The business challenges keeping execs up at night

5 WAYS HEALTHCARE COULD CHANGE IN 2019
What Every Healthcare Executive Must Remember

We play a critical role in driving healthcare forward

After the midterm election votes were tallied, pundits and thought leaders began offering their perspectives of what the results mean for citizens, taxpayers, and businesses. In some ways, the results offer more clarity about what we can expect for America’s healthcare future. In other ways, they raise more questions.

This month’s issue reveals the results of our annual State of The Industry Survey (see page 26). They provide insight into how our peers are responding to major industry changes, and what challenges they see coming in 2019. While we all want to predict the future so we can avoid obstacles, we cannot allow our desire for clarity to become an obstacle itself. As healthcare leaders, we have tremendous control over our own destinies—and countless opportunities to improve American health and wellness.

Over the past two years in particular, healthcare has been the focus of several high-profile—and sometimes heated—policy debates. America’s Health Insurance Plans (AHIP) has been at the center of many of them. In responding to the immediate, urgent policy questions on the table, we are also looking for the opportunities to drive healthcare improvements:

- As we engaged in the repeal-and-replace debate, we put forth recommendations at the federal and state level for improving costs in the individual market, promoting access to affordable, comprehensive coverage for everyone.
- As we responded to the 2019 annual rate notice for Medicare Advantage plans, we advocated for greater flexibility that would permit plans to offer more choices for beneficiaries.
- As states consider the future of their Medicaid programs, we continue to offer studies and resources that demonstrate the benefits the managed care offers for enrollees and taxpayers.
- As lawmakers debate the value of private-market healthcare coverage, our Coverage@Work initiative demonstrates how insurance providers protect the health and financial security of the 180 million people who receive coverage through their jobs.
- As Congress developed legislation to battle the opioid epidemic, we advocated for changes that would help keep people safe from the risks of addiction. We also launched the Safe, Transparent Opioid Prescribing initiative to support the widespread adoption of clinical guidelines for pain care and opioid prescribing.

Individually, health insurance providers have been making their own bold moves to improve what’s working, and to fix what isn’t. They are improving care access by leveraging on-demand technologies like telemedicine. A deeply-held personal favorite, they are investing in social determinants of health (see Special Report on page 34), to help entire communities get healthier faster and stay healthier longer. They are adopting new value-based models to bring down prices of prescription drugs and medical treatments. They are introducing new measures to better understand and drive member satisfaction; creating new collaborative relationships with doctors, nurses, and hospitals to break down barriers to care and find real solutions that will work in their communities; and launching new education initiatives to help people understand how healthcare works, and how to get the most out of their coverage and care.

It is important to take part in the policy debates. At the same time, I encourage managed care leaders to lean in to how we differentiate ourselves as a private market industry in very tangible ways. Focus your strategies relentlessly on patients and consumers. Invest in initiatives that will make sustainable improvements in health and living. Find new ways to offer more choices and value. Consider hiring executives in charge of social determinants of health. By driving innovation for more affordable choices that help people maintain their health without breaking the bank, we can truly make a difference for a better American healthcare system.

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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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Cover Story: State of the Industry

Annual survey responses reveal top industry challenges and opportunities  PAGE 26

Essentials

13 MIDTERM ELECTION RESULTS: 5 WAYS HEALTHCARE COULD CHANGE IN 2019

15 IMPROVE THE MEMBER EXPERIENCE

17 HOW BLOCKCHAIN COULD MAKE WAVES IN HEALTHCARE

22 MICHAEL J. DOWLING, PRESIDENT AND CEO, NORTHWEST HEALTH

31 WHAT’S BEHIND GROWTH OF URGENT CARE CLINICS?

32 TOP BLOCKBUSTER DRUGS FOR 2019

33 EMAIL EFFICIENCY BOOSTERS

34 NONCLINICAL FACTORS IMPACT PATIENT OUTCOMES

42 IS PRECISION MEDICINE WORTH THE HYPE?

44 ACADEMY OF MANAGED CARE PHARMACY NEXUS 2018

Commentary

5 WHAT EVERY HEALTHCARE EXECUTIVE MUST REMEMBER by John Mathewson

Departments

6 ADVISORY BOARD

48 THE BOTTOM LINE
Midterm Election Results: 5 Ways Healthcare Could Change in 2019

Here’s how experts predict healthcare will unfold in 2019  by KAREN APPOLD

When Americans voted in the 2018 midterm election, healthcare was a hot issue. Consider the fact that in a PwC Health Research Institute Consumer Survey in September 2018, 59% of the 1,500 respondents cited healthcare as the most important issue. So now that the Democrats will control the House and Republicans will have a greater majority in the Senate, will they attempt to address the healthcare issues Americans are complaining about?

Congress will start with a clean slate in January. “Many bill sponsors and co-sponsors from the 115th Congress are no longer Congressional members,” says Annette Bechtold, senior vice president of Regulatory Affairs and Reform Initiatives at OneDigital, which provides employers with benefit advisory services. “All old bills that were introduced will be dismissed and all previously proposed legislation will need to be reintroduced. Educating new members while finding new sponsors and co-sponsors will add to the lengthy timeline of getting things accomplished.”

Here’s how experts predict healthcare will unfold in 2019.

1. There could be more changes to the ACA

The Democrats’ midterm wins will likely slow, but not stop, the Republicans’ pursuit of their healthcare agenda—which has focused on deemphasizing the role of the federal government in the U.S. health system, says Benjamin Isgur, health research institute leader, PwC, which analyzes trends affecting health-related industries.

Democratic control of the House likely means that Republican lawmakers will not undertake another attempt for wholesale repeal and replace of the ACA. Rather, the most substantive action related to the ACA will happen as the result of regulation and executive action. Without overwhelming majorities that can grant veto power, however, Democratic lawmakers will have little room to pursue their own agenda without bipartisan support.

But Michael Strazzella, co-
head, Washington office and group practice leader of federal government relations at the law firm Buchanan, Ingersoll, & Rooney, PC, believes the Senate, having grown its majority, will make efforts to repeal the ACA as it did in the 115th Congress. “Unlike the last Congress, however, I expect them to ensure that pre-existing conditions are protected in order to ensure that the issue can be avoided during the 2020 elections,” he says. “The House will hold hearings to highlight pieces of the ACA that they consider to be successful. Moreover, they will attempt to further block executive branch efforts to impede implementation of the ACA.”

2. **The Trump administration will continue to use regulatory agencies in an attempt to transform Medicaid, roll back industry regulations, and address drug pricing**

These changes can be made without congressional input. HHS will move full speed ahead with initiating block grant pilots and enabling states to reduce their Medicaid programs through premium and work requirements, reducing benefits, and raising income thresholds, in order to create savings for poorer states and reduce the federal match to help fund tax reductions, says Gerry Hinkley, JD, leader of the healthcare industry team at Pillsbury Law, which provides legal services that support the healthcare industry. HHS will also continue the “reducing reporting burden” approach carried forward in the 2019 Inpatient Prospective Payment System rule as a basis for accelerating the reduction in Medicare support for inpatient care.

Regarding drug pricing, the recently-enacted Know the Lowest Price Act and Patient Right to Know Drug Prices Act will improve transparency of drug pricing for patients. “I expect the president to continue to pressure pharmaceutical manufacturers to reduce drug prices, but it’s not clear when or whether further action will be taken by regulatory agencies,” says Eric D. Fader, JD, partner in the law firm Rivkin Radler LLP.

3. **The Trump administration will continue to embrace value-based care models, including mandatory ones**

The administration is looking for ways to improve the affordability of healthcare and Alex Azar, HHS secretary, has affirmed that this will be the agency’s strategy. Value-based care models are predicated on success and efficiency; they focus on the best care for the best price and reward those outcomes. “More accountability on providers and education of consumers will be the key to bringing healthcare costs in line,” Bechtold says.

4. **Certain healthcare initiatives that Republicans and Democrats agree on could gain momentum**

Two areas that both parties agree on are prescription drug regulation and stabilizing the individual market, says Arthur Tacchino, JD, chief innovation officer, Sync-Stream Solutions, a provider of healthcare reporting and compliance solutions. Prescription drugs have been targeted due to their incredibly high prices, and the country’s opioid crisis has drawn attention to them from a health and welfare perspective. “Even prior to the midterm elections there was bipartisan support to help stabilize the individual market, especially because the ACA’s individual mandate was effectively repealed with the GOP tax reform bill in 2017,” he says.

Mark Luck Olson, chief executive officer, Trainer Rx, an outcomes focused, evidenced-based, and patient-centric telerehab platform, says the topic of pre-existing conditions surfaced during the midterm elections, with both political parties considering it important. “They define pre-existing conditions differently, however,” he says. “While Democrats view pre-existing conditions as a necessary right, the Republicans view it as a forced purchase. Ultimately it becomes a question of whether payers think healthcare is a service to be purchased or a right that everyone should have.”

5. **Democrats will gain some power**

Democrats do not have enough power at the federal level to make any significant changes in the healthcare industry without bipartisan support. However, they will now have enough unilateral power to stop Republican efforts. “Any substantive change through legislation would require both the House and Senate to pass it, and now that Democrats have taken control of the House they have the ability to quash any Republican efforts they do not agree with,” Tacchino says.

Isgur says Democrats will gain more oversight authority, allowing them to hold hearings on the administration’s actions and subpoena agency leaders.

Democrats also will have a greater say in the federal budget. “One priority for them will be to include more resources to shore up the ACA individual markets,” Isgur says. “This can take the form of restoring funding for programs that connect beneficiaries to ACA navigators or pushing for restoration of ACA cost-sharing reduction payments to insurers.”

Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.
When patients search for a new doctor, they typically begin by clicking through online results on a payer’s website or ask friends for recommendations. But even the best online searches only provide minimal information, like a physician's gender, age, educational qualifications or practice locations.

Here are four ways payers are improving the member experience:

1. **Providing a concierge care model**

   When a patient is sick, they don’t want to be just a number to the insurance customer service representative who answers their call. That’s why when a member reaches out to New York City-based Oscar Health, they connect with one of five staff on the concierge team at the health insurance company. The team also includes a registered nurse, says Chelsea Cooper, senior vice president of strategy and operations. The member can communicate by phone, secure messaging, or email with any staffer on the concierge team, or they can request to speak to a specific staffer.

   When a member calls their concierge team with a clinical question, they can also be connected with a doctor for a virtual visit through Oscar’s Doctor on Call feature. During the virtual visit, the member is asked about their symptoms and health history; in return and if appropriate, the member receives a diagnosis and plan, and prescriptions can be sent to their pharmacy.

   The information gleaned about virtual doctor visits is stored within the member’s profile, which allows the payer to know more about each individual member, according to Cooper.

   In addition, members have access to the Oscar web, Android, and iOS apps, where they can search for care based on the reason for visit, type of doctor, and location. They can also book appointments and pay their bills and access a pre-selected network of hospitals and physicians.

   Members with more complex health needs—such as diabetes—are assigned to the complex case management team; this assessment is based on claims data, says Cooper. This team includes doctors, nurses, and social workers, who can go into members’ homes to do assessments and set up medical devices.

   Oscar Health launched the concierge team model to some of its members in 2016 and transitioned all members by the second quarter of 2017, says Cooper.

2. **Increasing access to medication-assisted treatment recovery**

   More than half of the estimated 2.5 million people with substance abuse disorders in the United States are without dependable access to medicated-assisted recovery options, according to Boston area-based Neighborhood Health Plan, a payer arm of Partners HealthCare.

   That’s why Neighborhood Health Plan is trying to improve the experience for members and non-members by offsetting the cost for providers to dispense buprenorphine products—such as Suboxone, which is used to treat cravings and withdrawal symptoms related to opioid dependency—and other

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**Money Matters**

Consumers are increasingly incorporating cost into their healthcare decisions. Savvy managed care organizations are doing all they can to increase price transparency.

“Payers can do this by providing more clear pricing transparency through publishing accurate prices for cash-pay individuals and participating in emerging on-demand health platforms,” says Bill Shea, vice president at professional services company Cognizant. “Consumers should have readily accessible platforms that translate complex pricing language into terms that customers can understand.”

Healthcare organizations should also help members navigate healthcare payments, from understanding terminology such as deductible, copay, and coinsurance, to allowing members to pay all of their providers using a digital wallet, says Deirdre Ruttle, vice president of strategy at healthcare payments network InstaMed. “By doing this, payers also make it easier for providers to connect with their patients and streamline their payment processes as well.”
THERE’S EYLEA—a treatment option that can fit your plans for proven visual acuity outcomes

✔ EYLEA has proven outcomes as demonstrated in phase 3 clinical trials in patients with Wet AMD, Macular Edema following RVO, DME, and DR in patients with DME

✔ With monthly and every-other-month dosing,† EYLEA offers flexible dosing options to meet the needs of your providers and your members

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

• EYLEA® (aflibercept) Injection is indicated for the treatment of patients with Neovascular (Wet) Age-related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR) in Patients with DME.

CONTRAINDICATIONS

• EYLEA® (aflibercept) Injection is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

WARNINGS AND PRECAUTIONS

• Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.

• Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

• There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

ADVERSE REACTIONS

• Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.

• The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous floaters, intraocular pressure increased, and vitreous detachment.

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5.3 Thromboembolic Events. There is a potential risk of arterial and/or venous thromboembolic events (ATEs) in patients treated with EYLEA. Anticoagulants are recommended for high-risk patients who have had a thromboembolic event and for patients who had an arterial or venous thromboembolic event within the prior 12 months.

5.4 Diabetic Macular Edema (DME). Macular edema secondary to diabetes was defined as 200 μm of retinal thickness by optical coherence tomography (OCT) in the macular region of the retina, and endophthalmitis or retinal detachment. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise patients to seek medical attention. The incidence of reported thromboembolic events in wet AMD studies during the first 12 weeks (N=578) of patients treated with EYLEA was 0.8%. The incidence of thromboembolic events in the DME studies was 3.5% (N=578) after repeated intravitreal dosing with vascular endothelial growth factor (VEGF) inhibitors. Intravitreal pressure and the perfusion of the optic nerve head should be monitored and managed appropriately (see Dosage and Administration).

5.5 Warnings and Precautions

5.5.1 Endothelial and Retinal Detachments. Intravitreal injections, including those with EYLEA, have been associated with endothelial and retinal detachments (see Adverse Reactions). Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed on proper eye care, including suggestions for proper self-care of a retinal detachment without delay and should be managed appropriately (see Dosage and Administration and Patient Counseling Information).

5.5.2 Increase in Intraocular Pressure. Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA (see Adverse Reactions). Sustained increases in intraocular pressure have been observed in patients with diabetic macular edema treated with intravitreal diazoxide and vascular endothelial growth factor (VEGF) inhibitors. Intravitreal pressure and the perfusion of the optic nerve head should be monitored and managed appropriately (see Dosage and Administration).
No pre-authorization requirements for Suboxone.
No copays for Narcan (naloxone), which is used to reverse opioid overdoses; pharmacists inform members about their eligibility for free supplies of Narcan when they receive a prescription for high-dose narcotic painkillers.
Two trained and certified recovery coaches who work with at-risk patients and, hopefully, prevent life-threatening relapses.

Neighborhood Health Plan’s strategy is to optimize access to treatment, says Dodek. “The problem is related to access to medication-assisted therapy,” he says, noting that evidence shows the most effective way to treat opioid addiction is with medications such as Suboxone, in conjunction with counseling. Currently, there aren’t enough providers in Massachusetts with this training—which means patients don’t have access to medical-assisted recovery from opioid dependence, he says.

In Massachusetts, physicians with DEA-required training can prescribe these medications, according to the state’s board of registration in medicine. Advanced practice registered nurses, physician assistants, and pharmacists can also prescribe some medications. Physician assistants and advanced practice clinicians must be supervised by a physician licensed in the state.

3 Incorporating compassion training
Members want to hear a friendly, calm, informed voice at the other end of the phone when they call their health insurer.

To support members during stressful times, Minnetonka, MN-based UnitedHealthcare trains its customer service personnel on what it calls its “compassion code.” The payer defines this as taking an empathetic approach to members’ needs by paying attention to their voices and the language they use during the phone interaction, says Rebecca Madsen, chief consumer officer. This approach allows a customer service representative to understand the member’s state of mind.

Customer service representatives learn about the compassion code during extensive training, which features soft skills, technical skills, and operational policies and procedures. They are then evaluated based on an improvement in member satisfaction, says Madsen. These variables include:

- Single-call resolution: Was the issue resolved correctly on the first call?
- Positive connection: Was the member treated with care, concern, and respect?
- Compliance: Did the interaction meet privacy and regulatory requirements?
- Adherence to business requirements: Did the call adhere to operational policies and procedures?

4 Supporting members’ weight loss goals
Weight loss is difficult—and many who lose weight are unlikely to maintain that loss long term. Being overweight is also dangerous since it increases the chance of developing diabetes, heart disease, and other chronic diseases.

To help its members lose weight, UnitedHealthcare developed Real Appeal, a personalized, interactive online weight-loss program. The program uses personal coaches and well-known celebrities—like Dr. Oz and actresses Jennie Garth and Vivica A. Fox—to support members in their weight-loss journey.

At its core, Real Appeal combines social support, entertainment, and science to support members. The program includes a web program that features segments on fitness, cooking, stress management, and sleep.

Program participants receive exercise DVDs and resistance bands, along with measuring cups and a food scale to help control portion size. Also included are booklets with weight-loss information and a measuring tape to track waist size and a weighing scale.

Since the program was launched in late 2015, more than 100,000 enrolled members have collectively lost more than 1 million pounds or an average of 7% of their body weight, according to UnitedHealthcare. The program has saved employers up to 16% in annual medical costs.
Blockchain technology, in many ways, is like Google Docs, the online platform where a group of users can contribute to and edit a shared document to create a record of information—but perhaps a bit more sophisticated.

Blockchain, often associated with cryptocurrency and digital trading, is a cooperatively maintained repository for information. The technology enables multiple users to upload and share information to provide a single accurate collection of details using a blockchain database, according to Mike Jacobs, senior engineer of Optum, a business unit of UnitedHealth Group.

For example, blockchain can aggregate health records from other providers for more effective healthcare delivery that isn’t tripped up by, for example, health insurance claims getting denied due to inaccurate patient data.

The blockchain users could be multiple companies, such as medical provider groups and health insurance companies, who want to access the same information so insurance claims can be processed and paid efficiently the first time.

Some small bits of information can be stored on the blockchain itself, but the rest of the data is kept in existing users’ computer systems or “off-chain”—in other storage locations.

In this case, the blockchain stores information about transactions, such as the time stamp and where the data lives. To gain access to data, users must have a special password. “You want to have the two ends of the transaction have the same information for it to happen in a frictionless way,” says Jacobs. Take the example of insurance claims. Currently, numerous problems often come up when processing claims, because details about provider contacts, provider information such as an in-network designation, and/or insurance rules regarding coverage can all result in data that don’t match up among companies’ databases.

Blockchain can provide a single source of accurate information, thereby avoiding such problems, Jacobs says.

Blockchain is also known as distributed ledger technology. Just as a person keeps a ledger when paying bills, blockchain is the same—only in an electronic format, says Debbie Bucci, IT Architect with the Office of the National Coordinator for Health IT, a part of HHS.

“Multiple workers or participants are writing to it at one time, and they can craft different transactions one at a time and can’t erase it,” Bucci says.

**Blockchain in healthcare**

Blockchain’s healthcare applications are still emerging. Humana, the MultiPlan PPO network, Quest Diagnostics, UnitedHealth Group, Optum, Aetna, and Ascension have joined in a blockchain-driven effort to address provider data issues.

**What’s next?**

Opinions differ on whether blockchain can help healthcare.

On the “benefits” side is Robert Chu, MEng, MCS, founder and CEO of Embleema, a Metuchen, New Jersey-based healthcare blockchain network that launched a public beta release in mid-July. It allows patients to share their medical histories with providers, and in future versions, with pharmaceutical companies seeking subjects for clinical trials and, potentially, with health insurers. Embleema secures data so providers can see a complete medical history without the need for patients to fill out forms at every visit. Pharmaceutical companies seeking patients for new clinical trials will also be able to search Embleema’s database in the future to find candidates.

Others are more skeptical.

“I don’t think anyone has clearly demonstrated what patients will see or get out of it, nor has the industry been successful, beyond proof of concepts or small target pilot demonstrations, to link multiple hospital systems,” Bucci says.

“It looks like a potential solution to a security problem, but nobody has implemented it for that purpose, as of yet.”

**Cheryl Alkon** is a freelance writer for Medical Economics, our sister publication in which this article first appeared.
Growing up in Limerick, Ireland, Michael J. Dowling admits his family situation was a little complicated—his mother was deaf and his father suffered from heart disease and arthritis. “Because of that, I already had an interest in the health and human services field and I think that’s what led me to the arena,” Dowling says. “When I went to college I got involved volunteer-wise in a lot of health issues and homeless issues, and it just was natural to me. I always was drawn to it.”

That early passion for health-care has never ebbed.

Today, Dowling serves as president and CEO of Northwell Health, the largest integrated healthcare system in New York State with more than 67,000 employees. Under his leadership, the healthcare system has grown from an organization with 30,000 employees, 18 hospitals, and a few dozen outpatient locations to more than 67,000 employees, 23 hospitals, and over 665 ambulatory facilities. Quality has also improved. The health system’s education, awareness and clinical efforts have helped reduce sepsis mortality by more than 60% over the past decade.

“We were the first health system to be created in New York and we are currently the largest and we continue to expand,” he says.

In addition to those impressive hospitals and ambulatory location numbers, Northwell also boasts 6,675 hospital and long-term care beds, a full complement of long-term care services, a research institute, and medical and graduate nursing schools. Overall, Northwell is one of the largest health systems in the U.S., with $11 billion in annual revenue.

“We have all components of the healthcare business, we have everything from primary care all the way to end of life,” Dowling says. “We are very committed to serving everybody irrespective of circumstance. Many organizations like to focus in on those things that only do well financially. We take care of everybody, including people with substance abuse, alcoholism abuse, etc., so you want to be an organization that is focused that way.”

From politics to healthcare

Dowling earned his undergraduate degree from Ireland’s University College Cork and his master’s degree from Fordham University, picking up honorary doctorates over the years from Queen’s University Belfast, University College Dublin, Hofstra University, Dowling College, and Fordham University.

After graduation, Dowling became a professor of social policy and assistant dean at the Fordham University Graduate School of Social Services and director of the Fordham campus in Westchester County.

When Mario Cuomo was elected governor in 1983, Dowling was offered a position on his administration as deputy commissioner in the Department of Social Services, which was responsible for all welfare programs in the state. Dowling didn’t know Cuomo and had never really been involved in politics before, and he declined the position—at first.

Then he decided it was a chance to make a difference on some of the issues he cared about, and decided to give it a go.

“I’m a risk taker, and thought it would be a good new experience,” Dowling says.

Although he expected to stay about one year, Dowling ended up spending 12 in the administration. During that time, he was continually promoted, including serving as state director of Health, Education, and Human Services, and as deputy secretary to the governor and social services commissioner.

“I had all of the welfare programs, health programs, education programs, and mental health, substance abuse—all behavioral health as part of my portfolio,” Dowling says.
Dowling says, "I worked with some very great people, we did some very interesting things, and I’m very fortunate that I was asked to serve because having the opportunity to work with Mario Cuomo was one of the best things that ever happened to me."

One program Dowling is most proud of from that time is Child Health Plus.

“It was a program that provided coverage to kids who didn’t have it and it was a very innovative program at the time and still exists,” he says. "That was the one that I think I spent probably the most of my time on during those couple of years and was one I always look back on as something of a success."

The road to Northwell

After Dowling left the government, he became a senior executive at Blue Cross Blue Shield in Manhattan, but he stayed less than two years.

“I’m not a person who likes to just sit in my office looking at paperwork; I like to be out in the field where the real action occurs,” he says. "I got a call from North Shore University Hospital asking if I would be interested in talking to them and I was excited about the possibility."

Dowling accepted a position as chief operating officer of North Shore University Hospital, a large tertiary campus where Northwell Health’s creation began, in the early 1990s.

“I was ready to leave the insurance side to get back into the world of where I thought the real work occurred, which is to be on the provider side where you actually were dealing with patients every day and making a difference in people’s lives each and every day,” he says.

He moved up to president and CEO of Northwell Health in 2002, and not a day goes by when he doesn’t deal with people—his favorite part of the job. For instance, each Monday morning he meets with all new employees to the organization, averaging about 150 a week.

“You have to be innovative and creative in this world today. You don’t want to be a prisoner of the past.”

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Michael Dowling

- Born in Limerick, Ireland; moved to U.S. at 16
- Earned BS at University College Cork and MA in social work from Fordham University
- Former professor of social policy and assistant dean at the Fordham University Graduate School of Social Services, and director of the Fordham campus in Westchester County
- Former state director of Health, Education, and Human Services and deputy secretary to New York Governor Mario Cuomo. Also, commissioner of the New York State Department of Social Services
- Former senior vice president at Empire Blue Cross/Blue Shield
- Current president and CEO of Northwell Health
Away from the office

When he does allow himself time to unwind, Dowling spends time with his family, wife Kathy, son Brian who works in healthcare, and daughter Elizabeth, an oncology nurse.

He also enjoys reading, and regularly hands out lists of books that he’s read to his staff.

“I like to read things that I think I can actually learn something from, so I’m always reading two or three books at a time,” he says. “I like autobiography, I like history, I like politics and economics—things that are real.”

Here, are five book recommendations from Dowling:

1. Lincoln and the Irish by Niall O’Dowd.
2. How Democracies Die by Daniel Ziblatt and Steven Levitsky.
3. The Tyranny of Metrics by Jerry Muller.
4. The Everything Store: Jeff Bezos and the Age of Amazon by Brad Stone.

Besides meeting and mentoring staff, he deals with the press, works with politicians, offers opinions to the board, works with community organizations, and oversees the administrative, technical, and budgetary initiatives.

“Every day is a little bit different and things pop up all the time because when you’re on the provider side, when something goes wrong, if it really goes badly wrong, it’s dangerous because it’s mostly life and death situations,” Dowling says. “In healthcare, a bad decision can result in a very, very bad outcome for somebody so that’s why you’ve got to have the right people and the right physicians, officers, and administrative leaders in the right positions, to make sure that those things happen rarely and are not a common occurrence.”

The power of innovation

A unique program at Northwell Health replicates the show “Shark Tank,” where it holds an annual competition among employees called the Innovation Challenge in which it invests more than $1 million a year to support promising commercialization ideas that originate with the health system’s physicians, researchers, and other staff.

“We try a lot of new things. Our medical school is very innovative, our nursing school is innovative,” Dowling says. “We do a lot of innovation programs. We’ve built up new businesses based upon ideas coming from staff.”

For instance, as part of this year’s President’s Award for Innovation, it awarded $500,000 to researchers at its Feinstein Institute for Medical Research to further develop a non-invasive approach to diagnosing endometriosis, a painful condition that affects one in 10 women and can cause infertility.

“You have to be innovative and creative in this world today. You don’t want to be a prisoner of the past,” Dowling says. “You want to be an organization that is constantly pushing the edges of the envelope and known as the place where people can get the best care, best coordinated in a holistic way, and you want to be a place where people enjoy coming to work.”

Dowling is a big believer in the team and his philosophy is to guide the ship but let the people that he puts into place do the work. He wants his employees to understand they have an obligation and responsibility, not necessarily a job.

“I try to light a fire in people rather than lighting a fire under them,” he says. “I try to inspire people, try to convince people that what we’re doing is good. I’m an optimist, I believe that we do great work in healthcare, and I think it’s important to get people to understand that they’ve got to be proud of what they do, acknowledge the great things that they do, and feel optimistic about the potential, while acknowledging the fact that they need to get better and better all the time.”

When Dowling reflects on his career and his work at Northwell Health, he is happy that he gets to come to work every day and be with a group of great people who share his views on helping people.

“When you’re in healthcare and you walk around the hospital and you walk through the children’s hospital, you walk through the oncology ward, it gives you perspective on life. You realize how fortunate you are to be working in such a place, and also how fortunate you are that you are today temporarily healthy,” he says. “By the end of the day, you can say, ‘Today we helped people, we made people better today.’ We did the right thing for those people who depend upon us for the care.”

Keith Loria is an award-winning journalist who has been writing for major newspapers and magazines for close to 20 years.
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Annual survey responses reveal top industry challenges and opportunities

How do healthcare executives feel about the healthcare landscape moving into 2019? Here’s your chance to find out. During the third quarter of 2018, nearly 200 executives from provider organizations, benefit management organizations, health plans, long-term care organizations, and group purchasing organizations took Managed Healthcare Executive’s annual State of the Industry Survey. Their responses reveal the top industry challenges, opportunities, priorities, and initiatives to watch in the year ahead.

Q: What do you think is the biggest challenge facing healthcare organizations?

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Complying with policy changes/government requirements</td>
<td>32%</td>
</tr>
<tr>
<td>Value-based care/population health management</td>
<td>30%</td>
</tr>
<tr>
<td>Addressing rising pharmaceutical costs</td>
<td>15%</td>
</tr>
<tr>
<td>Technology acquisitions, investments, and implementation</td>
<td>10%</td>
</tr>
<tr>
<td>Other</td>
<td>13%</td>
</tr>
</tbody>
</table>

“It's no surprise that value-based care/population health management was voted as one of the biggest challenges. Many organizations across the U.S. are talking about value-based care and population health management but few are gaining traction in the implementation.”

—Cynthia Hundorfean, is president and CEO of Allegheny Health Network (AHN), an integrated healthcare delivery system that serves Western Pennsylvania. AHN is part of the Highmark Health family of companies.

“Due to the increasing burden of policy changes and government requirements from the current administration, life is more difficult for Medicare and Medicaid health plans. With commercial plans, the challenge is to have more value-based contracting with providers and other vendors (e.g., drug companies).”

—Perry Cohen, PharmD, is chief executive officer of The Pharmacy Group and the TPG family of companies, which provides services to associations, healthcare and information technology organizations, payers and pharmaceutical companies.
Q: Where would you say your organization is in the shift toward value-based care?

10% We have not yet started.
50% We have a few initiatives started.
26% We have many initiatives started.
14% Most of our business/operations is focused on the value.

Q: How well would you say your organization is using big data to improve healthcare quality and reduce healthcare costs?

12% Very well. Our use of big data is making a big impact.
46% Well. We’ve come a long way but still have a lot of work to do in this area.
30% Not very well. We’re trying but there’s still a lot of confusion about how to fully utilize big data.
12% Not well at all. We are doing very little in this area.

Q: If you could venture a guess, how do you think your business revenue in 2019 will compare to 2018?

39% 2017 35% 2018

35% 19% 30%

39%
It will be a better year revenue-wise

35%
It will be a worse year revenue-wise

42%
It will be about the same

“While I’m encouraged to see that 90% of those surveyed have become at least somewhat engaged in value-based care, it appears we still have more followers than leaders. This will unfortunately continue to be the case until we adequately align the incentives of providers and purchasers alike.”


“The results of this question are encouraging in that the majority of respondents indicate that their organizations have moved forward with efforts in this area. As these models proliferate, all stakeholders across the healthcare system should benefit via more team-oriented approaches to patient care; more integrated data and analytics capabilities; and an enhanced ability to measure patient outcomes. With time, many believe (myself included) that this model offers us the greatest likelihood of improving cost-efficiency in healthcare while simultaneously driving higher degrees of quality of care and empowering people to lead healthier lives.”

—David Calabrese, RPh, MHP, is senior vice president and chief pharmacy officer at OptumRx, a pharmacy benefits firm that provides pharmacy care services for more than 65 million lives.
Q: What patient-centered area is your organization most focused on?

- Improving customer/patient satisfaction: 66%
- More cost/quality transparency: 30%
- Providing more financial counseling: 4%

“I agree with the results, in addition to a focus on value-based care, there is a huge push to create a differentiated experience for the patient. Consumers across all industries are demanding a differentiated and streamlined experience and the healthcare industry has a lot of room for improvement.”

—Hundorfean

Q: What do you think will have the biggest impact on controlling rising specialty drug costs?

- 23% Value-based (outcomes-based) pharma contracts
- 21% Government interference
- 13% Integrated pharmacy and medical benefits
- 11% Cost-effective pharmacy plan design
- 10% Utilization management
- 8% Biosimilars
- 6% Other
- 5% Pharmacy benefit managers and specialty pharmacies
- 3% Increasing member copays

“Clearly the wide disbursement in responses here is indicative of the challenges we face as an industry in managing costs while preserving proper access and clinical quality within the specialty pharmacy. These responses also reflect the reality that effective management of the rapidly-expanding specialty market will require a highly diverse, multidimensional set of tools and strategies. As has been well-demonstrated to date, there remains no ‘magic-bullet’ approach in this area, and this will continue to remain one of the biggest challenges, if not ‘the’ biggest challenge, facing payers and pharmacy benefit managers into the future.”

—Calabrese

Q: What is the most effective way to increase consumer engagement?

- 29% Incentives/wellness programs
- 29% Technology (remote patient monitoring/mobile health)
- 29% Improved/more patient education
- 13% Penalties/cost increases

“It is interesting to note that pharmacy benefit managers and specialty pharmacies are viewed as having little impact on managing specialty drug costs, but integrating pharmacy and medical benefits along with plan design and utilization management are more effective ways to manage these costs. I totally agree with the survey responses.”

—Cohen
**Q:** Top 9 Therapeutic Categories Health Execs Will Focus on in 2019

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Diabetes</td>
<td>66%</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>53%</td>
</tr>
<tr>
<td>Behavioral health/mental health</td>
<td>40%</td>
</tr>
<tr>
<td>Opioid crisis</td>
<td>37%</td>
</tr>
<tr>
<td>Cancer</td>
<td>31%</td>
</tr>
<tr>
<td>Obesity</td>
<td>30%</td>
</tr>
<tr>
<td>Respiratory illnesses</td>
<td>26%</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>6%</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>4%</td>
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</table>

**Q:** What is the biggest leadership challenge healthcare executives face?

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Navigating a changing environment (value-based care, policy changes, new government mandates, population health management)</td>
<td>58%</td>
</tr>
<tr>
<td>Lack of resources (time, money, staff) to accomplish what they need to accomplish</td>
<td>19%</td>
</tr>
<tr>
<td>Dealing with unreasonable expectations (from their own organization or outside entities such as the government or payers or other partners)</td>
<td>16%</td>
</tr>
<tr>
<td>Other</td>
<td>5%</td>
</tr>
<tr>
<td>Difficulty securing buy-in for initiatives from staff and other leadership</td>
<td>2%</td>
</tr>
</tbody>
</table>

“In I’m not surprised that the ‘challenge of change’ tops the list, given our collective tendency to cling to the status quo. I also continue to believe that government mandates will, to a large extent, drive the pace of change, as CMS and other governmental agencies can be very effective motivators.”

—Chaet

**In general, I feel that I have:**

- No ability to improve the cost and quality of care at my organization: 7%
- A small role in determining the cost and quality of care at my organization: 29%
- A moderate role in determining the cost and quality of care at my organization: 32%
- A large role in determining the cost and quality of care at my organization: 32%
The primary factor that I believe holds me back from making a larger impact is:

- **33%** Too many competing priorities (new ideas and initiatives don’t get as much attention as they should)
- **22%** Lack of resources (time/money) to explore different options
- **20%** Policy/government regulations and mandates
- **14%** Barriers from the administration (i.e., they aren’t open to new ideas/initiatives)
- **11%** Other

Q: What is your general feeling about the current state of the healthcare industry?

- **50%** Quality and costs are worsening
- **32%** Quality and costs remain about the same
- **18%** Quality and costs are improving

Q: What industry problem keeps you up at night?

**Our patients**
- “High-quality affordable healthcare for everyone.”
- “Affordability of and accessibility to quality healthcare.”
- “How can we best meet the needs of high-cost, high-utilizing patients?”
- “Caring for the underserved, uninsured patient population.”
- “Consumerism.”
- “Encouraging patients to seek medical attention at our facilities and not the ER.”
- “Precision medicine.”

**Pharma issues**
- “Opioid crisis.”

**Value-based care**
- “High cost of pharmaceuticals.”
- “Cost of oncology meds.”
- “Educating legislators where the costs of pharmaceuticals are spent to prevent ineffective and damaging policy changes.”
- “Manufacturer drug pricing.”
- “Drug shortages.”

**Regulatory demands**
- “Government changes in healthcare coverage.”
- “Regulatory compliance.”
- “Not knowing what the feds are or are not going to do next.”
- “Over-regulation.”
- “Acquisitions.”

**Staffing**
- “Physician burnout.”
- “Finding and keeping talent.”
- “Decreasing revenues and employees wanting significant raises.”
What’s Behind Growth of Urgent Care Clinics?

by CHERYL ALKON

Patients seeking medical care don’t want to wait. Urgent care clinics, with their longer hours and walk-in appointments, fulfill that need in a way traditional physicians’ offices can’t.

“This is the age of the patient as a consumer, where fast and convenient is never fast and convenient enough,” says Richard Park, MD, CEO and cofounder of CityMD, a group of urgent care clinics in New Jersey, New York, and Washington state, and president-elect of the Urgent Care Association (UCA).

Sean McNeeley, MD, medical director of University Hospitals Urgent Care Network based in Cleveland, says the cost of an urgent care visit is typically similar to a primary care physician visit, and much less than an ED visit. Also, urgent care clinics offer more services than most primary care offices. “We can do more, such as run IVs, splint a fracture, or sew wounds,” says McNeeley, who is also president of the board of directors of the UCA.

Faster, easier, cheaper

Millennials make up a quarter of all visits to urgent care clinics, according to a 2015 PNC Healthcare survey. “I think it’s very appealing to that generation,” says Laurel Stoimenoff, CEO of the UCA.

Other patient groups also report not always turning to a primary care physician for care. A UCA study of patients over age 65 found that 11% said they had no primary care physician. A Kaiser study from 2014-2016 reported that, on average, 17% of women in the U.S. didn’t use a primary care provider. For men it was 28%.

Rural areas in particular are benefiting from the rise in urgent care clinics. A report by FAIR Health, a nonprofit that studies insurance claims, found that from 2007 to 2017 there was a 2,308% increase in insurance claims for procedures done in rural urgent care facilities compared to a 1,675% increase in urban areas.

And with more patients paying out-of-pocket for healthcare services, more are turning to urgent care because costs are lower, says Park. “About 35% of employees are on high-deductible health insurance plans, and that number is growing,” he says. Many of those patients pay from $6,000 to $8,000 out-of-pocket before insurance pays anything. About 80 percent of them never meet their deductible, so they are essentially self-paying and want to pay the lowest fees.

“Urgent care is one service that checks both boxes,” says Park. “It is faster, better, and less expensive, and relative to primary care physicians, urgent care centers provide better access and an extended scope of practice.”

### Urgent care by the numbers

- **$18** BILLION annual revenues of U.S. urgent care clinics, with a projected 5.8% growth this year
- **89** MILLION Number of patient visits handled by urgent care clinics each year
- **29** MILLION Share of primary care visits conducted annually in U.S. urgent care clinics

Source: The Urgent Care Association
Major blockbuster drugs slated for launch in 2019 are expected to have a significant impact on treating certain cancers, diabetes, peanut allergies, and other conditions.

Many medication launches will treat a variety of cancers, according to Christopher Peterson, PharmD, director of Emerging Therapeutics at Express Scripts. “Cancer therapies represent about one-third of all specialty drugs in the pipeline, so a significant number of cancer drug approvals is expected into the future,” he says.

Cancer drugs
Sacituzumab govitecan (Immunomedics), a novel, first-in-class antibody-drug conjugate (ADC) for treating breast cancer, was granted priority review by the FDA in July 2018. It is one of the top cancer medications expected to receive FDA approval in early 2019, according to Aimee Tharaldson, PharmD, senior pharmacist with Emerging Therapeutics at Express Scripts.

Elzonris (tagraxofusp, Stemline Therapeutics), for treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) cancer, is also expected to receive final approval in February.

Other expected major cancer drug launches include oral selinexor (Karyopharm Therapeutics) to treat multiple myeloma and oral erdafitinib (Janssen), which received breakthrough therapy designation in March 2018, for urothelial cancer.

LOXO-292 (Loxo Oncology), received breakthrough designation from the FDA for patients with metastatic RET-fusion-positive non-small cell lung cancer (NSCLC) as well as a last-line treatment of RET-positive thyroid cancer, is another cancer therapy to watch, says John Santilli, president of Market Access Intelligence.

In the lucrative diabetes drug market, Ozempic (semaglutide, Novo Nordisk), a GLP-1 agonist for type 2 diabetes approved in 2018, may achieve blockbuster status in 2019, Santilli says. “Ozempic has been gaining market share during this year in Canada and Denmark, in addition to the United States.”

In the innovative diabetes drug market, Ozempic (semaglutide, Novo Nordisk), a GLP-1 agonist for type 2 diabetes approved in 2018, may achieve blockbuster status in 2019, Santilli says. “Ozempic has been gaining market share during this year in Canada and Denmark, in addition to the United States.”

Inflammatry conditions
Potential big new drugs in 2019 for inflammatory conditions include upadacitinib (AbbVie) for rheumatoid arthritis and risankizumab (Boehringer Ingelheim and Abb-Vie) for psoriatic arthritis, Crohn’s disease, and other inflammatory conditions, says Tharaldson.

Viaskin Peanut (DBV Technologies), which has a PDUFA date of June 22, is a novel allergy immunotherapy administered daily via transdermal patch for desensitizing pediatric patients with peanut allergies. “This could be a blockbuster medication,” Tharaldson says.

Another potential blockbuster drug is esketamine (Ketanest, Janssen) nasal spray, which received breakthrough designation and is expected to be approved by FDA in early May 2019. Esketamine treats major depressive disorder, which affects about 16 million Americans, who are at imminent risk for suicide.

HIV
In the HIV market, bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy, Gilead Sciences), launched in 2018, will "continue to provide strong growth for the company in 2019 on its way to becoming a blockbuster drug," Santilli says. "This HIV ‘triplet’ medicine, combining different treatments into a single formulation, recently demonstrated high efficacy, high barrier to resistance, and long-term tolerability, reaffirming the drug as a first-line treatment option for suitable adult HIV patients who are starting therapy."

Christine Blank, a veteran freelance editor and writer, covers the pharmaceutical industry.
Email Efficiency Boosters

Ready to conquer your email inbox? Here are tips for healthcare executives by AINE CRYTS

Don’t reach for your cellphone to check your email—even if you have a few minutes, says Joe Tye, CEO and head coach at Values Coach, a training and consulting firm in Solon, Iowa.

Checking email on your cellphone can distract you from your focus. “Seeing focus as a core value and not just a matter of how I allocate my time and attention helps me appreciate that how I spend my minutes is a reflection of my character and what I value,” he says.

As with everything in life, setting expectations is important. That’s according to a recent Harvard Business Review article that recommends setting appropriate “expectations and norms” about the types of emails CEOs need to receive—and when CEOs are expected to respond. According to the article, regardless of your role at your healthcare organization, if you don’t set expectations regarding email appropriately, it leads to wasted hours and steals precious personal time from employees.

Here are seven ways to conquer your inbox:

Ask why you’re using email
If it takes more than 30 to 60 seconds to read the email, pick up the phone, says Jess Jones, managing director at Boston-based Huron Healthcare Consulting. Often, a five-minute phone call can help you avoid a stream of back-and-forth emails that eats up precious time and delays important action or resolution of an issue, she says.

Use—and encourage your team to utilize—subject lines that accurately represent the action required
Jones tells executives to avoid using general subjects, such as “info,” “notes,” or “hi.” And if you receive emails using these subject lines, change them. “Your team will get the picture pretty quickly of your expectations.”

Turn off email notifications on your cellphone
That means no physical notifications, such as vibrations or beeps, for new emails, says Kalyan Jonnalagadda, a leader in Bain & Company’s healthcare practice. And keep your phone out of reach during meetings, off hours, and on weekends.

Deploy your executive assistant
Your executive assistant’s mission? Filter messages and delegate as many as possible so you never see them, according to the Harvard Business Review article.

Implement a hierarchy of senders
Steve Burrill, vice chairman and U.S. healthcare providers leader at consulting firm Deloitte, tames his inbox by prioritizing inbound messages from clients. Next on his priority list are emails written to him personally, where few others are included.

Large group emails? He deprioritizes them, since they often don’t pertain to him or they can wait until the top priorities have been addressed.

Cut down on the number of people included in the email
“Keep in mind that the more people in the ‘to’ line, the less likely you will be to get a response,” says Jones.

Don’t send gratuitous “thank you” messages
This insight comes from Kirsty Boyd, director of process improvement of Newton-Wellesley Hospital, which is part of Boston’s Partners HealthCare. If the issue is personal, always pick up the phone, she says.

Aine Cryts is a writer based in Boston.
Nonclinical Factors Impact Patient Outcomes

BY KAYT SUKEL

When Gregory Kane, MD, chair of medicine at Thomas Jefferson University’s Sidney Kimmel School of Medicine, started his career in pulmonary medicine in Philadelphia 30 years ago, he quickly noticed that patient outcomes were not solely dictated by the patient’s medical condition. Two patients with similar cases, who were treated in comparable ways, could—and often did—respond to those treatments differently.

“Early on, I recognized that my patients’ neighborhood and their domicile was a major contributing factor to flares of their disease,” he says. “Those who work in healthcare understand that poverty level, access to healthcare insurance, and social situation contribute to disease and outcomes.”

With the ACA passage in 2010 and a greater focus by payers and providers on value-based care, such social determinants of health (SDOH)—defined by the World Health Organization as “the conditions in which people are born, grow, live, work, and age”—have become a major public health concern.

Julia Andrieni, MD, vice president of Population Health and Primary Care at Houston Methodist, an eight-hospital health system with more than 6,700 physicians in Houston, says research shows that SDOH-related inequities don’t just impact access to care—but overall health outcomes. In fact, according to Healthy People 2020, a report put out by the CDC, social and economic factors play an integral role in whether a patient can or will engage in behaviors known to promote health or follow a doctor’s recommendations or treatments after being diagnosed with a chronic condition.

Andrieni says that SDOH “affect every aspect of healthcare ... We’re learning that we have to address not only clinical factors that affect a patient’s health but also the nonclinical ones if we are going to successfully treat patients. Patients may have the same conditions, but they are not the same. If you have one patient with diabetes who has a good education and predictable income, and another who has food insecurity, an inability to pay for medicine, and a lack of transportation, there are disparities there that require more than a prescription to address. This is a major public health concern.”

Across the United States, a growing number of programs and initiatives are tracking SDOH and exploring how it can inform effective, evidence-based patient care. While it’s not easy, it’s important, says Bita Kash, PhD, director of the Center for Outcomes Research at Houston Methodist Hospital.

“The overall goal is to achieve the same...
outcomes for every patient regardless of their income, where they live, or education level,” she says. “The problems that arise from these factors are often manageable—if we understand them and their effect on care—and healthcare payers and providers should be able to come up with pertinent interventions to reduce variations and outcome disparities due to socioeconomic factors.”

OVERCOMING DISPARITIES

It’s well known that the United States’ healthcare spend greatly surpasses other first-world nations. Yet, despite spending 17.8% of its GDP on healthcare, patient outcomes are no better—and are often poorer—than other high-income countries. As noted by a recent Commonwealth Fund report, “Health Care Spending in the United States and Other High-Income Countries,” lower rates of insurance coverage and mixed levels of population health programs likely play a role.

A lack of investment in social services that could help mitigate many of the SDOH that negatively impact health—and, as a consequence, drive up healthcare costs—also need to be tackled, says Krista Drobac, chairwoman of Aligning for Health, a payer coalition that advocates for better integration of social service programs into the healthcare system.

“We’re spending a lot of money on clinical care that would be better spent if we invested it upfront to help deal with these inequities,” she says. “There’s been a lot of research about how SDOH impact healthcare. It’s well-documented at this point. But they don’t answer the really critical question: What is the next step? What is it that we have to do to actually integrate SDOH into patient care in a robust and meaningful way?”

Aligning for Health believes it starts by breaking down funding silos in federal programs and testing community pilot programs that address specific SDOH issues. As a federal advocacy organization, the coalition is lobbying the federal government to allow for “lending and breeding of funding” across different departments like the United States Department of Agriculture, Housing and Urban Development, and HHS.

“Right now, there isn’t transfer or waiver authority across programs,” says Drobac. “We’re trying to create county-level pilots that would be able to get across all of these different departments and really address the whole patient—because that’s what’s needed to really address these disparities.”

The coalition is relying on data from payers and providers about SDOH, as well as other federal or community programs that patients may be utilizing. But that data can only take them so far, says Drobac—the right connections between healthcare and community problems to address these issues are also vital.

“Unless [a] provider has the ability to actively refer the patient to a program,” says

“Those who work in healthcare understand that poverty level, access to healthcare insurance, and social situation contribute to disease and outcomes. We see it every day.”

GREGORY KANE, MD, THOMAS JEFFERSON UNIVERSITY’S SIDNEY KIMMEL SCHOOL OF MEDICINE

<table>
<thead>
<tr>
<th>SDOH deaths in 2000</th>
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<tr>
<td>245,000: Deaths attributable to low education</td>
</tr>
<tr>
<td>176,000: Deaths attributable to racial segregation</td>
</tr>
<tr>
<td>162,000: Deaths attributable to low social support</td>
</tr>
<tr>
<td>133,000: Deaths attributable to individual-level poverty</td>
</tr>
<tr>
<td>39,000: Deaths attributable to area-level poverty</td>
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</table>


Impact of Different Factors on Risk of Premature Death

- Genetics 30%
- Individual Behavior 40%
- Social and Environment al Factors 20%
- Healthcare 10%

Source: Kaiser Family Foundation. Original Data Source: “We Can Do Better: Improving the Health of the American People,” NEJM.
“Social determinants of health affect every aspect of healthcare. We’re learning that we have to address not only clinical factors that affect a patient’s health but also the nonclinical ones if we are going to successfully treat patients.”

**Julia Andrieni, MD, Houston Methodist Hospital**

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**Healthy People 2020: Where we are in 2018**

Healthy People is an HHS initiative that has been around for over 30 years, providing 10-year action plans to create a healthier society. Healthy People 2020 began in 2010, providing a plan for health promotion and disease prevention. Part of that plan involved identifying 26 leading health indicators and then tracking those indicators’ performances over the 10-year period. Many of those indicators are directly linked to SDOH. Overall, four of those indicators have met or exceed their targets and 10 are improving. Here are fewer of those key indicators, along with the latest available data.

**Clinical preventive services**
- Between 2008 and 2015, the percentage of adults aged 50-75 years who received a colorectal screening increased 19.8%, from 52.1% to 62.4%.
- Between 2005-2008 and 2013-2016, there was little change in poor glycemic control among diagnosed diabetics—18.0% in 2005-2008 and 18.7% in 2013-2016.

**Environmental quality**
- Between 2005-2008 and 2011-2014, second-hand smoke exposure among children aged 3-11 years decreased 24.7%.

**Maternal, infant, and child health**
- Between 2006 and 2015, the infant mortality rate decreased 11.9%.

**Mental health**
- Between 2007 and 2016, the suicide rate increased 19.5%.
- Between 2008 and 2016, the rate of major depressive episodes among adolescents aged 12-17 years increased 54.2%.

**Nutrition, physical activity, and obesity**
- Between 2008 and 2016, the rate of adults over aged 18 who met aerobic and muscle-strengthening activity guidelines increased 13.9%, from 33.9% to 38.6%.
- Between 2005-2008 and 2013-2016, the obesity rate among adults aged 20 years and over increased by 13.9%, from 33.9% to 38.6%.

**Social determinants**
- Between the 2010-11 and 2015-16 school years, the rate of on-time high school graduation increased from 79% to 84%.

Source: HHS
“We found that being a Medicaid patient is the best indicator of an avoidable readmission. Even with all the other ADI data, it seems to be a good proxy for disadvantaged populations,” Kash says. “The other factors included patients who are older than 45 years of age, patients who are discharged to a skilled nursing facility or discharge themselves against medical advice, patients who have a diagnosis of chronic obstructive pulmonary disease, and patients who have severe illness. But when it comes to reducing readmissions, it seems to come back that simple insurance status really is a predictor of outcomes.”

Kash hopes that studies like hers will encourage payer organizations to consider SDOH when calculating readmission penalties. But she also hopes that more healthcare systems will find ways to incorporate the findings into clinical care.

“We want this to result in some kind of actionable strategy,” she says. “And this is something that could be easily implemented with some kind of alert or reminder in the EHR. We recommend that patients who meet these criteria get more detailed and comprehensive discharge instructions, especially around self-care and symptom recognition and management. And we also recommend follow-up phone calls and home visits. They work—and they don’t cost all that much in the long run.”

HOSPITAL-SPECIFIC APPROACH

While it would be easy to add a few checkboxes to a patient record on an EHR, Kash is quick to point out that every hospital and health system needs to develop their own approach to addressing SDOH.

“Each hospital really caters to a different type of patient population,” she says. “We’ve learned, if you really want to close these gaps, it’s important to come up with strategies that are very specific to your region and the needs of the patients within that region. And that means understanding, at the patient level, the SDOH that may interfere with positive outcomes.”

Kane agrees, using the community in Flint, Michigan, as an example. “They have very specific community issues that affect the health of all their residents,” he says. Because of infrastructure issues in that community, he explains, children in that area have a much greater chance of experiencing learning disabilities, of chronic kidney disease, and potential growth retardation—all because that community has struggled with providing basic human services like water, transportation, sewage, and safe housing to everyone. “Even the opioid epidemic, in some ways, could be considered a byproduct of SDOH, because of an environment with jobs with more physical demands that led to injuries, to higher rates of prescriptions, to targeted pharmaceutical advertising.”

BROADER EFFORT NEEDED

In an April 2018 position paper for the American College of Physicians, Kane and his colleagues called for “health in all policies.”

“Payers and providers can’t do this alone,” Kane says. “Legislators need to consider the health of the population when they implement policies in their city, state, or region. It really is an important first step.”

Yet, he acknowledges that dealing with SDOH must be a team effort.

“We can do a much better job of teaching our students so they know what to look for when caring for individual patients,” he says. “Healthcare systems need to think creatively about how to address all those little things that can influence care—how patients get transportation to their facilities for follow up, how the neighborhood may contribute to exacerbating an underlying condition, or how to make sure that patients have access to fresh fruits and vegetables.

“Providers are collecting data about whether or not a patient has adequate nutrition or lives in a safe home but often they just don’t know what to do with it.”

Kayt Sukel is a science and technology writer based outside Houston.
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INDICATION
BIKTARVY is indicated as a complete regimen for the treatment of HIV-1 infection in adults who have no
antiretroviral (ARV) treatment history or to replace the
current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies per mL) on a stable
ARV regimen for ≥3 months with no history of
treatment failure and no known resistance to any
component of BIKTARVY.

IMPORTANT SAFETY INFORMATION
BOXED WARNING: POST TREATMENT ACUTE
EXACERBATION OF HEPATITIS B

- Severe acute exacerbations of hepatitis B have been
reported in patients who are coinfected with HIV-1
and HBV and have discontinued products containing
emtricitabine (FTC) and/or tenofovir disoproxil
fumarate (TDF), and may occur with discontinuation
of BIKTARVY. Closely monitor hepatic function with
both clinical and laboratory follow-up for at least several
months in patients who are coinfected with HIV-1
and HBV and discontinue BIKTARVY. If appropriate,
anti-hepatitis B therapy may be warranted.

Contraindications

- Coadministration: Do not use BIKTARVY with dofetilide
or rifampin.

IMPORTANT SAFETY INFORMATION (cont’d)

Warnings and precautions

- Drug interactions: See Contraindications and Drug
Interactions sections. Consider the potential for drug
interactions prior to and during BIKTARVY therapy and
monitor for adverse reactions.

- Immune reconstitution syndrome, including the occurrence
of autoimmune disorders with variable time to onset, has
been reported.

- New onset or worsening renal impairment: Cases of acute
renal failure and Fanconi syndrome have been reported
with the use of tenofovir prodrugs. In clinical trials of
BIKTARVY, there have been no cases of Fanconi syndrome
or proximal renal tubulopathy (PRT). Do not initiate
BIKTARVY in patients with estimated creatinine clearance
(CrCl) <30 mL/min. Patients with impaired renal function
and/or taking nephrotoxic agents (including NSAIDs) are at
increased risk of renal-related adverse reactions. Discontinue
BIKTARVY in patients who develop clinically significant
decreases in renal function or evidence of Fanconi syndrome.
Renal monitoring: Prior to or when initiating BIKTARVY
and during therapy, assess serum creatinine, CrCl, urine
glucose, and urine protein in all patients as clinically
appropriate.

In patients with chronic kidney disease, also assess serum
phosphorus.

- Lactic acidosis and severe hepatomegaly with steatosis:
Fatal cases have been reported with the use of nucleoside
analogs, including FTC and TDF. Discontinue BIKTARVY if
clinical or laboratory findings suggestive of lactic acidosis
or pronounced hepatotoxicity develop, including
hepatomegaly and steatosis in the absence of marked
transaminase elevations.
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1 tablet taken once daily with or without food.

- **Renal impairment:** Not recommended in patients with CrCl <30 mL/min.
- **Hepatic impairment:** Not recommended in patients with severe hepatic impairment.

**Pregnancy and lactation**

- **Pregnancy:** There is insufficient human data on the use of BIKTARVY during pregnancy. An Antiretroviral Pregnancy Registry (APR) has been established. Available data from the APR for FTC shows no difference in the rates of birth defects compared with a US reference population.

- **Lactation:** Women infected with HIV-1 should be instructed not to breastfeed, due to the potential for HIV-1 transmission.

*FTC 200 mg/TAF 25 mg.

**References:**
BIKTARVY® (bictegravir 50 mg, emtricitabine 200 mg, and tenofovir alafenamide 25 mg) tablets, for oral use

Brief Summary of full Prescribing Information. See full Prescribing Information. Rx only.

WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B
Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF), and may occur with discontinuation of BIKTARVY. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue BIKTARVY. If appropriate, anti-hepatitis B therapy may be warranted [see Warnings and Precautions].

INDICATIONS AND USAGE
BIKTARVY is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 3 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of BIKTARVY.

DOSAGE AND ADMINISTRATION
Also see Warnings and Precautions and Use in Specific Populations.
Testing Prior to or When Initiating: Test patients for HIV infection.
Testing Prior to or When Initiating, and During Treatment: As clinically appropriate, assess serum creatinine, estimated creatinine clearance (CrCl), urine glucose, and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus.
Dosage: One tablet taken once daily with or without food.
Renal Impairment: BIKTARVY is not recommended in patients with CrCl <30 mL/min.
Hepatic Impairment: BIKTARVY is not recommended in patients with severe hepatic impairment.

CONTRAINDICATIONS
Also see Drug Interactions.
BIKTARVY is contraindicated to be co-administered with:
- dofetilide due to the potential for increased dofetilide plasma concentrations and associated serious and/or life-threatening events
- rifampin due to decreased BIC plasma concentrations, which may result in the loss of therapeutic effect and development of resistance to BIKTARVY

WARNINGS AND PRECAUTIONS
Also see BOXED WARNING, Contraindications, Adverse Reactions, and Drug Interactions.
Severe Acute Exacerbation of Hepatitis B in Patients Coinfected with HIV-1 and HBV: Patients with HIV-1 should be tested for the presence of chronic hepatitis B virus (HBV) before or when initiating ARV therapy. Severe acute exacerbations of hepatitis B (e.g., liver decompensation and liver failure) have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued products containing FTC and/or TDF, and may occur with discontinuation of BIKTARVY. Patients coinfected with HIV-1 and HBV who discontinue BIKTARVY should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment. If appropriate, anti-hepatitis B therapy may be warranted, especially in patients with advanced liver disease or cirrhosis since post-treatment exacerbation of hepatitis may lead to hepatic decompensation and liver failure.

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions: Coadministration of BIKTARVY with certain other drugs may result in known or potentially significant drug interactions; this may lead to loss of efficacy and development of resistance to BIKTARVY or clinically significant adverse reactions from greater exposures of concomitant drugs. Consider the potential for drug interactions and review concomitant medications prior to and during therapy. Monitor for adverse reactions associated with concomitant drugs.

Immune Reconstitution Syndrome (IRS): IRS has been reported in patients treated with combination ARV therapy. During the initial phase of treatment, patients whose immune systems respond may develop an inflammatory response to indolent or residual opportunistic infections, which may necessitate further evaluation and treatment. Autoimmune disorders have been reported to occur in the setting of immune reconstitution; the time to onset is variable, and can occur many months after initiation of treatment.

New Onset or Worsening Renal Impairment: Renal impairment, including acute renal failure and Fanconi syndrome, has been reported with the use of tenofovir prodrugs in animal studies and human trials. In clinical trials of BIKTARVY in subjects with no antiretroviral treatment history with eGFRs >30 mL/min, and in virologically suppressed subjects switched to BIKTARVY with eGFRs >50 mL/min, renal serious adverse events were encountered in less than 1% of subjects treated with BIKTARVY through Week 48. BIKTARVY is not recommended in patients with CrCl <30 mL/min. Patients taking tenofovir prodrugs who have renal impairment and/or are taking nephrotoxic agents including NSAIDs are at increased risk of developing renal-related adverse reactions. Discontinue BIKTARVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome.

Renal Monitoring: Prior to or when initiating BIKTARVY, and during treatment with BIKTARVY, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, also assess serum phosphorus.

Lactic Acidosis/Severe Hepatomegaly with Steatosis: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including FTC and TDF. Treatment with BIKTARVY should be suspended in any individual who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

ADVERSE REACTIONS
Also see BOXED WARNING and Warnings and Precautions.
In Adults with No ARV Treatment History:
The safety assessment of BIKTARVY is based on Week 48 data from two randomized, double-blind, active-controlled trials: 1489 (n=314) and 1490 (n=320), in HIV-1 infected, ARV treatment-naïve adults. Through Week 48, 1% of subjects discontinued BIKTARVY due to adverse events, regardless of severity.

Adverse Reactions: Adverse reactions (all Grades) reported in ≥2% of subjects receiving BIKTARVY through Week 48 in Trials 1489 and 1490, respectively were: amylase >2.0 x ULN (4%, 4%), ALT >5.0 x ULN (1%, 2%), AST >5.0 x ULN (2%, 1%), AST >5.0 x ULN (2%, 1%), Creatine Kinase ≥10.0 x ULN (4%, 4%), Neutrophils <750 mm^3 (2%, 2%), and fasted LDL-cholesterol ≥190 mg/dL (2%, 3%).

Continued on next page.
Changes in Bilirubin: In Trials 1489 and 1490, total bilirubin increases were observed in 12% of subjects administered BIKTARVY through Week 48.

In Virologically Suppressed Adults: The safety of BIKTARVY in HIV-1 infected, virologically suppressed adults is based on Week 48 data from 282 subjects in a randomized, double-blind, active-controlled trial in which virologically suppressed subjects were switched from either DTG + ABC/3TC or ABC/DTG/3TC to BIKTARVY; and Week 48 data from 290 subjects in an open-label, active-controlled trial in which virologically suppressed subjects were switched from a regimen containing atazanavir (ATV) (given with cobicistat or ritonavir) or darunavir (DRV) (given with cobicistat or ritonavir) plus either FTC/TDF or ABC/3TC, to BIKTARVY.

Adverse Reactions: Overall, the safety profile in virologically suppressed adult subjects was similar to that in subjects with no antiretroviral treatment history.

DRUG INTERACTIONS

Also see Indications and Usage, Contraindications, and Warnings and Precautions.

Other Antiretroviral Medications: BIKTARVY is a complete regimen for the treatment of HIV-1 infection, BIKTARVY coadministration with other ARV medications for treatment of HIV-1 infection is not recommended. Complete information regarding potential drug interactions with other ARV medications is not provided.

Potential for BIKTARVY to Affect Other Drugs: BIC inhibits organic cation transporter 2 (OCT2) and multidrug and toxin extrusion transporter 1 (MATE1) in vitro. Co-administration of BIKTARVY with drugs that are substrates of OCT2 and MATE1 (e.g., dofetilide) may increase their plasma concentrations.

Potential Effect of Other Drugs to Affect BIKTARVY: BIC is a substrate of CYP3A and UGT1A1. A drug that is a strong inducer of CYP3A and also an inducer of UGT1A1 can substantially decrease the plasma concentrations of BIC which may lead to loss of efficacy and development of resistance. The use of BIKTARVY with a drug that is a strong inhibitor of CYP3A and also an inhibitor of UGT1A1 may significantly increase the plasma concentrations of BIC. TAF is a substrate of P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP). Co-administration of drugs that inhibit P-gp and BCRP may increase the absorption and plasma concentrations of TAF. Co-administration of drugs that induce P-gp activity are expected to decrease the absorption of TAF, resulting in decreased plasma concentration of TAF, which may lead to loss of efficacy and development of resistance.

Drugs Affecting Renal Function: Because FTC and tenofovir are primarily excreted by the kidneys by a combination of glomerular filtration and active tubular secretion, coadministration of BIKTARVY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC, tenofovir, and other renally eliminated drugs, which may increase the risk of adverse reactions.

Established and Potentially Significant Drug Interactions: The listing of established or potentially clinically significant drug interactions with recommended prevention or management strategies described are based on studies conducted with either BIKTARVY, the components of BIKTARVY (BIC, FTC, and TAF) as individual agents, or are drug interactions that may occur with BIKTARVY. An alteration in regimen may be recommended.

- Antiarhythmics: dofetilide. Coadministration is contraindicated due to potential for serious and/or life-threatening events.
- Anticonvulsants: carbamazepine, oxcarbazepine, phenobarbital, phenytoin. Coadministration with alternative anticonvulsants should be considered.
- Antimycobacterials: rifampin. Coadministration is contraindicated due to the effect on BIKTARVY. Rifabutin, rifampentine. Coadministration is not recommended.
- Herbal Products: St. John's wort. Coadministration is not recommended.
- Medications/oral supplements containing polyvalent cations (e.g., Mg, Al, Ca, Fe): Antacids containing Al/Mg or Calcium: BIKTARVY can be taken under fasting conditions 2 hours before antacids containing Al/Mg or calcium. Routine administration of BIKTARVY simultaneously with, or 2 hours after, antacids containing Al/Mg or calcium is not recommended. Supplements containing Calcium or Iron: BIKTARVY and supplements containing calcium or iron can be taken together with food. Routine administration of BIKTARVY under fasting conditions simultaneously with, or 2 hours after, supplements containing calcium or iron is not recommended.
- Metformin: Refer to the prescribing information of metformin for assessing the benefit and risk of concomitant use of BIKTARVY and metformin.

Consult the full Prescribing Information prior to and during treatment with BIKTARVY for important drug interactions; this list is not all inclusive.

USE IN SPECIFIC POPULATIONS

Also see Dosage and Administration, Warnings and Precautions, and Adverse Reactions.

Pregnancy: Pregnancy Exclusion Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to BIKTARVY during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263. Risk Summary: There are insufficient human data on the use of BIKTARVY during pregnancy to inform a drug-associated risk of birth defects and miscarriage. BIC and TAF use in women during pregnancy has not been evaluated; however, FTC use during pregnancy has been evaluated in a limited number of women as reported to the APR. Available data from the APR show no difference in the overall risk of major birth defects for FTC compared with the background rate for major birth defects of 2.7% in a U.S. reference population of the Metropolitan Atlanta Congenital Defects Program (MACDP). The rate of miscarriage is not reported in the APR.

Lactation: The Centers for Disease Control and Prevention recommend that HIV-infected mothers not breastfeed their infants to avoid risking postnatal transmission of HIV. Based on published data, FTC has been detected in human milk; it is not known whether BIKTARVY or all of the components of BIKTARVY are present in human breast milk, affects human milk production, or has effects on the breastfed infant. BIC was detected in the plasma of nursing rat pups likely due to the presence of BIC in milk, and tenofovir has been shown to be present in the milk of lactating rats and rhesus monkeys after administration of TDF. It is unknown if TAF is present in animal milk. Because of the potential for HIV transmission in HIV-negative infants, developing viral resistance in HIV-positive infants, and adverse reactions in nursing infants, mothers should be instructed not to breastfeed.

Pediatric Use: Safety and effectiveness of BIKTARVY in pediatric patients less than 18 years of age have not been established.

Geriatric Use: Clinical studies of BIKTARVY did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Renal Impairment: BIKTARVY is not recommended in patients with severe renal impairment (CrCl <30mL/min). No dosage adjustment of BIKTARVY is recommended in patients with CrCl >30mL/min.

Hepatic Impairment: No dosage adjustment of BIKTARVY is recommended in patients with mild (Child–Pugh Class A) or moderate (Child–Pugh Class B) hepatic impairment. BIKTARVY is not recommended for use in patients with severe hepatic impairment (Child–Pugh Class C) as BIKTARVY has not been studied in these patients.

OVERDOSE:
If overdose occurs, monitor the patient for evidence of toxicity. Treatment consists of general supportive measures including monitoring of vital signs as well as observation of the clinical status of the patient.

210251-GS-000 February 2018

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While slightly less than half of oncologists view precision medicine as a potential game-changer, most say it’s too soon to predict its long-term impact. That’s according to new research from Cardinal Health Specialty Solutions, which provides important insights on how oncologists view precision medicine, a treatment approach that targets the molecular underpinnings of the disease. The research was fielded at three live summit events hosted by Cardinal Health Specialty Solutions in February, March, and April 2018. More than 160 oncologists from a mix of community and hospital-based practices participated.

The research found that while nearly four in 10 oncologists view precision medicine as groundbreaking, 57% say it’s too soon to predict its long-term impact. Oncologists see several barriers to adoption including:

- Cost of the drugs (51%);
- Cost of genomic testing (25%); and
- Lack of decision support tools (14%).

The research findings may be particularly relevant given the recent advances in targeted therapies, including FDA approval of two CAR T-cell therapies. Targeted medicines for acute myeloid leukemia, bladder, ovarian, breast, and lung cancers are also now available.

The research also highlights issues around availability and timeliness of genomic testing. About two-thirds of participating oncologists say they use genomic testing, while another 23% report that they are likely to begin using it in 2019. Yet 58% say testing is not available at their local institution, and 36% say they wait 15 or more days for results.

**Other unique findings**

- Challenges in interpreting results was cited as the most common reason for not using comprehensive genomic testing.
- Practices regarding pre-authorizations for genomic testing vary widely among payers.

“One of the most important things hospitals can do is participate in clinical trials to investigate the efficacy of precision medicines,” says Chadi Nabhan, MD, MBA, FACP, chief medical officer, Cardinal Health Specialty Solutions. “This will allow their patients to access novel study drugs, while providing hospital-based providers with firsthand experience managing side effects and determining efficacy.”

**Process improvement recommendations**

The research highlights the role health systems can play in improving the processes around genomic testing and interpretation. Recommendations include:

- **Improve access.** Given the concerns about availability and timeliness of these tests, more hospitals should provide testing locally rather than outsourcing it, says Nabhan. “Turnaround times are critical, yet most health systems batch the tests once a week, leading to delays. Critical examination of processes around logistics of these tests is recommended,” he says.

- **Provide comprehensive training for physicians.** “Training should focus on the recent trends in genomic testing, its indications, where the tests fit in guidelines, and interpreting the results.” Nabhan says. “These are all essential components of optimizing the testing process to benefit the patient.”

- **Engage payers.** Many payers still deny properly ordered tests or require a pre-authorization process that is long and cumbersome. “Hospital systems can engage payers effectively using evidence generated from clinical trials,” Nabhan says.

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**Tracey Walker is content manager for Managed Healthcare Executive.**
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Migraines are debilitating and costly—both to patients in lost wages and treatment, and to healthcare as a whole. But new treatments and technologies can help. That’s according to Machaon Bonafede, PhD, MPH, senior director of outcomes research at IBM Watson Health, and Nicole Hahn, PharmD, BCACP, clinical pharmacy specialist in neurology at Kaiser Permanente Colorado. They delivered a presentation, “Developments in migraine treatment and management,” October 23 at the Academy of Managed Care Pharmacy Nexus 2018 in Orlando.

For Managed Healthcare Executive (MHE), Hahn highlighted new innovations that may drastically improve migraine management.

Q: MHE: What is your goal in highlighting migraines at AMCP Nexus?

Hahn: Migraines seem to be a very hot topic right now, especially with three medications approved for preventing migraines. They all belong to a new class of medications with a novel mechanism. My copresenter, Machaon Bonafede, and I hope listeners will learn more about these new medications, including their efficacy and safety as well as recognize the economic and quality of life impact of chronic migraine sufferer. We will be able to discuss the current health economics and outcomes, as well as available research data for chronic migraine.

Q: MHE: A migraine isn’t just the occasional headache, right?

Hahn: A migraine is a type of headache where people experience a pulsating, throbbing pain, and it is accompanied by other symptoms such as nausea and/or vomiting and sensitivity to light, noise, and/or smells. If migraines are severe enough, they can disrupt daily activities (work, school, home, etc.) as patients often have to retreat to a cold, dark, quiet room until the pain subsides. Migraines can occur at different frequencies depending on the patient. For example, some migraine patients only have a migraine once a year—some more infrequent than that, while others can suffer from migraine attacks more than half of the days every month—that level of frequency will likely be diagnosed as having chronic migraines.

Q: MHE: Discuss the economic impact of migraine management for patients and managed care providers/payers.

Hahn: Patients with frequent migraine headaches or migraine headaches that do not respond to medications increase utilization of healthcare services, such as office visits, urgent care visits, and ED visits.

Hahn: Before these medications in this new "CGRP" class were approved, we most often utilized therapies such as certain anti-hypertensives, anticonvulsants, antidepressants, onabotulinumtoxinA, and some over-the-counter products as a way to reduce the number of migraines a patient was experiencing. These are also considered to be preventive therapy options. The choice of which option to try often depends on the patients’ other medical conditions, risk of side effects, as well as level of evidence. The new CGRP therapies provide a novel, migraine-specific mechanism with effective results. Currently approved treatments are erenumab, galcanezumab, and fremanezumab. As with currently approved preventive options, CGRP’s don’t improve migraines for everyone who takes them, and there are some lingering questions on the safety of using these medications in certain patient populations. We’ll have to wait and see how and if these medications improve both cost and quality of life.

Rachel Zimlich, RN, is a writer in Columbia Station, Ohio.
What To Do About High Cost Therapies

by NICHOLAS HAMM

One of the biggest problems facing healthcare today is the inability of traditional healthcare models to keep up with the rapid pace of innovation. This is especially true with new advances like gene therapies, which can cost hundreds of thousands of dollars even as they hold great promise for patient treatments.

To help payers better navigate the problem of absorbing these high-cost medications, Jane F. Barlow, MD, MPH, MBA, senior advisor at the MIT Center for Biomedical Innovation, gave a talk at AMCP Nexus titled “Coverage and Reimbursement for High Cost Curative Therapeutics: Does a Solution Exist?”

While there are still only a handful of gene therapies available, Barlow said the number of approved therapies is likely to be around 40 by 2022—although there are a total of 932 in the pipeline. According to Barlow, around half of those approvals will be in the oncology market, around a third will be in the orphan drugs category, and about an eighth will be in what Barlow called the “quantum leap” category—drugs that will radically alter current treatment paradigms.

**Challenges**

Barlow identified three main concerns for payers attempting to cope with the coming onslaught of these high-cost therapies:

1. **Timing.** The timing of payments is and will be a problem with these medications. Since most require only a one-time treatment, the cost of treatment is largely front loaded. The problem for payers is how to divide up these costs over time. This raises additional concerns over patients who move from plans during that payment period—if a patient moves from plan X to plan Y three years into a five-year payment plan, should plan X still be on the hook for those payments?

2. **Product performance and value.** While these therapies promise great value, there is no long-term evidence of efficacy. Payers must ask questions of efficacy and durability—who will these treatments work for? For how long?

3. **Actuarial risk.** Most gene therapies will only be utilized by very small populations, meaning that smaller plans aren’t likely to even see a patient needing coverage. Payers must weigh the likelihood of encountering the need for certain therapies.

As new therapies are announced and gain more coverage, more payers are thinking about what they will mean for their plans. Barlow cited payer surveys from early 2017, late 2017, and early 2018. In the earliest studies (before the approval of Kymriah, the first CAR T therapy), very few payers were even thinking about gene therapies as a potential problem. Later surveys indicated that more payers were even thinking about gene therapies as a potential problem. Later surveys indicated that more payers are considering how they will react—many indicated that they are looking for alternative financing and reimbursement models.

Another key takeaway from those surveys is that different payers will require different models based on the payer’s size and needs. Therefore, any new plans would need to be tailored to individual payers to some degree.

**Possible solutions**

Barlow offered some economic models for how payers can adapt. The first was milestone-based contracts. These are short (less than two-year duration) and have a series of pre-determined milestones that will trigger payouts.

The second model Barlow discussed was performance-based annuities. This plan is longer (more than two years, likely between three and five). This kind of plan would spread payments out over that period, or could even pay the cost upfront with reimbursement for poor performance.

Overall, Barlow stressed that new models will require some common structural elements:

1. Patients must be treated only to the therapy’s label.
2. The annuity duration must remain constant (e.g., 20% every year over five years).
3. A common performance metric.
4. An arrangement in place for patients who move from a plan to another participating plan.

However, payers will also have plan-specific elements:

1. Price of a therapeutic.
2. Provider reimbursement for initial treatment and follow-up care.
3. Specific patient deductible and copay levels.
4. An arrangement when patients move to another non-participating plan.
5. Program implementation mechanics.

Nicholas Hamm is an editor for Managed Healthcare Executive.
Specialty pharmaceuticals make up a huge part of the current drug market, and their impact is only going to grow over the next few years. That’s according to an analysis of the specialty market and pipeline by Aimee Tharaldson, PharmD, senior clinical consultant of emerging therapeutics at Express Scripts, who spoke about specialty pharmaceuticals in development at the AMCP Nexus meeting in Orlando.

The specialty market made up 41% of the total drug spend in 2017. That number, Tharaldson said, is likely to increase to about a 50% split between specialty and traditional medications in the coming years.

In total, the 2017 per member per year specialty spend was $444. Of that amount, the largest contributor was inflammatory medications ($157), followed by oncology ($70), multiple sclerosis ($60), HIV ($45), and hep C ($19).

Here are five things you should know about the specialty pharma pipeline:

1/ The number of newly-approved drugs is increasing every year

The FDA is helping propel the specialty market forward—for at least the last eight years, the agency has approved more specialty drugs than traditional drugs. In 2017, the agency approved a record 36 specialty medications. In 2018, it has already approved 32 with more are on the way. Of those 32, 12 are for cancers, 10 for orphan conditions, five for HIV, three for thrombocytopenia, and two for inflammatory conditions.

The future of specialty medications, according to Tharaldson, will be defined by increased competition and a variety of high-impact indications.

2/ The biggest competition factor will be biosimilar approvals

Through 2022, there will be a $54.4 billion potential for biosimilars as 71 specialty drug patents will expire, Tharaldson said. Biosimilars could provide “significant” cost savings, but they are not without their problems, she said. Biosimilars face a variety of legal hurdles and will also struggle to gain market share.

Orphan drugs make up the largest slice of the specialty pipeline at 45%, with cancer drugs the second-largest class at 20%.

3/ The top two pipeline categories are cancer and orphan drugs

Tharaldson also covered several important categories that will be largely influenced by specialty medications in the coming years. The two biggest pipeline categories are oncology and orphan drugs, but other smaller indications could still play a significant role, she said.

Orphan drugs make up the largest slice of the specialty pipeline at 45%, with cancer drugs the second-largest class at 20%. According to Tharaldson, 30% of new orphan drugs will be blockbuster drugs.

4/ NASH could see major drug developments in 2019

One other notable treatment class is for nonalcoholic steatohepatitis (NASH). Currently, NASH has no treatment. But according to Tharaldson’s data, there are 10 medications in the pipeline, and one could be approved as early as the end of 2019. Some analysts expect this could be as much as a $35 billion per year industry, although Tharaldson said this number is likely too high.

5/ The Alzheimer’s pipeline is promising

In the even longer term, Tharaldson pointed out the Alzheimer’s pipeline. Current treatments for Alzheimer’s are only symptom modifying, whereas new drugs could finally be disease modifying agents. While these drugs—if they are even approved—won’t be available for years, they could significantly alter the Alzheimer’s treatment landscape.

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Since it peaked in 1991, the cancer mortality rate has decreased dramatically—the rate has fallen over 25%, resulting in 2.4 million fewer deaths in the last 27 years. That great progress, however, has not come without costs.

Rebecca Borgert, PharmD, BCOP, director of clinical oncology product development at Magellan Rx Management, called these costs “unsustainable” during an AMCP Nexus presentation, “Medical Oncology Drug Cost Trends and Innovative Practical Payer Management Strategies.” Borgert and Amy Miller, PharmD, BCPS, clinical pharmacist and program manager of medical pharmacy at Medica, discussed practical ways payers can create sustainable oncology spending.

The costs
Borgert and Miller highlighted several key figures that demonstrate how untenable the current situation is for payers:

1. The United States is expected to spend a staggering $174 billion per year on cancer care by 2020.

2. From 2016 to 2017, the MCO pharmacy benefit drug spend grew by 12%, an average of 21% of the overall pharmacy benefit budget.

3. During the same period, the MCO medical benefit increased by 19%, an average of 14% of overall medical benefit budgets.

4. The medical benefit spend of oncology for commercial plans was $10.12 per member per month in 2017, the highest single category and over three times the second highest category, Crohn’s disease/ulcerative colitis at $3.01.

5. For Medicare plans, the per member per month spend was $24.25.

The oncology market will only grow as the FDA is expected to continue approving record numbers of oncology medications in the coming years.

A practical solution
In 2016, BMJ published an article detailing waste caused by the use of single-use vials. That study estimated wastage amounting to over $3 billion per year. Many drug manufacturers have moved to single-use vials in recent years, citing patient safety, according to Borgert and Miller. The BMJ article was picked up by mainstream media outlets and caused a public outcry.

Since that article, the National Comprehensive Care Network (NCCN) updated its guidelines, allowing for biologics and cytotoxic agents to be rounded to the nearest vial size within 10% of the prescribed dose—based on research that found a 10% rounding made no clinical difference on the safety or efficacy of a therapy. Under these new guidelines, prescribers are able to make more creative use of dosing options, even when only single-use vials are available.

In one example Borgert and Miller provided, a hypothetical cancer drug is only available in 100 mg doses. If a patient is prescribed 520 mg of the drug every 21 days, the patient is required to use six 100 mg vials—wasting 80 mg of medication in the process. Under the new NCCN guidelines, that dose could be rounded down to 500 mg over 21 days—well within the 10% limit, but reducing the need for a sixth vial, according to the presenters.

In one real-world example they shared, similar personalized dosing of a single medication—pembrolizumab (Keytruda)—could result in annual savings of $825 million.

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How consumers use digital health tools

- Around half use a fitness tracker
- 61% use an online patient/provider portal
- 3 out of 4 research symptoms before going to the hospital
- 37% have felt more knowledgeable than their provider

Source: University of Phoenix, BeckerHospitalReview.com

QUOTABLE: “I’m not surprised that the ‘challenge of change’ tops the list, given our collective tendency to cling to the status quo. I also continue to believe that government mandates will, to a large extent, drive the pace of change, as CMS and other governmental agencies can be very effective motivators.”

— Douglas L. Chaet, FACHE, Sentara Healthcare, see PAGE 26

18% of provider organizations’ medical devices were impacted by malware or ransomware in the last 18 months.

Source: KLAS Research

34% In 2017, 34% of U.S. healthcare payments, representing around 226.3 million Americans and 77% of the covered population, were part of Alternative Payment Models.

Source: LAN