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DATA COLLECTION AND USE DURING COVID-19: KEY THEMES AND CONSIDERATIONS

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INTRODUCTION

The COVID-19 pandemic has affected every inch of the globe, with every country scrambling to contain the spread, care for the sick, and ultimately eradicate the virus. Despite being arguably the country that should have been best prepared to face the pandemic based on resources and technology alone, the United States continues to struggle to “flatten the curve” and contain the virus’s spread. As of June 2020, the United States has more reported cases than any other country or region in the world.¹ The country so far lacks the national coordination needed to deliver a centralized, swift, and efficient response. COVID-19 has highlighted the cracks in the foundation of the United States’ health-care and medical research systems; more specifically, it has exposed inefficiencies in the mechanisms through which learnings gleaned from care effectively inform and advance research.

Although big tech and public-private partnerships have undertaken many initiatives, reflecting a widespread and unprecedented desire to collaborate in the fight against the virus, efforts to collect and report consistent data to slow the spread remain uncoordinated and largely unsuccessful. Many of these efforts have exposed a lack of data interoperability, an inability to aggregate data from disparate sources quickly, difficulties with analyzing data in real time, and a crisis of consumer trust in big tech. This paper explores these key themes and challenges as they relate to the advancement of medical research and discusses how their importance has been highlighted during the COVID-19 pandemic. We also underscore the importance of implementing clear guardrails and conditions that specify circumstances in which data use is allowable, given the highly sensitive nature of health data. Ultimately, without better systems and standards in place to streamline data collection and reliable channels with which to funnel health-care data into research, we lack the toolset and capabilities to target research to the areas of highest need amid a crisis. We miss opportunities to use what data we have to gain a comprehensive understanding of what is occurring in real time.

1. “COVID-19 Dashboard,” Center for Systems Science and Engineering, Johns Hopkins University, accessed May 11, 2020, <https://www.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6>.



KEY THEMES

PROMOTION OF DATA INTEROPERABILITY

The rapid, global spread of the COVID-19 virus has magnified the importance of secure access to and easy sharing of health information. Readily available health data are critical in allowing clinicians to appropriately diagnose and treat patients across various health systems, geographic locations, and devices, and grants researchers information critical to the development of clinical trial protocols.²

Interoperable electronic health records (EHRs) enable clinicians and patients to view medical records regardless of when or where a patient previously received care. Interoperability has long been an essential priority of the medical system, given that health systems routinely upgrade to new EHR systems, and patients routinely switch clinicians due to changes in health insurance coverage. These changes often lead to incomplete and inaccurate patient data, which create inefficiencies in clinical care and inhibit research efforts.

The COVID-19 crisis has spawned an influx of collaborative efforts to aggregate data from many sources to inform research and care efforts. For example, the newly formed 4CE consortium integrated data from 96 hospitals across five countries through the use of shared data platforms that mapped to a single common data model.³ Another effort, the COVID-19 Research Database,⁴ uses tokenized patient keys to encrypt identifiable patient data while allowing decentralized and seamless transfer of data between other sites using the same software. This database will serve as a secure source of real-world, Health Information Portability and Accountability Act (HIPAA)-compliant, de-identified data sets, including medical claims, pharmacy claims, electronic health records, and demographic data. All of these data are available for free to public health and policy researchers so that they can extract insights to help combat the virus.⁵

2. For the purposes of this paper, we recognize The American Health Information Management Association's definition of "health information" as the data related to a person's medical history, including symptoms, diagnoses, procedures, and outcomes. Health information records include patient histories, lab results, x-rays, clinical information, and notes. For more: <https://www.ahima.org/careers/healthinfo>.
3. Gabriel A. Brat, et al., "International Electronic Health Record-Derived COVID-19 Clinical Course Profiles: The 4CE Consortium" (The Consortium for Clinical Characterization of COVID-19 by EHR [4CE], April 30, 2020), <https://www.medrxiv.org/content/10.1101/2020.04.13.20059691v4>.
4. "COVID-19 Research Database," COVID-19 Research Database, accessed May 1, 2020, <https://covid19researchdatabase.org/>.
5. Sarah Rowe, "Leading Healthcare Companies Announce COVID-19 Research Database," Datavant, 2020, <https://datavant.com/news/leading-healthcare-companies-announce-covid-19-research-database/>.



However, despite the vast advances in data infrastructure and unprecedented collaborations in the time of COVID-19, these innovative methods for data sharing are not the norm. A recent data brief from the Office of the National Coordinator for Health Information Technology (ONC) reported little to no improvement in data interoperability since 2015. The brief revealed that “only about 10 percent of physicians were able to send, receive, and integrate health data into their respective EHR systems.”⁶ Anecdotally, disease foundations working with patients still report that some physicians submit prior authorization forms for medication through paper-based fax machines. Given this notable gap in the system, ONC mandated interoperability through a series of final rules released along with the Centers for Medicare and Medicaid Services (CMS) in early March 2020. These rules require public and private entities to collect specified core data elements in EHRs and to adopt specific data standards to facilitate data exchange among different systems and software applications through secure APIs.⁷ The use of core data elements, standards, and APIs would improve clinicians’ and health researchers’ access to crucial patient information, such as previous drugs, diagnoses, and co-morbidities. However, ONC has postponed enforcement of these rules because of the pandemic.⁸

Since the passage of HIPAA in 1996, health information technology experts have touted the concept of the National Patient Identifier as an effective and efficient way to match patients accurately to their medical records regardless of the provider, health system, or the EHR platform.⁹ Members of the US Congress from both parties have long supported the establishment of a National Patient Identifier mechanism to resolve interoperability issues. Recently, a group of members asked the Government Accountability Office (GAO) to revisit the concept.¹⁰

6. Christopher Jason, “3 Ways to Enhance Healthcare Interoperability with Health IT,” *EHRIntelligence*, February 10, 2020, <https://ehrintelligence.com/news/3-ways-to-enhance-healthcare-interoperability-with-health-it>.
7. “HHS Finalized Historic Rules to Provide Patients More Control of Their Health Data,” US Department of Health and Human Services, March 9, 2020, <https://www.hhs.gov/about/news/2020/03/09/hhs-finalizes-historic-rules-to-provide-patients-more-control-of-their-health-data.html>.
8. “CMS Interoperability and Patient Access final rule,” Centers for Medicare and Medicaid Services, April 21, 2020, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index>.
9. Christopher Jason, “The Pros and Cons of a National Patient Identifier (NPI) System,” *EHRIntelligence*, December 4, 2019, <https://ehrintelligence.com/news/the-pros-and-cons-of-a-national-patient-identifier-npi-system>.
10. Kate Monica, “Senators Request GAO Assist ONC in Improving Patient Matching,” *EHRIntelligence*, October 5, 2017, <https://ehrintelligence.com/news/senators-request-gao-assist-onc-in-improving-patient-matching>.



Several countries, including the United Kingdom, have successfully used Unique National Patient Identifiers for years to capture health information, which researchers use to develop better treatments and, therefore, better health outcomes.¹¹ For example, the United Kingdom’s RECOVERY trial, which is connected to the UK’s National Health Service, grants every COVID-19 patient the opportunity to participate in the trial. Patients are randomly assigned to receive either the standard of care or a promising therapeutic for COVID-19 recommended for evaluation by experts plus the standard of care.¹² The underlying data and study findings are automatically channeled into the country’s national health-care system. By adopting a similar national infrastructure, the US could streamline its data sharing and interoperability efforts and better leverage patient data for research purposes in real time.

INTEGRATION AND AGGREGATION OF DATA INTO EHRs

Many more factors than a person’s clinical profile make up their broader health status. For example, evidence is growing that a person’s zip code may be the single best predictor of their life expectancy.¹³ This is especially true in the context of COVID-19, as we have already seen that many social factors influence a person’s likelihood of getting sick, their ability to access high-quality care, and, ultimately, their health outcomes.¹⁴ In addition, several factors outside of the health sphere may indicate exposure to COVID-19, such as travel history, housing status, or having a high-risk, low-wage job. Given this multifaceted picture, to effectively monitor the course of COVID-19 and designate resources effectively and equitably, researchers must consider more than just clinical data.

11. “Individual Health Identifier (IHI),” eHealth Ireland, accessed May 6, 2020, <https://www.ehealthireland.ie/A2I-HIDs-Programme/Individual-Health-Identifier-IHI/>.

12. “RECOVERY: Randomized Evaluation of COVID-19 Therapy,” Nuffield Department of Population Health, accessed 2020, <https://www.recoverytrial.net/>.

13. Jamie Ducharme and Elijah Wolfson, “Your Zip Code Might Determine How Long You Live—And the Difference Could Be Decades,” *Time*, June 17, 2019, <https://time.com/5608268/zip-code-health/>.

14. Christine Ro, “Coronavirus: Why Some Racial Groups Are More Vulnerable” *BBC*, April 20, 2020, <https://www.bbc.com/future/article/20200420-coronavirus-why-some-racial-groups-are-more-vulnerable>.



Already in the United States, several programs have sought to standardize the collection and incorporation of social determinants of health (SDOH) data with clinical data. The most direct method leverages ICD-10 billing codes, which clinicians use to classify and record diagnoses, symptoms, treatments, and procedures. For example, United Healthcare and the American Medical Association announced a partnership in 2019 to support the creation of a variety of new SDOH-related ICD-10 codes, demonstrating a clear interest from the health-care community in furthering the incorporation of these descriptive patient elements, such as information about health literacy, educational attainment, and access to transportation, into EHRs.¹⁵ In addition, the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) is a standardized set of national core measures that can be built into most major EHR templates to assess and address SDOH. The SDOH measures in PRAPARE map directly to ICD-10 codes so that clinical staff can easily enter them.¹⁶ However, a 2020 JAMA study found that in the first two years that physicians could report SDOH-specific diagnostic codes in Medicare fee-for-service claims, they did so in just 1.4 percent of the total beneficiary population. Further, although while CMS has explained the importance of screening for factors such as food insecurity, housing instability, transportation needs, and interpersonal violence, only 25 percent of hospitals and 16 percent of physician practices screened for them.¹⁷ Mandating the use of SDOH on a national scale would inform not only population-level research but also care and treatment for individual patients.

USE OF REMOTE PATIENT MONITORING AND TELEHEALTH

During the pandemic, the US has faced an overburdened health-care system, especially in the heaviest hit regions of the country. Through wearable technology, physicians can remotely monitor patients with mild symptoms or recently discharged from the hospital—alleviating pressure on the system. The same technology can support virtual clinical trials to advance research, such as the University of Minnesota study of hydroxychloroquine for treatment of COVID-19 disease.¹⁸ In late March, the Food and Drug Administration (FDA) released guidance allowing

15. "UnitedHealthcare and the AMA Collaborate to Understand and Address Social Barriers Preventing People's Access to Better Health," United Healthcare, April 2, 2019, <https://newsroom.uhc.com/content/uhc/newsroom/news-releases/AMA-announcement.html>.
16. "About the PRAPARE Assessment Tool," National Association of Community Health Centers, accessed April 28, 2020, <http://www.nachc.org/research-and-data/prapare/about-the-prapare-assessment-tool/>.
17. Shannon Muchmore, "Codes for Social Determinants Rarely Used, Analysis Finds," *Healthcare Dive*, January 30, 2020, <https://www.healthcaredive.com/news/codes-for-social-determinants-rarely-used-analysis-finds/571264/>.
18. Kelly Glynn, "COVID-19 Clinical Trial Launches at University of Minnesota," University of Minnesota, March 17, 2020, <https://med.umn.edu/news-events/covid-19-clinical-trial-launches-university-minnesota>.



manufacturers to market specific non-invasive devices for expanded uses in remote monitoring.¹⁹ These devices measure vital signs such as blood pressure, respiration rate, and temperature in real time. Vital signs data are not only essential to clinicians monitoring their patients' health status but also enable researchers to identify patterns across patient populations that inform the development of treatments and vaccines. The resulting data from remote monitoring devices must become incorporated into EHRs and made readily available for health researchers in real time.²⁰ If disparately located and not readily available in a standardized format, these data cannot be used by clinical researchers seeking to develop treatments and vaccines for COVID-19.

In response to the pandemic, CMS has taken a historic step in expanding telehealth access to Medicare beneficiaries. This expansion allows physicians and other providers to deliver a broader range of care to Medicare beneficiaries in their homes for the duration of the COVID-19 emergency to prevent unnecessary exposure or risk while traveling to a health-care facility.²¹ Without full integration of digital care methods into traditional health care, we cannot ensure that digital health providers are providing sufficient controls to secure data and protect patient privacy. The Office for Civil Rights at the Department of Health and Human Services (HHS), the agency responsible for enforcing HIPAA, acknowledged that during the COVID-19 crisis, it would exercise its enforcement discretion and not impose penalties for noncompliance under HIPAA.²² Although this CMS action is groundbreaking, the changes are temporary and could compromise patient privacy. CMS should strongly consider making the expansion of telehealth access permanent and waiving limitations on the types of clinical practitioners that can provide Medicare telehealth services beyond the duration of the COVID-19 emergency, while in compliance with HIPAA.

Telehealth and remote patient monitoring are effective strategies to reduce the overwhelming stress that COVID-19 has placed on the US health system and provide an avenue for researchers to leverage data from new devices. For long-term sustainability, we must assess and balance the benefit of these technologies with the need to protect patients' privacy, as well as comprehensive policies that allow for greater integration of telehealth services and remote patient monitoring into EHRs.

19. "Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: Guidance for Industry and Food and Drug Administration Staff," US Food & Drug Administration, accessed April 30, 2020, <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19>.
20. Conor Hale, "FDA Looks to Expand Remote Monitoring to Free Up Hospital Space," *FierceBiotech*, March 20, 2020, https://www.fiercebiotech.com/medtech/fda-looks-to-expand-remote-monitoring-to-free-up-hospital-space?mc_cid=0bf64efcbb&mc_eid=eca4471d12.
21. "Trump Administration Issues Second Round of Sweeping Changes to Support US Healthcare System During COVID-19 Pandemic," Centers for Medicare and Medicaid Services (CMS), April 30, 2020, <https://www.cms.gov/newsroom/press-releases/trump-administration-issues-second-round-sweeping-changes-support-us-healthcare-system-during-covid>.



DATA PRIVACY AND TRUST IN BIG TECH

During the pandemic, organizations everywhere have been scrambling to put available data to use to fight the virus as efficiently and effectively as possible, and many governments have leveraged their most influential tech companies to do this. The Chinese government enlisted its largest tech companies, such as Tencent, Alibaba, and Megvii, to build and deploy technology that assigns users QR codes based on their health status, allowing for or preventing travel accordingly, as well as even technology that detects abnormal body temperature and can alert authorities.²³ In the US, Apple and Google announced an unprecedented collaboration to help the government reduce the spread of the virus by building a system using Bluetooth technology to enable contact tracing.²⁴ The companies maintain that this technology will only work on an opt-in basis and that they will implement strong protections around user privacy.

The growing global influence of tech comes at a time when trust in major tech companies is already significantly strained in the US, especially regarding health data. Importantly, health data are extremely sensitive because their misuse could lead to discrimination against patients in employment or insurance coverage and potentially expose them to social stigma. The Genetic Information Nondiscrimination Act (GINA), a federal law passed in 2008, protects individuals from genetic discrimination in health insurance and employment, but not in a variety of other domains, such as long-term care, disability, and life insurance.²⁵ Thus, it remains possible that individuals may face discrimination based on their medical information.

In 2019, several major tech companies used identifiable patient data to design software intended for patient care without explicit consent from those patients.²⁶ This event followed the high-profile Facebook Cambridge Analytica scandal, in which Facebook shared the personal data of millions of users, without their knowledge, with an analytics company that used the data to develop targeted political advertisements.²⁷ This high-profile event brought the potentially significant

23. Arjun Kharpal, "Coronavirus Could Be a 'Catalyst' for China to Boost Its Mass Surveillance Machine, Experts Say," *CNBC*, February 24, 2020, <https://www.cnbc.com/2020/02/25/coronavirus-china-to-boost-mass-surveillance-machine-experts-say.html>.

24. "Apple and Google Partner on COVID-19 Contact Tracing Technology," *Apple*, April 10, 2020, <https://www.apple.com/newsroom/2020/04/apple-and-google-partner-on-covid-19-contact-tracing-technology/>.

25. Sarah Zhang, "The Loopholes in the Law Prohibiting Genetic Discrimination," *The Atlantic*, March 13, 2017, <https://www.theatlantic.com/health/archive/2017/03/genetic-discrimination-law-gina/519216/>.

26. Rob Copeland, "Google's Project Nightingale Gathers Personal Health Data on Millions of Americans," *Wall Street Journal*, November 11, 2019, <https://www.wsj.com/articles/google-s-secret-project-nightingale-gathers-personal-health-data-on-millions-of-americans-11573496790>.

27. Kevin Granville, "Facebook and Cambridge Analytica: What You Need to Know as Fallout Widens," *New York Times*, March 19, 2018, <https://www.nytimes.com/2018/03/19/technology/facebook-cambridge-analytica-explained.html>.



consequences of data misuse to the attention of the public and began to sow the seeds of mistrust. A 2019 Rock Health Survey found that just 10 percent of respondents would be willing to share their health information with a tech company, compared with 73 percent willing to share those data with their physician.²⁸

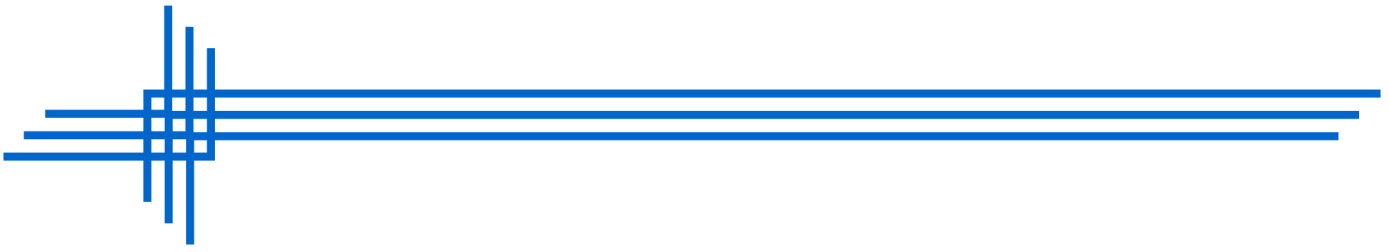
Further, the US does not have a single comprehensive law or policy regarding consumer data rights, usage, and privacy. As mentioned above, HIPAA was passed more than 20 years ago and was not designed with today's technology and landscape of health-care actors in mind. Commercial entities such as tech companies and social media companies all hold data from which health insights can be easily derived, and no comprehensive law or regulation protects these data from re-identification and misuse. Congress has proposed many national data protection and privacy bills but has yet to agree on any national data policy.²⁹ Individual states, such as California and New York, have passed privacy bills that went into effect in early 2020. However, many trade associations have requested delayed enforcement of these laws without the "operational capacity or time to bring their systems into compliance" amid the pandemic.³⁰

Of course, mistrust of data-holding companies may dissuade consumers from using apps or technology intended to improve individual or population health, such as that of Apple and Google's efforts in the case of COVID-19. The resulting pushback on big tech has forced companies such as Amazon and Google to cease certain initiatives, and while many consumers worry that the country still lacks proper data privacy protections, many others fear that the outcry over privacy will prevent the US from pooling and analyzing its data as quickly as it could, especially in an emergency such as COVID-19.³¹ Ultimately, clear federal policies delineating essential data privacy and security practices, and guardrails are needed to allow tech companies to further their efforts and assuage consumer concerns. Without such protections, consumers may not trust data-holding companies enough to opt in to data collection that might curtail the virus more successfully.

29. Makena Kelly, "All the Ways Congress Is Taking on the Tech Industry," *The Verge*, March 3, 2020, <https://www.theverge.com/2020/3/3/21153117/congress-tech-regulation-privacy-bill-coppa-ads-laws-legislators>.

30. Lori Tripoli, "CCPA, SHIELD Act to Take Back Seat During Coronavirus Pandemic?," *Compliance Week*, March 24, 2020, <https://www.complianceweek.com/data-privacy/ccpa-shield-act-to-take-back-seat-during-coronavirus-pandemic/28659.article>.

31. Naomi Klein, "How Big Tech Plans to Profit from the Pandemic," *The Guardian*, May 13, 2020, <https://www.theguardian.com/news/2020/may/13/naomi-klein-how-big-tech-plans-to-profit-from-coronavirus-pandemic>.



RECOMMENDATIONS

To address the challenges to coordinating the public health response to COVID-19, this section offers a series of recommendations in three categories: promoting the interoperability and integration of data, ensuring data privacy and protection, and advancing remote patient monitoring and telehealth to advance clinical research.

Promoting the Interoperability and Integration of Data

- The NIH should incentivize and expand the use of research consortia such as the COVID-19 Research Database,³² which makes de-identified, protected patient data from many sources available in one place to all researchers at no cost.
- The FDA should sustain recently scaled-up resources to harness and incorporate real-world evidence (including data collected during clinical care and through digital health products) into their approvals and decision-making.
- CMS should mandate health-care providers and provide incentives to record SDOH-specific information and diagnostic codes. The policy should also encourage the development and use of clinical practice guidelines and quality measures to establish new care pathways when a patient is deemed to be in a difficult situation that could harm their health or prevent their access to care.
- Congress should require the implementation of a National Patient Identifier to rectify ongoing patient attribution and record matching challenges across the health-care ecosystem.
- HHS should enforce and support ONC's interoperability efforts that urge the health-care industry to adopt standardized APIs to help individuals securely and easily access their data while using smartphone apps.³³

32. Rowe, "Leading Healthcare Companies."

33. "Notice of Proposed Rulemaking to Improve the Interoperability of Health Information," Office of the National Coordinator for Health Information Technology, <https://www.healthit.gov/topic/laws-regulation-and-policy/notice-proposed-rulemaking-improve-interoperability-health>.



Ensuring Data Privacy and Protections

- To increase public trust in applications that aim to advance research and coordinate a response to a public health emergency, developers should design apps for opt-in use only.
- Any company collecting or using data should regularly and transparently disseminate information about how it uses data, and in a format that is accessible and understandable to a diverse group of users. Companies should also quickly relay any information gleaned from their research or data analysis that might be of interest to their users, such as results comparing treatments or their effects on specific patient populations.
- Contact tracing or other apps that collect users' location and health data for a public health emergency should enable a quick and easy mechanism for users to submit complaints. As such, users could have a role in "surveilling" the app so that it may evolve based on their preferences.³⁴
- Developers should be transparent about best practices to make apps work as effectively as possible and explicit about their intended actions with the user data. For example, they should specify how long they will retain the data and the circumstances under which they will permit public health entities and researchers to use the data.³⁵
- Congress should expand GINA to prevent discrimination based on health information in additional domains, such as long-term care, disability, and life insurance. These other protections, if communicated to patients, might potentially increase willingness to participate in research.

34. Lilian Edwards, et al., "The Coronavirus (Safeguards) Bill 2020: Proposed Protections for Digital Interventions and in Relation to Immunity Certificates," LawArXiv, April 12, 2020, <https://osf.io/preprints/lawarxiv/yc6xu/>.

35. Ashkan Soltani, et al., "Contact-Tracing Apps Are Not a Solution to the COVID-19 Crisis," Brookings, April 27, 2020, <https://www.brookings.edu/techstream/inaccurate-and-insecure-why-contact-tracing-apps-could-be-a-disaster/>.



Advancing Remote Patient Monitoring and Telehealth

- The American Medical Association membership should adopt and promote recommendations from the Digital Medicine Payment Advisory Group to create a clear pathway for the integration of digital medicine technologies into clinical practice.³⁶
- The HHS' Federal Advisory Committees should lead the development and coordination of comprehensive plans that incorporate digital health, reimbursement, coding, and fraud control into current health-care processes.
- FDA should examine learnings during the pandemic of the use of remote monitoring technologies and telehealth to continue clinical trials or establish virtual clinical trials and provide long-term guidance on the use of these technologies.
- CMS should develop standard processes and mechanisms to generate and immediately use real-world evidence to understand the effects of digital health to better improve services.
- Efforts between regulatory agencies and health plans should be aligned and expedited to enable the use of approved remote monitoring devices for patients. Coordination between regulatory agencies and health plans is crucial for quick integration of coverage.

CONCLUSION

Faced with an unprecedented, rapidly evolving global pandemic, the US must move quickly to curtail the virus. Armed with new tools and technology, the US must employ foresight and appropriate caution to consider and address potential unintended consequences of actions. With the rapid advancement of biotechnology in recent years, we have scientific and technological tools that may pave the way for innovation at a speed that humankind has never seen. However, we can only use these tools to their full potential if we leverage them on a coordinated, national scale, ensure that our health systems can exchange data, and protect those data from misuse. If these systems remain fragmented and inefficient, patients will continue to wait for the treatments and cures they need.

36. "Digital Medicine Payment Advisory Group," The American Medical Association, Digital Medicine Payment Advisory Group, accessed June 2, 2020, <https://www.ama-assn.org/practice-management/digital/digital-medicine-payment-advisory-group>.



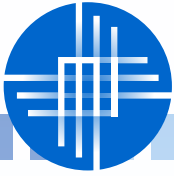
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