

October 2021

Produced in partnership with:

Consumer Technology Connected Health Association



INTRODUCTION

Disparities in health are a long-standing issue in the United States due to the complex intersection of race, poverty, education quality and access, as well as the urban and rural divide. These disparities do not only affect the individuals and communities experiencing the disparities. They also impact overall health and well-being, and result in higher costs for health care across the country. The issue is particularly relevant today given the increasing diversity of the U.S. population coupled with worsening health outcomes in the country more broadly as compared to other developed nations.¹

Not all people living in the United States have the same opportunities to pursue a healthy lifestyle and that people of color, people with disabilities and those living in rural and low-income areas often have worse health outcomes.

This is largely due to access barriers to high-quality health care and social determinants of health ("SDOH").

Social determinants of health are conditions in the environments in which people are born, live, learn, work, play, worship and age that affect health and quality-of-life outcomes and health risks. Inequities in factors like education, financial stability and food security are all driving forces behind the health disparities that exist in the United States today.

For instance, income tracks closely with health outcomes. Although Blacks and Hispanics have higher rates of disease overall than non-Hispanic Whites, these differences are "dwarfed by the disparities identified between high- and low-income populations within each racial/ethnic group."³ Blacks, Hispanics and American Indian/Alaska Native people with higher incomes have better health than those with lower incomes.

The impact of income disparities is reflected in health outcomes. Residents of high-poverty areas (county poverty rate greater than or equal to 20%) have a life expectancy of 76.7 years – 6.2 years shorter than the life expectancy for the residents of

SOCIAL DETERMINANTS OF HEALTH

Examples of social determinants of health

- Availability of resources to meet daily needs (e.g., safe housing and local food markets)
- Access to educational, economic, and job opportunities
- Access to healthcare services
- Quality of education and job training
- Transportation options
- Public safety
- Social support
- Socioeconomic conditions like concentrated poverty and the stressful conditions that accompany it
- Access to mass media and emerging technologies (e.g., cell phones, the internet, and social media)
- Residential segregation
- Language/Literacy
- Social norms and attitudes like discrimination, racism, and distrust of government
- Exposure to crime, violence and social disorder
- Culture

low-poverty areas (county poverty rate less than 5%). When stratified by gender, race and poverty level, life expectancy in 2012-2016 ranged from 71 years among Black men in high-poverty areas to 84.6 years among White women in low-poverty areas of the United States. Similar trends can be seen along the urban-rural divide and among those with and without a high school diploma.

COMMUNITIES IN CLOSE PROXIMITY – WORLDS APART ON HEALTH

When researchers use location geography to examine health disparities, they can evaluate SDOH factors from income and employment to health care access and environmental conditions that provide more insight into why particular communities face higher rates of health disparities.

The distance between one of the richest counties in the United States – Fairfax County, Virginia – and one of the poorest – McDowell County, West Virginia – is only 350 miles. But life expectancy between the two counties is vast. In Fairfax County, the average life expectancy of men is 82 years and women is 85 years, which is comparable to Sweden, a country with higher-than-average life expectancy. In McDowell County, the average life expectancy for men is 64 years and for women it is 73 years, which mirrors lraq, a country with lower-than-average life expectancy.

Within urban environments, there also can be wide disparities. In some cities, life expectancy can differ by as much as 25 years from one neighborhood to the next. Similar gaps in health-related outcomes across geographic areas can be found for infant mortality, obesity, violence and chronic diseases.

In St. Paul, Minnesota, the city's East Rondo neighborhood has <u>a life expectancy</u> of 65 years, while the adjacent neighborhood Summit Hill is 86 years. Over half of the tract's nearly 1500 residents live in poverty. Of the neighborhood's residents, almost 50% are Black, 13% are Asian, 12% are Hispanic, and the rest are White or multiracial. Less than 10% of adults have a bachelor's degree. In contrast, a 5-minute walk over the I-94 highway leads you to a neighborhood where 70% of residents have a college degree and almost 30% have a graduate degree. Nearly 85% of the area's almost 3000 residents are White.

HEALTH ANALYTICS MAKES INSIGHT INTO HEALTH DISPARITIES POSSIBLE

Insights into the factors that contribute to health disparities are made possible by recent trends in data collection and the use of health analytics. To track progress and improvements made over time, the federal government publishes critical reports about health equity.

The National Healthcare Quality and Disparities Reports has been published by the Agency for Healthcare Research and Quality ("AHRQ") of the Department of Health and Human Services ("HHS") for 17 years. Congress mandated this report to give a thorough view of health care quality and disparities in care experienced by different racial and socioeconomic groups.

The document tracks more than 300 health care process, outcome and access measures, covering a wide variety of conditions and settings, which demonstrate the complicated nature of research around this subject.

HEALTH STATISTICS ACROSS RACE AND ETHNICITY



The COVID-19 pandemic, which is devastating historically underserved communities and populations, has highlighted these health inequities across the United States. For example, a study of selected states and cities with data on COVID-19 deaths by race and ethnicity showed that 34% of deaths were among non-Hispanic Black people, though this group accounts for only 12% of the total U.S. population.⁵

This time of unparalleled need has also presented a unique opportunity for technology-driven innovations in digital health to help reduce demonstrate their role in reducing inequities in health outcomes.

During COVID-19, we have seen rapid adoption of health technologies such as telehealth and remote monitoring that provided people with alternate



means of accessing care. These same measures also helped hospitals and clinics take measures to control the spread of COVID-19. We saw a dramatic increase in personal use of health technology. People turned to technology to exercise as their gyms closed or to access mental health and wellbeing apps as pandemic-related stress took its toll.

But as the pandemic continues, many health technology solutions that have proven effective in response to COVID-19 are still not available to many Americans and face uncertain futures in equitable adoption without changes to federal laws and regulations. Now is the time to look ahead to an equitable future where digital health solutions facilitate wider access to care and improved health outcomes for everyone.

WHO WE ARE

The Consumer Technology Association (CTA)® and ACT | The App Association's Connected Health Initiative believe that the COVID-19 crisis presents a unique and unprecedented opportunity to think carefully about the greater use and adoption of health technology to improve the country's response to health disparities in geographies, communities and demographics. The two associations have worked together on various digital

health-related projects and decided to join forces in summer 2020 to determine how technology can be better used to address and help mitigate health disparities in the United States.

The result was the creation of the Health Equity and Access Leadership ("HEAL") Coalition, a group comprising about 35 organizations spanning the health ecosystem. The coalition is chaired by Dr. Lucienne Ide, founder and chief executive officer of Rimidi, a digital health company that enables personalized management of chronic conditions and Dr. Lisa Fitzpatrick, founder and chief executive officer of Grapevine Health, former chief medical officer for D.C. Medicaid, and one of five co-chairs of then-candidate Joe Biden's committee for health care policy.

The HEAL Coalition is dedicated to advancing health equity through digital health solutions. The group's mission is to reduce health disparities by eliminating access barriers to digital health. The HEAL Coalition analyzed three issue areas that hinder adoption of digital health solutions and recommends policy changes to address them:

- Access to broadband and technology. We analyzed digital health and the digital health-enabled solutions particularly suited to address health disparities and identify the barriers that prevent greater use of these solutions.
- Digital literacy and access. We analyzed the impact of low digital health literacy on health outcomes, and the degree to which it affects underserved communities.
- Data and privacy. We analyzed the impact that digital health data privacy, accessibility and trust concerns may have on health outcomes, and the degree to which these issues affect underserved communities.

Members of the HEAL Coalition:

American College of Cardiology, Anthem, Inc., Apple, American College of Cardiology, AT&T, Best Buy, Best Buy Health, Boston Children's Hospital, Brookings, Cambia Health Solutions, Digital Medicine Society, Digital Therapeutics Alliance, Fitbit (a Google company), Gallup, Genentech, GlobalForce Tech Consulting, Google, Grapevine Health, HP, Healthcare Strategy Bullpen, Intel, Kapor Center, Kinsa Health, Microsoft, MLC Strategies LLC, MLEM PLLC, Noom, The Omega Concern, Omron Healthcare, Phillips, Plum Alley Ventures, Propeller Health, ResMed, Rimidi, United Spinal Association, University of Mississippi Medical Center, University of Virginia Center for Telehealth, Validic, Wheel, and Xealth.

As North America's largest technology trade association, CTA® is the tech sector. Our members are the world's leading innovators - from startups to global brands—helping support more than 18 million American jobs. CTA owns and produces CES®, the most influential tech event in the world. CTA's Health Division works to advance the use of consumer-based technology-enabled health solutions to deliver better health outcomes and reduce overall health care cost. Among members in the Health Division are technology companies, digital health innovators, medical device manufacturers, retailers, insurance providers and biopharmaceutical companies. CTA® is also accredited by the American National Standards Institute as a Standards Development Organization and has a long history of developing voluntary national standards addressing a wide range of topics including artificial intelligence, digital therapeutics, mental health, mobile health solutions, sleep and stress monitoring.

ACT | The App Association represents more than 5000 app companies and information technology firms across the mobile economy. In 2017, the App Association launched the Connected Health Initiative ("CHI"), a leading multi-stakeholder policy and legal advocacy effort driven by a consensus of stakeholders from across the connected health ecosystem.

CHI aims to realize an environment in which Americans can see improvements in their health through policies that allow for connected health technologies to advance health outcomes and reduce costs. CHI members develop and use connected health technologies across a wide range of use cases and the organization actively advocates before federal and state government bodies on a wide array of issues including reimbursement/payment, privacy/security, effectiveness/quality assurance, regulations of digital health, health data interoperability and the rising role of artificial/augmented intelligence ("AI") in care delivery.

GLOSSARY

Digital equity: Condition in which all individuals and communities have the information technology capacity needed for full participation in our society, democracy and economy.⁶

Digital health: The use of technology and electronic communications tools, services and processes to deliver health care services or to facilitate better health. The term incorporates a broad array of evolving technologies in health care, including those designed to be used by consumers and includes telemedicine, remote monitoring, AI-enabled solutions, apps, trackers and digital therapeutics. It can be related to wellness and fitness, diagnosis, treatment, or ongoing monitoring of a health condition. The consumer can be a patient, provider, health system, caregiver, or sometimes government.

Digital health literacy: The ability to seek, find, understand and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem.¹¹

Digital health technologies: The electronic tools, systems, devices and resources that generate, store and process data in health care and include mobile health, wearable devices, telehealth, telemedicine, electronic health records, patient portals.

Health disparities: A particular type of health difference that is closely linked with social, economic and/or environmental disadvantage.⁷

Health equity: The idea that everyone has an equal opportunity to be as healthy as possible.⁸

Health inequities: The unfair and avoidable differences in health status seen within and between populations.⁹

Health literacy: The degree to which individuals have the capacity to obtain, process and understand basic health information needed to make appropriate health decisions.¹⁰

Social determinants of health: Conditions in the environments in which people are born, live, learn, work, play, worship and age that affect health and quality-of-life outcomes and health risks.

DIGITAL HEALTH SOLUTIONS CAN ADVANCE HEALTH EQUITY

How health care is delivered and consumed is shifting dramatically as technology advances.

Many stakeholders are developing and deploying innovative digital health tools. These can range from

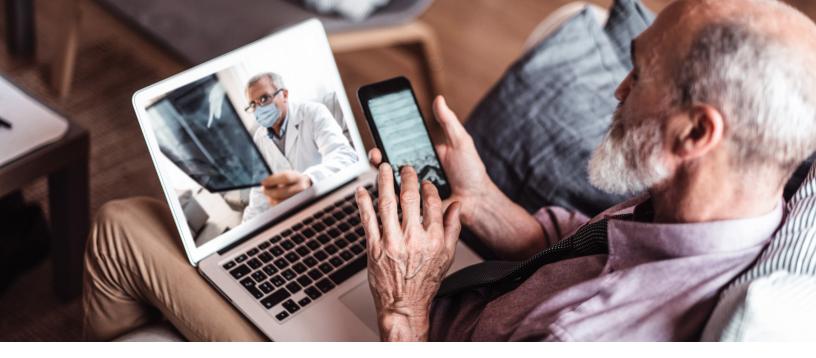
using artificial intelligence-driven clinical decision support to treat patients and reduce costs, to using social media to empower pregnant women with low incomes to seek care and reduce infant mortality. Digital health apps can even be used at the state and national level to track health trends, create early warning systems for spreading illness and direct interventions for people experiencing a change in health status, rather than waiting for them to enter the health care system.¹²

Underlying all these tools is technology. The technology of today creates the opportunity to research, track, deploy and refine health care services in ways that are more efficient and targeted to specific needs and populations.

As the Food and Drug Administration ("FDA") notes, "[d]igital tools are giving providers a more holistic view of patient health through access to data and giving patients more control over their health.

Digital health offers real opportunities to improve medical outcomes and enhance efficiency."¹³

For example, a pediatrician identified lead contamination in the water in Flint, Michigan by comparing blood test results stored in a hospital's electronic health record system ("EHR"). The doctor used data from the EHR to compare lead levels in children from before and after the change in water supply and the impact on Flint residents, which disproportionately affected Blacks and low-income populations. The EHR was not created for use in this way, but the technology has evolved to help identify health disparities.¹⁴



There are many benefits in using digital health:

For patients/consumers:

- Provides opportunities for consumers to better understand, monitor and self-manage their health.
- Increases access to more timely and convenient care and services, including specialty care.
- Improves medication management.
- Enhances the healthcare experience.
- Enables more predictive, preventative, personalized and participatory care.

For governments:

- Supports preparation and planning for, and managing response to, public health emergencies.
- Helps support equitable and universal access to quality health services.
- Supports more engagement in research and population health.
- Supports the development of new therapies and treatments.

For hospitals/health systems:

- Enables integration through greater interoperability and coordination of care pathways.
- Improves the economy, efficiency and effectiveness of systems and processes.
- Enables new models of care such as value-based care and population health management.

For clinicians:

- Supports clinical decision-making.
- Frees up capacity by automating repetitive tasks and improving triage.
- Improves job satisfaction by enabling clinicians to practice at the top of their license.
- Identifies and supports staff well-being needs.

TRI-CITIES DIABETES EQUITY PROJECT WITH RIMIDI

Diabetes affects Black Americans significantly more than White Americans. In 2018, non-Hispanic Blacks were twice as likely as non-Hispanic Whites to die from diabetes. Black adults are 60% more likely than non-Hispanic White adults to be diagnosed with diabetes by a physician. Diabetes Self-Management Education and Support ("DSME-S") is an important component of successful diabetes care. Yet, low DSME-S utilization rates have been observed in medically underserved populations in the United States due to the high cost and poor accessibility of these services. Typical barriers such as cost, availability and accessibility factor into these low participation rates.

Rimidi, a digital health company, developed and implemented a <u>DSME-S program</u> to bring diabetes education to individuals at-risk and in need of better solutions for their diabetes care. Based on proven DSME-S models, Rimidi's eight-lesson, video-based DSME-S digital course is accessible via smartphone and web browser and is tailored to reflect community demographics and resources, so it is relevant for participants.

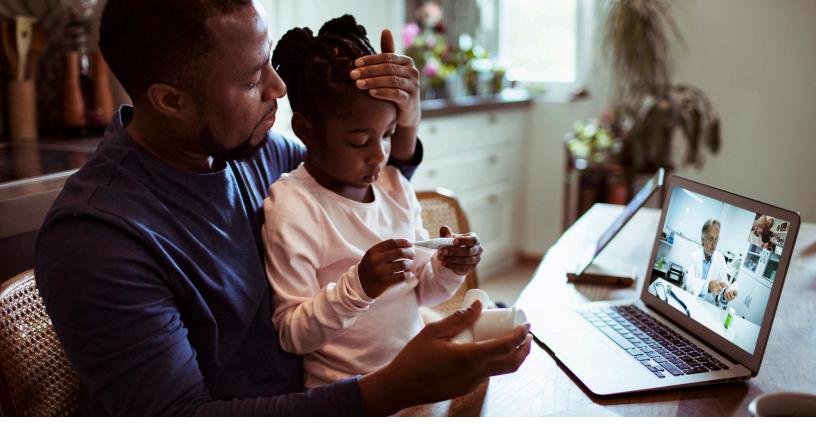
Through a partnership with the Atlanta
Regional Collaborative for Health
Improvement, a coalition of public, private
and nonprofit organizations committed to

improving the region's health, Rimidi brought its digital DSME-S to Atlanta's Tri-Cities communities of College Park, East Point and Hapeville, an area that has a disproportionately high rate of diabetes compared to neighboring communities. Census information shows Tri-Cities has 13-year life expectancy gap compared to more affluent areas of Atlanta.

Of the 111 participants enrolled, 75 (68%) completed Rimidi's DSME-S course.

Participants reported high satisfaction with course materials and course content. Most participants were Black (79%) and 35 years or older (93% and female (73%). A majority—75%—of the participants had never participated in a DSME-S course, despite it being a critical element of diabetes care.

By leveraging existing smartphone and webbased technologies, Rimidi's digital DSME-S course promoted patient accessibility, engagement and education. This project has the potential to be a cost-effective and scalable model for diabetes management at a time when the burden of chronic disease continues to grow in terms of morbidity, mortality and cost. Given the success of the pilot, Rimidi is partnering with a centrally located CVS Pharmacy™ to launch a diabetes management effort in the Tri-Cities community.



Similarly, health care systems and policymakers alike responded quickly to COVID-19 by leveraging digital health and expanding access to virtual care early in the pandemic. Health care systems across the country trained their clinical teams on various video-sharing platforms so they could continue to see patients, as they suspended non-emergency appointments to both help reduce the spread of the virus and to conserve personal protective equipment. Meanwhile, policymakers facilitated expanded use of digital health tools, specifically, telehealth, by modifying and increasing the flexibility of existing regulations and by implementing new temporary authorities.

However, adoption of telemedicine—whether video, text, or phone—was highest among people who had already shown in previous years high likelihood to adopt it: higher-income earners, more highly educated, middle-aged adults (35-54) and people with chronic conditions. Comparatively, there were lower adoption rates among groups historically less likely to use telemedicine: people 55 and older, lower-income respondents and those from more rural areas. Other studies also showed that patient groups who accessed telehealth services the least during the COVID-19

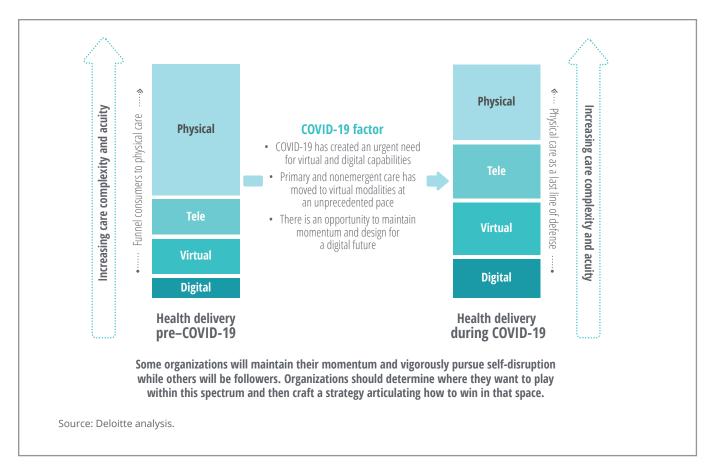
pandemic were female, non-English speaking, older and poorer patients.¹⁵ Health care disparities have highlighted the need to increase use of telemedicine among underserved groups.¹⁶

Overall consumer adoption rates of different digital health tools were as follows:

- After leveling off between 2018 and 2019, adoption of live video care increased 11% (from 32% to 43%) in 2020.
- Over half of respondents tracked a health metric in 2020 (e.g., weight, heart rate, blood pressure) using a digital tracker, up 12% from 2019.
- Wearable ownership and use were both up in 2020, jumping up 10 percentage points from 33% in 2019 to 43% in 2020, after not growing at all between 2018 and 2019.¹⁷

During COVID-19, more owners and users of wearables reported using them to manage a diagnosed health condition, including 66% of people who reported using a wearable for the first time and 51% of all wearable owners (up from 28% of wearable owners in 2019).¹⁸

The dramatic and immediate impact of COVID-19 on telehealth can be seen in the Medicare statistics.



Before COVID-19, approximately 13,000 beneficiaries in fee-for-service Medicare received telemedicine in a week. In the last week of April 2020, nearly 1.7 million beneficiaries received telehealth services.¹⁹

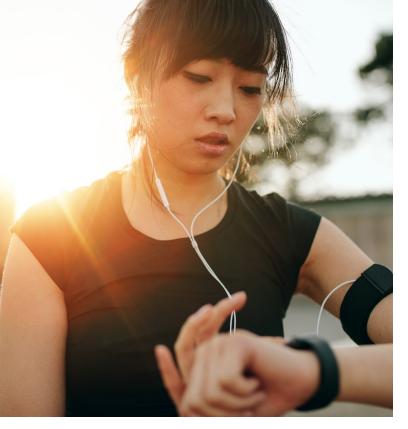
From mid-March through mid-June 2020, more than 9 million beneficiaries received a telehealth service. In its July 2020 review, the Centers for Medicare & Medicaid Services ("CMS") saw no significant differences by race or ethnicity among beneficiaries who received telemedicine services.

Current Medicare laws and regulations limit coverage of telehealth to rural areas and require patients to be present at certain approved originating sites such as hospitals and physician offices to receive telehealth services. During the pandemic, the federal government has waived these limitations. However, if Congress does not act, these restrictions will be put back in place at the end of the public health emergency. The restrictions regarding geographic location and originating site should be waived permanently. This will allow Medicare fee-for-service beneficiaries to continue

to receive telehealth services in their homes—regardless of whether they live in a rural or urban area.

With respect to Medicaid, CMS saw a similar drastic jump early in the pandemic. From March through June 2020, 34.5 million services were delivered through telehealth to the 91.8 million Americans enrolled across each state's Medicaid or the Children's Health Insurance Program for at least one day in the year. That 34.5 million in services represents 2632% more services delivered compared to March through June 2019. CMS found telehealth services were most frequently used by working-age adults, followed by children and older adults.

Mobile Digital Health: Mobile health tools use mobile or wireless technologies to provide healthcare services or information about one's health. These tools – smartphones, Bluetoothenabled patient monitoring devices and cloudbased software applications – can monitor and track patient metrics, offer the platform for clinicians to provide remote care, change individual behavior or offer patient education.



Mobile tools promote enhanced data management and increase the quality of clinical research around health outcomes. They also allow for the collection of real-time, privacy-protected signals which help monitor illness trends for public health purposes and help guide the allocation of critical resources.

In the United States, 85% of people own a smartphone—up from 35% in 2011, with almost no difference in rates of ownership across race or ethnic lines. ²¹ This rapid increase has allowed mobile health, in part, to grow in reach and sophistication. There are now more than 300,000 health-related applications available for download to a mobile device, with more than half of smartphone users collecting health-associated information on their devices. On the clinician side, more than 25% of physicians are using at least one mobile health app, and 93% of clinicians say mobile apps can enhance the quality of patient health. ²²

Telehealth/telemedicine: Historically, telehealth referred to a broad scope of remote health care services (including non-clinical services such as training and education) while telemedicine described actual clinical practice—via telecommunications technology. Reflecting industry

standards, we will be using the terms "telehealth" and "telemedicine" interchangeably, unless one of the terms is used in a specific context such as in laws and regulations. For purposes of this paper, telehealth and/or telemedicine means the delivery of health-related care, services, education and information via telecommunication technology—not to be confused with CMS or other insurance providers' definitions of telehealth.

Telehealth can allow for more effective treatment of chronic conditions and increase access to patients in rural or underserved areas. Telehealth can also help address challenges of physician burnout and shortage. For patients, telehealth can improve health outcomes by increasing access to certain health care services, including facilitating necessary prescriptions for treatment purposes. It can also lead to decreased use of emergency rooms.²³

Wearable Technology: Wearable products range from personal health and fitness trackers and smartwatches worn by individuals, to FDA-approved or cleared devices that continuously monitor health metrics. In some cases, wearable technology can detect certain diseases such as sleep apnea. For individuals not seeking specific care or treatment, these tools can provide real-time information on heart rate, sleep, and physical intensity of activity and stress level. For individuals seeking care, wearable solutions can provide real-time, continuous data to monitor certain diseases and conditions more effectively.²⁴

For physicians, wearable technology can provide relevant data to better assess a patient's health, which may lead to better treatment. In one survey, 62% of physicians said they believe wearable devices would increase the overall quality of care for their patients.²⁵ Additionally, almost two-thirds of physicians are excited about the growing use of technology within their field of medicine.²⁶

Potential benefits of wearables in chronic disease include:²⁷

- Promotion of healthy behaviors to improve overall health or for disease management.
- Increased confidence in condition and care management, including reduced fear and stress.
- Detection of life-threatening conditions or of underlying disease when there are no signs or symptoms.
- Collection of valuable biometric data to share with a clinician, coach or trainer, as well as contributing to aggregate public health monitoring.
- Reduction of office visits when clinicians can access data and correspond and check in with patients for certain conditions.
- Population health management tools for employers, health insurance providers and health systems.
- A valuable tool for researchers across a wide range of health research studies.
- Actionable alerts that can serve as medication.

The technology largely uses green light and the effect of melanin on green light absorption is well-documented. ²⁸ Importantly, wearable devices may not track heart rate as accurately with darker skin tones as it does for lighter skin tones. The research is not clear on the accuracy of consumer heart rate trackers for people with darker skin, as the issue has not been widely studied in part because of the rate of technology changes. ²⁹ Developers of wearable devices and other digital technology should continue to understand how their technology can be designed for equity.

Artificial Intelligence: All is a term that encompasses machine behavior and functions that reflect human intelligence and behavior. In heuristic or rules-based algorithm, the engineer directs the computer on how to specifically solve a problem. Typically, this involves using Boolean operators ("if—then" statements). Machine learning ("ML")

is an aspect of AI that involves a set of methods, including algorithms, data, tools and techniques enabling the training of software to recognize patterns and draw conclusions without providing or programming an explicit mathematic model for mapping input to output.³⁰

AI-based and AI-enabled solutions can leverage information from people's interactions with health and personal services and potentially automate recommendations and services, where applicable. Additionally, health care services and tools can integrate medical recognition, natural language processes and algorithmic data analytics. Increasingly, clinicians are using tools that can mine patient data and combine that with ML to identify patterns that could indicate potential health issues. Specifically, the growth of the use of AI/ML in medical imaging has been tremendous. In imaging, AI/ML is used to detect and classify lesions, automate image segmentation, enhance data analysis and reconstruct images. ML created programs to distinguish between images of benign and malignant moles with accuracy like that of board-certified dermatologists. This technology could significantly aid in the diagnosis and treatment of skin diseases and therefore improve patient care. But if it is not developed with inclusivity in mind, it could magnify existing health care disparities.31

There are long-standing and well-documented issues with AI regarding harmful bias and the lack of transparency. AI algorithms developed and trained with data that does not accurately represent all populations often perform worse for groups not represented in the data. Given the reliance on AI algorithms for high-stakes medical diagnosis and intervention, the consequences of an incorrect decision are potentially life threatening. AI algorithms need to be trained with diverse data sets from diverse populations, but this is not occurring consistently, as shown in a study that

found that algorithms trained on U.S. patient data were disproportionately trained on cohorts from just three states: California, Massachusetts and New York.

The study's authors wrote: "Both for technical performance and for fundamental reasons of equity and justice, the biomedical research community—academia, industry and regulatory bodies—should take steps to ensure that machine learning training data mirror the populations for which algorithms ultimately will be used."³²

Ways Digital Health Can Advance Health Equity

Stakeholders are beginning to develop digital health tools designed to directly impact health disparities. However, no one solution will work for all populations. Digital health can advance health equity in several critical ways, including to:

- Close communication gaps between patients and providers.
- Increase accessibility for people with disabilities (and older adults).
- Increase consumer access to healthcare providers and services.
- Increase patient engagement in understanding and managing health.
- Improve providers' ability to segment patient populations and tailor services.
- Improve decision-making by consumers and providers.

While digital health has tremendous potential to better democratize health care across the United States, there are concerns that limited access to these digital tools could result in an increase in existing disparities. These concerns can be lessened by using digital health in a way that is intentional in its design, distribution and delivery. Another way to mitigate potential issues is to understand the

data underlying the digital health tools and clinical algorithms. We must ensure the use of diverse datasets to avoid potential bias.

AIR LOUISVILLE COLLABORATION LEADS TO IMPROVED ASTHMA OUTCOMES AND POLICY CHANGES

Asthma affects 7.8% of people in the United States and disproportionately affects Black children (13.4%) and people with incomes below the federal poverty level (11.1%). In 2015, Propeller Health, a digital health company that creates products to treat chronic respiratory disease, partnered with the city of Louisville, Kentucky to launch AIR Louisville, a cross-sector effort to improve respiratory care outcomes of area residents. Propeller Health improves clinical outcomes through connectivity, analytics and companion digital experiences.

AIR Louisville's objectives were to help people control their symptoms, identify hot spots of respiratory disease symptoms and their environmental correlates, use the collected data to guide policy decisions, increase community awareness of air quality and health, and engage diverse local partners to make the collaboration sustainable. Patients on Propeller significantly improved their health outcomes—with a 78% reduction in rescue inhaler use and a 48% increase in symptom-free days. Propeller also mapped their unique respiratory care data geospatially to identify hot spots, building the largest database of where and when asthma symptoms occur.

The crowdsourced data on inhaler use combined with environmental data guided policy recommendations for Jefferson County. These included creating a real-time

alert system about potentially dangerous environmental conditions, enhancing the tree canopy in the city, mitigating tree removal, zooning for air pollution emission buffers and shifting truck routes away from neighborhoods with the highest asthma burden.

In addition to the improved health outcomes and quality of life related to reducing asthma interventions, there is a cost benefit to better controlling asthma. Between 2008 and 2013, the annual per-asthmatic incremental medical cost of treatment was \$3266, and aggregate annual medical costs attributable to asthma were over \$50 billion in 2015 dollars. (Nurmagambetov T, Kuwahara R, Garbe P (2018) The economic burden of asthma in the United States, 2008-2013. Ann Am Thorac Soc 15:348–356

HEAL Coalition Partner Initiatives

Current trends among Medicaid beneficiaries indicate that they are potentially a highly receptive audience for mobile health apps. In 2018, 86% of the more than 70 million Americans on Medicaid owned a smartphone and 69% owned tablets, which mirrors the rate of the general adult U.S. population at 86% and 72%, respectively.³³

For about 20% of Americans, a mobile device is the only way of connecting to the internet while at home. That rate of "smartphone dependence" is even higher among people with lower incomes. From 2013 to 2018, reliance on smartphones rather than broadband increased from 12% to 31% for people with average incomes less than \$30,000, while only increasing from 5% to 9% for people with incomes over \$75,000.34

Many digital health companies recognize this opportunity to advance health equity with mobile-enabled tools. The following are some examples of digital health supporting underserved communities.

Fitbit Health Equity Research Initiative: To increase use of Fitbit products in studies related to health disparities, Fitbit is awarding up to \$500,000 in Fitbit products and services to early-career researchers who are actively investigating health disparities while aiming to improve health across historically underserved populations. In addition to collecting activity, sleep and heart rate data, researchers can seek to pair Fitbit services, like health coaching and premium memberships, to address a variety of behavior change and health research questions.

Fitbit hopes to generate new evidence and methods for addressing health disparities that will inform lasting change in traditionally underserved communities by putting additional resources in the hands of health disparities investigators and encouraging wearable research in the field. Fitbit is also partnering with Fitabase on the effort to ensure awardees have the tools to maximize study participation and data collection. Fitabase has a comprehensive data management platform designed to support research projects using wearable and internet-connected devices.

Kinsa Health School Program: Kinsa Health created the first-ever FDA-cleared smartphone-connected thermometer in 2013. The company created a sponsorship program for corporate donors to fund thermometer donations to Title I schools, which serve high numbers of poor students. Before receiving a Kinsa Health thermometer through the program, 40% of these students did not have a thermometer in their house. The program has helped schools improve attendance and has yielded years of real-time data on fever rates and data models to help track illnesses.



A collaborative effort through the Alliance for Better Health distributed about 7500 Kinsa Health thermometers during COVID-19 to community-based organizations and their members to help protect public health workers and the communities they serve. The Alliance for Better Health is made up of health insurance providers, hospitals and nearly 36 organizations around the New York capital region. The Bluetooth-enabled thermometers enabled real-time insights into COVID-19 hot spots in the area and across the country.³⁶

University of Mississippi Medical Center:

Mississippi faces great challenges in rurality and health care disparities. But the state has successfully leveraged the connections offered by technology to improve the lives of residents through telehealth. The University of Mississippi Medical Center ("UMMC") has been a leader in telehealth for over a decade. The UMMC Center for Telehealth allows providers to examine and treat patients using live, two-way audiovisual technology, store-and-forward technology and remote patient monitoring ("RPM") programs on computers, tablets and smartphones.

In 2017, the Health Resources and Services
Administration named UMMC a Telehealth
Center of Excellence, one of only two programs
in the country to receive that designation. The
UMMC Center for Telehealth was also awarded
a \$1 million federal grant from the Federal
Communications Commission as part of the
agency's COVID-19 Telehealth Program. UMMC
is filling a void by providing telehealth through
partnerships with community-based hospitals,
critical access hospitals, clinics, community
mental health clinics, community health centers,
businesses, schools and colleges.

Along with technology and provider community leaders, the Center created the Mississippi Diabetes Telehealth Network, which enabled remote patient monitoring to patients in the Mississippi Delta across multiple chronic diseases. Projections show cost savings in chronic care medical expenses of almost \$190 million due to the use remote patient monitoring.³⁷

Notwithstanding the increasing number of innovative projects and initiatives to address health equity issues, there are serious barriers to wider adoption of digital health in many communities. The potential for technology to meaningfully address health disparities will be unrealized until these are addressed.

BARRIERS TO DIGITAL HEALTH ADOPTION IN UNDERSERVED COMMUNITIES

Increasing availability of digital health tools for medically underserved communities is an important step toward realizing the potential for technology to help address health disparities. However, the HEAL Coalition has identified three significant barriers to widespread digital health adoption:

- Access to broadband and technology, also described as digital equity;
- Health literacy, particularly as it applies to digital health; and
- Data privacy protections.

Access to Broadband and Technology is a Barrier to Digital Health Adoption

Federal, state and local governments can work together to foster digital equity by expanding affordable broadband access and access to technology-enabling devices. Developers of digital health solutions can ensure that new technology is compatible with slower connection speeds adaptable to technology capabilities.

Like disparities in access to health care, healthy foods, high-quality schools and safe environments, there are also disparities in access to broadband technology. Research shows that 44% of adults in households making less than \$30,000 annually

do not have a high-speed internet connection. A similar statistic shows that 38% of households earning less than \$20,000 lack a broadband subscription.³⁹ The digital divide persists even as Americans with low incomes have made gains in technology adoption, and the government and other institutions have invested billions in subsidies and grants to carriers to sustain, extend and improve broadband in rural America over the past few years.⁴⁰

The Federal Communications Commission ("FCC") says the number of Americans living in areas without access to the FCC's current benchmark of at least 25/3 Mbps has dropped from more than 18.1 million Americans at the end of 2018 to fewer than 14.5 million at the end of 2019, a decrease of more than 20%. The rural-urban divide is rapidly closing: the gap between the percentage of urban Americans and the percentage of rural Americans with access to 25/3 Mbps fixed broadband has been nearly halved, falling from 30% at the end of 2016 to just 16% at the end of 2019.⁴¹ Other research shows that 63% of rural Americans say they have a broadband internet connection at home. Rural Americans are now 12% less likely than Americans overall to have home broadband.42

Adoption of broadband usage has barely budged despite the investments and increased access. A Microsoft study concludes that 162.8 million people in the United States do not use the internet at broadband speeds. The study contends that "[t]he government's most current broadband statistics come from the FCC and suggest 25 million Americans lack access to a broadband connection. There's strong evidence, though, that the percentage of Americans without broadband access is much higher than the figures reported by the FCC." 44

Additionally, even though people with lower incomes and people of color own smartphones at about the same rates, there is a gap in whether they can access digital health information and tools consistently and effectively on their mobile devices.

Given the trend to provide and package health information and health decision-making guidance online or through digital tools, underserved communities are at a disadvantage. Older U.S. adults show significant differences in computer ownership, internet access and use of digital health information across racial and ethnic groups. A study showed participants who were older, less educated, had a lower income and from particular ethnic groups (Black, Afro-Caribbean, or Hispanic) were up to five times less likely to have access to digital health information than those who were younger, more highly educated, had a higher income, or were White.⁴⁵

A similar study found that older Blacks and Hispanics were less likely to use technology for health-related purposes. They were also less likely to make or receive phone calls, use health management sites, search the web for health information and use brain games for their health.⁴⁶

These results demonstrate how important it is to understand the use of health-related technology across underserved communities to effectively tailor interventions designed to improve their health and eliminate health disparities.

Recommended Strategies to Improve Broadband Access

Federal and state governments must develop a coherent and meaningful expansion of broadband coverage and adequate device access to ensure true connectivity reaches rural and underserved areas.

Many digital health products and applications offered today work most effectively with a broadband connection. The range of the tools and the speed at which they are being made available to health care providers and consumers show it is critical that quality broadband service be accessible to all populations. While important steps have been taken toward this goal (for example, the \$7 billion Emergency Connectivity Fund under the American Rescue Plan), much work remains to be done.

Even for many with access to broadband service, affordability and quality is an issue.

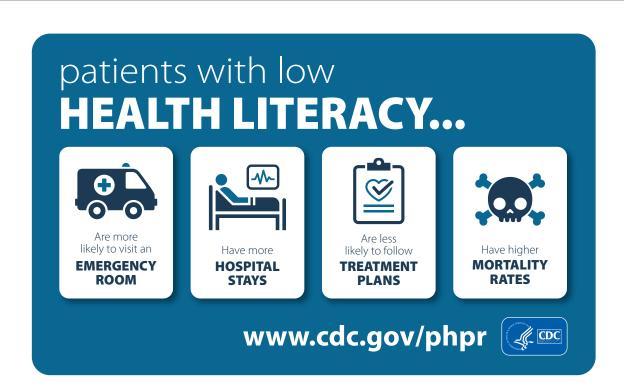
- Congress and the FCC should consider awareness and outreach support to connect consumers to broadband-based initiatives.
- Additionally, Congress should encourage agencies such as CMS and the FCC to seek opportunities to expand access to technologies, including devices, that facilitate access to video and audio care for unserved and underserved populations.

Low Health Literacy is a Barrier to Digital Health Adoption

Increasing health literacy, particularly among underserved communities, is critical in getting people to use digital health tools and find them useful.

Approximately half of American adults exhibit low health literacy and consequently struggle to find and use health information. Health literacy is an individual's capacity to obtain, process and understand basic health information needed to make appropriate health decisions. ⁴⁷ The Agency for Healthcare Research and Quality indicates that only 12% of adults have proficient health literacy. ⁴⁸ Over a third of adults "have difficulty with common health tasks, such as following directions on a prescription drug label or adhering to a childhood immunization schedule using a standard chart."

Low health literacy is associated with negative outcomes including overall poorer health.⁴⁹ Low or limited health literacy skills are more prevalent among certain population groups and may be linked to many poor health outcomes.⁵⁰ Potential communication barriers between patients and health care providers created by low health literacy may lead to a variety of negative health outcomes for the patient. For example, communication barriers have been associated with patients being more likely to be hospitalized.⁵¹



The impact of health literacy on skills needed to make health-related decisions may affect a patient's adherence to a treatment regimen which may decrease its benefits. Additionally, people with low health literacy tend to use the emergency department more often and are more likely to return to the emergency department after two weeks. ⁵² People with low health literacy were less likely to use digital health tools or perceive them as useful. ⁵³

Digital health literacy is the ability to seek, find, understand and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem.⁵⁴ People who are digitally health literate can take a more active role in managing their own health.

Increasing reliance on technology in health care may negatively impact people already at risk for low health literacy and health disparities. Digital health literacy tracks closely with disparities in socioeconomic status, education, race and geography and age.⁵⁵

"Technology solutions have the potential to both promote health literacy or be a barrier. To be effective, health technology solutions should go beyond building literacy and numeracy skills to functional and critical skills, such as navigating the health care system, communication with health care providers and shared decision making."56

Recommended Strategies to Improve Health Literacy and Access

The most effective examples of digital health use among underserved populations are a collaboration of trusted community organizations, health care systems, government agencies and companies providing specific digital health tools. Stakeholders can work together to remove barriers to digital health literacy and access:

 Develop culturally competent digital health tools and patient education materials to engage diverse populations by leveraging collaboration and dialogue between diverse patients, caregivers, technology developers and other health care stakeholders.

- Ensure adequate language interpreter access be included in consumer-facing digital health tools.
- Track digital health access and use to ensure digital health solutions are appropriately serving the whole community.
- Train clinicians to deliver digital health in culturally competent ways to reach diverse demographics.
- Build relationships with diverse patient groups, associations and alliances (e.g., age, ethnicity, educational level, disability, language fluency, tech literacy) and seek their feedback on products during all stages of development.
- Offer education to, and engagement of, community stakeholders regarding digital health.
- Develop technologies designed for people with different levels of digital competency and assistance needed in using these tools (such as those with disabilities).
- Provide community health workers with digital tools that can respond to or supplement lowtech monitoring or modalities (texting, etc.) and be a liaison between providers and patients/ consumers.
- Develop training programs targeted at clinicians to extend their skills to enable them to effectively use health technology among various demographics.

Developers of digital health solutions can ensure that design, engineering, data and clinical teams properly evaluate health equity factors (e.g., mitigating potential bias) from the earliest stages of development. They also need to promote patient safety, ethics, and privacy and ensure solutions are inclusive to traditionally underserved communities. In some circumstances, developers should consider building solutions in which the most vital functions can run on 2G instead of 4G or 5G—thereby increasing accessibility.

Have CMS require hospitals and health systems to routinely assess a patient's ability to access digital services and their digital literacy.

• The assessment should be incorporated into EHRs. The lack of routine assessment prior to COVID-19 meant that some patients fell between the cracks as care shifted to nearly all virtual. Incorporating this and other social determinants of health into the EHR encourages more consistent documentation and allows assessment of population-level metrics of access. When digital skill and connectivity gaps are assessed systematically and universally, a hospital or health system can document overall population-level metrics, examine disparities and track changes over time.

The federal government should consider providing incentives for state and local governments to develop a network of digital hubs that can train, educate and support patients and health care providers in using various digital health solutions.

- Training programs will need to: (1) educate consumers about the benefits and limitations of digital health tools and how to maximize them most effectively; (2) tailor program materials to ensure appropriate cultural and linguistic fit; (3) include both in-person and online/digital programming; and (4) include training specific to the health care workforce to ensure care providers are sufficiently able to assess, adopt and implement new health technologies into health care services.
- In addition, training programs should prioritize partnering with community organizations with expertise in training in digital literacy skills and facilitating connectivity. For example, many libraries and community centers offer internet access and related services such as training programs to teach digital literacy and other skills required to access specific applications and services.



Data Privacy Issues Are a Barrier to Digital Health Adoption

Given increasing consumer concerns associated with the use of digital tools, ensuring trustworthy and transparent data practices and standards are keys to increasing digital health use in underserved communities.

Data privacy issues are one of the primary reasons for lack of trust in many aspects of the health care system. A survey found that 57% of health care consumers are skeptical of using health technology because of data privacy and security. Patients were most concerned that their pharmacy (90%), mental health (99%) and chronic condition (89%) data was sent (without their consent) to third parties such as the government, employers and retailers. Patients (93%) were also concerned about the security of their financial information used in hospital billing departments. A recent study of mobile health apps found serious privacy problems and that a vast majority of apps included code with the ability to collect user data.⁵⁷ As noted by some researchers, "the use of health information technology exacerbates patients' privacy concerns because it expands the availability of patient data to numerous members of the health care team.⁵⁸

Data leaks, breaches and loose privacy practices chip away at consumer trust. Trust is critical in health care, particularly in communities with longstanding trust issues with the U.S. health system.

The United States has adopted a sectoral approach to privacy laws at the federal level unlike other jurisdictions. This means that the privacy regulations that apply to data collected in the United States depend on the *type* and *context* of the data collected.

Perhaps the most well-known federal privacy law in the health care sector, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), applies to "covered entities" and their "business associates." "Covered entities" consist of health insurance providers, health care clearinghouse (entities that assist the submission of claims to health insurance providers), and health care providers.⁵⁹ "Business associates" are third parties that create, receive, maintain, or transmit protected health information ("PHI") on behalf of covered entities. However, identifiable health information collected by public health agencies is not protected by HIPAA as governmental agencies are not covered by HIPAA (unless such health information is collected in the public health agency's capacity as payor).



Many entities that collect, use, store, or disclose consumers' health information remain beyond HIPAA's scope. To best protect consumers and increase trust, these entities should be required to maintain a similar level of robust privacy and security controls as HIPAA-covered entities. Covered entities are generally required to obtain written authorization from individuals before using or disclosing their PHI unless an exception applies. Generally, disclosures for "treatment," "payment," and "health care operations" purposes do not require a written authorization. Disclosure of PHI to public health authorities authorized by law to collect such PHI also does not require a written authorization. Any PHI disclosed to a public health agency must be limited to the "minimum necessary" required for the purpose of the public health agency's authorized information collection. The "minimum necessary" requirement can make disclosures of PHI to public health agencies difficult for covered entities—as they must evaluate what constitutes the minimum necessary and separate the PHI that is not part of the minimum necessary PHI for the disclosure.

Typically, business associates are permitted to disclose PHI only as permitted by their agreements with covered entities. They cannot disclose PHI for public health purposes unless the covered entity has first agreed to permit the business associate

to do so. Recognizing this limitation, OCR, the agency within HHS charged with enforcing HIPAA, instituted a policy to exercise enforcement discretion to permit business associates to make a good faith use of, or disclose, a covered entity's PHI for public health activities during the COVID-19 pandemic. To take advantage of this flexibility the business associate must inform the covered entity within 10 calendar days of making a disclosure.

For stakeholders not covered under HIPAA (such as third-party app developers), the Federal Trade Commission ("FTC") is the primary federal regulator in data privacy and has broad jurisdiction over the data privacy and security practices of for-profit entities. The FTC derives its primary authority from Section 5 of the FTC Act, which prohibits "unfair or deceptive acts or practices in or affecting commerce." The FTC has used this broad jurisdiction to pursue enforcement actions against companies for engaging in "deceptive" practices by not complying with their own privacy policies, privacy settings, or other representations to consumers. In addition, the FTC has brought enforcement actions asserting a company's use of personal data in a manner that would be inconsistent with a consumer's reasonable expectations, including by failing to implement reasonable security measures, is an "unfair" trade practice. Accordingly, if an organization uses data in a materially different way than it originally disclosed to consumers, such as for a new purpose, the company must provide notice and obtain consumer consent. In addition, the FTC enforces the Health Breach Notification Rule that requires certain businesses not covered under HIPAA to notify their customers and others if there has been a breach of unsecured individually identifiable electronic health information.

Many current laws do not align with the assumptions consumers may have about the privacy safeguards that apply to their health information or public narratives about what privacy laws do and do not prohibit. Consumers may falsely believe that health information is better protected than it is under the current legal framework, mistakenly believing that most activities involving their health

information cannot occur without their knowledge or consent. As health apps come to market that allow patients to download their medical record into the app of their choosing, many consumers are not aware that the data is no longer protected by HIPAA from that point forward. Pathways under current legal regimes, however, permit the use and disclosure of health information for research, development and other commercial purposes without consent. Moreover, many organizations that store and use health information are not covered under HIPAA and their activities fall within a grey area that does not offer consumers the kind of privacy protection they may expect. Lastly, stakeholders may have to navigate a patchwork of state laws; while it is beyond the scope of this paper to delve into state laws, we note that this patchwork approach is a barrier to digital health adoption.

Recommended Strategies to Improve Data Privacy Protections

Congress should consider enacting comprehensive federal privacy legislation creating one national standard specifically covering stakeholders not covered by other privacy laws and regulations (e.g., HIPAA). Legislation should balance the need for privacy and security on the one hand while facilitating data mobility and innovation on the other. Specifically, federal privacy legislation should:

- Provide individuals with transparency about how their health data is collected, used, stored and shared through a privacy policy or other public statement that clearly outlines the organization's policies and practices with respect to the collection, use and disclosure of the data.
- Prohibit disclosing health data unless required by law, the transfer is tied to providing the product or service, or the individual has consented to the disclosure.
- Require companies to provide individuals the ability to access, delete and correct their health data that those companies collect or maintain. Clarify health care and consumer protection agencies' (e.g., the FTC) role in enforcing where appropriate against entities that process health care data (or do so on behalf of another entity)

- in a manner that results in harmful bias or discrimination. In addition, the FTC should be the primary regulator for new applications that use, disclose, store and transmit health data. This will create comparable protections as offered by HIPAA.
- Incentivize privacy by design and scalable risk management practices including data minimization, de-identification and differential access. Organizations should be prohibited from knowingly retaining individuals' health data beyond the time appropriate to provide the expected function or service, unless otherwise agreed to by the individual or required by law. Additionally, organizations should be required to limit internal access to health data to only those employees or third-party service providers whose access is necessary to provide products or services to the individual to whom the data pertains, within the context of the company's ongoing relationship with the individual.

CONCLUSION

The COVID-19 pandemic amplified longstanding health inequities in the U.S. health system. Historically underserved communities—rural, lowincome and minority—face barriers in accessing quality health care, but the pandemic has shown the role health technology can play to meaningfully address these disparities. Barriers, including unequal access to broadband and technology for connectivity, low digital health literacy and laws and regulations that stifle digital health adoption, must be overcome to fully realize this potential. The HEAL Coalition recognizes that greater and appropriate use of digital health plays a significant role in addressing and mitigating health inequities in the United States. We must ensure there is intentionality in design, distribution and delivery.

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About

Consumer Technology Association

Consumer Technology Association

As North America's largest technology trade association, CTA is the tech sector. Our members are the world's leading innovators—from startups to global brands – helping support more than 18 million American jobs. CTA owns and produces CES, the most influential tech event in the world. Find us at CTA.tech. Follow us @CTAtech.



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The Connected Health Initiative (CHI) is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of digital health innovations and support an environment in which patients and consumers can see improvements in their health. We seek policy changes that will enable all Americans to realize the benefits of an information and communications technology-enabled healthcare system. For more information, see www.connectedhi.com.





For more information please contact:

Rene Quashie

Vice President, Policy & Regulatory Affairs, Digital Health CTA

membership@CTA.tech

Brian Scarpelli

Senior Global Policy Counsel Connected Health Initiative BScarpelli@actonline.org