

COVID-19: Shaping the Next Normal in the Pharma Ecosystem

Part 1: How the COVID-19 pandemic has exposed shortcomings in the U.S. healthcare system

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INTRODUCTION

The direct effects of the COVID-19 pandemic — the human tragedy, the economic losses — are well documented, inescapable, and have already significantly changed the lives of most people. Suffice it to say, the old reality of being able to engage with others, move around freely, and enjoy the comfort of a healthy living environment may become as distant as a world with rotary telephones and 8-track tapes. Every newscast, every social media post, and each mask-covered awkward glance shared with a fellow grocery shopper are immediate reminders of the world we live in today.

Less understood, however, are the indirect consequences of the strains this pandemic has put on each stakeholder in the U.S. healthcare ecosystem: healthcare professionals (HCPs), payers, drug manufacturers, and, most importantly, all of us as patients. It's hard to predict which of these effects are fleeting, which ones will linger for years, and how they will affect each group in the long term.

But one thing is clear: The COVID-19 pandemic has exposed shortcomings in the U.S. healthcare system — shortcomings that we can no longer ignore or hope will go away. Overcoming some of these difficulties will require that stakeholders engage with one another in new ways that maximize value and improve patient, financial, and quality outcomes. Just as the spread of the Internet and smartphones disrupted countless business models, there is no question that these technological advancements have left us better off as a whole.

And so begins the task of evaluating, understanding, and implementing the next wave of advancements in healthcare — and the reality that we will be much better off in the “next normal.”

THE PANDEMIC'S RIPPLE EFFECTS

Taking nothing away from the heroic efforts of healthcare workers, the COVID-19 pandemic has shown how vulnerable our system is to disruption in a public health crisis. The ripple effects of these disruptions are less obvious and carry longer-term implications for each stakeholder.

Providers

Most hospitals, health systems, and HCPs have been forced to limit or shut nonessential operations to ensure that resources and capacity are available to those infected with COVID-19.

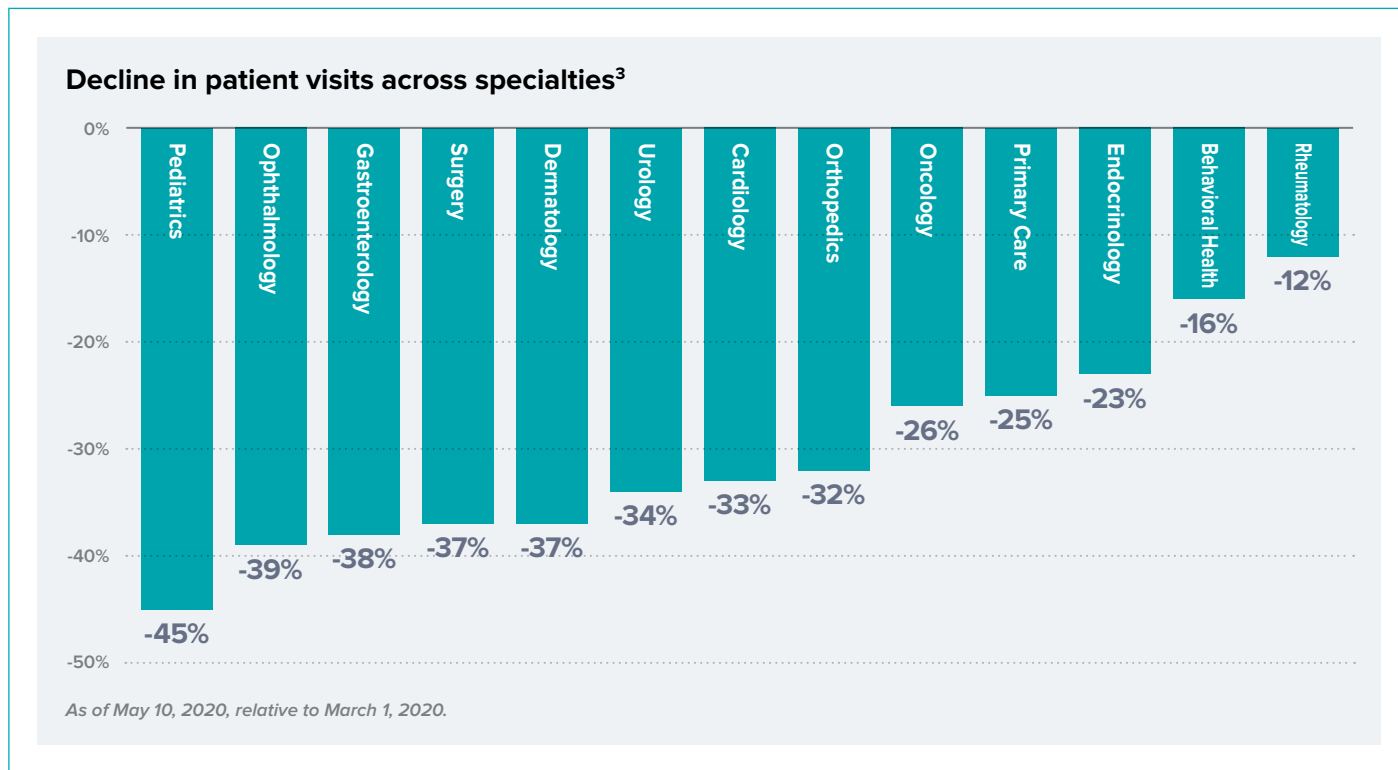
Through early May, American hospitals had delayed more than 4 million elective procedures, creating a 45-week backlog.¹ And it wasn't just knee and hip replacements — cash cows that help to offset urgent-care costs — that got the bump. Some were more worrisome problems like cancer surgeries, more than 20% of which were cancelled.

As a result, hospitals, clinics, and distributors have stockpiles of unused buy-and-bill drugs. Threatened with the waste of costly medications, cancer centers, specialists, and others who administer infused drugs may ultimately decide that specialty pharmacy is a less risky proposition. That would accelerate changes to the buy-and-bill landscape, primarily the migration from in-office to home infusions,² that are already set in motion.

Unable to see patients, primary care and specialist practices are struggling financially. A recent Commonwealth Fund study found that primary care visits in mid-April were half of what they were at the beginning of March. Despite the beginnings of a rebound, all ambulatory visits overall were still down 31% through May 10.³ “Within my lifetime, I have not seen anything of this magnitude,” Ateev Mehrotra, a Harvard Medical School professor who led the study, told *Vox*.⁴

Certain specialties have been hurt more than others (Figure), but the economics are difficult for any practice that lacks the reserves of a large

health system. Practice consolidation is almost a certain outcome in a post-pandemic America.⁴



Patients

Of more immediate concern, a drop in face-to-face visits for chronic illness management has raised concerns about disparities in medication adherence. To be sure, patients are taking advantage of payer policy changes expanding access to mail-order pharmacy and easing quantity limits. But in one key indicator of adherence — early refills — high-risk patients appear to be less likely to fill prescriptions early than low-risk patients.⁵

In “provider deserts” — rural areas with few clinicians who have certain specialized skills — some services may not be accessible at all. Rare disease centers, often based in hospitals, largely have been closed. In a survey of 700 patients and caregivers by the National Organization for Rare Disorders, 74% of patients with rare diseases have had medical appointments cancelled.⁶

As patients experience difficulty accessing in-person services, fallback options for chronic disease maintenance have failed. Patients can’t get through to flooded nurse helplines. Skeleton

office staffs are overwhelmed and unable to conduct outreach to high-risk patients.⁷ Ironically, many of these non-COVID-19 patients are at higher risk for the virus.

Affordability is another aspect of access, and thanks to the most severe economic downturn since the creation of employee benefits, it is increasingly a concern to patients. In April, the U.S. unemployment rate reached 14.7%,⁸ and though not all job losses result in loss of healthcare coverage, the effect of layoffs on coverage will be severe. A Kaiser Family Foundation analysis estimated that 27 million workers and dependents could lose employer-based coverage.⁹

Many who do lose their coverage will migrate to the exchanges, as receipt of unemployment benefits will rule out their eligibility for Medicaid.¹⁰ Exchange plans are notorious for high deductibles and cost sharing, forcing many enrollees to use exchange plans the way they would use catastrophic coverage. Out-of-pocket cost is a well-established barrier to medication

adherence. Connecting the dots, it's not difficult to imagine worse health outcomes for those who cannot afford to take their medications or see a doctor for chronic disease flare-ups.

Payers

Operating in “crisis mode,” payers are dealing with immediate concerns and pushing nonessential business aside. That's not to say they aren't keeping a nervous eye on the future — with the cost of the pandemic or its aftermath anything but certain, they absolutely are.

For now, commercial payers are relaxing benefit design and gatekeeping requirements to support a number of immediate needs: telemedicine; changes in site of care; home infusions; and expanded access to mail-order pharmacy, to name a few. Payers are also waiving utilization management techniques for COVID-19–related treatment, as many provider billing systems aren't yet programmed to handle new Medicare-related COVID-19–related billing codes.

The emphasis on these acute needs means that health plans have placed much of the behind-the-scenes work on hold. This includes most drug therapy coverage reviews.¹¹ P&T committees that meet at all may be more concerned about opening access to antiviral drugs than about new medications for inflammatory conditions or rare diseases.

From an actuarial standpoint, plans are flying blind. While loss of existing coverage is a “life event” allowing for access to the exchanges, at least 12 states have fully reopened exchange enrollment for the newly unemployed.^{12,13} With no idea who will walk through their doors, insurers are bracing for a spike in applications.¹⁴ They may be looking at Utah, whose Medicaid expansion that began this year turned into a giant unplanned experiment. In March, Utah saw a 46% increase in Medicaid applications.¹⁵

“We expect economic impact and resulting unemployment to drive increases in members,” CEO Michael Neidorff of managed Medicaid giant Centene told analysts in a late-April earnings call.

As for next year, payers worry that hospitals unable to provide high-cost procedures and

patients unable to access them in 2020 will demand them in 2021. Under premium-hike pressure from states and nearing a deadline to present next year's offerings to insurance commissioners, insurers may well be considering benefit structures that would prevent an influx of backlogged procedures.

Manufacturers

The biotech and pharmaceutical industries are experiencing operational bottlenecks that are choking a number of functions, including research and development, sales, and distribution.

With patients unable to get into oncology centers and academic sites, clinical trials have been placed on hold – potentially compromising the results of studies in progress. In some disease areas, the Food and Drug Administration is granting provisional marketing approval based on phase 2 and, sometimes, phase 1 studies. Data from smaller studies may not be acceptable to payers, putting the onus on manufacturers to develop novel ways of communicating value. “Earlier approvals will meet resistance from payers, who will label these products as experimental,” notes Jim Clement, partner at Coeus Consulting Group in Strategy and Outcomes. “Manufacturers will be pushed to offer ‘shared-risk’ solutions as real-world evidence is generated.”

The COVID-19 pandemic has grounded sales forces that have always relied on in-person visits with prescribers. Sales representatives do their best to pitch new therapies through e-mail blasts and remote slide presentations, but virtual launches have not yet matured into a robust substitute for person-to-person learning opportunities. One major manufacturer delayed the launch of a new multiple sclerosis treatment until face-to-face meetings are permitted again because of the amount of education involved.¹⁶

“You do miss something in non-personal engagement you get from an in-person conversation, whether it's being able to read the room, being able to understand what's really on the mind of the customer,” Bristol Myers Squibb Chief Commercial Officer Chris Boerner told the *Wall Street Journal*.

Disruptions to the supply chain also hurt product launches, not to mention the ability to get existing therapies into the hands of patients who need them. Shut out of doctors' offices, sales representatives cannot drop off samples. Shortages of more than two dozen drugs have been reported.¹⁷ And for people in provider deserts who have rare diseases and are treated by the only specialist in the area, closure of a clinic could imperil access to life-saving therapies.

THE NEXT NORMAL

The depth of the coronavirus crisis is a reminder of past events that reshaped the way we engage with institutions and with one other: the Great Depression, the OPEC oil embargo, September 11. Each of these events revealed vulnerabilities, leading to changes that had a lasting impact on society. This will, too.

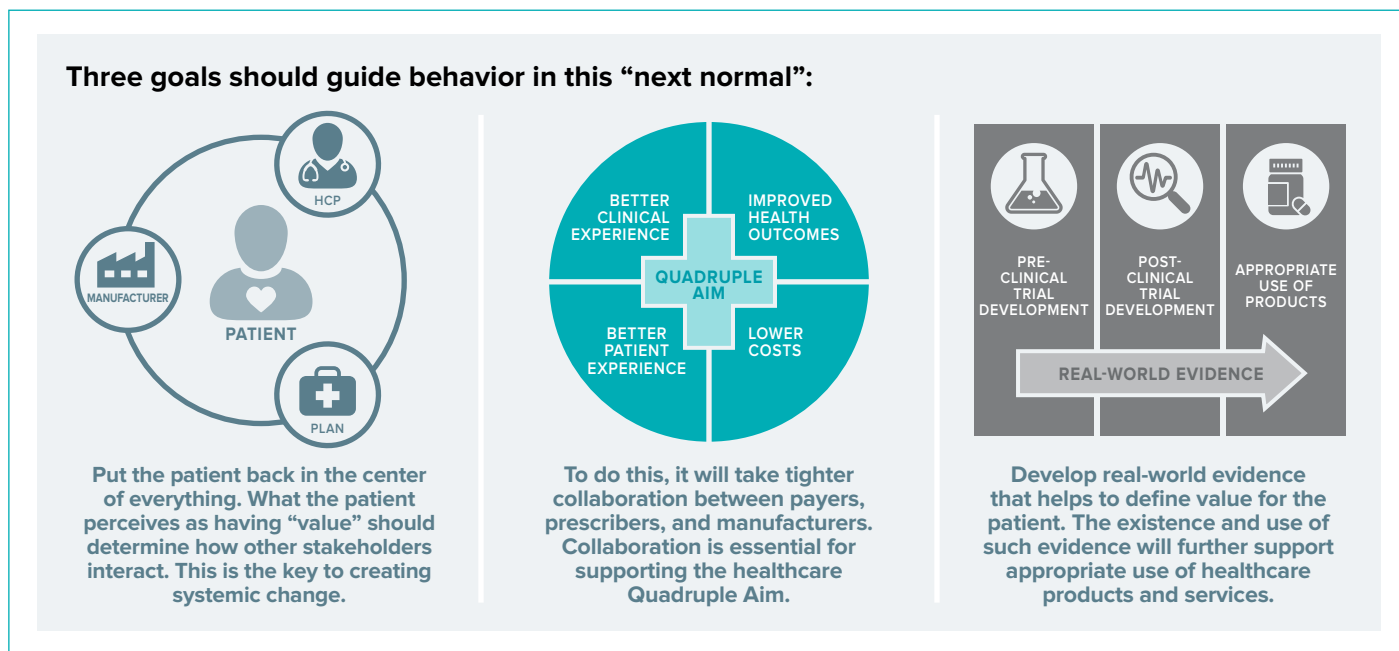
The COVID-19 pandemic has laid bare multiple shortcomings of our system of healthcare delivery and financing: maldistribution of resources, a

focus on the short term, failure to consider each stakeholder in the value equation, and, worst of all, failure to put the patient at the center of everything we do. We see the effects of seclusion, health inequities, and the inadequacies in the system's safety nets. As we emerge from this crisis, an evolution is inevitable.

"This evolution is likely to usher in a new call for and embrace of innovative and disruptive solutions, a new wave of broadened partnerships, and a need for even greater levels of differentiated value in the marketplace," Cigna CEO David Cordani told investors on April 30.

The biotech and pharmaceutical industries have an opportunity to shape that evolution by changing the way they interact with stakeholders. Rethinking relationships and engagement offers an opportunity to re-create the healthcare system in a way that empowers all, aligns perceptions of value, and has the potential to improve clinical, financial, and quality outcomes.

But how?



Going forward, defining true value to the healthcare system will be critical for all participants and stakeholders within the healthcare system. We will explore how this new model of collaboration may look and who benefits and why in Part 2 of this series.

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References

1. COVIDSurg Collaborative, Nepogodiev D, Bhangu A. Elective surgery cancellations due to the COVID-19 pandemic: global predictive modelling to inform surgical recovery plans. *Br J Surg*. Prepublication draft accepted May 12, 2020. <https://doi.org/10.1002/bjs.11746>.
2. Fein A. Three early signs that COVID-19 could disrupt the buy-and-bill channel. *Drug Channels*. April 21, 2020. <https://www.drugchannels.net/2020/04/three-early-signs-that-covid-19-could.html>. Accessed May 28, 2020.
3. Mehrotra A, Chernew M, Linetsky D, et al. The impact of the COVID-19 pandemic on outpatient visits: a rebound emerges. *The Commonwealth Fund*. May 19, 2020. <https://www.commonwealthfund.org/publications/2020/apr/impact-covid-19-outpatient-visits>. Accessed May 28, 2020.
4. Scott D. Coronavirus has created a crisis for primary care doctors and their patients. *Vox*. April 27, 2020. <https://www.vox.com/2020/4/27/21231528/coronavirus-covid-19-primary-care-doctors-crisis>. Accessed May 28, 2020.
5. Allazo Health. COVID-19 widens disparities in medication adherence between patient populations. March 30, 2020. <https://allazohealth.com/covid-19-adherence>. Accessed May 28, 2020.
6. National Organization for Rare Disorders. Called to action: NORD's response to COVID-19. Webinar. April 2020. https://rarediseases.org/wp-content/uploads/2020/04/Called-to-Action_FINAL.pdf. Accessed May 28, 2020.
7. Hurst T, Reid V, Wirth C. How COVID-19 should change your chronic disease outreach. *The Advisory Board Co*. April 24, 2020. <https://www.advisory.com/daily-briefing/2020/04/24/chronic-disease-outreach>. Accessed May 28, 2020.
8. Bureau of Labor Statistics. The employment situation — April 2020. May 8, 2020. <https://www.bls.gov/news.release/pdf/empst.pdf>. Accessed May 28, 2020.
9. Garfield R, Claxton G, Damico A, Levitt L. Eligibility for ACA health coverage following job loss. *Kaiser Family Foundation*. May 13, 2020. <https://www.kff.org/coronavirus-covid-19/issue-brief/eligibility-for-aca-health-coverage-following-job-loss>. Accessed May 28, 2020.
10. King R. KFF: More than 20M of newly unemployed could qualify for ACA tax credits. *Fierce Healthcare*. May 13, 2020. <https://www.fiercehealthcare.com/payer/kff-more-than-20m-newly-unemployed-could-qualify-for-aca-tax-credits>. Accessed May 28, 2020.
11. Studin I. May 2020 Snapshot: The impact of COVID-19 on health plans from a pharmacy point-of-view. *Pharmacy Times*. May 14, 2020. https://www.pharmacytimes.com/news/may-2020-snapshot-the-impact-of-covid-19-on-health-plans-from-a-pharmacy-point-of-view?sp_url=coronavirus. Accessed May 28, 2020.
12. Nania R. Some states hold special ACA open enrollments due to the coronavirus. *AARP*. May 26, 2020. <https://www.aarp.org/health/health-insurance/info-2020/coronavirus-aca-open-enrollment.html>. Accessed May 28, 2020.
13. Rodriguez CH. 9 states reopen ACA insurance enrollment to broaden health coverage. *National Public Radio*. March 20, 2020. <https://www.npr.org/sections/health-shots/2020/03/20/818981380/9-states-reopen-aca-insurance-enrollment-to-broaden-health-coverage>. Accessed May 28, 2020.
14. Japsen B. Insurers brace for big influx of jobless Americans to Obamacare and Medicaid. *Forbes*. May 3, 2020. <https://www.aarp.org/health/health-insurance/info-2020/coronavirus-aca-open-enrollment.html>. Accessed May 28, 2020.
15. Luthra S, Galewitz P, Bluth R. Medicaid nearing 'eye of the storm' as newly unemployed look for coverage. *Kaiser Health News*. April 3, 2020. <https://khn.org/news/medicaid-nearing-eye-of-the-storm-as-newly-unemployed-look-for-coverage>. Accessed May 28, 2020.
16. Loftus P, Hopkins JS. Drugmakers overhaul the sales pitch amid coronavirus lockdowns. *Wall Street Journal*. May 11, 2020. <https://www.wsj.com/articles/drugmakers-overhaul-the-sales-pitch-amid-coronavirus-lockdowns-11589194800> (registration required). Accessed May 28, 2020.
17. Marsh T. Live updates: Which drugs are in shortage because of COVID-19? *GoodRx*. May 19, 2020. <https://www.goodrx.com/blog/covid-19-drug-shortages-updates>. Accessed May 28, 2020.