

INTRODUCTION: THE RISE OF DIGITAL HEALTHCARE TECHNOLOGY

Among its many disruptions, the COVID-19 pandemic has created a tumultuous environment for innovation and entrepreneurship in US healthcare. Prior to early 2020, start-up activity in healthcare was relatively steady, increasing only slightly each year.¹ Despite representing nearly a fifth of US gross domestic product, ² the US healthcare industry has historically been challenging for innovators due to high startup costs, strong competition, myriad regulations, and numerous market players.

However, the landscape changed with the COVID-19 pandemic. With in-person care restricted and routine procedures delayed, healthcare providers and payers were forced to find new ways of delivering care. As with many other industries, healthcare providers leaned on technology to address these issues. Subsequently, digital healthcare innovation began to explode. The number of digital start-up deals doubled between 2019 and 2021, and funding for digital health more than quadrupled in the same period.³

Organizations would complain about how long it takes to make change, how long it takes to shift directions, but we know that narrative is no longer true because we watched hospitals and healthcare organizations, everything from insurance to your doctor visits, change dramatically, and change fast.

> – RICO GRANT, MANAGING DIRECTOR OF SOCAP ACCELERATE AT NORTHERN KENTUCKY UNIVERSITY

With the increased reliance on technology, many of the old paradigms and assumptions about healthcare suddenly became fluid. Patients also started expecting more from their healthcare experiences – more convenience, more personalization, and more availability. The changing expectations led to opportunities for innovation in an industry that has been traditionally resistant to change.

COMMON BARRIERS IN HEALTHCARE INNOVATION

Although innovation is strong in healthcare, several barriers exist. Many innovators are healthcare professionals themselves, often searching for a solution to a problem in their work. However, many healthcare professionals lack knowledge of how to translate their ideas into workable innovations or how to promote and secure funding. Innovation is also a time-consuming and resourcedemanding processes; many healthcare professionals may not have the time or energy to focus on innovation in addition to their clinical work.⁴

Along with individual time, effort and knowledge, more macro-level barriers include regulations, clinician buy-in, and reimbursement. Healthcare is one of the most regulated industries in the US; while it is important to ensure only quality health products are given to consumers, the stringent approval and testing requirements can deter many from developing their ideas.⁵

One of the biggest hurdles for innovation, specifically for new medical products or procedures, is receiving approval from the Food and Drug Administration (FDA). To get FDA approval, innovators must identify how their concept or product provides a "clinical benefit," which requires trial and testing data to prove. Clinical trials are very expensive, again creating barriers for innovators without backing from investors or established organizations.⁶

In addition, innovators must get buy-in from other healthcare professionals on their concept or product; even if an innovation is fully funded, it won't go far if other healthcare professionals don't see the value.⁷

Finally, reimbursement by health insurance companies remains a strong barrier to innovation. The US healthcare system operates primarily on a fee-for-service system: providers are reimbursed for the specific services they give. Insurance companies act as gatekeepers in this system; if an insurance company decides not to reimburse a new procedure, it likely won't be utilized.

Given all these barriers, many potential healthcare innovators, especially those without a business background, can quickly become discouraged without proper coaching and support. Equipping entrepreneurs with business training and pairing them with experienced mentors is essential to fostering successful innovation.

People underestimate all the complexities that can and do occur when it comes to taking a new idea forward. If people haven't done it before, or they haven't been exposed to these concepts, what I see is people have great ideas and then lose because they don't realize how much there is to do. It's not that it's impossible ; you just need to go into it knowing that there's a process.

- DOUG LADD,

EXECUTIVE ENTREPRENEUR IN RESIDENCE AND PROFESSOR OF PRACTICE, INSTITUTE FOR HEALTH INNOVATION, NORTHERN KENTUCKY UNIVERSITY

KEY INNOVATION AREAS

Three top areas of innovation in healthcare expanded rapidly over the last few years in part because of the pandemic: telehealth, digital health infrastructure, and behavioral health.

Telehealth

Certainly, anything around telehealth, or distributed health, anything that can break down the traditional healthcare delivery model where a patient must go see doctor in order to get care, that is where I'm seeing a lot of activity.

- DOUG LADD, EXECUTIVE ENTREPRENEUR IN RESIDENCE AND PROFESSOR OF PRACTICE, INSTITUTE FOR HEALTH INNOVATION, NORTHERN KENTUCKY UNIVERSITY

One of the most direct effects of the pandemic on healthcare delivery was the rapid adoption of telehealth. Prior to the start of the pandemic, only around 10% of physicians regularly utilized any sort of technology to deliver services remotely, with around two-thirds of physicians never using telehealth. At the time, physicians were reimbursed at a lower level for remote visits, coverage for telehealth by insurance companies and Medicare was spotty, and many states had burdensome regulations such as requiring patients to have another healthcare provider physically present during a telehealth session.

When the pandemic hit, however, telehealth became the primary delivery method for healthcare: at the peak of the pandemic, 98% of physicians used telehealth at least some of the time. Many of the regulations were eased, insurance companies broadened coverage, and reimbursement levels were increased in some areas. As the barriers to using telehealth started easing, both patients and providers started seeing the benefit of remote healthcare delivery.⁸

Telehealth service and platform providers were relatively niche players prior to the pandemic. As the demand for telehealth grew, so did the size of these companies: Teladoc, founded in 2002, saw an 85% increase in revenue, triple the number of visits, and double the number of paid U.S. memberships in Q2 of 2020 compared to the previous year.⁹ American Well (now Amwell), founded in 2006, saw a 1000% increase in visits during the early months of the pandemic and raised nearly \$200 million within two months to keep up with demand.¹⁰ Other companies that grew included Caregility, Doximity, Updox, Mend, and Vsee. Newer telehealth companies also emerged, such as Forward and Ro, with a focus on a direct-to-patient model rather than enhancing the existing model.¹¹

Digital Health Infrastructure and Interoperability

Another top innovation area accelerated by the pandemic is improving digital health infrastructure, or how healthcare facilities acquire, use, store, and transfer electronic medical records (EMRs). Despite recent advances in digitizing medical records via electronic health record systems (EHRs), much of the health data created are siloed and difficult to access. Sharing, aggregating, and analyzing EMRs can lead to vast improvements in the effectiveness and efficiency of healthcare, but without digital infrastructure, these improvements remain mostly conceptual.¹²

Entrepreneurs have stepped in to create interoperability solutions for patients, allowing health data to be shared across facilities. The value for digital health infrastructure and interoperability start-ups tripled between 2020 and 2021, moving from just under \$750 million to over \$2.2 billion.¹³ Some of the top startups raised substantial funds to improve this area: H1 raised \$123 million to help connect biotech firms with providers for clinical trials,¹⁴ Abacus Insights raised \$28 million to develop its cloud-based interoperability platform,¹⁵ and Moxe Health raised \$30 million to improve secure health data exchanges.¹⁶

Behavioral Health

The COVID-19 pandemic brought attention to behavioral health treatment in the United States, especially the relative lack of telehealth options. Psychologists and other behavioral health providers have traditionally resisted using telehealth and had relatively few guidelines or regulations around its use. Thus, as COVID-19 lockdowns and restrictions increased stress levels while decreasing availability of in-person therapy, those looking for treatment found relatively few options. The pandemic quickly forced many behavioral health providers to move online: telehealth moved from only .3% of mental health visits in 2018 to nearly 40% by 2020.¹⁷

With a massive increase in need for behavioral health due to the pandemic and a lack of infrastructure to support it, entrepreneurs worked furiously to bolster mechanisms for behavioral health providers and patients to connect. Digital behavioral health startups raised \$588 million in funding in just the first six months of 2020 – roughly the same amount they raised in the entirely of 2019. Some companies, such as BetterHelp (part of Teledoc) or Talkspace, focused on recruiting consumers directly onto their platform and, initially, working without health insurance coverage. Other companies focused on developing digital platforms and services for behavioral health providers to use or join, including Lyra Health, Eleanor Health, and Hurdle. Still others focused more on promoting general mental wellness, with apps such as Headspace and Calm providing easy-to-understand meditation and sleep assistance programs directly to consumers.¹⁸

The opportunity for innovation in behavioral health is still very much present: the behavioral health market is projected to rise from \$73 billion in 2021 to nearly \$100 billion in 2028, with a CAGR of 3.6%.¹⁹ Consumers are also likely to continue their use of telehealth post-pandemic, as telehealth continues to be used for about two-in-five behavioral health visits.²⁰

Democratizing the access to mental health providers has been a nice benefit [of innovation], and where I've seen growth. You've seen innovation in access becoming better, period. It's not as hard to find a mental health provider that might be a better match for you and your need. I think wellness in general, and democratizing wellness specifically, is a significant trend.

– **MATT HOLLENKAMP**, VP MARKETING/COMMUNICATIONS AND PR, ST. ELIZABETH HEALTHCARE

Other Areas of Innovation

While telehealth, interoperability, and behavioral health are some of the top areas for innovation and funding, other healthcare topics have also received attention recently. A prime area for innovation is in the use of artificial intelligence (AI) to improve patient care through detecting anomalies and reducing health inequities, predicting cardiac arrest,²¹ improving oxygen level accuracy in Black patients,²² and predicting sepsis-related mortality.²³ Other technology-based innovations include using facial recognition to detect anomalies, using robots to detect and kill dangerous germs in hospitals, and using VR to help physicians and nurses train in critical situations. Researchers have also been working to create smart contact lenses that deliver glaucoma drugs on demand,²⁴ contact lenses designed to reduce digital eye fatigue²⁵ and make ultrasound machines more portable.²⁶

HEALTHCARE INNOVATION IN CINCINNATI/NORTHERN KENTUCKY

The Cincinnati area has become a strong hub for healthcare innovation, given its proximity to many major research and healthcare facilities. Over the last two years, several startups have attracted significant funding to improve patient experience:

Enable Injections, based in Mason, OH, is a medical device company that focuses on manufacturing at-home intravenous treatment platforms. Enable has raised more than \$300 million since it was founded in 2010 and has announced plans to build a \$45 million headquarters capable of holding more than 1,000 employees.²⁷

Bexion Pharmaceuticals is a mid-stage clinical biopharmaceutical company based in Covington, KY, that is developing new therapies for cancers and chemotherapy-induced peripheral neuropathy. Bexion recently announced their first patient dosed in its trial of a drug aimed to ease nerve damage in chemotherapy patients.²⁸

HerMD is a healthcare services company that operates female-focused centers dedicated women's health and providing a stigma-free environment. After raising \$10 million in March 2022,²⁹ HerMD has grown its telehealth capabilities as well as expanded physical locations beyond the Cincinnati area.³⁰

TeleSMART and **BandConnect** are two startups backed by University of Cincinnati's Venture Lab focused on developing products to assist at-home treatments.^{31 32}

The Cincinnati area features a number of hubs for healthcare innovation, including the **Cincinnati Innovation District**, which includes UC Health and Cincinnati Children's Hospital, and the **Northern Kentucky University Institute for Health Innovation**.

IMPACT OF RECENT ECONOMIC DOWNTURN ON HEALTHCARE INNOVATION

While 2021 and early 2022 saw a whirlwind of new startups and record funding, the momentum stalled with the economic downturn starting in Q1-Q2 2022. Digital health startups raised \$6 billion in the first quarter of 2022, an impressive amount when compared to historical numbers but below the \$7.3 billion raised in the fourth quarter of 2021. This decline started speculation that 2021 was the high-water mark for digital innovation,³³ which has largely proven to be true: through Q3 of 2022, digital health raised \$12.6 billion, well under the \$29.2 billion raised in all of 2021 (though close to the \$14.7 billion raised in 2020). The decline mirrors the broader downward trend for the tech industry in 2022, as reduced demand and higher labor costs hampered progress from an incredibly profitable year in 2021.³⁴

The economic downturn also had an impact on existing startups, many of which had increased staffing and capacity in 2020-2021 to meet surging demand. The wave of layoffs started when Ro, which had a \$7 billion valuation in early 2022, laid off 18% of its workforce in June 2022, citing the economic downturn as the cause.³⁵ Since then over 25 health tech startups have reduced staff, including Cerebral (mental health), Cedar (medical payments), Olive (healthcare AI), Calm (mental wellness), Noom (weight loss), and TruePill (digital pharmacy).³⁶

This downward turn, however, may have benefits. Many industry analysts and investors see the slowdown as a correction from the vast growth of 2021, and that startups with responsible oversight and solid foundations will thrive while others will be weeded out. Analysts feel that digital health innovation is still a strong need in the industry and the downturn will allow talent to be unlocked from poorer-performing companies as the market fluctuates. Some comparisons have been made to the dot-com crash of the early 2000s, which saw massive layoffs and company collapses but forged the enduring companies still around today.³⁷

FUTURE DIRECTION FOR HEALTH INNOVATION: BACK TO BASICS?

While tech solutions are the current focus of healthcare innovation, consumers may be looking to solve more mundane issues. When asked what element of healthcare they would most like to break down and rebuild, US consumers focused on the basics of receiving care: cost transparency, finding a new doctor, and making appointments. Consumers seem frustrated that, despite all the advances in medical technology, so many hoops remain to jump through when simply finding a new physician, making appointments, and understanding what a procedure is going to cost before it is conducted.³⁸

Basically, it's ludicrous that as a customer receiving a service, you don't know how much it will cost upfront. There's absolutely no need for it to be so opaque. I would want healthcare to be like pretty much everything else; before I consent to receiving something, you tell me how much it's going to cost.

- US HEALTHCARE CONSUMER, BURKE 2022 OMNIBUS PROGRAM

Price transparency is an especially difficult challenge, requiring collaboration between health insurance payers, hospital systems, and individual physicians. Recent legislation may be helping in this area, however: as of January 2021, hospitals are required to make clear and accessible pricing information available to consumers; health insurers were given the same requirement as of July 2022. With this information now freely available, innovators can create ways for consumers to easily compare prices for similar services.³⁹

In addition to the concerns of individual consumers, the healthcare industry faces broader challenges in 2023 that will require innovative solutions. Stubborn inflation and labor shortages will drive operating costs up, pressuring providers to find more cost-effective ways of delivering care. Treating endemic COVID-19 and long COVID will continue to be a burden, highlighting the need for more research and better prevention. Increasing cyberattacks on healthcare systems jeopardize patient data and require stronger defenses to prevent disruptions in care.

CONCLUSION: PERPETUAL DISRUPTION CREATES CONTINUED OPPORTUNITIES

While momentum for health innovation has slowed since its apex in late 2021/early 2022, the underlying issues driving innovation persist. Telehealth, behavioral health, and interoperability will likely remain top opportunity areas for innovators in 2023.^{40 41} Furthermore, the continued crises seen across the world—from COVID-19's persistence to the war in Ukraine to continued political polarization in the US—have created a perpetual sense of disruption to nearly all aspects of life. While this disruption creates many problems, it also opens the door to new ways of thinking on entrenched systems such as healthcare.

Healthcare innovators will continue to find solutions and efficiencies in the coming years, despite the recent economic downturn. While there are many barriers, the US healthcare system remains fertile ground for new ideas and processes. Improvements in technology, especially the ever-increasing capabilities of machine learning and artificial intelligence, are likely to be at the forefront of innovations for years to come. As these innovations mature, ideally it will lead to a healthcare system that is more efficient, available, and equitable for all consumers.

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