DISCUSSION PAPER

Telehealth and Mobile Health

Case Study for Understanding and Anticipating Emerging Science and Technology

Debra Mathews, PhD, MA, Johns Hopkins Berman Institute of Bioethics; **Amy Abernethy, MD, PhD,** Verily; **Atul J. Butte, MD, PhD, U**niversity of California, San Francisco; **Paul Ginsburg, PhD,** University of Southern California; **Bob Kocher,** Venrock; **Lewis Levy, MD,** Teladoc Health; **Catherine Novelli, JD, LLM,** Listening for America; **Lewis Sandy, MD,** Sulu Coaching; **John Smee, PhD,** Qualcomm Technologies, Inc.; **Rachel Fabi, PhD,** Upstate Medical University; **Anaeze C. Offodile II, MD, MPH,** Memorial Sloan Kettering Cancer Center; **Jacob S. Sherkow, JD, MA,** University of Illinois at Urbana-Champaign; **Rebecca D. Sullenger, BS,** Duke University School of Medicine; **Emma Freiling, BA,** National Academy of Medicine; and **Celynne Balatbat, BA,** National Academy of Medicine

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This discussion paper is one in a series of three that present case studies of emerging science and technology applications in order to better understand, anticipate, and develop governance for the development of similar emerging technologies, with attention to their potential societal, ethical, legal, and health-related impacts. These case studies were developed by members, academic collaborators, and staff of the National Academy of Medicine's Committee on Emerging Science, Technology, and Innovation in Health and Medicine (CESTI) and should be used to spur conversation and further investigation into the potential impacts of emerging technologies. Read more about CESTI at https://nam.edu/programs/committee-on-emerging-science-technology-and-innovation-in-health-and-medicine.

Introduction

This case study was developed as one of a set of three studies, focusing on somewhat mature but rapidly evolving technologies. These case studies are intended to draw out lessons for the development of a cross-sectoral governance framework for emerging technologies in health and medicine. The focus of the case studies is the governance ecosystem in the United States, though where appropriate, the international landscape is included to provide context. Each of these case studies:

- describes how governance of the technology has developed within and across sectors and how it has succeeded, created challenges, or fallen down;
- outlines ethical, legal, and social issues that arise within and across sectors;
- considers a multitude of factors (market incentives, intellectual property, etc.) that shape the evolution of emerging technologies; and
- identifies key stakeholders.

Each case study begins with two short vignettes designed to highlight and make concrete a subset of the ethical issues raised by the case (see *Box 1* and *Box 2*). These vignettes are not intended to be comprehensive but rather to provide a sense of the kinds of ethical issues being raised today by the technology in question.

The cases are structured by a set of guiding questions, outlined subsequently. These questions are followed by the historical context for the case to allow for clearer understanding of the trajectory and impact of the technology over time, and the current status (status quo) of the technology. The bulk of the case consists of a cross-sectoral analysis organized according to the following sectors: academia, health care/nonprofit, government, private sector, and volunteer/consumer. Of note, no system of dividing up the world will be perfect—there will inevitably be overlap and imperfect fits. For example, "government" could be broken into many categories, including international, national,

BOX 1 | Telehealth Vignette 1

In 2023, Park Pilhyun, a Korean immigrant and permanent resident, is living with his wife and young daughter in a remote town in Alaska. He receives psychiatric care for his depression from a doctor in Korea during a scheduled work break on his overnight shift in the plant where he works. This is very convenient for him, as he does not need to take time off work to access care, he is able to receive care in his native language, and his Korean doctor is less expensive than the mental health clinic in his town in Alaska. Pilhyun's care is assisted by a cognitive behavioral therapy mobile health app that monitors his behavior and app use, tracks symptoms, and provides education and coaching. At $10/month, it is more than he would like to pay, but it is not covered by insurance, and it seems to be helping.

Potential benefits: Access to mental health care, affordability, convenience, in native language with cultural competence

Potential concerns: Data privacy, reimbursement, cross-jurisdiction physician practice issues, liability, safety, efficacy, and regulation of mobile health apps

BOX 2 | Telehealth Vignette 2

In 2020, the Sanchez family all became symptomatic with COVID-19 following an exposure to Mr. Sanchez at the restaurant where he works. While Mrs. Sanchez and her mother have their green cards and the Sanchez children are U.S. citizens, Mr. Sanchez is an undocumented immigrant to the United States. The family was asked to isolate at home and were offered video visits with a nurse practitioner. The nurse became frustrated when, despite repeated reminder texts and messages through the patient portal, Mr. Sanchez was not available at the portal at the scheduled time; she ultimately resorted to telephone. The nurse learned from the teenaged son, who served as the translator for the phone call, that no one in the family had a primary care physician and that they were not familiar with the patient portal.

In their small apartment, private phone calls are impossible. Mr. Sanchez does not want to worry his family and so does not disclose to the nurse practitioner how severe his symptoms are, and without the video or the home blood pressure or pulse oximeter readings to which she had become accustomed, the nurse cannot adequately assess his condition. His family only realizes how sick Mr. Sanchez is days later, when he suddenly becomes very tired and unable to walk, and they must call an ambulance.

Potential benefits: At-home access to health care, access for all family members at the same time, convenience

Potential concerns: Personal privacy, care delays, safety, weak patient-provider relationship

tribal, sovereign, regional, state, city, civilian, or military. The sectoral analysis is further organized into the following domains: science and technology, governance and enforcement, affordability and reimbursement, private companies, and social and ethical considerations. Following the cross-sectoral analysis is a broad, nonsectoral list of additional questions regarding the ethical and societal implications raised by the technology.

The next section of the case is designed to broaden the lens beyond the history and current status of the technology at the center of the case. The "Beyond" section highlights additional technologies in the broad area the focal technology occupies (e.g., neurotechnology), as well as facilitating technologies that can expand the capacity or reach of the focal technology. The "Visioning" section is designed to stretch the imagination to envision the future development of the technology (and society), highlighting potential hopes and fears for one possible evolutionary trajectory that a governance framework should take into account.

Finally, lessons learned from the case are identified—including both the core case and the visioning exercise. These lessons will be used, along with the cases themselves, to help inform the development of a cross-sectoral governance framework, intended to be shaped and guided by a set of overarching principles. This governance framework will be created by a committee of the National Academies of Sciences, Engineering, and Medicine (https://www.nationalacademies.org/our-work/creating-a-framework-for-emerging-science-technology-and-innovation-in-health-and-medicine).

Case Study: Telehealth

As far back as the Civil War, the United States has used electronic means (in this early example, telegraphs) to communicate patient health information. After a long, slow ramp-up, there has been steady evolution and growth in electronic health data and communication since 1990, pulled by advances in technology and pushed by changes in regulation.

Prior to the COVID-19 pandemic, which began in March 2020, three broad trends were under way in the evolution of telehealth: first, a shift in application from efforts to expand health care access that motivated early use to the use of telehealth to control costs; second, the expansion of telehealth use from the context of acute care to the management of chronic conditions; and third, a transition of the site of care from health care institutions to patients' homes and mobile devices (Dorsey and Topol, 2016). The recent exponential increase in mobile health applications and physical distancing requirements that accompanied the pandemic have dramatically accelerated the evolution and adoption of telehealth (Olla and Shimskey, 2014).

It is important to note that "telehealth" and "mobile health (mHealth)" do not have consensus definitions, nor do many other terms used in this space, such as "electronic health (eHealth)," "telemedicine," and "digital health" (HealthIT.gov, 2019; Doarn et al., 2014; WHO, 2010). From a regulatory perspective, definitions are important because countries and states must describe what they do and do not regulate and how (Hashiguchi, 2020). In the United States, telehealth is generally the umbrella term covering telemedicine (defined as provider-based medical care at a distance); telemedicine within medical specialties such as telepsychiatry, telestroke, and teledermatology; and mHealth (initially used to describe care provision through text messaging, but now includes the use of wearable and ambient sensors, mobile apps, social media, and location-tracking technology in service of health and wellness) (APAa, 2020; Sim, 2019; CMS, 2011).

One widely used definition of telemedicine—the component of telehealth with the longest history—is from the World Health Organization (WHO), which defines it as, "The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interest of advancing the health of individuals and their communities" (WHO, 2010).

In Norway, an early adopter and regulator of telemedicine, "telemedicine" is defined by law as "the use of videoconferencing to perform an outpatient consultation, examination, or treatment at a distance" (Zanaboni et al., 2014). In South Africa, by contrast, telemedicine is defined not by statute but by the Health Professions Council of South Africa as "using electronic communications, information technology or other electronic means between a health care practitioner in one location and a health care practitioner in another location for the purpose of facilitating, improving and enhancing clinical, educational and scientific health care and research" (HPCSA, 2020).

Telehealth can include everything from medical websites (e.g., the Mayo Clinic, WebMD) to remotely controlled surgical robots. Telehealth can also be categorized into groups of technologies, including interactive telemedicine (including video visits and electronic consults between providers), telemonitoring, store-and-forward technology (the collection and use of non-urgent medical information), and mHealth.

Early applications of telehealth were designed to expand access, and in fact, telehealth has been critical (if not entirely successful) in this regard. There are, of course, long-standing and persistent concerns about the number and geographic distribution of health care providers, and telehealth has improved access to those in remote and historically underserved populations in states such as Alaska and Texas, as well as for those in the military (e.g., those at sea or in a combat zone), prisons, and astronauts (NRHA, n.d.). Telehealth has also expanded access to language interpreters and specialists for patients with rare disease.

Telehealth, as it is traditionally construed, offers significant benefits, but it also raises a number of concerns. These concerns pertain to the use of telehealth in and of itself and the ways in which availability has been exponentially and almost instantaneously expanded in response to the COVID-19 pandemic and in recent years by mHealth. One broad issue, at least in the United States prior to the COVID-19 pandemic, is the shift mentioned previously from a focus on the use of telehealth to expand access to health care to the use of this technology to cut health care costs (Dorsey and Topol, 2016). In addition, and despite the dramatic expansion in telehealth, many of those most in need remain without access to high-quality health care (Park et al., 2018). On the individual level, telehealth raises concerns not only about privacy, both due to the site of care and the transmission, storage, and sharing of data, but also about both concrete and intangible losses related to physical distancing from the care relationship and 'the healing touch' (Bauer, 2001).

Guiding Questions (derived from Global Neuroethics Summit Delegates, 2018; Mathews, 2017)

The following guiding questions were used to frame and develop this case study.

- **Historical context:** What are the key scientific antecedents and ethics touchstones?
- **Status quo:** What are the key questions, research areas, and products/applications today?
- **Cross-sectoral footprint:** Which individuals, groups, and institutions have an interest or role in emerging biomedical technology?

- **Ethical and societal implications:** What is morally at stake? What are the sources of ethical controversy? Does this technology or application raise different and unique equity concerns?

Additional guiding questions to consider include the following:

- **Key assumptions around technology:** What are the key assumptions of both the scientists around the technology and the other stakeholders that may impede communication and understanding or illuminate attitudes?
- **International context and relevant international comparisons:** How are the technology and associated ethics and governance landscape evolving internationally?
- **Legal and regulatory landscape:** What are the laws and policies that currently apply, and what are the holes or challenges in current oversight?
- **Social goals of the research:** What are the goals that are oriented toward improving the human condition? Are there other goals?

Historical Context

What are the key scientific antecedents and ethics touchstones?

Despite its association for most people with the last decade or even just with the COVID-19 pandemic, telehealth was first employed in the United States more than 100 years ago—one of the first health-related telephone calls was described in 1874 (Nesbitt and Katz-Bell, 2018). In 1905, the first "telecardiogram" was recorded and sent by telephone wire from a laboratory to a hospital (IOM, 2012). By the 1920s, Norwegian providers began giving medical advice to clinics on ships over radio, a use that quickly spread to other parts of the world (Ryu, 2010).

Over time, technology and applications expanded to include transmission of images and video. Teleradiology has been used for more than 60 years in the United States, with some of the first radiologic images transmitted by telephone between West Chester, Pennsylvania and Philadelphia, Pennsylvania, in 1948 (Gershon-Cohen and Cooley, 1950). Similar use in Canada soon followed.

The first use of interactive video in health care communications in the United States likely occurred at the University of Nebraska in 1959, through the transmission of neurological exams (Wittson and Benschoter, 1972). In an early and famous use of telemedicine, Norfolk State Hospital employees provided psychiatric consultations for the Nebraska Psychiatric Institute in the 1950s and 1960s (IOM, 1996). Wireless transfers of electrocardiogram and X-rays became prominent around this time as well (IOM, 1996).

In collaboration with the state of Arizona, the National Aeronautics and Space Administration (NASA) advanced satellite-based telemedicine in order to provide future care to astronauts, while also benefiting the Papago Indians in Arizona through a demonstration project called the STARPAHC (Space Technology Applied to Rural Papago Advanced Health Care) project (Freiburger et al., 2007). During the 1970s, the use of this technology spread to other parts of the United States, serving remote and historically underserved communities, such as those in Alaska (Nesbitt and Katz-Bell, 2018). However, without private-sector investment, such projects were not sustainable, leaving the populations they were designed help without the capacity to maintain the expanded access (Greene, 2020).

Following slow growth in the 1980s, the 1990s saw a great expansion of telehealth use and services through the development of statewide telemedicine projects, passage of state and federal legislation making telemedicine services reimbursable, and increasing affordability of telemedicine (Nesbitt and Katz-Bell, 2018). The hub-and-spoke model emerged in which multiple distant care sites were connected to a larger specialty health center. These programs were often funded through legislative appropriations or grants and focused on increasing outpatient access to specialty care (particularly for patients in remote or historically underserved areas) and provision of continuing provider education. Many health systems, which have traditionally operated as competitors, formed telehealth alliances, such as the New Mexico American Telemedicine Association, in order to decrease barriers to health care (Nesbitt and Katz-Bell, 2018).

State and federal governments recognized the need for adequate reimbursement to further expand telehealth. California led the way in passing the Telemedicine Development Act of 1996, which revoked the mandate of in-person visits between providers and patients and required the state's Medicaid program to reimburse telemedicine services (Andrews, 1996). Shortly after, other states passed similar legislation and addressed the need for providers to obtain telemedicine licensure (Nesbitt and Katz-Bell, 2018). Telemedicine reimbursement expanded to the federal level with the passage of the Balanced Budget Act of 1997, which mandated that Medicare reimburse certain telemedicine services (Puskin, 2001). However, reimbursement was restricted to a limited number of providers, Medicare enrollees in medically underserved rural areas only, and for only a limited set of the Centers for Medicare & Medicaid Services (CMS)-approved billing codes (Puskin, 2001).

Research on the efficacy of telehealth also dramatically increased in the 1990s. Publications from the Veterans Health Administration (VHA) and Kaiser Permanente added to the telehealth evidence base and suggested that home telehealth may benefit some patients (Darkins, 2014; Johnston et al., 2000). Telehealth also became more common in correctional facilities due to the costs and significant risks in transporting patients to physically see health care providers (Nesbitt and Katz-Bell, 2018).

Throughout the early 2000s, telemedicine platforms multiplied across states (every state had a platform by 2010) and around the world (Nesbitt and Katz-Bell, 2018). The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act, enacted in 2001, lowered barriers to telehealth in a number of ways, including requiring payment parity (equivalent payment for in-person and telemedicine visits) by Medicare, requiring Medicare to pay a $24 facility fee payment to the originating site for each telehealth visit, and expanding the range of telehealth services covered under Medicare (Gilman and Stensland, 2013; 106th Congress, 1999). In addition, Teladoc Health, now the world's largest telemedicine company, was launched in 2002 (Teladoc Health, 2022).

Inpatient and emergency care telehealth services then started to become more common. teleICU care increased and began to incorporate interactive video conferencing and smart alarms in intensive care units (ICUs) (Lilly et al., 2011). The Department of Veterans Affairs (VA) led the way in adapting telehealth to care for patients with chronic health conditions (Nesbitt and Katz-Bell, 2018).

In 2008, the Medicare Improvements for Patients and Providers Act further expanded both covered services and eligible providers, including community mental health centers (Gilman and Stensland, 2013). As internet speed and affordability improved, the Federal Communications Commission (FCC) provided grants to expand broadband to rural areas, further increasing the number of Americans who could access telehealth. In addition, the American Recovery and Reinvestment Act of 2009 helped expand telehealth services, with a focus on disaster preparedness (Nesbitt and Katz-Bell, 2018). The Office for the Advancement of Telehealth, within Health Resources and Services Administration (HRSA), part of the Department of Health and Human Services (HHS), helped start state clinical telehealth networks and funded telehealth research (Nesbitt and Katz-Bell, 2018).

By 2010, 11 states (California, Colorado, Georgia, Hawaii, Kentucky, Louisiana, Maine, New Hampshire, Oklahoma, Oregon, and Texas) had mandated that insurance payers cover telemedicine services (although each state's rules varied) (Nesbitt and Katz-Bell, 2018). In addition, 36 states covered telehealth services under Medicaid (CCHP, 2018). In 2011, CMS approved proxy credentialing of providers for telehealth services, greatly decreasing barriers to access. Although some state Medicaid programs began to reimburse for more telehealth services, there was tremendous variation across states (Nesbitt and Katz-Bell, 2018). In 2016, 48 states and Washington, DC, reimbursed for live video telemedicine services, and 19 reimbursed for remote patient monitoring (CCHP, 2021). However, despite significant improvements in access for many, telehealth has increasingly received more attention from venture capital than from the sort of government and nonprofit actors that might deliver on the original promise of telehealth for the expansion of health care access to low-income and rural populations (Greene, 2020).

By 2016, 46 percent of health care providers reported using multiple forms of telehealth technology in practice (HIMSS Analytics, 2016). At this time, the top seven diagnoses for Medicare beneficiaries receiving telehealth services were related to mental health (CMS, 2018). In 2020, 85.8 percent of Americans had access to the internet, suggesting that a greater proportion of people in the United States might be able to access telehealth services (Johnson, 2022). However, access to the internet is far from the only barrier to accessing telehealth, while it is a major barrier—others include language barriers between patients and providers, digital literacy, and access to equipment (more on this subsequently) (Park et al., 2018).

Status Quo

What are the key questions, research areas, and products or applications today?

Telehealth and telemedicine occupy a rapidly evolving evidence development and regulatory space. While the literature on telehealth effectiveness is limited, it is expanding rapidly. A 2019 Agency for Healthcare Research and Quality (AHRQ) evidence review included 106 studies of telehealth effectiveness (Seehusen and Azrak, 2019). While evidence was insufficient or low for many specialties, moderate strength of evidence was found for telehealth effectiveness in wound care, psychiatric care, and chronic disease management. Furthermore, patient satisfaction with telehealth services has been consistently found to be high (Orlando et al., 2019; Kruse et al., 2017).

International regulation of telemedicine varies widely. In contrast to other areas of complex regulation, there have been to date no generally applicable treaties governing telemedicine or attempts at legally harmonizing the practice across jurisdictions. This even includes an absence of general laws across countries that are otherwise bound together by supranational organizations like the European Union (EU) (Callens, 2010). Where specific regulations do exist governing telemedicine apart from traditional medicine, almost all countries broadly regulate telemedicine on a national or supranational level in contrast the United States' federalist (i.e., subnational) approach. Exceptions to this general observation include countries with similarly robust federalist structures like Spain, Australia, Canada, and, to a lesser extent, Germany, which, like the United States, allows subnational jurisdictions to implement their own regulations governing telemedicine (Hashiguchi, 2020). Countries that have specific broad, national legislation implementing a permissive approach to telemedicine include the Netherlands, Finland, Iceland, and Norway (Hashiguchi, 2020). Hungary stands, to date, as a major exception among countries with explicit telemedicine policy, with national legislation restricting (rather than permitting) the practice of telemedicine beyond what would be afforded absent the law (Hashiguchi, 2020).

In the United States, telehealth options for Medicare Advantage patients expanded in January 2020 with the enactment of the 2018 Bipartisan Budget Act, which removed requirements with respect to the originating (patient) and distant (physician) sites, allowing patients to access telehealth services from home (Contreras et al., 2020). In response to the COVID-19 pandemic, the U.S. federal government has relaxed many telehealth regulations and increased telehealth funding. The number of telemedicine visits dramatically increased across the country during the pandemic (Mehrotra et al., 2020). The CMS 1135 waiver and the Coronavirus Preparedness and Response Supplemental Appropriations Act, enacted in March 2020, expanded telehealth benefits for Medicare Advantage patients to patients with standard Medicare by removing requirements that patients be physically located within a health care facility in order to participate in telemedicine (116th Congress, 2020; CMS, 2020). CMS also established equivalent reimbursement (parity) for video telemedicine visits and traditional in-person visits (CMS, 2020). Furthermore, the HHS Office for Civil Rights relaxed the enforcement of software-based violations of the Health Insurance Portability and Accountability Act (HIPAA), enabling flexibility in platforms through which telemedicine is delivered, as huge amounts of health care shifted to telemedicine in a matter of days following the onset of the COVID-19 pandemic (HHS, 2020).

Medicaid has always allowed states the flexibility to reimburse telemedicine visits in whatever way they deemed best, and although many states already required private health insurance and Medicaid plans to cover telehealth, many more expanded these policies in response to the COVID-19 pandemic (APAb, 2022). Some states also relaxed state-specific licensure requirements, allowing providers to conduct telehealth (and teletherapy) services more easily across state lines, although as the pandemic wanes in the United States, states have begun rolling back such measures (PSYPACT, n.d.; Richardson et al., 2022).

Relaxed requirements and reduced barriers to access do not necessarily mean uniform increased utilization, however. A 2018 study found that from 2013 to 2016, though overall telehealth use increased dramatically, this increased use was largely driven by higher-income populations and younger Medicare beneficiaries (Park et al., 2018). Telehealth was less likely to be used by Medicaid beneficiaries and low-income and rural populations, even in states with less restrictive state telehealth policies (Park et al., 2018).

mHealth is much newer than telehealth, and its evidence base is smaller, but it is rapidly growing, seeing $8.1 billion in investments in 2018, aided tremendously by the high-powered computers the vast majority of us carry on our persons, the smartphone, which is designed to track our motion and position in three-dimensional space (Day and Zweig, 2019). mHealth app and device developers have taken advantage of this capacity to turn smartphones into fall detectors, spirometers, heart-rate sensors, and much more, not only expanding diagnostic and treatment options but also generating new kinds of health data and evidence (Sim, 2019). The Apple Health app can combine data collected from the iPhone or Apple watch with a consumer/patient's electronic health record. The lucrative segment of mHealth focused on concierge care for those with means does expand access to care, but not in the way originally envisioned in the 1970s (Greene, 2020).

Apps specific to COVID-19 have also proliferated in the mHealth space. A survey of iOS and Android apps available between April 27 and May 2, 2020, identified 114 COVID-related apps, 84 (74%) of which were categorized as either health and well-being/fitness or medicine apps. About half of all apps were developed by regional or national governments, and all but one was free (Collado-Borrell et al., 2020).

As alluded to previously, access to the full range of telehealth services is dependent on access to high-speed internet ("broadband"), although it is important to note that a great deal of telehealth still happens by phone. According to the 2018 American Communities Survey (ACS), 18 million U.S. households lacked access to broadband, 60 percent of which had household incomes below $35,000/year (Siefer and Callahan, 2020). Additionally, the substantial racial disparities present in access to broadband can exacerbate racial disparities in use of telehealth (Singh et al., 2020). Internationally, it has been suggested that a 10 percent increase in internet access yields 1–2 percent increase in GDP (DeLaTorre, 2022). Policies aiming to address the "digital divide" are often targeted at building internet infrastructure in rural areas, but many Americans who lack access to broadband actually live in urban regions and are simply unable to afford all but the slowest internet speeds—a fact that has been made clear by stories of children and parents doing their schooling and jobs from the parking lots of public libraries and fast food restaurants during the COVID-19 pandemic (Greene, 2020; Kang, 2020). More inclusive efforts to close the digital divide have emerged, particularly in response to the growing need for broadband in the era of COVID-19. The HEROES Act, a COVID-19 relief bill passed by the U.S. House of Representatives in May 2020, included significant funding to help low-income households pay for broadband and acquire internet-capable devices, as well as funding to expand broadband access to urban health care providers left out of previous efforts to reach rural providers, though it did not receive a vote in the Senate (116th Congress, 2020; Cochrane, 2020). Versions of many of these provisions were maintained in the $900 billion stimulus bill that was signed into law in December 2020 (Montague, 2020).

Currently, the regulation of telehealth in the United States is at a major inflection point. The COVID-19 pandemic has dramatically altered the way that health care is sought and provided, and it is unlikely that the practice of medicine will return to the pre-COVID-19 status quo after the pandemic recedes. The rapid expansion in use of, and reimbursement for, telehealth services in the face of a global pandemic has accelerated the shift from

traditional in-person medicine to a normalization of telemedicine. Similarly, the use of (largely non-evidence-based) health and wellness apps, as well as apps that enable digital contact tracing, has expanded over the course of the pandemic. How these products will be used and regulated in a post-COVID-19 world remains to be seen (Figueroa and Aguilera, 2020; JHU, 2020; Lagasse, 2020).

Cross-Sectoral Footprint

The cross-sectoral analysis is structured according to sectors (academia, health care, private sector, government, and volunteer/consumer—see *Figure 1*) and domains (science and technology, governance and enforcement, end-user affordability and insurance reimbursement [affordability and reimbursement], private companies, and social and ethical considerations). The sectors described subsequently are intended to be sufficiently broad to encompass a number of individuals, groups, and institutions that have an interest or role in telehealth. Health care is the primary nonprofit actor of interest, and so in this structure, 'health care' has replaced 'nonprofit', though other nonprofit actors may have a role in this and other emerging technologies, and, of course, not all health care institutions are nonprofits.

Today, many telehealth technologies are researched, developed, and promoted by a scientific-industrial complex largely driven by market-oriented goals. The development of various components of telehealth may be altered by differing IP regimes. This larger ecosystem is also embedded in a broad geopolitical context, in which the political and the economic are deeply intertwined, shaping national and regional investment and regulation. The political economy of emerging technologies involves and affects not only global markets and regulatory systems across different levels of government but also non-state actors and international governance bodies. Individuals and societies subsequently adopt emerging technologies, adjusting their own values, attitudes, and norms as necessary, even as these technologies begin to shape the environments where they are deployed or adopted. Furthermore, individual and collective interests may change as the "hype cycle" of an emerging technology evolves (Gartner, n.d.). Stakeholders in this process may include researchers, technologists, business firms and industry associations, government officials, civil society groups, worker safety groups, privacy advocates, and environmental protection groups, as well as economic and social justice-focused stakeholders (Marchant et al., 2014).

This intricate ecosystem of stakeholders and interests may be further complicated by the simultaneous introduction of other technologies and platforms with different constellations of ethical issues, modes of governance, and political economy contexts. In contrast to the development of therapeutics or, to a lesser extent, medical devices, the development of telehealth technologies and platforms has not appeared to be controlled by the availability of intellectual property (McGowan et al., 2012). Subsequently, this ecosystem is disaggregated and organized for ease of presentation. This section will address both telehealth and mHealth but will endeavor to address telehealth first and then mHealth in the subsections. It is important to keep in mind that there are entanglements and feedback loops between and among the different sectors, such that pulling on a single thread in one sector often affects multiple areas and actors across the broader ecosystem.

Cross-Sectoral Analysis

Academia

For the purposes of this case study, the primary actors within the academic sector interested are those engaging in cost-effectiveness, comparative effectiveness, health services, basic and trans-

FIGURE 1 | Sectors for Cross-Sectoral Analysis

SOURCE: Developed by authors.

lational device, and mHealth research; and scholars working in bioethics.

- *Science and technology:* Research on telemedicine has been conducted for decades, primarily focusing on effectiveness and cost relative to traditional in-person care (Torre-Diez et al., 2015). While the literature on telehealth effectiveness is limited, it is expanding rapidly. A 2019 AHRQ evidence review included 106 studies of telehealth effectiveness (Seehusen and Azrak, 2019). While evidence was insufficient or low for many specialties, moderate strength of evidence was found for telehealth effectiveness in wound care, psychiatric care, and chronic disease management. Furthermore, patient satisfaction with telehealth services has been consistently found to be high (Orlando et al., 2019). The evidence base for the use of telehealth and wellness apps (mHealth) is small, and more research is needed, particularly on the effects these technologies may have on reducing or exacerbating existing health disparities.
- *Governance and enforcement:* Within the research context, governance is primarily through institutional human subject research review boards and research ethics boards, research funding bodies, academic publication standards, and scientific and professional societies (i.e., self-regulation).
- *Affordability and reimbursement:* N/A
- *Private companies:* N/A
- *Social and ethical considerations:* There has been some academic research on social factors related to telehealth adoption and use, as well as ethical issues associated with telehealth adoption. There are related, growing literatures on the privacy and other implications of persistent data collection, big data, digital phenotyping, and so forth, with direct relevance to mHealth.

Health Care

Given the focus of CESTI on health and medicine, for the purpose of this case study, the primary actors within the nonprofit sector are those involved in health care.

- *Science and technology:* As noted previously, research on efficacy across specialties is ongoing but limited.
- *Governance and enforcement:* Health care systems are the main hubs for telemedicine. Their use of these technologies is subject to HIPAA regulation, as well as the licensing requirements of the state in which they operate. Proposals related to licensing for practicing across state lines could potentially change the reach of health systems (e.g., a proposal that licensing requirements only apply for the location of the telemedicine provider would enable a provider in a health system located in only one state to reach patients across the country) (Lee et al., 2020).

  Physicians are governed by their respective state licensing boards. In general—and with the exception of psychiatry—state licensing boards do not grant their physicians blanket permissions or prohibitions to practice telemedicine, requiring only (again, in general) that physicians provide their patients "competent care" (APAb, 2022).

  Professional bodies have also developed position papers regarding telehealth, including in the context of the pandemic (AHA, 2020). In Europe, there are cross-sectoral committees that include academics, industry/technology representatives, and regulators; similarly cross-sectoral committees were established in the United States to address the COVID-19 pandemic (NIH, 2020). These committees could potentially serve as a model for coordination of cross-sectoral governance of emerging technologies.
- *Affordability and reimbursement:* The United States' multimodal payer system makes reimbursement and payment for medical services in the United States difficult to summarize. Federally organized public payers (e.g., Medicare, Medicaid, the VHA) are largely governed by federal law, while strictures on state-level public and private payers are governed by state law. Each payer—including administrative agencies—sets different rates and schedules for each service, including those pertaining to telemedicine. Beyond this, states may have additional laws in place governing which services must be covered by private insurers.

  Parity in reimbursement between in-person and telemedicine-based services remains an issue, and laws in some states require insurers to reimburse telemedicine visits at the same rate as in-person visits. From a health system perspective, this might make telemedicine an attractive option, as it is often less expensive to provide relative to traditional face-to-face care, though state medical boards have often required an in-person consultation before allowing for telehealth services (Lee et al., 2020). Furthermore, the traditional reimbursement model does not incentivize physicians to use telemedicine because they get paid more for in-person services and procedures (Goldberg et al., 2022). There are also basic questions related to implementation of telemedicine more broadly: What are the clinical workflows for telehealth care? How can physicians/health systems leverage and utilize remote monitoring effectively? How does data flow into the health system? Should these data be integrated with the medical record, and if so, how? Who is responsible for understanding and analyzing a potentially near-real-time stream of patient data? What are the shared expectations and liability concerns around these new platforms?

- *Private companies:* Health care institutions partner with private companies that provide many enabling technologies for telehealth, including telemedicine care delivery platforms, monitoring and management technologies, mHealth apps, and more. While some of these technologies may be protected by trade secrets (e.g., confidential algorithms), few are robustly protected by patents given the difficulties in patenting software applications (Price, 2015). Furthermore, there have been calls for more rigorous testing of many of these technologies for clinical effectiveness (Sim, 2019).
- *Social and ethical considerations:* While health data in the United States is regulated by HIPAA, there is no blanket data privacy law (104th Congress, 1996). Data privacy, like medical consent, is largely an issue of contract and tort. Data privacy is arguably the principal international issue concerning telemedicine regulation. Most significantly, the European Union's General Data Protection Regulation (GDPR) provides a robust set of rights to individuals' "personal data," that is, "any information relating to an identified or identifiable natural person" (European Parliament, 2016). This includes the right to forbid its collection; to demand a third party destroy it; and, if electronic, to download it where it resides. Health data, specifically, receives further protections under the GDPR (although there are public health exceptions). The GDPR's reach is not only cabined within the European Union but extends to anywhere in the world where the processing of European citizens' data occurs. Penalties for noncompliance can be stiff (European Parliament, 2016). While other countries invested in telemedicine—including Colombia, Costa Rica, and Peru—have data privacy laws, the GDPR seems unique in its global reach and effect on data transmission practices.

  In most countries, patient consent for telemedicine tracks with each respective country's model for other forms of health care delivery. For example, where delivery operates at the physician level, patients' consent typically is obtained through their physicians. Notable exceptions include Japan and Greece, which require explicit consent from patients before physicians can conduct treatment through telemedicine (Hashiguchi, 2020).

  Physicians, particularly in subspecialties conducive to telemedicine (e.g., dermatology and psychiatry) may have workforce concerns as restrictions on cross-jurisdictional medical practice are relaxed. Providers may resist lowering licensing barriers as this could allow for competition from other states' telehealth services (IOM, 2012).

  As mentioned previously, the digital divide has significant equity implications for telehealth access, in addition to other challenges, including language barriers between patients and providers, digital literacy, and access to necessary equipment (Park et al., 2018). There are special issues related to safety, efficacy, and privacy/data security when mHealth devices/toys are used in the treatment of children (Comscore, 2014).

Private Sector

For the purposes of this case study, the primary actors within the private sector are digital health platform providers, startups, and app developers.

- *Science and technology:* Telehealth startups are currently targeting large, self-insured employers with strong incentives to keep costs low (Dorsey and Topol, 2016). mHealth apps have been developed for a wide array of purposes, including tracking fertility and exercise; diabetes management; medication adherence; treating depression, anxiety, and traumatic brain injury; and preventing suicide.
- *Governance and enforcement:* Many companies in the telemedicine space offer services designed to help physicians do their jobs and so fall under the umbrella of "physician practice," which is not regulated by the U.S. Food and Drug Administration (FDA). Telemedicine platforms used by health systems are subject to stronger scrutiny, but in the interest of expanding access to telemedicine during the COVID-19 pandemic, the HHS Office for Civil Rights has "waived penalties for HIPAA violations against health care providers that serve patients through everyday communications technologies" during the public health emergency (HHS, 2020). There are thousands of health- and wellness-focused apps available for smartphones, some of which make dubious or unproven claims about their effectiveness. In addition to a shallow evidence base about the effectiveness of many health and wellness apps, they also raise significant privacy concerns because they are not all governed by the same privacy laws (like HIPAA) that protect sensitive patient information in traditional care settings (Singer, 2019). While some companies may be required or choose to engage third-party compliance services to monitor their data security, this is not a legal requirement for all.

  The FDA's Digital Health Software Precertification (Pre-Cert) Program has piloted new ways of regulating software-based medical devices, but this regulatory innovation has faced pushback from the U.S. Congress, suggesting that such innovation will be challenging (FDA, 2021; Warren et al., 2018).

- *Affordability and reimbursement:* As described in more detail subsequently, states can and have mandated that commercial insurance plans offer parity for telemedicine visits (Yang, 2016). Historically, concern about medical liability has been a persistent barrier to the broader adoption of telemedicine (WHO, 2010). The United States, which has a robust medical practice tort system, appears to assign liability in much the same way for errors in telemedicine as it does for traditional practice. There is frequently lack of clarity about who should pay for mHealth technology, in particular when prescribed by a physician. Many mHealth apps are free or low-cost to download, though the safety and efficacy of many of these apps are unclear, and there are significant associated data privacy concerns.

  As noted previously, an explicit goal of telehealth has long been expanded access in rural and remote areas. There are a number of companies that seek to address barriers to health and health care beyond geographic barriers and are focused squarely on improving equity in health care, such as ConsejoSano (SameSky Health), Hazel Health, and CareMessage (CareMessage, n.d., Hazel, n.d.; SameSky Health, n.d.).

  At the same time, another major driver of telehealth is lowering the cost of health care. Insurers are motivated by the low cost of telehealth compared to the high cost of in-person care and self-insured employers also highly motivated to reduce costs and maintain a healthy workforce.
- *Private companies:* One assessment of digital health startups highlighted 150 companies that had collectively raised more than $20 billion, and which had among them established partnerships with the American Heart Association, Sanofi, Cigna, Mount Sinai Health System, Mercy Health, and Arizona Care Network, demonstrating tremendous interest and growth in this space (CBInsights, 2021). Apple has partnered with both Aetna and the government of Singapore to incentivize individuals to engage in health-promoting behaviors. Fitbit has a similar partnership with United Health (Aetna, n.d.; Elegant, 2020; Gurdus, 2017).
- *Social and ethical considerations:* Significant concerns about privacy, transparency, and accountability with regard to the algorithms and data generation by commercial devices and apps. As noted previously, there have been calls for more rigorous testing of many of these technologies for clinical effectiveness (Sim, 2019). The is often a wide range of third parties involved in telehealth delivery, some of which will be outside the "covered entity" and be governed by different (or few) rules (Gerke et al., 2020). Equity concerns are raised by algorithms trained on the healthy, well-off, and White.

Government

For the purposes of this case study, the primary actors within the government sector are both the federal government and the states, which play critical gatekeeping (or facilitating) roles in the development and evolution of telehealth.

- *Science and technology:* As noted previously, NASA and the VA have been leaders in telehealth research and development. The federal government also partners with tribal governments to administer the Indian Health Service (IHS), which provides care to American Indian/Alaska Native (AI/AN) people across the country. Telemedicine is particularly important to the work of the IHS due to the rurality of many AI/AN communities, which has led to innovation in telehealth systems (Hays et al., 2014). The IHS also has a Telebehavioral Health Center of Excellence, which offers behavioral health care and mental health care through multiple telehealth modalities (IHS, n.d.).
- *Governance and enforcement:* U.S. federal and state governments have significant interests in the governance of telehealth. Prime among these is their interest in requiring public and private insurers to provide reimbursement for telemedicine services. As a result of the COVID-19 pandemic, CMS has waived reimbursement requirements that patients be physically located within a health center when receiving telemedicine services, making it possible for millions to access care safely from their homes. Every state has different reimbursement requirements for their state Medicaid plan, and states also have the power to control reimbursement parity for commercial insurance, which has led to the development of essentially 50 different reimbursement policies across the country.

  As noted, the VA has been a leader in telehealth adoption and implementation, as they retain significant control over telemedicine and telehealth offered within the VHA, including control over licensure requirements and copay amounts (CRS, 2019). Since 2012, the VA secretary has had the ability to waive copays for telemedicine provided to veterans in their homes, and VA-employed providers can practice telemedicine across state lines with any patients within the VHA (CRS, 2019).

  Another key role for the government is the protection of protected health information (PHI)—personally identifiable information that relates to a medical condition, the provision of care, or payment—which is regulated via HIPAA (104th Congress, 1996). HIPAA establishes restrictions on the dissemination of PHI by "covered enti-

ties"—providers, plans, clearinghouses, or business—without the express consent of the patient.

HIPAA is of particular concern in telemedicine because PHI is necessarily generated in telemonitoring and store-and-forward technologies. In addition, the nature of telemedicine is such that users of telemonitoring and store-and-forward technologies are almost certainly "covered entities" under the statute, that is, providers, businesses, or health care plans. In addition, HIPAA demands extra precautions from covered entities for most telemedicine applications under the HIPAA Security Rule, a regulation promulgated by HHS that concerns electronic PHI (CFR, 2011). Prior to the COVID-19 pandemic, the HIPAA Security Rule limited the types of platforms that could be used for the transmission of electronic PHI. In March 2020, the HHS Office for Civil Rights issued a Notification of Enforcement Discretion indicating that providers who engage in telemedicine using non-public-facing communication technologies in good faith will not be subject to penalties for noncompliance with HIPAA rules (HHS, 2021).

With respect to medical devices used in telemedicine, these are typically regulated at the federal level by the FDA (94th Congress, 1976). For example, the Da Vinci Xi Surgical System, a robotic surgical assistant and a form of interactive telemedicine, is regulated by the FDA as a Class II device (Stevenson, 2017).

Telemedicine encompasses devices in all three risk classes, from a WiFi-enabled digital pulse oximeter (Class I) to remotely controlled continuous glucose monitoring systems (Class III). In some instances, FDA considers software to constitute a medical device (FDA, 2017).

- *Affordability and reimbursement:* See the previous discussion of reimbursement. Various national efforts to expand internet access have been key to the expansion of telehealth access, and will continue to be critical moving forward, as advanced technologies demand higher bandwidth.
- *Private companies:* N/A
- *Social and ethical considerations:* Ethical issues raised by telehealth in the government sector include disparities in telehealth (and broadband) access, fiduciary duties of health care providers, privacy, equity, and workforce concerns.

Volunteer/Consumer

For the purposes of this case study, the primary actors within the volunteer/consumer sector are patients and consumers accessing telehealth, including mHealth. It is important to keep in mind that many members of "the public" nationally and internationally never have the opportunity to be patients or consumers of emerging technologies, and so do not show up in the following analysis. These members of the public may nonetheless be affected by the development, deployment, and use of such technologies, and those impacts should be taken into account.

- *Science and technology:* Prior to the COVID-19 pandemic, mHealth apps may have been most people's primary experience with telehealth, as many of these apps are free or low-cost to download for iOS and Android phones (Friedman et al., 2022). There is little data available on the safety and efficacy of many of these apps.
- *Governance and enforcement:* Currently, there is little regulatory enforcement of many mHealth apps, though a number of mHealth devices have received FDA clearance.
- *Affordability and reimbursement:* As noted previously, insurance coverage for telehealth has expanded dramatically in recent years, and particularly since the start of the COVID-19 pandemic. mHealth apps are free or low-cost to download, though they require that the consumer have a smartphone and internet access.
- *Private companies:* These include mHealth app developers and companies like Apple and FitBit, offering direct-to-consumer health and wellness applications outside health care institutions and employee-sponsored wellness programs.
- *Social and ethical considerations:* Potential drivers include adult children caring for aging parents at a distance, seeking the capacity to both monitor their parents' health and safety and communicate with their parents' health care providers; concerns about equity regarding access if Apple continues to expand in the mHealth space and Android continues to lag (more than half of U.S. smartphone owners have Androids, and Android users have a lower average income than iPhone users); and concerns about the use of mHealth devices/toys with children in regard to safety, efficacy, and privacy/data security (Comscore, 2014).

Ethical and Societal Implications

What is morally at stake? What are the sources of ethical controversy? Does this technology/application raise different and unique equity concerns?

In outlining the concerns of the authors in terms of the use of this technology, we considered the following ethical dimensions, as outlined in the recent National Academies of Sciences, Engineering, and Medicine report *A Framework for Addressing Ethical Dimensions of Emerging and Innovative Biomedical Technologies: A Synthesis of Relevant National Academies Reports* (NASEM, 2019).

- Promote societal value
- Minimize negative societal impact
- Protect the interests of research participants
- Advance the interests of patients
- Maximize scientific rigor and data quality
- Engage relevant communities
- Ensure oversight and accountability
- Recognize appropriate government and policy roles

It is important to keep in mind that different uses of this technology in different populations and contexts will raise different constellations of issues. For example, telephone-based telehealth can be very different than video- or app-based telehealth, with different implications when used to serve urban, high-income adults versus rural, low-income children. Some of the specific concerns might include the following (Nittari et al., 2020):

- Is the quality of care delivered via any given telehealth platform of comparable quality to in-person care? What is gained? What is lost?
- How does a focus on efficiency or cost savings affect compassion/patient welfare? (Jacobs, 2019)
- How is continuity of care affected by communication gaps or barriers between providers at a distance, the patient, a physically present clinical care team, mHealth applications, and documentation in the medical record?
- Are there risks to safety associated with virtual physical exams and treatment?
- What is the effect on the physician–patient relationship and the establishment of trust in the absence of any physical interaction?
- What are the risks to patient privacy and confidentiality, particularly in mHealth, and how can they be mitigated?
- What kind of access to and control over data produced by mHealth devices do patients/consumers have?
- What are the proprietary interests over domains of fragmented patient data and how do they affect care?
- How can governance address the blurring boundary between personal medical data, public health data, and monetized consumer data?
- What ought the requirements be for content and documentation of informed consent for telehealth as a mode of care, and within telehealth, for example, for the transmission and processing of health data?
- How should countries regulate telemedicine when telemedicine services and patients are split across jurisdictions? When the operation of devices is split across jurisdictions?
- How will the changing global political climate likely affect the regulation of telemedicine?
- What are the issues raised by telemedicine across state and national borders, including both ethical (e.g., lack of cultural awareness or familiarity) and legal (e.g., cross-jurisdictional credentialing, regulation, liability)?
- What is the level of reliability and fidelity of data transmitted from mHealth devices?
- Who, how, and with what permissions can various actors access, store, and use the vast amounts of data generated by various telehealth interactions?
- How transparent and accountable are the algorithms used by commercial telehealth devices/apps, as well as the data collection, storage, and use by telehealth companies?
- Which entities involved in telehealth are outside the "covered entity" for the purposes of HIPAA, and how do they collect, store, and use patient data?
- Will a shift to telehealth increase or decrease the isolation and quality of life of historically underserved and marginalized populations, including the elderly, and others with visual, hearing, or cognitive impairments? What about caregivers managing a dependent's telehealth participation?

Beyond Telehealth

mHealth "is at the swirling confluence of remote sensing, consumer-facing personal technologies, and artificial intelligence (AI)" (Sim, 2019). Currently, AI, wearable and ambient sensors, and other emerging technologies are being used in research and are able to suggest future possibilities, but these have not yet been realized in the market. AI, of course, brings with it a whole host of additional concerns related not only to the technical challenges, including reliability and explainability of autonomous systems but also significant ethical concerns, including those related to bias in training data leading to structural racism being replicated at scale with AI, trust, trustworthiness of systems, and so on. Smart homes, also in ascendance, hold potential in the telehealth space, but the potential health benefits (and risks) remain largely in the future.

Visioning

As alluded to previously, it is possible to foresee numerous future scenarios regarding the evolution of telehealth. In an effort to probe the kinds of worries the authors have about the trajectories of emerging technologies, to expand the range of lessons learned from each case, and ultimately to "pressure test" the governance framework, the authors have developed a brief "visioning" narrative that pushes the technology presented in the core case 10–15 years into the future, playing out one plausible (but imagined) trajectory. The narrative was developed iteratively in collaboration with a case-specific working group, with additional feedback from members of CESTI. All reviewers are acknowledged in the back matter of this paper. Each narrative is told from a particular perspective and is designed to highlight a

small set of social shifts that shape and are shaped by the evolving technology.

Telehealth Case Visioning Narrative

Perspective: A remote caregiver and digital health navigator dyad

Background

It is 2035, and the home has become the preferred site for the receipt of most acute and non-acute medical services (labs, imaging, nursing visits, retail pharmacy) in the United States. Termed hospital-at-home (HaH), it is also the dominant model for non-ICU-level in-person care in much of the world. Although this care paradigm has been around for decades, the COVID-19 pandemic catalyzed this shift due to physical distancing requirements and fears among patients about contracting the virus within the hospital setting. Massive investments from the private sector into telemedicine platforms, coupled with technology advancements in AI-enabled remote monitoring, voice-activated medical devices, augmented reality, and sensors were also pivotal in this care transformation. Results from randomized controlled trials showed that the HaH was just as effective as the traditional hospital setting for a wide range of medical conditions, and with lower cost. However, the data on patient safety has been mixed thus far, with certain kinds of care episodes demonstrating clear reductions in adverse events while others result in poorer outcomes, often due to poor recognition of the need for escalation to emergency care (e.g., malignant bowel obstruction being mistaken for constipation). Hospital visits are increasingly limited to serious conditions that mandate an in-person work-up (e.g., biopsy for a cancer diagnosis) or procedural intervention (e.g., surgical procedure or cardiac catheterization).

Chronic Disease Management

Beyond increasing access to specialty providers (physicians, nurses, pharmacists, physical therapists), this new care paradigm revolutionized chronic disease management. Through "digital touchpoints," providers were able to durably increase patients' engagement with their own self-care and remotely manage the trajectory of chronic diseases at increasingly earlier time points. By leveraging ambient clinical intelligence tools (i.e., Internet of Medical Things [IoMT]), all data became re-imagined as health care data, including music preferences, voice pitch, communication logs, gait, step counts, and sleep patterns—a process known as digital phenotyping. In this new personalized care paradigm, conditions such as hypertension, diabetes, heart failure, and renal insufficiency were now managed prospectively and continuously as opposed to in a reactive and episodic fashion. Patients could now be managed within the context of their lives, and for many, this meant the ability to safely "age in place." However, over time questions arose as to how the governance of emerging technologies intersects with the provision of care in the home. Specifically, issues regarding data standards, quality assurance, interoperability, oversight, bias, and transparency were yet to be definitively addressed in the context of care delivery. Whom should be held legally responsible in instances of harm due to erroneous automated diagnosis? How can the authenticity, accuracy, and integrity of such a wide variety of devices be reliably established?

Impact on Equity

Unfortunately, HaH in some cases led to a widening of existing equity gaps. This is because many of the infrastructural technologies were not developed through the lens of equity or cultural competency (e.g., to account for language barriers, vision/hearing/physical impairments, digital and health literacy, or other impacts of the social determinants of health). Non-English-speaking patients who were more than 80 years of age had tremendous difficulty engaging with this care model, as their communication preferences were more consistent with an in-person encounter. Although HaH uptake was relatively low in areas of high economic deprivation due to poor infrastructure and add-on device costs (smartphones and sensing equipment), great strides were made in improving access to rural communities, in step with investments in broadband and satellite internet service. For the first time, specialty care became available in many areas previously described as "medical deserts." There was also growing recognition that HaH models implicitly exclude individuals experiencing unstable housing or homelessness.

Impact on the Health Care Workforce

The often ad hoc implementation of these virtual workflows sent prevailing levels of physician burnout soaring even higher due to the lack of clear practice guidelines, time to engage with the data and patient communication that these systems generate, and concerns for liability exposure. Lengthy wait times were reported in many urban areas, as physicians now had to manage two distinct clinic schedules (in-person and virtual). There was also considerable displacement of many health care provider roles due to automation and the transition to HaH. Custodial staff, nursing assistants, clerical workers, and some administrative staff roles were transitioned out of the traditional medical infrastructure and into caretaker or home health worker roles. For those "essential health care workers" such as nurses and physicians, retraining was set in motion by credentialing bodies to ensure that fluency in statistics, data science, and information systems became core competencies, allowing these workers to remain relevant and effective in the new digital age. Rote memorization of medical facts was no longer the norm in medical schools. A stronger emphasis was also placed on the human skills that cannot be displaced with automation such as empathy, physical examination, and implicit bias awareness. New health care roles also emerged in this data-rich delivery paradigm, such as digital health navigators, telenurses, and health data specialists. How-

ever, many of these new positions and several traditional ones (e.g., physicians, nurses, care coordinators) were increasingly outsourced to global vendors in an attempt to reduce the administrative costs of health care. In this distributed staffing model, international hubs of excellence also began to emerge for certain conditions or treatments (e.g., Sweden for the best interpretation of radiology images). With this in mind, the broader question of how to appropriately regulate remote second opinions across international borders arose. What licensure requirements should be enforced for the practice of international telemedicine? In an increasingly networked world, do state-based licensures still make sense? Calls for the nationalization of medical licensure, or at a minimum the harmonization of requirements across states, were proposed by a variety of stakeholders.

Data Privacy, Trust, and the Wisdom of Crowds

Mr. Jeff Jackson is a 63-year-old Black male with hard-to-control type 2 diabetes, early-onset Alzheimer's disease, and stable chronic heart failure (CHF). He has chosen to live alone in Youngstown, Ohio, since his wife died 5 years ago. An implanted microchip is able to sample, interpret, and transmit biometric (heart rate, temperature, oxygen saturation) and biochemical data (blood glucose, sodium levels, creatinine levels) about Mr. Jackson at high frequency. AI algorithms embedded within wall-mounted camera-based sensors are also able to detect the progression of his Alzheimer's or warning signs of acute exacerbations of his CHF. All of this information is relayed 24/7 to a "digital health navigator" assigned by his health plan who serves as a health coach and care coordinator. As outlined in the consent agreement, monthly summaries of routine care are sent to his 23-year-old daughter, Jean, who resides in Miami, Florida. Potentially concerning events sensed in Ohio automatically trigger real-time "red alerts" to both the digital navigator and Jean. Arrangements like this raised many questions during their rollout, including but not limited to the potential vulnerability of these technologies to data breaches and cyberattacks, particularly since the identifiable medical record of every U.S. patient was transitioned to the cloud to facilitate interoperability and timely access. Should HIPAA include the home digital infrastructure in its scope? Under what circumstance should employers or insurance companies have access to personal data? What should be the recourse for care episodes involving harm due to egregious digital navigator negligence? Lastly, instances wherein elder or child abuse or domestic violence were detected using camera-based sensors ("bycatching") raised ethical concerns as to whether the gravity of these offenses justified circumventing the confidentiality, privacy, and anonymity of involved patients and family members. These events also give rise to the broader question of who owns or is able to repossess these data. Will commercial entities be able to contract and monetize passively captured (audio or video) personal information (e.g., targeted advertising on social media based on fridge contents)?

About 6 months ago, based on his personality traits, risk preferences, and at the strong suggestion of his daughter, Jeff joined a health platform called "All2Gether" that linked individuals across the globe based on more than 200 phenotypes. The goal was to provide phenotype-specific social support to reduce loneliness. The platform offered crowd-sourced medical advice based on lived experiences, behavioral change interventions, and in some instances, mental health therapies based on biofeedback techniques. The much-heralded age of "democratizing medical knowledge" had finally arrived, with these platforms now able to serve millions of people worldwide and drive robust engagement. Over time, Jean had grown much more comfortable entrusting her father's health data to these cloud-based platforms, rather than a primary care physician or the digital health navigation company. For Jean, this mistrust in her father's primary care physician and the digital health navigation company was undergirded by the fact that neither she nor Jeff had direct access to the raw data or proprietary algorithms that informed his care. Conspiracy theories and science denial began to rapidly proliferate on these platforms, casting doubt on the value of long-established medical treatments and entrenching health care mistrust. This accelerated in some quarters, a rejection of digital therapeutics and data-driven medicine all together, in favor of more relationship-based approaches to health care.

The international reach of these companies also made regulatory oversight difficult because the practice of medicine is usually controlled through state-specific licensure. Legal experts pointed out that these international platform companies are often predatory and in violation of the existing corporate practice of medicine. Proponents argue that these companies are not "health services establishments" and their business model does not constitute a "provider–patient relationship," in fact, they claim it is no different from a patient-initiated search engine query. Furthermore, for many patients in rural areas and parts of the developing world, these platforms are the only portal to timely and affordable medical advice. All of these issues are illustrative of the fact that many of the normative behaviors and standards around the practice of medicine evolved well before the information boom associated with the internet and digital care transformation catalyzed by the COVID-19 pandemic.

Telehealth Case Study: Lessons Learned

Some lessons drawn from the above core case and visioning exercise that can inform the development of a cross-sectoral governance framework for emerging technologies focused on societal benefit are given below.

- The coexistence of health and non-health (e.g., wellness) applications can complicate governance.
- It is important to keep in mind the dual roles of state and federal regulation, as well, potentially, of regional (e.g., European Union) regulation.

- There are opportunities for shared or distributed governance in the gaps between regulatory authorities.
- There is a potential role for cross-sectoral governance groups at multiple levels and stages of governance.
- It is important to keep in mind the role of key enabling technologies (e.g., internet access and speed) in the development of the primary technology of interest.
- Key stakeholders to a technology will need to be adequately prepared for large shifts (e.g., dramatic ramping up of telehealth).
- Opportunities for regulatory nimbleness have been revealed by the federal response to the COVID-19 pandemic (e.g., steps skipped).
- Attention must be paid to the equity implications of access (or lack thereof) to enabling technologies.
- Attention should be paid to identifying and assessing the impact of intangible losses (e.g., healing touch, patient–provider relationships).
- Despite an explicit focus and justification for telehealth based on concerns about equity and access, success has been mixed—improving access in some cases and recapitulating existing inequities in others.
- Special attention must be paid to technologies requiring collection, storage, and use of human data.
- As the degree to which our lives are lived online versus in-person, we can become increasingly alienated from our normal markers of trust.
- We lack appropriate governance tools for a health care delivery landscape that is becoming increasingly digital and international.
- We may need to reconsider the traditional risk/benefit analysis of health care treatments when the opportunity for "immediate rescue" in situations of acute decompensation, no longer exists due to physical distance.
- One person's valued benefit is another person's harm (and vice versa) (e.g., home monitoring for safety versus surveillance).
- In order to adequately assess the risk/benefit balance, we need to make the trade-offs explicit (e.g., gains in convenience versus loss of privacy).
- We need both ethics and governance frameworks for addressing instances of "bycatching" (e.g., elder abuse captured via camera-based sensors).
- Technology (beyond traditional social media) can drive or erode trust in medical expertise (e.g., dissemination of false information about available treatment options on online platforms).
- There is flexibility/lack of oversight in the grey area that exists following the development of promising data regarding a new technology, but before proven efficacy and regulated products; this lack of oversight can drive innovation and investment in emerging technologies or delivery models, but also comes with risks.
- In the digital home, there are no silos around work/personal or public/private. What happens when the same living environment has to pivot from a place of rest to a place of work (remote work) to a place to get care (hospital-at-home)?

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Author Information

Debra Mathews, PhD, MA, is Associate Director for Research and Programs at the Johns Hopkins Berman Institute of Bioethics and Professor, Department of Genetic Medicine at the Johns Hopkins University School of Medicine. **Amy Abernethy, MD, PhD,** is President of Product Development and Chief Medical Officer at Verily. **Atul J. Butte, MD, PhD,** is Priscilla Chan and Mark Zuckerberg Distinguished Professor at the University of California, San Francisco. **Paul Ginsburg, PhD,** is Professor of the Practice of Health Policy and Management at the University of Southern California and Senior Fellow at the USC Schaeffer Center. **Bob Kocher** is Partner at Venrock. **Lewis Levy, MD,** is Prinicpal and Co-founder, Sulu Coaching. **Catherine Novelli, JD, LLM,** is President of the Board of Directors at Listening for America. **Lewis Sandy, MD,** is Executive Vice President, Clinical Advancement at UnitedHealth Group. **John Smee, PhD,** is Senior VP Engineering at Qualcomm Technologies, Inc. **Rachel Fabi, PhD,** is Associate Professor, Center for Bioethics and Humanities at the Upstate Medical University. **Anaeze C. Offodile II, MD, MPH,** is Chief Strategy Officer at Memorial Sloan Kettering Cancer Center. **Jacob S. Sherkow, JD, MA,** is Professor of Law at the Illinois College of Law, Professor of Medicine at the Carle Illinois College of Medicine, Professor at the European Union Center, and Affiliate of the Carl R. Woese Institute for Genomic Biology at the University of Illinois. **Rebecca D. Sullenger, BSPH,** is a medical student at the Duke University School of Medicine. **Emma Freiling, BA,** is a Research Associate at the National Academy of Medicine. **Celynne Balatbat, BA,** was the Special Assistant to the NAM President at the National Academy of Medicine while this paper was authored.

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Correspondence

Questions or comments should be directed to Debra Mathews at dmathews@jhu.edu.

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