DIABETES IMPROVEMENTS
Innovations shake up industry

- Smarter glucose monitors
- Concentrated insulin
- Artificial pancreas

PAGE 16

FAILED PAYER MERGERS
MCOs RETHINK GROWTH PLANS
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Win the war against obesity

Humana thinks outside the box to help physicians modify patient behaviors

The past century has seen major advancements against once deadly infectious diseases and cancer, so it seems illogical that the diseases that stymie us now are almost completely preventable. We have not been able to stop obesity and its related disorders from reaching epidemic levels. That’s because we’ve been taking the wrong approach.

We’ve been treating the disease rather than treating the whole person. If we’re going to curb the obesity epidemic and the chronic conditions that stem from it, we must take a holistic approach to treatment and prevention.

For lifestyle diseases, prevention requires sustained behavioral change, which can be difficult. Every physician and clinician remembers a patient who could have prevented negative health outcomes with a simple behavior change—but just couldn’t seem to make the change. We need to look at all of the reasons people struggle to change behavior. Is the person depressed or lonely? Is it difficult for her to access healthy food? Is there another health issue at play? Until we address all the issues, we won’t be effective in treating obesity or diabetes.

Holistic perspective needed

Humana is thinking holistically to help physicians create behavior changes among their patients.

One example is Humana’s partnership with Omada Health. The “Prevent” program uses data to help physicians identify patients at risk for diabetes and combines digital health with human coaching to change behavior and reduce risk. People who have participated in the program had a 7.5 percent weight loss and had improvements in glucose control, total cholesterol, well-being, depression, and self-care.

In Florida, we’re studying how behavior changes when physicians write prescriptions for their patients to visit a park or spend time outdoors as part of their treatment plan. For example, in the MetCare clinic in Plantation, Florida, primary care physicians have written more than 400 prescriptions for parks over the past 10 months. The full research results will be presented at the American College of Preventive Medicine conference in Portland, Oregon, in May.

Also, we have developed a model that predicts which people are likely to progress from prediabetes to actual diabetes during a 12-month period. And we use those predictors to redirect people to their physicians for treatment or participation in a Humana clinical program.

Another example is our Go365 program, an online wellness and rewards program. I think of it as the gamification of wellness, as it encourages participants to take a variety of healthy actions. People earn points by completing activities that contribute to a healthy lifestyle. Points then turn into rewards, such as discounts on healthy food at grocery stores.

As we’ve rolled out these initiatives over the past few years, we’ve spent a lot of time thinking about physicians, their patients, and how they interact with our programs. Committing to value-based care means working with physicians differently and looking at a person’s total health. It’s the only way to help them change. By implementing a holistic approach we will not just help those individuals already struggling with obesity and diabetes, but eventually win the fight against this epidemic.

“Committing to value-based care means working with physicians differently and looking at a person’s total health. It’s the only way to help them change.”

ABOUT THE AUTHOR

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Mission: Managed Healthcare Executive provides healthcare executives at health plans and provider organizations with analysis, insights, and strategies to pursue value-driven solutions.

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</tbody>
</table>
DIABETES IMPROVEMENTS

Innovations shake up industry

ESSENTIALS

7 HEALTH MANAGEMENT
Paramedics combat ED visits, readmissions
by Rachael Zimlich, RN

10 HOSPITALS AND PROVIDERS
Why diabetic patients don’t comply
by Aine Cryts

12 BUSINESS STRATEGY
New priorities drive new C-suite positions
by Rachael Zimlich, RN

17 DRUGS IN THE PIPELINE
Diabetes drugs to watch
by Erin Bastick, PharmD, RPh

21 TECHNOLOGY
Could new tech solve the diabetes crisis?
by Donna Marbury

23 SPECIAL REPORT
Payers rethink growth plans after failed mergers
by Aine Cryts

25 THE LIST
Six things other industries can learn from healthcare
by Aubrey Westgate

30 GAME-CHANGING IDEAS
Specialty intensive medical home
by Tracey Walker

COMMENTARY

1 OPINION
Win the war against obesity
by Roy A. Beveridge, MD

32 INDUSTRY ANALYSIS
Top four patient engagement trends
by Tracey Walker

DEPARTMENTS

2 EDITORIAL ADVISORS
IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS
Trulance™ is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile mice administration of a single oral dose of plecanatide caused deaths due to dehydration. Use of Trulance should be avoided in patients 6 years to less than 18 years of age. The safety and efficacy of Trulance have not been established in pediatric patients less than 18 years of age.

Contraindications
• Trulance is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.
• Trulance is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions
Risk of Serious Dehydration in Pediatric Patients
• Trulance is contraindicated in patients less than 6 years of age. The safety and effectiveness of Trulance in patients less than 18 years of age have not been established. In young juvenile mice (human age equivalent of approximately 1 month to less than 2 years), plecanatide increased fluid secretion as a consequence of stimulation of guanylate cyclase-C (GC-C), resulting in mortality in some mice within the first 24 hours, apparently due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than older patients to develop severe diarrhea and its potentially serious consequences.
• Use of Trulance should be avoided in patients 6 years to less than 18 years of age. Although there were no deaths in older juvenile mice, given the deaths in young mice and the lack of clinical safety and efficacy data in pediatric patients, use of Trulance should be avoided in patients 6 years to less than 18 years of age.

Diarrhea
• Diarrhea was the most common adverse reaction in the two placebo-controlled clinical trials. Severe diarrhea was reported in 0.6% of patients.
• If severe diarrhea occurs, the health care provider should suspend dosing and rehydrate the patient.

Adverse Reactions
• In the two combined CIC clinical trials, the most common adverse reaction in Trulance-treated patients (incidence ≥2% and greater than in the placebo group) was diarrhea (5% vs 1% placebo).
NEW FOR ADULTS WITH CHRONIC IDIOPATHIC CONSTIPATION (CIC)

Diarrhea is not efficacy—it’s time to address the age-old tradeoff in CIC.1,2

Introducing Trulance—structurally identical to naturally occurring uroguanylin with the exception of one amino acid.3-6

Trulance provided more regular, well-formed bowel movements.3*

Efficacy, true to form.

TrulanceTM offers convenient once-daily dosing, with or without food.3

For more information about Trulance, please contact your account manager with NDC #70194-003-30. Learn more at TrulanceHCP.com

*Results over 12 weeks were statistically significant vs placebo, as shown in two Phase 3 clinical studies.3

Indication

• Trulance (plecanatide) 3 mg tablets is indicated in adults for the treatment of chronic idiopathic constipation (CIC).


Please see Brief Summary of full Prescribing Information, including Box Warning, on the following page.

Trulance™ (plecanatide)
Trulance™ (plecanatide) tablets, for oral use

Rx only

Brief Summary — Consult the package insert for complete prescribing information.

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS

• Trulance is contraindicated in patients less than 6 years of age; in non-clinical studies in young juvenile mice, administration of a single oral dose of plecanatide caused death due to dehydration (see Contraindications, Use in Specific Populations).
• Avoid use of Trulance in patients 6 years to less than 18 years of age (see Warnings and Precautions, Use in Specific Populations).
• The safety and effectiveness of Trulance have not been established in patients less than 18 years of age (see Use in Specific Populations).

INDICATIONS AND USAGE:

• Patients with known or suspected mechanical gastrointestinal obstruction.

WARNINGS AND PRECAUTIONS:

Avoid the use of Trulance in patients 6 years to less than 18 years of age. Although there were no deaths in older cyclase-C (GC-C), resulting in mortality in some mice within the first 24 hours, apparently due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than patients 6 years of age and older to develop severe diarrhea and its potentially serious consequences.

Avoid the use of Trulance in patients 6 years to less than 18 years of age. Although there were no deaths in older juvenile mice, the death in younger mice and the lack of clinical safety and efficacy data in pediatric patients, avoided the use of Trulance in patients 6 years to less than 18 years of age (see Contraindications, Warnings and Precautions, Use in Specific Populations).

Diarrhea

Diarrhea was the most common adverse reaction in the two placebo-controlled clinical trials. Severe diarrhea was reported in 0.6% of patients (see Adverse Reactions). If severe diarrhea occurs, suspend dosing and rehydrate the patient.

Adverse Reactions:

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

The safety data described below reflect data from 1733 adult patients with IBD randomized in two double-blind, placebo-controlled clinical trials (Study 1 and Study 2) to receive placebo or 3 mg of Trulance once daily for 12 weeks. Demographic characteristics were comparable between the Trulance and placebo group (see Clinical Studies in the full Prescribing Information).

Most Common Adverse Reactions:

Table 1 provides the incidence of adverse reactions reported in at least 2% of patients in the Trulance-treated group and at an incidence that was greater than in the placebo group.

Table 1: Most Common Adverse Reactions* in Two Placebo-Controlled Trials of Trulance (Study 1 and Study 2) in Patients with IBD

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Trulance, 3 mg (N = 863)</th>
<th>Placebo (N = 870)</th>
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<tr>
<td>Diarrhea</td>
<td>5%</td>
<td>1%</td>
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<td>*reported in at least 2% of Trulance-treated patients and at an incidence greater than placebo</td>
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Diarrhea may resolve with suspension of dosing and has been reported in 0.6% of patients (see Adverse Reactions). If severe diarrhea occurs, suspend dosing and rehydrate the patient.

Adverse Reactions Leading to Discontinuation

Discontinuations due to adverse reactions occurred in 4% of Trulance-treated patients and 2% of placebo-treated patients. The most common adverse reaction leading to discontinuation was diarrhea: 2% of Trulance-treated patients and 0.5% of placebo-treated patients withdrew due to diarrhea.

Less Common Adverse Reactions

Adverse reactions reported in less than 2% of Trulance-treated patients and at an incidence greater than placebo were: sinusitis, upper abdominal pain, upper respiratory tract infection, abdominal distension, flatulence, abdominal tenderness, and increased liver biochemical tests (2 patients with alanine aminotransferase (ALT) greater than 5 to 15 times the upper limit of normal and 3 patients with aspartate aminotransferase (AST) greater than 5 times the upper limit of normal).

USE IN SPECIFIC POPULATIONS: Pregnancy – Risk Summary

Plecanatide and its active metabolite are negligibly absorbed systemically following oral administration

(see Clinical Pharmacology in the full Prescribing Information) and maternal use is not expected to result in fetal exposure to the drug.

The available data on Trulance use in pregnant women are not sufficient to inform any drug-associated risks for major birth defects and miscarriage.

In animal developmental studies, no effects on embryo-fetal development were observed with oral administration of plecanatide in mice and rabbits during organogenesis at doses much higher than the recommended human dosage.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the United States general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data

Pregnant mice and rabbits were administered plecanatide during the period of organogenesis. There was no evidence of harm to embryo-fetal development at oral doses up to 800 mg/kg/day in mice and 250 mg/kg/day in rabbits.

Oral administration of up to 600 mg/kg/day in mice during organogenesis through lactation produced no developmental abnormalities or effects on growth, learning and memory, or fertility in the offspring through maturation.

The maximum recommended human dose is approximately 0.05 mg/kg/day, based on a 60-kg body weight. Limited systemic exposure to plecanatide was achieved in animals during organogenesis (area under the plasma concentration-time curve (AUC) = 449 mg•h/mL in rabbits given 250 mg/kg/day). Plecanatide and its active metabolite are not measurable in human plasma following administration of the recommended clinical dosage.

Therefore, animal and human doses should not be compared directly for evaluating relative exposure.

Lactation

Risk Summary

There is no information regarding the presence of plecanatide in human milk, or its effects on milk production or the breastfed infant. No lactation studies in animals have been conducted. Plecanatide and its active metabolite are negligibly absorbed systemically following oral administration (see Clinical Pharmacology in the full Prescribing Information).

It is unknown whether the negligible systemic absorption of plecanatide by adults will result in a clinically relevant exposure to breastfed infants. Exposure to plecanatide in breastfed infants has the potential for serious adverse effects (see Use in Special Populations).

Therefore, the developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for Trulance and any potential adverse effects on the breastfed infant from Trulance or from the underlying maternal condition.

Pedicure Use

Trulance is contraindicated in pediatric patients less than 6 years of age. Avoid use of Trulance in patients 6 years to less than 18 years of age (see Contraindications, Warnings and Precautions).

The safety and effectiveness of Trulance in patients less than 18 years of age have not been established.

In nonclinical studies, deaths occurred within 24 hours in young juvenile mice (human age equivalent of approximately 1 month to less than 2 years) following oral administration of plecanatide, as described below in Juvenile Animal Toxicity Data. Because of increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than patients 6 years of age and older to develop diarrhea and its potentially serious consequences. Trulance is contraindicated in patients less than 6 years of age. Given the deaths in young juvenile mice and the lack of clinical safety and efficacy data in pediatric patients, avoid the use of Trulance in patients 6 years to less than 18 years of age.

Juvenile Animal Toxicity Data

Single oral doses of plecanatide at 0.5 mg/kg and 10 mg/kg caused mortality in young juvenile mice on postnatal days 7 and 14, respectively (human age equivalent of approximately 1 month to less than 2 years). Treatment-related increases in the weight of intestinal contents were observed in juvenile mice following single doses of plecanatide on postnatal day 14 (human age equivalent of approximately less than 2 years), consistent with increased fluid in the intestinal lumen. Although the recommended human dose is approximately 0.05 mg/kg/day, based on a 60-kg body weight, plecanatide and its active metabolite are not measurable in adult human plasma, whereas systemic absorption was demonstrated in the juvenile animal toxicity studies. Animal and human doses should not be compared directly for evaluating relative exposure.

Geriatric Use

Clinical studies of Trulance did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from patients 18 years to less than 65 years of age. Of 2630 subjects in clinical trials of Trulance, 273 (10%) were 65 years of age and over, and 47 (2%) were 75 years and over. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

DOSEAGE AND ADMINISTRATION: Recommended Dosage – The recommended adult dosage of Trulance is 3 mg taken orally once daily, with or without food. (See Preparation and Administration Instructions in the full Prescribing Information).

Date of Issue: 01/17

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Paramedics combat ED visits, readmissions

More plans, providers recognize potential

by Rachael Zimlich, RN

ne recurring problem payers and providers grapple with is 30-day readmissions, and the financial penalties associated with them. To help address this issue, and improve patient outcomes, more organizations are turning to community paramedic (CP) programs that enlist the services of EMS teams to answer calls and offer short-term interventions that help divert patients away from emergency departments and funnel them back into appropriate care channels.

Kevin McGinnis, MPS, program manager of Community Paramedicine-Mobile Integrated Healthcare and Rural Emergency Care for the National Association of State EMS Officials, says community paramedicine got its roots in the late 1990s in the Northeast United States and Canada but didn’t come to prominence until the mid-2000s. There are roughly 170 documented CP programs nationwide.

“We can start to help the health system affect savings where others in the traditional healthcare system can’t because we’re in the community 24/7 and we’re used to being in patients’ homes,” McGinnis says. Data suggests CP programs are effective in reducing repeat ED admissions and 30-day hospital readmissions, he adds. “This is one small solution that the healthcare system can invoke.”

**Diversion tactics**

CP programs work by allowing EMS personnel to answer emergency calls and assess patients’ needs to determine whether less-costly, more beneficial interventions are appropriate. Patients may need a quick fix for low blood glucose and a referral to an endocrinologist, for example. “They can take care of the issue right then and refer the patient for primary care at a future date. Or they can refer the patient to a higher level of care more immediately,” McGinnis says. “It’s very powerful. It’s that triage force. You don’t want triage being done in the ED, you want to come out in front of the ED to do that.”

CP programs are also offering additional services. Dan Swayze, DrPH, MBA, MEMS, vice president and chief operating officer of the Center for Emergency Medicine of Western Pennsylvania, which provides emergency services, research, training, and community paramedic programs, says that while community programs vary from state to state, most utilize the services of paramedics for areas within their scope of practice where there are gaps in traditional care, such as for patients without insurance who don’t qualify for home health nurse visits. “Some home nursing agencies are actually contracting with CP services to supplement their care, to help reduce the likelihood their patients will be readmitted to the hospital,” Swayze says.

CP programs are also helping bridge the gap between health and human services, he says. They can provide patient navigation and patient advocacy services for patients who can’t get them on their own or who need help finding the right program.

“Our CPs often accompany patients to their providers’ visits so
we can reinforce and translate the next steps in ways the patients will understand when they get back home,” Swayze says. “Once we address the underlying social determinant issues facing the patient, we find that their dependence on 911 and the local emergency department goes down drastically. It’s much more effective to have a paramedic call these patients than it is to continue to react as we have traditionally done.”

He adds that more CP programs are coming from hospitals that operate their own ambulance services. “The medics are already FTEs in the healthcare system, and hospital administrators are beginning to realize it’s more cost effective to deploy the medics to the patient based on their predictive and risk stratification models rather than waiting for the patient to call 911,” he says.

Financial drivers
Matt Zavadsky is director of public affairs for MedStar Mobile Healthcare, a governmental agency that is the regional 911 emergency medical services provider for 15 Texas cities, including Fort Worth. MedStar also operates a CP program.

Zavadsky says EMS teams have traditionally only been paid for transporting patients to the hospital or emergency department with no reimbursement for patients treated on the scene without transport. “So we transport them to pay our employees and that’s just silly,” Zavadsky says.

Now, hospitals and payers are using incentives from the ACA, such as those earned through lower admissions and readmissions, to change the reimbursement structure, says Swayze.

“Any health system migrating to a population health strategy has to recognize that all their efforts can be thwarted by the patient with a quick call to 911,” Swayze says. As systems consider how best to transition to value-based care, they should take a serious look at their local EMS agencies as partners in the process.”

MedStar is paid primarily for 911 ambulance service, Zavadsky says, but it is also paid for CP services. Hospitals and other agencies, such as an IPA, pay an enrollment fee for services. MedStar also receives per member per month payment from hospice agencies.

Third party payers are negotiating with the cost savings plan, though it was not yet in effect at press time, says Zavadsky.

Some payers are starting to pay capitated rates each month on high utilizers, paying CPs to respond to calls, helping patients and the payers avoid costly transports, ED visits, or hospital stays.

Filling an unmet need
Zavadsky says patients who are surveyed after hospital stays say they only understand their discharge instructions 40% of the time. They may have questions that come up after they leave the hospital, then forget by their next appointment. These things can lead to ED visits and readmissions.

“It’s not that they want to be noncompliant, it’s just that they don’t know any other way to be. Nobody has the time to sit with that patient in an area that’s comfortable for that patient and explain,” says Zavadsky.

“We’ve put 3,000 to 5,000 patients through these [CP programs] and 80% of what we’re doing with these patients isn’t clinical. It’s educational.”

Zavadsky says his agency has tracked 475 patients using the community paramedic mobile healthcare services and found that EMS calls were reduced by about 55%. That translates to an estimated $8 million cost savings to health systems thanks to the change in patients’ utilization of services.

That estimate, Zavadsky says, is based on ED facility payments and Medicare cost savings and isn’t inclusive of additional costs for lab work or specialist care.

Rachael Zimlich is a writer in Columbia Station, Ohio.

Any health system migrating to a population health strategy has to recognize that all their efforts can be thwarted by the patient with a quick call to 911.”

—DAN SWAYZE, CENTER FOR EMERGENCY MEDICINE OF WESTERN PENNSYLVANIA
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Reference:
Family physician Marcus Blackstone, MD, puts his finger squarely on the cost of insulin as a key reason patients fail to comply with their treatment regimens.

Thus, Blackstone, who treats patients at Bon Secours St. Francis Health System in Greenville, South Carolina, recommends that payers and providers partner to create more affordable options for patients’ medications.

Insulin vials typically cost patients with insurance as much as $50 a month, and the cost of pens runs close to $100 a month, says Blackstone. For patients without insurance, vials set them back more than $300 a month and pens more than $445. In addition, you’ll find very few diabetes patients who are just on insulin; they often have multiple other conditions along with diabetes, he adds.

During conversations with patients, Blackstone says primary care providers need to continually reinforce the long-term complications associated with the disease, and the need for active monitoring and dietary changes.

Patricia Bononi, MD, medical director of the Center for Diabetes at Allegheny Health Network in Pittsburgh, describes diabetes as an “overwhelming” disease. “The majority of treatment falls in the hands of patients who are faced with food choices and activity choices every day. Basically, everything they do affects their diabetes,” she says.

Thus, Bononi advises physicians to stop making assumptions about patients’ diet choices, for example. It’s not as simple as poor access to food, she says. Often, it’s because patients don’t know how to cook those foods. Or, if their medications are too expensive, it could be that they’re too embarrassed to tell their physicians that they can’t afford them.

Another reality is many patients have high-deductible plans. Many physicians will assume that if their patient is employed they should be able to afford their medications. Insulin, however, represents a significant out-of-pocket expense for these patients, she says.

Here are nine ways physicians can help diabetes patients adhere to treatment plans:

1. **Seek community support.** Not everyone has access to a nutritionist, says Bononi, who recommends that physicians connect patients with food insecurity issues to a local food pantry. Further, she has advice for food pantries serving diabetic patients: Teach them how to cook the healthy foods available at the food pantry. “It all comes down to communication,” she says. “You have to meet patients where they are.”

2. **Educate skilled nursing facilities on nutritious food choices.** Blackstone recommends having a diabetes educator walk through the kitchens of these facilities to assess the relative healthiness of the food provided to patients. He notes that while Bon Secours St. Francis doesn’t own the 10 skilled nursing facilities where the health system sends patients, the facilities are grateful for access to diabetes educators. The health system’s clinicians also take part in weekly calls with these skilled nursing facilities to determine where dietary support for patients is appropriate, he says.

3. **Build relationships with patients’ family.**
One of the first questions Blackstone asks his patients is: “Who does the cooking in your house?” That’s because he wants this person to come to the patient’s appointments. If this person is educated about diabetes just as the patient is, it will increase the likelihood that the patient will be compliant. Blackstone tells the primary cook about proper nutrition (for example, by explaining that carbohydrate-dense foods convert into sugar within the patient’s body). Most family members aren’t aware of this, he adds.

4 Schedule regular diabetes-specific appointments with patients. Diabetes management is time-consuming and it can’t be squeezed into a brief 15-minute appointment slot, says Cory White, MD, an endocrinologist at Bon Secours St. Francis. During these condition-specific appointments, emphasize the long-term consequences of uncontrolled diabetes and help patients set achievable goals and targets for their fingerstick blood glucose and hemoglobin levels, adds White. He notes that working with nonphysician providers such as nurse practitioners and physician assistants can make this possible.

5 Determine the root cause of patients’ resistance to taking medications. Often, patients will be uncomfortable about issues such as weight gain that can be associated with taking insulin, says William Yancy, MD, director of the Duke University Diet and Fitness Center. It’s also important to clear up any misperceptions that patients may have about insulin. For example, Yancy cites one patient who thought that taking insulin resulted in a friend’s need to have her foot amputated.

6 Practice nonjudgment. Yancy recommends that providers ask this question: “I know that some patients have difficulty taking their medications and miss doses. Has that happened to you? How often?” Often a physician will think they’re providing clear guidance to a patient on taking their medications, but something gets lost in translation, he says.

7 Use motivational interviewing techniques to tap into patients’ goals. Focus on asking patients about their goals, which could include spending more time with their grandchildren, says Yancy.

8 Teach patients how to exercise. At the Duke University Diet and Fitness Center, participants learn how to exercise in a safe environment. Often, patients who don’t work out can feel uncomfortable doing so around people who exercise regularly, Yancy says.

9 Pursue strategic partnerships with payers and pharma companies. To educate and encourage diabetic patients about healthy food options, Bononi’s team at the Allegheny Health Network received funding from the Highmark Foundation and educational materials from Novo Nordisk for a program that provided $50 a week to diabetic patients over a period of five months. The 40 patients could only spend the money on fruits or vegetables at a nearby farmers market. Participants also attended three educational sessions about healthy eating, and could tour the farmers market with a certified diabetes educator.

As a result of the program, participants experienced an almost 1% decrease in their A1c levels. Bononi says her team is now working with Highmark to develop an appropriate reimbursement model to support this treatment approach.

Aine Cryts is a writer based in Boston.
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New priorities drive new C-suite positions

Chief experience officers hit the ground running by RACHAEL ZIMLICH, RN

As payers tie more reimbursement to patient satisfaction scores and demonstrated outcomes, and as patients are more informed about the choices they can make, health systems are increasingly developing new ways to improve performance. Some of these methods include the creation of new executive roles aimed at ensuring patients and caregivers have the tools they need for success.

One such role is chief population health officer (CPHO), driven primarily by a movement from fee-for-service to value-based reimbursements. CPHOs and another newer role, data scientists, identify data and trends to support improved outcomes and processes.

These roles support a larger executive trend: chief experience officer (CXO), which is driven by the desire to improve the larger patient experience—a combination of excellence in clinical care and patient perception—and the experience of caregivers.

Bridget Duffy, MD, chief medical officer of Vocera, which provides secure communication platforms to healthcare organizations, served as the nation's first chief experience officer at the Cleveland Clinic from June 2007 to July 2009. She says the creation of the CXO role follows the historically reactive nature of the industry. Chief quality officer roles, for example, weren't created until after adverse events were noted. Likewise, chief experience officer roles didn't really take hold until after the government mandated higher patient satisfaction and quality, and tied reimbursement to it.

Before Duffy took on the role of CXO at the Cleveland Clinic, she told leadership that it had to be willing to address fundamental problems with the culture and structure of the organization. Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scores were between 40% and 60%, and people came to the Cleveland Clinic for its reputation of clinical excellence while tolerating the poor service that accompanied it, Duffy says. So, she spent nearly three years working with staff to repair broken trust and relationships between physicians and nurses and addressing caregiver burnout.

"Instead of taking on 100 things, organizations should just focus on culture, communication and fostering trusted relationships," she says. "The ones that have moved the scores are the ones that have focused first and foremost on culture and leadership."

Addressing a flawed system

Liz Boehm, director of research at Vocera, has explored the emergence of CXOs extensively. These individuals have their work cut out for them, says Boehm. "We're reaching a place now where there's concerns about cost but also access and coverage," she says. "We need to take a deeper look at the systems we've created and the challenges."

This means asking how healthcare can be restructured at equal or lower costs to deliver more powerful outcomes—outcomes that are about health, not just procedural success, she says.

"If we're honest about the motivation of many of the organizations [in creating CXOs], it comes primarily through the reimbursement tied through HCAHPS," she says.
Boehm says, “For others, there’s a deeper understanding that HCAHPS points out that there is a flaw in the system: It is an imperfect measurement system.”

Focusing on simply making patients happy isn’t enough, says Duffy, adding that health systems that focus on hospitality measures to improve scores are a bit misguided. “It’s not that the customer is always right. It’s that the patient is always heard and feels heard and is connected,” Boehm adds. “It’s about making the experience more healing for patients and families, but also more fulfilling and humane for the physicians, nurses and other care team members.”

Beyond customer service
Executive positions, like chief experience officers, population health officers, and data scientists, must work together to identify deficits and build better structures and training protocols that make the humanized experience the path of least resistance so that it’s easier to deliver care with dignity and respect.

“Some organizations do look at it as customer service, but there’s a much deeper work to it,” Boehm says. “One role is to recognize that compassion needs to be nurtured. Part of the success is recognizing that there is a provider and a patient and a family side. Piling patient experience work on clinicians is not a strategy for success. They need care for themselves in addition to aspirations for the patient.”

Patient and caregiver experience must also be linked to quality and safety. “When you are providing a more humanized experience, you are delivering better quality,” Boehm says. “If you train those as separate silos, it becomes easy as a clinical to focus on safety and quality and forget that human component.”

Health systems need to find a way to integrate these teams, agrees Duffy. In the future, she says CXOs might work under an umbrella of an innovation or resiliency department, where the entire patient and caregiver experience is considered.

“What I see now is a movement back toward integration and more coordination of roles and a changing or shifting of titles due to what I call the silo-ification of healthcare,” Duffy says. “Too many silos have been created that are focused on different things without aligning the efforts within an institution.”

Heart of the matter
Susan Murphy, RN, is the chief experience and innovation officer at The University of Chicago Medicine. Although she has the executive title, Murphy says she considers herself first and foremost a caregiver and that drives her work.

“As caregivers, we’re just trying to do our check list and end up putting our blinders on. How do we take that moment, and take that breath, and put those observers on?” Murphy says. “The most powerful thing we do, which is kind of simple, is when we’re going...
to work with a new team, we ask them why they’re here. When you open that dialogue, when you get to the heart of the leaders and caregivers, you get to the heart of the patient, and that’s what I feel our job is. There’s a certain kind of person it takes to walk into a patient’s life and start doing very personal things to them.”

Murphy says her role isn’t to tell caregivers how to improve scores or performance, but to serve as a mentor and coach and support the frontline providers to make sure they have the tools and equipment they need to do what they already know how to do. Skills are one thing, but helping caregivers remain patient-oriented and not task-oriented can take some work.

“People who come in and care for people every day may not recognize that what they’re doing every day is changing people’s lives,” Murphy says. “People know me, they know me here. I don’t really look at scores. The scores will come when we look at stories and we look at how caregivers feel when they’re here in the organization.”

**Back to the basics**

Caregivers who feel appreciated and supported can better focus on the needs of their patient and, in turn, improve their own performance and their patient’s satisfaction, says Murphy.

“It’s really about providing the options of individualized patient care and remembering the physician and nurses need ways to find out what works for the patient. To talk to them. To have a dialogue with them,” she says.

Providers also need to learn to meet the patient where they are. In terms of both technology and wellness, it’s not enough to provide the tools, says Murphy. Providers must realize that each patient is coming from a different place and it may be more beneficial to find out where they are in terms of willingness and ability to learn and change rather than to hand them a generic recipe for their health.

For example, an elderly patient with a joint replacement might not buy into the care path that requires physical therapy and rehabilitation. Instead of pushing a plan that the patient will never follow, the provider might instead educate the patient on being their best with limited mobility—such as how to prevent pressure ulcers and eat properly.

“I think it’s really about not making people feel bad for who they are and what they do, but giving people at the frontline the tools they need to take care of patients in the future,” Murphy says. “Patient experience is not just about the scores and not just about what goes on inside the four walls of the hospital, but about the whole picture. We want to help them feel when they walk away that ‘they really care about me’.”

**Chief experience officers voice top priorities**

Survey of 113 director-level and above experience officers in the U.S.

Source: “The Rise of the Healthcare Chief Experience Officer,” Vocera

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“Too many silos have been created that are focused on different things without aligning the efforts within an institution.”

—BRIDGET DUFFY, MD, VOCERA
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EARLY 86 MILLION AMERICANS have pre-diabetes and another 30 million have diabetes; roughly 1 million individuals are added to these figures each year, according to the American Diabetes Association (ADA). The overall cost annually to treat pre-diabetes and diabetes in the United States has escalated to $322 billion. In fact, one-third of all Medicare dollars are spent caring for people with diabetes. Overall, 20% of all healthcare dollars go to diabetes care.

Just like the number of diabetes cases continues to increase, the cost of diabetes treatment and medications is rising. Many people with diabetes have multiple complex comorbidities (e.g., heart disease, high blood pressure, high cholesterol, and obesity), which also require intensive management. Diabetes patients incur medical expenses that are 2.3 times higher than those without diabetes and their average medical expenditures are about $13,700 per year, of which some $7,900 are attributed directly to diabetes, according to the ADA.

In addition, many of these patients require newer and/or more expensive therapies, such

Continued on page 17
as insulin. "A significant increase in the cost of vital diabetes medications has occurred over the past few decades, particularly with insulin therapy," says Kevin M. Pantalone, DO, staff endocrinologist and director of clinical research, Department of Endocrinology, Cleveland Clinic, Cleveland, Ohio. "This has caused significant difficulty in getting patients the medications they need, especially those who are on a fixed income and Medicare patients who lose drug coverage when they hit their insurance coverage gap (i.e., the 'donut hole')."

Depending on their type of insurance coverage—such high-deductible plans—many patients with diabetes cannot afford some of the newer therapies that may provide numerous benefits over older medications such as sulfonylureas, Pantalone continues. Newer medications, such as dipeptidyl peptidase 4 (DPP-4) inhibitors, glucagon-like peptide 1 receptor agonists (GLP-1RA), and sodium-glucose co-transporter 2 (SGLT-2) inhibitors are not associated with an increased risk of hypoglycemia (low blood sugar levels). They are also associated with weight loss or are weight neutral.

The healthcare industry continues to focus efforts on treatments that work better, and ideally are less expensive and less invasive for patients. Here are five advances in diabetes treatments, including new medications and those in the pipeline.

1. SMARTER GLUCOSE MONITORING

Continuous glucose monitoring (CGM) and connected blood glucose monitoring (cBGM) devices provide actionable data to diabetic patients and their providers. "As a technology, CGM provides nearly continuous glucose measurements in real time, which translates to almost 300 readings a day for providers to review and respond [to] with therapeutic adjustments," says Andrew S. Rhinehart, MD, chief medical officer, Glytec. "Presently, CGM is mainly used for individuals with type 1 diabetes, but that may change over time depending upon reimbursement and outcomes data for people with type 2 diabetes."

New CGM systems, such as the Dexcom G5 Mobile CGM system and Abbott’s FreeStyle Libre, consist of a small disposable sensor that is inserted into the skin. A transmitter connected to the sensor wirelessly sends results to a receiver that displays real-time glucose information, explains Stephenie Lucas, MD, medical director of the diabetes treatment center at Beaumont Health, Grosse Pointe, Michigan. These devices require fingersticks as infrequently as twice a day for calibration and users can safely and conveniently access and share their dynamic glucose data anywhere and anytime.

FreeStyle Libre is now available across 32 countries around the world, although still under FDA review in the U.S. The professional version of the system, FreeStyle Libre Pro, is approved in the U.S. and was launched toward the end of 2016.

cBGMs include meters with cellular or Bluetooth capabilities that allow blood glucose data to be transmitted to the cloud, making it easily accessible to providers. "This allows for better patient engagement, and if acted upon properly, better patient outcomes," Rhinehart says. The first cellular meter was launched by Telcare in 2010.

Diabetes therapy management software with decision support for dosing and titration is the final piece of the therapeutic puzzle. In concert with data made available through CGM and cBGM, this software can help providers properly dose and titrate diabetes medications, especially insulin, and choose which diabetes medications may work best for each patient. Diabetes therapy management software, in its earliest form, was launched by Glytec in 2006.

The combination of connected devices and [therapy management software] may be the holy grail of personalized diabetes management."

—ANDREW S. RHINEHART, MD, GLYTEC
“For most providers, this is the most challenging aspect of diabetes management, but also the most important,” Rhinehart says. “Having providers choose the right medications and making the necessary dosing adjustments in a timely manner is critical to achieving and maintaining acceptable A1C levels. The combination of connected devices and this type of therapy management software may be the holy grail of personalized diabetes management.”

**ARTIFICIAL PANCREAS**

Innovative companies are making great strides in the development of the artificial pancreas. Although these systems do not replace the pancreas, they closely mimic a healthy pancreas’ glucose regulating function. These systems can administer insulin when sugar levels are elevated and discontinue insulin when sugar is low. This minimizes the risk of serious low and high blood sugars.

One advancement debuting in the United States this year is the hybrid artificial pancreas. The system, designed for use with Medtronic’s MiniMed 670G insulin pump (approved by the FDA in September 2016), automates basal insulin delivery to maximize the time glucose levels are in a healthy range throughout the day and night.

“The system will give many people with diabetes new freedom and peace of mind as for the first time, they may be able to sleep through the night without periodically waking up to check and manage their blood glucose levels,” Lucas says.

A study published in *JAMA* found that on the 670G system, 124 patients had no episodes of severe hypoglycemia or ketoacidosis over 12,389 patient days. Further, the 670G system kept people with type 1 diabetes within their desired blood sugar range 73.4% of the time, compared to 67.8% without the system. At night, the most dangerous time for blood sugar highs and lows, the difference was even more pronounced—76.4% of readings were in range versus 67.8% without the system.

An artificial pancreas system consists of three devices that closely mimic the glucose regulating function of a healthy pancreas, says Deena Adimoolam, MD, assistant professor of medicine, endocrinology, diabetes, and bone disease at the Icahn School of Medicine at Mount Sinai, New York. These devices include:

- A motorized infusion pump that can deliver two important hormones—insulin and glucagon;
- A CGM to evaluate blood glucose throughout the day; and
A glucometer, as the patient needs to check fingersticks at least twice daily to calibrate the continuous glucose monitor.

These systems communicate directly with one another through a sophisticated computer-controlled algorithm. “Ultimately, the glucose values detected by the CGM determine whether or not the pump gives the patient insulin to decrease glucose values or glucagon to increase glucose values; therefore, keeping blood glucose values in a target range,” Adimoolam says.

Another type of artificial pancreas under development is the bionic pancreas. This CGM and pump system is scheduled to undergo a large clinical trial, and was not yet approved by the FDA at press time. It consists of an insulin-only system, as well as a system that uses two hormones—glucagon and insulin—with the pump system, in conjunction with the CGM.

“The system controls the patient’s blood sugar; the patient only has to perform a few blood glucose checks per day in order to calibrate the CGM device,” Pantalone says. “Mathematical algorithms use the CGM information to continually adjust the rates of hormone infusion in order to obtain better blood sugar control.”

MEDICATIONS THAT TREAT DIABETES AND CARDIOVASCULAR DISEASE

For the first time, medical evidence supports a cardiovascular risk reduction treatment associated with some anti-diabetic therapies: two GLP-1 receptor agonists: Victoza (liraglutide), currently available, and semaglutide (began the FDA approval process in December 2016); and one SGLT-2 transport inhibitor: Jardiance (emglibliflozin).

“These cardiovascular outcomes trials were published in 2015 and 2016 and were groundbreaking,” Pantalone says. “For the first time, some diabetes drugs were demonstrated to have an effect beyond simply lowering blood sugar levels. This is very important, as cardiovascular disease is the number one cause of death in patients with diabetes type 2. If a therapy can lower blood sugar levels and simultaneously potentially lower a patient’s risk of cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke, it would be preferred to use these therapies in patients considered high risk (those with established cardiovascular disease or those with numerous risk factors for cardiovascular disease).”

In a clinical study published in The New Eng-
Diabetes innovations shake up the industry

Not so dire diagnosis

Thirty years ago, it was assumed that anyone with diabetes would have a shortened lifespan and at least one complication; however, a report in *The New England Journal of Medicine* shows that in fact, with good control, many people with diabetes can have a normal lifespan and most can avoid serious complications.

"Modern advancements in treating diabetes have been game changers," says Jay H. Shubrook, DO, professor, primary care department; and director, clinical research and diabetes services, Touro University California College of Osteopathic Medicine, San Francisco Bay Area, California.

empagliflozin is currently being debated."

In another clinical trial published in *The New England Journal of Medicine*, liraglutide reported a 15% reduction in all-cause mortality, but most relate this to a cumulative effect of reductions from heart attack and strokes, Triplitt says. Upon further analysis, patients who took the drug as prescribed received the cardiovascular benefit. Both empagliflozin and liraglutide also reported improvements in renal outcomes; further strengthening their potential use in therapy. The cardiovascular outcome trials of the remaining FDA-approved GLP-1 receptor agonists (Bydureon and Byetta [exenatide] once weekly, Tanzeum [albiglutide], and Trulicity [dulaglutide]), and the other SGLT-2 transport inhibitors (Invokana [canagliflozin] and Farxiga [dapagliflozin]) are still in progress and should conclude over the next few years. "If these studies find similar results, that would be something to watch, as we can then say that the observed cardiovascular risk reduction is actually a class effect, and not specific to just a few agents within the class," Pantalone says.

BARIATRIC SURGERY: PROS & CONS

From a healthcare perspective, bariatric surgery is considered one of the most effective options for short-term and sustained weight loss. But does the investment pay off?


4 CONCENTRATED INSULIN

Another advancement stems from the development of more concentrated insulins to benefit patients who have difficulty absorbing insulin. The most commonly prescribed insulins are known as "U100" insulin, in which 100 units of insulin are in 1 milliliter of fluid.

"Some diabetics are quite insulin resistant and require high doses of insulin," says Adimoolam. "We suspect that when insulin is injected at high volumes, it’s possible that 100% is not absorbed. Therefore, the patient is not getting the true amount of insulin being prescribed and their glucose values remain elevated."

Concentrated insulins, referred to as "U200," "U300," or "U500," can provide much more insulin per 1 milliliter of liquid. For example, U200 consists of 200 units of insulin per milliliter, U300 consists of 300 units of insulin per milliliter, and so forth. These insulins became publicly available in 2016.

"Concentrated insulins are better absorbed than U100 insulins because absorption of insulin is improved," Adimoolam explains. "Concentrated insulins have helped improve diabetes control in those who take a significant amount of insulin (more than 40 units daily). Concentrated insulins cause less hypoglycemia in comparison to U100 insulin."

5 CELL-BASED THERAPIES

Some challenges related to pancreas transplants are the ability to harvest enough pancreatic cells and the ability to stop the body’s immune system from destroying these cells. Progress has been made in stem cell research and efforts to reprogram tissue-specific cells to overcome these barriers.

"A number of surgical advances have improved the early success rate of transplantation, and modern immunosuppressive strategies have improved the rate of longer term survival of tissue grafts," Lucas says.

Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.
Diabetes medications were the most expensive traditional therapy drugs in 2016, with an overall trend of 19.4%, according to the latest Express Scripts drug trend report. This positive trend is reflective of both utilization and cost increases.

Here’s how pipeline developments could change the landscape.

**Pipeline treatments**

“While I do not see any game-changing medications within the diabetes class that will reach the market within the next several years, there are a few updates that we are watching,” says Chris Peterson, director in the emerging therapeutics department at Express Scripts.

He points to the continued growth of the sodium-dependent glucose cotransporter-2 (SGLT-2) inhibitor class—sparked by the positive cardiovascular outcomes from empagliflozin (Jardiance, Boehringer Ingelheim/Eli Lilly), a previously approved SGLT2 inhibitor. Pipeline SGLT-2 inhibitors include investigational ertugliflozin (Merck and Pfizer) and bexagliflozin (Chugai Pharma), both in phase 3 development at press time. Sotagliflozin (Lexicon Pharmaceuticals) is a first-in-class oral dual SGLT-1 and SGLT-2 inhibitor for type 1 and type 2 diabetes, that is also in phase 3. If approved, it will be the first oral drug approved for type 1 diabetes, a disease that typically has been managed by lifestyle modifications and insulins, says Farrah Wong, PharmD, director, pipeline and drug surveillance at OptumRx.

The glucagon-like peptide-1 (GLP-1) analog class is also expected to grow, says Peterson. This is driven by cardiovascular outcomes data with liraglutide (Victoza, Novo Nordisk) and the introduction of the fixed-dose combination GLP-1 agonist/long-acting insulin products, insulin glargine and lixisenatide injection (Soliqua 100/3, Sanofi) and insulin degludec/liraglutide (Xultophy, Novo Nordisk).

Semaglutide is a GLP-1 agonist in development for glycemic control in patients with type 2 diabetes. It is being developed as both subcutaneous formulation and oral form. If approved, it will be the first oral GLP-1 agonist on the market.

“As oral drugs are easier to administer and less invasive than injectable drugs, oral semaglutide may offer these advantages over other GLP-1 agonists,” says Wong.

“Furthermore, type 2 diabetics will have another oral therapeutic option in a class of drugs that thus far were only injectable drugs.”

Exenatide osmotic mini-pump (ITCA 650, Intarcia Therapeutics, Inc.) is a subcutaneous implant that continuously delivers the GLP-1 agonist, exenatide, for three months (introductory dose) or six months (maintenance dose) to treat type 2 diabetes. Approval is expected in November 2017, says Peterson.

New insulin products are also expected to receive approval soon, including insulin tregopil (Biocon Ltd.), an oral insulin in phase 2 development for type 1 and type 2 diabetes at press time.

“Currently, insulins are either injected or inhaled,” says Wong. "If an oral insulin product is available, the ease of administration..."
Drugs In The Pipeline

Drugs In The Pipeline may drive some of the market share to shift from injectable/inhaled insulins to the oral product.

Insulin glargine injection (Basaglar, Eli Lilly/Boehringer Ingelheim) approved last year, was the first “follow-on” insulin glargine product to treat diabetes. Another “follow-on” insulin glargine product, known as MK-1293 (Merck/Samsung Bioepis), will be competing as a brand product within the market and is expected to be approved in the second quarter of 2017. Basalog is yet another insulin glargine product currently in phase 3 development; however, it is not yet clear whether the manufacturer, Mylan, will seek approval as a competing brand or as a generic to Lantus (Sanofi). Finally, Sanofi is developing SAR342434, a follow-on protein to Lilly’s Humalog (insulin lispro), for the treatment of diabetes mellitus. If approved, it will compete as a brand with the other rapid-acting insulins.

Non-pharmacologic treatments

Continued development of non-pharmacologic treatments is expected. Three key areas to watch, according to Kim White, vice president, Numerof & Associates, Inc., include:

- Artificial pancreas technology,
- Islet cell transplantation, and
- Medical management technology.

Artificial pancreas technology continuously monitors blood glucose levels and adjusts insulin doses automatically. According to White, an artificial pancreas device from Medtronic was approved last fall and Bigfoot Biomedical and Insulet Corporation are currently working on similar technology.

Islet cell transplantation is being studied for type 1 diabetes, says White. According to the American Diabetes Association, islets are clusters of cells in the pancreas that make insulin. Islet cell transplantation is a procedure in which islets from the pancreas of a deceased organ donor are purified, processed, and transferred to another person.

“Although first identified as a way to treat people with type 1 diabetes in the 1960s, islet cell transplantation has been difficult to develop as a viable treatment for type 1 diabetes, which is due largely to the challenges of collecting enough islet cells to transplant and preventing transplant rejection,” says White. “However, last year an NIH [National Institutes of Health]-funded study was completed that will pave the way for manufacturing of purified human pancreatic islet cells.”

Mobile technology has been a growing area of interest for diabetes management, says White. Although many blood glucose monitor manufacturers already have web-based programs and apps available to support diabetes management, there is ongoing research by numerous companies to better connect physicians and patients to patients’ blood glucose levels and other measurements like blood pressure.

Business implications

Peterson says these new products will add more competitors to the already existing therapy classes, helping to mitigate the increasing trend within the diabetes class.

He explains that the trend in the diabetes therapy class is just one example of why it is critical for payers to manage their benefit. Express Scripts has developed several initiatives to address the affordability and accessibility of diabetes treatments including a new partnership with Eli Lilly and Blink Health that will provide a 40% discount on Eli Lilly insulin products for uninsured patients with diabetes.

Express Scripts also recently launched a diabetes remote monitoring solution to improve outcomes and address the 42.8% of people with diabetes who are nonadherent to therapy. By using a connected glucose meter and ongoing monitoring from their Diabetes Therapeutic Resource Center, patients learn how to control their blood sugar levels, according to Express Scripts.

“The challenge facing managed healthcare executives is striking the right balance between providing the necessary support to prevent, treat, and manage the disease with ensuring the patient is compliant and adheres to physician guidance,” says White. “The current developments [in the pipeline] have the potential to dramatically improve patient outcomes by minimizing individual errors caused by missed or inappropriate medication dosing and developing accountability loops with providers.”

Erin Bastick, PharmD, RPh is a staff pharmacist at Southwest General Health Center in Middleburg Heights, Ohio.

29 MILLION people in the United States have diabetes, according to the CDC.

30% of those are undiagnosed and the number of people with prediabetes continues to grow.
Could new tech solve the diabetes crisis?

As capabilities expand, so does potential

by DONNA MARBURY

It’s no secret that diabetes is one of the most difficult and expensive chronic conditions to manage in healthcare. Nearly 30 million Americans have diabetes, which costs an average of $13,700 in medical expenses per patient, per year, according to the most recent study released by the American Diabetes Association (ADA). The medical expenditures of diabetes patients are more than double the costs of someone without the ailment, according to the ADA.

There’s hope that technology will solve the diabetes problem, though experts stress that finding solutions takes more than just creating mobile apps and collecting large amounts of data. “Technology can lower the barriers between patients and physicians, but we are not there yet,” says Ameet Bhattacharya, director of the healthcare practice for iVEDiX, a data, analytics and mobile technology company. “The ultimate goal is to have the technology take a back seat, and bring the patients and clinicians closer together. We need to get to that point.”

Consumer demand for easy to use, minimally-invasive diabetes devices continues to surge as the elderly population grows and more plans and government programs seek to support newly diagnosed patients, according to a May 2016 report by Grand View Research, Inc. The report found that the global diabetes device market could reach $35.5 billion by 2024. Test strips and blood glucose monitoring devices currently make up the largest market share, however new technology that can offer continuous care to patients will be common-place in the market, according to the report.

Bhattacharya says the future of diabetes technology includes more intelligent data management. “Artificial intelligence becomes more and more valuable to send clinicians appropriate alerts—they won’t be alerted for every event a patient has. Encounter management systems will play a big part so that clinicians are not flooded with data,” he says.

Mobile apps get smarter

Empowering patients to adhere to treatment is the goal for the next generation of mobile apps for diabetes patients.

For example, the Sugar.IQ app developed in partnership with Medtronic and IBM Watson technology, makes lifestyle and food suggestions to patients based on data collected from continuous glucose monitoring devices. Eli Lilly recently received FDA clearance for Go Dose, a mobile app for patients and clinicians that allows patients to enter data and receive insulin dosage recommendations. Also, WellDoc received FDA clearance for the non-prescription version of its popular BlueStar mobile app for type 2 diabetes management that will also feature an insulin dosage calculator.

Gaining FDA clearance for these mobile apps has another intention: to make it easier for health plans to adopt them for patient care and engagement. In November 2016, the AMA approved guidance on coverage and payment policies for mobile health technology.

“The new AMA principles aim to foster the integration of digital health innovations into clinical
practice by promoting coverage and payment policies that are contingent upon whether mobile health apps and related devices are evidence-based, validated, interoperable and actionable,” said Steven J. Stack, MD, AMA immediate past president, in a statement.

Wearables as predictive tools
New research suggests that wearables that monitor heart rate, blood oxygen levels, physical activity and other continuous body functions can help clinicians predict illnesses, including diabetes. Researchers at Stanford University used seven activity trackers, including Scanadu, Basis, and Masimo, to track essential data from 60 patients. Researchers found physiological differences between people with normal insulin levels and those who were insulin sensitive or resistant.

In a study published in January 2017 in *PLOS Biology*, the researchers state that the infrequent monitoring of these vital statistics makes it harder to detect early insulin resistance before it can be treated. The data collected from activity tracker wearables can assist clinicians in finding diabetes before patients have symptoms, they said.

“If a healthy person with reasonable healthcare access visits his or her physician every two years for a routine visit, then a condition may arise many months, or even longer, prior to a clinical symptom onset and thus go undetected for some time,” the authors wrote. They added, “Because sparse clinical measurements of an individual are often compared to the average measurements of a population, the large variation within and among individuals results in a difficult medical assessment”.

The study found correlations between elevated heart rate that fluctuated at night and during the day, as a precursor to cardiovascular disease and insulin resistance. “The fact that these differences can be measured using wearable devices raises the likelihood that this approach may someday be a useful measure for early detection of insulin resistance and risk for type 2 diabetes,” they wrote.

Artificial pancreas device systems
Several artificial pancreas devices are in development, with the Medtronic MiniMed 670G System being the first to receive FDA approval in September 2016. The device is attached to a patient’s abdomen and monitors blood sugar and adjusts basal insulin doses in people with type 1 diabetes. Because treatment for diabetes varies depending on type, artificial pancreas devices offer various treatment options for patients. For those with type 1 diabetes, the devices are closed loop, meaning that they are continuous glucose monitors and insulin pumps that can administer nonstop insulin to patients painlessly right below the skin.

Devices to monitor type 2 diabetes can predict low glucose levels in patients. These devices aren’t fully automated (non-closed loop)—they can require patients to approve dosage changes or alert them to glucose level changes.

A study in the May 2016 issue of *Diabetes Science and Technology*, found that artificial pancreas devices to treat and manage type 1 diabetes are easier and more effective than those for type 2 diabetes, which were labeled “first-generation” systems.

In the study, 18 different closed-loop artificial pancreas devices were analyzed, and researchers found that the usability of the devices will pay a big part in how effective they will be for patients.

“How an artificial pancreas device system looks and feels from the users’ perspective will be vitally important. There are various ways in which the three key functions of an artificial pancreas device (to monitor, control and treat) might be configured in commercial products,” the study’s authors say, adding that some devices include their own, separate monitor device, while others have mobile apps that collect data and allow users to make changes. “For this new form of technology to be adopted successfully, developers would also need to ensure that their products meet user expectations in terms of design, functionality and impact on quality of life.”

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During the AMA Interim Meeting in November 2016, physicians voted to approve a list of principles to guide coverage and payment policies supporting the use of mHealth apps and associated devices. They include:

- Support the establishment or continuation of a valid patient-physician relationship;
- Have a clinical evidence base to support their use;
- Support data portability and interoperability; and
- Abide by state licensure laws and state medical practice laws and requirements.

Donna Marbury is a writer in Columbus, Ohio.
The blocked Aetna-Humana and Anthem-Cigna mergers are raising questions about the future viability of healthcare consolidation among payers and providers. Add to that the resulting news that Cigna is suing Anthem for a combined $14.85 billion dollars, which includes damages and its contractual "break up" fee, and it's clear that mergers are a complex issue with multiple risk factors for the parties involved.

Matt Fisher, an attorney with Boston area-based law firm Mirick O’Connell, isn’t surprised by the rulings against the mergers, largely because of the level of skepticism that was swirling about the proposed transactions. “The combinations of such large insurers would create a much different market dynamic that would have far-reaching effects. The courts definitely had a lot of questions as to how the mergers would benefit the market and not result in the ability to control it,” he says.

Absent answers to these questions, these mergers were unlikely, he says. Still, while the payers are considering their legal options—Anthem was appealing at press time—Fisher doesn’t anticipate that any resulting appeals will be successful. The primary reason for the payers to pursue their legal options at this point is because “a lot of time and money has been spent,” he says. At the same time, Fisher doesn’t anticipate that the rulings will have an impact on other payer or provider mergers. He calls out the Aetna-Humana and Anthem-Cigna mergers as "somewhat unique in their size," while noting that the Obama administration wasn’t supportive of such mergers. As with so many hot button issues in healthcare today, it’s impossible to know the Trump administration’s intentions in terms of antitrust enforcement—and, thus, it’s difficult to know whether future deals will be challenged, says Fisher.

Tom Schramski, president and managing partner of Vertess, a healthcare mergers and acquisitions firm, says that "horizontal mergers" such as these will continue to attract scrutiny about market share and the potential negative impact on consumers. “I think this attitude will continue through the Trump administration and, if you look at the rulings, the judges involved were relatively equally nominated by Democrats and Republicans,” he says.

The impact on future mergers in the healthcare space? According to Schramski, many payers may reconsider their growth and diversification strategies.

Where Schramski sees the most merger and acquisition opportunity is in vertical combinations, such as Optum’s acquisition of McKesson’s pharmacy business. He notes that we live in a world where consolidation is a non-negotiable.”
of Surgical Care Associates, which operates 205 surgical facilities in more than 30 states. Schramski describes this move as an attempt to more fully manage the care continuum “with an eye on the emerging preference for outpatient healthcare,” which is also more cost-effective for Optum (an entity of UnitedHealth Group).

In a statement, Larry C. Renfro, vice chairman of UnitedHealth Group and Optum’s CEO, highlighted that the deal would enable the company to work with “payer partners to implement care models that reward independent surgeons and specialists for quality and care efficiency.” Announced in January, the deal is expected to close in the first half of 2017; the transaction will be revenue-neutral for UnitedHealth Group.

A FLURRY OF MERGER ACTIVITY
While 2016 was an “active year” for mergers and acquisitions in healthcare, it didn’t achieve the volume witnessed in 2015, according to a report from PwC. The consulting firm shows that the total reported deal value was $71.7 billion in 2016, a decrease of 59.6% from 2015.

One city that has seen a dramatic uptick in this type of activity over the last several years is Chicago, where Ethan Rii, an attorney and shareholder with the law firm Vedder Price, practices. Historically, Chicago had been a diversified market with about two dozen academic medical centers and safety-net hospitals. But that has changed over the last decade.

One such example is the University of Chicago Medical Center’s acquisition of Ingalls Health System, a community health system in Harvey, Illinois, in late 2016. Rii notes that this type of activity has been going on nationally for years as well.

Rii expects a slowdown in merger and acquisition activity, as regulators consider whether further consolidation will result in better quality of care or a reduction in costs. Case in point: The interest by Advocate Healthcare, Illinois’ largest health system, in combining with NorthShore University Health System, an integrated healthcare delivery system serving patients in the Chicago metropolitan area. One of the greatest issues of concern with the proposed merger is the health systems’ multiple overlapping markets, and how that would impact patients served by those markets, says Rii.

THE TRUMP EFFECT
With a new president in the White House—in particular, one who has set repealing the

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Consolidation trends that will continue or accelerate this year

<table>
<thead>
<tr>
<th>Trends</th>
<th>Potential impact</th>
<th>Legislative drivers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Consolidation</strong></td>
<td>Potential consolidation of regional payers</td>
<td>Health insurance sales across state lines might incentivize regional payers to partner/merge</td>
</tr>
<tr>
<td></td>
<td>Continued provider consolidation</td>
<td>The insured population will decrease, increasing competition for a favorable patient mix</td>
</tr>
<tr>
<td><strong>Collaboration</strong></td>
<td>Increased provider-driven collaboration with payers</td>
<td>The government will no longer lead alternative payment models or payer/provider alignment, but payer/provider collaborations will still be critical to the success of lowering medical costs</td>
</tr>
</tbody>
</table>

Source: PwC

SLIGHT DIP IN DEAL VALUE
The total reported deal value for mergers and acquisitions in 2016 was $71.7 billion, a decrease of 59.6% from 2015.

THE TRUMP EFFECT
With a new president in the White House—in particular, one who has set repealing the
Affordable Care Act (ACA) as a priority, it’s difficult to know what the future will bring. Some experts say this uncertainty could result in a slowdown in merger and acquisition activity, whereas others insist that savvy investors are always looking to apply smart business know-how to fix some of the nation’s most intractable problems, even in a heavily regulated industry such as healthcare, says Rii.

Rii anticipates that health systems and regional providers will continue to grow and expand their footprints. While he projects that the market might take a “slight dip”—largely due to the uncertainty associated with the Trump administration and the impact repealing the ACA could have on enrollees—he still sees the merger and acquisition market as a “ripe” one.

There’s more “near-term uncertainty” among providers than among payers regarding how Trump’s presidency will impact them, says Zach Hafner, a partner at The Advisory Board. That’s why he expects more providers to take a “wait and see” approach in terms of their merger and acquisition activity.

Taking a historical perspective, he notes that the shift to value-based care, financial risk, and population health management that occurred during the Obama administration—which he describes as an encroachment into payer territory—could shift back to an environment under the Trump administration where power returns to the insurance industry.

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The M&A market might take a “slight dip” due to the uncertainty associated with the Trump administration, but it will still be a ripe market.

-ETHAN RII, VEDDER PRICE

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**ATTRACTIVE ALTERNATIVE**

One area that has created a lot of buzz is partnerships between well-established healthcare providers, such as between Advocate Health Care in Chicago and SSM Health in St. Louis, Missouri, both of which are partnering separately with Walgreens. These partnerships involve the provider organizations running the retail clinics, which Hafner says will also allow them to attract new patients to their primary care physicians.

The increasing role of patients as consumers is driving these strategic moves by providers, says Hafner. “As we continue to move into an era of consumers who are looking for much more of an engaged and activated consumer experience, health systems and payers are in a race to win.”

Health systems, in particular, are focused on whether they have the right footprint that allows patients to access their providers. He says that the options providers will continue to consider include partnering with retail health providers, virtual access to care, walk-in clinics and urgent care, and same-day visits with specialists. “That’s how [providers] win with consumers—by thinking of access first.”

Issues top of mind for payers as they map out their strategy for the year ahead include demonstrating their value to their customers, since there’s some risk of being commoditized. “This has always been a problem for payers,” says Hafner. He anticipates that payers will continue to focus on price transparency initiatives, enabling convenient access to care, and communicating with patients about their financial obligations.

Since patients increasingly have higher deductible plans, that’s going to influence how products are priced and the decisions consumers make when choosing their...
health plan, he says. This reality will force payers to look at strategic partnerships in an effort to respond to the evolving demands of consumers.

**SHARED-SERVICES APPROACH**

In addition to full-on mergers, health systems and hospitals are pursuing joint operating arrangements where they’re able to share operating expenses. While these arrangements don’t require the healthcare entities to affiliate completely, they have the benefit of sharing costs, revenues, and capital risk, says Rii.

One such arrangement is between Centura Health in Denver and Catholic Health Initiatives in Englewood, Colorado. Centura Health is one of a handful of “joint operating companies” around the country. In these types of arrangements, says Rii, two independent health systems come together to retain their separate identities and governance boards, and a measure of autonomy. The two organizations also shift significant management and financial authority to a separate joint operating company. The agreement between the two organizations outlines the intended legal relationship between the parties while addressing various governance, management, and financial issues, in addition to ways to terminate the agreement.

Centura Health was created in 1996 when PorterCare Adventist Health System and Catholic Health Initiatives chose to collaborate on the delivery of hospital services, says Rii. Catholic Health Initiatives is currently in talks with Dignity Health, which won’t materially adversely affect the Centura Health structure, he says.

Fisher is also witnessing smaller physician groups join with larger practices as they grow concerned about achieving the regulatory requirements that come with running an independent physician practice.

While partnerships, affiliations, and acquisitions are driven by similar motivations—largely, the desire to centralize administrative burdens and responsibilities—a partnership or affiliation is looser than an acquisition, says Fisher. “The partnership is akin to an initial step and typically based on a contractual relationship set up as a joint venture. This means that the parties in the arrangement can also back out more easily if it’s not going as expected. In an acquisition, one entity sells all of its assets or equity to another entity. The selling entity is therefore fully tied to the buying entity and could be subject to penalty to leave or [it] would need to reacquire its assets. From this perspective, an acquisition is ‘going all in.’”

So what might a partnership look like? Independent practices might create a managed services model or independent physician association, which would employ administrative staff and provide a variety of services, such as billing, compliance, contract negotiation, and human resources, says Fisher. Independent practices that are interested in these services would either contract with the managed care organization or become a participating member in a more formalized arrangement, he adds. Practices that decide to combine in this way also might have the added benefit of collective action when it comes to negotiating with payers.

*Aine Cryts* is a writer based in Boston.
The List

Six things other industries can learn from healthcare

INDUSTRY LEADERS WEIGH IN  by AUBREY WESTGATE

1 To think local
“There is still a significant role, and consumer and purchaser demand, for community-based organizations. Their knowledge of their markets leads to a different level of service and a different level of community engagement—and consumers notice and appreciate the difference. Beneficiaries have voted with their feet: community-based plans now account for almost half of the coverage in Medicaid managed care.”
—Margaret Murray, CEO, Association for Community Affiliated Plans, Managed Healthcare Executive editorial advisor

2 To navigate compliance challenges
“Healthcare presents some unique problems that other industries do not experience to the same degree—intense all pervasive regulation being the most notable. Other industries can learn how healthcare companies cope with and manage with the heavy compliance oversight but still improve outcomes for their patients and shareholders/stakeholders.”
—David Schmidt, president of the TPG International Health Academy, Managed Healthcare Executive editorial advisor

3 To consider the broader impact
“One of the primary considerations always at the front of every healthcare executive’s mind is how our decisions affect the health and wellness of the patients and families we serve. Healthcare is very unique in the sense that all of our actions directly impact people across our communities, state, country and, in many cases, the world. This filter, applied more generally across all industries, would spur a powerful paradigm shift in how industry and corporate America affects each and every one of us.”
—Chad Johnson, senior vice president and executive director, Phoenix Children’s Care Network

4 To be authentic
“One of the scariest things we did was stop staging our healthcare marketing—no actors, no scripts, no sound tracks. We call it #LivingProof. It forced us to trust the story and revealed such small, but amazing moments of real emotion and human drama that are part of the healthcare journey.”
—Cindy Donohoe, senior vice president of marketing, Highmark Health.

5 To value smart investments
“The biggest learnings that other industries can ascertain from healthcare is the value of conscientious investments in higher standards of education; technology; research; collaboration and sharing of best practices that will inevitably help to drive success no matter what the industry.”
—David Calabrese, vice president and chief pharmacy officer, OptumRx, Managed Healthcare Executive editorial advisor

6 What not to do
“Sadly, I think that most of what other industries can learn from healthcare is how to not do things. Compared to other industries, we don’t do a good job of innovation, implementation of technologies, meeting customer expectations, controlling quality and cost management.”
—Don Hall, principal, DeltaSigma LLC, Managed Healthcare Executive editorial advisor
Q & A: Donna Levigne
Divisional senior vice president, Illinois Health Care Delivery, Blue Cross and Blue Shield of Illinois

Q: What is the goal of the intensive medical home (IMH)?
Levigne: Intensive medical homes and specialty intensive medical homes are part of our suite of value-based care (VBC) models. VBC is the payment structure that rewards physicians and hospitals for achieving the best possible outcomes for patients at the lowest possible cost. BCBSIL introduced VBC in the late 1970s with the launch of HMO Illinois. Specialty medical homes are one of the ways we are evolving and customizing these programs—there isn’t a one-size-fits-all solution to meet the needs of patients, payers and providers.

For many with chronic illnesses, their specialist serves essentially as their primary care physician. So, by developing IMH programs with specialty groups we are helping patients who can benefit the most from the enhanced access, care coordination and illness management that VBC provides.

Q: How are IMHs different from traditional medical homes?
Levigne: When we started our initial specialty IMH with Illinois Gastroenterology Group in 2014, it was the first specialty IMH in the state of Illinois. It uses a tool developed by SonarMD, which utilizes smartphones to help physicians monitor a patient’s status. BCBSIL has now contracted to expand that IMH program to other gastroenterology groups.

The BCBSIL intensive medical home programs initially focused on large primary care physician groups and have expanded to include hospitals, small primary care practices and specialists. BCBSIL’s specialty IMH’s use evidence-based clinical guidelines and clinical data to help drive medical decision making and improve quality of care for our members.

Specialty intensive medical home
Real-world model improves care, lowers costs

Q & A: Donna Levigne
Divisional senior vice president, Illinois Health Care Delivery, Blue Cross and Blue Shield of Illinois

Blue Cross and Blue Shield of Illinois (BCBSIL) members are benefiting from a new patient care model: Intensive medical homes (IMHs). These initiatives, based in physician practices, focus on improving patient access, care coordination and illness management, especially among patients with chronic conditions. The aim is to move away from fee-for-service to providing incentives for quality outcomes and improved population health.

Specialty IMHs

Back in September 2014, BCBSIL announced the first specialty IMH in the state at Illinois Gastroenterology Group (IGG), the state’s largest independent gastroenterology practice. This IMH focuses on patients with Crohn’s disease. Today, nearly 350 patients are participating, according to Donna Levigne, divisional senior vice president, Illinois Health Care Delivery, BCBSIL.

“Recent results show that for Crohn’s specific costs and utilization—the IGG population is out-performing in all areas: hospital admissions, emergency room, outpatient visits and office visits,” says Levigne. “We will be adding three more gastro IMHs this year.”
How it works
Patients receive a call, letter or email inviting them to enroll in the program at no cost. At an initial intake visit with the patient, a nurse care manager assesses the patient’s medical and psychosocial needs and develops an action plan. The nurse monitors the patient’s progress against the action plan, assists with care coordination and offers resources.

Illinois Gastroenterology Group uses a care management tool developed by SonarMD to enhance communications with its IMH patients. Once enrolled in the platform, patients receive monthly secure communications, which include questions designed to tell staff how the patients are doing. The answers to the questions produce a “Sonar Score,” a numerical value that correlates with symptom intensity. The slope of this score is then plotted over time to reveal trends. This monitoring can lead to intervention by a physician earlier than a patient would have initiated it.

The result: a decrease in emergency room visits, hospitalization rates and their associated complications, according to BCBSIL. “The goal is to improve their quality of life, while reducing avoidable complications and associated treatment costs,” says Levigne. “It supports our goals of improved outcomes and better health for our members, while moving reimbursement away from fee-for-service payments to those that are payments for value.”

Expanded reach
In March 2016, BCBSIL announced the first oncology IMH pilot program in Illinois with Illinois Cancer Specialists. To qualify, patients must be receiving chemotherapy or hormone therapy, with a cancer diagnosis of breast, colon, lung, pancreatic, prostate and any non-Hodgkin’s lymphoma. Key goals include:

- Coordinating care, with the central focus on patients;
- Efficient care, with treatment provided in a high-quality, low-cost setting;
- Continuously improving care by measuring and benchmarking results against other facilities providing care.

Payment model: BCBSIL provides incentives for quality outcomes and improved population health in a physician practice.

Cost savings: The first IMH provider groups produced an average cost reduction rate of 7.7%, based on the initial year of participation, according to BCBSIL.

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Q: MHE: Can you tell us more about the technology used in the IMHs?

Levigne: Project Sonar uses smartphone technology to enhance physicians’ communications with their IMH patients with Crohn’s disease. We’ve signed an exclusive contract with Sonar and plan to use it to expand and add more IMH’s this year.

Q: MHE: What specific results can you share as far as the Crohn’s disease program goes?

Levigne: Enrollees get texts with information/reminders and those who respond or acknowledge receipt are considered “pingers.” We’ve found $6,000 in savings for each “pinger” versus “non-pinger.” There were 81 pingers—resulting in almost half a million dollar savings.

Q: MHE: What are some of the challenges of IMHs?

Levigne: It’s tough work to come up with solutions to help patients manage complex diseases. We believe the specialty IMH model, aimed at improving patient care while reducing costs, has enormous potential for making the healthcare system work in a sustainable way. We’re interested in targeting diabetes, multiple sclerosis and other disease states.

Q: MHE: What have you learned in this implementation process? What advice do you have for executives?

Levigne: The SonarMD platform works because it is built by physicians, utilizes existing practice resources and is incredibly targeted. The platform is currently appropriate for Crohn’s and ulcerative colitis patients and since it’s not trying to be all things to all people with all chronic illnesses but rather built by a physician who understands this small population with a very specific chronic illness it is built for success.

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Tracey Walker is content manager for Managed Healthcare Executive.
Top four patient engagement trends

Noteworthy survey findings

Tracye Walker
Content Manager

Both patients and providers are eager for more effective patient engagement, according to a new study.

Seventy percent of the 200 patients who responded to CDW’s 2017 “Patient Engagement Perspective Study,” released at the Healthcare Information and Management Systems Society 2017 conference, say they have become more engaged with their healthcare during the past two years—up from 57% in 2016.

Sixty percent of the 200 providers who took the survey say that improving overall patient care motivates them to improve patient engagement.

Providers say they are encouraging patients to access their health information (83%), offering them the ability to sign up for a patient portal (81%), and communicating via email (53%).

“Patients, as a result, are becoming more knowledgeable about personal medical information, saving time, increasing their overall engagement with personal healthcare, and experiencing greater convenience,” says Nancy Ragont, senior manager, customer insights, CDW Healthcare.

Four key survey findings:

1. Patients continue to see the benefits of online access.

Seventy percent of patient survey respondents say they’ve become more knowledgeable about their personal medical information thanks to online resources, and 50% say they’ve noticed increased overall engagement with personal healthcare.

2. There’s power in patient portals.

Ninety percent of patient respondents say they can access a patient portal, and 81% of providers who say they’ve improved patient engagement credit patient portals. “Over the last year, patient portals have surpassed web-based access to healthcare information as the number one method of encouraging engagement for both patients and providers,” Ragont says.

3. Mobility is key.

Patients are increasingly comfortable with mobile access to their health information. Eighty-three percent of patient respondents say they would be comfortable communicating via mobile apps, and 77% say they would be comfortable texting with their healthcare provider, according to the study. However, only 34% are comfortable communicating via social media.

4. There’s room for improvement.

Just 29% of patient respondents say they would give their healthcare providers an “A” for their use of technology to interact with and engage patients, and 89% of patients would like to be able to more easily access their personal healthcare records.
Right in the middle of where payers and providers meet

The Managed Healthcare Executive mobile app for iPad and iTunes

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