Telehealth and Mobile Health

Case Study for Understanding and Anticipating Emerging Science and Technology

Debra Mathews, PhD, MA, Johns Hopkins Berman Institute of Bioethics and Johns Hopkins University School of Medicine; **Amy Abernethy, MD, PhD,** Verily; **Atul J. Butte, MD, PhD,** University of California, San Francisco; **Paul Ginsburg, PhD,** University of Southern California and USC Schaeffer Center; **Bob Kocher, MD,** Venrock;

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

organized according to the following sectors: academia, health
care/nonprofit, government, private sector, and volunteer/
consumer4TaOfnot , co oss,temof minide10(ing tupth)10(e forrl witl bec)]TJT.0391 Tw[(Ipr)-2109(focto—t)10.1(e)e ditl binevitble bec vernla

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 waythod78T.gAw[(c0

- **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

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 telemedi-

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).

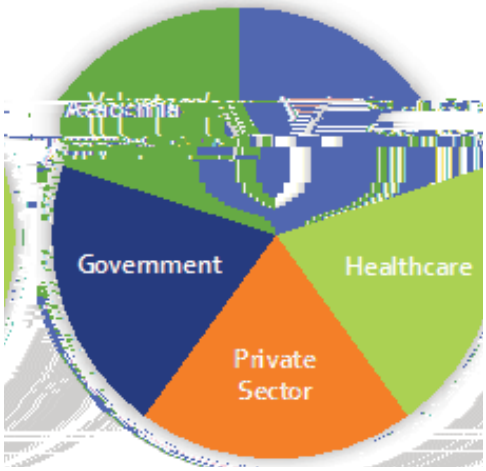
Cross-Sectoral Footprint

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.

FIGURE 1 | Sectors for Cross-Sectoral Analysis



SOURCE: Developed by authors.

mote 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

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 adop-

able 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 entities"—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,

tively 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

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. However, 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 "em5(o oncjn. Witn th)1digilth navigoach er, . and condcanli(an.1(cedfor th)10P)7(oten vulntemper)bili(ol t)-many of th an ogro1igo.1(5(ould)]TJT2.0265 Twbu)14igo Wir quc vu1(eanted came pre pct thcaol t-ata sstaffiearedves eaect thb(a-bamatandomet-)]TJT220988 Tfeedbd Blwchnider . T30('of th)2much-ct thionw[(")emocsature, bt

- 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 re-

ending a 4-year struggle. *The New York Times*, February 2. Available at: https://www.nytimes.com/1996/02/02/business/communications-reshaped-overhaul-congress-votes-reshape-communications-industry.html (accessed July 6, 2022).

11. Bauer, K. A. 2001. Home-based telemedicine: A survey of ethical issues. *Cambridge Quarterly of Healthcare Ethics* 10(2):137–146. https://doi.org/10.1017/s0963180101002043.
12. Callens, S. 2010. The EU legal framework on e-health. In *Health Systems Governance in Europe*, edited by E. Mossialos, G. Permanand, R. Baeten, and T. Hervey. Available at: https://www.euro.who.int/__data/assets/pdf_file/0006/138147/E94886_prelims.pdf (accessed July 6, 2022).
13. CareMessage. n.d. *Our mission.* Available at: https://www.caremessage.org (accessed July 7, 2022).
14. CBInsights. 2021. *The digital health 150: The 8(t1SV-21(: ht)D ht)15051.3 TD.07s6e(veyp5(50: T)31(n-communicpanid60alth2)0(3)2*
ssed July

14. CBI1/CMS-1327.5()0(2)15112(7)0(0)1/F3 1 Tf9.15056.772.2881 Tw0(ed)10(Inform-indu-52(Mici(emesessag d)10hing
514. (/)9

1RCarThe New York Times, ThMay 4. CBI5Car
6, 22-communsimulus-raccessed
Avva-Bueno,25(0Hermewossaanz-AldusoT)52(.M. Sanjurjo-Sae)acz.V* .0214 T2961able a212
July 6, 2022).
F H-F2 1 120.8691D.0969 T137(Health(ic A su Joo.nala52(.eba00(- System33 1 Tf15.695 2.7351D0Tw[1381able a)0(2)1(537(409
wwwebruaro0(esss:/ /wunJ/F2 1 Tf15.6953.331(fi028 Tw014(able aSept1)136.9(3TJE7.7.381.7.0803TD.2268 Tw1(fi)230(ailable

ing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0679 (accessed July 7, 2022).
33. Figueroa, C. A., and A. Aguilera. 2020. The need for a mental health technology revolution in the COVID-19 pandemic. *Frontiers*, June 3. https://doi.org/10.3389/fpsyt.2020.00523.
34. U.S. Food and Drug Administration (FDA). 2021. *Digital health software precertification (pre-cert) program.* Available at: https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-program (accessed July 7, 2022).
35. FDA. 2017. *Software as a medical device (SAMD): Clinical evaluation.* Available at: https://www.fda.gov/media/100714/download (accessed July 7, 2022).
36. Freiburger, G., M. Holcomb, and D. Piper. 2007. The STAR-PAHC collection: Part of an archive of the history of telemedicine. *Journal of Telemedicine and Telecare* 13(5):221–223. https://doi.org/10.1258/135763307781458949.
37. Friedman, A. B., S. Gervasi, H. Song, A. M. Bond, A. T. Chen, A. Bergman, G. David, J. M. Bailey, R. Brooks, and A. Smith-McLallen. 2022. Telemedicine catches on: Changes in the utilization of telemedicine services during the COVID-19 pandemic. *The American Journal of Managed Care* 28(1). Available at: https://www.ajmc.com/view/telemedicine-catches-on-changes-in-the-utilization-of-telemedicine-services-during-the-covid-19-pandemic (accessed July 7, 2022).
38. Gartner. n.d. *Gartner hype cycle.* Available at: https://www.gartner.com/en/research/methodologies/gartner-hype-cycle (accessed July 7, 2022).
39. Gerke, S., C. Shachar, P. R. Chai, and I. G. Cohen. 2020. Regulatory, safety, and privacy concerns of home monitoring technologies during COVID-19. *Nature Medicine* 26:1176–1182. https://doi.org/10.1038/s41591-020-0994-1.
40. Gershon-Cohen, J., and A. G. Cooley. 1950. Telognosis. *Radiology* 55(4):582–587. https://doi.org/10.1148/55.4.582.
41. Gilman, M., and J. Stensland. 2013. Telehealth and Medicare: Payment policy, current use, and prospects for growth. *Medicare & Medicaid Research Review* 3(4):mmrr.003.04.a04. https://doi.org/10.5600/mmrr.003.04.a04.
42. Global Neuroethics Summit Delegates, K. S. Rommelfanger, S.-J. Jeong, A. Ema, T. Fuushi, K. Kasai, K. M. Ramos, A. Salles, and I. Singh. 2018. Neuroethics questions to guide ethical research in the international brain initiatives. *Neuron* 100(1):19–36. https://doi.org/10.1016/j.neuron.2018.09.021.
43. Goldberg, E. M., M. P. Lin, L. G. Burke, F. N. Jimenez, N. M. Davoodi, and R. C. Merchant. 2022. Perspectives on telehealth for older adults during the COVID-19 pandemic using the quadruple aim: Interviews with 48 physicians. *BMC Geriatrics* 22(188). https://doi.org/10.1186/s12877-022-02860-8.
44. Greene, J. A. 2020. As telemedicine surges, will community health suffer? *Boston Review*, April 13. Available at: https://

Available at: https://www.nih.gov/research-training/medical-research-initiatives/activ (accessed July 7, 2022).

73. National Rural Health Association (NRHA). n.d. *About rural health care.* Available at: https://www.ruralhealthweb.org/about-nrha/about-rural-health-care (accessed July 1, 2020).
74. Nesbitt, T. S., and J. Katz-Bell. 2018. History of telehealth. In *Understanding telehealth*, edited by K. S. Rheuban and E. A. Krupinski. New York: McGraw-Hill Education. Available at: https://accessmedicine.mhmedical.com/content.aspx?bookid=2217&sectionid=187794434.
75. Nittari, G., R. Khuman, S. Baldoni, G. Pallotta, G. Battineni, A. Sirignano, F. Amenta, and G. Ricci. 2020. Telemedicine practice: Review of the current ethical and legal challenges. *Telemedicine Journal and e-Health* 26(12):1427-1437. https://doi.org/10.1089/tmj.2019.0158.
76. Olla, P., and C. Shimskey. 2014. mHealth taxonomy: A literature survey of mobile health applications. *Health Technology* 4(4):299–308. https://doi.org/10.1007/s12553-014-0093-8.
77. Orlando, J. F., M. Beard, and S. Kumar. 2019. Systematic review of patient and caregivers' satisfaction with telehealth videoconferencing as a mode of service delivery in managing patients' health.

95. World Health Organization (WHO). 2010. *Telemedicine: Opportunities and developments in member states: report on the second global survey on eHealth.* Geneva, Switzerland: World Health Organization. Available at: https://apps.who.int/iris/handle/10665/44497.
96. Yang, Y. T. 2016. Telehealth parity laws. *Health Affairs.* https://doi.org/10.1377/hpb20160815.244795.
97. Zanaboni, P., U. Knarvik, and R. Wootton. 2014. Adoption of routine telemedicine in Norway: The current picture. *Global Health Action* 7:22801. https://doi.org/10.3402/gha.v7.22801.

DOI

https://doi.org/10.3147/202311e

Suggested Citation

Mathews, D., A. Abernethy, A. J. Butte, P. Ginsburg, B. Kocher, C. Novelli, L. Sandy, J. Smee, R. Fabi, A. C. Offodile II, J. S. Sherkow, R. D. Sullenger, E. Freiling, and C. Balatbat. 2023. Telehealth and Mobile Health: Case Study for Understanding and Anticipating Emerging Science and Technology. *NAM Perspectives.* Discussion Paper, National Academy of Medicine, Washington, DC. https://doi.org/10.31478/202311e.

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, MD,** is Partner at Venrock. **Catherine Novelli, JD, LLM,** is President of Listening for America. **Lewis Sandy, MD,** is Principal and Co-founder, Sulu Coaching. **John Smee, PhD,** is Senior VP Engineering at Qualcomm Technologies, Inc. **Rachel Fabi, PhD**, is Associate Professor, Center for Bioethics and Humanities at SUNY 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 1 Tf15.6ǻ686 0 T sBlcine at-61i5aecca D. Sullenger, BSPH,
udent at the Duke University School of Medicine.
ing, BA,

of Health, personal fees from Expert Consulting services, outside the submitted work.

Correspondence

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

Disclaimer

The views expressed in this paper are those of the authors and not necessarily of the authors' organizations, the National Academy of Medicine (NAM), or the National Academies of Sciences, Engineering, and Medicine (the National Academies). The paper is intended to help inform and stimulate discussion. It is not a report of the NAM or the National Academies.