# Virtual Health in a Post–COVID World: Optimizing Regulation, Reimbursement, and Regularity

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## ABSTRACT

Virtual health is the sum of telehealth (patient–provider communication at a distance) and autonomous health (electronic devices communicating with providers and patients at a distance). The COVID-19 pandemic and its attendant social distancing led to a sharp increase in the use of virtual health. In this paper, we ask which public policies would encourage the continued use and expansion of virtual health. We find that the answers lie in the three Rs: regulations to support easier access to virtual health, reimbursement that incentivizes appropriate care, and regularity—the social and cultural acceptance of virtual health.

*JEL* codes: I100, I11, I18, I0, I1

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It's not an overstatement to say that the world of healthcare is now divided into pre–COVID and post–COVID eras, with sometime in early 2020 being the point of demarcation. This is certainly true for virtual health. (And, as COVID is likely to remain endemic in perpetuity, we define "post–COVID" to mean after the *beginning* of the pandemic.)

A common phrase we have heard during the COVID-19 pandemic is "the new normal," especially as it pertains to healthcare. In the outpatient setting, this new normal was most obviously characterized by the quick shift from office-based care to telehealth visits, driven by the need to avoid face-to-face exposure, bolstered by well-aligned changes in both reimbursement and regulatory policies. According to a McKinsey report, by midsummer 2020, doctors were seeing patients virtually 50 to 175 times as often as they were a mere 6 months before.[1] The height of US telehealth utilization was seen in April 2020, when over 50 percent of all billable outpatient care was being delivered via telehealth.[2] It should be noted this high percentage was in the context of overall outpatient visit numbers decreasing by over 50 percent from baseline; but by July 2020, overall utilization had recovered to over 90 percent of pre–COVID levels.[3] Since then, telehealth visits have stabilized in the range of 17–21 percent of total visits.[4] (Other sources including Medicare data have it more in the 5–10 percent range.[5]) Also of note, the differences across specialties were dramatic. For example, in January 2021, 66 percent of psychiatry visits were via telehealth, versus roughly 20 percent for family medicine, internal medicine, and

1. Oleg Bestsenyy, Greg Gilbert, Alex Harris, and Jennifer Rost, "Telehealth: A Quarter-Trillion-Dollar Post-COVID-19 Reality?" *McKinsey & Company Healthcare Systems & Services*, July 9, 2021.
2. "Telehealth Adoption Tracker," The Chartis Group, accessed December 28, 2021, https://reports.chartis.com/telehealth_trends_and_implications-aug2020/ (see Telehealth Adoption Tracker chart).
3. Ateev Mehrotra, Michael Chernew, David Linetsky, Hilary Hatch, David Cutler, and Eric Schneider, "The Impact of the COVID-19 Pandemic on Outpatient Visits: Changing Patterns of Care in the Newest COVID-19 Hot Spots," *The Commonwealth Fund*, August 13, 2020.
4. "Telehealth Adoption Tracker."
5. Mehrotra, Chernew, Linetsky, et al., "The Impact of COVID-19 on Outpatient Visits in 2020."

pediatrics. Meanwhile, in fields like orthopedics, dermatology, and ophthalmology, telehealth visits accounted for fewer than 3 percent of total billable visits.[6]

It is important to note that this dramatic rise in telehealth is merely part of a broader trend: the rise of "virtual health," which includes telehealth as well as a variety of remote health and autonomous care technologies. Lyle Berkowitz extolled the increasing prominence of virtual health in a blog preceding the pandemic by several months,[7] but the "pandem-acceleration" of virtual health was indeed profound.

Virtual health has the potential to enhance healthcare provision if it is widely used, but for that to happen, it is important to optimize the three Rs. This paper will explore virtual health on a deeper level, asking questions like: What is virtual health? What obstacles lie in the way of widespread adoption and normalization of virtual care within the larger system of care? How do federal and state regulations impede or expedite the diffusion of virtual health technologies? What challenges do reimbursement procedures pose for virtual health? What are the cultural barriers to virtual health—inside and outside of the healthcare professions? And how do the different parts of virtual health mesh with one another?

By our definition, virtual health is the combination of telehealth and autonomous health. "Telehealth" refers to physicians and other providers communicating with, diagnosing, and treating patients at a distance via electronic medium, primarily via video, audio, or messaging. It also involves training, education, administration, and public health by remote means. Meanwhile, "autonomous health" refers to intelligent machines actively or passively communicating with patients or providers to automate the processes of data collection, diagnostics, and treatment.

Virtual health is thus a means of altering the production function for healthcare—stretching resources further to avert or accommodate the perceived "physician shortage." It also opens possibilities for qualitatively improving the patient experience as compared to traditional in-person healthcare. For example, unlike in-office medical care, a patient feeling ill can seek immediate help at any hour of the day or night from any location where some mode of electronic communication is available; thus, patients can engage in early intervention and stave off crises that would otherwise have occurred while waiting for an in-office appointment or ignoring their developing problem.[8] For another example, there is at least anecdotal evidence from telepsychiatry that some patients

6. "Telehealth Adoption Tracker."
7. Lyle Berkowitz, "We Might Just Save Healthcare After All!" *Linkedin*, November 4, 2019.
8. Robert Graboyes, "Telemedicine as Lifesaver: Ian Tong and Doctor on Demand" (Mercatus Expert Commentary, Mercatus Center at George Mason University, Arlington, VA, October 2016).

are more cooperative and compliant when they can access care from their own homes or offices.[9,10] In addition to these access benefits, virtual health offers possible ways to reduce costs of healthcare as well.

Of course, doing anything new in healthcare is hard. Obstacles slowing the diffusion of virtual health have traditionally included regulatory hurdles at the state and federal levels, poor or nonexistent reimbursement for any care outside the traditional face-to-face visit, and cultural resistance from both patients and providers about doing something different.

Over the years, state regulators have erected batteries of restrictions on how, when, where, and by whom telehealth can be delivered. In some cases, the restrictions were motivated by fear of unknown technologies. In other cases, restrictions were provider-based and self-serving—aimed at limiting competition from physicians without a physical presence, especially if from another state. Meanwhile, at the federal level, the Food and Drug Administration's (FDA) sluggish and sometimes backward-looking processes have slowed the use of medical software essential to the dissemination of autonomous health.

Some policymakers may have been concerned that the ease of accessing telehealth would ramp up demands for visits and, hence, overall costs. This raises both ethical and empirical questions. First is whether it is ethical to make access to care more cumbersome as a cost-saving measure. Second is whether discouraging care would actually lower costs; to the contrary, it is plausible that earlier intervention would diminish costs overall by catching illnesses before they become more serious.

Reimbursement issues have also created an impediment to the spread of virtual health. Traditionally, some states had serious restrictions on whether and how Medicaid could reimburse remote care. Similarly, until COVID-19, the federal Medicare program's reimbursement policies were not particularly telehealth-friendly. Private insurers, too, had their limitations on whether and how to reimburse providers for remote care. And for the most part, providers are not compensated for the time they spend attending to patients outside of online screen time. For example, after a reimbursable audio or video telehealth encounter, a doctor may engage in lengthy, time-consuming follow-up conversations with the patient by text message or secure messaging without additional reimbursement. In general, such additional communications, necessary though they might be, are not subject to reimbursement by insurers. (Of course, the same can be said of in-person visits, whose

9. Robert Graboyes, "Telepsychiatry—Serving the Underserved," *Insidesources*, October 9, 2019.
10. Jeff Lagasse, "Behavioral Health Providers Embracing Telehealth during the COVID-19 Pandemic," *Healthcare Finance*, September 24, 2020.

follow-up correspondence and administrative work are not reimbursed, either. Perhaps that is a problem for the efficiency of in-person care, as well.)

As for cultural barriers, even where telehealth was allowable before COVID-19, it was little used, thanks to inertia, cultural resistance among both providers and patients, and reimbursement rules that disfavor telehealth. Patients were unfamiliar with or unaccustomed to having providers perform full visits via electronic technologies. During the first year of COVID-19, all these motivations became untenable as both patients and providers sought to maintain physical distance from each other. Some physicians have resisted the rise of telehealth for a variety of reasons, including concerns about medical errors, data security, and privacy.[11] Others worry that out-of-state telehealth providers will threaten the revenues of in-state providers.[12]

As we will argue, virtual health can be greater than the sum of its parts. Allowing patients to consult with physicians via video or audio is a great way to extend access and sometimes improve efficiency. But using more autonomous or asynchronous care offers far greater access and efficiencies. For example, imagine a cardiac patient who needs regular ECG monitoring. In the traditional healthcare world, this might require him to come in and see his cardiologist monthly for an onsite ECG. In a simple telehealth world, the patient might go to a local clinic for the ECG and do a video visit with the cardiologist afterward. But in the full virtual health world, our patient would wear a continuous heart monitor that feeds directly into an artificial intelligence system that will alert the patient and provider only if there is an issue that requires their attention. And when there is an important issue, a video call can be set up quickly to determine next steps. Thus, in this new virtual health world, a single cardiologist can actually monitor a larger population via autonomous care, and then use telehealth only with the small percentage who truly need it and do so in a timelier manner.

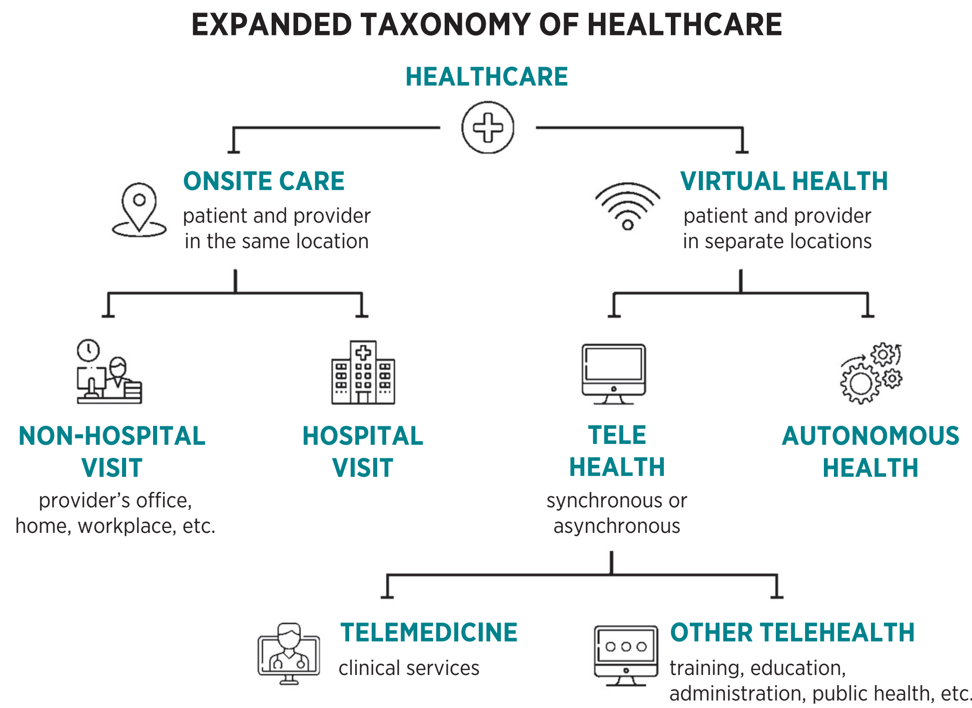
The following sections will address the issues and discussion points outlined earlier in greater detail.

## VIRTUAL HEALTH DEFINED

The term "virtual health" does not have a universal definition at this time. Therefore, in a recent essay,[13] the authors of this paper offered specific definitions and

11. Mandy Roth, "Why Physicians Resist Telemedicine's Growth," *healthleaders*, July 24, 2018.
12. Matt Volz, "The Boom in Out-of-State Telehealth Threatens In-State Providers," *Kaiser Health News*, February 2021.
13. Robert Graboyes, Darcy Bryan, and Lyle Berkowitz, "What Is Virtual Health?" *The Mercatus Center—The Bridge*, May 20, 2021.

FIGURE 1. TAXONOMY OF HEALTHCARE




Source: Adapted from Lyle Berkowitz, Steve Ommen, and John Halamka, "Virtual Health—Near Term Analysis of the COVID-19 Pandemic," *Telehealth and Medicine Today* 5, no. 3 (2020), https://doi.org/10.30953/tmt.v5.210.

a brief taxonomy. Much of the information in this section is borrowed directly or indirectly from that piece. As in that brief, we stress that we are offering a taxonomy while noting that different observers may use the relevant terms in different ways.

## Taxonomies of Virtual Health

We adopt the view that virtual health is the combination of telehealth and autonomous health. Berkowitz, Ommen, and Halamka[14] summed up healthcare in the hierarchical diagram (figure 1), where healthcare can be onsite (face-to-face) care or virtual health (remote communications between patients, providers, and intelligent machines).

*Telehealth* consists of encounters between patients and providers (including physician assistants, nurse practitioners, other advance practice registered

14. Lyle Berkowitz, Steve Ommen, and John Halamka, "TMT Editorial: The Future of Virtual Health—Near Term Analysis of the COVID-19 Pandemic," *Telemedicine and Medicine Today* 5, no. 3 (2020).

nurses, pharmacists, psychologists, optometrists, opticians, therapists, and others, along with agents or employees of any of these), where the two parties are geographically separated and connected via electronic media. While "telemedicine" and "telehealth" are often used interchangeably, we view the former as referring to clinical services only, whereas the latter includes nonclinical communications, including training, education, administration, and public health.

Modalities for telehealth can include laptops, tablets, smartphones, ordinary telephones, or specialized biometric devices (e.g., home temperature, pulse, blood pressure) or telemetry machines (e.g., an AliveCor smartphone-based electrocardiogram device).

Communications can be synchronous, which can be audio plus video (e.g., a video consultation) or audio only (e.g., an old-fashioned phone call). Or, communications can be asynchronous—as with a thread of emails, text messages, webform inputs, or biometric telemetry that submits data to a provider, who may evaluate the data immediately or at a later time.

Of course, it is also important to note that the legal or regulatory definition of telehealth may differ across states or payors or other similar entities. For example, some states exclude audio-only telephone conversations from their definition of telehealth.

*Autonomous health* consists of exchanges of information between providers or patients on one end and intelligent machines on the other end. These can take the form of conversations, data sharing, or direct patient intervention. This can include the use of expert-based systems, artificial intelligence (AI), or machine learning (ML)[15] to support diagnostics, treatment, and compliance. The machines can thus analyze data and offer advice to patients.[16] Like telehealth, autonomous health can be synchronous or asynchronous.

These two dichotomies—telehealth versus autonomous health and synchronous versus asynchronous—yield a two-by-two taxonomy represented in figure 2.[17] Figure 2 includes examples of each of the four quadrants. It is important to note that the boundaries of these four quadrants are porous. A particular vendor or technology may combine aspects of telemedicine and autonomous health, or synchronous and asynchronous. For example, the AliveCor Kardia (consumer-operated electro-

15. Jianxing He, Sally L. Baxter, Jie Xu, Jiming Xu, Xingtao Zhou, and Kang Zhang, "The Practical Implementation of Artificial Intelligence Technologies in Medicine," *Nature Medicine* 25 (2019): 30–36.
16. Stan Benjamens, Pranavsingh Dhunnoo, and Bertalan Meskó, "The State of Artificial Intelligence-Based FDA-Approved Medical Devices and Algorithms: An Online Database," *npj Digital Medicine* 3 (2020).
17. Graboyes, Bryan, and Berkowitz, "What Is Virtual Health?"

FIGURE 2. COMPONENTS AND EXAMPLES OF VIRTUAL HEALTH

### SYNCHRONOUS TELEHEALTH

**Patient and provider communicate in real time via electronic devices (e.g., laptop, tablet, smartphone, landline telephone)**

- Virginia-based patient with a sinus infection does video consult with a New York physician via Doctor on Demand's telehealth app
- Patient experiencing high blood pressure while visiting Colorado telephones her doctor in Ohio
- Veteran with PTSD consults with psychiatrist at Genoa Telepsychiatry via video call
- Doctor conducts an office-based physical examination, while the audio and video are live-streamed to an Augmedix assistant who produces an electronic health record in real time
- Surgeons in New York remove the gall bladder of a patient in Paris via robot

### SYNCHRONOUS AUTONOMOUS HEALTH

**Patient, provider, or both communicate with intelligent machines In real time**

- Singaporean COVID patients interact with "Doctor Covid" chatbot for advice during quarantine
- Patient uses Apple Watch EKG app to determine whether he has atrial fibrillation
- Robotic surgery device ties sutures on its own
- Computer-savvy parent uses Nightscout software to build a remote alert system to monitor her daughter's glucose levels
- Drone carries defibrillator to a heart attack victim on a city street and issues directions for a passerby to give assistance
- Remote clinic in Rwanda summons drone in the capital to deliver units of AB blood to hemorrhaging mother in childbirth
- A "smart pill" gathers data on a patient and releases drugs into the bloodstream accordingly

### ASYNCHRONOUS TELEHEALTH

**Patient and provider communicate back and forth over time via electronic devices (e.g., laptop, tablet, smartphone)**

- Primary care provider and patient communicate via email, text, or webform input
- Patient uses AliveCor EKG app to test for atrial fibrillation and emails his test result to a cardiologist who reviews it later in the day
- Patient orders anxiety medication through Lemonaid and physician reviews the order and patient details the next day
- Patient with missing limb sends data via e-NABLE for high school student to manufacture 3D-printed prosthetic

### ASYNCHRONOUS AUTONOMOUS HEALTH

**Patient, provider, or both send data to intelligent machines for later use**

- Holter monitor sends cardiac data to provider for later review
- Hospital in Japan sends leukemia patient's records and genome scan to IBM's Watson computer, which then reviews 20 million journal articles and returns a diagnosis 10 minutes later
- Patient uses laptop and smartphone to conduct an eyeglass refraction through Visibly app; then, an ophthalmologist reviews the results later and writes an eyeglass prescription
- Patient's Fitbit data is downloaded into her electronic health record
- Patient with depression uses interactive myStrength app to improve mental health, and the app learns the patient's behavior over time and adjusts its advice accordingly

Source: Robert Graboyes, Darcy N. Bryan, and Lyle Berkowitz, "What Is Virtual Health? The Promise of Technology and the Chaos of Terminology," Expert Commentary, *The Bridge*, May 20, 2021. https://www.mercatus.org/bridge/commentary/what-virtual-health-promise-technology-and-chaos-terminology.

cardiogram device) can serve as autonomous health (by taking an EKG and telling the patient whether he is experiencing atrial fibrillation). But when that patient emails the EKG to his cardiologist, this becomes an example of asynchronous telehealth.

To elaborate on a few items in that chart and a few items not included in the chart:

*Synchronous telehealth:*

- Doctor on Demand[18] is a telehealth company that connects patients and physicians 24/7/365. The specific description in the chart involved one of the three co-authors of this article (Graboyes).
- New York surgeons conducted a robot-assisted surgery on a patient in Paris in 2001.[19]

*Asynchronous telehealth:*

- The e-NABLE organization arranged for the construction of thousands of working prosthetics, 3D-printed by a variety of "makers," including high school students.[20]
- The AliveCor Kardia[21] device allows patients to use their smartphones as electrocardiogram devices for monitoring their heart rhythms for atrial fibrillation.[22] The results are stored on AliveCor's computers, as well, enabling patients to save results over time. In case of undesirable results, the app also allows patients to have their results read by either a cardiac technician or by a cardiologist. Results can also be forwarded by email to the patient's healthcare providers. Of note, the Apple Watch ECG[23] has a similar built-in ECG functionality.
- Lemonaid Health[24] is a telehealth company that uses an autonomous triage agent. Patients fill out a questionnaire at any hour of the day or night, and a

18. Doctor on Demand homepage, accessed December 29, 2021, https://www.doctorondemand.com/.
19. "Surgeons in New York Operate on Patient in France," *Oncology News International* 10, no. 12 (December 1, 2001).
20. Scott Grunewald, "Alberta High School Students Teaming Up with e-NABLE to 3D Print 30 Prosthetic Hands," *3Dprint.com*, January 6, 2016.
21. "EKG Anywhere, Anytime | AliveCor," Kardia, accessed December 29, 2021, https://www.alivecor.com/.
22. Robert Graboyes, "Patient as Diagnostician—David Albert and AliveCor," *InsideSources*, September 28, 2016.
23. "Watch - Apple," Apple, accessed December 29, 2021, https://www.apple.com/watch/.
24. "U.S. Online Doctor | Meds Delivered to Your Door," Lemonaid, accessed December 29, 2021, https://www.lemonaidhealth.com/.

system of algorithmic queries only sends patients for a telehealth visit after it confirms appropriateness for a consult. Hence, this is a blend of autonomous health and telehealth.

*Synchronous autonomous health:*

- The government of Singapore instituted a chatbot called "Doctor Covid," aimed at facilitating communication between providers and patients in community care facilities[25] (isolation facilities for low-risk COVID-19 patients). It answers patients' questions and facilitates treatment compliance by sending reminders and other information to patients. This reduces physicians' and nurses' exposure to the coronavirus by eliminating the need for many would-be face-to-face encounters. The system also aggregates and anonymizes data to generate population data for researchers.[26] In multiple languages, it helps with compliance efforts, monitors mental well-being, and offers wellness tips and entertainment. The system's creators are next planning to add natural language capabilities to the input process.[27]
- Nightscout[28] is an open-source software package—designed by amateurs outside of the formal healthcare system—that monitors insulin pumps. A parent, for example, can monitor their type 1 diabetic child's insulin and glucose levels remotely. If the metrics indicate a problem, the system alerts the parent, who can then telephone the child to give them instructions—to get an injection of insulin or to drink a glass of orange juice, for example.
- Qualcomm Tricorder: In 2011, the XPRIZE Foundation offered the Qualcomm Tricorder XPRIZE—$6 million to the first team that could develop a "device that will accurately diagnose 13 health conditions (12 diseases and the absence of conditions) and capture five real-time health vital signs, independent of a healthcare worker or facility, and in a way that provides a compelling consumer experience." Some measured conditions were specified. The device had to weigh under 5 pounds and its diagnoses 70 percent

25. Ming Li Chia, Dickson Hong Him Chau, Kheng Sit Lim, Christopher Wei Yang Liu, Hiang Khoon Tan, and Yan Ru Tan, "Managing COVID-19 in a Novel, Rapidly Deployable Community Isolation Quarantine Facility," *Annals of Internal Medicine* (2020).
26. Kester Poh, "How Chatbots Have Been at the Centre in the Fight against COVID-19," *Entrepreneur*, October 8, 2020.
27. "SingHealth and A*STAR Co-develop Smart Chatbot to Enhance Care for COVID-19 Patients at Community Care Facilities," *SingHealth*, June 24, 2020.
28. "The Nightscout Project—We Are Not Waiting," Nightscout, accessed December 29, 2021, http://www.nightscout.info/.

accurate. In the end, no team accomplished all the goals, but $10 million was spread among three competitors.[29]

- In an online database published in 2020, Stan Benjamens, Pranavsingh Dhunnoo, and Bertalan Meskó provide a detailed table of 29 artificial intelligence–based devices that have received FDA approval. Their table tells the purpose of each device, the medical specialty for which it is designed, and the manufacturer.[30]

*Asynchronous autonomous health:*

- QuantX helps radiologists to evaluate breast abnormalities via machine learning and image analysis. According to docwirenews.com, "In a clinical study, QuantX use led to a 39% reduction in overlooked breast cancers and a 20% improvement in overall diagnostic improvement."[31]
- Aidoc lets radiologists identify acute intercranial hemorrhages in head CT scans and warns of particularly dangerous cases.[32]
- IBM'S Watson: One of the more dramatic cases of artificial intelligence was that of a Japanese woman whose cancer was not responding to treatment. After multiple doctors at multiple hospitals saw no progress on the case, IBM's Watson computer was called into the case. The patient's genetic information was fed into the computer, which then read 20 million articles on the subject. The computer's diagnostic capabilities determined that doctors had misdiagnosed the particular type of leukemia the patient had. After Watson's diagnosis, the treatment regimen was altered, and the patient began to improve. For Watson, the entire process took around 10 minutes to complete.[33]

## Varying Definitions of Virtual Health

While we have offered our preferred definition of virtual health and its components, it is important to note that the terminology is not broadly settled.

29. Robert Graboyes, "Doctors as Weavers—The Qualcomm Tricorder XPrize," *InsideSources*, February 8, 2017.
30. "Table 2, Database of the 29 FDA-Approved, AI/ML-Based Medical Technologies" (dataset), in Benjamens, Dhunnoo, and Meskó, "The State of Artificial Intelligence-Based FDA-Approved Medical Devices and Algorithms."
31. Jack Carfagno, "5 FDA Approved Uses of AI in Healthcare," *docwirenews*, July 18, 2019.
32. Jack Carfagno, "5 FDA Approved Uses of AI in Healthcare."
33. Nurfilzah Rohaidi, "IBM's Watson Detected Rare Leukemia in Just 10 Minutes," *AsianScientist*, August 15, 2016.

For example, below are three different virtual health definitions that might be encountered. This is important to understand as we explain our views based on our definition, as they might not fully apply to other definitions that could be encountered.

1. An Aetna webpage seems to see virtual health and video-based telehealth as synonyms. "Virtual care is the capability to access a doctor through a video call on your phone or computer, anytime, anywhere in the world."[34]
2. To the Care Innovations consulting group, "Virtual healthcare is actually a component of telehealth, which is a broader term encompassing the entirety of remote and/or technology-driven healthcare."[35] This is essentially the opposite of our terminology, as we defined telehealth as a component of virtual health.
3. PricewaterhouseCoopers/Canada's concept of virtual health is the most similar to our own: "Virtual health . . . includes health-care professionals who collect patient data and deliver care remotely, giving patients and caregivers more transparency (i.e. full visibility of their care plans, clinical histories, authorizations and more) and influence in how, when and where they're treated. And virtual health goes beyond interactions with physicians, such as visits with chiropractors and therapists as well as interactions with pharmacists and insurance providers. It also includes an abundance of health and wellness apps and mobile monitoring devices."[36]

## Relationship with Electronic Health Records and Drones

Electronic health records (EHRs) will be an essential component of maximizing the value of virtual health—the connective tissue that binds office visits, hospital visits, telehealth, and autonomous health together into a coherent, relatively seamless system.

When we tout the virtues of EHRs in general, we want to recognize that today's EHRs are not yet ideal, and in fact often are reimbursement-focused,

34. "What Is Virtual Health?" Aetna, accessed December 29, 2021, https://www.aetnainternational.com/en/about-us/explore/future-health/technology-revolutionzing-healthcare-expats-globally-mobile.html.
35. "What Is Virtual Healthcare, and How Does It Fit into Telehealth?" CareInnovations, accessed December 29, 2021, https://news.careinnovations.com/blog/what-is-virtual-healthcare-how-does-it-fit-into-telehealth.
36. "Virtual Health 2.0: A Vision for Virtual Health Care in Canada," PwC, accessed on December 29, 2021, https://www.pwc.com/ca/en/industries/healthcare/health-issues-18/virtual-health-2.html.

fragmentary, inefficiently structured, nonintuitive, and the bane of doctors' existence.

However, the next generation of EHRs may (or should) have the capacity to turbocharge both telehealth and autonomous health by forming a massive database of information on both individuals and populations. By way of analogy, ridesharing services like Uber connect geographically separated drivers and passengers; similarly, virtual health connects geographically separated providers and patients. But the real force of Uber lies in its massive virtual map of the streets of the world—and its capacity to evaluate road conditions in real time. When drivers and passengers connect, the transaction costs of the engagement are greatly reduced because the virtual map instantaneously and autonomously answers most of the questions that would have required verbal back-and-forth and perhaps a stroll through a map book during a taxi ride of yore. In addition, the virtual map is constantly updated to reflect extant traffic conditions, so Uber replaces the traditional taxi driver's knowledge about average travel times along various routes with precise knowledge of travel times at the moment. One can imagine advanced EHRs serving similar functions with respect to healthcare—eliminating the repetitive questions that precede today's telehealth encounters (name, age, comorbidities, etc.) and providing up-to-date data on, say, potential drug interactions and prevalence of infectious disease in specific localities. And the accumulation of data across the American population will allow algorithms to better diagnose individuals and to allocate scarce resources as localized epidemics occur. With machine learning, such a virtual map of American health also has the capacity to inform providers and intelligent machines of emerging patterns of health and sickness that providers might otherwise miss.

With that in mind, two of this paper's authors (Graboyes and Bryan) have previously offered 12 principles for a new generation of EHRs. We dubbed them "digital health biographies" (DHBs) to differentiate them from the present-day EHRs that so many providers despise.[37] At present, patients may have separate EHRs in the possession of different providers—one for the primary care provider, one for the allergist, one for the cardiologist, one for the orthopedist. They often do not contain patient input or data from Fitbits, insulin pumps, or cardiac monitors. They usually do not include structured family history or genetic information. And they often suffer from "note bloat"—the same information repeated over and over from multiple rounds of copying and pasting. In other words,

37. Robert Graboyes and Darcy Bryan, "From Electronic Health Records to Digital Health Biographies" (Mercatus Research, Mercatus Center at George Mason University, Arlington, VA, February 2018).

today's EHRs often require cumbersome input procedures, and the output is highly nonintuitive.

In 2010, one of this paper's authors (Berkowitz) said, "How did we make bad [EHRs]? Because [doctors] keep telling vendors 'Make this look like paper. Because that's what I'm used to.' Big mistake. The problem is, computers aren't really good at replicating paper." His talk further elaborates on how the appearance of EHRs might be enhanced for clinical purposes.[38]

A coherent, efficient system of virtual health will require a different kind of EHRs (or DHBs). It is not enough for a patient to be able to contact a cardiologist through his or her iPad. The cardiologist must have rapid access to information on the patient's medical history, medications, family characteristics, and so forth. And they must be presented in intuitive forms so the cardiologist isn't searching for needles in haystacks. Other segments of the economy—finance, for example—have developed streamlined graphical interfaces that make the extraction of information more intuitive.

Efficient, effective autonomous health similarly means that the intelligent machines involved in healthcare be able to obtain whatever information they need to function.[39]

The holy grail of EHRs is interoperability—the ability to merge information across providers, across insurers, across patients. Efficiency also means the capacity to extract data from a whole population's EHRs for purposes of scientific evaluation. All of these will help and augment the concept of virtual health in the future by improving data sharing.

We also note later that medical applications of unmanned aerial vehicles (UAVs, or "drones") are already integrated into virtual health. In several nations in Africa and elsewhere, unmanned aerial vehicles are already in frequent use to transport blood supplies and other medical goods. During the COVID-19 pandemic, China used passenger drones to transport medical supplies to and from hot zones.[40] Graboyes, Bryan, and Coglianese discuss other present-day and prospective healthcare applications of UAVs in a 2020 paper.[41]

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38. Lyle Berkowitz, MD, address at the Transform 2010 Symposium, Mayo Clinic Center for Innovation, September 24, 2010, https://www.youtube.com/watch?v=oSVIAG11OXM.
39. Robert Graboyes, Darcy Bryan, and Lyle Berkowitz, "Simplicity, Interoperability, Symmetry, and Privacy Are All Important Goals for New Healthcare Information Rules" (Mercatus Public Comments, Mercatus Center at George Mason University, Arlington, VA, January 4, 2021).
40. "EHang Implements Air Transport to Aid Coronavirus Medical Emergencies," *Transport Up*, February 26, 2020.
41. Robert Graboyes, Darcy Bryan, and John Coglianese, "Overcoming Technological and Policy Challenges to Medical Uses of Unmanned Aerial Vehicles" (Mercatus Research, Mercatus Center at George Mason University, Arlington, VA, January 2020).

## HISTORY, BENEFITS, POTENTIAL, AND POLICIES OF VIRTUAL HEALTH

As long as there have been doctors, priests, and healers, the sick have struggled to overcome geographic barriers to obtain expert help. The history of telehealth is simply a more recent chapter in the age-old battle against isolation, scarce resources, and disease.

Technology's power to increase connectivity between patient and provider has certainly increased the probability of victory against illness. This connectivity framework has been built on the invention of communication devices of evolving complexity and power, starting with the telegraph, telephone, and radio, further developing to video conferencing, the internet, satellite communications, and other future modalities yet to be discovered. Einthoven, inventor of the electrocardiogram (ECG), is believed to be the first to use the term "tele" in relation to transmission of healthcare information over distance, when he suggested the use of "telecardiogramme" in 1906.[42] In 1905, Einthoven had started transmitting ECGs from the hospital to his laboratory by telephone cables.[43] It was in 1927 that the term "telemedicine" was first used by a writer to the *Tribune*: "If we have telephotography, why can't we have telemedicine, so that you could walk up to the radio machine, drop your dollar in the slot, take down the particular receiver required and apply it to that part of your anatomy where the pain is?"[44]

The first case report of telemedicine (although not labeled such at the time) was published in *The Lancet* in 1879 as a short note that described relatives of a small child with a severe cough, worried about the croup, calling their family doctor.[45] The doctor then asked the child to cough into the phone and announced that the matter could wait until morning since it didn't sound serious. Ever since, patients have been calling providers, trying to decide whether to go to the hospital or clinic, or to stay home. Very few patients want to go to the hospital or clinic if they can avoid it. In a 2012 paper, Robert Eikelboom argues that telehealth preceded the invention of the telephone. He documented medical uses of telegraph communications several years prior to the first telephones.[46]

One promise of virtual health is the ability to stay home and still receive expert care and assistance—from human providers and from intelligent

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42. Anton Vladzymyrsky, Malina Jordanova, and Frank Lievens, *A Century of Telemedicine: Curatio Sine Distantia et Tempora* (Malina Jordanova, 2016), 3.
43. "Nobel Laureate Series: Willem Einthoven," *CardioPulse* 40, no. 37 (2019): 3076.
44. Vladzymyrsky, Jordanova, and Lievens, *A Century of Telemedicine*, 4.
45. "Practice by Telephone," *The Lancet* 114 (1879): 819.
46. Robert Eikelboom, "The Telegraph and the Beginnings of Telemedicine in Australia," *Studies in Health Technology and Informatics* 182 (2012): 67–72.

machines. For most patients, home is safe, comfortable, and inexpensive. Auerswald analyzed the cost savings and quality improvements that can be achieved in the healthcare sector by providing services in the home.[47] A 2008 study by Litan showed an estimated net savings of $197 billion cumulatively over a 25-year period through increased use of remote monitoring by virtual health in the Medicare system alone.[48] A 2020 estimate by the McKinsey consulting firm projects that $250 billion in healthcare spending could shift to virtual health as the industry seeks to diminish cost of care.[49]

We add the caveat that the ultimate effect of virtual health on aggregate healthcare spending cannot really be known in advance any more than expenditures on laptops or iPhones or Uber could be known in the infancy of those products. Virtual health could lower costs by reducing the need for bricks and mortar, by allowing providers to live and work in lower-cost regions of the country, by smoothing peak-load demands across regions, and by nipping illnesses in the bud before they become more expensive. On the other hand, virtual health could *increase* healthcare expenditures by making care more convenient for patients and providers and therefore ramping up demand for services. Adding another layer to this argument, more early intervention could lead to greater demand for follow-up services, as well.

What might home healthcare be like in the future with the evolution of virtual health? In part, that is equivalent to asking someone in 1995 what we might expect in the future from the internet and cell phones. A good deal of our discussion is and must be speculative. What we do know from the early 1990s is that a considerable number of innovators had the idea that connectivity would bring big changes—mostly, though not entirely, good—and through a series of decisions, Congress decided to step out of the way and allow such innovation to occur.[50] The results would have been unimaginable in those early days.

While we can only speculate about the future possibilities of virtual health, we already have a significant number of tools in place, with the internet of things

47. Philip Auerswald, "Healthcare to the Home: Enabling Distributed Health Service Delivery by Removing Barriers to Entrepreneurial Exploration" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, September 2020).
48. Robert Litan, "Vital Signs via Broadband: Remote Health Monitoring Transmits Savings, Enhances Lives" (Working Paper, Better Health Care Together, Washington, DC, October 2008).
49. Paddy Padmanabhan, "Beyond Telehealth: The Virtual Care Technology Trends That Will Transform Healthcare," *Healthcare IT News*, June 20, 2020.
50. Adam Thierer quotes: "America took a commanding lead in the digital economy because, in the mid-1990s, Congress and the Clinton administration crafted a nonpartisan vision for the Internet that protected 'permissionless innovation'—the idea that experimentation with new technologies and business models should generally be permitted without prior approval." Accessed at https://www.mercatus.org/publications/technology-and-innovation/connected-world-examining-internet-things.

making common household appliances increasingly "intelligent" and automated. Remote monitoring of vital signs through wearable devices and e-sensors can send data to providers with alert mechanisms programmed to trigger emergency responses as needed. A "smart" home can notify occupants of medication schedules, workout routines, doctors' appointments, and the need for pharmacy refills.

The smartphone (along with apps and peripherals) combines a computer, camera, and cellular phone into one unit that then acts as a medical device, encompassing such diverse functions as an ECG, stethoscope, ophthalmoscope, and EEG.[51] Through the use of videoconferencing, healthcare providers can be consulted and data collected from wearable personal devices and smartphones uploaded in store-and-forward programming for further analysis.

Artificial intelligence promises to automate basic healthcare provision by answering common healthcare questions in real time using chatbots, alerting providers when more sophisticated intervention is warranted. It has even been projected that unmanned aircraft systems (aka drones) can facilitate the home delivery of medical supplies and medications, as well as pickup of labs and return of equipment.

On the provider side, virtual health promises to improve efficiency, allowing providers to function at the top of their license while decreasing incidence of medical errors. For example, virtual assistants powered by artificial intelligence will be able to make appointments, send prescriptions, and transcribe provider notes into the electronic health record. EHR programs can have decision-support systems that facilitate standard-of-care treatment plans, prevent prescriber errors, and alert providers to unaddressed patient issues. Once program interoperability standards are achieved, virtual health promises to overcome institutional silos of data and improve data transmission to providers when and however needed without the current significant delays.

Artificial intelligence also promises to enable providers to predict future outcomes through data analytics, calculating the likelihood a patient will have a stroke, a heart attack, cancer, or another devastating event. This will also enable providers to craft preventative health plans in a timely fashion. In 2020, the Centers for Medicare and Medicaid Services (CMS) approved the first reimbursements for artificial intelligence–augmented medical care.[52]

On a population-health level, virtual health can manage global emergencies, such as pandemics, through easier and faster contact tracing while providing rapidly accessible education and triage through chatbots, as seen in Singapore

51. "Can Smartphones Be Used as a Medical Device?" *Care Centrix*, May 13, 2019.
52. Luke Oakden-Rayner, "The Medical AI Floodgates Open, at a Cost of $1000 per Patient," *The Health Care Blog*, September 10, 2020.

during the COVID-19 pandemic.[53] Part of the promise of virtual health is the capacity to democratize care, allowing laypersons to play a larger role in improving individual and population health. In 2015–2016, for example, social media were crucial in identifying Zika virus as the cause of Brazil's sudden increase in microcephaly among newborns.[54] Oliver Sacks told how the internet altered the lives and medical treatment of people with achromatopsia (a rare and extreme form of color blindness). Preinternet, a doctor treating an achromat would likely never have seen another case in his career, and there was little capacity for information sharing; the internet facilitated the development of crowd-sourced information between patients and providers around the globe, "helping people who had no chance of communicating at all, at least with any depth."[55]

All these tools offer the possibility of simultaneously decreasing healthcare costs and increasing quality and access by reducing hospital admissions, facilitating patient cooperation with care plans, and improving patient education and health outcomes. Of course, only time will tell whether or not it can bring about improvements along all three dimensions. The cost of care continues to explode, and this is paired with the fact that hospital complication and infection rates are notoriously high. Hospital-acquired infection can significantly slow recovery. Approximately 4.5 out of every 100 hospital admissions result in a healthcare-associated infection.[56] For those who must be in hospitals, autonomous health can reduce the risks. An example is Cerner's St. John Sepsis Surveillance Agent,[57] which monitors hospital patients' data and applies artificial intelligence to sound early warnings of the onset of hospital-borne infection. Studies showed that this software could detect potentially lethal infections hours before human providers would notice and, curiously, also provided early warnings of PTSD and suicide.[58]

Not surprisingly, as complexity in healthcare provision increases, the work of healthcare becomes more error prone. The most common sources of iatrogenic morbidity and mortality[59] are (1) poor communication amongst various providers

53. Shamini Priya, "Singapore Government Launches COVID-19 Chatbot," *OpenGov*, February 24, 2020.
54. See https://bigthink.com/articles/whatapps-zika-brazil/.
55. John Alderman, "For Sacks, Cyberspace Is a Colorblind Island," *Wired*, January 20, 1997.
56. R. Douglas Scott II, "The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention" (working paper, Centers for Disease Control and Prevention, National Center for Preparedness, Detection, Division of Healthcare Quality Promotion, Atlanta, GA, March 2009).
57. "Saving Lives through Sepsis Surveillance," *Cerner*, March 27, 2017.
58. Robert Graboyes, "Passion, Persuasion and Serendipity in Innovation—St. John Sepsis Agent," *InsideSources*, December 21, 2016.
59. Martin Makary and Michael Daniel, "Medical Error—The Third Leading Cause of Death in the US," *British Medical Journal* 353 (2016): i2139.

in a patient's care team, (2) inadequate transmission of critical data—often siloed between healthcare institutions, (3) provider fatigue with bare-bones staffing, and (4) inadequate institutional policies—all the more reason to stay out of the hospital if possible.

La Pietra et al. describe strategies for reducing medical errors, including "electronic systems to communicate key pieces of asynchronous data."[60] Remote monitors and artificial intelligence do not get bored or tired and can perform repetitive tasks without losing focus. Intelligent machines can absorb vast amounts of data in seconds and identify patterns that human eyes would never see. Machine learning takes this a step further, by allowing those patterns to evolve as new data are added.

Dr. Devi Prasad Shetty, CEO of India's Narayana Health, has argued that "software will prevent us from making mistakes, be more efficient and help patients have better experience."[61] As an example, Shetty said, "[I]n the U.S., every year, close to 10,000 people die due to prescription errors. Hospitals must have a policy that prescriptions should be made only using specialized software that can make prescriptions. This is already available. . . . No doctor in this world has the presence of mind, round the clock, to calculate drug interaction accurately every single time."[62]

In 2017, Frans van Houten, CEO and chairman of Dutch technology giant Royal Philips, argued that telehealth can help prevent clinical errors, thereby saving lives. His logic was that telehealth can "connect all of the different caregivers in these different silos from diagnosis to treatment." Telehealth, he argued, can provide immediate access to comprehensive patient data at each point of care. Patient data can be processed through AI and analytical engines to predict oncoming events. In van Houten's words, "It's a great advantage to be able to look forward in time rather than backward in time."[63]

Riaz, Riaz, and Latif cited telehealth as a strategy for limiting clinical errors.[64] Specifically, they discussed how telehealth (including telepharmacy) can reduce the incidence of errors with medications. According to Casey et al.

60. L. La Pietra, L. Calligaris, L. Molendini, R. Quattrin, and S. Brusaferro, "Medical Errors and Clinical Risk Management: State of the Art," *ACTA Otorhinolaryngologica Italica* 25, no. 6 (2005): 339–46.
61. "Software Will Prevent Doctors from Making Mistakes: Shetty," *The Times of India*, July 21, 2018.
62. Ershad Kaleebullah, "Within a Decade, All Indians Will Have Access to High-Tech Healthcare: Dr. Devi Shetty," *ComputerWorld*, February 5, 2013.
63. Eric Wicklund, "Royal Philips: mHealth, Telehealth Can Prevent Medical Errors," *mHealth Intelligence*, February 5, 2017.
64. Muhammad Kashif Riaz, Muhammad Riaz, and Abida Latif, "Medication Errors and Strategies for Their Prevention," *Pakistan Journal of Pharmaceutical Sciences* 30, no. 3 (2017): 921–28.

"most hospitals reported that they track medication error rates, and some said error rates have improved since telepharmacy implementation."[65]

As Bashshur and Shannon wrote: "Integration of telemedicine with EHRs is essential for realizing the full medical and economic benefits of both technologies. For providers, ready access to patients presenting complaints and symptoms, medical history, and results from diagnostic tests would minimize medical errors, duplication, and unnecessary tests and procedures."[66]

Many of these studies focus on errors in inpatient hospital care. Errors, of course, occur outside of hospitals, as well. But a more fundamental problem with measuring the quantity and effects of medical errors is that there is no agreed-upon definition of medical error. It is tempting to define errors in terms of extant law—an error is an action that is realistically litigable. We might say that in the context of these studies, a "medical error" consists of a provider failing to follow acceptable practices—given the information available to that provider. But one of the most promising aspects of virtual health (and especially of autonomous health) is that it offers pathways to enhance the information available to human providers in hospitals or in other venues.

As an example, in the aforementioned case of a Japanese leukemia patient,[67] doctors appear to have erred in their diagnosis, but there may have been no "medical error" in any legal or best practices sense. Using the available data on the patient, multiple oncologists in multiple institutions arrived at similar diagnoses and treatment regimens. IBM's Watson computer, however, was able to absorb enormous quantities of data in a few minutes—far more than any physician (or group of physicians) could hope to do. And, using that data, Watson was able to identify patterns that eluded human providers. We can imagine countless situations where a provider makes decisions that differ from what he or she would prescribe *had the provider possessed better information*.

We can only guess as to the extent to which medical decision-making will improve with the advent of superior and more comprehensive data and less variation in its flow.

65. Michelle Casey, Todd Sorensen, Walter Elias, Alana Knudson, and Walter Gregg, "Current Practices and State Regulations Regarding Telepharmacy in Rural Hospitals," *American Journal of Health-System Pharmacy* 67, no. 13 (2010): 1085–92.
66. Rashid Bashshur and Gary Shannon, "National Telemedicine Initiatives: Essential to Healthcare Reform," *Telemedicine and e-Health* 15, no. 6 (2009): 600–10.
67. Rohaidi, "IBM's Watson Detected Rare Leukemia in Just 10 Minutes."

## Virtual Health Barriers and Breakthroughs

Prior to the COVID pandemic, even though there was great promise, the use of virtual health was limited due to the three R barriers we have mentioned: regulations, reimbursement, and regularity. In 2016, Dr. Licurse, Medical Director for Telehealth at Brigham and Women's Hospital, Boston, Massachusetts, described virtual care as being at the "cusp of transition" to a standard service and advised that five questions needed to be answered before initiation:[68] (1) Which clinical services should be offered virtually? (2) What technology tools are needed for these services? (3) Should telehealth programs be offered directly to patients or only among providers? (4) Does virtual health create value? and (5) How can the value be assessed from the patient's perspective as well as the organization's?

Organizational and provider ambivalence about the benefits of telehealth was a given. The *Journal of the American Medical Association* (JAMA) published a survey study, conducted between February and April 2019, asking participants about their use of different telehealth modalities. Of 2,555 respondents, only 4 percent had engaged in videoconferencing visits.[69] Adults older than 65, African Americans, and individuals living below or near the poverty line were less likely to report a willingness to use videoconferencing.[70]

We note in passing that such disparities are often present in the early days of a new technology. In 1940, for example, the Bell Telephone System found it necessary to produce a 20-minute film, *Dial Comes to Town*, to address the concerns that the elderly and others would have difficulty adapting to the idea of dialing their own telephone calls.[71] In 1961, Dwight Eisenhower, after serving as supreme commander of the Allied Expeditionary Force in Europe, president of Columbia University, and president of the United States, could not operate a rotary phone and was deeply frustrated by his first attempt.[72]

The COVID pandemic to a large extent has positively answered questions of value, purpose, and importance in use of virtual health. Within weeks of the

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68. Adam Licurse, "One Hospital's Experiments in Virtual Health Care," *Harvard Business Review*, December 9, 2016.
69. Shira Fischer, Kristin N. Ray, Ateev Mehrotra, Erika Litvin Bloom, Lori Uscher-Pines, "Prevalence and Characteristics of Telehealth Utilization in the United States," *JAMA Network Open* 3, no. 10 (2020).
70. Fischer et al., "Prevalence and Characteristics of Telehealth Utilization in the United States."
71. "The Dial Comes to Town," YouTube, December 13, 2012, https://www.youtube.com/watch?v=p45T7U5oi9Q.
72. "President Eisenhower Didn't Know How to Use a Rotary-Dial Telephone, Even Though He Had the 50 Millionth Phone," ClickAmerica, https://clickamericana.com/eras/1950s/president-eisenhower-the-rotary-dial-telephone-1955.

declaration of a national crisis, COVID instigated a rapid transition from brick-and-mortar primary care to telehealth. Incrementalism in the form of pilot studies, provider education, and business planning was compressed into a few days in order to coordinate remote care for patients and providers concerned about COVID exposure.[73]

Another JAMA study analyzed the use of primary care telehealth visits before and after the pandemic.[74] Between January 1, 2018 and December 31, 2019, 92.9 percent of US primary care visits were office-based and 1.1 percent of the total were via telehealth. At the beginning of 2020, that amount increased to 4.1 percent and in the second quarter of the year, to 35.3 percent of visits.[75]

The peak of telehealth visits occurred in April 2020 according to national data from Epic (an EHR company), with 69 percent of visits on their platform facilitated by telehealth. In the middle of July, that number declined to 21 percent of total encounters, upending predictions and business models.[76] However, on closer analysis, the initial high percentages were in part due to the denominator (number of total visits) being lower than normal, as previously described. Regardless, providers are struggling to find the right balance between telehealth and traditional visits, especially as systemic barriers to virtual health still exist, despite dramatic regulatory changes.

The most obvious of these barriers is the stifling of healthcare innovation and entrepreneurship through an unpredictable regulatory environment. Each state has its unique set of telehealth laws, defining what telehealth is, how and when it may be used, and who pays for it.[77] Telehealth is a technology designed to cross barriers of distance through increased connectivity, but has been partially hamstrung by state-based regulations, making it difficult at times for providers, vendors, and investors to amplify impact and financial returns.

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73. Ateev Mehrotra, Kristin Ray, Diane M. Brockmeyer, Michael L. Barnett, and Jessica Anne Bender, "Rapidly Converting to 'Virtual Practices': Outpatient Care in the Era of Covid-19," *NEJM Catalyst* (2020).
74. Caleb Alexander, Matthew Tajanlangit, James Heyward, Omar Mansour, Dima M. Qato, Randall S. Stafford, "Use and Content of Primary Care Office-Based vs Telemedicine Care Visits during the COVID-19 Pandemic in the US," *JAMA Network Open* 3, no. 10 (2020).
75. Alexander et al., "Use and Content of Primary Care Office-Based vs Telemedicine Care Visits during the COVID-19 Pandemic in the US."
76. Casey Ross, "Telehealth Grew Wildly Popular amid COVID-19. Now Visits Are Plunging, Forcing Providers to Recalibrate," *STAT*, September 1, 2020.
77. Jared Rhoads, Darcy Bryan, and Robert Graboyes, "Healthcare Openness and Access Project: 2020" (Research Papers, Mercatus Center at George Mason University, Arlington, VA, March 2020).

In addition to an uncertain regulatory environment, entrenched provider prejudices and patient and provider discomfort with technology have made initiation of virtual health modalities difficult. To build a successful virtual health business model, providers will have to forge uncharted strategic partnerships with new integrated delivery networks and leave old partnerships and networks behind. Integration of virtual healthcare technology within the workflow of a healthcare organization will require a radical restructuring of goals and priorities, imposing a new advertising, marketing, and business culture on traditional "hands-on" brick-and-mortar businesses.[78]

The benefits to patients through use of virtual health are obvious. Unfortunately, those patients with chronic disease, the socioeconomically challenged, or the rural residents who will likely benefit the most from virtual health's ability to leverage cost and quality improvement in disease management are often those patients with the least access to technology or are the least comfortable with its use. So the more we can address the regulatory, reimbursement, and regularity issues, the greater the opportunity to harness virtual health to improve our society's health.

## The Role of Regulation

Pre–COVID-19, federal and state regulations contained a web of provisions to impede the development and diffusion of telehealth and autonomous health. Consider the state regulations first. By and large, physicians were unable to treat patients across state lines unless they first obtained a license to practice in the states where the patients reside—a potentially expensive and time-consuming effort. This problem has been partially eased by the existence of the Interstate Medical Licensure Compact, whose member states offer reciprocal recognition of medical licenses.[79] In some states, patients could only engage in virtual visits with physicians whom they had previously seen in person. Some states required telehealth patients to be accompanied by "telepresenters"—say, a nurse who would sit with the patient while that patient would converse with a remote doctor. Pre–COVID, which telehealth services were covered by Medicaid differed markedly from state to state.[80]

78. V. M. Harrop, "Virtual Healthcare Delivery: Defined, Modeled, and Predictive Barriers to Implementation Identified," *Proceedings of the AMIA Symposium* (2001): 244–48.
79. "Interstate Medical Licensure Compact," Interstate Medical Licensure Compact, accessed December 30, 2021, https://www.imlcc.org/.
80. "Medical Reimbursement for Telemedicine," Chrion, accessed December 30, 2021, https://chironhealth.com/telemedicine/reimbursement/medicaid/.

Since 2016, the Mercatus Center's Healthcare Openness and Access Project (HOAP) has presented data on the degree to which patients and providers have discretion in treatment. As of early 2021, the most recent HOAP release was in December 2020.[81] However, due to the wildly fluctuating data during the pandemic, no attempt was made to revise data past that collected in late 2019 and early 2020. Of the 41 indicators (variables) reported in HOAP, at least seven have direct impact on telehealth:

- State allows medical licensure reciprocity with other states.
- State reimburses Medicaid providers at parity for store-and-forward telemedicine.
- State has less restrictive telepresenter requirements.
- State reimburses Medicaid providers at parity for remote monitoring.
- State allows online prescribing.
- State has less restrictive telepharmacy location laws.
- State allows online eye exams.

There are also four indicators related to scope of practice (for nurse practitioners, behavioral health providers, midwives, pharmacists) that could impact the provision of telehealth. In early 2021, these data may be primarily of historical interest, as temporary and permanent legal and regulatory changes have altered the landscape for telehealth. Similarly, the American Medical Association posted data on telehealth in the states in April 2020.[82] More up-to-date state regulations can be found on the websites of the National Conference of State Legislatures[83] and the Center for Connected Health Policy.[84]

Pandemic-era changes in telehealth policy for physician and nonphysician providers are found at the US Department of Health and Human Services (HHS) website.[85] A table of state-by-state regulations is also provided by the Federation

81. Rhoads, Bryan, and Graboyes, "Healthcare Openness and Access Project 2020."
82. American Medical Association, "Advocacy Resource Center" (dataset), April 2020, https://www.ama-assn.org/system/files/2020-04/telemedicine-state-orders-directives-chart.pdf.
83. "State Telehealth Policies," National Conference of State Legislatures, accessed December 30, 2021, https://www.ncsl.org/research/health/state-coverage-for-telehealth-services.aspx.
84. "Center for Connected Health Policy," Center for Connected Health Policy, accessed December 30, 2021, https://www.cchpca.org/telehealth-policy/current-state-laws-and-reimbursement-policies.
85. "Telehealth Licensing Requirements and Interstate Compacts," United States Department of Health and Human Services, last updated September 8, 2021, https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency/telehealth-licensing-requirements-and-interstate-compacts/.

of State Medical Boards.[86] Whether these changes remain extant after the pandemic dissipates is a state-by-state question. Some states are moving to make COVID-era changes permanent; an example is Colorado's SB20–212.[87] Detailed data on telehealth use during COVID are provided by the Centers for Disease Control and Prevention.[88]

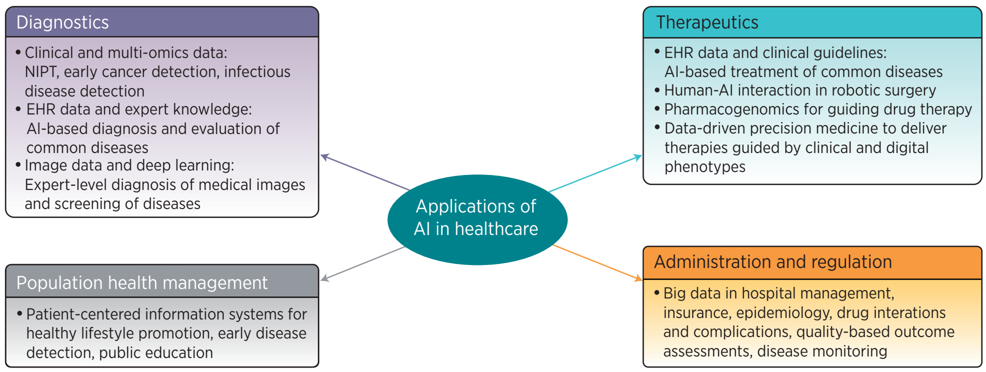
Federal regulations had a damping effect on autonomous health. First, a great deal of autonomous health was not reimbursable. Second, medical devices—including those using AI—must generally pass muster with the US Food and Drug Administration (FDA), whose approval processes can be slow, unpredictable, and costly. Williams, Graboyes, and Thierer, in a 2015 paper, review problems with the FDA's approval process for medical devices.[89] In his book, *Innovation Breakdown*, Joseph Golfo gives a riveting account of his struggle to gain FDA approval of an AI device to detect skin cancer;[90] approval was ultimately granted, but not before Gulfo's company was in financial ruins from the approval process. Medicare's pre–COVID failure to reimburse some telehealth and some autonomous health had a damping effect on research, development, and diffusion of promising technologies.

The FDA is aware of its shortcomings, writing that "the FDA's traditional paradigm of medical device regulation was not designed for adaptive artificial intelligence and machine learning technologies."[91]

In a 2019 paper, Jianxing He et al. review the status of AI in medicine and the obstacles that lie in the way of implementation.[92] The categories of AI that they list include (but are not limited to) "machine learning, representation learning, deep learning, and natural language processing." Figure 3 offers a good

86. Federation of State Medical Boards, "State and Territory COVID Telehealth Waivers" (dataset), March 3, 2021, https://www.fsmb.org/siteassets/advocacy/pdf/state-by-state-emergency-telehealth-information.pdf.
87. An Act Concerning Reimbursement for Health Care Services Provided through Telehealth, and, in Connection Therewith, Making as Appropriation Colorado Senate Bill 20–212 (2020).
88. Hanna Demeke, Sharifa Merali, Suzanne Marks, et al., "Trends in Use of Telehealth among Health Centers during the COVID-19 Pandemic—United States, June 26–November 6, 2020," *Centers for Disease Control* 70, no. 7 (2021): 240–44.
89. Richard Williams, Robert Graboyes, and Adam Thierer, "US Medical Devices: Choices and Consequences" (Research papers, Mercatus Center at George Mason University, Arlington, VA, October 21, 2015).
90. Joseph Gulfo, *Innovation Breakdown* (Franklin, TN: Post Hill Press, 2014).
91. "Artificial Intelligence and Machine Learning in Software as a Medical Device," United States Food and Drug Administration, last modified September 22, 2021, https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device.
92. He, Baxter, Xu, et al, "The Practical Implementation of Artificial Intelligence Technologies in Medicine," 30–36.

FIGURE 3. POTENTIAL ROLES OF AI-BASED TECHNOLOGIES IN HEALTHCARE




Source: Jianxing He, Sally L. Baxter, Jie Xu, Jiming Xu, Xingtao Zhou, and Kang Zhang, "The Practical Implementation of Artificial Intelligence Technologies in Medicine," *Nature Medicine* 25, no. 1 (2019), 30–36.

overview of applications. He et al. summarize the purposes of all these as "to use computer algorithms to uncover relevant information from data and to assist clinical decision-making. The areas in which barriers exist include data sharing and privacy, transparency of algorithms, data standardization, and interoperability across multiple platforms, and concern for patient safety." They also mention the need to educate an AI-literate workforce.

In seeking to devise a list of FDA-approved AI/ML devices, Benjamens, Dhunnoo, and Bertalan note that a challenge lies in the fact that the definitions are not exactly clear.[93] Bootstrapping off of terminology, they define as AI/ML as any technologies that use the terms "deep learning," "machine learning," deep neural networks," "artificial intelligence," and or "AI." But they note that some clearly AI/ML devices (e.g., AliveCor Kardia) are not described in such terms in FDA documentation. For purposes of regulatory approval, they argue, it is essential to have consistent working definitions of AI/ML, to clearly document which devices qualify for the definition, and to devise practicable rules for dealing with changes in software. Gaining FDA approval of every change in software, for example, is not practicable.

Thierer, O'Sullivan, and Russell note that "policymakers may initially be tempted to preemptively restrict AI technologies out of an abundance of caution because of the perceived safety, welfare, and market risks these new technologies

93. Benjamens, Dhunnoo, and Bertalan, "The State of Artificial Intelligence-Based FDA-Approved Medical Devices and Algorithms."

might seem to pose."[94] They also note that a different policy bias against artificial intelligence is the notion that AI will displace jobs and institutions. However, in reviewing the literature on creative destruction, they note that throughout history, technologies that automate repetitive processes often lead to greater opportunities in new positions.

Thierer has written widely of two sharply conflicting worldviews in healthcare regulation: the precautionary principle and permissionless innovation.[95] In its simplest form, the former view holds that technologies should be restricted or prohibited by regulators until evidence is strong that they are safe. Permissionless innovation is the notion that new technologies should be allowed on the market until and unless there is strong evidence of their lack of safety. To put it metaphorically, the precautionary principle says of new technologies, "Guilty until proven innocent," while permissionless says, "Innocent until proven guilty."

In a similar vein, Graboyes, in his 2014 paper, "Fortress and Frontier in American Health Care," refers to two worldviews—the Fortress and the Frontier. The Fortress view, he argues, focuses on protecting well-established insider producers and minimizing risks for consumers. The Frontier viewpoint "celebrates and rewards risk," by both producers and consumers. The medical professions tend to embrace the Fortress view while the information technology industry tends to prefer the Frontier view.[96]

Funding of future virtual health innovations may be well served by using retrospective prizes in lieu of prospective grants for financing innovation. The 21st Century Cures Act[97] included retrospective Eureka Prizes[98] for specific achievements in research and development, modeled on the prizes awarded by the XPRIZE Foundation (e.g., the Qualcomm Tricorder XPRIZE mentioned earlier).[99] In many circumstances, governments have no special insights into who will or will not shine as an innovator in the future. There are also reasons to assume that grants will go to well-heeled, well-established entities—including rent-seeking and risk-aversion

94. Adam Thierer, Andrea O'Sullivan, and Raymond Russell, "Artificial Intelligence and Public Policy" (Research Papers, Mercatus Center at George Mason University, Arlington, VA, August 23, 2017).
95. Adam Thierer, "Permissionless Innovation: The Continuing Case for Comprehensive Technological Freedom" (Arlington, VA: Mercatus Center at George Mason University, 2016).
96. Robert Graboyes, "Fortress and Frontier in American Health Care" (Mercatus Research, Mercatus Center at George Mason University, Arlington, VA, October 2014).
97. "21st Century Cures Act," United States Food and Drug Administration, last updated January 31, 2020, https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act.
98. Robert Graboyes, "How Eureka Prizes Will Create a New Age of Discovery," *Washington Examiner*, December 5, 2016.
99. XPRIZE, accessed December 30, 2021, https://www.xprize.org/.

and cognitive biases on the part of grant reviewers. Very likely, for instance, no government bureau would have funded Apple or Blackberry in advance.

The University of Cincinnati recently devised a pilot project to fuse telehealth with unmanned aerial vehicles (drones).[100] In the course of telehealth, the drone can deliver medical supplies or pick up specimens from the patient. Graboyes, Bryan, and Coglianese[101] and Graboyes and Skorup[102] explored the applications of unmanned aerial vehicle (drone) technology to medical purposes. Such purposes include the rapid transportation of blood products and other medical goods via drone. Other potential purposes include unmanned air ambulances and rapid delivery of defibrillator units by air.

## Policy Recommendations

Following are five sets of policy recommendations, compiled by the authors of this paper. The suggested regulatory changes would help expand the ability for providers to more easily provide virtual health services while also aligning financial incentives to focus on taking care of a patient regardless of location:

The first set of policy recommendations, 12 in all, concern telehealth.

**1.1.** Make temporary COVID-related telehealth exigencies permanent through state and federal law and regulation.

**1.2.** Allow medical licensure reciprocity with other states, thereby expanding the pool of available telephysicians for a given location. Prior to the pandemic, the general rule was that a physician could only offer telemedicine visits to patients in states where that physician held a license. Hence, physicians wishing to offer telemedical services nationwide would have to spend considerable time and expense seeking licenses on a state-by-state basis. Some states, such as members of the Interstate Medical Licensure Compact, did offer reciprocity. Since the pandemic began, some states have moved toward this reciprocity.

**1.3.** Grant nurse practitioners, behavioral health providers, nurse midwives, and pharmacists broader scope of practice and autonomy, thereby allowing them to

100. Michael Miller, "New UC Telehealth Drone Makes House Calls," *UC News*, March 15, 2021.
101. Graboyes, Bryan, and Coglianese, "Overcoming Technological and Policy Challenges to Medical Uses of Unmanned Aerial Vehicles."
102. Robert Graboyes and Brent Skorup, "Medical Drones in the United States and a Survey of Technical and Policy Challenges" (Mercatus Policy Brief, Mercatus Center at George Mason University, Arlington, VA, February 2020).

expand all they can do both locally and remotely. Scope-of-practice regulations often prohibit nonphysician providers from performing services for which they are trained and competent. Mandatory collaborative practice agreements limit the availability of these providers and impose costs and administrative tasks on them.

**1.4.** Reduce or eliminate telepresenter requirements (the requirement that a nurse or other healthcare professional be with the patient during a telehealth encounter). Some states required a nurse or other provider to be physically present with the patient during a telemedicine encounter, thus limiting the circumstances in which a patient can tap telemedicine for help.

**1.5.** Reduce restrictions on telepharmacy to allow greater online prescribing.[103] Some states currently limit telepharmacy to areas a certain distance from traditional pharmacies. Others impose physical facility and staffing requirements that may be inefficient for telepharmacy. Others impose limits of telepharmacy provision by out-of-state pharmacies.

**1.6.** Allow online eyeglass refraction exams. Some states prohibit such remote testing for glasses.

**1.7.** Include asynchronous services and telephone consultations within the definitions of telehealth. Nowadays, a considerable portion of patient-provider communication occurs via asynchronous methods (e.g., email, texts).

**1.8.** Ensure the Medicare and Medicaid site of care regulations allow the home to be used for telehealth. As the temporary HIPAA waivers are dropped, consider how we can retain some flexibility to ensure that providers are not stopped from communicating with patients in an emergency due to HIPAA provisions. Requiring off-site locations decreases the odds that a patient will access telehealth.

**1.9.** Invest in broadband infrastructure in underserved areas—rural, urban, and other. Telehealth requires a good deal of signal strength and reliability.

**1.10.** Take steps, via the FDA, to expedite the approval of medical devices related to virtual health—especially with regard to updating existing software. The FDA's role in evaluating changes in digital technologies can be hazy.

**1.11.** *Fund some telehealth research and development via retrospective prizes rather than by prospective research grants*. The 21st Century Cures Act created the Eureka Prizes for this purpose, in some ways mimicking the privately funded XPRIZEs.

103. Courtney Henecke, "State by State Telepharmacy Regulation Analysis Whitepaper," *TelePharm*, April 9, 2020.

**1.12.** *Fund quality improvement initiatives* to improve access to and usability of video visits in vulnerable populations. A considerable source of concern is that virtual health will serve the wealthy and not various disadvantaged people.

It is likely that the efficacy of virtual health will be enhanced by electronic health records, though significantly more powerful EHRs than exist today. In the future, a more comprehensive, intuitive set of EHRs may be able to expedite the provider's knowledge of a patient, or to give greater context to any autonomous health devices. In a 2018 paper, Graboyes and Bryan suggested general principles for improving the flow of data into and out of EHRs or, as they dub next-generation EHRs, "digital health biographies" (DHBs).[104] Graboyes, Bryan, and Berkowitz[105] added some caveats on the principles described by Graboyes and Bryan in their 2020 paper and noted that Berkowitz[106] anticipated some of their arguments ten years earlier.

In a 2017 *Wall Street Journal* article, Andy Kessler describes the promise of artificial intelligence in healthcare and argues that interoperable EHRs are an essential component of their ultimate success. However, he argues that EHR companies have found it in their interest to resist interoperability.[107]

More comprehensive, interoperable EHRs could allow telehealth providers to begin a visit with greater knowledge of the patient—or easy, comprehensible access to such knowledge as needed. The second set of recommendations, 4 in all, would increase the capacity of EHRs to facilitate virtual health.

**2.1.** Incorporate data from multiple providers—primary care physicians, specialists, hospitals, nurse practitioners, emergency rooms, pharmacists, therapists, etc. in a single EHR. A present-day patient typically has multiple EHRs from multiple providers. Interoperability is limited, so it is generally impossible to meld these separate EHRs into a holistic image of the patient.

**2.2.** Incorporate data from wearable telemetry such as Fitbits, insulin pumps, and heart monitors, along with subjective data entered by patients, including family history, childhood illness recollections, fears, and feelings. Present-day EHRs focus on information obtained while the patient is in the provider's office—an artificial environment. Wearable telemetry, patient perceptions, family histories, and so forth are essential to treatment.

104. Graboyes and Bryan, "From Electronic Health Records to Digital Health Biographies."
105. Robert Graboyes, Darcy Bryan, and Lyle Berkowitz, "Technical Expert Panel on Electronic Health Record Data Quality Best Practices for Increased Scientific Acceptability" (Public Interest Comments, Mercatus Center at George Mason University, Arlington, VA, October 30, 2020).
106. Berkowitz, address at the Transform 2010 Symposium.
107. Andy Kessler, "Siri, Am I About to Have a Heart Attack?" *Wall Street Journal*, January 9, 2017.

**2.3.** Require telehealth providers to uphold meaningful use criteria in EHRs they have self-developed. The Medicare EHR Incentive Program offers financial incentives for providers who use EHRs in a "meaningful" manner; hence the term of art, "meaningful use."[108] EHRs are only valuable to patients to the extent that they inform providers in their clinical duties. Their value is determined more by outputs than by inputs.

**2.4.** Establish a common protocol or protocols to minimize the cost and difficulty of shifting from one input or output vendor to another. Interoperability has been the elusive goal of EHRs. Decades ago, common software protocols enabled the internet to expand massively while integrating easily with a broad array of hardware and software.

The third set of recommendations, 5 in all, would increase the capacity of unmanned aerial vehicles (UAVs, or "drones") to facilitate virtual health by augmenting the capacity to deliver medical goods such as drugs and blood supplies to homes or other remote locations:

**3.1.** Develop adequate satellite communications to safely operate large numbers of drones. Communications with unmanned vehicles must be robust for safety and security reasons.

**3.2.** Have the Federal Aviation Administration reconfigure the architecture of American airspace to accommodate a new class of airborne vehicles. Present-day airspace architecture is inadequate to accommodate a large-scale increase in drone usage.

**3.3.** Have the Federal Communications Commission (FCC) devise protocols to ensure ultra-reliable ground-to-drone communications. Again, communications with unmanned vehicles must be robust for safety and security reasons.

**3.4.** Establish security standards to minimize the possibility of hostile forces harnessing drones for espionage purposes. A large proportion of drones are built in China, and concerns have been raised about imbedded spyware. Domestic hackers also have the capacity to harness drones to cause chaos.

**3.5.** Begin to establish state and local regulatory roles for drones. Federal action on drones is insufficient. State and local authorities must be deeply involved in the planning for this capability.

108. "Meaningful Use," HealthIT.gov, last modified October 22, 2019, https://www.healthit.gov/topic/meaningful-use-and-macra/meaningful-use.

## The Role of Reimbursement

Financial incentives can alter the mission of an enterprise, though not always in a positive fashion.

Healthcare as big business has been traditionally funded by fee for service. The fee-for-service model has led to more utilization of clinic visits, procedures, and overall interventions with no clear link to quality or improved outcomes. Volume equals money, but not necessarily quality. Regulators have attempted to flatten the cost curve by an ever-increasing flurry of codes, bundles, and restrictive cost interventions, with varying levels of largess attached depending on insurance type.

But the real issue for both population and individual health is whether money spent translates to the stated core value of healthcare: "making the sick better" (or keeping the healthy well). Attempted resolution to the fee-for-service reimbursement model's perverse incentives is made with a system of value-based healthcare delivery.[109] With the value-based model, hospitals and healthcare providers are paid based on patient health outcomes and rewarded for helping patients improve their health and manage their chronic disease.

A fee-for-service model disincentivizes providers from innovating by micromanaging what will and will not be paid for (i.e., an in-office visit may be compensated while a telemedicine visit is not). A value-based healthcare delivery model ideally rewards providers for innovating—paying for good outcomes while not dictating how the provider achieves their positive result, as long as it is cost-effective.

Another major cost driver in healthcare is the expense of skilled labor.[110] Skilled labor continues to increase in cost across various sectors of the economy. Healthcare, by and large, is a service industry, driven by expertise requiring many years of training and education. All of this adds to the cost of care.

As Auerswald points out in his analysis of the benefits of moving healthcare into the home, the only way to diminish costs of healthcare is to reduce the total costs of labor inputs, either by using less labor in existing service models or changing the service model to replace high-cost labor with technology and lower-cost labor.[111] Use of deep learning or artificial intelligence is a promising technology area that can be used for automating billing, medical records, and

109. "What Is Value-Based Healthcare?" *NEJM Catalyst*, January 1, 2017.
110. Eric Helland and Alexander Tabarrok, *Why Are the Prices So D*mn High? Health Education, and the Baumol Effect* (Arlington, VA: Mercatus Center at George Mason University, 2019).
111. Auerswald, "Healthcare to the Home."

other costly administrative tasks. Additionally, as IBM's Watson has shown, many diagnostic tasks that have been the traditional purview of the healthcare professional can be done by AI. Chatbots can answer common medical questions in real time, replacing paramedical providers that have typically performed this task. Less human labor through automation means more efficiency and lower costs in healthcare provision.

It is commonly stated that America faces a coming physician shortage. But as one of the co-authors of this paper (Berkowitz) said, "The answer may not be in increasing the number of professionals available, but in using them more efficiently in a team-based fashion."[112] Berkowitz also wrote an article called, "We Don't Have a Shortage of PCPs, We Have a Shortage of Using Them Efficiently."[113] Another co-author (Graboyes) postulated a "Calendar Test," whereby some healthcare reform either does or does not clear some time on the physician's calendar—without compromising the quality of care: "shifting some tasks from the physician's calendar to nonphysicians (like nurses or technicians), intelligent machines (like computer diagnostics), or patients themselves (by using home diagnostic equipment, for example). Digital technologies make this possible in previously unimaginable ways."[114]

A *Modern Healthcare* article stated that "virtual health is not about technology replacing humans in health care, but about augmenting and supplementing providers to improve the delivery of care—moving from a focus on bedside to 'webside' manner. Virtual care may help relieve clinicians of mundane, administrative, or routine tasks, affording them more opportunities to practice at the top of their license."[115]

Value-based reimbursement promises to help virtual health flourish. In the meantime, this sector has been stymied by healthcare providers unwilling to invest in autonomous technology, since there is no pathway to reimbursement through fee for service. Deep learning technology (i.e., a particular corner of artificial intelligence) has been shown to work and will likely save lives and decrease medical errors. But there is no compensation for business outgo.[116]

112. "Medical Community Wrestles with Physician Shortage," *Lancet*, March 18, 2013.
113. Lyle Berkowitz, "We Don't Have a Shortage of PCPs, We Have a Shortage of Using Them Efficiently," *drlyle.blogspot.com*, January 6, 2013.
114. Robert Graboyes, "Cutting Health Care Costs—the Calendar Test," *InsideSources*, October 11, 2017.
115. Ken Abrams and Chris Shudes, "Virtual Health: Extending the Human Touch in Care Delivery," *Modern Healthcare*, March 15, 2019.
116. "Artificial Intelligence in Healthcare–Reimbursement (Part One of a Four-Part Series)," *Health Capital Topics* 10, no. 4 (2017).

Business incentives and technological innovation must align. Improved patient outcomes need to become the trigger for payment.

One company, Viz.ai, has received FDA clearance for a deep-learning system that automatically identifies suspected large vessel occlusion strokes on CT and notifies the neurointerventionalist directly, improving response time by 89 minutes.[117,118] Viz has received the first New Technology Add-On payment from CMS for AI software, establishing an innovative payment model that will allow the technology to thrive and save lives.[119] However, this is only one company. Many other medical AI startups are likely to collapse, taking life-saving technology into oblivion or delaying initiation for many more years to come. Part of the problem lies with the slow, expensive, and often unpredictable FDA approval process.[120] Another factor is inadequate reimbursement to compensate providers for developing and using AI capabilities in treating patients.[121]

Telehealth remains a cautionary tale. Technologies with the potential to improve patient health and satisfaction are discouraged by reimbursement models that do not reward these benefits. Multiple clinical trials suggest that telehealth is safe and beneficial for patient care. (We recognize that we are in the early stages of such analysis.) However, regulatory uncertainty, state medical licensing barriers, and varying-to-nonexistent reimbursement had made telehealth utilization of minimal impact in the pre–COVID healthcare landscape. However the data eventually shake out, the big question addressed here is whether central authorities should attempt to predetermine the availability of telehealth, or whether the questions should be determined in a decentralized fashion by providers and patients.

With the COVID pandemic, CMS passed emergency measures under the 1135 waiver authority and Coronavirus Preparedness and Response Supplemental Appropriations Act that allowed Medicare to pay for hospital and office telehealth visits covering a wide array of healthcare providers.[122] The CARES

117. "The Future of AI-Powered Intelligent Care Coordination," Viz.ai, accessed December 30, 2021, https://www.viz.ai/.
118. Luke Oakden-Rayner, "It's Complicated. A Deep Dive into the Viz/Medicare AI Reimbursement Model," *The Health Care Blog*, September 24, 2020.
119. Oakden-Rayner, "The Medical AI Floodgates Open, at a Cost of $1000 per Patient."
120. See Richard Williams, Robert Graboyes, and Adam Thierer, "US Medical Devices: Choices and Consequences" (Mercatus Research, Mercatus Center at George Mason University, Arlington, VA, October 2015).
121. "Artificial Intelligence in Healthcare—Reimbursement (Part One of a Four-Part Series)," *Health Capital Topics* 10, no. 4 (2017).
122. "Medicare Telemedicine Health Care Provider Fact Sheet," Centers for Medicare and Medicaid Services, last modified March 17, 2020, https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet.

Act also awarded $200 million through the FCC to help medical groups fund broadband installation.[123] In a 2020 paper, Keith Mueller and Hannah Rochford examined how the rise of telehealth during COVID-19 was affecting rural areas of the country.[124] Their article describes recommendations from the Bipartisan Policy Center.

However, many insurers remain concerned that telehealth will increase utilization of care and be a source of waste, abuse, and fraud. This last concern has proven to be a real issue, as increased fraud has become one of the negatives of increasing telehealth activity. For example, in September 2020, the Department of Justice charged 345 medical professionals (physicians, nurses, and others) with fraud. Of $6 billion in losses, $4.5 billion was related to telehealth. Providers ordered unnecessary tests and equipment for patients with whom they had had little or no contact.[125] Mike Cohen of the HHS Inspector General's Office stated, "There are unscrupulous providers out there, and they have much greater reach with telehealth . . . Just a few can do a whole lot of damage."[126] In the battle against COVID-19, a lot of the government's protective barriers against fraud have been waived in order to expedite treatment. For example, with the waiver of co-pays and deductibles, anti-kickback measures were significantly hampered.[127] Telehealth companies argue that telehealth is no more likely to result in fraud than brick-and-mortar visits. However, the criticism has been levied that virtual visits are easier to falsify.

Commercial insurers have already taken steps to decrease payments and coverage of telehealth unless the visit is directly linked to COVID. On October 1, 2020, several private health insurance companies ceased offering full coverage for virtual visits.[128] CMS appears to be committed to extending Medicare and Medicaid telehealth waivers until COVID is no longer considered a public health emergency,[129] but providers remain in a state of uncertainty regarding future reimbursement for telehealth visits.

123. Fred Schulte, "Coronavirus Fuels Explosive Growth in Telehealth—and Concerns about Fraud," *Kaiser Health News*, April 22, 2020.
124. Keith Mueller and Hannah Rochford, "The Evolving Landscape of National Telehealth Policies during a Public Health Emergency: Responsiveness to Rural Needs," *Rural Policy Research Institute* (2020).
125. Jeff Lagasse, "DOJ Charges 86 Defendants with $4.5 Billion in Telehealth Fraud," *Healthcare Finance*, October 1, 2020.
126. Schulte, "Coronavirus Fuels Explosive Growth in Telehealth."
127. Schulte, "Coronavirus Fuels Explosive Growth in Telehealth."
128. Rebecca Robbins and Erin Brodwin, "As Insurers Move This Week to Stop Waiving Telehealth Copays, Patients May Have to Pay More for Virtual Care," *STAT News*, September 29, 2020.
129. Robbins and Brodwin, "As Insurers Move This Week to Stop Waiving Telehealth Copays."

Overall, the move by commercial insurers away from telehealth compensation is linked to their concerns that telehealth will be overutilized by patients and that providers will bill for telehealth visits over issues that traditionally would have been handled without charge by a simple telephone call.

Fortunately, preliminary data exist regarding the impact of open access to telehealth and cost of utilization. Medicare fee-for-service data analysis of telehealth utilization after the COVID pandemic shows total healthcare visits did not increase, suggesting that telehealth substituted for in-person care without increasing overall utilization.[130] A US Department of Veterans Affairs study indicated that from March to May 2020, a 56 percent decline in in-person visits was replaced by a twofold increase in telephone and video visits. Once again, telehealth replaced in-person visits but did not increase overall utilization.[131]

The Taskforce on Telehealth Policy (TTP) points out five factors that impact the cost savings of telehealth: (1) substitution of in-person care; (2) preventing more costly care; (3) lower no-show rates; (4) greater transitional care management; and (5) lowering skilled nursing facility transfers.[132]

In other words, evidence accumulated during the pandemic suggests that patients use telehealth as a replacement for in-person clinic visits, not in addition to those visits. There is also some evidence that telehealth access keeps patients out of costly emergency department and urgent care centers.[133] It remains to be seen whether these hold true when the pandemic abates.

Because of telehealth's convenience, more patients are also able to keep their appointments, in part due to decreased travel costs and time. In fact, CMS has estimated that telehealth will save patients $100 million dollars in travel expenses by 2024.[134] (At the same time, some worry that the ease of using telehealth could lead to higher levels of utilization and spending.) Transitional care management is also important for decreasing hospital readmission rates, which

130. "Taskforce on Telehealth Policy (TTP) Findings and Recommendations," *National Committee for Quality Assurance* (2020).
131. "Taskforce on Telehealth Policy (TTP) Findings and Recommendations."
132. "Taskforce on Telehealth Policy (TTP) Findings and Recommendations," 21.
133. "Ascension Task Force on Telehealth Policy," *Ascension* (2020); Shayan Vyas, Joanne Murren-Boezem, and Patricia Solo-Josephson, "Analysis of Pediatric Telemedicine Program," *f* (2018); Susan Morse, "Telemedicine Eliminates Time and Distance to Save Money," *Healthcare Finance*, October 16, 2019; Bill Siwicki, "At Cigna, Telehealth Reduces Patient Costs and ER Visits, and Boosts Use of Generic Rx," *Healthcare IT News*, November 20, 2019.
134. "Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021," 83 Fed. Reg. 54982 (proposed November 1, 2018).

often lead to financial penalties for providers. Telehealth is an excellent modality for tracking patient well-being and averting preventable readmissions. Another large cost that telehealth mitigates is transfer rates from skilled-nursing facilities to the hospital, which costs Medicare over $4 billion each year.[135]

Virtual health holds promise for cost reduction in healthcare. But private and government payer concerns regarding increased waste, fraud, and abuse associated with the technology must be aggressively addressed. Compliance training is an integral component to avoiding up-coding and misrepresentation of the virtual service provided. Businesses using telehealth must closely monitor their bills and charts for patterns of fraud and abuse and have a mechanism in place for reporting bad actors. Equally important is instigating adequate cybersecurity technology to authenticate patient identities before healthcare provision and to protect telehealth platforms from being hacked.[136]

Questions as to whether telehealth visits should be compensated at parity with brick-and-mortar clinic visits and whether care must be video (versus audio only), or synchronous (versus asynchronous) to qualify for compensation are inevitable in a fee-for-service reimbursement model where care modalities are highly regulated. Note that asynchronous care includes store-and-forward telehealth and remote patient monitoring, whereas communication occurring in real time between patient and provider is considered synchronous, whether via just audio (phone) or video with audio.

Many states have parity laws that require insurers to pay providers for telehealth services at the same rate as an office visit. However, there is a lack of uniformity across states' laws, making it widely variable on a state-by-state basis as to which telehealth services will be covered.[137]

Synchronous care has a clear pathway for compensation and far exceeds reimbursement for store-and-forward and remote patient monitoring.[138] Effective treatment plans would compensate a provider for using all three types of services, with a projected savings in the United States of $4.28 billion on healthcare spending per year based on much lower pre–COVID volumes in

135. David Grabowski and A. James O'Malley, "Use of Telemedicine Can Reduce Hospitalizations of Nursing Home Residents and Generate Savings for Medicare," *Health Affairs* 33, no. 2 (2014): 244–50.
136. Tony Raval, "Fighting Telemedicine Fraud: Why Robust Verification Is Needed," *Forbes*, August 25, 2020.
137. Katherine Restrepo, "The Case against Telemedicine Parity Laws: Let the Market Thrive in America's Most Regulated Industry," *John Locke Foundation* (2017).
138. Center for Connected Health Policy, "CCHP: Updated 50 State Telehealth Laws & Reimbursement Policies Report: Fall 2019," *Center for Connected Health Policy* (2019).

2016.[139] Examples are slowly rolling out, such as in Nebraska where recently passed legislation requires payers to cover asynchronous telehealth services by dermatologists. However, these are piecemeal movements and there is still much to be done.

Therefore, it is clear we need stronger policy advocacy for improved and expanded virtual health reimbursement. One basic issue is the wide variance in how telehealth is defined on a state-by-state basis. States and the federal government should work on standardizing regulatory nomenclature as it pertains to virtual health. This will enable tracking of policy outcomes on a state-by-state basis, with policy modeling of those states that have most successfully reduced costs and improved quality through use of the technology. Additionally, regulators should avoid picking "favorite" modalities (i.e., synchronous over asynchronous care), types of conditions that may be treated by virtual health, or kinds of clinicians eligible to use virtual health, focusing rather on facilitating healthcare outcomes and quality as the ultimate goal, rather than whether a certain act was performed.

Incentivizing an efficient virtual health capability will demand innovative reimbursement mechanisms. During the COVID-19 pandemic, federal and state governments have edged toward parity requirements—equal compensation for virtual and in-office encounters. But if virtual health, indeed, has cost advantages, then rigid parity rules may prevent the healthcare system from enjoying such economies. For example, if the true cost of an in-office visit is $100 and the true cost of a telehealth visit is $70 (say, because the facility costs less), then a rigid parity regime may prevent the telehealth provider from offering the visit for less than $100. An alternative would be a rule that states that in-office visits will be reimbursed at a rate of $100, whereas the telehealth visit is reimbursed at a rate of *up to* $100—leaving the provider the option of charging less to increase market share.

Policymakers and healthcare businesses need to rationalize the reimbursement of virtual health. Here is one personal, anecdotal example:

One of this paper's authors recently had a temporary health crisis that required frequent interaction with a primary care provider (PCP). The PCP received reimbursement for two virtual visits of approximately 15 minutes apiece. But the doctor and patient then had a lengthy, time-consuming exchange via the doctor's secure portal—with the doctor spending considerably more time on correspondence than the reimbursable telehealth visits. The same concept is

139. Tony Yang, "Telehealth Parity Laws: Ongoing Reforms Are Expanding the Landscape of Telehealth in the US Health Care System but Challenges Remain" (Policy Brief, *Health Affairs*, August 15, 2016).

often found with administrative tasks related to patients' cases as well. They are time-consuming and essential, but not reimbursable.

While attorneys, accountants, and most every other professional can bill for any such use of time, the third-party payor system makes this concept problematic in healthcare. In this example described, the doctor received no compensation for anything outside of the two virtual visits. Queried about the experience, the doctor said the following (lightly edited for punctuation):

"Under our current system the only thing that generates income are in-person visits, virtual [video] visits ([although] some insurances aren't covering them), and some telephone visits. We charge nominal fees for forms and letters but otherwise, my time is not compensated, and it's all code-based. The coding system is not taught in medical school and not based in any medicine. It is a completely separate billing system based off Medicare laws and insurance companies. I have to learn two mutually exclusive ways to understand my patients' conditions—one to help them and one to get paid. If there is a question—the coder is always right. I have to fix codes every day."

The costs of such dysfunction fall on the patients, whose physical well-being must compete with the doctor's financial well-being.

The fourth set of policy recommendations, 4 in all, would make reimbursement methodologies more conducive to virtual health.

**4.1.** Ensure that Medicare and Medicaid reimbursement for remote monitoring is optimized for both patients and providers by reviewing adoption and evolving rules to increase adoption and success. Remote monitoring today is reimbursed on a spotty basis.

**4.2.** Pass legislation making virtual visit reimbursement permanent. Broad reimbursement de facto reforms were implemented ad hoc during the pandemic. The question remains whether those reforms remain in place or are rolled back as the pandemic (or reactions to the pandemic) abates.

**4.3.** Maintain reimbursement parity between video and telephone visits. Parity may be inadvisable for televisits versus in-person visits, because the cost bases are quite different (e.g., differential need for bricks-and-mortar). However, the cost differences for audio plus video televisits and audio-only visits would appear to be small. Parity between these two modalities would assure that audio-only phone time will be reimbursable.

**4.4.** Reimburse providers for asynchronous care (aka store-and-forward telemedicine), perhaps at parity with office or other telehealth visits. Asynchronous telemedicine has advantages and disadvantages vis-à-vis synchronous telemedicine in the same way that in everyday life email has advantages and disadvantages vis-à-vis telephone calls. Parity between the two—whatever that means—may or may not be advisable.

## The Role of Regularity (Cultural Acceptance by Providers and Patients)

In addition to having regulatory and reimbursement changes that support the expanded use of virtual health, we also need patients, providers, and payors to all accept virtual health as a regular and important part of the care process. This will involve ensuring that all parties are comfortable with the quality of virtual health, as well as the introduction of new roles and technologies that will weave into our regular workflows and processes.

Let us start with what many regard as the major concern people have about telehealth—whether the quality will be equivalent to the "regular" office-based visit. The pragmatic reality is that it may range from worse to similar to better, depending on a variety of factors. And so, we need to better answer this issue by framing the question as to how we define quality and how we measure it at both an individual and population level. The definition cannot simply be how well it mimics what is done in an office visit. Rather, the key points to help us better understand virtual health quality will be the three A's: appropriateness, access, and assurance.

The first point to accept is that telehealth is particularly appropriate for routine, repeatable types of medical care, which often represents over half of the care that is delivered in the outpatient setting. This may include minor urgent care issues (e.g., sinus infections, colds), stable chronic care issues (e.g., refills of meds in a stable patient), and preventive care (e.g., reviewing guidelines and ordering screening tests). These types of routine care should be backed by evidence-based or consensus-based guidelines, and have minimal risk involved.

Importantly, telehealth may also be appropriate for use in supplementing higher risk or complex care, such as tele-stroke consults en route to an emergency room, specialists' consults from hospital to hospital, or eICU monitoring. In all cases, an online specialist can add value to the nonphysician staff or less specialized doctors who are directly with a patient, such as by ordering or interpreting diagnostic tests, changing management, or triaging to determine if a higher level of care is required. On the other hand, telehealth is less appropriate for highly complex or unstable patients who require a physical examination or procedure or extended period of face-to-face contact directly with a specialized doctor. Ideally, by increasing the amount of telehealth used for some types of care, doctors will be able to help provide care for more patients overall, and may also find they have more time for face-to-face care with those who really need that type of on-site attention.

The second point to understand is that by improving access to care across geographies and time, telehealth can improve quality at both an individual and population level. In other words, telehealth gives many people the option to receive quality medical care at a time and place that is convenient to them, without wasting hours of time traveling to the doctor's office and waiting in an examination room. Compared to a trip to an office, urgent care facility, or emergency department, telehealth visits are not only more convenient, but are almost always cheaper (in terms of money and time), thus increasing the likelihood of being used. This reduced patient cost may include travel costs and parking, less time off from work, and lower co-pays. This convenience and decreased cost are critical, as many patients would delay or go without care if telehealth were not an option, which then may result in worsening symptoms and thus more expensive patient care long term.

This importance of how telehealth increases access to care was highlighted in the National Quality Forum's whitepaper on "Creating a Framework to Support Measure Development for Telehealth."[140] In this report, Judd Hollander, MD, the co-chair of the National Quality Forum's Telehealth Committee, noted, "For many patients, telehealth can mean the difference between seeing their doctor or receiving no care at all." This concept can be applied to populations in two ways. For well-served patients who already have easy access to care, it can decrease the stress on their providers, thus freeing up time for office-based care for those who truly need it. For underserved patients, it can provide a way to access care they were not getting otherwise, or where they were using the urgent care or emergency room as their first point of contact due to its convenience.

Finally, any high-quality telehealth providers should have a quality assurance program in place to define, measure, and report on their quality over time. Understanding how a telehealth company strategizes and executes on their quality program is an important point that patients, providers, and payors should review as they choose whom to work with.

The fifth set of policy recommendations, 10 in all, would help telehealth professionals to provide the highest-quality standards of care.

**5.1.** Well-defined quality metrics with easy-to-use dashboard and reporting, including general and individual provider scorecards and analytics describing

140. Judd Hollander, "Creating a Framework to Support Measure Development for Telehealth" (Final Report, National Quality Forum, August 31, 2017).

performance against predetermined benchmarks and network peers. This would ensure transparency that is currently lacking.

**5.2.** Creation of telehealth-specific clinical guidelines for physicians based on evidence- and consensus-based sources, which are then made easily available to providers. Best practices for telehealth will differ in some ways from best practices in face-to-face medicine. Guidelines would be advantageous, for the same reasons that emergency medicine practitioners and hospitalists today have guidelines that differ from, say, a primary care physician in an office setting. Telehealth guidelines can also diminish malpractice concerns.

**5.3.** Incorporation of clinical guidelines into the visit workflow via intake questions, highlighted diagnostic and treatment options, and quality metrics. The motives here are similar to those in the previous paragraph.

**5.4.** Proactive and reactive antibiotic stewardship to avoid the inappropriate prescribing of antibiotics. This is not unique to telehealth, though the particulars of implementation will differ from in-office encounters.

**5.5.** Peer-reviewed monitoring of visits for both routine analysis and specific complaint review—at the very least this can be via chart review, but may include review of audio or video if the visit is recorded for quality purposes. This will be important for transparency, safety, and quality assurance.

**5.6.** Use of expert systems, advanced analytics, and predictive modeling programs to better understand all aspects of care, including antibiotic utilization, triaging, documentation accuracy, diagnostics, treatment choice, patient satisfaction, and fraud detection. We do this in other areas of medicine. Widespread telehealth is too new for protocols to have been established. Payors will be more likely to compensate for telehealth with this in place.

**5.7.** Standardized accreditations, such as from National Committee for Quality Assurance (NCQA) and URAC (formerly the Utilization Review Accreditation Commission). Such controls are in place in other areas of medicine. Again, widespread use of telehealth is too new for such protocols to have been in place.

In addition to ensuring that virtual health is done in a high-quality manner, other important attributes to ensure consistent and wide adoption as a regular part of healthcare culture will include the following.

**5.8.** The rise of “virtualists,” providers who are specially trained and spend most of their time doing virtual care. Similar to the rise of hospitalists at the turn of the century, this will allow a smaller group of doctors to become highly proficient and efficient at this type of care and help the field advance more quickly.[141,142,143] Medical education that incorporates the use of video, phone, and asynchronous care;[144,145,146,147] as well as the use of AI and other machine-learning tools to help augment some care and replace other parts of care.[148,149] Technology and tools that make telehealth better, faster, cheaper, and easier, including:

- Advanced video codec abilities to ensure better quality of video when they are being used;
- Previsit intake systems that allow for appropriate triage (does this patient qualify for autonomous care, telehealth, or office-based care; or do they need an emergency room visit);
- Mobile tools that allow for easier capture of vital signs and other physical exam elements (e.g., ear visualization, heart and lung exam, photo capture of skin lesions);
- AI-based tools that help with diagnostics based on audio and video inputs, from helping to diagnose skin conditions to depression.

This would increase the likelihood of quality care, making virtual health an ethical and acceptable modality.

**5.9.** Security and privacy tools to ensure safety of data, such as:

- Technology to ensure all data are held and transmitted in a secure manner, especially with the rise of cyberattacks.

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141. Micheal Nochomovitz and Rahul Sharma, "Is It Time for a New Medical Specialty?" *JAMA Network*, February 6, 2018.
142. Daniel Oran, "The Rise of the Virtualist," *The Lancet*, July 6, 2019.
143. Kevin Fickenscher, Joseph Kvedar, and Joseph Nichols, "Beyond the Medical Virtualists: Creating Capacity in the Health Care Team," *HealthAffairs*, March 22, 2018.
144. Oranicha Jumreornvong, Emmy Yang, Jasmine Race, and Jacob Appel, "Telemedicine and Medical Education in the Age of COVID-19," *Academic Medicine* 95, no. 12 (2020): 1838–43.
145. Shayan Waseh and Adam Dicker, "Telemedicine Training in Undergraduate Medical Education: Mixed-Methods Review," *Journal of Medical and Internet Research Medical Education* 5, no. 1 (2019).
146. "Educators Discuss Integrating Telehealth in Student Curriculum," American Medical Association, last modified January 27, 2021, https://www.ama-assn.org/practice-management/digital/educators-discuss-integrating-telehealth-student-curriculum.
147. Robin Warshaw, "From Bedside to Webside: Future Doctors Learn How to Practice Remotely," *Association of American Medical Colleges*, April 24, 2018.
148. Ketan Paranjape, Michiel Schinkel, Rishi Nannan Panday, Josip Car, and Prabath Nanayakkara, "Introducing Artificial Intelligence Training in Medical Education," *Journal of Medical Internet Research* 5, no. 2 (2019).
149. Vanessa Rampton, Michael Mittelman, and Jörg Goldhahn, "Implications of Artificial Intelligence for Medical Education," *The Lancet*, March 2020.

- Policies that ensure data are used appropriately and only with consent, especially as companies are willing to sell patient data as a new revenue source.

Without such controls, HIPAA compliance is problematic, and the failure of a security system could cost providers sizable government fines.

**5.10.** Guidance to distinguish ambulatory care best suited for virtual versus in-person care. This is important from the standpoint of patient health and critical for malpractice risk reduction.

## Conclusion: Virtual Health Is Critical to the Future of Healthcare

It is clear that the COVID-19 pandemic has certainly caused many ills, but it has also acted as a spur, ushering in a new era of virtual health to improve access and convenience for so many patients across the nation.

In 1928, Dr. William Mayo noted that while "the aim of medicine is to prevent disease and prolong life, the *ideal* of medicine is to eliminate the need of a physician."[150] In that vein, we need to understand that simply switching an office visit to a video visit is not enough if we genuinely want to scale our ability to use technology to increase access, reduce costs, improve quality, and enhance the experience of patients along multiple parts of their healthcare journey. More specifically, we need to define a broader vision of virtual health, which combines autonomous care with telehealth in ways that can provide the best care for as many people as possible by optimizing technologies and strategies to ensure the right care, at the right time, by the right people (or machines), and in the right setting.

For this vision to succeed and expand in the United States, we must have good alignment of the "three Rs": reimbursement, regulation, and regularity. This paper describes a framework, a roadmap, and specific points on how we can accomplish this for both telehealth and autonomous care. We hope this advice will be used to help create a future where we can provide more care online via both automation and telehealth, while ensuring the most complex and serious patients can be seen in person when and where they need. This will allow us to move more quickly to a healthcare system that combines the best of technology with the best of humanity.

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150. Thomas M. Habermann and Amit K. Ghosh, *Mayo Clinic Internal Medicine Concise Textbook* (London: CRC Press, 2007), foreword by Dr. William Mayo, p. vi.

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