EXCLUSIVE
2020 ANNUAL
PHARMACY SURVEY

Findings Show COVID-19 Effect:
Lots of Change, Some Hope

PLUS

Population Health
How 3 organizations are tackling diabetes management

Drug Pipeline
New drugs for autoimmune disease

Formulary/Pharmacy Development
Are biosimilars finally catching on?

Managed Healthcare Executive.com
Results of Our 2020 Pharmacy Survey

“Just when I thought I was out, they pull me back in!” says an older Michael Corleone in The Godfather, part three. It’s a famous line and GIF.

COVID-19 is feeling a little like that these days. Cases are surging in many areas of the country, and we are seeing overwhelmed hospitals in Houston and Arizona like we did in New York City in April (how long ago that seems). We’ve been disabused of any flickering notions that COVID-19 is an acute, passing phenomenon and that the country would bounce back to normal, however newish and strange that normal might be. The bounce back now seems more likely to be a hard climb.

Results of our annual pharmacy survey only partly reflect these sentiments because we stopped collecting responses before the recent surge in cases. Our questions are varied, so the responses are that proverbial mixed bag, but change is a common thread. A majority (57%) see increased use of telehealth as the most important, lasting impact of COVID-19 on the U.S. healthcare system. A sizable minority (37%) see increased use of mail-order pharmacy as the most indelible mark the pandemic will leave on the pharmaceutical sector. Remember when Medicare for all and high drug prices seemed like they would be the top healthcare issues in the presidential campaign? It’s no surprise that a super majority (78%) of our respondents see the federal government’s response to COVID-19 as likely to receive the most attention.

The survey reveals some worry and pessimism. Almost two-thirds (64%) see an economic downturn, with a major effect on the healthcare, as a likely consequence of the COVID-19. Interestingly, far more respondents (about 70%) rated the chances of a safe and effective antiviral in 2020 at varying degrees of unlikely than those who saw it as likely (about 30%).

Opinion on a COVID-19 vaccine had more of an optimistic bent to it, with 21% of the respondents indicating that they believe a vaccine would be available for limited use during the last quarter of this year and about the same proportion seeing it coming during the first quarter of 2021. The faction who foresee a vaccine for broad use becoming available is far smaller.

As time goes on, the importance of a safe and effective vaccine for COVID-19 looms larger and larger. It seems that until we have one, every time we are about to get out of this COVID-19 crisis, the virus will pull us back in.

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Mike Hennessy Sr.
Chairman and Founder
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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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Pharmacy care has always played a critical role in supporting patients’ access to needed services and overall health. At the onset of the COVID-19 pandemic, pharmacies’ ability to proactively engage and monitor patients became even more important as we saw a significant drop in the number of prescriptions filled, an increase in provider and pharmacy access challenges, and a greater need to monitor and protect high-demand medications.

As restrictions are lifted across the country, I anticipate many pharmacy care services that evolved to meet market needs brought on by COVID-19 will continue. Digital platforms, home care services, prescription home deliveries and behavioral health support tools have helped pharmacies provide more affordable, higher quality, more efficient care.

Digital health shift

Digital health services, including telehealth and remote monitoring, quickly transitioned from a “value add” to a “must-have” during the pandemic. Nationally, consumers of all ages appear more comfortable and willing to engage digitally than before. We’ve seen this among Optum members, with an 86% increase in first-time users of OptumRx virtual capabilities, such as digitally transferring chronic medications from retail to home delivery. In addition, nine out of 10 of our community pharmacies serving patients with mental health, substance use disorders and other complex, chronic health conditions are using telehealth to provide more care.

Focus on mental health

The COVID-19 pandemic and its subsequent social and economic effects have taken their toll on the mental well-being of our society. Data suggest that the incidence of mental health and substance use disorders is increasing. OptumRx analytics show that in March the number of prescriptions for anti-anxiety medications increased 15%; for antidepressants, 14%; and for sedative hypnotics, 5%.

Virtual services will continue to be a powerful support tool for those requiring more high-touch care, including patients with mental health, substance use disorders and other complex, chronic health conditions. OptumRx has leveraged its Genoa Healthcare footprint to provide support through telepsychiatry, our Optum Emotional Health line, virtual visits and complimentary, on-demand emotional support via the Sanvello mobile app.

In this new healthcare environment, pharmacy benefit managers are uniquely positioned to help protect continuity of care, given the vast and diverse resources at our disposal. Our collective goal should be to build upon what we have learned during this time. We should continue to deploy and refine tools that will yield positive clinical and financial value while also improving care and service in a post-pandemic environment.

David Calabrese, RPh, M.H.P., is senior vice president and chief pharmacy officer for OptumRx and a member of the Managed Healthcare Executive® Editorial Advisory Board.
New Drugs Take Aim at Autoimmune Diseases

Potential agents to battle inflammation and other processes move through development pipeline. by KEITH LORIA

Autoimmune diseases are often debilitating and, in some cases, life-threatening. A National Institutes of Health study revealed that as many as 23.5 million Americans experience one of more than 80 autoimmune diseases, and that number continues to rise every year.

Here is a look at some drugs at various stages of development for autoimmune diseases.

**Tepezza (teprotumumab-trbw)**
In January, the FDA approved Tepezza for thyroid eye disease (TED) in adults. Srini Ramanathan, Ph.D., vice president of developmental sciences at Horizon Therapeutics, which is headquartered in Ireland, says the company is investigating uses for Tepezza beyond TED. The drug blocks insulinlike growth factor type 1 receptor, which is part of the signaling pathway activated by autoantibodies in TED, leading to inflammation and expansion of tissue behind the eye.

"With Tepezza, we are currently conducting a trial in fibrotic TED, in which there is no longer active inflammation, but symptoms such as eye bulging and double vision remain," Ramanathan says. "Beyond TED, we believe that Tepezza has a role in addressing the underlying mechanisms of fibrosis, which means it may have activity in diseases like systemic sclerosis."

Horizon Therapeutics will begin an exploratory clinical trial later this year of diffuse cutaneous systemic sclerosis (dcSSc), a subtype of systemic sclerosis that causes fibrosis over large areas of the skin and often involves internal organ damage, especially to the lungs, kidneys and gastrointestinal tract.

"We are excited about the possibilities for Tepezza because it interferes with underlying biology of inflammation and fibrosis at a mechanistic level," Ramanathan says. "That could make it a promising candidate for systemic sclerosis or other diseases that involve fibrosis, and our development program will explore some of those opportunities in coming months."

**HZN-825**
Another drug under investigation at Horizon is HZN-825, which is scheduled to be evaluated in a phase 2b trial in 2021.

"HZN-825 is an inhibitor of the lysophosphatidic acid receptor LPAR1," Ramanathan says. "Lysophosphatidic acid (LPA) is a bioactive lipid that is normally produced at sites of inflammation or injury to promote healing. But in autoimmune diseases like dcSSc, elevated levels of LPA can bind with LPAR1 and lead to fibrosis."

Ramanathan says Horizon was encouraged by the results of a phase 2a study in patients with dcSSc published in 2018 that showed an im-
New Drugs Take Aim at Autoimmune Diseases

Drugs In The Pipeline

Olokizumab and ibrutinib
Because currently approved medications can’t control rheumatoid arthritis (RA) in about 1 in 4 patients with the disease, there is a need for new therapies.

Anca Askanase, M.D., MPH, a rheumatologist at Columbia University Irving Medical Center in New York City and director of rheumatology clinical trials, shares a long list of candidates: selective JAK inhibitors, Bruton tyrosine kinase inhibitors, phosphoinositide-3-kinase pathway inhibitors, antibodies to the granulocyte-macrophage colony-stimulating factor receptor and bisspecific antibodies that target type 2 cytokines. But she singles out two for special mention.

“Olokizumab is an anti-IL6 immune modulator in late phase 3 trials, and ibrutinib (Imbruvica) is an oral BTK inhibitor, an important regulator of B-cell proliferation and myeloid cell activity, which was effective and safe in the treatment of MTX (methotrexate) nonresponders in a phase 2 trial,” she says.

“Each new drug, each new MOA (mechanism of action) is a step forward,” Askanase says. “RA pathogenesis is not fully understood. The medications we have used thus far provide limited response rates, (and) combination therapies have higher success rates but are limited by (adverse) effects.”

Interferon alfa-2b
People with autoimmune diseases are particularly vulnerable to COVID-19, which is why BetterLife Pharma has been putting efforts into researching drugs that can help.

Ahmad Doroudian, Ph.D., CEO of the Montreal company, says it is investigating the effectiveness of interferon alfa-2b for patients with COVID-19 and plans to launch a randomized, double-blind, placebo-controlled phase 3 study in the coming weeks.

“Interferons are antiviral agents that modulate functions of the immune system,” Doroudian explains. “First identified in 1957, they were named for their ability to interfere with viral replication by protecting cells from infections. Interferon marshals the body’s own defenses against a broad spectrum of infections.” These agents also work in a variety of ways, such as by altering cell membranes to deny viruses entry or exit. Interferons are generally classified into three groups: IFN-1, IFN2 and IFN-3.

“At (BetterLife), my team and I have been working on our own version of interferon alfa-2 (IFNa2b), AP-003,” Doroudian says. “It is our patented, isoform-free inhalation formulation, and its first target indication will be early stage COVID-19 disease. We chose to focus on developing IFNa2b and believe it will be successful because, while all IFNs are important for fighting viral infections and for the regulation of the immune system, IFN-1s are among the first cytokines produced during a viral infection.”

He says he believes AP-003 will be a significant breakthrough for patients with COVID-19 because IFNa2b has already been studied against other coronaviruses, including MERS-CoV, which causes Middle East respiratory syndrome, and SARS-CoV, which causes severe acute respiratory syndrome.

Keith Loria is a freelance writer in the Washington, D.C., area.

Lenabasum
Yuval Cohen, Ph.D., CEO of Corbus Pharmaceuticals in Norwood, Massachusetts, touts lenabasum (JBT-101), an oral, nonimmunosuppressive small molecule that binds to the cannabinoid receptor type 2 on immune cells, as a new drug in the pipeline. This receptor plays a key part in inflammation and fibrosis. If successful, lenabasum would be the first drug in this class to be approved.

“We have promising preclinical and clinical data on lenabasum in a variety of animal models and in three separate clinical indications where it was tested,” Cohen says. “For each of these indications, lenabasum is currently in its final, large, multinational clinical study seeking to confirm its efficacy and provide the basis for its approval.”

The indications are systemic sclerosis, dermatomyositis and cystic fibrosis. Lenabasum, which was previously called anabasum, also is being tested in an early stage clinical study for lupus.

Top-line data from studies of lenabasum as a treatment for systemic sclerosis and cystic fibrosis are expected this summer, Cohen says. Systemic sclerosis, which causes a buildup of scar tissue, affects the skin and sometimes the joints, gastrointestinal tract and other organs. The autoimmune disease affects up to 75,000 Americans.

A key unmet need in cystic fibrosis is the treatment of inflammation to reduce pulmonary exacerbations, an acute worsening of inflammation in the lungs with an increase in respiratory symptoms, Cohen says. Lenabasum is being tested as a treatment.

Ahmad Doroudian, Ph.D., CEO of the Montreal company, says it is investigating the effectiveness of interferon alfa-2b for patients with COVID-19 and plans to launch a randomized, double-blind, place-
The passage of the Biologics Price Competition and Innovation Act (BPCIA) a decade ago was supposed to usher in a new era: High-priced biologic drugs would have competitors, called biosimilars, that were just as safe and effective. This price competition would then drive down healthcare costs.

That was the theory anyway.

In actuality, just as the broader ACA continues to be tied up in court battles, the biosimilars market has been hobbled by legal wrangling. Although the BPCIA was just one provision of the ACA, biosimilars were seen as one of the surest market-oriented ways to reduce healthcare costs. Optimists see hope in the growing number of FDA-approved biosimilars. Their less-sunny counterparts, however, see unfulfilled potential and a gap between the number of approved biosimilars and the number on the market.

The ‘similar’ in biosimilar
Biologics — agents derived from living organisms rather than chemicals — date back to the beginning of the 20th century. But recombinant DNA technology developed in the 1970s and 1980s launched a new era: synthesized biologics instead of animal-derived agents. The price tags on some of the biologics were in the tens of thousands of dollars, which, at the time, seemed expensive.

The BPCIA created an accelerated pathway for drugmakers to gain approval for products that were substantially similar to existing biologics. Unlike small-molecule generics, biosimilars are not exact copies of their reference products. A small-molecule drug may comprise a couple dozen atoms; a biological, hundreds or thousands. The chemical processes used to make small-molecule drugs ensure an exact copy (although the inactive ingredients to make the pill that contains the drug may differ). The fact that biologics are derived from living organisms also adds some slight — but not necessarily meaningful — variability.

Christine Simmon, executive director of the Biosimilars Council, a group that lobbies for the industry, says that although biosimilars are costly to produce, they offer enormous potential to lower prescription drug costs. “(Biosimilars) represent a tremendous savings opportunity for patients and taxpayers,” she says. “We are seeing ... up to 30% discounts now with biosimilars that are on the market.”

The FDA has approved 28 biosimilars so far. The first, approved in 2015, was Sandoz’s Zarxio (filgrastim-sndz), a biosimilar of Amgen’s cancer drug Neupogen (filgrastim). Zarxio came on the market just six months after approval, but most other biosimilars have not had such a quick journey. Seventeen of the 28 approved biosimilars were on the market at the beginning of July, so the gap is narrowing but still there. The approved, on-the-market biosimilars include a handful of Genentech’s chemotherapy drug Herceptin (trastuzumab), as well as biosimilars of Amgen’s bone-marrow stimulant Neulasta (pegfilgrastim) and Janssen Biotech’s immunosuppressant Remicade (infliximab). Six biosimilars for AbbVie’s Humira (adalimumab) have also been approved, dating back to September 2016, but none have yet made it to market.

Perilous patents
Simmon says the Humira biosimilars and others aren’t on the market because of litigation brought by the makers of the reference products on which the biosimilars are based. As the costly lawsuits drag out, they extend market exclusivity for the higher-cost brand-name products. Critics, however, charge that the lawsuits are based less on valid legal objections and more on a fear of competition.

Simmon says one way that... Continued on page 8
### Biosimilars in the U.S.

<table>
<thead>
<tr>
<th>Biosimilar product (manufacturer)</th>
<th>Nonproprietary Name</th>
<th>Reference product (manufacturer)</th>
<th>Date approved</th>
<th>Date marketed</th>
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<tr>
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Source: Center for Biosimilars
Continued from page 6

brand-name drugmakers seek to protect market exclusivity is by filing and defending copious patents. “It’s very common for a brand-name biologic manufacturer to obtain as many patents as possible,” she says, noting that the patents often cover things far beyond the underlying biologic, even extending to language on product labels.

In the case of Humira, AbbVie’s legal strategy prompted a grocer’s union to file a class-action lawsuit arguing that the biopharmaceutical company is unfairly using a “legal thicket” to prolong its monopoly. AbbVie, however, has reached settlement agreements with all of its potential competitors to preserve Humira’s market exclusivity until at least 2023. In resolving the final such lawsuit last year, AbbVie’s chief legal officer, Laura J. Schumacher, said the company’s patents fund innovation. “As an innovation-driven biopharmaceutical company, we will continue to develop novel cures for the toughest health challenges and rely on a robust patent system to protect that investment in innovation,” she said in a press release.

**Market challenges**

Reference product manufacturers have also sought to limit the impact of biosimilars once they eventually reach the market, according to Ameet Sarpatwari, J.D., Ph.D., an assistant professor at Harvard Medical School. “One strategy originator manufacturers have employed to limit biosimilar uptake has been to negotiate formulary exclusivity with payers,” wrote Sarpatwari and his co-authors in an article about biosimilars not living up to their promise published in the August 2019 American Medical Association Journal of Ethics. Such deals often include rebates for payers or PBMs that essentially create an incentive structure that keeps higher-priced products on the market. That, in turn, has the effect of reinforcing physician comfort with the brand-name drugs, wrote Sarpatwari.

Insurers and PBMs have questions about how the biosimilars market will eventually shape up, Simmon says. A physician can prescribe the generic of a small-molecule drug and know that no matter who the manufacturer is, the generic will almost certainly be available at the pharmacy and will work the same way as the reference product. Will the same be true of biosimilars? “Plans and PBMs, generally speaking, have questions about whether or not there will be a lot of interchangeable biosimilars in the future, as well as how much growth we can expect in the availability of biosimilars,” she says.

**Pushing for change**

For Simmon, one priority is avoiding lengthy court battles. She wants to preserve the opportunity for drug companies to enter into patent settlement agreements, which offer a way to quickly legal disputes. She also wants to see patent disputes go through the inter partes review process before the Patent and Trademark Office, rather than get ensnared in protracted court cases. Also on Simmon’s wish list is patent reform that puts limits on what can be patented. Finally, she says, the FDA needs to find a better way for interested parties to locate relevant patents — without having to hire costly law firms. “Right now that’s very time-consuming and expensive,” she says, “because there is no resource you can just search through and find patents.”

Additionally, America’s Health Insurance Plans (AHIP) is asking lawmakers to reduce the patent life for biologics from 12 years to seven, arguing that doing so would facilitate earlier availability of biosimilars and further open up the market. Drugmakers are opposed, saying they need a long period of exclusivity to earn back their investment and that it serves the larger purpose of encouraging biotech innovation.

Although it’s clear that biosimilars are here to stay — hundreds remain in development — such regulatory changes could be the deciding factors in when biosimilars finally achieve acceptance and realize their potential in this, their second decade.

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**Jared Kaltwasser** is a healthcare reporter based in Iowa.
Tackling Diabetes While Curbing Costs

Three healthcare organizations provide models for managing the disease and keeping a close eye on the bottom line.

by KAREN APPOLD

Diabetes, especially Type 2 diabetes, has a split personality. It is one of the most common diseases in the United States; currently 1 in 10 Americans has Type 2 diabetes, and some projections show that proportion increasing to 1 in 3 by midcentury. Diabetes is also among the country’s costliest diseases. Medical expenditures for people who have diabetes are $16,752 per year, on average, of which about $9,600 is attributed to diabetes, according to the American Diabetes Association. Those expenditures are approximately 2.3 times higher than those, on average, for people without diabetes.

The dire facts and figures about diabetes could fill pages. But diabetes is also one of the most preventable and, under the right circumstances, manageable diseases. Diet and exercise can lower the risk of getting prediabetes, which is defined by A1C and blood sugar levels that are above normal but shy of those that would indicate diabetes. Doses of healthy eating and physical activity can lower the risk of prediabetes worsening and crossing the line into full-fledged diabetes. Once people have diabetes, lifestyle changes, medications and monitoring for neuropathy, among other things, can lower the risk of developing complications such as lower-limb amputations and cardiovascular disease.

Payers and others are keeping tabs on the efforts to prevent and control diabetes. "Quality metrics associated with diabetes have gained increased national support, and efforts to improve care have been associated with improved control of blood glucose in acute care settings," says Sally O. Gerard, D.N.P., RN, CDE, CNL, a diabetes educator at Stamford Health, a healthcare system in Stamford, Connecticut. "A more focused analysis of costs associated with diabetes would strengthen efforts for organizational support of diabetes improvement initiatives."

Here’s a look at how three healthcare organizations have addressed the management of diabetes and its related costs.

**Geisinger Health System**
The Geisinger Health System is an integrated delivery system headquartered in Danville, Pennsylvania, a small town about 150 miles northwest of Philadelphia. For years, Geisinger has enjoyed a reputation for delivering high-quality, relatively low-cost care — a city on the hill amid a healthcare system that teems with expense and waste. As such, it’s not surprising that Geisinger has an inventive, well-rounded program for tackling diabetes.

"Since both of these conditions (diabetes and prediabetes) can be managed and even reversed with lifestyle changes, we have directed our efforts to programs that support long-term behavior changes that support a healthy lifestyle," says Allison Hess, Geisinger’s vice president of health and wellness. "These programs complement existing clinical interventions targeted at diabetes management."

Almost two decades ago, the health system started a diabetes care management program led by registered nurses who were also certified diabetes educators. The program combined education and glucose monitoring to improve diabetes management. Over the years, the diabetes programs have evolved, and diabetes educators are now part of a larger care team of primary care providers, pharmacists, health coaches and clinical nutritionists, among others. "The team closely monitors patients. Beyond managing blood glucose and A1C levels, the groups adjust medications and guide patients through managing their dis-
ease themselves as much as possible.

Geisinger also has an innovative outcomes-based wellness program, including diabetes management, for its employees. The program was designed to help employees maintain and enhance their well-being through comprehensive benefits, health education and resources. The flagship is myHealth Rewards, a wellness program that provides discounts on insurance costs as incentives for members who reach certain health goals. The program is voluntary and participation is not 100%, so Geisinger conducted a clinical trial last year to test which email strategy is most effective at getting people to join.

For several years now, the American Diabetes Association has put a lot of effort and money into bringing prediabetes management into clinical and public health practice. The push was predicated in part on results of the Diabetes Prevention Program (DPP), a multicenter trial funded by the NIH that showed that diet and physical activity leading to weight loss could reduce the chances of developing diabetes by 58%. Various government programs have been launched to prevent diabetes and prediabetes, including a lifestyle change program recognized by the CDC. At Geisinger, 59% of myHealth Rewards participants with an A1C in the prediabetes range decreased their blood glucose to a normal level. Hess says the myHealth Rewards program has also reduced the incidence of unmanaged Type 2 diabetes as well as long-term complications of the disease, including stroke and heart attack.

Geisinger has also launched the Fresh Food Farmacy program to pilot “food as medicine” for people with Type 2 diabetes. The program provides 10 meals a week consisting of nutritious foods — whole grains, lean meats, fruits and vegetables — for patients who are food insecure and have uncontrolled Type 2 diabetes. The meals are paired with clinical support and education, including individual and group sessions. “Early indicators have shown promising results,” says Hess. Many patients have successfully lowered their A1C levels, fasting blood sugar, weight, triglycerides and low-density lipoprotein cholesterol. And how about costs? “We are currently looking at the financial outcomes, including emergency department visits and hospital admissions,” says Hess.

In addition to achieving the highest tier of CDC recognition, Geisinger was recently approved as a Medicare DPP supplier. This allows for reimbursement for providing the DPP plan to at-risk Medicare beneficiaries. This is especially important because diabetes affects more than 25% of Americans ages 65 and older.

Indiana University Health

The state of Indiana is not a standout when it comes to diabetes. Based on deaths from the disease, it ranks 26th in the country. CDC data show that 10.4% of Indiana’s adults have been diagnosed with diabetes, which is higher than the national average of 8.5% but less than the proportion in Alabama (13.2%) and Arkansas (12.1%). But patients with diabetes have always represented a substantial proportion of physicians’ panels at Indiana University (IU) Health, says Victoria Bratcher, director of...
population health for the 17-hospital healthcare system headquartered in Indianapolis.

Three years ago, the system began a concerted, multispecialty initiative to address diabetes more effectively through comprehensive management programs. It zeroes in on social determinants of health and lifestyle factors that contribute to poor management of diabetes, such as barriers to healthy food, poor medication management and care coordination. One program weaves together diabetes education and pharmacy services to provide better coordinated care. IU Health’s education program is accredited by the American Association of Diabetes Educators and consists of two classes. One is a self-management class in which patients learn about diabetes and how to better manage their disease. The other is an individualized class with a dietitian who teaches patients about making healthful food choices and provides a meal plan designed to help keep diabetes well managed. (Foods with a low glycemic index can help avoid spikes in blood sugar levels.) While addressing the social determinants of health has been part of the program for a while, the focus on food is relatively new. Pharmacists are also on the care team, performing medication reconciliation and offering guidance to keep A1C levels under control. If these efforts are not effective in holding down someone’s A1C level, then the patient is referred to an endocrinologist, says Bratcher.

IU Health is also actively addressing food insecurity by addressing any education gaps and supplying food and other resources, such as transportation, as needed. Cost sharing can be a hurdle to taking medications that control diabetes, so an IU diabetes educator works with patients on finding ways to get prescription assistance from drug companies, if the patient is eligible, or copay cards.

The results of these efforts are showing up as solid progress if not quite show-stopping success. Since 2017, IU Health has increased the number of patients who are considered to have their diabetes well managed by 8.3%, according to Bratcher. Reductions in A1C levels among Medicare beneficiaries have resulted in a $80 to $100 per-member, per-month reduction in Medicare expenditures.

Stamford Health

Three years ago, Stamford Health implemented a comprehensive set of care initiatives to improve patient outcomes, including mortality and length of hospital stay. Previous efforts had focused on improving glucose control in critically ill patients and were successful. The organization then turned its attention to the people who weren’t so ill.

“Decreasing length of stay is the most direct link to financial savings currently available for patients with diabetes, as poor glucose control can result in extended stays,” says Gerard, the diabetes educator. Stamford Health formed an interdisciplinary team to address improvements for noncritical patients in 2017. The institution employs quality initiatives set by the Society of Hospital Medicine that support comprehensive programs across the continuum of care.

Among its efforts was formation of a glycemic care committee comprising an interdisciplinary team of providers to address blood glucose control in noncritical patients. The team assessed opportunities to improve care based on glucose data, systems analysis, end-user feedback and patient outcomes.

The team also evaluated existing orders related to blood glucose control and updated them to provide more evidence-based treatments. Insulin is the primary medication used to treat hospitalized patients with diabetes, and in a hospital setting, it is considered a high-risk medication because it can push blood sugar levels too low. For patients requiring blood glucose testing, nurses were given standing physician orders to treat hypoglycemia with an appropriate medication. Parameters for the appropriate treatment were added to each patient’s electronic medical record to reduce wait times for treatment. These changes allowed nurses to move quickly to treat hypoglycemia. Stamford Health is also teaching nurses about the variances of blood sugar levels, insulin use and the timing of medications with meals to guard against any blood sugar-related dangers.
As it has done with so much else in healthcare, COVID-19 dominated our 2020 annual pharmacy survey. The disease was addressed in 10 of our 13 areas we covered, either within the question itself or as a possible answer. Overall, the responses paint a picture of the pandemic having a major impact, which is not surprising, and reveal some optimism; for example, 78% of the respondents expect to see at least limited use of a COVID-19 vaccine by the first quarter of 2021.

What will be the most important, lasting impact of COVID-19 on the U.S. healthcare system?

- Increased use of telehealth: 57%
- Hospitals and physician practices going out of business: 16%
- Increased provider/hospital consolidation: 7%
- Pressure on the FDA for faster drug approvals: 7%
- Expedited and expanded uptake of digital health/therapeutics: 6%
- Other: 8%

The survey was conducted in May and June. We received 114 responses. For some questions, the percentages of the responses do not add up to 100 because of rounding. Some questions also allowed the respondents to pick more than one answer.
What will be the most important, lasting impact of COVID-19 on the pharmaceutical sector?

- Increased use of mail-order pharmacy: 37%
- Switches from infused to self-administered medication: 18%
- Greater transition from hospital- and clinic-administered infusion to home infusion: 16%
- Increased adoption of more restrictive, limited formulary/drug benefit offerings: 15%
- Decreased adoption of drugs newly approved by FDA: 5%

Which of the following are likely to occur in 2020 as a consequence of the COVID-19 outbreak?

- Healthcare expenditures, excluding spending on medications, dropped 38% in April 2020 compared with April 2019, according to Kaiser Family Foundation calculations. If that level of spending were to continue for a year, it would mean a drop of $1 trillion in spending. Most economists and industry observers expect a rebound in healthcare spending, but how much of one depends on many factors.
Which do you believe is the most likely scenario regarding an FDA-approved COVID-19 vaccine?

- Broad use: general population
- Limited use: e.g., healthcare workers; essential workers
- Limited or broad use

<table>
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<tr>
<th>Scenario</th>
<th>Quarter 4, 2020</th>
<th>Quarter 1, 2021</th>
<th>Quarter 2, 2021</th>
<th>Quarter 3, 2021, or later</th>
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<td>9%</td>
<td>5%</td>
<td>15%</td>
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<tr>
<td>Limited or broad use</td>
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<td>12%</td>
<td>12%</td>
<td>16%</td>
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<tr>
<td>Broad use</td>
<td>23%</td>
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<td>21%</td>
<td>21%</td>
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How likely is it that a safe and effective antiviral will be approved for broad use this year?

- Extremely unlikely
- Very unlikely
- Somewhat unlikely
- Somewhat likely
- Very likely
- Extremely likely

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<thead>
<tr>
<th>Likelihood</th>
<th>10%</th>
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<td>18%</td>
<td>10%</td>
<td>3%</td>
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What is the most effective way to reduce pharmaceutical costs (traditional)?

- 25% Improving price transparency
- 23% Enhanced point-of-prescribing tools to encourage use of most cost-effective medications
- 12% Revised benefit design to create incentives to choose low-cost options
- 11% Adoption and enforcement of clinical pathways
- 11% Reduce out-of-pocket costs for high-value medications
- 8% Narrower, simpler formulary design with more exclusions

Other: 11%

What is the best way to reduce specialty pharmacy costs?

- 31% Performance-based (outcomes-based) contracting between payers and drug manufacturers
- 22% Medicare price negotiation
- 20% Widespread use of biosimilars
- 7% More expanded tools/resources to manage infused specialty products under the medical benefit
- 6% More aggressive and operationally expensive utilization management strategies

Other: 14%
What will be the biggest influence on specialty drug expenditures in 2020?

- 31% Growing demand because of an aging population with multiple chronic conditions
- 30% COVID-related dynamics
- 17% Shift from traditional to specialty medications for common diseases
- 14% Manufacturer price increases
- 9% Other

How will PBM contracts change in the future?

- 41% Greater emphasis on performance-based and shared-savings contracts
- 33% Fewer rebates and narrower formularies
- 19% Greater emphasis on transparency and pass-through pricing
- 7% Full-risk capitation

Which condition will account for the most significant upward pressure on drug expenditures in the next 12 months?

When Express Scripts calculated how much the cost of drugs for certain diseases contributed to the increases in drug spend in its 2019 Drug Trend Report, drug costs for inflammatory conditions far outpaced drug costs for diabetes (43.7% vs. 8.7%).

- Heart disease 4%
- Depression 5%
- Rheumatoid arthritis 6%
- Blood cancers 9%
- Solid tumors 10%
- Autoimmune diseases 10%
- Diabetes 11%
- COVID-19 41%

*Other than multiple sclerosis and rheumatoid arthritis.
Which of these drugs that came on the market in the past year holds the most promise for reducing morbidity and mortality?

- **Trikanta** (elexacaftor, tezacaftor, ivacaftor) — cystic fibrosis
  - 43%
- **Zolgensma** (onasemnogene abeparvovec) — gene therapy for spinal muscular atrophy
  - 19%
- **Adakveo** (crizanlizumab) — sickle cell disease
  - 15%
- **Oxbryta** (voxolotor) — sickle cell disease
  - 11%
- **Givlaari** (givosiran) — treatment of adults with acute hepatic porphyria
  - 11%

Which healthcare issue will receive the most attention during the presidential campaign this fall?

- **COVID-19 and the federal government’s response**
  - 78%
- **High list prices for prescription medications**
  - 8%
- **Medicare for all**
  - 7%
- **Other**
  - 7%

Which of these drugs in development holds the most promise?

- **Aducanumab** — Alzheimer’s disease
  - 52%
- **Roxadustat** — anemia associated with chronic kidney disease
  - 25%
- **Valoctocogene roxaparvovec** — first gene therapy for hemophilia type A
  - 18%
- **Zynteglo** — gene therapy for beta thalassemia
  - 4%
- **Lenti-D** — gene therapy for cerebral adrenomyeloneuropathy
  - 2%

Biogen surprised the biotech world when it relaunched trials of aducanumab after pulling the plug on phase 3 trials last year when an interim analysis showed that the drug was unlikely to meet its primary endpoint. Biogen announced on July 8 that it had completed the submission of a Biologics License Application to the FDA for approval of aducanumab.
Nonmedical Use of Prescription Stimulants: Risk Factors, Outcomes, and Risk-Reduction Strategies

This Managed Healthcare Executive® publication provides key information regarding a review by Faraone, et al, which was originally published in the Journal of the American Academy of Child & Adolescent Psychiatry (doi: 10.1016/j.jaac.2019.06.012). The authors of the original review are Faraone SV, Rostain AL, Montano CB, Mason O, Antshel KM, Newcorn JH. Please consult the full published review for complete information and author affiliations.

BACKGROUND
Stimulant medications (eg, methylphenidate, amphetamine, and lisdexamfetamine) are frequently prescribed for attention-deficit/hyperactivity disorder (ADHD). According to data from the US Drug Enforcement Administration's Automation of Reports and Consolidated Orders Systems, amphetamine use increased 2.5 times between 2006 to 2016, from 7.9 to 20 tons. In that same time period, methylphenidate use increased from 16.5 tons to 18.6 tons, with peak consumption in 2012 (19.4 tons).

While considered first-line treatments for ADHD, stimulant medications are frequently used for nonmedical purposes. Because stimulant medications induce euphoria and improve alertness and concentration, their potential for abuse, misuse, and diversion is high. Abuse is “the intentional, nontherapeutic use of a drug product or substance, even once, to achieve a desirable psychological or physiological effect,” whereas misuse is “the intentional therapeutic use of a drug product in an inappropriate way and specifically excludes the definition of abuse.” Nonmedical use, which includes both abuse and misuse, is the use of a prescription medication without a prescription, or in a way other than prescribed. Data from the 2016 National Survey on Drug Use and Health determined that an estimated 5.6 million individuals at least 12 years of age misused stimulant medications at some point during the past year.

Stimulant misuse is common among high school and college students. A national multicohort study found that 9.5% of high school seniors used stimulant medications for nonmedical uses. Data reported by Garnier-Dykstra et al indicated that over a 4-year period, 61% of the college students who participated in the study were offered prescription stimulant medications at least once, and 31% of study participants reported using them for nonmedical purposes. This is particularly concerning because another peer reviewed study by Wilens et al demonstrated that compared with controls (subjects who were not being treated with stimulant medications and had never misused), stimulant medication misusers are at a higher risk for ADHD and/or multiple drug-and/or alcohol-use disorders.

Because of their abuse potential, both the American Academy of Pediatrics (AAP) and the American Academy of Child and Adolescent Psychiatry...
recommend that clinicians assess for symptoms of substance abuse in adolescent patients receiving stimulant medications. According to recently released guidelines from the AAP, “Clinicians should monitor the adolescent’s symptoms and prescription refill requests for signs of misuse or diversion of ADHD medication, including by parents, classmates, or other acquaintances of the adolescent.”

RATIONALE FOR REVIEW BY FARAOONE, ET AL
To better understand the nonmedical use of prescription stimulants across the lifespan, Faraone et al conducted a systematic review to explore risk factors and motivations for the use of stimulant medications for nonmedical uses. The goal for this review was to add to existing research to assist with identifying high-risk patients and developing more sophisticated approaches to management.

METHODS
A literature review was conducted using Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines to examine the epidemiology, risk factors, motivations, and outcomes of the nonmedical use of stimulant medications, specifically methylphenidate and amphetamine. PubMed, PsycINFO, and SCOPUS were searched using ADHD, nonmedical use, illicit use, abuse, misuse, enhancements, stimulants, and other similar terms. Studies relating to nonmedical use, diversion, shoplifting behavior, or malingering of ADHD were included in the analysis. Two reviewers evaluated the studies to ensure inclusion and exclusion criteria were met before the necessary data were extracted.

RESULTS
A total of 86 studies that examined the epidemiology of stimulant nonmedical use and diversion were identified. Self-reported rates of nonmedical use varied considerably among the studies. The majority of studies used the term “nonmedical use,” but others used terms such as misuse and abuse or it was not clearly defined. Reported rates of nonmedical use ranged from 2.1% to 58.7%, depending on definition used, study design, and population studied. In 50% to 90% of nonmedical cases, the stimulant medications were obtained from family or friends. Between 4% to 35% of individuals reported using their own prescribed stimulant medications for nonmedical uses. A total of 20% of adults who reported nonmedical use of stimulants in the past year revealed that they obtained prescriptions fraudulently. College students reported that it was “easy” and rarely difficult to obtain stimulants. The most frequent route of administration was oral (52%-95%), but snorting (nasal route: 7%-48%), smoking (1%-6%), or injecting intravenously (1%-11%) were also noted.

Risk Factors for the Nonmedical Use of Prescription Stimulant Medications
The nonmedical use of prescription stimulant medications was most common in individuals aged 18 to 25 years. Among middle and high school students, those in higher grades were more likely to use stimulant medications for nonmedical uses compared with those in lower grades. Although there were some exceptions, male students were at greater risk for nonmedical use than females, across all age groups. Nonmedical use of stimulants was higher with white students than with Hispanic or African American students. An inverse relationship was observed between grade point average (GPA) and nonmedical use of stimulant medications. Among college students, those belonging to sororities and fraternities were more likely to use stimulants nonmedically than others. Individuals who reported nonmedical use of stimulant medications generally had higher levels of ADHD symptoms versus those who did not report

<table>
<thead>
<tr>
<th>RISK FACTORS ASSOCIATED WITH THE NONMEDICAL USE OF STIMULANT MEDICATIONS</th>
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<tbody>
<tr>
<td>Male sex</td>
</tr>
<tr>
<td>White ethnicity</td>
</tr>
<tr>
<td>Age 18 to 25 years</td>
</tr>
<tr>
<td>Lower grade point average</td>
</tr>
<tr>
<td>Higher level of ADHD symptoms*</td>
</tr>
<tr>
<td>Other substance abuse disorders</td>
</tr>
<tr>
<td>Eating disorders (in some studies)</td>
</tr>
</tbody>
</table>

ADHD indicates attention-deficit/hyperactivity disorder.

*Note that this may be self-reported, as this association was not found in some studies.

TABLE

ADHD indicates attention-deficit/hyperactivity disorder.

*Note that this may be self-reported, as this association was not found in some studies.
such use, though self-reporting of symptoms may be a confounding factor. Certain conditions were also associated with higher levels of misuse. These included eating disorders and other substance-use disorders (eg, alcohol, marijuana, cocaine, tranquilizers/sedatives, hallucinogens, heroin, inhalants, and pain relievers).

**Motivations for the Nonmedical Use of Prescription Stimulant Medications**

Academic motivations (cited by 50%-89%) were the primary reason for nonmedical use of stimulants in college students, and 40% of adults reported nonmedical use to improve productivity. Other motivations included recreation, “getting high,” curious/wanting to experiment, boosting the effects of alcohol, augmenting social situations, socialization, enhanced wakefulness, and weight loss.

**Undesired Outcomes**

The adverse effects of stimulant medications from nonmedical use were generally similar to those reported in clinical trials (eg, headache, stomachache, irritability, feeling sad, reduced appetite, sleep difficulties, and dizziness). The outcomes observed in this systematic review were further divided into medical and academic outcomes.

Medical outcomes associated with prescription stimulant nonmedical use were determined to be burdensome for health care facilities. The authors noted an increased number of emergency department (ED) visits due to nonmedical use of stimulant medications in adults. Amphetamine abuse was associated with high rates of ED visits and a high number of ED visits and admissions to critical care units. Route of administration also played a role in the risk of adverse outcomes. Nasal and intravenous amphetamine abusers had higher rates of death compared with nonabusers. In one study, amphetamine nasal abusers had a mortality rate of 0.5% and intravenous abusers had a 1.2% mortality rate, compared with 0.03% for nonabusers. Compared with nonabusers, the mortality rate was 13x greater for nasal abusers and 22x greater for intravenous abusers.

Academic outcomes were a common motivation for the nonmedical use of stimulant medications; however, data do not correlate with positive academic improvements. This review demonstrated that there were no improvements in academic performance when students without a diagnosis of ADHD used stimulants. Conversely, students who were prescribed stimulant medications did not have lower educational achievement.

**DISCUSSION**

Five Strategies for Addressing the Nonmedical Use of Stimulant Medications

Misuse of stimulant ADHD medications is associated with safety concerns such as overdose and drug-drug interactions. An unmet need exists for better methods of identifying and mitigating the use of stimulant medications for nonmedical uses. Five such strategies are discussed below.

I Prescriber participation and education are essential components of any strategy.

Prescribers not only have the platform to explain the health risks associated with medication abuse, but also the legal consequences of such activity. Utilizing prescribers as allies in adolescent education provides the opportunity to inform students of pertinent judicial considerations in addition to standard clinical concepts. Because of the potential for abuse and diversion, it is important that prescribers screen all patients for comorbid disorders prior to prescribing stimulant medications for ADHD.

II It is important to proactively identify individuals and households at risk for using stimulant medications for nonmedical purposes.

Risk factors associated with the nonmedical use of stimulant medications are provided in the Table. In addition to these risk factors, household diversion should also be considered. Data suggest that homes with children taking ADHD medications are likely to have family members who use stimulant medications for nonmedical purposes.

III Better identification methods are needed for patients who are malingering.

Data suggest that it can be difficult for clinicians to detect malingering. When assessing patients for symptoms of ADHD, clinicians need to consider malingering and fully understand the diagnostic criteria for ADHD. Improving validity testing could be useful in identifying patients who exaggerate their ADHD symptoms.

IV Increased support and deterrents can be established to minimize the nonmedical use of stimulant medications.

Tutoring programs for students having difficulty keeping up in school and counseling for those who are struggling with body image are methods aimed to...
discourage misuse. In addition, incorporating these choices into academic dishonesty policies in high schools and colleges holds individuals accountable for the decisions they make. Because students frequently overestimate the nonmedical use of stimulant medications among their peers, correcting this misconception may help reduce such use and reiterate its illegality.

**V**

Misconstrued beliefs about the benefits of using stimulant medications for nonmedical uses should be addressed.

The most frequently reported reason for the nonmedical use of stimulant medications among college students was academic enhancement. Although widely believed to improve productivity, attention, and cognitive performance in academic settings, prescription stimulant medications have not been proven to elevate scholastic achievements in individuals without a diagnosis of ADHD. Moreover, studies in student populations show an inverse relationship between nonmedical use of stimulant medications and GPA improvements.

It is important to highlight these data so that individuals, especially adolescents, understand that the use of stimulant medications to enhance academics is not beneficial in those who do not have ADHD. Challenging this misbelief may reduce the nonmedical use of stimulants.

**FUTURE DIRECTIONS**

When used as prescribed, ADHD stimulants are not associated with an increased risk of substance abuse. However, the misuse and/or abuse of prescription stimulants may lead to a substance use disorder. It is evident that various systemic improvements are needed to evoke necessary changes regarding the nonmedical use of stimulant medications. A combination of techniques is required to best combat this serious issue. Screening tools are needed to help detect patients at risk for nonmedical use, to allow clinicians to direct prevention and treatment efforts to the appropriate patients.

**References**


Although it is a new disease, COVID-19 has a way of peeling back layers and bringing other medical issues to the surface. For example, research has shown that people with high blood pressure are more likely to become seriously ill. A study published in the April 22 issue of JAMA of 5,700 patients hospitalized with COVID-19 in the New York City area found that 56% had hypertension, making it the most common comorbidity.

The death rate from cardiovascular disease has been declining, but it remains the leading cause of death in the United States. According to the CDC, 647,457 Americans died of heart disease and 146,383 of stroke in 2017. (Of course, this year COVID-19 has scrambled the usual list of the leading causes of death in this country.)

“(Cardiovascular disease) has to be a priority of health systems and the government. We haven’t really attacked it as well as we should have,” says Martha Gulati, M.D., M.S., FACC, FAHA, division chief of cardiology at the University of Arizona College of Medicine in Phoenix and editor-in-chief at CardioSmart.org, a website run by the American College of Cardiology aimed at educating patients about heart disease. “The whole population has to be involved in this,” with a focus on preventing cardiovascular disease, Gulati says.

“By working on the risk factors, we can change the overall outcome of the population.”

— MARIELL JESSUP, M.D., FAHA, CHIEF SCIENCE AND MEDICAL OFFICER OF THE AMERICAN HEART ASSOCIATION

More than 100 million American adults, or almost half the country’s adult population, had hypertension in 2018, according to the American Heart Association (AHA). But that proportion grew significantly in 2017, when the AHA revised its definition of high blood pressure. Previously, high blood pressure was defined as a reading of 140/90 mm Hg or higher. Now it is defined as a reading of 130/80 mm Hg, a change that increased the percentage of Americans with high blood pressure from 32% to 46%.

Blood pressure often increases with age, but for people who reach age 50 with normal blood pressure, “the chance of developing cardiovascular disease and stroke immensely decreases,” notes Mariell Jessup, M.D., FAHA, the AHA’s chief science and medical officer. The AHA campaign Life’s Simple 7 highlights seven modifiable risk factors for heart disease, such as losing weight and increasing physical activity. “By working on the risk factors, we can change the overall outcome of the population,” Jessup says.

Cardiovascular disease risk translates into expense. A study of more than 9,000 employees of Baptist Health South Florida, a health system in Coral Gables, collected information on diet, physical activity levels, blood pressure and several other risk factors. Researchers then classified the participants as having optimal, moderate or low cardiovascular health. Results of the study published in Mayo Clinic Proceedings in 2017 showed that the average annual healthcare expenditure for people with low cardiovascular health was $2,021 more than for those in the optimal category and $940 more for those in the moderate one.
"Bringing the program to you"

The prevalence of diagnosed and undiagnosed hypertension among adult African American men (59% using the new 130/80 threshold) and women (56%) is among the highest in the world. Many programs to address the problem have been launched, with mixed results. A study published in *Circulation: Cardiovascular Quality and Outcomes* in 2018 involved black churchgoers in New York who had uncontrolled hypertension. One group received “therapeutic lifestyle change” and motivational interviewing about healthy habits, such as improving their diet, increasing physical activity and losing weight, along with religious and personal encouragement. The second group received standard health education. At six months, the difference between the two groups was significant. The systolic blood pressure of the therapeutic lifestyle group was, on average, 5.79 millimeters of mercury lower than the health education group. At nine months, there was still a difference, but it was narrow and didn’t meet the usual standard for statistical significance.

In many cases, improving hypertension requires the involvement of community partners, notes Jessup, because most people go to the doctor just once or twice a year. Through programs such as the one conducted at New York churches, “we’re bringing the program to you, rather than making people come to the program,” she says. But it takes money and people to make such programs work, Jessup says.

Gulati points a finger at fee-for-service reimbursement that pays providers more for, say, implanting a stent than for helping a patient keep their blood pressure and cholesterol under control. “We’re a sick care system,” she says. “We’re not so good at preventing cardiovascular disease.”

Providers instead need to focus on educating patients on cardiovascular risk and screening those who may be at risk, Gulati says. They also need to get patients engaged in caring for their own health by encouraging home monitoring of blood pressure and adherence to hypertension medications.

By doing so, the healthcare system can “save money by spending money upfront,” Gulati says.

The overlap between the risk factors for serious COVID-19 illness and cardiovascular disease is remarkable. Obesity, diabetes and hypertension appear on both lists. Gulati says COVID-19 has helped shift the conversation to why a healthy population is important.

**Telehealth may help**

For physicians and nurses involved in the care of people with cardiovascular disease or its many risk factors, telehealth can yield clues about their patients’ exercise and dietary habits. “Seeing a patient in their home environment tells so much about the patient’s life,” Gulati says. There has been a surge in patients using telehealth during the COVID-19 crisis. Not-for-profit FAIR Health analyzed its database of private insurance claims and reported that telehealth jumped more than 4,300% in March compared with March 2019. But oo keep that in perspective, the March 2020 telehealth claims still were only 7.5% of all insurance claims that month.

Hospitals have reported a steep drop in patients experiencing heart attacks and strokes since the pandemic began. Data from Kaiser Permanente Northern California showed a 48% drop in hospitalizations for heart attacks in early April compared with earlier in 2020. Explanations vary. Some people may be dying at home or having relatively mild heart attacks that will lead to more serious problems later.

Mitchell Kaminski, M.D., MBA, a family physician and director of the population health program at Thomas Jefferson University in Philadelphia, says the surge in virtual visits may mean more providers are managing patients with medication rather than referring them to the hospital for a procedure such as cardiac catheterization.

“Medication management might sometimes be safer for some categories of patients. We may learn less is more when we analyze all the data,” Kaminski says. “(The COVID-19 pandemic provides) a unique opportunity to step back and analyze data and see what we can learn from it to provide better care for our population.”

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*Source: National Vital Statistics Reports, June 24, 2019*

<table>
<thead>
<tr>
<th>CAUSE OF DEATH</th>
<th>DEATHS</th>
</tr>
</thead>
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<td>All causes</td>
<td>2,813,503</td>
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<tr>
<td>Diseases of heart</td>
<td>647,457 (23%)</td>
</tr>
<tr>
<td>Cerebrovascular diseases (strokes)</td>
<td>146,383 (5.25%)</td>
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</tbody>
</table>

**TABLE Cardiovascular deaths in the United States, 2017**

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Susan Ladika is a health and business writer in Tampa, Florida.
During the past decade, physicians, dentists and other providers latched on to electronic reminders to get patients to come to appointments by pinging them with text and email messages. Patients now are getting nudged (some may argue they’re being nagged) to take their medications.

Yet adherence problems persist. “In patients with chronic disease, nearly half do not take their medicines as prescribed, and more than a quarter of newly written prescriptions are never brought to the pharmacy to be filled, including those for high blood pressure, diabetes and high cholesterol,” said Katie Koziara, director of public affairs at PhRMA, in an email interview.

Research and experience have shown that reminder texts and emails go only so far when it comes to adherence. Patients need to be motivated, especially because many medications for chronic diseases don’t necessarily make a person feel better right away. Positive feedback comes when patients see the medication control the disease and influence results of laboratory tests.

Patients definitely have the most at stake because their health is on the line. But aside from wanting to do right by their patients, providers participating in value-based care programs also have a financial incentive to encourage medication adherence, because nonadherent patients make it harder to meet financial benchmarks. They also will jeopardize good grades on quality metrics. For payers, the nonadherent patient stands a good chance of being the more expensive member or beneficiary because of the well-documented association between nonadherence and expensive events such as rehospitalizations. Adherence also is a factor in ratings systems that govern payment levels, and it makes the pharmaceutical industry’s products more effective, which presumably translates into sales.

Available technologies addressing adherence range from embedding medications with ingestible sensors to digital reminders to patients to take their pills. Here are three technology companies that use a varied approach to adherence, combining chatbots, artificial technology (AI), ‘gamification’ techniques, real-time monitoring and personalized messages:

1. **GROOVE HEALTH**

Groove Health, a Chicago health tech company, works with payers, hospitals, and Medicare and Medicaid plans to target patients at highest risk of nonadherence. Using an analytics platform, the company mines client data to identify those who would most benefit from the program, including patients who are likely to cost the company the most money because of low adherence. Its mobile app populates the medications from insurance company claims data. Patients schedule reminders to take their medication and log in to mark when it was taken or give a reason it wasn’t. “We get a good sense about adherence levels for a particular person and how they manage their medications,” says CEO and founder Andrew Hourani.

Groove Health also uses conversational AI and its Maxwell chatbot to help identify barriers to adherence. “Nearly everybody will have their own unique reasons for not taking a medication. It could be needing a ride to pick it up or a side effect,” Hourani says. The members of the patient’s care team are alerted about the barriers on their dashboard, so they can follow up. Patients also receive specialized content and resources to address the potential barrier to adherence.

One common barrier: thinking medication is unnecessary when feeling fine. The system sends the patient educational messages about why it’s important to stay on the medication regardless of how they feel.
Not all technology programs integrate with providers, but Groove Health does. “I don’t think there’s any replacement for human-to-human interaction,” Hourani says. “Technology can automate a lot of the initial tasks relating to data collection and engagement, but technology and human-to-human interaction are complementary.”

The web-based platform allows for real-time data views by providers who then use the information to compile call lists and get in touch with patients directly.

Despite the perception that technology may flummox elderly patients, Hourani says, the Medicare population is highly engaged with it. Groove Health partners with Medicare Advantage plans that are interested in improving their CMS star ratings, because medication adherence measures are highly weighted in determining reimbursement levels.

**HEALTHPRIZE TECHNOLOGIES**

HealthPrize Technologies in Norwalk, Connecticut, works with patients and drug companies, using gamification, behavioral economics and loyalty marketing techniques to encourage medication adherence. “Human behavior is complex,” says Vishal Khanna, the company’s vice president of marketing and communications. “Even simple technology solutions like a reminder app or feed aren’t enough to get a person to take medications for chronic diseases that (they) don’t want to take or (that remind them they) have a disease and are facing fears of mortality.” Technology solutions that don’t work with the negative thoughts and feelings people have about taking medications will have only a limited effect, he says.

Rewards programs such as those used by airlines or credit cards don’t work for medication adherence, according to Khanna: “You can motivate the person once or twice, but you have to think long term.”

HealthPrize blends human behaviors with health and motivational techniques that have been validated in peer-reviewed studies. The program starts extrinsically, giving patients points for every action taken to help them develop habits. Interventions are added sequentially to give short educational lessons over long periods of time. These messages might include the type of medication information given after an in-person visit, but in HealthPrize, it’s broken down into smaller pieces. The program moves to intrinsic motivations when the patient finds value in their actions, not just rewards for taking them, Khanna says.

Still, HealthPrize is true to its name and uses rewards and prizes. According to Khanna, patients log on an average of five times a week, for about 2 minutes, 10 seconds each visit. That adds up to 30 to 40 minutes a month. Patients get points for reporting whether they took their medications; the points vary daily to keep it interesting. The company offers prizes such as gift cards for reaching certain levels, and patients can use points to earn health-related items or make charitable donations. No one wins a car or an all-expenses paid trip to Las Vegas. Prize amounts are capped at $75 a year, in keeping with Medicare and Medicaid regulations.

HealthPrize also gives patients daily tips about general health and wellness or their medications. Quizzes test knowledge and convey disease information, but about a third of the daily content is unrelated to health so that patients aren’t continually reminded about their condition. The site hosts weekly competitions, based on the number of check-ins, between participant groups.

Khanna says HealthPrize’s program results, on average, in a 50% increase in medication adherence over the pharmaceutical company’s baseline (ranging from 44% to 66%, depending on the disease program). That results in an average of 2.2 extra verified fills per year compared with copay card programs that patients had been involved in previously. The point system rewards people for filling their prescriptions. If patients are taking their medications more regularly, presumably their condition is better controlled, which will improve their health.

HealthPrize’s clients are pharmaceutical companies; it has no re-
relationship with providers. Patients can make a PDF of their adherence statistics to share with their physician, Khanna says.

3 **MEDISAFE**

Medisafe uses an app that collects patient information and creates data algorithms to personalize patient messages. Its software creates a personal profile, using demographic and medication information. The Boston-based company has collected more than 15 billion data points from patient usage and used them to refine its Just-in-Time-Interventions messaging, which incorporates interventions used with other patients and identifies what worked best. The interventions include a reminder with therapeutic or scientific content and anonymized patient stories. Medisafe has found that simply asking patients why they didn’t take a missed dose can be a useful intervention, says Omri Shor, CEO and co-founder of Medisafe.

Medisafe lets patients document biometrics such as blood pressure, blood glucose levels and blood oxygen levels and correlate that information with their medication adherence. The software also allows patients to connect with a drug company’s support center if they have questions about the medication. The company has business arrangements with pharmacies to provide home delivery of medications, which has been helpful during the COVID-19 pandemic, Shor says. Medisafe says its app results in high adherence rates in a population that, on average, takes five medications per day.

Medisafe contracts with the pharmaceutical companies, and the app becomes “part of the drug experience for the patient,” Shor says. Medisafe has content portals in the app for specific drugs that partner with the pharmaceutical company. In addition to receiving personalized content and push notifications to take medication, patients can have alerts regarding a missed dose sent to an interested person. Medisafe also integrates coupons and discounts from the manufacturer. “It’s everything you need in the process of using that drug,” Shor says.

**COVID-19 and adherence**

The pandemic is increasing the use of technology solutions, Hourani says. "With COVID-19 and quarantine, that’s accelerating the shift to digital health, not only for those employing telehealth, but (also) for patients using telehealth for the first time. Patients are seeing that it can help with their healthcare management.”

Chatbot use is also rising, offered by healthcare organizations and insurance companies to help identify medical issues and direct patients to the right resources.

"Adherence as a patient issue has everything to do with COVID-19," Khanna says, because there have been fewer in-person visits, fewer new prescriptions and new indications not necessarily being managed, along with continuity-of-care issues. “Patients are dipping in adherence 15% to 20%, from the data I saw,” Khanna says. Fill rates of 90-day prescriptions rose in mid-March, he says, and now are dropping below that level, a clear trend toward nonadherence.

It’s essential to think about adherence. “Those who haven’t come up with adherence solutions are behind the times. The new normal will have to provide a level of digital support,” Khanna says. Patients and providers will need to adopt more digital ways to engage with each other.

Medication adherence requires a holistic approach, said Koziara, the PhRMA public affairs official. Technology is just one tool, along with patient education, counseling, decision-making strategies, medication therapy, refill synchronization policies and innovative contracting arrangements.

“Technology is one component of that overall care plan, and it can be dialed up or down depending on the patient’s goals and care preferences,” said Koziara.

**Technology**

“Nearly everybody will have their own unique reasons for not taking a medication. It could be needing a ride to pick it up or a side effect.”

– ANDREW HOURANI, CEO AND FOUNDER OF GROOVE HEALTH

**Deborah Abrams Kaplan** covers medical and practice management topics.
Protecting the Integrity of EHR Clinical Decision Support Tools

Practice Fusion case spotlights how technology can be corrupted by commercial interests. by AINE CRYTS

If physicians are going to trust clinical decision support tools embedded in electronic health records (EHRs), the tools must be free of commercial influence and based on evidence and best clinical practices. That’s the takeaway from a commentary in May’s JAMA Internal Medicine, which discussed the EHR vendor Practice Fusion and the $145 million it is paying to resolve civil and criminal investigations into its clinical decision support tools.

According to a U.S. Department of Justice (DOJ) announcement earlier this year, San Francisco-based Practice Fusion admitted to soliciting and receiving kickbacks from a major pharmaceutical company in exchange for using its EHR software to influence physicians prescribing opioid pain medications. The company received $1 million to develop a tool that prompted doctors to increase their prescriptions of extended-release opioids, said the announcement. DOJ did not name the pharmaceutical company, although media outlets have identified it as Purdue Pharma. Chicago-based Allscripts acquired Practice Fusion in 2018 after this conduct occurred.

Electronic health records have been blamed for physician burnout and assorted other ills, wrote the co-authors of the commentary, Julie Taitsman, Andrew VanLandingham and Christi Grimm, staff members of HHS’ inspector general’s office. “Although these criticisms may be overstated, an insidious aspect of EHR has largely escaped scrutiny: corruption of clinical decision-making.”

Physicians who actively engage in EHR deployment and management can help maintain the integrity of clinical decision support tools, experts say. But healthcare executives also have a role in exercising due diligence about vendors’ finances.

Healthcare systems need to be able to trust that their EHR vendor will base any formulary changes on clinical evidence, not on a relationship with a pharmaceutical manufacturer, says Aaron Miri, chief information officer (CIO) of the University of Texas’ Dell Medical School in Austin. Miri says he doubts that a major vendor, such as Epic or Cerner, would jeopardize its relationships with providers by meddling with EHR in an inappropriate way. These relationships are “predicated on trust,” Miri says. “Practice Fusion’s overall business model was really sketchy to begin with,” he says. “It is ridiculous that this business model was allowed to thrive in the health IT environment.”

Physicians have to be actively engaged because of their clinical training. The role of a CIO in an EHR deployment or management is to serve as “head Sherpa,” Miri says. “That means you’re not the sole person. Your job is to create a coalition of the willing, which includes doctors and nurses and pharmacists who make steering decisions on quality teams” that govern EHR use.

KLAS Research, a healthcare IT research company in Orem, Utah, is a valuable source of information about EHR companies, says James Ellzy, M.D., FAAFP, a family physician in Washington, D.C., and a member of the American Academy of Family Physicians’ board of directors. Ellzy encourages provider organizations to pay for KLAS membership, which gives them access to its reports and direct communication with company officials.

Practice Fusion’s EHR was free to physicians who were willing to view pharmaceutical ads. That should have been a red flag, experts say. Technology is expensive to maintain, and storage isn’t free, Ellzy observes.

Miri says executives should comb through publicly traded EHR companies’ earnings statements to see if they sell deidentified data. If they do, the health system can write in their contract that the manufacturer can’t sell its deidentified data without written permission. 

Aine Cryts is a healthcare writer based in Boston.
The alphabet soup of healthcare C-suite titles seems to be in constant flux, with new titles popping up as part of the leadership. Some of the titles — chief people officer, chief wellness officer — may induce eye rolls because of the touchy-feely factor. But in many cases, they reflect new priorities and cultural shifts. The CEO and healthcare systems’ boards of directors are adding to the C-suite or renaming old positions as a response to competition and the need for greater accountability.

Determining the size of the C-suite and the titles within it is a case-by-case proposition. “The C-suite should only be as big as it needs to be to be responsive to the needs of that business,” says Joseph Fournier, J.D., M.H.A., president of InveniasPartners, a healthcare executive search and strategy company in Chicago. The core leadership almost always includes the CEO, chief financial officer (CFO), chief operating officer (COO) and, for healthcare systems, chief nursing and physician executives, he says.

“Then we need to start filling in around that,” Fournier says.

Trending titles
Trendy titles may be relevant even if they sound less traditional. They often represent new challenges or a focus affecting the culture and bottom line.

CDO
With the growth in electronic health records and other digital initiatives, the chief digital officer (CDO) role is gaining prominence, according to Fournier. The chief information security role is also picking up steam because of cyberattacks and the risks posed by health and financial information data breaches. The CDO might also oversee the chief analytics officer (CAO), who is responsible for sifting through the terabytes of healthcare data that many healthcare organizations have at their disposal because of EHRs and that old mainstay, claims databases. “There’s a need for usable data that tells real stories about patients and can connect to health information,” Fournier says.

The CAO’s position also is climbing up the organizational charts of payers, notes Thomas Quinn, senior partner and managed care practice leader at WittKieffer, an executive search firm in Boston. Harnessing data to make quick decisions is...
critical when a member is at high risk of hospital admission or is a high utilizer. Identifying and sharing that information with the care management team can affect the patient’s health and care, as well as associated costs and revenue. “We’re seeing that role being elevated, put under the CFO or sometimes the COO,” Quinn says.

CWO
In 2017, California’s Stanford Medicine became the first academic center to add a chief wellness officer (CWO). Since then, at least a dozen more centers have added a CWO, sometimes called chief well-being officer. The focus has been on helping physicians and other caregivers with burnout and making sure they have appropriate services to deliver safe and effective care, according to Fournier. But the position and the person in it have a broader role, he says.

“A chief well-being officer can really understand the goals of the business and the needs of the patients and (can) integrate well-being into the culture and DNA of the organization,” Fournier says. The position may not succeed in all healthcare organizations — leaders who stick to traditional thinking may not be receptive to a role that can be thought of as coddling, he notes.

CGO
Among payers, the chief growth officer (CGO) is catching on, says Quinn. He differentiates the role of CGOs from traditional sales because CGOs are supposed to think and act more strategically. It’s the CGO’s job to scout out potential partners and alliances to grow membership and suss out new market segments. The role uses “a different skill set than a traditional sales guy who works the brokers,” says Quinn. Whereas the marketing staff may have undergraduate degrees, a CGO probably has a master’s degree — or at least that skill set.

CGP
Another hot title is chief of government programs (CGP) or government markets, says Quinn. Margins have been better in Medicare and Medicaid dual programs in the past four to five years, he says, and the role, which spearheads federal solutions, reflects that.

Size matters
Adding C-suite titles can help solve real problems as well as give an organization additional cachet. But the titles also can be a luxury. Smaller and midsize hospitals are not typically adding the management titles seen elsewhere, with the exception being some academic institutions that are more willing to invest at the C-suite.
level, says Brandt Jewell, senior vice president at Coker Group, a national healthcare advisory firm in Alpharetta, Georgia. “Smaller and midsize hospitals don’t have that bandwidth,” Jewell says.

Physician leadership positions lag in systems with fewer than hundred providers, observes Jewell. Partly it’s because the systems may not have enough doctors to invest in the chief medical officer role. But Jewell says he’s observed that doctors tend to be less interested in working with the profit-and-loss statements and more interested in value-based care. That’s an area where physicians can be more easily recruited for leadership development.

**Which titles are needed?**

Boards and organizational leaders use titles to delegate accountability for things they consider important. “When I see C-suite invest in a new C role around something like value-based care, it’s saying, ‘This is important to us, and we need someone with the highest level of expertise to focus on it,’” says Jewell.

Fournier says organizational leaders — often the governance committee of the board and the executive committee — need to hash out what they are trying to accomplish. In a highly competitive environment, executives should look at the factors that make their organization stand out. If a certain factor or experience is critical to success, the organization can signal that strength with a position and a title — and with putting a strong leader in that role, says Fournier. This doesn’t mean the position needs to be at the C-suite level, but the person needs to have the operational abilities and budget to succeed. “The executive team needs to think about how to attach people and strategy ... and look at the critical bodies of work to see where that role needs to sit,” Fournier says.

Payers and providers used to live in their own bubbles, but healthcare systems are expanding how they do business, including entering into joint ventures. A person running a joint venture may have the title of president without having many executives reporting to them, says Jewell.

**Changing with the times**

The CEO, the CFO, the COO, the CIO — those are C-suite constants that aren’t going away. But Fournier says C-suite organization and titles should be viewed as dynamic, not static. Roles may emerge and then fade away. “Or they may decide after a while that it’s not a role that matters, because the C-suite roles become synthesizers of information. ‘They’re really there to tie together workstreams for leaders,’” Fournier says. A chief experience officer might, for example, oversee the work of those responsible for both the employee experience and patient experience. The chief legal officer may oversee the risk portfolio, including the chief compliance officer and general counsel.

Mergers are another time to reconsider the structure of the C-suite. “In general, consolidations have taken away more executive jobs than they’ve created,” notes Quinn. Many of these deals are set up to allow the local hospitals to continue running themselves, at least for a few years, says Jewell. “Every local hospital has their own C-suite to go along with the regional and national C-suites. A lot of systems are hesitant to blow that up locally,” he says.

Often the layoffs occur at the operational level, affecting employees in human resources, revenue cycle management and technology as those functions get pulled into a centralized operation in the name of efficiency and standardization. With many acquisitions, the C-suite stays put for two to four years, and then changes may be made.

C-suite roles will continue to change with healthcare trends. Roles may disappear when a particular person leaves; the executive committee and board may use the departure as an opportunity to tweak a role and title — or abandon it because more pressing issues have arisen.

It would not be surprising to see positions added related to emergency preparedness, diversity and inequity — if not to the C-suite, at least to the level in the organizational chart that reports to the C-suite. “As different needs emerge in the organization and at different times, some roles become more prominent or get more attention than others,” Fournier says.

Deborah Abrams Kaplan covers medical and practice management topics.
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Racial Disparities in Cancer Enter the Spotlight

Underrepresentation of blacks in clinical trials is garnering special attention by PETER WEHRWEIN

In 1968, the Kerner Commission concluded: "Our nation is moving toward two societies, one black, one white — separate and unequal." In many ways, cancer in this country — its incidence, prevalence, treatment access and outcomes — also is riven by race, with black Americans faring worse than whites.

Blacks "have the highest death rate and shortest survival of any racial/ethnic group in the U.S. for most cancers," according to the 2019-2021 American Cancer Society's Cancer Facts & Figures for African Americans. Recognition of racial disparities in cancer is not new, and the many questions about disparities have not gone unexamined. A PubMed search of "racial disparity cancer" brings up 1,906 results for just the past five years. A similar keyword search of the abstracts presented at the 2020 meeting of the American Society of Clinical Oncology (ASCO) in May brought up 22 abstracts. The National Cancer Institute has a Center to Reduce Cancer Health Disparities, and its Surveillance, Epidemiology and End Results database is easily searchable by race. The cancer society has been publishing its biannual facts and figures reports about African Americans' health for at least 15 years. But Americans now are seeing a wide range of issues through the lens of race and racism like never before, and racial disparities in cancer have gained new salience. There's evidence of fresh interest and commitment on the part of prominent cancer research groups and pharmaceutical companies. As part of a virtual meeting in late June, the American Association for Cancer Research held a panel discussion titled "Racism and Racial Inequities in Cancer Research," led by the organization's president, Antoni Ribas, M.D., Ph.D., FAACR. When the discussion turned to the under-representation of African Americans in cancer clinical trials, Ken Frazier, CEO of Merck, acknowledged that "too often we go to the usual suspects — the academic medical centers that we are very used to using." Frazier promised to work with the FDA and others "to make sure that this isn't just something that has enormous rhetorical appeal but happens in reality."

**Black-white differences**

Fifty years ago, the overall cancer death rate was lower among blacks than among whites. But since the 1960s, the death rate of black Americans has been higher than that of whites, according to the American Cancer Society report. When all cancers are included, the death rate among black men was 22% higher than among white men in 2012-2016, the most recent period discussed in the cancer society's report. Not every cancer is more lethal for black men. The death rates for leukemia, esophageal, bladder and brain cancers are higher for white men than for black men. But those are relatively rare cancers. The death rates for common cancers such as prostate, lung and colorectal are higher for black men, sometimes much higher. For example, the death rate for prostate cancer is more than twice as high among black men as it is among white men (39.8 per 100,000 population versus 18.1). At 13%, the difference in the death rate between black and white women is narrower but still sizable. The death rate for some of the most common cancers, including breast and colorectal, is higher among black women than it is among white women.

For men, the incidence patterns, by and large, fit the death rate patterns, with black men more likely to receive cancer diagnoses than white men (22% vs. 9%). But cancer incidence among black women is actually lower by 7% than it is among white women.
**Sociopolitical grouping**

The reasons for racial disparities in cancer data hinge on how race is defined. Increasingly, investigators are viewing race primarily as a sociopolitical category.

“To categorize people by race is almost like slicing soup — it is impossible,” said Otis Brawley, M.D., in a podcast last year on redefining race. Brawley, now a professor at Johns Hopkins University in Baltimore, was chief medical officer at the American Cancer Society for about 10 years. Brawley says in the podcast that race should be taken into account, but as a sociopolitical grouping, and that cancers may be affected by factors associated with a sociopolitical group such as poverty or living in a more polluted area.

Viewing race as a sociopolitical grouping doesn’t mean there aren’t noteworthy genetic and biologic differences among those groupings. For example, black women are twice as likely to have triple-negative breast cancer (lacking estrogen and progesterone receptors and excess HER2 protein) as white women, and women who have this type of cancer tend to have worse outcomes.

**Fixing enrollment**

Addressing racial disparity root and branch would mean dealing with racism, housing, employment opportunities, education, nutrition, environmental issues — it’s a daunting list.

A perhaps more manageable problem for organized oncology is the one that Frazier said Merck is working on: improving the representation of African Americans in clinical trials. Samer Al Hadidi, a postdoctoral fellow at Baylor College of Medicine in Houston, and his colleagues reported findings in the *Annals of Internal Medicine* in June that showed how underrepresented African Americans are in trials. They calculated a participation-to-prevalence ratio of the clinical trials related to 75 FDA-approved cancer drugs. A 1.0 ratio would mean that the number of African Americans in the trials matched the number of African Americans in the patient population. Instead, Al Hadidi found a 0.31 ratio for all cancers combined; for prostate and multiple myeloma, 0.18 and 0.04, respectively.

“For all cancers, the number is extremely low, and it is very low in the cancers that are common among African Americans,” Al Hadidi says.

Manali Bhave, M.D., a medical oncologist and assistant professor at Emory University School of Medicine in Atlanta, presented findings about black-white differences in investigator-initiated trials of metastatic breast cancer at Emory’s Winship Cancer Institute at ASCO’s annual meeting this year. Some of the results from the small study (62 patients) go against the narrative. Bhave and her colleagues did not, for example, find that African American women were under-represented (perhaps because of Atlanta’s large black population), nor was there evidence of African American women enrolling after receiving more lines of treatment, which can indicate reluctance to enroll in a clinical trial, lack of referral by doctors or both.

Bhave did spot a trend of shorter survival of African American women in the trials and a greater likelihood that their breast cancer progressed. “I think that, perhaps, suggests there are differences in the disease biology and the response to new drugs that requires some additional investigation,” Bhave says. “There seems to be something about the underlying disease that contributes, at least in part, to poorer outcomes.”

She points to an article written by her Emory colleague, Bassel Nazha, M.D., and others that argues that African Americans may not respond to the current crop of cancer immunotherapies because of immune system differences. Nazha’s article was published in the education book of background and think pieces that ASCO puts out in conjunction with each year’s annual meeting.

One of the reasons investigators believe it is important to solve the underrepresentation problem in clinical trials is to discover early on whether African Americans respond differently to a drug. Al Hadidi also notes that clinical trials are a form of access, and if the experimental drug is safe and effective, it gives participants access to better treatment. For some patients, Al Hadidi says, “if they were not getting those medications, they may not be alive and with us.”

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“To categorize people by race is almost like slicing soup — it is impossible.”

—OTIS BRAWLEY, M.D., PROFESSOR AT JOHNS HOPKINS UNIVERSITY.