PHI may be a breach, unless the practice can demonstrate a low probability that the information has been compromised, explains Kenneth Rashbaum, JD, a health law attorney with Rashbaum Associates in New York, New York.

"These changes are a big deal because the standard [of what constitutes a reportable breach] is much lower, and as a result there's now a presumption of harm to the patient by virtue of the breah by the entity that made the disclosures," Rashbaum says.

Given the new standard, the most important action practices can take to protect themselves against penalties, experts emphasize, is to encrypt patient data, both within the practice itself and when they are taken outside the practice in a laptop computer, smartphone, or other portable device. Why? "In the [omnibus] rule now, they're defining a breach as the loss of unsecured PHI," explains Juli A. Ochs, CPA, healthcare engagement director for the consulting and accounting firm CliftonLarsonAllen LLP. "So anything that renders the data 'unusable, unreadable, or undecipherable' is now not considered a breach." (See "Encrypting your patient's health information" for suggestions on how to encrypt data in a way that meets HHS requirements.)

DETERMINING RISK OF HARM

Whenever a breach does occur, it is presumed to be reportable to HHS unless the practice can demonstrate a low risk of probability that the PHI will be compromised, meaning that anyone will be harmed as a

result. Demonstrating the risk contains four components:

- **The nature and extent of the data involved.** "Was the information just a list of patients? Did it include identifying data like Social Security numbers or other financial information? Were there intimate medical or psychotherapy records? Those are the types of questions that need to be asked," says Aldo Leiva, JD, a data security and privacy attorney in Coral Gables, Florida.
- **The unauthorized person** who used the PHI or to whom it was disclosed (something you can't know if the breach resulted from a device being lost or stolen).
- **Whether the PHI was actually acquired or viewed.**
- **The extent to which the risk has been mitigated after the fact.** An example, Leiva says, might be having a contractor to whom the PHI accidentally was sent sign a non-disclosure agreement.

In addition, the rule requires practices to notify patients whose PHI has been breached within 60 days of discovery of the breach. If the breach affects more than 500 patients, then HHS and the local news media must be notified within the same 60-day timeframe. Practices must keep a log of all breaches regardless of the number of patients affected, and they must submit the log annually to HHS.

Another requirement of the rule is that practices and other covered entities conduct a risk analysis. The purpose of the exercise is to discover where the practice might be vulnerable to having its patient information lost or stolen—through theft of a laptop computer on which data are stored, for example—and putting in place policies and procedures to reduce those vulnerabilities.

"People get overwhelmed by this, because they think it needs to be a formal process," Ochs says, "but it can be just everyone in the practice sitting down to talk about where are we vulnerable, assessing the risk of each vulnerability, deciding how to address it, and then documenting that they've gone through the process."

In addition, practices should appoint a privacy and security officer with the responsibility for making sure the practice has policies and procedures for complying with the rules and that staff members are trained in them. Practices can—and often do—assign the responsibilities to a current employee rather than hire someone new, Ochs says. "The main thing is just that it's assigned," she adds.

Violators of the privacy and security rules will be fined in amounts ranging from $100 to $50,000 per violation (see "HIPAA rule violation categories and penalty amounts"). The maximum a practice or other covered entity can be fined in a year is $1.5 million.

RELATIONS WITH BUSINESS ASSOCIATES

After changes to the PHI security and breach notification rules, the omnibus rule changes of greatest interest to practices are those affecting their relationships with "business associates," vendors that have access to a practice's PHI. Such vendors are now directly responsible to HHS for securing and guarding the privacy of PHI in the same way that practices are, and they are subject to the same penalties.

"Before [the omnibus rule], physicians and medical organizations might be protecting patient data the way they were supposed to, but their third-party providers were not obligated except under the terms of their contract with the providers," notes Jorge Rey, CISA, CISM, director of security and compliance for Kaufman, Rossin & Co. "Now the rules say that if you have access to patient healthcare-related information, you need to comply with all the privacy requirements." The rule also puts subcontractors to practice vendors under HHS jurisdiction.

The increased responsibility of business associates does not let doctors off the hook entirely. That's because even if the business associate loses PHI or has it stolen, the medical practice ultimately is responsible for notifying affected patients and reporting the breach to HHS.

Leiva notes that many health information technology (HIT) vendors and consultants include boilerplate language in their contracts absolving them from liability for data loss. Consequently, he advises reviewing all contracts with HIT vendors to ensure that their wording conforms with the omnibus rules governing relations between covered entities and their business associates. (A sample business associate agreement is available from the government at www.cms.gov/Medicare/Prescription-Drug-Coverage/

COMMENTS

"It kills me that #HIPAA compliance has become a more important goal than good patient care. #suffferinginprivacy"
MICHAEL TOMASSON
@MTOMASSON

"Seems apps r coming but MDs won't use MT @BillWinterberg: I'd like an app in which I can text my doctor. App can enforce HIPAA and copy to EMR."
ATUL GAWANDE
@ATUL_GAWANDE

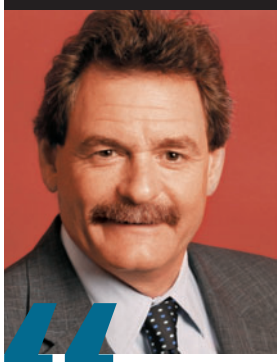
"How can you "de-identify" patient information to stay in compliance with #HIPAA? http://ow.ly/jXM6M #privacy"
MEDICAL ECONOMICS
@MEDECONOMICS

"HHS Aims To Strengthen Gun Background Checks by Easing HIPAA Barriers - http://bit.ly/Zig1Do"
IHEALTHBEAT.ORG
@IHEALTHBEAT

"Snapchat might not be exact solution healthcare CIOs need re: #HIPAA-compliant patient texting... but interesting idea"
DON FLUCKINGER
@DONFLUCKINGER

+Q Will you be ready for the expanded HIPAA provisions?
Comment today @ https://www.facebook.com/questions/62344404370899

To view current poll results and other responses, visit https://www.facebook.com/questions/623244404370899



"These changes are a big deal because the standard [of what constitutes a reportable breach] is much lower and... there's now a presumption of harm to the patient by virtue of the breach."
KENNETH RASHBAUM, JD

PrescriptionDrugCovContra/Downloads/DraftTrOOPPartDBAA_111606.pdf.)

GREATER PATIENT CONTROL

The third part of the omnibus rule affecting doctors' practices concerns patients' rights related to their own health information. The rules gives patients the right to:

- obtain copies of their health information in an electronic format within 30 days of requesting it, with one 30-day extension permitted, and
- instruct his or her doctor not to share information about a test or treatment for which the patient has paid out-of-pocket with his or her insurance company.

In addition, the rule requires practices to update their notice-of-privacy policies (NPPs) to reflect the changes to patients' rights included in the omnibus rule and requires sending the updated NPP to all patients and posting it prominently in the practice and on the practice's Web site.

Complying with the changes likely will be challenging for doctors due to the limitations of EHR systems. "EHRs were designed so that you could share information easily between healthcare providers and insurance providers," notes the AAFP's Cain. "Now we have this law saying that if a patient pays cash, the condition won't be revealed to insurance providers, which is problematic for the way most EHRs are built."

The design of EHRs also makes it difficult to share information with individuals who don't have EHRs, Cain notes. "That's going to be a problem and something the vendors will have to help us with," he says.

In the meantime, possible alternatives include joining a private health information exchange network or a one of the regional or statewide networks many states are establishing. Regional extension centers and state and local medical societies are good sources of information about health information exchange networks.

Doctors should ask their EHR vendors about a timetable for implementing a function that allows them to meet the requirement by the September 23 deadline, advises Lisa Gallagher, CISM, vice president of technology solutions for the Healthcare Information and Management Systems Society. If a vendor won't be ready to provide such a feature, then the practice will have to still find a way to meet the requirement, maybe through a different way of recording the patient's data until the function is available, Gallagher says.

"Sometimes regulatory requirements are misaligned," she adds. "What's happened here is the requirement for the provider to do something, and the requirement hasn't made its way down to the vendor. But the important thing for everyone to realize is that HHS has said this requirement is going into effect and you have to meet it."

Cain says that most AAFP members understand the need to provide patients with greater control over who can see their information and the need to guard confidentiality generally. Nevertheless, "it does add another layer of administrative complexity to managing an office practice," he says.

"All the rules are well-intentioned, but they may interact in ways that aren't understood when they are developed," Cain adds. "The law of unintended consequences is challenging for office-based physicians."

VIDEO

More on the HIPAA omnibus rule

For additional information about the omnibus rule, view a video presentation by Keith Carrington, compliance officer for the healthcare information technology firm CompuTech City, at http://bit.ly/12cBJ7N

Visit http://bit.ly/12cBJ7N

What would you like to know about HIPAA?

Post your questions to our Facebook page at www.facebook.com/MedicalEconomics or email us at medec@advanstar.com. We'll present answers in future articles.

Interest in primary care up, but shortage still looms

Care models, training programs, proposed legislation could provide needed answers to demand, experts say

by **TRACEY WALKER**

HIGHLIGHTS

01 The Affordable Care Act and models of care such as the Patient-Centered Medical Home and accountable care organization are increasing the need for primary care physicians and also are leading medical students to take a second look at primary care.

02 New medical schools, scholarship and loan programs, and proposed legislation are attempting to make primary care a more attractive career choice.

Although more medical students are turning to primary care professions again, the marketplace is still expected to face a worsening shortage of primary care physicians (PCPs) in the coming years.

According to this year's National Resident Matching Program, graduating medical students increasingly appear to be interested in careers in primary care. The percentage of students choosing residencies in family medicine was up 39% in 2013 from 2012, and increases also were seen in those choosing internal medicine–primary care. (See "Interest in primary care," page 27.) This year's intern/resident registration program for osteopathic physicians also saw an increased interest in primary care.

Whether the trend will bolster the numbers of PCPs long term is undetermined. High levels of student debt and lower salaries compared with other medical specialties have been cited as major obstacles to recruiting physicians to long-term careers in primary care.

American Academy of Family Physicians (AAFP) President Jeffrey J. Cain, MD, FAAFP, remains hopeful. "Reforms in our healthcare system—such as team-based care that brings the expertise of the physician, nurses, nurse practitioners, physician assistants, and the whole array of health professionals together to meet the patient's individual needs—will do much to meet demand. But that demand is growing, and we need to increase the number of PCPs and all the other health professionals who comprise the team," he says.

The demand is indeed growing, according to the Association of American Medical Colleges (AAMC). With up to 30 million people newly gaining insurance coverage starting in 2014 and 10,000 Americans turning 65 every day for the next 2 decades, the nation faces a shortage of more than 91,000 physicians by 2020, split evenly between primary and specialty care, the AAMC predicts.

"Physician shortages are occurring because demand is increasing but the supply is not increasing at the same pace, as a result of the cap Congress has imposed on Medicare support for residency training," says the AAMC's Tannaz Rasouli, MPH, director of government relations. "In the 2013 match, a significant number of highly qualified U.S. medical school graduates did not match to residency training positions, and nearly all positions were filled. So, it will not be possible to address shortages of both primary and specialty care physicians unless Congress lifts the cap on Medicare support for residencies."

Cynthia Ambres, MD, MS, partner, Global Healthcare Center of Excellence at KPMG, believes that the primary care field had been decreasing in attractiveness in recent years due to low satisfaction and poor reimbursement "as well as a sense that the PCP was becoming nothing more than the 'triage officer' for specialists," she says.

"THE GROWTH OF PATIENT-CENTERED CARE, WHERE DOCTORS PRACTICE IN A TEAM ENVIRONMENT AND CAN OFFER MORE PERSONALIZED CARE, IS ALSO A KEY REASON MORE DOCTORS ARE SEEKING PRIMARY CARE CAREERS."

RICHARD SNYDER, MD, CHIEF MEDICAL OFFICER, INDEPENDENCE BLUE CROSS

But as the shift to accountable care and payment for value over volume and procedures takes hold, Ambres adds, "the focus is on the PCP as the true coordinator of quality care and even cost containment."

The Affordable Care Act (ACA) puts more focus on the delivery of quality care rather than the quantity of medical services doctors provide, according to Richard Snyder, MD, chief medical officer at Independence Blue Cross (IBC), the leading health insurer in Philadelphia, Pennsylvania.

"This in itself is a very important shift, affecting not just how doctors are paid, but also how they practice medicine," he says. "Similarly, the growth of patient-centered care, where doctors practice in a team environment and can offer more personalized care, is also a key reason more doctors are seeking primary care careers. There is definitely momentum, but lots more progress needs to be made to meet the growing demand for PCPs. One way to do this is through more medical education about the importance of primary care. That's why here at IBC we're so passionate about our partnerships with residency training programs in the Philadelphia region that are training the doctors of tomorrow to practice patient-centered care. It's a trend we'd like to see catch fire more broadly."

Shortages will not be offset easily, according to Ambres. "[Midlevel providers], such as physician assistants, nurse practitioners, med techs, and others, are becoming more and more important to leverage the skill set of the PCP optimally," she says. "Modalities such as online care, allowing PCPs to access specialists to assist in patient care, as well as consult patients directly, are invaluable as we look to ensure timely access to care."

HOW ACO, PCMH MODELS MIGHT INFLUENCE PCP DEMAND

The accountable care organization (ACO) and Patient-Centered Medical Home (PCMH) models solidify the importance of PCPs in the way they provide health services, according to Cain.

"The PCMH is based on team-based, comprehensive primary medical care, and the ACO relies on the PCMH to coordinate the full array of the patient's care—from the community setting to inpatient care to post-hospitalization care—to ensure that patient gets the right care from the right health professional at the right time, to reduce re-hospitalization, and to prevent illness or complications from existing conditions," he says.

"Both ACOs and PCMHs will greatly increase the demand for PCPs, thereby increasing the need to ensure that more future physicians go into the practice of primary care," American Osteopathic Association (AOA) President Ray E. Stowers, DO, says.

The success of the ACO will depend on PCPs and their ability, with the aid of technology and appropriate payment models, to coordinate care for patients, according to Ambres.

"PCMHs are good models of care delivery that are already showing the potential for cost reductions based on an evidence-based team approach that reduces duplication and variation, increases provider efficiency, and focuses on wellness, prevention, and patient engagement," she says. "This model is extremely attractive to physicians in primary care and to medical students choosing specialties."

ACOs include the full spectrum of patient care—PCPs, surgeons, other physician specialists, nursing homes, and hospital care. "Advanced coordination of care is the foundation of ACOs. However, the majority of them utilize PCPs as the core," Stowers says. "The hope is that ACOs will meet what has been called 'the triple aim,' which is to improve the health of the population, improve the individual patient experience, and reduce the total cost of care."

ACOs are designed to do this by:

- making physicians accountable for the care of their patients;
- providing incentives to encourage preventive care; and
- saving money though reducing unnecessary hospitalizations, tests, and procedures.

The PCMH model also encompasses coordinated care. Recognizing the importance of the PCMH to the future of healthcare delivery, the AOA was a founding member of the Patient-Centered Primary Care Collaborative, which is dedicated to advancing an effective and efficient health system built on a strong foundation of primary care and use of the PCMH model, according to Stowers.

IBC's Snyder says he believes that the interest in the PCMH model has never been stronger.

"This is particularly important as healthcare is more complex and people with chronic illnesses are getting care from many different doctors in different settings," he says. "Patient-centered care increases both physician and patient satisfaction by providing a team approach to healthcare, with a family doctor and support staff that knows all of your care and can best advocate for all your needs.

"Changes in how doctors are rewarded for providing quality care are also attracting more doctors to primary care. We have created a unique financial incentive to help PCPs make the investments necessary to deliver more patient-centered care."

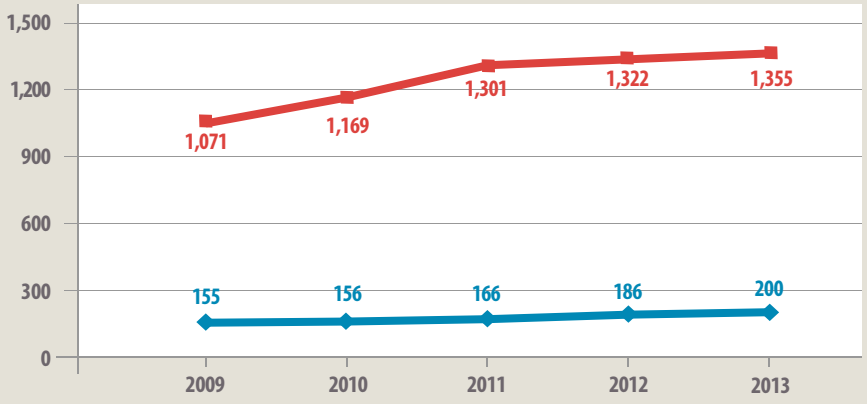
More than one-third of the PCPs in IBC's network practice in a medical home, which Snyder says is the highest concentration of medical homes in the nation. "We see PCPs in general and PCMHs in specific as foundational to the development of successful ACOs that align incentives and better coordinate the care of populations across all providers and facilities," he says.

It is too early to know the short- or long-term effect these emerging efforts will have on future ➔30

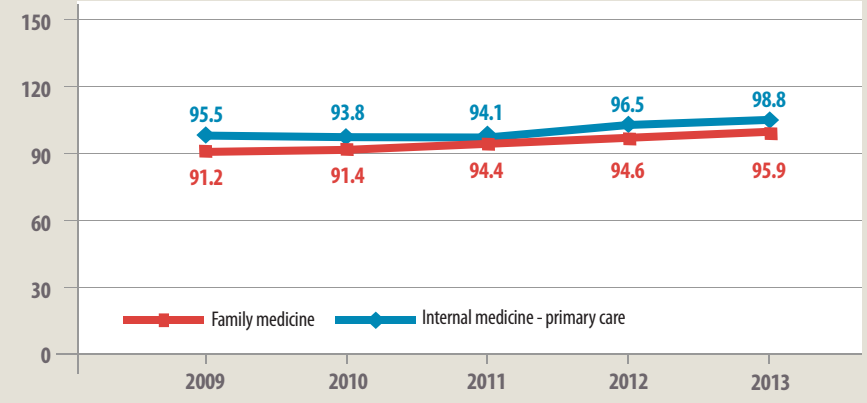
INTEREST IN PRIMARY CARE

Interest in primary care careers is growing among U.S. medical students, as evidenced by their residency choices over the past several years. For more results, see www.nrmp.org/data/advancedtables2013.pdf.

U.S. MEDICAL SCHOOL SENIORS' CHOICE OF RESIDENCY PROGRAM



PERCENT OF OFFERED RESIDENCY POSITIONS FILLED



Source: National Resident Matching Program

6 WAYS the PCP shortage could affect you

1/ It may be more difficult for you to find a primary care physician (PCP) to join (or buy) your practice at a time when patient volume is expected to increase as a result of the Affordable Care Act.

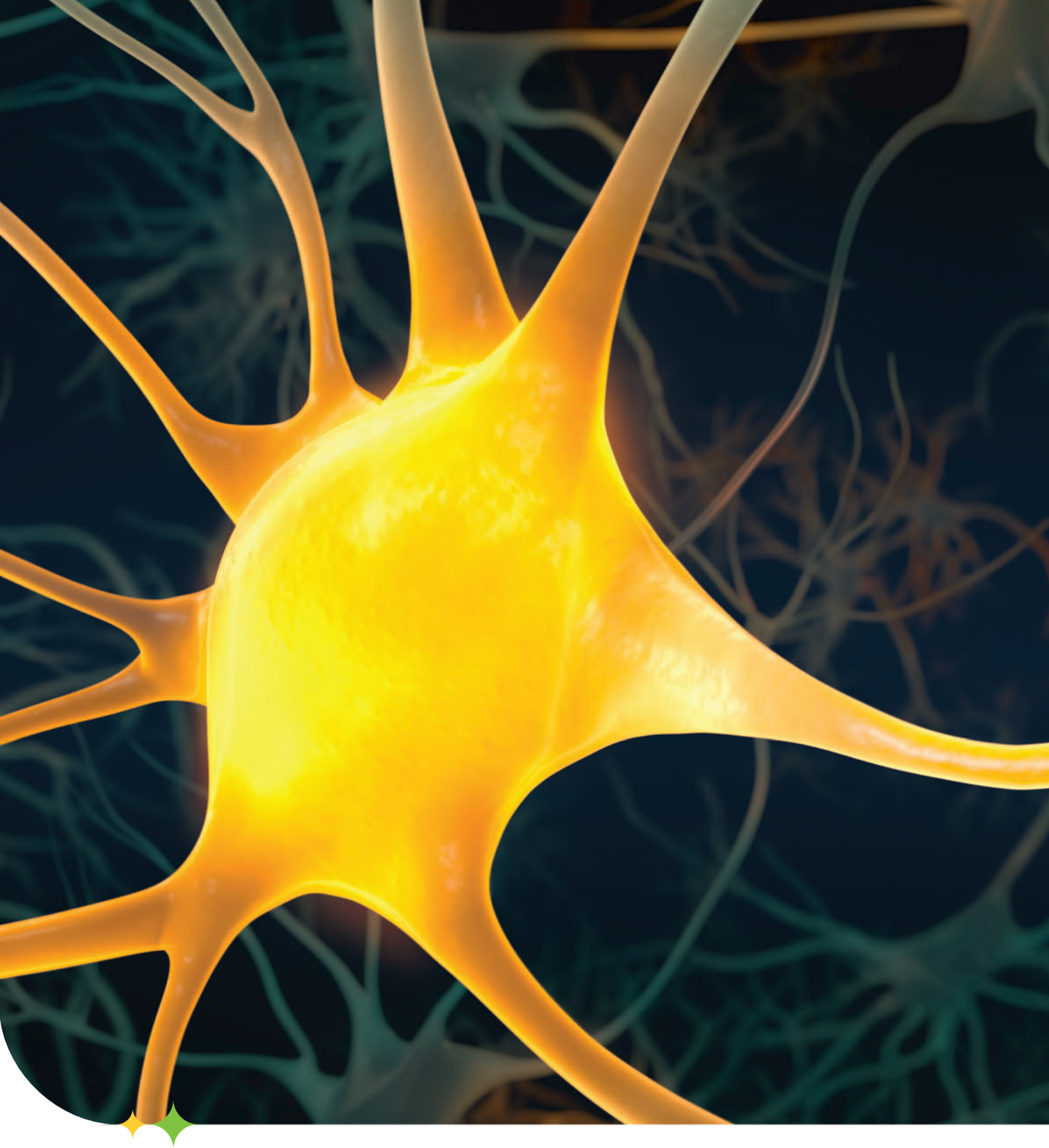
2/ Your practice may need to limit or close to new patients because of staffing shortages.

3/ Your practice may need to hire midlevel providers—or additional midlevel providers—to perform functions formerly handled by PCPs in your practice.

4/ New patients may be sicker when they see you because they postponed needed care.

5/ Existing patients may seek care elsewhere due to increased wait times for scheduling office visits.

6/ If demand for PCPs is unmet, market forces will expand to fill the void with other professionals or organizations.



*Based on a randomized, double-blind, placebo-controlled, 90-day, phase IIb trial.

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References: 1. Henderson ST. Ketone bodies as a therapeutic for Alzheimer's disease. *Neurotherapeutics*. 2008;5(3):470-480. **2.** National Institute on Aging. Alzheimer's disease [fact sheet]. http://www.nia.nih.gov/sites/default/files/alzheimers_disease_fact_sheet_0.pdf. Reprinted September 2012. Accessed December 7, 2012. **3.** Henderson ST, Vogel JL, Barr LJ, et al. Study of the ketogenic agent AC-1202 in mild to moderate Alzheimer's disease: a randomized, double-blind, placebo-controlled, multicenter trial. *Nutr Metab (Lond)*. 2009;6:31. **4.** Reger MA, Henderson ST, Hale C, et al. Effects of β-hydroxybutyrate on cognition in memory-impaired adults. *Neurobiol Aging*. 2004;25(3):311-314.

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"BOTH ACOs AND PCMHs WILL GREATLY INCREASE THE DEMAND FOR PCPs."

RAY E. STOWERS, DO, PRESIDENT, AMERICAN OSTEOPATHIC ASSOCIATION

@ For more information, on the Patient-Centered Medical Home model and care coordination, see the article beginning on page 44.

➔27 workforce needs, believes the AAMC's Rasouli. "These changes will take years to come to fruition, and in the interim, it would be irresponsible to ignore the nation's growing healthcare needs. As demonstrated in Massachusetts, expanding insurance coverage leads to an initial increase in utilization of both primary and subspecialty care.

"Delivery system innovations that improve efficiency, integrate care, and expand use of healthcare teams may help relieve some of the burden on both patients and overwhelmed providers but will not obviate the need to train more doctors in both primary and specialty care," she adds.

NHSC AND TITLE VII: PART OF THE SOLUTION?

The National Health Services Corp. (NHSC) awards scholarships and student loan repayment to individuals enrolled or accepted into certain health profession degree programs, including osteopathic and allopathic students, who agree to serve in NHSC-approved sites in high-need urban, rural, and frontier communities across the nation upon graduation and completion of their training. Title VII of the Public Health Services Act (Title VII) provides scholarships and loan repayment to minority students and students who agree to work in medically underserved areas for 3 years.

These programs are vital to the growth of primary medical care, and, in the case of the NHSC, to providing care in underserved areas, according to Cain. "Research consistently shows that students attending medical schools receiving Title VII grants for departments of family medicine are more likely to go into primary care and to serve in underserved areas," he says. "NHSC is equally vital to growing the primary care physician workforce and helping ensure that people in underserved areas get the care they need."

Despite this year's increase in medical students choosing primary care, anecdotal evidence shows that students are still apprehensive of becoming PCPs due to high levels of student loan debt coupled with lower payments for the medical services that PCPs provide.

Both the NHSC and Title VII address this dilemma, according to the AOA's Stowers.

"Physicians who participate in these programs also are more likely than other medical school graduates to continue practicing in medically underserved communities. Unfortunately, these programs are temporary," Stowers says. "Congress should seek to extend, expand, or make them permanent. The AOA supports efforts to maintain and expand each of those programs to encourage medical students to train and practice in primary care, as well as in rural and medically underserved areas."

What Rasouli calls "relatively modest" federal investment in the NHSC and the Title VII programs yields tremendous dividends in shaping the healthcare workforce. Chronic underfunding of these programs,

New medical schools cater to primary care

The healthcare system needs more primary care physicians (PCPs), and at least two new schools are trying to answer that call.

Quinnipiac's Schools of Health Sciences and Nursing is one of the new medical schools offering primary care-specific training to medical students. Quinnipiac's new Frank H. Netter, MD, School of Medicine will focus on training PCPs to become members of patient-centered healthcare teams, according to Bruce Koeppen, MD, founding dean of the school.

The new school plans to enroll its first incoming class this fall, and the school's admissions committee is selecting candidates most likely to match the school's mission of education future PCPs.

The medical program will be housed in a new, 325,000-square-foot facility on Quinnipiac's North Haven, Connecticut, campus.

Quinnipiac's new program is not alone in its quest to create more PCPs.

The University of California, Riverside, opened about a year ago with the main focus of helping resolve a PCP shortage in California. Because many medical students turn away from primary care to pay down school debts, Riverside seeks to head off those problems by offering a scholarship-to-loan program where scholarships are awarded based on merit and need. If students stay in the area after graduation and practice primary care, then they keep the money as a scholarship. If they choose another area of practice, then the money becomes a loan each student will have to repay.

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*__Source:__ Employee Morale Survey conducted by Carbonview Research, Inc., 2013

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PCPs DO NOT HISTORICALLY SEE COMPENSATION EQUAL TO THEIR SPECIALIST COLLEAGUES AND OFTEN HAVE MUCH MORE DIFFICULTY REPAYING VERY HIGH DEBTS WHEN THEY ARE JUST BEGINNING THEIR PRACTICES."

CYNTHIA AMBRES, MD, MS, PARTNER, GLOBAL HEALTHCARE CENTER OF EXCELLENCE, KPMG

however, undermines the efforts to mitigate such challenges facing the workforce, she says.

"Funding for Title VII is 35% less than it was a decade ago, while funding for the NHSC expires in the next few years, leaving questions about how Congress will maintain the program after fiscal year 2015," Rasouli says. "And as critical as both programs are to shaping the workforce, efforts to substantially increase the number of physicians will require legislation to lift the cap on Medicare support for residency training."

Ambres, who was a recipient of a NHSC grant that assisted her with funding part of her medical school education, says it made a great difference in her life. "It took some financial pressure off, while allowing me to experience the tremendous gratification received from giving service to the poor and underserved populations of New York City in return for this assistance," she says. "PCPs do not historically see compensation equal to their specialist colleagues and often have much more difficulty repaying very high debts when they are just beginning their practices."

LEGISLATION IN THE WORKS COULD BE THE ANSWER

"Congress recognizes the need to build the PCP workforce, and several bills have been introduced with the goal of increasing the number of students who go into primary care specialties," Cain says.

For example, legislation has been introduced that will increase the cap on residency training positions. "If we can reserve a certain percentage or number for primary care training, this will help increase the number of PCPs," he says.

The AAFP is reviewing these bills to determine whether they will help meet the nation's need for PCPs.

In addition, the AAFP has supported the Primary Care Workforce Access Improvement Act, introduced by Reps. Cathy McMorris-Rodgers (R-Washington), and Mike Thompson (D-California).

"This bill would establish a pilot that would look at providing direct graduate medical education funding to community-based residency programs—an approach that would provide more support to community-based primary care residency training," Cain says. "Also, we'll be watching the appropriations process in upcoming weeks and months to see if Congress continues to support Title VII and the NHSC."

Legislation introduced in both the House and the Senate aims to increase the number of Medicare-supported graduate medical education residency positions. Both the bipartisan H.R. 1201 Training Tomorrow's Doctors Today Act and H.R. 1180, the Resident Physician Shortage Reduction Act of 2013, would begin to alleviate the doctor shortage facing the nation by allowing medical schools and teaching hospitals to train between 3,000 and 4,000 more physicians a year, according to Rasouli.

"Timely enactment of this legislation will be critical to averting the physician shortage crisis and minimizing the time patients must wait to book an appointment with primary and specialty care physicians," she says.

The AOA endorses the H.R. 487 Primary Care Workforce Access Improvement Act of 2013 and recently endorsed the Training Tomorrow's Doctors Today Act and H.R. 1180, the Resident Physician Shortage Reduction Act of 2013, and S. 577, the Resident Physician Shortage Reduction Act of 2013.

The American Medical Association also supports H.R. 1180, the Resident Physician Shortage Reduction Act of 2013, and S. 577, the Resident Physician Shortage Reduction Act of 2013.

"Since the enactment of the Balanced Budget Act of 1997, teaching hospitals have been prohibited from increasing the number of resident physicians trained in their institutions," Stowers explains. "Communities experiencing rapid growth in population are beginning to outgrow the number of physicians practicing there. Hospitals that are currently training residents over their cap, residing in states with new medical schools, and those emphasizing training in community-based settings, stand to benefit from passage of this legislation.

"Furthermore, measures that are part of the ACA, including the Primary Care Incentive Payment Program, which offers bonus payments for primary care services to physicians who treat Medicare patients, and another that increases Medicaid payment levels to at least the minimum Medicare levels, could bolster primary care in certain areas," Stowers adds.

Legally Speaking

LLCS: STILL THE ULTIMATE ASSET FIREWALL

by **STEVEN ABERNATHY AND BRIAN LUSTER**

YOU, YOUR FELLOW PHYSICIANS, and your practices often have a substantial amount of assets at risk. Have you examined how your practice would fare if it were faced with baseless lawsuits or overzealous creditors?

One would be hard-pressed to find a better entity for asset protection than a limited liability company (LLC). It can effectively insulate you and your practice from certain financial risks and offer tax benefits.

First introduced in Wyoming in 1978, LLCs have been adopted by all 50 states. They were promulgated to solve some of the problems inherent in both corporate and partnership structures. For instance, the tax treatment of LLCs, like partnerships, is pass-through, resulting in only one layer of tax. Unlike partnerships, however, which require at least two parties, LLCs can be formed with only one member (and the pass-through tax treatment preserved by electing to treat it as a "disregarded entity" for income tax purposes). And they do not require the maintenance of rules and formalities of corporations.

Consider setting up multiple LLCs for ultimate protection. Certain states (for instance, Texas and Illinois) allow the use of the series LLC, the purpose of which is to streamline the ability to separate assets into their own entities, minimize liability, and reduce paperwork and formation costs. Such structures involve a "father" LLC and several "children" LLCs, each sub-LLC with its own books and members.

LLCs are relatively easy-to-understand asset protection firewalls. Ask yourself whether you are better off investing a small amount to protect valuables you have worked your entire life to earn. If the answer is yes, then think of an LLC as a driver in your golf bag—not the only club in your asset protection bag, but certainly not a bad tool with which to tee off.

No better method exists to protet your savings from creditors than by ensuring that they remain untouchable through impermeable trusts and proper estate-planning. That element is the essence of asset protection.

LEARNING THE HARD WAY

One of our successful physician colleagues, whom we will call Dr. Stevens, learned that lesson the hard way. He owned multiple assets, including a speedboat, a vacation home, an apartment building, a brokerage account, and a plot of undeveloped land. One day, his son and a group of his friends took a joyride in Dr. Steven's speedboat. His son ended up hitting a dock at full speed, crippling his two friends. Alcohol was involved, and Dr. Stevens was slapped with a multi-million dollar lawsuit, far in excess of the speedboat's policy limits.

Dr. Stevens believed he was adequately protected. Years earlier, a patent lawyer had advised him to put his brokerage account, vacation home, and land in a corporation. Doing so, the attorney had said, would insulate him from liability because of the limited liability benefits of a corporation.

That was poor advice. Although a corporation provides a level of protection from liability, this protection typically only applies to negligent actions of the corporation itself. And because the damage was the result of the speedboat accident (and the boat was not owned by the corporation), nothing was stopping the plaintiffs from simply seizing the stock and then dissolving the company. In addition, the corporation was subject to double taxation at both the corporate and shareholder level, meaning that his brokerage account gains were taxed twice.

Dr. Stevens, unsurprisingly, failed to keep up with a bevy of required corporate formalities.

He would have been better served had he put his remaining assets, including the speedboat, in an LLC—preferably separate LLCs—thereby protecting assets from both inside and outside liability. If Dr. Stevens' brokerage account and land had been in separate LLCs, the plaintiffs would have had a difficult time directly seizing them.

OUTSIDE, INSIDE LIABILITY

This is an example of outside liability, or, said another way, liability not related to the property. Because nothing exists for the litigants to go after, the rest of his assets are protected. In such a case,

Legally Speaking

the litigants most likely will accept the insurance company's policy limit.

Inside liability involves liability stemming from the property itself. Suppose a tenant slipped on the sidewalk of one of Dr. Steven's rental properties. If this property is in an LLC, then he is safe from claims stemming from the injury, because he is shielded from negligent actions associated with the business.

At the heart of the LLC asset protection is the ability to increase one's bargaining power. Because Dr. Stevens' assets are protected, his pockets are suddenly much shallower, making him a far less tantalizing target for personal injury attorneys. He is now in a better position to settle the case for a fraction of what he is being sued.

Note, however, that recent case law has revealed chinks in the LLC armor. California and Florida have both ruled that, although a creditor cannot seize assets in the LLC, it can foreclose on the member interest on the LLC. Before these rulings, a creditor's only remedy was to obtain a charging order, which essentially allows the creditor to obtain any distributions. This remedy largely was toothless, however, because it could not force distributions. Be sure to consult your professional advisers to determine the appropriate business arrangement for your practice and ensure that it is set up properly so you can maximize the benefits. ■

Luster, left, and Abernathy, are physicians' advocates and founders of the first Physician Family Office in the country, which sells no products, receives no commissions, and is independent, employee-owned, and governed by an advisory board. Send your health law questions to ***medec@advanstar.com****.*

Operations

The return of the house call?

Technology, reimbursements, growing population of elderly patients drive growth of home visits

by **KIMBERLY BONVISSUTO**

HIGHLIGHTS

01 House call visits to elderly and homebound patients have been increasing over the past decade. Some experts say the trend is being driven by technology, patient need, and increased reimbursements to reduce unnecessary hospital readmissions.

02 The Centers for Medicare and Medicaid Services launched a 3-year project last year to test the effectiveness of delivering in-home, comprehensive care services and document success in rewarding healthcare providers.

03 The downside? Being accessible to patients during off hours, travel time, and reimbursements. The upside? Flexibility in schedules and a sophisticated level of medical management of cases.

Healthcare in the 1930s: Back then, 40% of patient encounters occurred in the home, and it was a time that characterized, even idolized, the physician and his iconic black bag of cures. By 1950, the house calls were vanishing because of the centralization of medicine and advances in equipment. ▸▸

▸▸ **BUT THE NORMAN ROCKWELL** image of the family doctor paying a house call is making a comeback, and it is being driven by technology, the societal need to care for an aging homebound population of patients, and payment models that will reward care and reduce hospital admissions.

THE COMEBACK

According to data from Medicare Part B billings, the number of house calls increased from 1.4 million visits in 1999 to 2.3 million in 2009. Part of the reason is the graying of America—by 2030, 70 million of us will be aged more than 65 years. And the American Academy of Family Physicians (AAFP) expects the demand for house calls to increase because the existing long-term care and assisted living infrastructure does not have the capacity for the increasing numbers of elderly patients needing services.

More and more, the house call is becoming a tool for primary care physicians to provide access and reduce institutionalization of their elderly patients by delivering care in the ultimate patient-centered home: the patient's home.

The Affordable Care Act supports the idea of the house call through many initiatives, including accountable care organization (ACO) pilots and Patient-Centered Medical Home (PCMH) pilot projects.

➔40

"IT'S NOT THE ANSWER TO ALL OF YOUR PROBLEMS, BUT IT'S A LOT OF FUN AND CAN FIT AS PART OF AN OVERALL MODEL OF HEALTHCARE."

ANDREA BRAND, MD

WHAT TO PACK IN THAT BLACK BAG

- bandage scissors,
- cell phone,
- cerumen spoons,
- gauze/tape/packing,
- gloves (sterile and nonsterile),
- glucometer,
- lubricant,
- maps or GPS,
- otoscope/ophthalmoscope,
- phlebotomy equipment,
- sharps container,
- sphygmomanometer (variety of sizes),
- sterile specimen cups,
- stethoscope,
- tape measure,
- thermometer,
- tongue depressors, and
- tuning fork.

OPTIONAL EQUIPMENT

- computer (portable printer and fax, wireless card, electronic health record),
- dictaphone,
- externally worn hearing amplifier,
- personal digital assistant,
- portable electrocardiograph,
- pulse oximeter, and
- vaccines.

DOCUMENTATION

- advance packet (names, phone numbers, policies, scope of services, questionnaires and patient forms),
- assessment tools (mini-mental state examination, geriatric depression scale, screen for caregiver burden),
- billing documentation,
- business cards/appointment cards,
- patient record,
- phonebook of essential community numbers and services, and
- prescription pad.

Source: American Academy of Family Physicians

"PHYSICIANS IN THIS GENERATION ARE NOT TRAINED IN HOME CARE. IT IS SOMETHING PEOPLE WILL HAVE TO LEARN SOMETHING ABOUT."

CONSTANCE F. ROW, EXECUTIVE DIRECTOR, AMERICAN ACADEMY OF HOME CARE PHYSICIANS

➔37

The Independence at Home Act demonstration project through the Centers for Medicare and Medicaid Services (CMS) Innovation Center is a 3-year project begun in 2012 that will test the effectiveness of delivering comprehensive primary care services at home, the ability to improve care for Medicare beneficiaries with chronic multiple conditions, and the success in rewarding healthcare providers who reduce costs through quality care.

The U.S. Department of Veterans Affairs' Home-Based Primary Care program, which uses a multidisciplinary care team to serve frail elderly patients in the home, is another model that has demonstrated fewer hospital admissions, shorter lengths of stay, reduction in readmission rates, and reduction in long-term care facility stays.

A VIABLE PRACTICE MODEL?

Family physicians also are looking to alternative practice models that offer more flexibility and greater career satisfaction in the face of administrative complexities and expenses of health plans, according to the AAFP.

With that said, remember that office-based practices and centralized facilities opened for many financial and administrative reasons. Much of them had to do with time and efficiency related to insurance reimbursements. So, if you're considering offering house calls, examine the pros and cons of establishing it as a service mix by conducting a thorough review of the elderly patients in your panel who could benefit from this service. Look at fixed costs to the practice, vehicle expenses, travel time, li-

> IT REQUIRES A SOPHISTICATED LEVEL OF MEDICAL MANAGEMENT OF THESE PATIENTS TO HELP THEM TO LIVE SAFELY AND COMFORTABLY AT HOME."
>
> BRENT FEORENE, PRESIDENT, COLONNADE HEALTHCARE SOLUTIONS

ability implications of delivering care offsite, potential of injury, and costs or lost revenue from being away from practice versus public and private reimbursement levels.

Samantha Pozner, MD, opened her practice, Springfield Family Practice in New Jersey, in 2000 and began making house calls in 2002 when an elderly patient no longer could make it in to see her.

"She didn't live that far away from my office. When I needed to see her, I left the house early. I would see her on my way in, and then I was on my way," Pozner says. "Once you have it in your head you can do that, the opportunities present themselves."

Over the past 10 years Pozner has seen about 30 patients through home visits. She says her success is based on defining parameters that work for her: she only visits patients who live between her home and office or near where she drops off her children. She adds that she doesn't carve specific time out for house calls; rather, she fits them in when she can around her office practice.

Andrea Brand, MD, a family physician in Florida, left a traditional office practice for a cash-only house call practice, Dr. Brand at Your Door, in 2004. For 7 years, she handled about 300 patients, starting her business with a $5,000 budget and working out of the trunk of her car. Her patients came via word of mouth.

Although the house call practice had numerous benefits—Brand was her own boss, she made her own schedule, she had more time with patients, and overhead was low—after 7 years, she decided to find a part-time job that allowed her to have a life beyond being available to her patients 24/7.

"It's not the answer to all of your problems, but it's a lot of fun and can fit as part of an overall model of healthcare," Brand says.

THE FUTURE

Constance F. Row, executive director of the American Academy of Home Care Physicians, says, "Seniors want to age in their homes. They need to be supported in doing that if we're ever going to solve the cost problem in this country. All we need is for more people to think about it, even though a big barrier is physicians in this generation are not trained in home care. It is something people will have to learn something about."

Row says that caring for patients in the home ideally will become a routine part of training for all primary care professionals.

"I'm very hopeful this will become a permanent part of the U.S. healthcare system. I feel it must," Row says, adding that a 3.7% increase in the number of house calls paid by Medicare occurred from 2010 to 2011.

Brent Feorene, president of Colonnade Healthcare Solutions, a Westlake, Ohio-based management consulting firm, says a renewed interest in house calls surfaced in 1999 when Medicare developed codes specific to house calls. Healthcare reform's fee-for-service push refocused concern on what happens to patients comprehensively. The house call, he says, became a tool targeted at the top 3% to 5% of elderly

Medicare definition of HOMEBOUND

To be eligible for home health services, a Medicare beneficiary must:

- need intermittent skilled nursing care, or physical, speech, or occupational therapy;
- be confined to the home (normal inability to leave; requires considerable and taxing effort to leave; requires supportive devices such as canes, wheelchairs, and walkers to leave; requires special transportation to leave; requires help from another person to leave; medical contraindication for leaving the home);
- be under a plan of care established and periodically reviewed by a physician; or
- be receiving the services from a Medicare-participating home health agency.

Source: American Academy of Family Physicians

"IF WE GO UPSTREAM TO KEEP PEOPLE OUT OF HOSPITALS AND EMERGENCY [DEPARTMENTS], THEY DO BETTER, HAVE BETTER OUTCOMES, AND IT'S LESS COST OVERALL TO THE SYSTEM."

REBECCA CONANT, MD

patients who cannot access the healthcare system in a normal way.

House calls can differentiate a practice, he adds, and make it more attractive by using a different approach to delivering primary care. But he says a learning curve exists.

"You're not dealing with sore throats," Feorene says. "These are all frail, elderly individuals with multiple chronic conditions. It requires a sophisticated level of medical management of these patients to help them to live safely and comfortably at home and not have to go to the hospital or to avoid a nursing home."

ON THE CUSP OF CHANGE?

Rebecca Conant, MD, is the founding director of the University of California, San Francisco (UCSF), Housecalls program, which has provided in-home primary care to more than 300 frail, homebound elderly patients since 2001. A strong sense exists that home visits are critical to providing care to an overall population of patients, she says.

The Housecalls program is operated as a nonprofit organization, supported by local foundations and donors. About 80% of patients are poverty level or low income. The program began with a philanthropic gift to teach medical students about home health, but it quickly became clear that a whole cohort of patients was not receiving ongoing primary medical care because they were homebound and unable to travel to clinics, Conant explains.

"Their only interactions were through emergency [departments] and hospitals when they would hit a crisis," she says, adding that the original donor agreed to broaden the program from a strictly teaching program to an ongoing medical care provider program through UCSF faculty.

The capability of providing care in the home has increased dramatically over the past 10 to 15 years through the portability of electronic health records, equipment, and supplies, she adds.

"We're just seeing the cusp of this, with the focus on chronic care management and chronic illness, with medical homes pushing that back out into the community," Conant says. "If we go upstream to keep people out of hospitals and emergency [departments], they do better, have better outcomes, and it's less cost overall to the system."

A study published in the November/December 2012 issue of the *Journal of the American Board of Family Medicine* reported that the number of house calls made to Medicare beneficiaries more than doubled in recent years, although the number of physicians making the calls decreased.

"I THINK [HOUSE CALLS] WILL FOLLOW A LOT OF TRENDS WE SEE WITH THE HOSPITALIST MODEL AND THE SKILLED NURSING FACILITY MODEL. MORE AND MORE OF THOSE PHYSICIANS ARE ENTIRELY FOCUSED ON THAT PARTICULAR VENUE."

STEVEN H. LANDERS, MD, MPH

One of the study co-authors, Steven H. Landers, MD, MPH, president and chief executive officer of VNA Health Group in New Jersey, says home care medicine is becoming a specialty, of sorts, within primary care. Increased payments from Medicare, an aging population, consumer preference for all types of care at home, mobile technology, and a new focus on PCMHs and ACOs is influencing the resurgence of the house call as a viable healthcare delivery model for frail, homebound elderly patients.

"I think it will follow a lot of trends we see with the hospitalist model and the skilled nursing facility model," Landers says. "More and more of those physicians are entirely focused on that particular venue."

Community providers, home health agencies, hospice care workers, home health aides, and personal care workers all provide services that can augment a house call practice. Landers says that a need exists for more physicians support and leadership among these community-based agencies, and establishing relationships with those entities can help patients stay in their homes longer.

Coding Insights

EXPECT A PRODUCTIVITY DECLINE AS YOU IMPLEMENT ICD-10

Q I've read a lot about the new International Classification of Diseases, 10th Revision (ICD-10), coding system, but other than necessitating that I learn new codes, what additional effects will it have on my practice?

THE MAJOR IMPACT you can expect to see in your practice due to ICD-10 is a drop in productivity.

The code sets associated with ICD-10, provided by the Centers for Medicare and Medicaid Services and the National Center for Health Statistics, are not a simple update. Rather, they adopt changes in structure and concepts that differentiate them greatly from ICD-9. In fact, this change will increase the number of codes from 17,000 to 140,000, including clinical modification (for diagnoses) and procedure coding system codes (for inpatient care).

In 2014, when ICD-10 takes effect, mastering the new code set will take even seasoned coders longer than it took to conquer ICD-9. Don't expect efficiency to normalize immediately following ICD-10 implementation, as payer interpretation of the new coding system will adversely affect productivity. Financial risk may be more favorable for either the payer or the provider, depending on which is better prepared to take on ICD-10.

Productivity will be affected for all participants in the healthcare system:

- **Physicians will be required to provide more detailed documentation related to disease etiology, anatomic site, and severity; healing stages; weeks in pregnancy; and episodes of care.**
- **Practice managers will have to establish a budget, create initial and ongoing training agendas, and review contracts to determine the impact of ICD-10.**
- **Nurses and laboratory staff will need to deal with revised forms, provide increased documentation, and learn revised authorization policies.**
- **Billing, coding, and front-desk personnel will be confronted with a new advanced beneficiary notice based on local and national coverage determinations; the need for updated and more complex super bills and encounter forms; and the increase in the number of codes.**

ICD-10 also will require greater knowledge of anatomy and medical terminology. Although the changes are extensive, the government believes this approach ultimately will lower costs and improve healthcare quality. ◻

YOU WILL BE REQUIRED TO PROVIDE MORE DETAILED DOCUMENTATION OF DISEASE ETIOLOGY, ANATOMIC SITE, AND SEVERITY; HEALING STAGES; WEEKS IN PREGNANCY; AND EPISODES OF CARE.

*The answer to this reader's question was provided by **Erline C. Franks,** CCS-P, CMRS, an associate director at SS&G Healthcare, Akron, Ohio. Send your primary care-related coding questions to **medec@advanstar.com**.*

How to coordinate care in a medical home

A good information system and engaged staff and patients are key to success

by **RACHAEL ZIMLICH,** *Associate Editor*

HIGHLIGHTS

01 The incentive to invest in the medical home is the knowledge that you'll be paid more for the quality of care you're delivering to the population you're taking care of rather than just treating them.

02 Soon, practices may use Patient-Centered Medical Home status as a marketing tool, and patients will begin to decide whether to keep a physician or find a new one based on how well they are cared for.

Becoming a Patient-Centered Medical Home (PCMH) isn't as simple as marking a few items off a checklist and incorporating them into a traditional practice. The transition usually involves a culture change within the practice and buy-in from the care delivery team to improve efficiency and patient health.

Although the benefits of becoming a PCMH—better outcomes, greater efficiencies and improved care coordination—have been well-documented, it is still difficult for many physicians to make the transition. This article explores some of the most important considerations for physicians in office-based practices and outlines the steps necessary in becoming a PCMH.

The first step in creating a practice focused on care coordination, says Bruce Bagley, MD, FAAFP, interim president and chief executive officer of TransforMed, is to identify the patient population within your practice most in need of this kind of care. Ultimately, you are creating a system to coordinate care for all patients—touching base with their specialists, getting copies of lab results, and following up on any treatment plans. To start, identify those patients with multiple referrals or hospital admissions.

Once you have identified this population, you will need to carefully consider a myriad of organizational questions and financial realities, including staff costs, time, software, and reimbursement. What system is in place to track all those patients, how will you pay for the software that best enables data collection and tracking and appoint an employee within your practice to facilitate patient care coordination?

1/ Decide whether you can afford the price

Offering your patients intimate, personalized care; coordinating their care with other providers; and improving their access to your services comes with a price. Costs are involved with implementing a PCMH and achieving the certification necessary to even begin thinking about leveraging PCMH status for increased reimbursements.

Salvatore Volpe, MD, FAAP, FACP, CHCQM, owns a small practice in Staten Island, New York. An early adopter of the PCMH model, Volpe says he first pursued recognition as a medical home in 2008, although he always believed his practice to be one.

"I knew I wanted to continue doing what I did," says Volpe, a member of the *Medical Economics* Editorial Board. "I think I've always practiced a PCMH. It was Marcus Welby, a Normal Rockwell practice. The ideal is there."

But back in 2008, and even now, Volpe says, increased reimbursements merely for achieving PCMH certification can be difficult to come by. Enhanced reimbursement is available, but it's difficult to find initially, he adds.

➔ 50

"YOU'RE NOT GOING TO WANT TO DO SOMETHING THAT TAKES MORE WORK UNLESS THERE'S A FINANCIAL BENEFIT."

JOSEPH E. SCHERGER, MD, MPH

➔44

"You don't want to do all this work—[especially if] you're an independent practice—and not get paid for it," adds Joseph Scherger, MD, MPH, also a member of the *Medical Economics* Editorial Board. Scherger is vice president of primary care and academic affairs at Eisenhower Medical Center in La Quinta, California.

Physicians need to be certain their finances can handle the transition to a PCMH before embarking on the journey, he says. That's because payment to cover care coordination is included as part of a PCMH's increased reimbursement, and from meeting quality metrics, rather than being billed under a specific code.

"You're not going to want to do something that takes more work and money unless there's a financial benefit," Scherger says.

In his community, Volpe says, increased reimbursements from payers for becoming a PCMH is more the exception than the rule, but it's different in other parts of the country. Some payers will provide grants or financial assistance for a practice to participate in a pilot program—an opportunity that Volpe says was available in his area.

"For the past 25 years, we have tried to do the right thing, even though there was little or no reimbursement for the time and effort," he says.

But physicians simply cannot depend on payers closing the income gap that can result after becoming a PCMH, Volpe says. He knew that he would have no significant reimbursements for his PCMH implementation costs and that it would cost him $50,000 to $75,000 to run his PCMH in terms of lost opportunities.

"If I could see 25 patients in an 8-hour day before becoming a medical home, I would probably only be able to see 15 patients in a day as a medical home," Volpe says.

Much of the burden in running a small practice as a medical home falls on the shoulders of the individual physician or physicians. You may not be able to afford to staff a care coordinator or more nursing staff, so if you are spending more time talking with patients and coordinating care, it obviously will mean that the volume of patients you are able to see will decrease, he explains.

Looking at patients metaphorically as an iceberg, Volpe explains that the current model of care only allows physicians to treat what is at the tip of the iceberg and get paid for that service. But as a medical home, Volpe says, he spends part of his time in the exam room treating the issue that brought the patient into his office and the remainder of the time talking about anything and everything else—what specialists he or she has seen since the last visit, how the family is at home, what is going on in his or her personal life, and how it is affecting the patient's health.

"That solidified the PCMH. It's what we want to take care of," Volpe says before returning to his iceberg analogy. "Most healthcare just deals with the little tip that's above the water. It doesn't give you a lot of opportunity to address all the health issues that patient might have. The only way to look under that water line is to give [the patient] time."

Although time is what will cost a physician most in missed opportunity with other patients, it also will provide room for possible bonuses. Volpe says that some payers are now offering reimbursement to cover additional communications with patients, such as secure emails and private patient portals. Some providers even charge fees for access to patient portals outside the exam room.

"That covers this missed opportunity cost," Volpe says.

Other options to offset the costs of running a PCMH include tapping into different payers or state and regional medical societies, getting involved in pilot programs, or finding side work—Volpe says his consulting work has been helpful in cushioning his "missed opportunities."

"I was willing to provide the best care I could, and I'm lucky enough to get consulting jobs, so that absorbs some of that $50,000 to $75,000 loss," Volpe says. "[But] if you can't absorb loss by providing more intensive care, then you can't afford it. If you willing to absorb it as a loss in income, that's a business decision. If you're lucky enough to have payers reimburse you better, that's the best way."

2/ Make a plan, and engage your staff

Once you're made the decision that your practice is ready and able to transition to a PCMH, Volpe recommends reviewing the many avenues to certification and choosing one. Several free resources are available, and Volpe recommends going through the National Committee for Quality Assurance (NCQA), a private, not-for-profit organization that offers guides ➔53

➔50 and accreditation resources based on where you are in the transition process. The organization's Web site, www.ncqa.org, he says, is helpful—even more so than when he started in the process.

"They've recognized that there are certain people who were willing to be early adopters and do more on their own, but to become more of the norm, they need more tools out there. And they have a lot of great free tools," Volpe says, adding that physicians can request a free copy of the standards and guidelines for becoming a certified PCMH as an early step to crafting their plan to become a medical home.

Once you've found some resources and started a plan, make sure your staff knows what's going on and is supportive of the practice's new direction, Volpe says.

"Make sure you have buy-in from your staff," he says. "It will require some refinement in how the practice operates."

"Leadership is key," Bagley says. "It's getting everyone to do something they normally wouldn't do on their own. If you have someone who's leading the effort to motivate everyone's hearts and minds to get them to work differently…that certainly is a key ingredient."

Scherger emphasizes to his staff the importance of being pro-active in managing conditions, especially diabetes and other chronic diseases.

"The traditional practice is about reacting to the needs of the patients who come in that day," he adds. "Under the PCMH, we reach out to the patient. 'Your last lab results were out of control. Are you taking your meds?' That's the approach we emphasize to our staff," he says.

Regional extension centers associated with the Office of the National Coordinator for Health Information Technology can provide additional assistance, Volpe says. Originally set up to provide support for meaningful use requirements, the agency's goals overlap much with PCMH initiatives. They both support new ways to collect information, offering data transparency for patients, and the idea that the patient and physician need to work as a team.

As you increase connectivity between the patient and the provider and attest to meaningful use, you are already about one-third of the way toward achieving PCMH status, Volpe says.

3/ Check your information systems, and assign a care coordinator

"You can't start at all until you've got an information system that allows you to look at your population," Scherger says. "It isn't just paper charts on a wall and you're taking care of patients one at a time. You have to be able to pull up who your diabetic patients are. Who are your patients with high blood pressure? You need to be able to begin to look at your practice as a population."

One of the real "scandals" of electronic health records (EHR) systems has been the lack of registry functions, Scherger says. Early EHR systems didn't have any way to search a patient database for population information. Now, that capability finally is being added.

"You've got to make sure that your EHR has registry function that lets you do population management," Scherger says. "If you don't, it needs to be upgraded or changed or you can't be a PCMH."

Sometimes, practices will have to buy an add-on, but Scherger says it's imperative to be able to capture all your core criteria. The registry doesn't even need to be in your EHR system, he adds. Freestanding registry systems are available, he adds, reiterating that the key is getting a system and a mindset that gets you to think about your practice in terms of population management. The continuous, coordinated care at the center of the PCMH philosophy depends on being able to see where your patients have been and where they are now. (For more information on stand-alone registries as well as those that are part of EHRs, see the article that begins on page 58.)

A good registry should have five key functions, Bagley adds:

- It has to be able to create a list of all your patients with a specific condition.
- It has to be able to generate a status report for each of those patients outlining what parameters are in range so you can quickly assess where there are gaps in care.
- It should be able to aggregate all the patients within the practice who have that condition so you can begin to offer population-based care to the group.
- It should support outreach efforts. Once a population is identified, the registry should be able to easily provide phone numbers or other

"LEADERSHIP IS KEY. IT'S GETTING EVERYONE TO DO SOMETHING THEY NORMALLY WOULDN'T DO ON THEIR OWN."

BRUCE BAGLEY, MD, FAAFP

Critical steps along the way to PCMH care coordination

Costs, engagement of staff and patients, and certification requirements all important as you change your practice

☑ STEP 1: Identify costs of implementation within your practice.
Do you have an electronic health record (EHR) system? Does it include a registry function? If you must purchase a registry system, how much will an interface with your EHR system cost? Do you have an existing employee to appoint as a care coordinator for the practice, or do you have to hire one? After identifying these costs, decide whether your practice can absorb those additional costs or whether you need to seek out grants, become part of a pilot program, or negotiate higher payments from payers.

☑ STEP 2: Engage staff.
Becoming a Patient-Centered Medical Home (PCMH) isn't all about costly new technology systems. It's about transforming the way your practice operates from treating patients individually to treating them by population groups and coordinating their care—even the care they receive outside your practice. A PCMH also relies on the idea that the practice is more than just the physician. Some clinical duties and much of the care coordination work can and should be delegated to other members of the practice team. Becoming a PCMH is a cultural change, experts say, and it requires strong leadership and staff buy-in if it is going to work.

☑ STEP 3: Set up information technology systems to allow for better care coordination.
An ideal system will track patients with specific conditions by population group and provide the practice with data about their baselines and what specialists they are seeing, facilitate communication with those specialists, track necessary services and what appointments are needed, and allow someone within the practice to contact the patient for scheduling. Making sure care of each patient within a population is coordinated across each of their providers is a key element to becoming a PCMH.

☑ STEP 4: Engage patients, and make them a part of the process.
Many PCMHs have found success in engaging patients in the care process by creating personalized resources, online portals, and support groups. Giving patients greater access to their health records and bringing them into the process will help them to become more actively engaged in the process, thereby creating a two-way dialogue between the healthcare provider and the patient.

☑ STEP 5: Know the requirements for certification, and seek out a program that can help guide you through the process.
The National Committee for Quality Assurance (www.ncqa.org), the American College of Physicians (www.acponline.org), the Commonwealth Fund (www.commonwealthfund.org), the Patient-Centered Primary Care Collaborative (www.pcpp.net), the American Academy of Family Physicians (www.aafp.org), and the Agency for Healthcare Research and Quality (www.pcmh.ahrq.gov) are just a few of the organizations that have guides, online tools, and resources to help walk practices along the path to PCMH certification.

ways to get in touch with those patients for additional follow-up or appointment scheduling.

- It should include a function to report quality measures for PCMH certification purposes.

This all takes time and work, Bagley says, and many practices appoint a care coordinator.

"Care coordination can vary with the acuity of the patient mix," says Volpe. "For us it can run from 10% to as much as 30% of the work week.

Designating a staff member as a care coordinator is ideal, Scherger says. In his practice each physican is assigned a care doordinator, who spends 1 to 2 hours per day performingcoordination-related tasks." A larger practice could have a full-time nurse doing it 40 hours per week," he says.

Contrary to popular belief, Bagley says, the care coordination doesn't necessarily need to be a full-time employee. In small practices especially, he says physicians should select one loyal staff member and obtain for him or her the training needed to perform the care coordination functions.

But your practice needs someone to co-

ordinate care on a daily basis, making sure referrals happen, ensuring that the right lab work is being done, making sure that diabetic patients are getting in on time and that they are seeing their other specialists. Practices operating this way are able to offer care proactively.

"Medicine traditionally is visit-based and is almost 100% reactive," Scherger says, adding it helps to have an information system that can tell you how you're doing and a care coordinator to reach out to patients and get them in for care that allows the physician to become strategically proactive with their care coordination. "That makes a huge difference."

For example, a good information system will deliver to the practice data on how many women aged more than 50 years the practice cares for and how many haven't had a mammogram in the past 2 years. A care coordinator then could call and schedule a mammogram for those patients who are in need, Scherger says. In a PCMH, more than half of patients in a subgroup should be getting the recommended care—and up to 85% in an advanced PCMH.

The care coordinator also will track referrals. He or she should be aware of all referrals being made from the practice, Scherger says. Every medical assistant (MA) should be performing that task, too, and information systems should back up staff efforts.

A good medical home practice refers a patient, then sends the specialist a summary of the patient's medical records. The primary care physician then should receive information back from the referral source or should request it if needed, and review those data before the patients' next visit.

"You go beyond the days where you're seeing a patient without the information you need," Scherger says.

But to achieve this system of care, Scherger says, practices will need to operate more efficiently and make better use of their resources.

"You need to begin to assign to your staff everything they can do within their license," he adds. In a traditional practice, the doctor does everything and everyone else is ancillary. In a medical home, the delivery of healthcare is now a team activity where MAs have been trained to know what patients need.

"Make sure your staff comes to work every day not just wondering what their schedule looks like but how they will make population healthier," Scherger says.

4/ Engage patients to become partners

The public didn't warm up to online banking, booking their own travel, or other self-service initiatives overnight, and their traditionally passive role in their own healthcare will take some time to change. But Scherger says that giving patients more access and power will help them take control and become more actively engaged in their healthcare decisions.

The goal of the PCMH is informed and activated patients, he says. When they know what they're supposed to do and can access their records more easily, they can take more ownership of the process. At Kaiser, Scherger says, patients order all of their own medical tests—under the observation of their healthcare team, of course. The system has reduced patient visits by 25% by letting patients do more online. Although decreased visits may seem counterproductive, Scherger says the case is actually the opposite.

"In many offices, doctors wish they had more time with the patients who really need to be there," he says. "If you can offer continuous access online to some patients, you can reserve office time for the patients who need it more."

Online platforms help increase patient engagement, as do group visits that focus on particular subgroups. Gather all of the diabetic patients together to discuss their care and what the medical home can do for them; let them know you want to be as helpful as possible, Scherger says. Patients will begin to ask more questions, and you can urge them to keep their own calendars of the things they need to do.

"Get away from the paternalism, and put the responsibility on the patient," he says. "Patients have not had any power or ability. I think that's why they've stayed relatively passive."

Secure patient portals create an entire new dynamic with patients and increase efficiencies within the practice by allowing staff to handle simpler matters in less time.

For example, a recent study found that out of 2,000 patients, roughly 50 need something from the office on a given day, Scherger says. A visit will take about 20 minutes of a physician's time,

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"IF I COULD SEE 25 PATIENTS IN AN 8-HOUR DAY BEFORE BECOMING A MEDICAL HOME, I WOULD PROBABLY BE ABLE TO SEE 15 PATIENTS IN A DAY AS A MEDICAL HOME."

SALVATORE VOLPE, MD, FAAP, FACP, CHC-QM


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→55 and patient requests and questions by phone require an average of 7 to 8 minutes of synchronous communication. But what if you could handle 20 or 30 of your daily requests at your mutual convenience online? The average time to process an online request is about a minute, Scherger says.

"You can re-engineer your practice to care for more people in less time through efficiency," he says. "Continuous care means taking your demand and handling it way more efficiently."

MORE CHANGES TO COME

For those about to go down the PCMH path or thinking about it, Volpe says it will get easier.

Increasingly, EHR companies are realizing that a lack of searchable data is a barrier to many practices. This functionality has to make it easier for physicians to provide evidence for the organizations that provide recognition, Volpe says. Indeally, physicians could add data into their EHR systems and have a report created for recognition agencies within the scope of the patient visit.

EHRs also could help identify better reimbursement models in the future, Volpe says. For example, he adds, his EHR service is now offering to meet virtually with practices and look at what kinds of additional reimbursements are available in their areas in terms of meaningful use money and grants. For a fee, it will provide a physician with the reporting tools to help apply for those grants.

Headway already is being made in terms of the time it takes to satisfy the requirements to become certified as a medical home, Volpe says.

"It took me a whole year to attest for 2008, in terms of getting all the evidence," he says. "Every weekend, my office manager and I would go through the electronic records and say, 'How do we prove to NCQA how we did this?' For 2011, the EHR was a little bit more mature, and there were more and more reports we could press a button and generate, but there was still a certain amount of manual data extraction that had to be one. Newer EHRs are making it easier for doctors."

EHR vendors may make you pay for newer modules that help you extract the data you need, but the cost is relative, Volpe says. If it takes a physician 50 hours to compile the data, considering the value of his or her time and the cost of the program, Volpe says, he would gladly pay the money up front.

"If I could be spending time with my family, why would I want to be making a spreadsheet?" he asks.

Scherger adds that although physicians may worry about how to pay for the PCMH transition now, that won't be as much of a concern in the future.

"Everything is moving toward quality being the new finance," he says. "The real imperative to invest in the medical home is the understanding that you'll be paid more for the quality of care you're delivering to the population you're taking care of rather than just treating them."

Volpe estimates that the likelihood of enhanced reimbursement for PCMH status will continue to increase over the next year. PCMH status will become a marketing tool, and patients will begin to decide whether to keep their physician or find a new one based on how well they are cared for in the future, he says.

"The next thing in primary care will be patients asking, 'Is he a PCMH Level 3?' To be book smart and not provide the services some people want is not enough," Volpe says. "Just provide the extra time to better help patients help themselves. You patients will appreciate it better, and you're more likely to hold on to patients if you do it."

Technology

Registries: Powerful tools to track, manage chronic diseases

Although many EHR systems are building in registry functionality, a usable system can be simple and inexpensive to implement for common diseases

by **JOSEPH JALKIEWICZ**

HIGHLIGHTS

01 A registry helps you compile and review aggregate data on common—and often preventable—health conditions and provide improved patient care.

02 Newer electronic health record systems come with registry functions or can interface with a registry. Stand-alone registries also are available.

The practice of medicine is shifting from one rooted in episodic care to one that focuses on better managing chronic disease conditions and improving the overall health status of a physician's patient panel.

HELPING TO fuel this transition is the emergence of new pay-for-performance models and federal mandates that tie physicians' financial health more closely to the health of their patients.

Some of the electronic health record (EHR) systems have built in this functionality to enable you to easily compile and review aggregate data relating to some of the most common—and often preventable—health conditions, including obesity and diabetes, as well as others that can be more effectively managed, such as hypertension, arthritis, and heart disease. But not all systems have this functionality.

So just how can small family or internal medicine practices track and monitor data to improve care of patients with chronic illnesses if the EHR system used in the practice does not include this capability? How can you identify the top areas to track within your own patient population, including immunizations, pre-hypertension and hypertension, obesity, and other conditions? What are the best strategies to use population health statistics to better develop programs for the most common conditions seen in family and internal medicine practice?

"Registries," says Bruce Bagley, MD, medical director for quality improvement for the American →60

Diminished cerebral glucose metabolism: A key pathology in Alzheimer's disease

More than three decades of research have revealed that diminished cerebral glucose metabolism (DCGM), also known as glucose hypometabolism, is a key underlying pathological change in the Alzheimer's brain.[1] DCGM leaves a large portion of the brain's energy needs unfulfilled and correlates with cell death and cognitive dysfunction.[2] DCGM occurs years before clinical symptoms of cognitive decline become evident.[1] Targeting DCGM represents a promising new therapeutic strategy for patients with Alzheimer's disease (AD).

The brain depends on glucose for cognitive function

The human brain is one of the most metabolically active organs in the body and metabolizes a large amount of glucose to produce adenosine triphosphate (ATP).[1] Despite its high energy demands, the brain is relatively inflexible in its ability to utilize substrates for energy production and relies almost entirely on circulating glucose for its energy needs.[1,2] This dependence on glucose puts the brain at risk if the supply of glucose is interrupted, or if its ability to metabolize glucose becomes defective.[2] If the brain is not able to produce ATP, synapses cannot be maintained and cells cannot function, ultimately leading to impaired cognition.[2]

DCGM is a well-characterized feature of AD

DCGM was an early observation in AD. Studies from almost 30 years ago found a 17%-24% decline in cerebral glucose metabolism in patients with AD, compared with age-matched controls.[3] Numerous imaging studies have since confirmed this observation.[1]

Abnormally low rates of cerebral glucose metabolism are found in a characteristic pattern in the AD brain, particularly in the posterior cingulate, parietal, temporal, and prefrontal cortices. This pattern is reproducible and has even been proposed as a diagnostic tool for AD.[1]

DCGM occurs early in the disease process

In a pivotal study, Reiman and colleagues demonstrated how early the pathology can begin. The study compared cerebral glucose metabolism in patients with probable AD and young adults (mean age 30.7 years) at high genetic risk of AD (APOE4 carriers). The young adult APOE4 carriers showed no signs of cognitive impairment or plaque deposition, yet DCGM was detected in the same areas of the brain as subjects with AD.[4]

DCGM is not exclusive to APOE4 carriers. By the time Alzheimer's has been diagnosed, DCGM occurs across genotypes APOE3/E4, APOE3/E3, and APOE4/E4.[5]

Given that DCGM occurs before other clinical changes occur, it is unlikely to be due to the gross cell loss observed in AD.[2]

Targeting DCGM in AD

Improving memory performance by chronically raising glucose levels has had some success in animal models and humans. However, this approach is impractical and may not address the problem of DCGM, particularly as glucose levels generally remain normal in AD. This has led to the exploration of alternative fuel sources, such as ketones, to help fuel the brain.[2]

Fueling the brain with ketones in neurodegenerative diseases

During times of diminished cerebral glucose metabolism, the brain is able to use ketones as a back-up fuel source. When glucose levels are low, for example when food is scarce, the liver is naturally triggered to generate ketones as a survival mechanism.[1]

In AD, this natural ketone back-up system can be harnessed to address DCGM. Research has shown that exogenously raising ketone levels is neuroprotective *in vitro* and can enhance memory and cognition *in vivo*.[6-8,10] Indeed, ketogenic diets have a long and successful clinical history. However, they can be impractical, particularly in patients with AD.[2]

Safe elevation of ketone levels

Inducing ketosis through the administration of medium-chain triglycerides (MCTs) has produced promising results in AD. MCTs have unique ketogenic properties due to their medium fatty acid chain lengths. Importantly, MCTs are converted to ketones regardless of other macronutrients consumed; therefore, no dietary restrictions are required.[1]

Now, there is a prescription **medical food** available that safely increases the concentration of ketones. Axona® contains MCTs that are converted to ketones in the liver and then transported to the brain to be used as fuel along with glucose.[9]

Fuel memory and cognition by targeting DCGM in AD

In a phase IIb, 90-day clinical trial, Axona enhanced memory and cognition in APOE4(-) patients with mild to moderate AD. Approximately 80% of trial patients took Axona in combination with one or more approved medications for AD. At the end of the trial period, patients continued with their existing medication, but stopped taking Axona. During this time, the significant effects of Axona ceased.[10]

Axona is the only available prescription therapy that addresses diminished cerebral glucose metabolism, an underlying pathology of AD. Current treatments only target symptoms of the disease.[1] Adding Axona to traditional therapies addresses different aspects of AD at the same time and can help make the biggest impact in enhancing memory and cognition.[10]

References: 1. Henderson ST. Ketone bodies as a therapeutic for Alzheimer's disease. *Neurotherapeutics.* 2008;5(3):470-480. **2.** Costantini LC, Barr LJ, Vogel JL, Henderson ST. Hypometabolism as a therapeutic target in Alzheimer's disease. *BMC Neurosci.* 2008;9(Suppl 2):S16. **3.** de Leon MJ, Ferris SH, George AE, et al. Positron emission tomographic studies of aging and Alzheimer disease. *AJNR Am J Neuroradiol.* 1983;4(3):568-571. **4.** Reiman EM, Chen K, Alexander GE, et al. Functional brain abnormalities in young adults at genetic risk for late-onset Alzheimer's dementia. *Proc Natl Acad Sci USA.* 2004;101(1):284-289. **5.** Corder EH, Jelic V, Basun H, et al. No difference in cerebral glucose metabolism in patients with Alzheimer disease and differing apolipoprotein E genotypes. *Arch Neurol.* 1997;54(3):273-277. **6.** Reger MA, Henderson ST, Hale C, et al. Effects of β-hydroxybutyrate on cognition in memory-impaired adults. *Neurobiol Aging.* 2004;25(3):311-314. **7.** Kashiwaya Y, Takeshima T, Mori N, et al. D-β-Hydroxybutyrate protects neurons in models of Alzheimer's and Parkinson's disease. *Proc Natl Acad Sci USA.* 2000;97(10):5440-5444. **8.** Van der Auwera I, Wera S, Van Leuven F, Henderson ST. A ketogenic diet reduces amyloid beta 40 and 42 in a mouse model of Alzheimer's disease. *Nutr Metab (Lond).* 2005;2:28. **9.** Axona [prescribing information]. Broomfield, CO: Accera, Inc.; November 2012. **10.** Henderson ST, Vogel JL, Barr LJ, et al. Study of the ketogenic agent AC-1202 in mild to moderate Alzheimer's disease: a randomized, double-blind, placebo-controlled, multicenter trial. *Nutr Metab (Lond).* 2009;6:31.

For more information on DCGM in Alzheimer's disease, visit **www.dcgm.com**.

"YOU SIMPLY CANNOT TAKE GOOD CARE OF PATIENTS WITHOUT A REGISTRY. YOU JUST CAN'T."

BRUCE BAGLEY, MD

SETTING UP A REGISTRY

STEPS

- Install a patient registry system.
- Input data.
- Integrate data collection into the care process.
- Identify needed care.

WHAT YOU WILL NEED

- A patient registry function, available in certain electronic health record systems, a database program, or Internet access.
- Time to input data.
- Training to learn how to use the registry system.

@ FOR MORE INFORMATION: www.aafp.org/pcmh/registry

Source: American Academy of Family Physicians

HOW TO CHOOSE AND USE A REGISTRY

Here's what to focus on if you are looking to a registry to help you manage chronic conditions in your practice:

- **Choose a registry that supports the chronic conditions you most frequently see in your practice.**
- **Be sure the registry fits within the technical and financial limitations of your practice. If you are choosing an electronic health record system, buy one with the capabilities of a registry or the capability to interface with a registry. Otherwise, for a stand-alone registry or open registry, you will need one or more computers and an Internet connection or private network.**
- **Be sure that the data you enter are up to date, complete, and accurate.**
- **Incorporate use of the registry into your normal workflow. Rethink how you prepare for and conduct patient visits, create new processes for follow-up, and produce and distribute feedback reports.**

Source: "Using Computerized Registries in Chronic Disease Care," California HealthCare Foundation

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Academy of Family Physicians (AAFP). "Registries, registries, registries. They're the answer to every one of those questions."

In its simplest form, a registry can be built as a way to track a disease or condition in your patient panel, or you can join an open registry to share and compare data with other providers about a chronic disease condition.

Like their big brothers, full-blown EHR systems, disease registries can be used to track clinical patient data across a wide range of conditions and measure the quality of patient care against various payer and government standards.

According to the Health Resources and Services Administration, part of the U.S. Department of Health and Human Services, registries can help a practice with:

- **printed patient reports at the point of care, which remind practitioners of appropriate tests and interventions as well as record-updating responsibilities;**
- **progress reports, which provide information about patient improvement or areas of concern;**
- **registry-generated exception reports, which point out patients due for care as well as those whose results do not fall within acceptable ranges; and**

Miserable over EHRs? You have company

Healthcare in general and many providers in particular are having a tough time making the most of electronic health record (EHR) systems, according to recently published white papers and study results.

"Significant challenges still lie in the way of health care's ability to leverage big data effectively. [H]ealth care data [are] rarely standardized, often fragmented, or generated in legacy [information technology] systems with incompatible formats. Healthcare data [are] also diverse and distributed in hard-to-penetrate silos owned by a multitude of stakeholders," reports Transforming Health Care Through Big Data, a white paper published in February by the Institute for Healthcare Technology Transformation, a Washington, D.C., health information technology consulting firm.

The paper cites a 2012 poll conducted by Oracle stating that although healthcare organizations are accumulating 85% more data than they did in 2010, 77% of healthcare executives give their organizations a "C" or below for managing their data. Oracle polled 333 U.S. and Canadian C-level executives from healthcare and 10 other industries. Moreover, 43% of the healthcare leaders polled reported being unable to collect sufficient data to improve care of their patient population.

In addition, the results of a survey reported at the 2013 HIMSS conference in New Orleans, Louisiana, indicate growing dissatisfaction among physicians with their EHR systems. Conducted by AmericanEHR in conjunction with 10 professional societies between 2010 and 2012, the survey found:

- An overall 12% drop in "satisfied" EHR users during the 2-year period and a corresponding 10% increase in "very dissatisfied" users.
- In 2012, 39% of clinicians would not recommend their EHR to a colleague.
- The number of users who were "very satisfied" with their EHRs ability to improve patient care dropped 6%; the number of "very dissatisfied" users grew by 10%.
- Satisfaction with ease of use dropped 13%; 37% of physicians reported increased dissatisfaction in 2012 compared with 23% in 2010.
- 34% of users in 2012 were very dissatisfied with the ability to decrease workload compared with 19% in 2010.

"DATA COLLECTION HAS TO BE TIED TO THE CARE DELIVERY WORKFLOW WHENEVER POSSIBLE."

NEIL TREISTER, MD

- stratified population reports, which look at patients across a practice.

Bagley unabashedly believes that registries represent the single best way for small primary care practices not just to meet the mandates of meaningful use, but also to help take the best possible care of patients who have chronic conditions such as diabetes, asthma, heart disease, hypertension, and depression, among others.

REGISTRY REALITIES

Registries can be labor intensive to launch and maintain, at least in the early stages of implementation.

According to the AAFP, the typical family medicine practice patient panel includes anywhere from 10 to 20 patients with chronic obstructive pulmonary disease to 150 to 200 patients who have diabetes and associated conditions.

Like EHRs, many open registries still suffer from a lack of interconnectivity, the technical term for the systems' inability to "play well" with outside systems, such as those operated by radiology clinics, laboratories, and even transcription services.

"Something needs to be said about interfaces to labs, hospitals, radiology, etc.," says Neil Treister, MD, FACC, medical informatics officer at ➔64

"It's huge to access patient data through Greenway's PrimeSUITE EHR — to do it in real time, at night or on the weekend from wherever I am."

David Savage, MD
Orthopedic Surgeon
Texas Orthopedics, Sports and Rehabilitation Associates
Austin, TX

HEALTHCARE REVOLVES AROUND DATA AND REPORTING, SO BUILDING A CONNECTED COMMUNITY is a no-brainer. But how? Greenway provides a solution that your affiliate staff will embrace, that provides the right clinical analytics, uses standards-based interoperability with acute care systems, and is backed by customer service that's the envy of the industry. We believe that building a smarter healthcare system can begin today. How can we help you?

"Finally, we have a solution in Greenway for patients to get what they need, with the security that everyone needs."

Michele A. Kettles, MD, MSPH
Chief Operations Officer
Cooper Clinic
Dallas, TX

"With PrimeSUITE, the data's there and I don't have to worry about shuffling through a chart. I spend my time talking to the patient about how we're going to use this to improve things."

W. Reese Baxter, MD
Medical Director
COMCARE, P.A.
Salina, KS

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"It's unbelievable the timesaving that we're able to do just by setting it up. Ease of use is a huge, huge timesaver."

Twyla Fuertes
Chief Business Officer
Texas Orthopedics, Sports and Rehabilitation Associates
Austin, TX

"We have no regrets. It's been an amazing journey."

Mona S. Engle, RN
Practice Administrator
Doctors May•Grant Associates
Lancaster, PA

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Resources

The American Academy of Family Physicians (AAFP) offers resources for getting started with patient registries:

- **"Improve Care with Patient Registries." This AAFP video reviews the purpose, functions, and benefits of patient registries and offers advice on getting started. www.aafp.org/pcmh/videos**
- **"Set up a Patient Registry." This Web page summarizes the steps involved in developing a registry. www.aafp.org/pcmh/registry**

@ For additional information on registries, especially how they are used in Patient-Centered Medical Homes, see the article beginning on page 44.

➔61 the Sharp Community Medical Group in San Diego, California. "Those are incredibly problematic and expensive. And yet having that information electronically is critical for making the office paperless. I think 90% of our frustration is connecting to other entities."

"He's right," Bagley says, "but the technology's getting better all the time, and vendors are beginning to address those issues with advances in the technology."

In the meantime, Bagley and other physicians offer the following suggestions for leveraging electronic health information to improve care of patients with chronic conditions:

Metrics: Start small, and retain control.
"Decide on a single metric, and commit to measuring it," says Jason Mitchell, MD, assistant director of the AAFP's Center for Health Information Technology.

Alan Wynn, MD, FACP, who operates a two-physician family practice in Woodbridge, Virginia, agrees.

"Tackle just one or two diseases, and understand how the EHR can help," he says. "I would suggest selecting a high-volume disease, an area in need of improvement, or an area of interest. For example, if diabetes, I would want to know my quality statistics and want to show that I provide excellent care."

Although defining metrics and objectives was difficult in the past, they now exist for some areas, Wynn says, noting that the National Committee for Quality Assurance provides population standards for diabetes and hypertension management.

"I also used Healthy People 2010—now Healthy People 2020—for other goals such as colonoscopy and mammogram rates," he says. "Centricity voluntarily collected data from users and had a database with several million patients, and I could compare my results to this database."

Another key for smaller family and internal medicine practices, Wynn says, is to focus on metrics that can be easily controlled.

"I can administer [pneumonia] and flu shots, but many of my patients see a gynecologist for mammograms and Pap smears," he says. "Sometimes, the gynecologist would send me a copy of the results, but often I had to rely on the patient telling me the test was done. I made the decision that the time and effort to track down the hard copy of the results is not a good use of office staff time."

Don't rely solely on vendor promises or off-the-shelf products.
"Meaningful panel management and quality improvement requires intensive customization of EHR systems or the addition of other systems to your existing EHR to get real results," Mitchell says. "Unfortunately, it is a lot of work and it really shouldn't be. Meaningful quality measurement and improvement should be a by-product of appropriate clinical care."

Foster a culture of continuous quality improvement.
"Firing up the latest expensive health information technology quality improvement tool will not make a bit of difference if your practice doesn't have the capacity and commitment to adapt," Mitchell says.

Data entry: Go team!
"The real bang for the buck is using the office staff to complete the quality data," Wynn says. "For example, if a patient has diabetes, the [medical assistant (MA)] should have the patient remove [his or her] shoes for the foot exam. If the MA is trained, [he or she] could even perform and chart the foot exam. Protocols can be set up for staff to administer vaccines to selected patients and enter orders for mammograms and colonoscopies."

Treister agrees. "Data collection has to be tied to the care delivery workflow whenever possible," he says. "Duplication of efforts to collect data for chronic care management is too resource intensive."

THE BOTTOM LINE

Ultimately, leveraging electronic health information to improve the physical health of your patients with chronic disease while improving the financial health of your practice relies on a multi-pronged approach involving teamwork and flexibility, both in terms of data and the infrastructure being used to gather and employ it.

"Data liquidity is the key," Mitchell says. "Monolithic EHRs are not the only way to manage health information effectively and, in fact, dependence on a single system from a single vendor may be seriously impeding our ability to improve the care we provide.

"We need to be able to collect health information once and leverage it across multiple systems for multiple purposes, all in the interest of improving our patients' health and wellness," he concludes. ◘

For the treatment of hypertension




BYSTOLIC.

Significant blood pressure reductions with a low incidence of side effects.

- Significant blood pressure reductions as monotherapy[1-5]
- Significant blood pressure reductions as add-on therapy or initial combination therapy[1,4,6,7]
- Low incidence of side effects[1]
  - — Discontinuation rate due to adverse events was 2.8% for BYSTOLIC vs 2.2% for placebo[1]

Important information about the cardiovascular benefits of lowering blood pressure

- The Food and Drug Administration (FDA) issued a guidance to explicitly make the connection between lowering blood pressure and improved cardiovascular outcomes in antihypertensive class labeling to address the public health concern of inadequate treatment of hypertension[8]
- The BYSTOLIC Prescribing Information has been updated based on this guidance
  - — BYSTOLIC reduces blood pressure[1]
  - — Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions[1]
  - — There are no controlled trials demonstrating risk reduction with BYSTOLIC, but at least one pharmacologically similar drug has demonstrated such benefits[1]
  - — Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake[1]
  - — Many patients will require more than one drug to achieve blood pressure goals[1]

Important Safety Information

Contraindications

- BYSTOLIC is contraindicated in patients with severe bradycardia, heart block greater than first degree, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome (unless a permanent pacemaker is in place), severe hepatic impairment (Child-Pugh >B), and in patients who are hypersensitive to any component of this product.

Warnings and Precautions

- Do not abruptly discontinue BYSTOLIC therapy in patients with coronary artery disease. Severe exacerbation of angina, myocardial infarction, and ventricular arrhythmias have been reported following the abrupt discontinuation of therapy with beta blockers. Myocardial infarction and ventricular arrhythmias may occur with or without preceding exacerbation of the angina pectoris. Caution patients without overt coronary artery disease against interruption or abrupt discontinuation of therapy. As with other beta blockers, when discontinuation of BYSTOLIC is planned, carefully observe and advise patients to minimize physical activity. Taper BYSTOLIC over 1 to 2 weeks when possible. If the angina worsens or acute coronary insufficiency develops, restart BYSTOLIC promptly, at least temporarily.

Adverse Reactions

- The most common adverse events with BYSTOLIC versus placebo (approximately ≥1% and greater than placebo) were headache, fatigue, dizziness, diarrhea, nausea, insomnia, chest pain, bradycardia, dyspnea, rash, and peripheral edema. The most common adverse events that led to discontinuation of BYSTOLIC were headache (0.4%), nausea (0.2%), and bradycardia (0.2%).

Please see full indication and additional Important Safety Information on the following page and brief summary of the full Prescribing Information on the last page of this advertisement.

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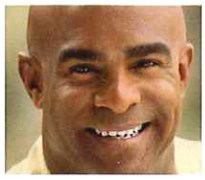


BYSTOLIC is widely available on commercial and Medicare Part D formularies.

85% unrestricted access on commercial formularies[9]

84% unrestricted access on Medicare Part D formularies[9]

Indication

- BYSTOLIC is indicated for the treatment of hypertension, to lower blood pressure. BYSTOLIC may be used alone or in combination with other antihypertensive agents. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. There are no controlled trials demonstrating risk reduction with BYSTOLIC, but at least one pharmacologically similar drug has demonstrated such benefits.
- Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals.

Important Safety Information (continued)

Warnings and Precautions

- BYSTOLIC was not studied in patients with angina pectoris or who had a recent MI.
- In general, patients with bronchospastic diseases should not receive beta blockers.
- Because beta blocker withdrawal has been associated with an increased risk of MI and chest pain, patients already on beta blockers should generally continue treatment throughout the perioperative period. If BYSTOLIC is to be continued perioperatively, monitor patients closely when anesthetic agents which depress myocardial function, such as ether, cyclopropane, and trichloroethylene are used. If beta-blocking therapy is withdrawn prior to major surgery, the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.
  The beta-blocking effects of BYSTOLIC can be reversed by beta agonists, eg, dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Additionally, difficulty in restarting and maintaining the heartbeat has been reported with beta blockers.
- Beta blockers may mask some of the manifestations of hypoglycemia, particularly tachycardia. Advise patients subject to spontaneous hypoglycemia and diabetic patients receiving insulin or oral hypoglycemic agents about these possibilities.
- Beta blockers may mask clinical signs of hyperthyroidism, such as tachycardia. Abrupt withdrawal of beta blockers in these patients may be followed by an exacerbation of symptoms or may precipitate a thyroid storm.
- Beta blockers can precipitate or aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease.
- Because of significant negative inotropic and chronotropic effects in patients treated with beta blockers and calcium channel blockers of the verapamil and diltiazem type, monitor the ECG and blood pressure of patients treated concomitantly with these agents.
- Use caution when BYSTOLIC is co-administered with CYP2D6 inhibitors (quinidine, propafenone, fluoxetine, paroxetine, etc). When BYSTOLIC is co-administered with an inhibitor or an inducer of CYP2D6, monitor patients closely and adjust the nebivolol dose according to blood pressure response. The dose of BYSTOLIC may need to be reduced. When BYSTOLIC is administered with fluoxetine, significant increases in d-nebivolol may be observed (ie, an 8-fold increase in AUC and a 3-fold increase in C_{max} for d-nebivolol).
- Renal clearance of nebivolol is decreased in patients with severe renal impairment. In patients with severe renal impairment (ClCr less than 30 mL/min) the recommended initial dose is 2.5 mg once daily; titrate up slowly if needed. BYSTOLIC has not been studied in patients receiving dialysis.
- Metabolism of nebivolol is decreased in patients with moderate hepatic impairment. In patients with moderate hepatic impairment, the recommended initial dose is 2.5 mg once daily; titrate up slowly if needed. BYSTOLIC has not been studied in patients with severe hepatic impairment and therefore it is not recommended in that population.
- Patients with a history of severe anaphylactic reactions to a variety of allergens may be more reactive to repeated challenge and may be unresponsive to the usual doses of epinephrine while taking beta blockers.
- In patients with known or suspected pheochromocytoma, initiate an alpha blocker prior to the use of any beta blocker.

Drug Interactions

- Do not use BYSTOLIC with other beta blockers.
- Both digitalis glycosides and beta blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia.
- BYSTOLIC can exacerbate the effects of myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists (particularly of the phenylalkylamine [verapamil] and benzothiazepine [diltiazem] classes), or antiarrhythmic agents, such as disopyramide.

Use in Specific Populations

- Use BYSTOLIC during pregnancy only if the potential benefit justifies the potential risk to the fetus. BYSTOLIC is not recommended during nursing.
- The safety and effectiveness of BYSTOLIC have not been established in pediatric patients.
- In a placebo-controlled trial of 2128 patients (1067 BYSTOLIC, 1061 placebo) over 70 years of age with chronic heart failure receiving a maximum dose of 10 mg per day for a median of 20 months, no worsening of heart failure was reported with nebivolol compared to placebo. However, if heart failure worsens, consider discontinuation of BYSTOLIC.

Please see brief summary of the full Prescribing Information on the following page of this advertisement.

References: 1. BYSTOLIC [package insert]. St. Louis, Mo: Forest Pharmaceuticals, Inc.; 2011. **2.** Germino FW. Efficacy and tolerability of nebivolol monotherapy by baseline systolic blood pressure: a retrospective analysis of pooled data from two multicenter, 12-week, randomized, double-blind, placebo-controlled, parallel-group, dose-ranging studies in patients with mild to moderate essential hypertension. *Clin Ther.* 2009;31:1946-1956. **3.** Data on file. Forest Laboratories, Inc. **4.** Lacourcière Y, Lefebvre J, Poirier L, Archambault F, Arnott W. Treatment of ambulatory hypertensives with nebivolol or hydrochlorothiazide alone and in combination: a randomized, double-blind, placebo-controlled, factorial-design trial. *Am J Hypertens.* 1994;7:137-145. **5.** Saunders E, Smith WB, DeSalvo KB, Sullivan WA. The efficacy and tolerability of nebivolol in hypertensive African American patients. *J Clin Hypertens.* 2007;9:866-875. **6.** Weber MA, Basile J, Stapff M, Khan B, Zhou D. Blood pressure effects of combined β-blocker and angiotensin-converting enzyme inhibitor therapy compared with the individual agents: a placebo-controlled study with nebivolol and lisinopril [published online ahead of print June 4, 2012]. *J Clin Hypertens.* doi:10.1111/j.1751-7176.2012.00666.x. **7.** Neutel JM, Smith DHG, Gradman AH. Adding nebivolol to ongoing antihypertensive therapy improves blood pressure and response rates in patients with uncontrolled stage I-II hypertension. *J Hum Hypertens.* 2010;24:64-73. **8.** U.S. Department of Health and Human Services Food and Drug Administration. Guidance for Industry Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims. March 2011. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075072.pdf. **9.** Fingertip Formulary® database, a registered trademark of Fingertip Formulary, LLC, as of July 2012. Data are subject to change.

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BYSTOLIC® (nebivolol) tablets **Rx Only**
Brief Summary of full Prescribing Information
Initial U.S. Approval: 2007

INDICATIONS AND USAGE: Hypertension - BYSTOLIC is indicated for the treatment of hypertension, to lower blood pressure. BYSTOLIC may be used alone or in combination with other antihypertensive agents. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes, including the class to which this drug principally belongs. There are no controlled trials demonstrating risk reduction with BYSTOLIC. Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals. For specific advice on goals and management, see published guidelines, such as those of the National High Blood Pressure Education Program's Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC). Numerous antihypertensive drugs, from a variety of pharmacologic classes and with different mechanisms of action, have been shown in randomized controlled trials to reduce cardiovascular morbidity and mortality, and it can be concluded that it is blood pressure reduction, and not some other pharmacologic property of the drugs, that is largely responsible for those benefits. The largest and most consistent cardiovascular outcome benefit has been a reduction in the risk of stroke, but reductions in myocardial infarction and cardiovascular mortality also have been seen regularly. Elevated systolic or diastolic pressure causes increased cardiovascular risk, and the absolute risk increase per mmHg is greater at higher blood pressures, so that even modest reductions of severe hypertension can provide substantial benefit. Relative risk reduction from blood pressure reduction is similar across populations with varying absolute risk, so the absolute benefit is greater in patients who are at higher risk independent of their hypertension (for example, patients with diabetes or hyperlipidemia), and such patients would be expected to benefit from more aggressive treatment to a lower blood pressure goal. Some antihypertensive drugs have smaller blood pressure effects (as monotherapy) in black patients, and many antihypertensive drugs have additional approved indications and effects (e.g., on angina, heart failure, or diabetic kidney disease). These considerations may guide selection of therapy.

CONTRAINDICATIONS: BYSTOLIC is contraindicated in the following conditions: Severe bradycardia; Heart block greater than first degree; Patients with cardiogenic shock; Decompensated cardiac failure; Sick sinus syndrome (unless a permanent pacemaker is in place); Patients with severe hepatic impairment (Child-Pugh >B); Patients who are hypersensitive to any component of this product.

WARNINGS AND PRECAUTIONS: Abrupt Cessation of Therapy - Do not abruptly discontinue BYSTOLIC therapy in patients with coronary artery disease. Severe exacerbation of angina, myocardial infarction and ventricular arrhythmias have been reported in patients with coronary artery disease following the abrupt discontinuation of therapy with β-blockers. Myocardial infarction and ventricular arrhythmias may occur with or without preceding exacerbation of the angina pectoris. Caution patients without overt coronary artery disease against interruption or abrupt discontinuation of therapy. As with other β-blockers, when discontinuation of BYSTOLIC is planned, carefully observe and advise patients to minimize physical activity. Taper BYSTOLIC over 1 to 2 weeks when possible. If the angina worsens or acute coronary insufficiency develops, re-start BYSTOLIC promptly, at least temporarily. **Angina and Acute Myocardial Infarction -** BYSTOLIC was not studied in patients with angina pectoris or who had a recent MI. **Bronchospastic Diseases -** In general, patients with bronchospastic diseases should not receive β-blockers. **Anesthesia and Major Surgery -** Because beta-blocker withdrawal has been associated with an increased risk of MI and chest pain, patients already on beta-blockers should generally continue treatment throughout the perioperative period. If BYSTOLIC is to be continued perioperatively, monitor patients closely when anesthetic agents which depress myocardial function, such as ether, cyclopropane, and trichloroethylene, are used. If β-blocking therapy is withdrawn prior to major surgery, the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures. The β-blocking effects of BYSTOLIC can be reversed by β-agonists, e.g., dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Additionally, difficulty in restarting and maintaining the heartbeat has been reported with β-blockers. **Diabetes and Hypoglycemia -** β-blockers may mask some of the manifestations of hypoglycemia, particularly tachycardia. Nonselective β-blockers may potentiate insulin-induced hypoglycemia and delay recovery of serum glucose levels. It is not known whether nebivolol has these effects. Advise patients subject to spontaneous hypoglycemia and diabetic patients receiving insulin or oral hypoglycemic agents about these possibilities. **Thyrotoxicosis -** β-blockers may mask clinical signs of hyperthyroidism, such as tachycardia. Abrupt withdrawal of β-blockers may be followed by an exacerbation of the symptoms of hyperthyroidism or may precipitate a thyroid storm. **Peripheral Vascular Disease -** β-blockers can precipitate or aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease. **Non-dihydropyridine Calcium Channel Blockers -** Because of significant negative inotropic and chronotropic effects in patients treated with β-blockers and calcium channel blockers of the verapamil and diltiazem type, monitor the ECG and blood pressure in patients treated concomitantly with these agents. **Use with CYP2D6 Inhibitors -** Nebivolol exposure increases with inhibition of CYP2D6. The dose of BYSTOLIC may need to be reduced. **Impaired Renal Function -** Renal clearance of nebivolol is decreased in patients with severe renal impairment. BYSTOLIC has not been studied in patients receiving dialysis. **Impaired Hepatic Function -** Metabolism of nebivolol is decreased in patients with moderate hepatic impairment. BYSTOLIC has not been studied in patients with severe hepatic impairment. **Risk of Anaphylactic Reactions -** While taking β-blockers, patients with a history of severe anaphylactic reactions to a variety of allergens may be more reactive to repeated accidental, diagnostic, or therapeutic challenge. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reactions. **Pheochromocytoma -** In patients with known or suspected pheochromocytoma, initiate an α-blocker prior to the use of any β-blocker.

ADVERSE REACTIONS: Clinical Studies Experience - BYSTOLIC has been evaluated for safety in patients with hypertension and in patients with heart failure. The observed adverse reaction profile was consistent with the pharmacology of the drug and the health status of the patients in the clinical trials. Adverse reactions reported for each of these patient populations are provided below. Excluded are adverse reactions considered too general to be informative and those not reasonably associated with the use of the drug because they were associated with the condition being treated or are very common in the treated population. The data described below reflect worldwide clinical trial exposure to BYSTOLIC in 6545 patients, including 5038 patients treated for hypertension and the remaining 1507 subjects treated for other cardiovascular diseases. Doses ranged from 0.5 mg to 40 mg. Patients received BYSTOLIC for up to 24 months, with over 1900 patients treated for at least 6 months, and approximately 1300 patients for more than one year. HYPERTENSION: In placebo-controlled clinical trials comparing BYSTOLIC with placebo, discontinuation of therapy due to adverse reactions was reported in 2.8% of patients treated with nebivolol and 2.2% of patients given placebo. The most common adverse reactions that led to discontinuation of BYSTOLIC were headache (0.4%), nausea (0.2%) and bradycardia (0.2%). **Table 1** lists treatment-emergent adverse reactions that were reported in three 12-week, placebo-controlled monotherapy trials involving 1597 hypertensive patients treated with either 5 mg, 10 mg, or 20-40 mg of BYSTOLIC and 205 patients given placebo and for which the rate of occurrence was at least 1% of patients treated with nebivolol and greater than the rate for those treated with placebo in at least one dose group. **Table 1.** Treatment-Emergent Adverse Reactions with an Incidence (over 6 weeks) ≥1% in BYSTOLIC-Treated Patients and at a Higher Frequency than Placebo-Treated Patients are listed below in the following order: System Organ Class Preferred Term [Placebo (n = 205), Nebivolol 5 mg (n = 459), Nebivolol 10 mg (n = 461), Nebivolol 20-40 mg (n = 677)] **Cardiac Disorders:** Bradycardia (0, 0, 0, 1); **Gastrointestinal Disorders:** Diarrhea (2, 2, 2, 3); Nausea (0, 1, 3, 2); **General Disorders:** Fatigue (1, 2, 2, 5); Chest pain (0, 0, 1, 1); Peripheral edema (0, 1, 1, 1); **Nervous System Disorders:** Headache (6, 9, 6, 7); Dizziness (2, 2, 3, 4); **Psychiatric Disorders:** Insomnia (0, 1, 1, 1); **Respiratory Disorders:** Dyspnea (0, 0, 1, 1); **Skin and subcutaneous Tissue Disorders:** Rash (0, 0, 1, 1). Listed below are other reported adverse reactions with an incidence of at least 1% in the more than 4300 patients treated with BYSTOLIC in controlled or open-label trials except for those already appearing in **Table 1**, terms too general to be informative, minor symptoms, or adverse reactions unlikely to be attributable to drug because they are common in the population. These adverse reactions were in most cases observed at a similar frequency in placebo-treated patients in the controlled studies. **Body as a Whole:** asthenia. **Gastrointestinal System Disorders:** abdominal pain. **Metabolic and Nutritional Disorders:** hypercholesterolemia. **Nervous System Disorders:** paraesthesia. **Laboratory Abnormalities -** In controlled monotherapy trials of hypertensive patients, BYSTOLIC was associated with an increase in BUN, uric acid, triglycerides and a decrease in HDL cholesterol and platelet count. **Postmarketing Experience -** The following adverse reactions have been identified from spontaneous reports of BYSTOLIC received worldwide and have not been listed elsewhere. These adverse reactions have been chosen for inclusion due to a combination of seriousness, frequency of reporting or potential causal connection to BYSTOLIC. Adverse reactions common in the population have generally been omitted. Because these adverse reactions were reported voluntarily from a population of uncertain size, it is not possible to estimate their frequency or establish a causal relationship to BYSTOLIC exposure: abnormal hepatic function (including increased AST, ALT and bilirubin), acute pulmonary edema, acute renal failure, atrioventricular block (both second and third degree), bronchospasm, erectile dysfunction, hypersensitivity (including urticaria, allergic vasculitis and rare reports of angioedema), myocardial infarction, pruritus, psoriasis, Raynaud's phenomenon, peripheral ischemia/claudication, somnolence, syncope, thrombocytopenia, various rashes and skin disorders, vertigo, and vomiting.

DRUG INTERACTIONS: CYP2D6 Inhibitors - Use caution when BYSTOLIC is co-administered with CYP2D6 inhibitors (quinidine, propafenone, fluoxetine, paroxetine, etc.). **Hypotensive Agents -** Do not use BYSTOLIC with other β-blockers. Closely monitor patients receiving catecholamine-depleting drugs, such as reserpine or guanethidine, because the added β-blocking action of BYSTOLIC may produce excessive reduction of sympathetic activity. In patients who are receiving BYSTOLIC and clonidine, discontinue BYSTOLIC for several days before the gradual tapering of clonidine. **Digitalis Glycosides -** Both digitalis glycosides and β-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia. **Calcium Channel Blockers -** BYSTOLIC can exacerbate the effects of myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists (particularly of the phenylalkylamine [verapamil] and benzothiazepine [diltiazem] classes), or antiarrhythmic agents, such as disopyramide.

USE IN SPECIFIC POPULATIONS: Pregnancy: Teratogenic Effects, Category C - Decreased pup body weights occurred at 1.25 and 2.5 mg/kg in rats, when exposed during the perinatal period (late gestation, parturition and lactation). At 5 mg/kg and higher doses (1.2 times the MRHD), prolonged gestation, dystocia and reduced maternal care were produced with corresponding increases in late fetal deaths and stillbirths and decreased birth weight, live litter size and pup survival. Insufficient numbers of pups survived at 5 mg/kg to evaluate the offspring for reproductive performance. In studies in which pregnant rats were given nebivolol during organogenesis, reduced fetal body weights were observed at maternally toxic doses of 20 and 40 mg/kg/day (5 and 10 times the MRHD), and small reversible delays in sternal and thoracic ossification associated with the reduced fetal body weights and a small increase in resorption occurred at 40 mg/kg/day (10 times the MRHD). No adverse effects on embryo-fetal viability, sex, weight or morphology were observed in studies in which nebivolol was given to pregnant rabbits at doses as high as 20 mg/kg/day (10 times the MRHD). **Labor and Delivery -** Nebivolol caused prolonged gestation and dystocia at doses ≥5 mg/kg in rats (1.2 times the MRHD). These effects were associated with increased fetal deaths and stillborn pups, and decreased birth weight, live litter size and pup survival rate, events that occurred only when nebivolol was given during the perinatal period (late gestation, parturition and lactation). No studies of nebivolol were conducted in pregnant women. Use BYSTOLIC during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nursing Mothers -** Studies in rats have shown that nebivolol or its metabolites cross the placental barrier and are excreted in breast milk. It is not known whether this drug is excreted in human milk. Because of the potential for β-blockers to produce serious adverse reactions in nursing infants, especially bradycardia, BYSTOLIC is not recommended during nursing. **Pediatric Use -** Safety and effectiveness in pediatric patients have not been established. Pediatric studies in ages newborn to 18 years old have not been conducted because of incomplete characterization of developmental toxicity and possible adverse effects on long-term fertility. **Geriatric Use -** Of the 2800 patients in the U.S. sponsored placebo-controlled clinical hypertension studies, 478 patients were 65 years of age or older. No overall differences in efficacy or in the incidence of adverse events were observed between older and younger patients. **Heart Failure -** In a placebo-controlled trial of 2128 patients (1067 BYSTOLIC, 1061 placebo) over 70 years of age with chronic heart failure receiving a maximum dose of 10 mg per day for a median of 20 months, no worsening of heart failure was reported with nebivolol compared to placebo. However, if heart failure worsens consider discontinuation of BYSTOLIC.

OVERDOSAGE: In clinical trials and worldwide postmarketing experience there were reports of BYSTOLIC overdose. The most common signs and symptoms associated with BYSTOLIC overdosage are bradycardia and hypotension. Other important adverse reactions reported with BYSTOLIC overdose include cardiac failure, dizziness, hypoglycemia, fatigue and vomiting. Other adverse reactions associated with β-blocker overdose include bronchospasm and heart block. The largest known ingestion of BYSTOLIC worldwide involved a patient who ingested up to 500 mg of BYSTOLIC along with several 100 mg tablets of acetylsalicylic acid in a suicide attempt. The patient experienced hyperhidrosis, pallor, depressed level of consciousness, hypokinesia, hypotension, sinus bradycardia, hypoglycemia, hypokalemia, respiratory failure, and vomiting. The patient recovered. Because of extensive drug binding to plasma proteins, hemodialysis is not expected to enhance nebivolol clearance. If overdose occurs, provide general supportive and specific symptomatic treatment. Based on expected pharmacologic actions and recommendations for other β-blockers, consider the following general measures, including stopping BYSTOLIC, when clinically warranted: *Bradycardia:* Administer IV atropine. If the response is inadequate, isoproterenol or another agent with positive chronotropic properties may be given cautiously. Under some circumstances, transthoracic or transvenous pacemaker placement may be necessary. *Hypotension:* Administer IV fluids and vasopressors. Intravenous glucagon may be useful. *Heart Block (second or third degree):* Monitor and treat with isoproterenol infusion. Under some circumstances, transthoracic or transvenous pacemaker placement may be necessary. *Congestive Heart Failure:* Initiate therapy with digitalis glycosides and diuretics. In certain cases, consider the use of inotropic and vasodilating agents. *Bronchospasm:* Administer bronchodilator therapy such as a short-acting inhaled β_2-agonist and/or aminophylline. *Hypoglycemia:* Administer IV glucose. Repeated doses of IV glucose or possibly glucagon may be required. Supportive measures should continue until clinical stability is achieved. The half-life of low doses of nebivolol is 12-19 hours. Call the National Poison Control Center (800-222-1222) for the most current information on β-blocker overdose treatment.

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Tech News

PROVIDERS: HIT HELPS REDUCE HEALTH ERRORS, MISCOMMUNICATION

Practicing clinicians strongly believe that health information technology (HIT) can overcome communication challenges among care providers, according to results of the 2013 iHIT study conducted by the Health Information and Management Systems Society (HIMSS) and HIMSS Analytics.

ACCORDING TO the study, the HIT tools in use at the respondents' provider organizations support clinical processes and provide improved access to the information needed to prepare for delivery of care. This includes having better access to information needed on patients being transferred to a clinician's unit/caseload, ultimately resulting in enhanced levels of patient care. Highlights of the survey results:

- **General advantages of HIT:** 70% of respondents noted that HIT benefitted their overall ability to provide care efficiently, including the information needed to understand their daily caseload.
- **Workflow implications of HIT:** 83% of survey respondents agreed that HIT can play an important role in the clinical processes needed to provide quality care.
- **Information provided by HIT:** 80% of respondents were highly likely to indicate that the information provided through the HIT tools at their organization helped clinicians process data and improved access to information needed to provide safe patient care.
- **Pharmacy response:** Pharmacists were far more likely than physicians or nurses to suggest that they benefitted from HIT.
- **Ability to independently make decisions:** Respondents working in technologically complex organizations were more likely to agree that electronic access to information has improved their ability to independently make decisions than those working for facilities in a less complex HIT environment.
- **Magnet status:** Responses from Magnet-designated hospitals scored higher on the iHIT response scale, ranging from four to eight points, than responses from non-Magnet-designated facilities. Magnet is the American Nursing Credentialing Center's national recognition program honoring healthcare organizations for quality patient care, nursing excellence, and innovations in professional nursing practice.

The use of health IT to support communication processes, data and information is a recent phenomenon," says Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN, vice president, informatics for HIMSS. "It is clear from this study that there are key opportunities for improvements in workflow and communication between colleagues through use of health IT tools and informatics competencies.

The iHIT scale, developed by HIMSS and HIMSS Analytics, is designed to measure the perception of practicing clinicians regarding the ways in which HIT influences interdisciplinary communication, workflow patterns, and the degree of satisfaction of clinicians with HIT applications and tools.

> THE HIT TOOLS IN USE AT THE RESPONDENTS' PROVIDER ORGANIZATIONS... PROVIDE IMPROVED ACCESS TO THE INFORMATION NEEDED...FOR DELIVERY OF CARE.

Designed to explore the role of health IT from an inter-professional communication perspective, more than 500 clinician respondents working in care delivery settings provided information on the value of health IT in support of quality care.

@ The full results of the 2013 iHIT Study are available at www.himss.org/ihit.

Tech Talk

EXAMINE ALL COSTS WHEN INVESTIGATING EHR PLATFORMS

by **LYLE MELICK**

Nearly 75% of U.S. medical practices are using electronic health record (EHR) systems, and because of federal mandates, such as meaningful use, the number is expected to grow.

If you are purchasing an EHR for the first time or considering switching systems, you need to first assess the needs of the practice and then consider the different system platforms (cloud- or SAAS-based, or server-based). With a server-based system, all the hardware and software, as well as the records themselves, are kept on-site. With a cloud-based system, patients' records are stored in a remote location hosted by the vendor, and doctors and their staffs access them via the Internet.

Server-based systems require you to purchase and service the equipment on which patient records are stored, but they provide the peace of mind of knowing that your patients' records are in your office (albeit in electronic form), and at less risk of being stolen while being sent to a remote server via the Internet.

Here is a more detailed look at the main elements of each type of system:

SERVER-BASED SYSTEMS:
If you choose a server-based system, you next need to consider the size of your server. Your EHR vendor will make a recommendation, but most small practices can function with a 200 to 300 gigabyte hard drive, which is enough to store records for about 10,000 patients. A server of this size will cost between $5,000 and $8,000, and you can expect it to last about 5 years.

Next you will need to decide whether to access the server via desktop computers or wireless devices. If you use desktops, I recommend purchasing "business class" machines. These will cost between about $800 and $1,000 per computer but last longer than computers purchased for home use.

Linking computers to the server and each other usually will cost roughly $150 and $200 per "run" (link). Specify the use of wiring that is at least category 5 to ensure that your data are transmitted quickly and reliably.

If you decide to use wireless devices for server access, you will need a Wi-Fi base station, which generally will cost $500 to $700. Check that wireless transmissions can work well in your building and that all your wireless devices have built-in Wi-Fi receivers.

After you've installed your EHR, keeping it running efficiently is crucial. Most small practices contract with an outside information technology (IT) company to maintain their systems. These companies can monitor your system's functions remotely and will send someone to your office if on-site trouble-shooting is required. Contracts with IT service companies usually cost around $300 to $500 per month. Ask your EHR vendor or hospital IT department for a recommendation.

CLOUD- OR SAAS-BASED SYSTEMS:
Cloud- or SAAS-based systems require a far smaller initial investment than do server-based systems. Usually all you will need are devices for accessing the Internet (computers, smart phones, iPads, etc.), an Internet connection, and a router—in addition to the licensing fee for the EHR itself. The vendor will charge a subscription fee based on the number of providers in your practice.

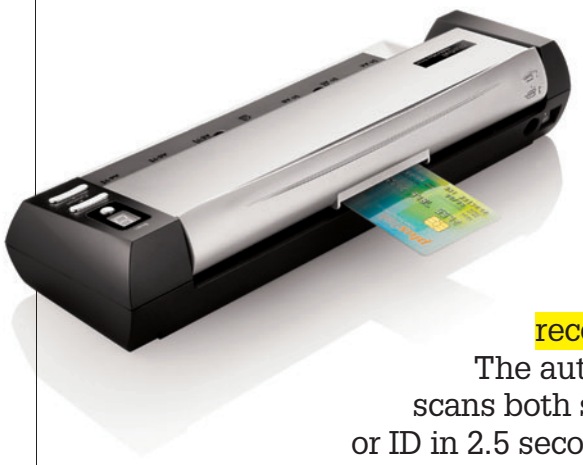
A possible pitfall of cloud-based systems is that vendors sometimes are less than cooperative about transferring patients' data if you decide to change vendors. It is a good idea to include in your contract a deadline by which the vendor must transfer your patients' information if you switch vendors.

Take the time to research systems thoroughly, interview vendors, and ask colleagues how satisfied they are with their system. Doing the homework at the beginning will save you from costly mistakes later. ◘

The author is information technology manager for SS&G Healthcare in Akron, Ohio. Send your practice management questions to ***medec@advanstar.com****.*

Doctor's Bag

SCANNER COULD INCREASE RECEPTION STAFF EFFICIENCY



The Plustek D430 scanner from Plustek Technology Inc. is designed to help practices transition patient registration documents to electronic health record (EHR) systems. The automatic document feeder scans both sides of a document or ID in 2.5 seconds, allowing it to be saved as a searchable PDF or image file.

Practices can digitize insurance cards, drivers' licenses, credit cards, Health Insurance Portability and Accountability Act forms, payment checks, medical prescriptions, and claim documents. The scanner's horizontal feeding and compact design—2.5 inches tall and about 15 inches when loaded with paper—are designed to be suitable for a typical reception station.

The scanner's ability to digitize documents at a high speed might increase office efficiency by reducing registration time, automating data entry, improving data accuracy, speeding up claim processing, and meeting meaningful use requirements. Software protocol TWAIN and Windows image acquisition drivers ensure integration with most registration and EHR software.

Plustek (714) 670-7713 | www.pluske.com/usa

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The Glide HD from Ergotron is a low-profile, height-adjustable display wall mount. The discreet mount is designed to be easily raised and lowered and to allow a display to be used without impeding on available space.

Designed to support displays from 20 to 40 pounds, the Glide HD offers 18 inches of height adjustability, improving viewing ergonomics for imaging, telepresence, diagnostic, digital signage, or interactive applications. Patented technology helps ensure that the display is easily adjustable while maintaining a discreet 2-inch profile. Height adjustability and tilt allow for a display to be positioned above instruments and equipment or at an appropriate height for video imaging.

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MODULE HELPS YOU EVALUATE YOUR PRACTICE

The Medical Group Management Association (MGMA)–American College of Medical Practice Executives has released the DataDive: 2012 Procedural Profile Module, a Web-based tool that practices can use to understand patient base, explore potential new service lines, and ensure adequate staffing.

The tool allows users to develop an organizational profile that can be benchmarked against peers using national and credible MGMA data. The data can then be used to better understand patient demand and future workload.

The module also can be used to compare procedures with those performed by other practices in the same specialty and region. Indicators allow practices to evaluate and make changes to expense allocations and determine staffing ratios based on types of procedures performed.

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CAREFULLY EVALUATE ECONOMIC IMPACT IF CONSIDERING NPPs

by **KEITH BORGLUM,** *CHBC, CBB*

If you are hiring, do your homework when it comes to examining labor costs. The fact is, most physicians do not give much thought to the financial upside to leveraging labor. But remember that you can't do more than one day's work per day yourself. The only way to render more care beyond your personal labor is to expand the reimbursed labor force in your practice.

EMPLOYING others involves risk, time, and effort for which you deserve to be compensated. You can employ more physicians, but most practice owners need to critically evaluate the financial impact of hiring non-physician practitioners (NPPs), simply because of the reduced labor cost.

According to the National Society of Certified Healthcare Business Consultants (NSCHBC), the median annual income of non-owner primary care physicians (PCPs) is approximately $200,000. Median compensation for NPPs in primary care, however, is less than half that. But because NPPs' productivity tends to be more than half that of PCPs, and their reimbursement ranges between 85% and 100% of physicians (depending on whether the service the PCP provides is "incident-to") the situation provides opportunities to profit on their employment.

Employing NPPs will increase your practice's variable costs, such as supplies and compensation, but not your fixed costs, such as rent, furnishings, and instrumentation. Therefore, the ratio of fixed costs per each employee goes down, increasing the margin of profit on each employee.

Calculate any additional costs incurred by hiring an NPP, then add those costs to the NPP's compensation to determine a break-even point.

Pre-tax profit on a full-time NPP generally doesn't occur until his or her annual collections exceed about $225,000. A poll of members of NSCHBC consultants found profits typically in the $10,000 to $40,000 range per NPP and as high as $140,000 for a top-notch NPP in a group office with broad ancillary services. Many practice owners choose to share profits with NPPs, typically in the form of a productivity bonus.

One of the most important factors in profiting from NPPs is making sure that they are coding appropriately, because the majority of providers at every level tend to under-code for their services. Both you and your NPPs should become good enough at coding that you could stand up before a group of peers and teach it. Without that level of skill, you lose money that is rightfully yours.

NPPs require more clinical supervision than employed physicians, which is another reason you need to profit from their labors. Consider, though, that reducing your own patient schedule by 30 minutes per day to supervise an NPP can allow for 7 to 8 extra clinical billable hours per day, per NPP. This is the definition of the beneficial leverage of labor.

Of course, patients often want to see the physician, not the NPP, so it is important to train your patients to accept them. I've found that the best approach is to tell patients that you work as a team, and that the scheduler will set their appointment based on the patient's clinical needs that day. Tell them in person, post the message in the waiting room, include it in your brochure, and post it on your practice's Web site.

Remember, hiring employees and profiting from their labor are key elements of operating a successful business. Doing so will help you provide your patients with the quality of medical care they expect. ◘

The author is a medical practice management consultant in Santa Rosa, California, and a Medical Economics *editorial consultant. Send your practice management questions to* **medec@advanstar.com**.

Trends

Hypertension: High prevalence signals new adherence challenges

How a patient-centered approach can motivate patients to make needed changes

by **NANCY GROVES**

HIGHLIGHTS

01 You can improve treatment adherence by including patients in the treatment plan, reviewing the management plan frequently, and helping patients address concerns about medication costs and side effects.

02 The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure is working on the eighth edition of guidelines, but a release date has not been announced.

Although one out of three adults—about 78 million people—has hypertension, only 52.5% of adults have it controlled. With direct medical expenses estimated at $47.5 billion a year and $3.5 billion in lost productivity, why are patients seemingly losing the war against a preventable disease? ▸▸

▸▸ **IT'S A KEY** question healthcare providers need to ask, especially considering the impact of an aging society against an increasingly prevalent disease that places people at greater risk for heart attacks, stroke, and kidney disease.

Since 2007, the 30% prevalence rate of hypertension in the United States has not budged. Data from the National Health and Examination Survey (NHANES) also show little improvement in the management and control of high blood pressure. And by 2030, the prevalence numbers are expected to get worse, not better—increasing another 7.2%.

That means change is needed, physicians say, in the way patients behave, how they monitor their disease and comply with recommendations, and how the healthcare team interacts with them long-term to keep their blood pressure within goal.

The healthcare delivery team's focus expands from an episode of care to helping patients make necessary behavioral and diet changes, schedule and access care, use better monitoring strategies, improve adherence to pharmacotherapies and other

> "[PATIENTS'] UNDERSTANDING [OF] THE LIFESTYLE FACTORS THAT THEY CAN TAKE CHARGE OF THAT CAN LOWER BLOOD PRESSURE... IS IMPORTANT."
>
> DONNA K. ARNETT, PHD, MSPH, PRESIDENT, AMERICAN HEART ASSOCIATION

management recommendations, and offer much more healthcare education.

The good news is that when patients with high blood pressure see a physician regularly, 70% have it controlled, says Brent Egan, MD, professor of medicine and pharmacology at the Medical University of South Carolina in Charleston. Egan is president of the American Society of Hypertension's Specialists Program.

Patients whose blood pressure is not under control are slightly more likely to be uninsured, but a more significant common denominator is that they're seen zero to one time a year in a healthcare setting, he says.

THE ADHERENCE CHALLENGE

Because hypertension is a silent disease, says Donna K. Arnett, PhD, MSPH, president of the American Heart Association, asymptomatic patients may not fully understand the negative consequences of not adhering to a physician's treatment recommendations. And it adds another layer of complexity related to the successful treatment and accurate monitoring, she says.

Another adherence challenge might include discontinuation of medications because of medication side effects. Or patients could just stop treatment or monitoring if they notice initial improvement.

About 12% of patients won't fill prescriptions at all, according to Arnett. Some patients won't refill prescriptions if they don't perceive a benefit or worry about the cost.

And evidence shows that lowering out-of-pocket expenses for medications works, adds David Meyers, MD, director of the Center for Primary Care, Prevention, and Clinical Partnership, Agency for Healthcare Research and Quality (AHRQ). "It might make a lot of economic sense if medication costs weren't the big drivers of care," he continues. Patients whose adherence improves because medication is affordable are less likely to develop serious and costly consequences such as stroke or heart attack. At your practice level, one of the ways to address nonadherence is to strengthen patient engagement, Arnett says. Here are three ways to do that:

Include patients in the treatment plan.

"Patients should be their own advocate in the treatment and management of their hypertension. Understanding what their blood pressure is, by taking home blood pressure measurements, is important," Arnett says. "Second, I think understanding the lifestyle factors that they can take charge of that can lower blood pressure, including increasing physical activity, limiting the amount of sodium consumption, and increasing potassium intake through lots of fruits and vegetables, is important. And a third thing is limiting alcohol."

Help patients overcome medication issues.

Physicians also need to improve their communications strategies to overcome patient reluctance to take medication or increase the number of pills, Egan says. More potent medications and single pill combinations can help.

Frequently review the management plan.

Aging is an obvious factor that will necessitate modifying medication and other aspects of treatment, Arnett says, but a family crisis, development of another acute or chronic condition, and many other things can cause patients to veer from what had been an effective management plan and have difficulty getting back on track. The approach has to be flexible to provide long-term blood pressure control, and this is more likely to happen when the patient and providers are in regular contact.

ROLE OF PCMH

Many impediments to effectively managing hypertension are built into the prevailing

1/3
OF ADULTS (78 MILLION)
Prevalence of hypertension in the United States

47.5%
The number of U.S. adults with uncontrolled hypertension

348,000+
Deaths in the United States from hypertension in 2009

$47.5 BILLION

Annual direct medical expenses related to hypertension

$3.5 BILLION

Annual hypertension-related costs related to lost productivity

70%

Incidence of controlled hypertension among patients who see a physician regularly

"IT MIGHT MAKE A LOT OF ECONOMIC SENSE IF MEDICATION COSTS WEREN'T THE BIG DRIVERS OF CARE."

DAVID MEYERS, MD, DIRECTOR, CENTER FOR PRIMARY CARE, PREVENTION, AND CLINICAL PARTNERSHIP, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

medical practice model in this country, according to Meyers, but the approach taken in a primary care physician office can help.

"Most patient visits are at the primary care level, and if primary care practices were set up in a way that it could really help people prevent disease, and when they have health conditions manage them effectively, then that is really empowering people to manage their own health care," he suggests. "By giving them the extra support they need for behavior change and the right information about the right medications, helping them make good healthcare decisions, the whole system benefits, the whole country benefits."

The PCMH model is an important consideration, Meyers says, because in PCMHs, primary care is responsible for helping patients meet their healthcare goals, and the model uses the skills and experience of a team of people to manage not just individuals and families but whole populations. Also, both providers and patients have the right health information technology (HIT) tools for clinical decision support and a back-and-forth flow of information, and providers are paid in a way that rewards quality and patient-centered care.

"The relationship between the healthcare system and people has to change," he adds. "We have to understand patients' goals, values, what they're trying to do, and work with them to come up with a plan that makes sense for them.

"We're at a very interesting time right now in healthcare systems thinking," Meyers adds. "Things are starting to change. People are exploring the idea of, 'Can we pay for this better? Can we pay doctors for outcomes and value and patient-centeredness?' We're experimenting with payment models. At the same time, HIT is really starting to make some of our visions possible, like patient portals and clinical decision information at your fingertips."

The Centers for Medicare and Medicaid Services (CMS) is one of the biggest players, evaluating several payment and service delivery models through the CMS Innovation Center, including a comprehensive primary care initiative. "If that model works and we can show that the quality of care went up and the cost went down, then Medicare has the power to roll that out and make that a national system," Meyers says.

Additional data on hypertension control also might improve hypertension management, Egan suggests. If data from a large study such as NHANES are based on a single exam, doctors don't know how reliable they are, and because many patients in the study whose pressure is uncontrolled are in the 140- to 150-mm Hg range, it's unclear how many are truly hypertensive. Similarly, an occasional office blood pressure measurement may not be a reliable indicator, due to white coat syndrome and blood pressure variability.

"In some ways, we may be overestimating the number of people who have high blood pressure and underestimating control just by the nature of the way it's being defined, in large part by a national survey that relies on just one examination," Egan explains.

THERAPEUTIC INERTIA

He also attributes some cases of uncontrolled hypertension to therapeutic inertia. Often, he says, physicians are reluctant to intensify therapy when blood pressure nears 140 mm Hg.

Through his involvement in the National Heart, Lung, and Blood Institute's Hypertension Initiative and Stroke Belt Elimination Initiative, Egan has observed a decline in therapeutic inertia in a network of about 400 clinics from seven out of eight visits to two out of three, which should improve hypertension control by 17%. This estimation was arrived at by calculating a therapeutic initiative score for each physician in the program,

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New guidelines on the way

When it comes to treating hypertension, one source of guidance for many physicians is the clinical practice guidelines written by the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. The eighth edition of these guidelines, updating those released a decade ago, is undergoing extensive review. The National Heart, Lung, and Blood Institute has not announced a release date.

Although the organization will not comment on the contents of the revised guidelines, they are expected to address:

- **when to initiate drug treatment,**
- **how far blood pressure should be lowered,**
- **how to achieve that target,**
- **the efficacy of treatment with combination drugs containing agents from different classes, and**
- **the importance of day-to-day variability of systolic blood pressure as a predictor of stroke risk independent of mean systolic blood pressure.**

The guidelines are to be based heavily on data from randomized clinical trials rather than expert opinion, according to Brent Egan, MD, professor of medicine and pharmacology at the Medical University of South Carolina in Charleston. Egan, president of the American Society of Hypertension's Specialists Program, is not a member of the committee preparing the guidelines.

"WE SPEND A LOT OF TIME IN THE PRIMARY CARE PHYSICIAN'S OFFICE TRYING TO CHANGE PATIENTS' BEHAVIOR, BUT THEN WE SEND THEM BACK OUT TRYING TO SWIM UPSTREAM AGAINST POPULATION BEHAVIOR."

BRENT EGAN, MD, PRESIDENT, AMERICAN SOCIETY OF HYPERTENSION'S SPECIALISTS PROGRAM

education, regular feedback, and leadership from influential physicians in the practice and community.

Egan adds that because therapeutic inertia is partly due to concern over the reliability of the measurement at any given office visit, the concern can be addressed through greater use of home and ambulatory monitoring and repeated automated measurements in the office without any observation.

IMPROVING POPULATION BEHAVIOR

But more effective hypertension management cannot be achieved solely through doctor-patient encounters. The public health sector also needs to be involved. Egan believes that effective public health messaging has been "lost" despite considerable success several decades ago in reducing smoking and lowering the intake of sodium and saturated fats.

"Our ability to create messaging for groups is better than it's ever been, but we haven't been using those advances in tailoring messages to affect population health behavior. I think we desperately need to reactivate those strategies," he says. "What happens is that we spend a lot of time in the primary care physician's office trying to change patients' behavior, but then we send them back out trying to swim upstream against population behavior. We're very much social creatures, and if we can begin creating healthier population behaviors, that will become the norm. Right now, healthier behaviors are not the norm, and we're paying the price for that."

Public health messaging would be helpful in motivating patients to make lifestyle changes—sooner rather than later—as well as helping them understand the risks of hypertension and encouraging adherence to medication use.

"We believe that getting 85% of treated patients under control is certainly possible, and most of the rest who are not controlled to less than 10 mm Hg from goal. A lot of the rest of this will require a partnership of public health and primary care. It will require reengineering reimbursement so physicians are paid for things that lead to results," Egan says. ◘

Resources

For more information about hypertension, you and your patients can consult these resources:

My Life Check, American Heart Association and American Stroke Association
http://mylifecheck.heart.org/

Million Hearts Initiative, U.S. Department of Health and Human Services
http://millionhearts.hhs.gov

Joint National Committee, NHLBI:
www.nhlbi.nih.gov/guidelines/hypertension/jnc8/index.htm

@ For resource centers related to hypertension and other topics in our Business of Health series, including obesity, immunization, pain management, and circulatory disorders, as well as collections of articles related to our EHR Best Practices Study, Patient-Centered Medical Homes, and accountable care organizations, see www.MedicalEconomics.com/ResourceCenterIndex.

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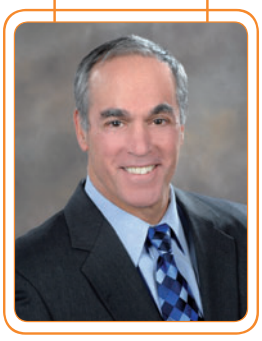

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Q&A

COST CONTROL MYTHS MUST BE ADDRESSED TO FIX HEALTH SYSTEM

From misunderstandings about the role of healthcare inflation to cost controls in the Affordable Care Act (ACA), three economic myths must be addressed for the healthcare system to function properly, says Theodore R. Marmor, PhD, Yale University professor emeritus of public policy and management as well as political science. He recently spoke with Medical Economics *Editor-in-Chief Lois A. Bowers, MA.*

Two of your many books are* Comparative Studies and the Politics of Modern Medical Care *and* Fads, Fallacies and Foolishness in Medicare Care Management and Policy. *What are the most relevant messages from them for primary care physicians today?

The biggest myth is that a country's experiences of medical inflation are proportionate to the rise in income of the country because of forces that are uncontrollable.

I've published a book on comparative studies, but people don't use comparative analysis in a very careful way. They're too cavalier about explaining why things are the way they are. They delude themselves into thinking that somehow, the Medicare program in 1965 meant that the United States could never get to any kind of cost control because Americans have different ideas. There's no basis for that at all.

The reason we had trouble with costs by comparison with everybody else is that the inflationary forces in medical care are powerful. The question is not what citizens believe; it's the structure of political power and whether or not the countervailing forces against inflation are well-organized or not institutionally.

If you ask why Canada was different from the United States between 1970 and 2012, it has nothing to do with Canadian beliefs. It has everything to do with the fact that there's a structure of decision-making. In other words, if inflation in medical care goes up by 10%, then the education or the transportation budget of every province has to fall to compensate for that, or taxes have to rise. There is no such mechanism in the United States.

What is another myth, in your opinion?

That the interplay of consumers shopping around for good deals from insurance companies will stem the rate of medical inflation, and that the evidence for that belief is what's happened since 1996 in Switzerland and since 2006 in the Netherlands.

That inference has been drawn by actors in the United States who have a theological commitment to the belief that since competition for shirts or automobiles typically takes place over both quality and price, the same will happen in the medical care area. The answer to that is, people don't treat health insurance that way.

And it didn't happen in Holland and Switzerland. In fact, they're probably the two most expensive countries now, even more than Canada, where health insurance is concerned.

Another myth involves the quest for the holy grail in health policy in the United States—that there's some magic bullet somewhere, from bundled payments to health maintenance organizations to accountable care organizations.

The conception of cost control as built into the ACA is naïve at best and idiotic at worst. It's difficult to turn private health insurance into a version of regulated social insurance, which is what obviously the ACA is trying to do. Especially in the United States, when you've got determined private health insurers who are not embarrassed by failing to work within the spirit of the law as opposed to the letter of the law.