COVID-19 HIT
Picking Up the Pieces of American Healthcare

Industry Analysis
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Population Health
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A COVID-19 vaccine this year?

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Technology
At-home pulse oximeters

Oncology
CAR-T
A Missed Opportunity to Recognize Narcolepsy Symptoms Can Have a Significant Impact on Pediatric Patients

Personality and Behavior
Anxiety, depression, introversion, feelings of inferiority, and sorrowfulness

Academic
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Economic
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Visit NarcolepsyLink.com/Pediatric to learn more about pediatric narcolepsy.

* Based on a health-related quality of life (HRQL) study assessed through a questionnaire completed by children and adolescents with narcolepsy (N=117) and control subjects (N=69). Academic performance was evaluated in the study.

† Based on a retrospective, cross-sectional, case-control, claims-based analysis of health care utilization and costs, that included narcolepsy patients ≤18 years of age (N=1427) and control subjects (N=4281).

Chairman’s Letter

We Will Need Resilience. We Will Need Innovation.

Just as we were emerging from the COVID-19 outbreak and businesses were beginning to open up to a “new normal,” a second crisis hit the country because of the killing of George Floyd in Minneapolis.

That new normal we were stepping back into, cautiously and gingerly, seems sedate compared with the overlapping crises we’re grappling with now.

The articles in this issue of Managed Healthcare Executive were written and edited when COVID-19 was challenge enough, and the pandemic seemed to have “unprecedented” to itself.

But our continuing coverage of COVID-19 includes a story about the disproportionate effect that COVID-19 has had on the African American community. So much evidence points to disparities in health and healthcare that disadvantage black Americans, it might have been surprising if COVID-19 had stood as an exception rather the rule. A quote from Melva Thompson-Robinson, Dr.PH., a professor at the University of Nevada, Las Vegas, School of Public Health, and executive director of the university’s Center for Health Disparities Research fittingly ends this story: “I hope that people will continue to ask the questions to understand why the differences exist and then will join together to fight the good fight to address the disparities.”

It will be impossible to cover healthcare from here on out without having healthcare disparities in mind.

And still there is COVID-19. As our cover story discusses, the economic sequelae for the healthcare sector have been stunning. Hospitals saw their revenues vanish and, amid a public health crisis, couldn’t cut expenses. Large health systems have huge reserves and can weather a bad month or two. But as James Blake, managing director at Kaufman Hall, says in our story, if there are too many more months like April 2020, even “those great balance sheets will no longer be great balance sheets.” So far, insurers have been largely spared, but they may soon be dealing with a shift away from employer-based insurance to Medicaid and Affordable Care Act health insurance exchange plans because of high unemployment.

The challenges aren’t over for American healthcare. Perhaps a new phase has started, a dynamic mix of recovery and “new normal” precautions, heightened concerns about disparities. But the inspiring resiliency, innovation and sense of purpose on display during the last several months will be needed in the months and years ahead.

Mike Hennessy Sr.
Chairman and Founder
of MJH Life Sciences®
Cover Story

COVID-19 Hit

Picking Up the Pieces of American Healthcare

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

Mark Boxer, Ph.D., is executive vice president and global chief information officer for Cigna, where he is responsible for driving the company’s worldwide technology strategy. Lili Brillstein is a nationally recognized thought leader in the advancement of Episodes of Care as a value-based approach for specialty care. She is the CEO of BC Collaborative, which works with stakeholders across the healthcare continuum to successfully make the move from fee for service to value-based healthcare.

Joel V. Brill, M.D., is the chief medical officer for Predictive Health, LLC, which partners with stakeholders to improve coverage of value-driven care that optimizes health for people. Virginia Calega, M.D., is vice president, medical affairs, Facilitated Health Networks at Independence Blue Cross. She oversees utilization management, medical cost, and health outcomes data, and interventions that optimize these outcomes.

David Calabrese, RPh, M.H.P., is senior vice president and chief pharmacy officer at OptumRx, a pharmacy benefits firm that provides pharmacy care services for more than 65 million lives nationally. Perry Cohen, Pharm.D., is chief executive officer of The Pharmacy Group and the TPG family of companies, which provides services to associations, healthcare and information technology organizations, payers and pharmaceutical companies.

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William Shrank, M.D., is Humana’s senior vice president and chief medical officer. In this role, he is responsible for leading and implementing the company’s integrated care delivery strategy. This strategy emphasizes a consumer-friendly, evidence-based, technology-enabled approach to personalized health improvement for the company’s more than 16 million Humana health plan members.
The COVID-19 outbreak has claimed more than 100,000 American lives, but evidence shows the disease has cut an especially wide swath of serious illness and death through African American communities in the United States. It is not entirely clear why, but healthcare experts say that complex, deeply rooted socioeconomic issues and healthcare inequities are the most probable explanation.

Any number of statistics reveal that COVID-19 has disproportionately affected African Americans. The COVID-19 database maintained by Johns Hopkins University shows that although African Americans represent only about 13% of the population in states reporting racial and ethnic information, they account for about 34% of total COVID-19 deaths in those states.

COVID-19 data from cities, states and health systems paint the same picture. In Chicago, 50% of cases and nearly 70% of deaths as of mid-April were black individuals, although African Americans comprise 30% of the city’s population. In Louisiana, roughly 70% of those who have died of COVID-19 are African American, yet African Americans make up only 32.2% of the state’s population. The disproportion is similar in Michigan: 33% of the COVID-19 cases and 40% of COVID-19-related deaths have been among African Americans, but African Americans comprise only 14% of the state’s population.

Researchers at Sutter Health, an integrated delivery system in California, reported in Health Affairs in late May that among the system’s 1,052 confirmed COVID-19 cases, African Americans who tested positive for COVID-19 were twice as likely to be hospitalized as white people who tested positive (52.5% versus 25.7%) and, once admitted, were more likely to be transferred to the ICU (24.6% versus 10.7%). However, when they looked at the 51 COVID-19-related deaths, they didn’t see a racial imbalance.

An analysis by researchers from Epic, the electronic health record company, conveys the same basic message. Using their access to data on 23 million patients from 27 health systems in 16 different states, the Epic researchers found that African American patients accounted for 27% of COVID-19 hospitalizations and 22% of the deaths although they made up 12% of the sample population.

Other minority groups have also been hit harder by COVID-19 than the general population, data show. In California, Latinos make up about 39% of the population but they accounted for 55% of the COVID-19 cases (34,809 of 63,505) in the California Department of Public Health’s

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**Deadly and Revealing:**

The Toll That COVID-19 Has Taken on the African American Community

Health and healthcare inequities are the most likely explanation for the disproportionate effect.  

BY KAREN APPOLD
MANAGED HEALTHCARE EXECUTIVE  |  JUNE 2020

Special Report | Deadly and Revealing

ethnic group data. The proportion of deaths, 38% (1,329 of 3,504), however, was in line with the population proportion. In Arizona, 17% of the COVID-19 cases and 12% of the deaths were Native Americans, although they make up only about 5% of the population.

FOCUSING ON COMORBIDITIES
An unknown biological or genetic factor could explain the disproportionate effect that COVID-19 has had on the African American community. But using race as a biological or genetic category is hugely problematic and has been rejected by many researchers. Socioeconomic and healthcare inequities are a better explanation. For generations, racist policies and program segregated African Americans into poor urban areas with limited access to education, employment opportunities, housing and healthcare services. One result is that African Americans are more likely to hold lower-paying jobs that require them to attend work in person rather than remotely and rely on public transportation, both of which make exposure to the virus more likely. People of color are more likely to work in lower-wage industries such as restaurants and hotels, notes Doug Wirth, president and CEO of Amida Care, a not-for-profit Medicaid special needs health plan in New York City. Stay-at-home and social distancing rules shut many of those business down. If they don’t bounce back, African Americans workers will be disproportionately affected.

It’s also well documented that people in communities of color are far more likely to suffer from chronic diseases such as diabetes, asthma, obesity, hypertension, and heart disease that put people at higher risk for COVID-19, Wirth observes. When the Epic researchers looked at patients with no comorbidities, African Americans were still overrepresented among COVID-19 cases and deaths but not by as much as in the population with comorbidities. The Epic study and others have found that the association between diabetes and hypertension and COVID-19 is especially pronounced. Among adults, ages 19 to 64, 29.5% of African Americans hospitalized for COVID-19 had diabetes and hypertension compared with 15.7% of the whites hospitalized for disease, according to the Epic data. In the population, ages 65 and older, 36.7% of African Americans hospitalized for COVID-19 had diabetes and hypertension, compared to 22.5% of whites.

Limited access to healthcare of any kind — and perhaps especially to high-quality care — increases the chances that those chronic diseases are poorly managed, and that increases the COVID-19 mortality rate, notes Renee P. Bullock-Palmer, M.D., director of noninvasive cardiac imaging and director of the Women’s Heart Center, Deborah Heart and Lung Center, in New Jersey. Many factors play into healthcare access, especially insurance coverage. Although the uninsured rate among African Americans decreased because of Medicaid expansion and the ACA exchange plans, blacks were still 1.5 times more likely to be uninsured than whites during the 2010-2018 time period, according to the Kaiser Foundation Family (KFF). The foundation’s numbers suggest that the rate of African Americans covered by health insurance is slipping. Even if they have insurance coverage through an employer, workers in low-paying jobs may be enrolled in less-than-stellar plans. “Limited insurance may impact a worker’s access to a large network of healthcare providers to tend to their healthcare needs,” says Bullock-Palmer. Work schedules or jobs without paid time off can be obstacles to visiting a doctor. The Sutter researchers said their previous research showed that African Americans are more likely to seek care later in the course of a disease and in acute-care settings, and that same pattern may explain the higher COVID-19 hospitalization rate among African Americans.

Andrea Polonijo, Ph.D., M.P.H., a medical sociologist and health disparities researcher at the University of California, Riverside, has seen COVID-19 healthcare resources being disproportionately distributed to wealthier and predominantly white neighborhoods, making it difficult for many African Americans to access testing and treatment. When African Americans do access care, healthcare professionals tend to take them less seriously, research has shown.

SOCIAL DETERMINANTS AND COVID-19
Since mid-March, social distancing (and wearing face masks) have been the main public health tactics for preventing the transmission of SARS-CoV-2, the virus that causes COVID-19. But for many African Americans, the tactics are difficult to put into practice. They have jobs in essential businesses that put

~DOUG WIRTH, PRESIDENT AND CEO OF AMIDA CARE

“While the data is shocking, it is not surprising that the coronavirus is impacting people of color. Such health disparities have existed for years and are now in plain view for the world to see.”
them on the front lines, notes Bullock-Palmer, so they can’t work from the relative safety of a home office.

Over the past several years, healthcare providers and payers have turned their attention to the social determinants of health (SDOH) — the influence that housing, nutrition, personal safety and other factors have on people’s health outside of traditional medical care. The toll that COVID-19 is taking on African Americans is more evidence of the power of SDOH, and the need to address them to affect health outcomes, say many observers — although with COVID-19 the list of SDOH has grown longer. Public transportation is an example: “[It] poses an increased risk of contracting the virus, because many of these essential workers have to take buses or subways to work,” says Bullock-Palmer.

A large body of research shows that poor housing is associated with chronic diseases ranging from conditions ranging from heart disease to obesity to anxiety. And crowded living conditions could be a factor in COVID-19 transmission.

“It is much harder to self-isolate to protect other family members and neighbors in close proximity,” observes Christopher Chen, M.D., CEO of ChenMed, a privately held company in Miami that operates CEO of ChenMed, a privately held company in Miami that operates 

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IMPLICATIONS FOR HEALTHCARE FACILITIES

Hospitals in low-income neighborhoods were overwhelmed and experienced the most severe equipment shortages as the COVID-19 outbreak grew larger, says Amida Care’s Wirth. Community health centers had to adapt quickly. Telemedicine visits were up but overall visits were down, leading to declines in revenue throughout the healthcare sector.

Many hospitals and federally qualified health centers depend on volume for revenue in fee-for-service arrangements. "With social distancing orders in place, there has been a marked decrease in volume at healthcare organizations,” Chen says. “Combined with increases in coronavirus infections, a decreased patient volume has resulted in significant revenue loss. Many healthcare facilities have resorted to salary cuts, hiring freezes and unpaid furloughs. Federal dollars have helped but have not nearly made up the difference.”

EFFECTS ON PAYERS

Many states are bracing for large budget shortfalls because of the economic downturn from COVID-19. Meanwhile, because of job losses, the number of Americans eligible for Medicaid coverage is expected to increase. A KFF projection estimated that 17 million more Americans may be enrolled in Medicaid next year. Chen describes COVID-19 as a “perfect storm to create a spike in demand for Medicaid coverage.”

It is difficult to know exactly how COVID-19 will affect the insurance coverage among African Americans. African Americans make up just over 13.4% of the country’s population; in 2018, roughly 20% of nonelderly Americans covered by Medicaid were African Americans, according to KFF figures. But many of the states that haven’t expanded Medicaid have large African American populations, including Mississippi (36%), Georgia (29%), and Alabama (26%). A surge in unemployment among African Americans in those states may not increase Medicaid enrollment as much as the number of those who are uninsured.

MORE THAN LIFESTYLE CHOICES

COVID-19 has brought to light several issues regarding African Americans’ health and healthcare. “First and foremost, COVID-19 has revealed the impact of centuries of inequality and racism that make up the African American experience as well as that of other people of color in the United States,” says Melva Thompson-Robinson, Dr.PH., a professor at the University of Nevada, Las Vegas, School of Public Health, and executive director of the university’s Center for Health Disparities Research. “Too often, lay people like to think that health disparities result from people’s lifestyle choices. But COVID-19 has highlighted differences in access to care, impact of unemployment, and lack of health insurance, as well as the impact of high housing density on health.”

With says that COVID-19 is just the latest public health crisis to lay bare the statistics showing the country’s health disparities and the gap between white Americans and communities of color. “While the data is shocking, it is not surprising that the coronavirus is impacting people of color. Such health disparities have existed for years and are now in plain view for the world to see.”

Polonijo says many steps could be taken that could also help lessen statistical inequalities in other preventable diseases. “Policies such as living wage and paid sick leave could help individuals to meet their basic needs and prevent disease transmission in the workplace,” she said. “Affordable healthcare and equitable allocation of healthcare resources could help alleviate barriers to healthcare access. Enhanced provider training in cultural competency and social determinants of health could help to improve patient/provider encounters for African Americans, as well as other marginalized populations.”

“I hope that people will continue to ask the questions to understand why the differences exist,” says Thompson-Robinson, “and then will join together to fight the good fight to address the disparities.”

Karen Appold is a medical writer in the Lehigh Valley region of Pennsylvania.
Healthcare is seen as a safe harbor in many economic downturns. People still get sick and go to the doctor or hospital; in fact, there may be even more sick people to care for. Job loss means people lose their employer-based insurance, but to some extent, public payers pick up where private ones leave off.

But the COVID-19 pandemic is toppling this conventional wisdom, along with many others. The outbreak of the infectious disease has led to an unprecedented drop in the use of healthcare services, and those services generate revenue in the healthcare sector, which still largely runs on fee-for-service payment.

Now everyone involved in healthcare is trying to figure out what will happen next. There’s the fundamental question of whether demand for services will bounce back — and how fast. Many healthcare economists see a near-term future of even more consolidation of providers, as doctors and hospitals with small financial reserves go out of business or get absorbed by larger providers. Consolidation usually leads to higher prices. Access to care may become even more difficult in rural and underserved areas if providers with weak balance sheets close their doors.

The situation is far less acute for payers, who haven’t seen their revenues contract. Meanwhile, their expenses have dipped for the same reason that revenues of providers have fallen. But this doesn’t mean it’s going to be smooth sailing. Massive unemployment may lead to far less employer-based insurance and a major shift toward Americans covered...
by Medicaid and ACA health insurance exchange plans. The public dollar stands to become even more important to insurers, but the influx may put even more strain on state budgets — and reshape the politics around healthcare coverage.

But there may be some winners. Value-based care with some aspect of capitation may hold more appeal to providers who have seen what happens when the spigot of fee-for-service revenue gets turned off. Francois de Brantes, senior vice president of Signify Health, says that employers and other payers may be able to get some price discounts from providers who are hungry for business. Patients may get some financial benefit if providers decide they need to offer some incentives for people to come back in to get routine or preventive care. And hardly a minute goes by without someone trumpet-telehealth — and remote care generally — as healthcare’s future.

WORST MONTH EVER FOR HOSPITALS

“You can’t even use the word historic because it is beyond historic,” says James Blake, managing director at Kaufman Hall, a management consulting firm in Chicago. “It was the worst month ever for hospitals.” Blake is referring to Kaufman Hall’s April 2020 National Hospital Flash Report on the financial health of hospitals, based on a representative sample of 800 hospitals. Some numbers behind Blake’s “worst month ever” assertion include a 61% drop in operating room minutes and a 50% drop in outpatient revenue compared with April 2019, and minus 23% in EBITDA operating margin. Meanwhile, hospital executives could not cut back on expenses because they had to be ready for COVID-19 cases, even though in many parts of the country the onslaught never quite materialized. “They did the right thing,” says Blake. “They didn’t manage to the margin. They managed to being clinically prepared.”

Todd Rothenhaus, M.D., CEO of Cohealo, a Boston health technology company, notes that, “Healthcare, including hospital care, is high-cost, low-margin work. While a few health systems have fared well, most hospitals operate on incredibly thin margins.

“The pandemic has only exacerbated these financial challenges. Health systems rely on elective surgeries to maintain a positive margin. Cancellation of these procedures means significant margin pressure and, for some hospitals, going out of business entirely.” He says health care executives will need to operate leaner, more efficient operations while not stinting on preparing for future pandemics. Going into this pandemic, hospitals had moved to just-in-time purchasing and “that all broke down within weeks of the pandemic,” says Rothenhaus. “The lack of a robust disaster-preparedness infrastructure in healthcare — one that should have augmented the supply of (personal protective equipment) or ventilators — will absolutely need to be addressed.” Some commentators — David Blumenthal, M.D., president of The Commonwealth Fund, among them — have argued that large hospital systems with large financial reserves can weather the COVID-19 financial crisis and don’t need bailing out. In late May, The New York Times published a story about fund distribution of the coronavirus relief bill with the headline, “Wealthiest Hospitals Got Billions in Bailout for Struggling Health Providers.” But Blake at Kaufman Hall says if there are too many more months like April, “those great balance sheets will no longer be great balance sheets.” Blake also says some small hospitals were in good financial shape pre-pandemic. “They might not have a fancy fountain in front, but they have saved their money and they have a good balance sheet. To say that they should be penalized for having a good balance sheet coming into this ...”

Squinting into the future, one of the most immediate questions is just how soon demand for routine medical services will snap back. Blake notes that the April drop-off in hospital care, revenue and operating margin was universal and not confined to COVID-19 hot spots or states with stay-at-home orders. He sees a slow recovery and one that will depend on people’s perceptions. “How do hospitals make sure that they can protect both their employees and their patients and their visitors — and what are the procedures for that?” Blake asks, noting that, “This is true whether you are a restaurant owner or a store owner, but it is particularly true for hospitals.”

H. Mallory Caldwell, Ernst & Young LLP transaction advisory services principal and
Cover Story | COVID-19 Hit

U.S. healthcare strategy and operations leader, says health systems are preparing for a potential influx of patients and for a “new normal.” But because of the financial hit this spring, some are executing furloughs and layoffs and cutting executive compensation.

The larger, perhaps quite bleak, economic situation will also have an effect, Caldwell observes. “The post-crisis economy will still be constrained, with elevated unemployment and decreased disposable income,” he predicts. And that, Caldwell adds, will mean a different payer mix: More patients covered by public payers (which pay at lower rates) or people possibly deferring care because of copays and higher deductibles.

Expect to see some tension between labor and management if the hospitals that are in financial trouble pare budgets, says Lyndean Lenhoff, J.D., president and CEO of Advis, a healthcare consultancy outside of Chicago. “There’s going to be a real push and pull between the real need for healthcare providers to continually cut expenses and staff demands, which the response to the crisis warrants,” she says. “Labor will likely demand compensation for what they’ve been through and might face again at any moment.”

Brick also foresees healthcare workers suffering from post-traumatic stress disorder if they were working in facilities with COVID-19 patients. Executives and managers will need to factor in their need for mental healthcare and support.

At the same time, many hospitals are, for the most part, emerging from COVID-19 with their reputations intact — and then some — as the front-line responders to the infectious disease that has taken more than 100,000 American lives. Blake says Congress and the federal government can get a “two-fer” by supporting hospitals.

“They can both have us be better prepared for the clinical (needs) — if we get a second wave in the fall. And it helps economically because in many communities, the hospital is the largest employer, and the last thing you want them to doing is laying off employees.”

INSURERS NOT HIT AS HARD

The massive reduction in the utilization of healthcare services meant that in the short term, health plans had fewer claims to pay, although many have stepped up various advance payment efforts to help providers. And like providers, they are watching and waiting to see if utilization springs back. If it doesn’t, medical-loss ratio rules may kick in. The surge in telehealth and the relaxation of reimbursement rules may offset the drop-off in conventional utilization and claims. But there’s little question that, financially and otherwise, the payer side of the street has not been hit as hard as the provider side.

However, industry insiders predict that payers are facing challenges like everyone else. In hot spot areas, claims related to COVID-19 could present operational challenges to even the most efficient organizations from a resource and staffing standpoint. “The payers will be under tremendous pressure to prioritize COVID-19 payments,” Rothenhaus says. “This will almost certainly result in delays in payments for routine and elective surgical procedures, which will have a downstream impact on the operating margins of hospitals and physician practices.”

Caldwell says that insurers “have been bracing for a potential swell of COVID-19-related claims, as well as for the potential backlog of deferred care.”

But payers are also looking ahead to an economic slump that, depending on its length and depth, could have a major impact on their revenues. “With an economic downturn, notes Caldwell, “fewer employed individuals means a decrease in premiums and a decrease in per-employee fees for administrative services among commercial insurers.” In a mid-May report, the Congressional Budget Office (CBO) said the labor market during the second quarter of this year “is projected to see the steepest deterioration since the 1930s” with an unemployment rate of 15%, an increase from a rate of less than 4% in the fourth quarter of 2019. But CBO economists also saw some stabilization in the months ahead and economic conditions improving; for example, they projected a slight increase in the number of payroll jobs in the third quarter.

According to a Kaiser Family Foundation projection, nearly 17 million more Americans may be eligible for Medicaid next year and another 6 million for ACA exchange plan subsidies, based solely on the job losses in March and April.

John Langenderfer, a senior vice president at Huntington National Bank in Cincinnati, notes that earnings reports from the publicly traded health insurers were generally positive for the beginning of the year. “Longer term,” he says, “their revenues may be impacted due to the loss of 30 million

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jobs, but for now, several of the public names have discontinued guidance of revenue and EBITDA, while others have guided to remain relatively flat.”

Brick at Advis expects a real outcry if relatively well-off payers don’t respond to the crisis. "The anger generated by Ruth’s Chris Steak House and Shake Shack taking the bailout ahead of the little guy is something payers should take note of and may have to face themselves,” she says. "They might see fewer insured, but there will be pressure on them to support the hospitals. That means reimbursement rates don’t get cut. They can’t hide behind the pandemic with claims of reduced profitability. A public demand will grow, forcing insurance companies to become social companies.”

The among the payers, the burden of COVID-19 may fall especially hard on public payers, Medicare and Medicaid. Age and socioeconomic status are two risk factors for COVID-19 and, of course, Medicare covers older adults and Medicaid, those with no or low income.

"With a downturn in the economy and an increase in unemployment, Medicaid and other government insurance will be the recipient of many new ‘covered lives,’ adding extra strain to an already challenging set of economics for the government,” Caldwell says.

Brick believes providers may become more hesitant about participating in full-risk Medicare and Medicaid plans. "The depletion of the Medicare trust fund has likely been hastened. It was scheduled to run out of money in seven years, and now it will likely see lower payroll tax revenue, further slowing its replenishment,” she says. “The government was counting on reaping savings from provider participation in risk sharing. Providers are likely to conclude they’re already shouldering sufficient risk. On the plus side, telehealth may save the system some money provided that Medicare continues to allow its widespread use and doesn’t repeal the new relaxed regulations.”

De Brantes, though, thinks there are some silver linings. Despite the further consolidation of providers that many expect, he sees a chance for more competition occurring, not less. "If you’re an ACO today, you’re going back to payers and saying, ‘Send me more patients.’ The COVID-19 pandemic has laid bare the deficiencies of fee for service, and this competition de Brantes envisions (and lower prices) may nudge American healthcare toward payment that is more closely aligned to good results. "When you actually have to compete for value, you have a different mindset,” says de Brantes.

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BACK TO A SOUND ECONOMY
Ashraf Shehata, partner, KPMG, says COVID-19 has generated a great deal of disruption in the healthcare and life sciences space and the broader economy overall, with some sectors laying off millions of people who are now seeking unemployment benefits.

"The government is spending trillions to help the economy adapt to several industries being devastated by a loss of demand,” he says. “There are a lot of questions about what will take place for people to come back to work and what new reality will emerge.”

The availability of COVID-19 testing and standards for how frequently people need to be tested to return to work will be important. "We also need to know more about the virus itself, such as whether a patient has lifetime immunity from it or whether it can return,” says Shehata. Health systems, he continues, will be an integral part of the effort to help the communities disproportionately affected by COVID-19. “It will be a challenge as health systems themselves will face a high degree of employee difficulties and financial challenges.”

Government, academia and pharma companies need to work together proactively to reduce the impact of future pandemics, in Langenderfer’s opinion. "Vaccines have been historically underfunded with low margins and use technology that is difficult to produce and deliver quickly.”

It’s important to recognize that we’ll be emerging from this pandemic into an environment that is quite different from the pre-COVID-19 world. Health consumers will behave differently, healthcare economics will be challenged and everyone should have a shared interest in evolving the system of care.

“One health crisis has forced us to ‘unfreeze’ old ways of working,” Caldwell says. “We will have a limited window of time to reset our approach before we refreeze into a new normal. Healthcare and industry at large should take full advantage of this window to make fundamental improvements in our healthcare system, for both greater efficiency and effectiveness.”

Keith Loria is a freelance writer based in northern Virginia.
Industry Analysis

4 Ways PBMs Are Changing

Pharmacy benefit managers are taking steps to be more responsible for the total cost of care and to become more transparent, while adding technology tools to support patients, payers and physicians in a post-COVID-19 world. by JOSEPH BURNS

PBMs argue that they play a vital role in the labyrinth of U.S. healthcare as pharmaceutical company intermediaries, serving purchasers (such as employers) and payers (such as Medicare and commercial health insurers). Critics, however, contend that PBMs serve the needs of pharmaceutical companies at the expense of purchasers, payers and, ultimately, patients.

Over the past two-plus years, PBMs have begun pushing back against this criticism, in part, by expanding their efforts and going beyond managing pharmaceutical costs — de-emphasizing rebates and streamlining formularies — to accepting more responsibility for managing the total cost of health care for their insurer and employer clients. The larger PBMs have also strengthened their market positions through mergers and acquisitions. PBMs have also improved their data analytics.

Here are four ways that the PBM industry is changing:

1. Supporting physicians and providers at the point of care

One of the most pressing problems PBMs face today is how to help physicians and other prescribers while face-to-face visits with patients are limited during the COVID-19 pandemic. Even though in-person visits are limited, doctors and other providers still need to prescribe, monitor and/or change medications, says David Calabrese, RPh, M.H.P., senior vice president and chief pharmacy officer at OptumRx and a member of the Managed Healthcare Executive® editorial advisory board. To address this challenge, OptumRx is supporting telemedicine visits between physicians and patients by having pharmacists participate in some visits. Calabrese says the company is also making digital engagement tools available to physicians and other providers. "We have tools to deliver information about patient adherence to improve cost efficiency and drive quality at the point of care," he says. "In our specialty pharmacies, for example, we use a video chat-type format to engage patients, educate them and empower them to take a more active role in their care."

Prime Therapeutics, a PBM in the suburban Twin Cities serving 23 Blue Cross Blue Shield Plans, also recognizes the increased need for virtual care and, additionally, has put more emphasis on infectious disease prevention for every patient, says Kelly McGrail-Pokuta, Prime’s vice president of pharmacy trade relations. “The COVID-19 pandemic has certainly altered every part of the healthcare system in the past couple months,” she comments. “No one knows exactly what the future will hold, but PBMs are working with all parts of the supply chain and with payers and providers to make the changes needed quickly and thoughtfully. All parties are aligned in helping to drive the best care in a consumer-focused manner at the most affordable price.”

2. Assuming more responsibility for the total cost of care

Historically, the function of PBMs has been to manage the cost of prescription medications. Now,
however, PBMs are "going beyond the pill" and assuming a larger role in managing the total cost of care. Last year Express Scripts signed a contract with eight of the 16 member-employers of the National Drug Purchasing Coalition to, among other things, hire care managers to improve medication adherence.

OptumRx aims to lower the total cost of care by working closely with patients who have chronic and costly conditions, such as diabetes. "Not only do we use pharmacists, but we also use certified diabetes educators, nurses and nutritionists across our Optum Enterprise to better care for patients with diabetes. Monitoring adherence is one of the main arrows in the PBM quiver. "We do that as one of the many components of our solution suite to manage the total cost of care. That's where we're focusing our efforts."

Prime Therapeutics is doing similar work under value-based care contracts in which payers and employers pay more for medications when pharmaceutical companies can show that their drugs are working as intended and helping to drive down the total cost of care, McGrail-Pokuta says. On the flip side, payers and employers pay less for medications that do not work as intended.

"Pharma is becoming more comfortable with value-based care agreements, which means they're collaborating with PBMs on how quality outcomes are defined for certain medications," McGrail-Pokuta notes. "Those agreements will continue to grow in number because validating drug performance using real-world evidence is a priority for most pharma companies and because payers want to ensure the treatments that they pay for actually work."

In addition, Prime Therapeutics is going outside the traditional PBM lane of managing the drug benefit only by taking on the medical benefit. "For some categories, such as specialty drugs, managing across benefits provides a more holistic view of total plan spending," she says. "We also offer reinsurance for some specialty drugs and apply predictive analytics to control spending for high-cost utilizers."

To the criticism that PBMs are greedy middlemen, McGrail-Pokuta offers this counterview: "Prime and other PBMs serve as a counterbalance against rising drug prices and are a part of the system that help control overall healthcare costs," she says. "Without them, drug prices would go unchecked."

3 Providing increased cost control and transparency in pharmacy benefit design

Utilization review, prior authorization, formulary tiers — familiar tools in the managed care toolkit. Today, PBMs are supplementing these tools with copay accumulators, point-of-service rebates and formularies that exclude high-cost or low-value medications. "These approaches can increase market share in preferred products and help save the member and payer on drug costs," McGrail-Pokuta explains. Prime Therapeutics also uses assessments from the Institute for Clinical and Economic Review (ICER), an independent drug pricing and value organization in Boston. "ICER's analyses help to shape our outcomes-based contracts and coverage determinations," she notes.

In an effort to eliminate wasteful, low-value medications, OptumRx announced a new formulary this year. "We've heard clearly from the client community that they want more aggressiveness in formulary design to eliminate waste in formularies and improve affordability," Calabrese explains. "Our Premium Value Formulary is designed to address those concerns and eliminate access to products that don't deliver value. The new formulary excludes high-cost, brand-name medications that have high rebates from pharmaceutical companies and instead includes lower-cost, generic alternatives Calabrese says that OptumRx's new formulary is designed to address those concerns and "eliminate access to products that don't deliver value. The new formulary excludes high-cost brand-name medications that have high rebates from pharmaceutical companies and instead includes
Historically, the function of PBMs has been to manage the cost of prescription medications. Now, however, PBMs are “going beyond the pill” and assuming a larger role in managing the total cost of care.

lower-cost generic alternatives that offer the same clinical outcomes. Some of the brand-name drugs excluded from OptumRx’s new Premium Value formulary because far less-expensive generic alternatives are available include Vyvanse (lisdexamfetamine), Clindagel (clindamycin gel) and Edarbi (azilsartan medoxomil). Calabrese says the new formulary allows OptumRx to move away from the traditional rebate model. “Instead,” he says, “we will contract with clients in a more performance-driven model where we are paid based on our ability to manage the cost and quality of pharmacy care.”

4 Responding to criticism about PBM contracting strategies

Like other PBMs, OptumRx and Prime Therapeutics have modified their business strategies in response to demands from payers and purchasers, particularly following criticism of PBM practices last year from Congress and some state legislatures.

OptumRx, for example, has sought to transform its operations. “We’ve moved away from a traditional business-focused type of model into what we like to refer to as more of a pharmacy-care services model,” Calabrese notes. "We do that by focusing on making medications more affordable for payers, purchasers and patients. In specialty drug management, in particular, we’re moving away from just managing the cost of drugs to managing the total cost of care.”

Prime Therapeutics also is going beyond the financial management of medications, says McGrail-Pokuta. “PBMs, including Prime, provide an important service in evaluating the clinical appropriateness of therapies to ensure members are receiving the appropriate drug in the right clinical setting,” she explains, noting that Prime and other PBMs have a hand in managing many aspects of prescribing, medication use and adherence. “

Rebates from drug companies are controversial because they may lead to formularies with low-value, high-cost medications. “Prime’s model is to pass all rebate dollars back to our client health plans so they can use those savings to help keep healthcare costs affordable for their members,” McGrail-Pokuta says. “Then they can use those funds to lower premiums (or) copays or to offer point-of-sale rebates.”

Joseph Burns is an independent journalist in Massachusetts who writes about healthcare.
Drugs In The Pipeline

High Hopes for Inclisiran.
Will the Third Time Be the Charm for PCSK9 Inhibition?

The two PCSK9 inhibitors have fallen far short of expectations. Inclisiran, which works by RNA inference, only needs to be injected twice a year. by ERIN JOHANEK, Pharm.D.

Cholesterol is one of the primary causal risk factors for developing atherosclerotic cardiovascular disease (ASCVD) and one of seven critical metrics the American Heart Association (AHA) has used to define cardiovascular health in adults and children, according to AHA's Heart Disease and Stroke Statistics — 2020 Update.

"High cholesterol is of significance because it can increase one's risk of heart attack or stroke, especially in patients with other risk factors, such as smoking, diabetes, hypertension and/or a family history of heart disease," says David Calabrese, RPh, M.H.P., senior vice president and chief pharmacy officer at Optum-Rx and a member of the Managed Healthcare Executive editorial advisory board.

Despite a variety of available treatment options, some patients fail to respond to common treatments, notes Calabrese, so alternatives must be considered.

"Hyperlipidemia's consequences for American health and healthcare are comparable to those from hypertension, says Elliot Marino, Pharm.D., BCPS, a CompleteRx pharmacist in Olean, New York. "Patients need to be tested regularly, and the impact on their health may not be noticed for decades, making it very difficult to realize benefits to treatment," says Marino.

Statins are, of course, the frontline therapy for hyperlipidemia. Repatha (evolocumab, Amgen) and Praluent (alirocumab, Sanofi and Regeneron) are currently the only FDA-approved medications in a relatively new drug class known as PCSK9 inhibitors.

Only a Very Few PCSK9 Prescriptions A team of researchers from the Mayo Clinic, the University of Florida, and other institutions used data from 18 health systems within the Patient-Centered Clinical Research Network (PCORnet) to examine which lipid-lowering drugs were prescribed between January 1, 2015, and March 31, 2017. The subsets of prescriptions add up to more than the overall number of lipid-lowering prescriptions because of switching and patients taking more than one lipid-lowering medication.

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<th>2,224,395 people with dyslipidemia*</th>
<th>942,902 with either coronary artery or coronary heart disease</th>
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<td>PCSK9 inhibitor</td>
<td>362</td>
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*Dyslipidemia includes high triglycerides and low HDL cholesterol
Source: Adapted from Chamberlain AM et al., Journal of the American Heart Association, published online April 25, 2019.
High Hopes for Inclisiran

Amgen and Sanofi dropped the price of their product by about 60% in late 2018 to just under $6,000 per year, but use is still far below the companies’ expectations when they launched their PCSK9 inhibitors in 2015.

proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors. PCSK9 is a protein that binds to and prevents LDL receptors in the liver from clearing circulating LDL cholesterol. PCSK9 inhibitors prevent this binding, thereby increasing the number of LDL receptors available to clear LDL from the bloodstream.

But PCSK9 inhibitors have had a difficult time catching on. The 2018 cholesterol guidelines from the AHA, the American College of Cardiology and other groups position them as third-line therapies after statins and Zetia (ezetimibe). What’s more, the guidelines say the cost of PCSK9 inhibitors would need reduced by 70% to 85% to meet conventional cost-effectiveness standards. Amgen and Sanofi dropped the price of their products by about 60% in late 2018 to just under $6,000 per year, but use is still far below the companies’ expectations when they launched their PCSK9 inhibitors in 2015. Sanofi CEO Paul Hudson announced late last year that the company was leaving the U.S. cardiovascular market, so Regeneron is now marketing Praluent on its own.

A study published last year in the *Journal of the American Heart Association* looked at a lipid-lowering prescribing data from Jan. 1, 2015, to March 31, 2017, for 2.2 million people with dyslipidemia (which includes high triglycerides and high LDL) and about 940,000 with coronary artery or coronary heart disease. Just 362 (0.02%) people with dyslipidemia had been prescribed a PCSK9 inhibitor, and 1,952 (0.02%) people with coronary artery disease or coronary heart disease had been prescribed a PCSK9 inhibitor.

A Few Newcomers

The bumpy ride of the PCSK9 inhibitors has, understandably, made drugmakers wary of jumping into the market for medications for hyperlipidemia, despite the many people affected. Still, there are a handful of newcomers. Nexletol (bempedoic acid. Esperion) was approved by the FDA in February 2020 as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established ASCVD who require additional lowering of LDL. Nexletol is a first-in-class ATP citrate lyase (ACL) inhibitor that lowers LDL levels by inhibiting cholesterol synthesis in the liver. Studies show that compared to placebo, Nexletol reduced LDL levels by an average of 18% when used with moderate or high intensity statins.

Evinacumab (Regeneron) is an angiopoietin-like 3 protein (ANGPTL3) antagonist currently being investigated to treat homozygous familial hypercholesterolemia. ANGPTL3 acts as an inhibitor of lipoprotein lipase and endothelial lipase and appears to play a central role in lipoprotein metabolism. In a phase 3 trial, evinacumab resulted in a 49% reduction in cholesterol compared to placebo.

Inclisiran (Novartis) may be the most intriguing candidate because like Repatha and Praluent, it is a PCSK9 inhibitor — although it works by another mechanism, RNA interference, that keeps PCSK9 from being made in the liver. Results published in the April 16, 2020, issue of the *New England Journal of Medicine* show that the new drug lowered LDL levels by about 50% in patients who still have high cholesterol despite taking statin therapy at the highest tolerated dose. Novartis has submitted inclisiran for FDA approval. If approved and launched, which seems likely, it will have one major advantage over Repatha and Praluent: Inclisiran only needs to be injected twice a year to be effective, whereas Repatha and Praluent need to be injected at least once a month. On the plus side for Repatha and Praluent, patients can inject themselves; a clinician needs to inject inclisiran. “Given that there are several existing treatments for high cholesterol on the market today, including several oral generic statins with extensive outcomes data, these new products are likely to be used as second- or third-line agents in patients who have failed to achieve optimal benefit or have contraindications or intolerances to first-line therapy,” says Calabrese.

One thing to watch for is research showing that these new agents influence cardiovascular disease — that they treat the disease and not just a number.

“Cardiovascular outcomes trials typically take years to complete but will significantly impact how these drugs are used in clinical practice down the road,” says Calabrese.

Erin Johanek, Pharm.D., is a pharmacist at Southwest General Health Center in Middleburg Heights, Ohio.
Following the race to develop a COVID-19 vaccine is both heartening and dizzying. It’s heartening because it seems to be a race that will have a winner — perhaps several of them. It’s dizzying because the vaccines and their developers are jockeying for position, and projected timeline seems to change almost daily depending on the early results and who’s doing the talking.

Anthony Fauci, M.D., director of the National Institute of Allergy and Infectious Disease (NIAID), has been a cautious but optimistic voice about vaccine development for months now, although his institute does have a dog in this fight: NIAID is collaborating with Moderna on one of the most promising vaccines. Testifying before a Senate committee on May 12, Fauci stuck to the 12-18 month timetable he has mentioned often but added an “if” to the “when.” “You can have everything you think that’s in place and you don’t induce the kind of immune response that turns out to be protective and durably protective.” In a Q&A transcript that Stat posted on June 1, Fauci spoke of having a “significant number of doses” available by the end of this year or by early 2021. “So I think it’s aspirational, but it’s certainly doable,” said Fauci, in the transcript.

Meanwhile, President Donald Trump announced Operation Warp Speed in May to accelerate vaccine development for COVID-19 at an unheard of — some say unrealistic — pace. The selection of Moncef Slaoui, Ph.D., former head of GlaxoSmithKline’s vaccine division, as its chief adviser garnered praise. Later in May, the effort lived up to its name when it announced that it was plowing $1.2 billion into hastening development of a vaccine that University of Oxford researchers and AstraZeneca are working on. A press release about the funds from the Department of Health and Human Services (HHS) noted that HHS and AstraZeneca are collaborating to make 300 million doses, "with the first doses delivered as early as October 2020."

Others are also talking optimistically about a sooner-rather-later schedule for a COVID-19 vaccine that would might be ready before winter, when many experts expect a second wave of cases because coronaviruses are seasonal. Part of the U.S. vaccine strategy as described by Fauci and others is to start manufacturing doses of vaccine candidates before the evidence of efficacy is in. "Fortunately, the U.S. is in the situation to scale up manufacture of vaccines even before you know they are going to work — maybe as early as the fall with billions of doses. That is the hope," said National Institutes of Health Director Francis Collins, M.D., Ph.D., in a JAMA Network video event in May. "I don’t want to be over the top in confidence about that, but I can ensure you that everyone in the public-private partnership is doing everything they can to make that happen."

Meanwhile, China also has an aggressive vaccine development program. Bloomberg reported recently that five vaccines developed by Chinese companies are in human trials and that one candidate, a joint project of the China National Biotec Group and the Beijing Institute of Biological Products, has completed phase 2 testing. The go-go approach to COVID-19 vaccine development is causing some concern about consequences if anything goes seriously wrong with an approved vaccine. An...
Another possible way of assessing efficacy is through “challenge trials,” which would involve purposely exposing healthy volunteers to SARS-CoV-2; some volunteers would receive the experimental vaccine and some, a placebo. A difference in COVID-19 cases and severity between the two groups would indicate whether the vaccine was effective.

Challenge trials ethics

So far, though, the speed of vaccine development has been mainly impressive. The public-private partnerships among pharmaceutical manufacturers, academic researchers and government agencies resulted in phase 1 trials starting in record time. “From the very first moment the viral RNA sequence was made public ... the first trial (Moderna) got started 63 days later,” Collins said in the JAMA Network video. “The phase 1 results look very promising — strong enough to say we are ready to go on to phase 2.”

Collins explained how the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) initiative is developing a harmonized master protocol for adaptive trials of multiple vaccines, as well as a trial network that could enroll as many as 100,000 volunteers in areas where COVID-19 is actively circulating. Although there are some surrogate markers for efficacy, such as levels of neutralizing antibodies, the clearest “efficacy signal” will be whether a vaccine has a protective effect — in areas where COVID-19 is actively circulating — against infection with SARS-CoV-2, the virus that causes COVID-19.

“You have to test it in a place (where) the vaccine is actively circulating. You won’t know if it works if the vaccine is not actively around them,” Collins said.

Another possible way of assessing efficacy is through “challenge trials,” which would involve purposely exposing healthy volunteers to SARS-CoV-2; some volunteers would receive the experimental vaccine and some, a placebo. A difference in COVID-19 cases and severity between the two groups would indicate whether the vaccine was effective. However, challenge trials, which have been used to test other vaccines, raise troubling ethical issues in this case because they would involve exposing people to a possibly fatal illness. In an article in The Journal of Infectious Diseases, Nir Eyal at Rutgers, Marc Lipstitch at the Harvard T.H. Chan School of Public Health, and Peter G. Smith at the Tropical Epidemiology Group at the London School of Hygiene & Tropical Medicine outlined how the health risk might be mitigated — healthy volunteers, careful monitoring and so on. They also carried the ethical objections with examples of other situations where people volunteer to take on possibly deadly risks for others: “We ask volunteer firefighters to rush into burning buildings, relatives to donate a live organ to loved ones, healthy volunteers to participate in drug and vaccine toxicity trials with no prospect of improving their health.”

Keeping score

By many counts, more than 100 COVID-19 vaccines are in some stage of development. At the beginning of the June, the WHO published a list that included 10 candidates in “clinical evaluation” — meaning in human clinical trials — and 123 in preclinical evaluation. Stat is keeping a COVID-19 vaccine tracker (and a separate one for treatment).

As we went to press, it listed six vaccines as being in phase 1 trials and Moderna’s as the only one in phase 2. The company said volunteers for the phase 2 trial, which is designed to eventually include 600 study subjects, started getting the vaccine on May 29. Moderna reported partial results from the phase 1 trial in a press release, but Fauci and others were critical of the lack of full report.

The Regulatory Affairs Professionals Society is also keeping a user-friendly vaccine tracker that listed eight vaccines as being in clinical trials as we went to press. Topping its list (and absent from Stat’s and WHO’s) is a phase 2/3 trial of the 100-year-old bacillus Calmette-Guérin, a vaccine used to protect against tuberculosis.
When mental healthcare providers mentioned using telehealth to deliver care, the thought-bubble emoticon of Chaynee Rummel stroked its chin and cocked its eyebrow. “Before, I was very skeptical about telehealth,” says Rummel, a licensed clinical professional counselor and certified alcohol and drug counselor who provides individual and group counseling for adolescents at Northwestern Medicine Central DuPage Hospital in Chicago’s western suburbs. But when Rummel began providing individual and group therapy virtually due to COVID-19, she became a believer. “I think we can gain a lot more from it than I previously thought.”

COVID-19 has pushed telehealth of all shapes and sizes to the forefront, including “telemental” care — which just might prove to have more staying power than other forms of telehealth. In March 2020, Forrester Research released its report, “Healthcare 2020: The State of the Doctor-Patient Relationship in the U.S.,” which predicted 36 million virtual visits across all specialties by the end of the year. This prediction came three days before President Donald Trump declared COVID-19 a national emergency. On April 2, Forrester published new estimates, projecting more than 1 billion virtual visits this year, with 80 million related to mental healthcare.

Any number of reasons explain the rapid adoption of using telehealth for behavioral health services. It’s not necessary to be in the same room with someone when you talk to them, and talk remains a primary mode of behavioral treatment. Payment and privacy laws rules have been relaxed. And while COVID-19 itself is not a mental health disorder, the stress of a pandemic, including social distancing and stay-at-home orders, have stirred up stress and anxiety in general and that people with existing mental health problems may feel more acutely.

Barriers fall suddenly

The quick pivot to telehealth for behavioral health has even taken some experts by surprise. Robert L. Caudill, M.D., director of the telemedicine and information technology programs at the University of Louisville School of Medicine and a member of the American Psychiatric Association’s Committee on Telepsychiatry, took part in a congressional briefing in February that identified what seemed to be an obstacle course of barriers to increased adoption of telehealth. Within about a 48-hour period in mid-March, more than half of those barriers had been removed, even if temporarily, says Caudill. “We had expected slow and incremental change over time. What we got was this game-changing opportunity to redefine what is possible.”

Before the pandemic, the CMS only paid providers for telehealth care that was delivered to certain geographically isolated areas, notes Caudill, who has worked to develop telepsychiatry programs for rural parts of Kentucky for more than a decade. But starting on March 6 — and as long as an official public health emergency stays in effect — CMS waived important restrictions on telehealth for Medicare patients, and commercial payers followed suit. Patients can now receive services in their homes. Visits can be held through applications like Skype instead of through HIPAA-compliant portals. And patients don’t need an existing relationship with the clinicians. CMS also began compensating providers at the same rate for virtual care as in-person care. Prior to the pandemic, several states required commercial payers to reimburse providers equally for in-person and virtual care. Now, however, a few have ordered reimbursement at rates “not lower than” in-person.
Rummel, who had been concerned she’d miss out on seeing her young patients’ body language via telehealth, has found that, “you see it all through the camera.” Telehealth is also providing new information about patients because she’s seeing them in their homes. “I think it’s kind of neat, seeing them in their own space,” she says, adding that one of her patients used part of the virtual visit to show off their pet snake. For adolescents in particular, a virtual visit “is no big deal. They’re so used to FaceTime and Snapchat,” Rummel says. The novelty of being introduced to a pet snake aside, Rummel notes one drawback to telehealth: Patients can get distracted by their pets or family members, in contrast to an in-person visit, behind a closed door.

Pros and cons
Peggy Vogt, a licensed clinical social worker with Philadelphia Consultation Center, which specializes in psychoanalysis, has also begun conducting virtual visits since the pandemic, and insurance is now reimbursing for it. Vogt has found that telehealth helps some patients get care when they might have otherwise just skipped it. Some of her patients used to have “horrible attendance” at their scheduled, in-person sessions, she notes. Physical limitations or financial issues were hurdles. With COVID-19 ushering in telehealth, the couch or chair in the clinician’s office has been replaced by home furnishings. Vogt says she has even conducted sessions with patients propped up in bed — who probably would not have come to an in-person session. In some instances, Vogt says, “it opens things up clinically” when the session is conducted remotely and the patient is in familiar surroundings. The possible drawback, says Vogt, is for some people — patients who are anxious in social situations, for example — getting out of the house for an appointment is “clinically useful.”

Ahead of the game
It seems like the rest of the world is finally catching up with Carly McCord, a psychologist and the director of telebehavioral health at Texas A&M University. McCord has used telehealth for a decade. When she was a doctoral student, McCord began providing telehealth care to patients in rural areas of Texas that lack behavioral healthcare providers. In areas where broadband connectivity is an issue, telehealth access points have been created at primary care resource centers in a seven-county region. Her experience and her research have shown that in many cases, “delivering behavioral health services via video doesn’t change (patient) outcomes,” McCord says.

She has seen the same “comforts of home” effect on therapy that Vogt described, recounting the story of one of her students who was working with a patient coping with trauma. When the patient began doing virtual visits from a cozy corner of their home with candles burning and their dog nearby, “the therapy (took) on (a) whole new depth,” McCord says. In another instance, a trauma survivor who took part in a virtual visit by phone, with no video, made great strides. “The eye contact was gone. The shame was gone,” McCord says. A subset of patients “actually do better” with virtual consultations, she says.

OhioHealth, a not-for-profit healthcare system based in Columbus, rolled out telehealth behavioral care in 2015 as a way to improve emergency department safety and provide consultations with psychiatrists and psychiatric social workers, says Megan Schabbing, M.D., medical director of psychiatric emergency services. The healthcare system also has integrated behavioral health into its outpatient primary care practices, and mental healthcare providers use telehealth to help manage patients, she says. Having access to telehealth consultations “provides a higher level of care throughout the system” and also helps address the severe shortage of
psychiatrists, Schabbing says. By 2025, the U.S. is expected to have a shortage of between 6,100 and 15,600 psychiatrists, according to a report by the National Council for Behavioral Health. Even when reimbursement for virtual care wasn’t possible, OhioHealth provided telehealth consultations because “it was the right thing for the patient,” Schabbing says. Now, with COVID-19, Schabbing is finding that some patients requesting behavioral healthcare don’t have a history of mental illness. “They are so stressed out about the crisis,” she says.

The new normal
Many believe telehealth is a COVID-19 genie that can’t be put back into the bottle. Of course, nothing happens in American healthcare unless it gets paid for. While Vogt is satisfied with her experience doing telehealth consultations, “what I’ll do — or not do — in the future is largely insurance driven,” she says.

One wild card is whether the CMS will continue its policy of relaxing its telehealth rules. It’s hard to imagine that it won’t, especially with little, if any, evidence of harm. Relaxing regulations has “greatly expanded access at a time when it is exactly what is needed,” says Caudill. “We are not in a perfect environment even now, but it is far improved from what it was just a month ago.”

“I think telemedicine is going to be part of the new normal,” says Obinna Moneme, M.D., OhioHealth’s service line chief for virtual health, although he expects tweaks to how virtual care is delivered. “It will be interesting to see what stays and what restrictions get put back after the crisis.”

Susan Ladika is an independent business and healthcare journalist in Tampa, Florida.

“For adolescents in particular, a virtual visit “is no big deal. They’re so used to FaceTime and Snapchat.”

— CHAYNEE RUMMEL, A LICENSED CLINICAL PROFESSIONAL COUNSELOR AND CERTIFIED ALCOHOL AND DRUG COUNSELOR WHO PROVIDES INDIVIDUAL AND GROUP COUNSELING FOR ADOLESCENTS AT NORTHWESTERN MEDICINE CENTRAL DUPAGE HOSPITAL IN CHICAGO’S WESTERN SUBURBS

Forrester Research projections of telehealth visits in 2020

36 MILLION
MADE BEFORE THE OUTBREAK

1 BILLION
MADE AFTER THE OUTBREAK

— Built with love by Agenturfotografien/Stock.Adobe.com

Managed Healthcare Executive.com

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Another Consequence of COVID-19: A Worsening of Drug Shortages

Demand for medications needed for patients who were intubated or put on a ventilator led to some shortages. The CARES Act has some provisions that may help deal with long-standing causes of the drug shortages that plague U.S. healthcare.

Although drug shortages are hardly a new problem for American healthcare, the COVID-19 outbreak has worsened them and put a spotlight on some festering problems that lead to imbalance between supply and demand for some important medications. The American Society of Health-Systems Pharmacists (ASHP) has close to 200 on its drug shortage list, while the FDA’s count is closer to 150. The two lists vary slightly with the FDA determining when demand exceeds supply, while ASHP’s list is based on manufacturers reporting and confirming shortages on a national scale. Tetracycline, an oral antibiotic, was listed as unavailable as of March, while the FDA reported that physicians were scrambling to find alternatives to cancer drugs, doxorubicin and methotrexate, according to ASHP.

COVID-19 has triggered a spike in demand for the sedatives, analgesics and neuromuscular medications used for patients on ventilators or who are intubated. The drugs in high demand include metoprolol, propofol, doxycycline hyclate injection, albuterol sulfate inhalers, cisatracurium, lidocaine, epinephrine and morphine. Demand for emergency syringes filled with sodium bicarbonate, sodium chloride and dextrose has also surged. In mid-March, ASHP listed five drugs associated with ventilator use as officially in short supply: norepinephrine, fentanyl injection, hydromorphone injection, rocuronium and vecuronium.

“The pandemic might not be causing the shortages, but it is exacerbating them,” says William A. Haseltine, Ph.D., a former Harvard Medical School professor and chairman and president of ACCESS Health International, a global health think tank based in New York. Haseltine says that drug shortages can be traced back to an underestimation of the number of COVID-19 patients who would be put on ventilators or intubated, drugs being used off-label for a variety of conditions and a shortage of the ingredients used to make many pharmaceuticals or, as they are called in drug manufacturing, active pharmaceutical ingredients (APIs).

“We need to reevaluate stockpiles to ensure there is a strategic reserve as we did during SARS and MERS, become less dependent on China and India and create long-range plans for long-term needs,” says Haseltine.

No Single Source of Information
Using its members’ purchase data, Vizient, a healthcare services company in Irving, Texas, calculated fill rates and the supply and demand of 13 drugs used in some aspect of COVID-19 treatment.

The demand for six sedatives and anesthetics used for patients who were intubated or put on ventilators increased by 140% from January to April. The fill rate — the percentage of customer demand that is met by immediate stock availability — dropped 50% for April. The demand for three analgesics from January to April increased 45%, while the fill rate dropped 72%.
in April; however, demand dropped 35% between the two work weeks.

The demand for four neuromuscular blockers increased 309% between January and April, while fill rates dropped 42% for April.

Although demand for drugs used to treat severe cases of COVID-19 has subsided some, there is still not enough supply, says Dan Kistner, Pharm.D., group senior vice president, pharmacy solutions for Vizient. He attributes drug shortages to problems with product quality and small surpluses of ingredients or products. But the entire situation is cloudy because there’s no single source of information and a lack of transparency makes it difficult to know to how much of a product is available and where it is being manufactured, says Kistner.

Premier Inc., a group purchasing organization in Charlotte, North Carolina, that provides a variety of other services, has a program, ProvideGx, that works with generic drug manufacturers to address drug shortages. The program has provided healthcare providers with access to 150 drugs recently designated as shortage medications and is targeting 50 more in the upcoming months, according to the company. Acyclovir, ribavirin, fentanyl, propofol and midazolam are among the drugs that the program is tracking. Ribavirin, for example showed a 200% increase in demand with only a 50% fill rate. In February, ProvideGx partnered with Pfizer to supply to drugs in short supply, including Cordaptive (ibutilide fumarate injection), used to treat atrial fibrillation, and vincristine sulfate injection, a cancer chemotherapy.

Patrick Sudol, senior director of ProvideGx, says that having just one API manufacturer and production requirements that require specialized equipment can lead to shortages. “We need forecasting to determine how much of a certain drug would be needed and to build a better supply chain,” notes Paula Gurz, senior director of pharmacy for Premier. She says most of the shortages are older drugs with regional supply lines. Because prices are low, suppliers are often scarce, Gurz explains. “Ideally we’d like to have three suppliers so if one exits the marketplace, there are still two to compete.”

SUGGESTIONS FOR FIXING DRUG SHORTAGES

Michael Alkire, president of Premier Inc., has several recommendations for dealing with drug shortages.

1. **Increase API transparency to increase confidence.**
   “The earlier we can detect potential risk for a drug shortage, the more equipped we are to determine alternatives in the market, identify different manufacturing channels, work with the government to incentivize production and intelligently distribute vital resources,” he says. “However, no one, including the FDA, has complete data on what portion of what essential medicines originate in which countries, making risks impossible to assess.”

2. **Pass the Preventing Drug Shortages Act.**
   According to Alkire, the legislation would strengthen drug shortage reporting requirements under the FDA’s Safety and Innovation Act of 2012, to include manufacturers of APIs and the cause, extent and expected duration of shortages.

3. **Diversify pharmaceutical production and bring more manufacturing home.**
   According to the FDA, only 28% of manufacturing facilities that produce APIs are in the United States, with the EU providing 26%, India 18% and China 13%. Among finished dosage products, 47% are completed in this country.
At-Home Pulse Oximeters: The ‘It’ Gadget of the COVID-19 Outbreak

Early detection of low blood oxygen levels may detect ‘silent hypoxia’ seen in some patients with COVID-19. But the American Lung Association advises against buying a pulse oximeter unnecessarily. by DEBORAH ABRAMS KAPLAN

Just as patients with chronic conditions use devices like blood pressure cuffs and glucose monitors, “home monitoring of oxygen is a way for patients to become familiar with their baseline saturation and to monitor themselves for decompensation,”

— LISA MORENO-WALTON, M.D., FAAEM, A PROFESSOR OF EMERGENCY MEDICINE AT THE LSU HEALTH NEW ORLEANS SCHOOL OF MEDICINE AND PRESIDENT-ELECT OF THE AMERICAN ACADEMY OF EMERGENCY MEDICINE.

Jen Singer became sick with an unidentified respiratory illness while visiting Seattle in February, before many knew enough to be worried about COVID-19. The fever and coughing delayed the 53-year-old’s trip back home to New Jersey.

During an April telehealth visit, Singer didn’t have traditional COVID-19 symptoms. She felt abdominal fullness and had difficulty breathing when climbing stairs. Suspecting a gallbladder issue, the doctor sent her to the emergency department (ED), where her heart rate hovered near 40 beats per minute. A normal resting rate is 60 to 100. Singer’s diagnosis? Fluid buildup in her liver from a third-degree heart block — and she tested positive for COVID-19. She was treated with a pacemaker.

“At-home pulse oximeter purchases have spiked more than 500% since the first COVID-19 case was identified in the U.S. The device can easily be purchased at drugstores and online retailers for as little as $40. But not all doctors agree that they’re helpful or that people need to self-monitor for potential COVID-19 exposure. False positives can cause unnecessary anxiety and lead people to seek unnecessary medical care. Many physicians, however, see pulse oximeters as an important way for people to identify declining lung function early and address the cause, including COVID-19, when it’s easier to treat.

Adjunct to Telehealth

Pulse oximeters are noninvasive clips typically used on the finger or the earlobe that measure light wavelengths to determine blood oxygen level. More precisely, the light is a measurement of the proportion of hemoglobin in the blood that is “saturated” with oxygen. A normal saturation level is 94% to 100%. Pulse oximeters also take a pulse, thus the “pulse” in pulse oximeter, and are commonly used in hospitals to monitor patients.
At-home pulse oximeters were in use before the COVID-19 outbreak, especially by people with chronic heart or lung problems. People getting supplemental oxygen use them to adjust the flow as needed, explains Albert Rizzo, M.D., FACP, chief medical officer of the American Lung Association. Some athletes use them for fitness monitoring.

In late April, the American Lung Association put out a statement that quoted Rizzo as saying that “unless you have a chronic lung or heart condition that affects your oxygen saturation level on a regular basis, most individuals do not need to have a pulse oximeter in their home.” The same statement said the lung association advised against buying pulse oximeters unnecessarily.

The role of pulse oximeters for people with chronic health problems that affect their lungs ad breathing is well established. Just as patients with chronic conditions use devices like blood pressure cuffs and glucose monitors, “home monitoring of oxygen is a way for patients to become familiar with their baseline saturation and to monitor themselves for decompensation,” says Lisa Moreno-Walton, M.D., FAAEM, a professor of emergency medicine at the LSU Health New Orleans School of Medicine and president-elect of the American Academy of Emergency Medicine. The patient and treating physician should determine a target number for when to seek medical help. Pulse oximetry can be a great adjunct to telemedicine, she says, providing useful information to inform further medical care. Ideally, patients should first use the device with guidance from a physician to be certain they’re using it correctly and that the readings are consistent with the pulse oximeters at the medical practice or hospital.

Some physicians believe that pulse oximeters can save lives amid the COVID-19 outbreak by prompting people to get medical help sooner. COVID-19 patients (how many is unclear) have shown up at the ED with “silent hypoxia,” abnormally low oxygen saturation levels without breathing difficulty. Silent hypoxia is not specific to COVID-19, but it may be more common than with other lung infections.

Over-reliance on a pulse oximeter and a good saturation rate can give a false sense of security, warns Rizzo, because oxygen saturation and heart rate are only two factors for determining a person’s condition. For COVID-19, Rizzo says that a doctor would also consider shortness of breath, fever, cough, gastrointestinal symptoms and headache. Pulse oximeters are available for as little as $25. It’s simple technology, says Rizzo. “You get what you pay for, but spending a couple hundred dollars isn’t necessary,” he explains, adding that if a cheaper one gives consistently accurate levels, it’s probably fine.

Patients should know that a pulse oximeter may be less accurate if they’re wearing dark or gel nail polish, says Rizzo. Cold fingers or poor circulation may also affect pulse oximeters. People should not rely on a single reading and should take measurements multiple times throughout the day to evaluate trends.

Now home from the hospital, Singer uses her $50 Ankovo pulse oximeter regularly. She also sent one to her college-age son as part of a care package — along with heart-healthy oatmeal.

“"If I’d had a pulse oximeter, I would have known that my heart rate had dropped to 42, and I would have rushed to the hospital sooner,”" – JEN SINGER, A NEW JERSEY RESIDENT WHO RECOVERED FROM COVID-19. PART OF HER TREATMENT WAS IMPLANTATION OF A PACEMAKER. 

Deborah Abrams Kaplan covers medical and practice management topics.
Early data from China suggested that CT scans of the lungs might be used to diagnose COVID-19. Recommendations to use CT scans came from both published and anecdotal reports, notes Harold Litt, M.D., Ph.D., division chief of cardiothoracic imaging at Penn Medicine in Philadelphia. “Colleagues of mine (in China) told me what their policies were. They were scanning everyone who showed up at the hospital because at that moment, they didn’t really know what they were dealing with and didn’t have adequate testing.”

Several studies conducted early in the pandemic in China compared noncontrast chest CT scans to real-time polymerase chain reaction (RT-PCR) swab testing for diagnosing COVID-19. Published online in mid-February in Radiology, a study by Yicheng Fang, of Affiliated Taizhou Hospital of Wenzhou Medical University, and colleagues found chest CT 98% sensitive for COVID-19 compared with 71% for RT-PCR. The authors suggested using CT chest screening, especially if RT-PCR testing was negative.

A study conducted by Tao Ai, of Tongji Hospital in Wuhan, and

Fleischner Society Chest Imaging Recommendations for COVID-19

Main Recommendations

- Imaging* is not routinely indicated as a screening test for COVID-19 in asymptomatic individuals.
- Imaging is not indicated for patients with mild features of COVID-19 unless they are at risk for disease progression.
- Imaging is indicated for patients with moderate to severe features of COVID-19 regardless of COVID-19 test results.
- Imaging is indicated for patients with COVID-19 and evidence of worsening respiratory status.
- In a resource constrained environment where access to CT is limited, CXR may be preferred for patients with COVID-19 unless features of respiratory worsening warrant the use of CT.

Additional Recommendations

- Daily chest radiographs are NOT indicated in stable intubated patients with COVID-19.
- CT is indicated in patients with functional impairment and/or hypoxemia after recovery from COVID-19.
- COVID-19 testing is indicated in patients incidentally found to have findings suggestive of COVID-19 on a CT scan.

*Imaging refers to both CT scans and chest X-rays.
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—HAROLD LITT, M.D., PH.D., DIVISION CHIEF OF CARDIOTHORACIC IMAGING AT PENN MEDICINE IN PHILADELPHIA

CT Scans for Diagnosing COVID-19? Not So Much.

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CT Scans for Diagnosing COVID-19? Not So Much.

Technology

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Colleagues also published online in February in Radiology and found chest CT sensitivity at 97% for those with positive RT-PCR results. In patients with negative RT-PCR tests, 75% had positive CT scans. Authors recommended CT as a primary COVID-19 diagnostic tool.

But as COVID-19 spread beyond China, RT-PCR testing improved, and researchers had more time to compare those initial studies with practices in other countries. The availability of RT-PCR is still an issue in the U.S., but recommendations for using CT scans to diagnose COVID-19 haven’t been adopted by major medical organizations and societies.

The American College of Radiology noted in a March 11 statement that CT scans should not be used to screen for COVID-19 or as a first-line test to diagnose the disease. The society noted that CT scans be reserved for patients who test positive for COVID-19 and are suspected of having complications involving the lungs.

But the Fleischner Society, an international, multidisciplinary thoracic radiology society, took a more nuanced stance and included CT scans on its decision trees. The Fleischner group recommended against CT scans (and chest X-rays) for screening COVID-19 in patients with no or mild symptoms unless they show “worsening respiratory symptoms,” but recommended imaging — either CT scans or chest X-rays — for people with “moderate to severe features” of COVID-19. The society’s recommendations say that chest X-rays are of little value early in disease but have a role in more advanced disease.

Litt and other radiologists also see problems with study design, biases and selection criteria used in some of Chinese CT scan studies. Clinicians at the hospitals in China scanned any symptomatic patient, with little understanding of where patients are in the disease process, says Litt. In the U.S., patients with mild to moderate symptoms have been told to stay home unless they have trouble breathing. Litt also notes that the study showing 71% sensitivity for RT-PCR testing used throat swabs. “We know [throat swabs] will miss quite a few positive patients compared to nasopharyngeal swabs,” says Litt, who also questions the high sensitivity rate of CT scans, adding that, “98% sensitivity is too high for anything in medicine.”

In addition, American College of Radiology says specificity is a problem with CT scans for COVID-19 because results can overlap with findings for pneumonia and lung issues stemming from other sorts of infections, including influenza. Moreover, says Litt, “we need to make a distinction between (the) coronavirus infection and COVID-19 pneumonia” because people can test positive for COVID-19 but haven’t developed pneumonia.

Expense is another consideration. It is impossible to put a single price on a CT scan; it is going to vary depending on the payer. It’s not negligible, though, and claims for CT scans range from several hundred dollars to several thousand.

The availability of CT scanners hasn’t been an issue at most U.S. facilities, says Litt, because of canceled or postponed elective procedures and other ordinary medical care.

What is an issue is that scanning patients increases the likelihood of staff members contracting the virus. “We’ve instituted universal cleaning protocols because we don’t know who has the [undetected COVID-19],” says Litt.

Then there’s the incidental finding, a common problem with imaging tests. Determining how to report and share them led to Litt and his colleagues publishing a Radiological Society of North America expert consensus statement on incidental COVID-19 findings. The statement proposed categorizing them into one of four categories: typical (of COVID-19), indeterminate, atypical or negative.

“This specific question of, ‘Is this abnormality reflective of COVID-19 pneumonia or something else?’ is going to be one with us for a while,” notes Litt, “and viral testing will be the way to resolve that.”

Deborah Abrams Kaplan covers medical and practice management topics.
The first pillar: surgical excision, which in the beginning was brutal and often disfiguring. In the mid-20th century, chemotherapy and radiation were added. They were also hard on patients as doctors pushed the outer bounds of what people could tolerate to rid the body of cancer. And pillar No. 4: therapies like Gleevec (imatinib), “smart bombs” that targeted the molecular-level underpinnings of cancer cell growth and division.

Now oncologists like Huda Salman, M.D., see immunotherapy as the fifth pillar of a cancer treatment edifice that is accretive and complex. Chimeric antigen receptor T cell (CAR-T) therapy, one of the main forms of immunotherapy, involves genetically engineering the patient’s own T cells so they recognize cancer cells and attack them in the way that unengineered T cells attack invasive organisms.

“The CAR-T treatment revs up the immune system and therefore causes immunotherapy-associated side effects, it is like hitting a beehive with a baseball bat.”

—CHANDLER PARK, M.D., AN ONCOLOGIST AT NORTON HEALTHCARE IN LOUISVILLE, KENTUCKY

Kymriah is approved as a treatment for a subgroup of pediatric and young adult patients with a form of acute lymphoblastic leukemia (ALL) and for adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). Yescarta is approved for four types of non-Hodgkin lymphoma in adult patients who have relapsed or not responded to other treatments: DLBCL, primary mediastinal large B-cell lymphoma, high-grade B-cell lymphoma and DLBCL arising from follicular lymphoma.

The price of CAR-T looms over its promise. The two FDA-approved versions have list prices well over $350,000; physician and hospital charges can easily push the total cost past the million-dollar mark. Payers, providers, and policymakers are puzzling through and arguing about how to possibly shoulder such a huge cost, while researchers continue to tweak the approach in hopes of making it a safe and effective treatment for many cancers — and potentially less costly.

Here are five recent developments in CAR-T therapy.

1. Potential Competition in CAR-NK

Parameswaran Hari, M.D., MRCP, professor and chief of the division of hematology and oncology at the Cancer Center at Froedtert Hospital in...
suburban Milwaukee, Wisconsin, says two major developments in CAR-T are the promise it is showing as an effective treatment for mantle cell lymphoma and the trials underway that could lead to it having an allogeneic future. There’s a lot of buzz about CAR therapies that would involve altering the natural killer (NK) cells of the immune system instead of T cells, Hari says. NK cells might have several advantages, partly because they recognize “nonself” cells without antibodies and major histocompatibility complex. If CAR-NK pans out, clinicians could draw the NK cells from people other than the patient and use them off the shelf rather than in the individualized way that CAR-T requires. “Price will perhaps be lower for allogeneic off-the-shelf CARs, since many steps are not needed and mass production is possible,” notes Hari.

A team of researchers from MD Anderson Cancer Center in Houston reported the results of a phase 1/2 trial of CAR-NK in the Feb. 6, 2020, issue of the New England Journal of Medicine. The trial included 11 patients with relapsed or refractory cluster of differentiation (CD) 19-positive cancers (non-Hodgkin lymphoma or chronic lymphocytic leukemia). Seven had a complete response, according to the authors, and the treatment was not associated with CAR-T side effects.

“This is very exciting because they didn’t just take natural killer cells from somebody but transduced natural killer cells from cord blood units,” says Guenther Koehne, M.D., Ph.D., deputy director and chief of blood and marrow transplantation and hematologic oncology at Miami Cancer Institute in Florida. By doing that, the researchers may have established an off-the-shelf version of CAR-T, although the moniker might be CAR-NK, not CAR-T.

2 **CD4 T Cells and CD8 T Cells in Equal Measure**

Koehne notes that one of the promising developments in CAR-T therapies this year is a new immunotherapeutic approach to treat patients who have relapsed following treatment for lymphoma or whose autologous transplant was unsuccessful. Researchers are testing the approach in a clinical trial, and the Miami Cancer Institute is one of the sites selected to participate, according to Koehne. The goal is to reduce the side effects of CAR-T cells and extend their duration once administered to the patient, he says.

What’s special about this approach is that clinicians select the CD4 T cells and the CD8 T cells separately prior to transducing the cells with the CAR product. In other words, explains Koehne, the CD4 T cells and the CD8 T cells are processed and modified separately and infused into patients in equal amounts.

“This appears to be critical for the duration of CAR T cells in the blood because the first generation of CAR T cells had a dominant CD8 component with few CD4 cells,” Koehne says. “The CD4 (T cells), which are also referred to as helper T cells, are providing support to enable longer duration of the CAR-T cells in the bloodstream and therefore could provide a better outcome.”

Reduction of side effects and time in the hospital could significantly help to reduce the expense, notes Koehne. “The overall costs are then driven by the development of cytokine release syndrome and neurotoxicity, which can easily increase the costs threefold to fourfold, since a high percentage of patients develop these side effects and need to be admitted, often to the ICU,” Koehne says. “Within no time at all, the average treatment costs are in the range of $1.2 to $1.5 million per patient.”

—PARAMESWARAN HARI, M.D., MRCP, PROFESSOR AND CHIEF OF THE DIVISION OF HEMATOLOGY AND ONCOLOGY AT THE CANCER CENTER AT FROEDERT HOSPITAL IN SUBURBAN MILWAUKEE, WISCONSIN
Not Just for Blood Cancers
Chandler Park, M.D., an oncologist at Norton Healthcare in Louisville, Kentucky, believes the biggest development in CAR-T this year will be the treatment’s application to nonblood cancers. “Many leading cancer centers will open up clinical trials for solid tumor cancers such as breast cancer, lung cancer and prostate cancer,” he predicts. He cautions, though, that CAR-T’s cost will be a factor in whether patients should receive this treatment. An informed discussion with the patient should include not only the efficacy and medical side effects of the treatment but also the risk of “financial toxicity,” says Park, using a term that oncologists have coined for high cost sharing.

Importantly, says Park, clinicians should recognize that the side effects of CAR-T are unlike the hair loss, nerve pain and low blood counts that sometimes accompany traditional chemotherapy. “The CAR-T treatment revs up the immune system and therefore causes immunotherapy-associated side effects,” Park says. “It is like hitting a beehive with a baseball bat.” The bees in Park’s metaphor are cytokines, the signaling proteins of the immune system, and the swarming, cytokine release syndrome, is one of the most common side effects of CAR-T. The symptoms of cytokine release syndrome range from mild flu-like symptoms to life-threatening, systemic inflammation.

Another major side effect is CAR-T-related encephalopathy syndrome (CRES). CAR-T can produce neurotoxicity that, like cytokine release syndrome, can lead to a range of symptoms, from a mild headache to seizures and even death. The common consequence is encephalopathy (brain damage). People affected by CRES may experience confusion, difficulty speaking (aphasia) and a dulling of consciousness (obtundation).

Impressive Results
Koehne says the results of the treatment for relapsed or refractory non-Hodgkin lymphoma with CAR-T cells are increasingly impressive. “Patients have a good and lasting response, which has been a limitation of initial CAR-T cell studies, which saw a high percentage of responses — up to 90% and in some studies even higher — but the responses didn’t last for too long,” he says. In most cases, additional treatment led to complete remission, and follow-up treatments were needed, says Koehne.

Multiple Myeloma Next in Line?
The first generation of CAR-T targeted the CD19 surface protein that is expressed on nearly all B-cell cancers, a group that includes chronic lymphocytic leukemia, ALL and many types of non-Hodgkin lymphoma. Now hope exists for a version of CAR-T that would target the B-cell maturation antigen expressed on the malignant plasma cells that characterize multiple myeloma. “The limitation, once again, is that we won’t know how long the responses will last,” says Koehne.

Keith Loria is an award-winning journalist who has been writing for major newspapers and magazines for close to 20 years.

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—GUENTHER KOEHNE, M.D., PH.D., DEPUTY DIRECTOR AND CHIEF OF BLOOD AND MARROW TRANSPLANTATION AND HEMATOLOGIC ONCOLOGY AT MIAMI CANCER INSTITUTE IN FLORIDA.

The two FDA-approved versions have list prices exceeding $350,000, physician and hospital charges can easily push the total cost past the $1M mark.
Post-Acute Care Was Broken Before COVID-19

The Response to the Pandemic Might Help Fix It

The COVID-19 pandemic has exposed weaknesses in how our healthcare system handles acute care. We’ve seen widely reported shortages in ICU beds and other critical care resources, limits in our ability to protect healthcare workers from infection and racial disparities in access to care. The pandemic is also putting a spotlight on the problems with post-acute care, and this is particularly troubling because we have seen some of the worst outbreaks of the disease in skilled nursing facilities, where much of post-acute care happens.

The problem is post-acute care – generally care provided after a patient leaves the hospital – is fragmented. Most patients are either referred to a facility or are sent home with little assistance or support. Nobody is overseeing their care, and primary care providers are often out of the loop.

During COVID-19, that’s a lose-lose scenario. Patients who were hospitalized with the virus are either coming home with a complicated set of instructions and medications. Some nursing homes are making judgment calls about protecting their own populations and refusing to take COVID-19 patients, leaving them with limited options.

This confusing post-acute care scenario is not a new problem that came with COVID-19. It was there all along. COVID-19 just exposed how bad the situation is. We simply need a better path after discharge from a hospital for all patients.

The best way to do this is to supercharge care at home, so that people can go home after being discharged from the hospital and heal with the support and care needed to fully recover. Here are three essential ingredients to quality home care for patients:

First, effective delivery of care in the home must include close coordination, follow-up and support throughout their healing process. For decades, we have effectively utilized registered nurses to coach patients after they leave the hospital. They are there to help patients understand their discharge instructions and answer any questions they may have about their health. Nurse coaches get to know their patients and help meet both clinical and nonclinical needs, including getting over social barriers to recovery like food, accessibility and lack of transportation.

After a hospitalization, patients are understandably worried about getting back to good health, managing their medications, and what follow-ups they need to do and where. On top of that, they have the general anxiety that comes with leaving the hospital setting, where there are nurses and other providers readily available to support them and answer their questions. We need to recreate that environment in the home.

Second, we need a robust telehealth system and other tools, like remote-patient monitoring, to ensure these patients get visits with their doctors and other providers frequently, without traveling to another healthcare facility. Although telehealth has existed for a long time, it has taken the COVID-19 pandemic to accelerate its adoption. We need to make it the norm for many types of medical appointments. There is a real opportunity to do this because CMS has updated some of its rules to ensure more telehealth can be delivered to patients. We need to keep those changes for the long haul.

Finally, we need to ensure we’re connecting patients with the community resources they need to heal effectively. That means understanding when patients face non-medical challenges and closing those gaps. For example, we need to be able to understand when patients need meal delivery and connect them with Meals on Wheels, or another local organization that can address non-clinical barriers to healing and recovering at home.

Ultimately, all three of these changes will not just build a better model of post-acute care for patients recovering from COVID-19 but must be adopted by all as a better path for post-acute care for all patients moving forward.

JASEN GUNDERSEN, M.D., MBA, is chief medical officer of CareCentrix, a post-acute care and home health company in Hartford, Connecticut.
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HVUADV1200001 February 2020
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The COVID-19 outbreak has tried the souls of people the world over, both personally and professionally, and healthcare executives are no exception. Despite seeing their plans and schedules torn up, executives can meet and master the unrelenting demands of leadership when a typical workday is anything but. Consider these tips from your industry peers to not just survive but also thrive — and to inspire your employees to do the same.

1 SUPPORT THE INGENUITY OF YOUR WORKFORCE
“Leaders must encourage innovative and creative solutions to solve big and small challenges,” says Jaewon Ryu, M.D., J.D., president and CEO of the Geisinger Health System in Danville, Pennsylvania. “For us, that has included creatively redeploying staff to areas of more pressing need, 3D printing of supplies with local community partners, rethinking how we use our space, refurbishing out-of-service ventilators and so much more. These solutions have come from all across our system, from people in a variety of roles and responsibilities.”

Richard S. Isaacs, M.D., FACS, a Permanente Medical groups executive operating officer of the hospital division at WellStar Health in the greater Atlanta area.

“Remember that standing behind your team members on the front lines of patient care is imperative,” Owen Plietz says. “It’s our responsibility to go above and beyond to support, encourage and protect them.”

2 STAY AHEAD OF THE CURVE CAN HELP FLATTEN IT
Geisinger serves 45 counties in northeastern and western Pennsylvania. “We are learning from our areas with higher or earlier COVID-19 prevalence to make sure we’re prepared for what may come,” says Ryu. “Better yet, we’re working to flatten the curve in our regions that haven’t been as heavily impacted yet.”

3 STAND BY — AND BEHIND — YOUR TEAM
“During these unprecedented times, we are intensely focused on fostering compassion for our caregivers and team members, who are the heroes of our health system and the communities we serve,” says Carrie Owen Plietz, FACHE, executive vice president and chief operating officer of the hospital division at WellStar Health in the greater Atlanta area.

4 MAKE MENTAL HEALTH SERVICES AVAILABLE AND CONFIDENTIAL
“It’s critical that messages be communicated from the top down to help everyone work as a great team and support each other,” says Samantha Meltzer-Brody, M.D., M.P.H., chair of the department of psychiatry at the University of North Carolina School of Medicine in Chapel Hill. She helps lead the school’s well-being program, “https://www.unchealthcare.org/wellbeing/” which has had added resources because of the COVID-19 outbreak. The well-being program is available to everyone from physicians to nurses to the staff providing dietary services, Meltzer-Brody says. “We want everyone to access these men-
tal health services without charge, confidentially, then be directed to different or additional levels of service tailored to the individual,” she notes. “That could be support groups, the employee assistance program or more formal psychotherapy if needed.”

5 LEARN FROM OTHERS

“As we work through and respond, draw on the expertise of those who have gone before us in this pandemic, both internationally and nationally, so we can be even better prepared,” Owen Plietz says. “We also regularly connect with our system leaders and industry peers, both locally and nationally, to share challenges and best practices.”

6 PREPARE AND PRACTICE

“Each of our 11 hospitals and other facilities has been preparing to support an expected influx of patients by monitoring and actively managing our staffing levels, capacity and supply chain to make sure we have adequate, continued access to the personnel needed to care for patients, as well as beds, materials and equipment,” Owen Plietz says. “In addition, we have an established, regular cadence of drills and simulations for different intake scenarios.”

7 COMMUNICATE REGULARLY AND OPENLY

Yes, leaders can lose people if they overcommunicate; even dedicated team members will tune out after a while. But holding back during a crisis can lead to rumors and worry. “Be visible, overcommunicate and be transparent with your people,” advises Isaacs.

Owen Plietz says communication via different, accessible platforms can be a two-way street of listening and sharing updates. The exchange “equips team members to be more engaged and invested, which strengthens us all,” she notes.

8 ACCEPT THAT SOMETIMES LUCK ENTERS IN

“Understand there are good and bad decisions you can make, and good luck and bad luck are associated with each outcome of a decision,” says Steve Messinger, president of ECG Management Consultants in Arlington, Virginia, and co-chair of healthcare at the Committee for Economic Development of The Conference Board.

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“Accept that sometimes luck enters in.”

Most healthcare organizations we’ve worked with are excellent during times of crisis, like a weather event or heavy-hitting flu season,” says Messinger. “They mobilize and understand logistics. This pandemic is really testing the fortitude of provider organizations due to its long-term duration.”

Messinger adds that leaders need to make sure their staffs are well supplied, a not-so-simple task during this outbreak, and address morale issues. His advice is to be kind and to listen — and to remind people of how important they are.

9 RECOGNIZE THAT THIS ONE IS DIFFERENT

“Understand there are good and bad decisions you can make, and good luck and bad luck are associated with each outcome of a decision,” says Steve Messinger, president of ECG Management Consultants in Arlington, Virginia, and co-chair of healthcare at the Committee for Economic Development of The Conference Board, a business group that advocates for national priorities. “Ask yourself, ‘Am I making a fundamentally sound decision, and is this a good framework?’”

Messinger has seen staffers use the best information they could to make a call and then be crushed by bad luck when they didn’t get the anticipated outcomes. “People really need to focus on the way they make decisions and on their style,” he says. “Bring people along, and help them understand the leadership role they’re taking. Be obvious, be consistent and be present.”

Stephanie Stephens is a journalist and radio and television producer and host in Orange County, California.