Consumer Technology Association Technology & Standards Forum and EXCITE International Health Innovations Joint White Paper

HealthFuture: The Shifting Paradigm of Heath Technology Innovation and Evidence-Based Adoption

"All over the world, the provision of fairer (equitable), comprehensive, and integrated health care is the aspiration that health care systems strive to achieve."[1]

Introduction

Digital health ("DH") technologies are transforming health care systems worldwide – systems' capabilities, their structures, their efficiencies, their costs. They are also transforming people's lives. The term "digital health" – meaning "the use of technology and electronic communications tools, services, and processes to deliver health care services or to facilitate better health"[2] – has an extremely broad scope and includes several types of technologies with numerous different functions. DH technologies have the capacity to improve access to health care services, increase systemic efficiency, promote and facilitate patient self-efficacy, enhance communications between all parts of our health care system, lower costs, and lead to better health outcomes.[3]

Although the US health system has begun taking advantage of these potential gains, DH still faces many barriers to broader adoption and greater realization of its promises. Uncertainty about the prospects for payer coverage and reimbursement for DH technologies and the evidence needed to obtain them causes misdirected resources and lost opportunities, for example. Actions also need to be taken to ensure that DH technologies do not further exacerbate the inequities in our health system that afflict disfavored groups. Concerns about how well patients' sensitive health information is protected hinder data collection and analysis that could provide great insights into a variety of diseases. The challenges of artificial/augmented intelligence are headline news and contribute to consumer and health care provider mistrust. Data from mobile apps and wearables are too often not integrated with information from patients' electronic health records ("EHRs") and other elements of the health information stream.[4]

This white paper addresses some of the most important factors that need to be considered to provide a stable and sustainable approach to the development and adoption of impactful digital health technologies that improve patient outcomes and/or health system efficiencies with the support of payers, expert end-users, and patients. It incorporates insights shared at two private conferences in 2023: *HealthFuture: The Shifting Paradigm of Health Technology Innovation and Evidence-Based Adoption* (May 2023), jointly sponsored by CTA and EXCITE International, and *Health AI+* (September 2023) sponsored by CTA, and also from a literature review. The key themes that were most prominent throughout the conferences comprise the topics for the paper. Although the points made throughout this paper focus on digital technologies, many could apply to any new health care technology.

After briefly reviewing the scope of DH technologies, the paper turns to the four main issues identified at the conferences: evidentiary requirements, equity, privacy, and AI.

Digital Health Technologies

Digital health technologies are defined as “the electronic tools, systems, devices and resources that generate, store and process data in health care.”[2] They constitute a remarkably diverse set and continue to rapidly evolve. Some of the most widely used technologies include:

- *wearables*: items worn on the body like fitness trackers, smartwatches, ECG or blood pressure monitors, and biosensors; these items collect a user's personal health information ("PHI") and some are able to communicate with and send data to the user's health care provider
- *smartphone apps*: extensive range of functions from health logs and diaries to behavioral change programs to directories of providers
- *electronic health records (“EHRs”)*
- *telemedicine*: programs that allow/facilitate virtual medical consultations in real time through secure videoconferencing
- *monitors*: these include smart versions of common clinical devices such as thermometers, stethoscopes, blood pressure cuffs, and scales that take readings and transmit them to a health care provider
- *patient portals*: these facilitate communication between patients and providers on an asynchronous basis and also allow patients to access their own health information
- *artificial/augmented intelligence*: perform functions like medical image analysis to assist with diagnoses, predictive analytics to predict likelihood of outcomes, chatbots
- *hybrids*: technologies that combine two or more of the above

This list is not exhaustive but is intended to provide an idea of the range of DH tools that are available.

DH technologies also can be classified by their functions, e.g.:

- health administration management
- information recording
- communication
- remote access
- monitoring
- diagnosis
- prevention
- disease management
- treatment
- outcome predictions
- clinical decision support
- education
- geospatial location/surveillance

Again, the list is not exhaustive and some of the classifications can overlap.

Occasionally, grouping by the stakeholder group that most benefits can be useful to understand where DH technologies fit into the health care system and what value they provide:

- hospitals and health systems: improve effectiveness and efficiency of systems and processes, facilitate value-based care
- clinicians: support clinical decision making, improve administrative efficiency, enable top quality work
- patients: improve access, including specialty care, facilitate health literacy, assist with self-monitoring and managing of health, enable more personalized care
- policy-makers: provide better data on which to make policy decisions, facilitate planning for and managing public health emergencies, support more equitable health care[2]

These are not mutually exclusive groups. DH technologies often have value for more than one stakeholder group. They also often provide a range of non-traditional benefits that can make them difficult to evaluate clinically and economically. DH tools often evolve more quickly than conventional medical devices in response to user feedback and continued technological advancement.[5] This circumstance can affect both the cost of the intervention and the clinical outcomes and further complicates assessments. More complex DH technologies, such as those that seek to inform or drive clinical management, often are interactive and personalized based on user input,[5] adding yet another layer of intricacy. The variety and range of DH technologies foretell the vast impact they will have on our health care system.

Evidentiary Requirements

One critical factor that must be addressed if DH technologies and tools are to be incorporated into the US health care system is the evidence needs of potential users and post-regulatory stakeholders like payers, clinicians, health systems, and employers. (This paper does not address evidentiary needs to obtain any necessary regulatory approval or clearance for marketing as FDA has promulgated a number of final and draft guidances to provide such direction.) After examining the value that DH solutions bring, this section reviews some evidentiary frameworks that can help guide product developers and evaluators, looks at an evidentiary issue of particular importance to clinicians, considers the role of various DH company funding models, and notes the evidence inputs other stakeholders could contribute.

Value. Without persuasive high-quality evidence to demonstrate value to *all* involved decision makers, a DH solution may not ultimately be adopted; however strongly it appeals to one stakeholder group, if it fails to meet the expectations and needs of any other stakeholder group in the relevant system, its full potential will not be realized. A wearable device that continuously measures blood glucose levels, for example, could appeal to wearers because of its light weight, attractive appearance, and potential to help with self-management. If clinicians are not convinced of its accuracy, however, or have difficulty interpreting the data it provides, then they will not use it to guide therapy or prescribe it if a prescription is required. If employers or health plans are not convinced of its cost-effectiveness or clinical utility, they will not pay to provide it to employees or beneficiaries.

The importance of understanding the difference between evidence to support initial market uptake and evidence needed to demonstrate value to health systems and payers is demonstrated by the bankruptcy of DH innovator Pear Therapeutics. Pear had pioneered a regulatory pathway through FDA and obtained clearance for three prescription apps to help treat substance use disorders and insomnia through behavioral therapy.[6–8] It developed a substantial portfolio of published studies providing evidence of the

apps' effectiveness, including a number of large randomized clinical trials.[7] This portfolio helped to convince physicians to write more than 45,000 prescriptions for Pear's products in 2022. The average selling price for an app was around $1200, however, and patients, many of whom were paying out of pocket, filled only about half the prescriptions.[6] Furthermore, Pear was able to collect payment for only 41% of those 50% of prescriptions that were filled.[6] When Pear declared bankruptcy in early 2023, its CEO largely blamed its demise on insurers' lack of coverage for the apps.[6]

Solid evidence of clinical benefit does not guarantee payer coverage. Unless coverage is mandated by statute, most payers want to see evidence that providing coverage would be, at bottom, a wise use of money. Analysts opined that insurers, before providing coverage for Pear products, had wanted to see compelling health economic data, including budget impact models and real world evidence for large numbers of users.[7] Given the price of the apps and the statistic that 9% of employed adults in the US (13.6 million people) have a substance use disorder,[9] providing each affected employee a single app would have cost payers more than $16 billion. Although no single payer would have been responsible for that full amount, providing coverage could have had a substantial budget impact and it is not surprising that insurers would want to see solid evidence of value. In September 2023, MassHealth, the Massachusetts Medicaid program, was reported to be presenting data suggesting that providing the Pear apps to its beneficiaries with substance use disorders had saved the program money.[10] Such evidence would have been extremely valuable to Pear but arrived too late to provide financial benefit.

In identifying the value proposition for various stakeholders, DH developers should bear in mind that DH solutions often differ from pharmaceuticals and more traditional medical devices because some or all of their value may be derived from factors other than clinical outcomes.[11] These include:

- improved access to health care
- improved quality of care
- more convenient care
- increased self-efficacy with respect to health management
- improved work flow or other administrative benefits
- improved interoperability with other DHTs
- larger contribution to big data analytics
- economic savings or efficiencies[11]

Not all decision makers will value all of these outcomes, nor will they necessarily value them similarly. Some value propositions (e.g., improved work flow) have little direct relationship to health but nevertheless will be important to specific stakeholder groups. Even within a stakeholder group, however, value propositions vary. For example, Pear products particularly appealed to state Medicaid programs[7,8] because people with substance use disorders are substantially overrepresented in their coverage population.[12] The same value was not present for most private payers.

Evidentiary frameworks. Because reimbursement will play a critical role in DH technology adoption, being able to demonstrate utility to payers will assist in speeding DH solution implementation. Currently, however, it seems that many insurers are frustrated because their evidentiary expectations are not being met, while DH technology developers are discouraged by the lack of knowledge of what evidence payers would find convincing.

A recent literature review identified more than 70 published evidentiary frameworks for evaluating DH technologies.[13] Some are useful only for specific stakeholder groups, many have limited development of clinical outcomes assessment, and few include evaluating evidence quality or bias.[13] Another review of a selection of regulatory authorities and health technology assessment ("HTA") agencies revealed that many of those frameworks are still in development and few of the existing frameworks are intended to be comprehensive.[14] Given the lack of standardization or agreement, it is difficult to draw conclusions about precisely what kind of evidence or studies are needed to satisfy various stakeholders.

In the US, FDA's regulatory approach to demonstrate safety and effectiveness and an initial assessment framework developed jointly by the Institute for Clinical and Economic Review ("ICER") and the Peterson Health Technology Institute ("PHTI"),[14] along with the evidence standards framework ("ESF") used by the UK HTA's National Institute for Health and Care Excellence ("NICE")[15] may provide the best general insights. Of these three, only the ICER-PHTI and NICE frameworks also address the economic evaluations that may be most relevant to technology assessors like payers and health care systems.

As different as these approaches are, they share some commonalities. In terms of clinical evaluations of DH technologies, the amount and type of evidence needed varies with the level of clinical risk associated with the technology, which in turn is affected by the technology's intended use. In general, the level of risk is determined by the clinical consequences of obtaining inaccurate information or of having the delivery of the intervention fail to achieve its purpose – both the probability and the magnitude of potential harm. At one end of the risk spectrum, DH technologies with administrative health functions (e.g., EHRs and e-prescribing platforms) are out of the scope of the ICER-PHTI framework but are subject to a number of NICE framework standards. At the other end of the spectrum, for DH technologies intended to provide treatment, such as an app providing cognitive behavioral therapy, evidentiary expectations generally include one or more high quality interventional trials such as a randomized clinical trial with an active comparator.[14,16]

In terms of economic evaluations, the ICER-PHTI framework expectation for any DH technology seeking payment is a "robust dossier of evidence" demonstrating the economic impact of the technology across the system, starting with a primary budget impact analysis.[14] NICE expects a budget impact analysis for any DH technology and, for those with higher financial risk, a cost-effectiveness analysis as well.[16] Both frameworks expect developers to have evidence of consideration of health equity concerns.

Evidentiary guidelines are intended not just to advise technology assessors but also to provide a consistency and stable environment for DHT developers, allowing them to make better choices about how or even whether to obtain the expected evidence. In that respect, one of the most important practical recommendations in the frameworks is for DH developers to have "extensive" discussions with the most relevant adoption decision makers as early in the development process as possible.[14] Goals of the discussions should include reaching agreement on (1) the levels of risk and corresponding evidence requirements, and (2) the most relevant specific outcomes, both clinically and economically.[14]
As previously mentioned, even within stakeholder groups there is diversity in terms of evidentiary needs and developers should not make assumptions, even if they are guided by frameworks.

If a DH solution is intended for use for patients with a specific disease, e.g., diabetes mellitus, developers may want to investigate whether or not a core outcome set ("COS") is available as a starting point for the discussions. Such sets, usually developed through multi-stakeholder consensus, represent the minimum set of outcomes that should be measured and reported in all clinical trials of a specific condition. The

COMET (Core Outcome Measures in Effectiveness Trials) Initiative maintains a database of COS available at https://www.comet-initiative.org/Studies that is free to search.

Finally, DH technology developers also may want to explore risk-sharing agreements with potential users or mechanisms like coverage with evidence development through which payers agree to provide coverage for a given period of time in order to obtain real-world evidence.

Payers and health care systems may well be cautious when making decisions about paying for DH technologies, particularly given "the rapid surge in product development, limited understanding of clinical impact, uncertain regulatory environment, logistical challenges, and potential budgetary impact."[12] If payers and developers can meaningfully communicate about evidentiary expectations, however, they can facilitate rapid and safe adoption of DH solutions.

Clinician evidentiary concerns. Participants at the joint EXCITE/CTA conference believed that clinicians were generally enthusiastic about DH technologies but had some concerns relating to data and evidence – specifically about data overload and alarm fatigue.

Data overload is nearly ubiquitous as more than 70% of US physicians report being overwhelmed by data.[17] It is one of the top-reported reasons physicians say adoption of connected care is slow.[18] The popularity of patient portals and patients' resulting ability to email sometimes complex medical questions certainly contributes to this burden – some physicians report spending two to four hours a day responding to patient queries.[19,20] Data from wearables and health trackers comprise the other main component. Clinicians can receive measurements of physical activity, heart rate, blood pressure, heart rhythms, blood oxygenation, and sleep quality, among other things, some of them being continuously monitored.[18] Assuming they can access the data in meaningful form, clinicians still have to confront what the data signify. Is an outlier value truly a matter of concern that needs to be followed up or is it normal, unchanged, and known only because of the technology that can now measure it? Without better parsing of the data provided and indications of actionability, physicians are being forced to make clinical decisions based on information with uncertain meaning. The situation is somewhat analogous to the risks associated with overuse of some screening tests: every anomaly has to be followed up for fear of liability, resulting in additional testing, possible overtreatment, and their attendant potential harms. Evidence of data significance is badly needed.

Perhaps at the other end of the spectrum is the condition of "alert fatigue," which describes how clinicians become desensitized to various digital alarms and alerts and therefore become less likely to respond to truly important alerts.[21] Alert fatigue derives from the sheer number of alarms and alerts clinicians face – up to 100 per day in a VA primary care practice, for example.[21] Many of these alerts originate in computerized provider order entry systems or clinical decision support ("CDS") systems. Clinicians need more meaningful evidence-based alerts and DH developers could accommodate by, for example:

- reducing or eliminating clinically inconsequential alerts
- tailoring alerts to patient characteristics
- putting alerts in tiers according to severity
- making only high levels alerts interruptive
- applying human factor principles in alert design (e.g., color, format, content)[21]

DH company funding models. One important factor contributing to the difficulty of collecting data relevant to payers, frequently overlooked, is the impact of many DH companies being funded through venture capital ("VC"). VC funding for DH companies grew from $7.4 billion in 2019, to $14.1 billion in 2020, to $29.3 billion in 2021, driven by the impact of the COVID-19 pandemic.[22,23] While investment in DH generally has slowed in the last few years,[23,24] funding for generative AI startups has ballooned from $5.1 billion in 2022 to $21.4 billion in the first three quarters of 2023.[25] Although VC is a critical funding source for innovative companies, the financing model creates some challenges in the health care field because of the frequent misalignment of the two spheres' goals.

In particular, the time frames preferred by VC funders and DH developers may be inconsistent. VC funders often are looking for substantial returns on their investments within three to seven years, (even quicker in some circumstances[7]) and thus prioritize short-term revenue generation over longer-term research and development activities or broader health care objectives like prevention.[26] As previously noted, obtaining evidence for payers tends to be a longer term project.[8] Short-term orientation also leads to prioritizing companies with the most potential for rapid growth and high value ("unicorns") rather than companies that may grow more slowly but have a higher impact on the quality or efficiency of patient care.[26] In terms of equity, VC's focus on maximizing revenues means it often tries to identify products that will appeal to the largest and most wealthy populations rather than addressing unmet needs of underserved populations.[26] Indeed, in 2021, VC funding for DH companies that focused on addressing inequities constituted only approximately 2% of the total investment.[27]

Remedies for this mismatch are not obvious. CTA-EXCITE conference participants reported that approaches like increasing communication and trying to improve collaboration have met with little success. Exceptions do exist, however. Jumpstart Nova, for example, is a Nashville- and Los Angeles-based VC fund with a goal, not only of achieving financial returns, but of backing Black health care entrepreneurs.[28,29] Financial supporters have included the hospital chain HCA, pharmaceutical company Eli Lilly, and medical supplier Cardinal Health, among others.[28]

DH startups also may have funding options besides VC, particularly if they can streamline their cash needs. Some possibilities include:[30]

- *Angel investors*: sometimes known as seed investors, they usually provide funding in the early stages in return for equity or sales royalties
- *Debt*: business loans from banks or other financial institutions
- *Crowdfunding*: through traditional platforms like Kickstarter or through platforms like Wefunder,[31] which facilitates unaccredited investors purchasing equity in startups
- *Grants*: may be offered by state and local governments, community organizations, or private entities

Other evidence gatherers. Although product developers are usually in the best position to acquire needed evidence as they proceed through the product lifecycle, they are not the only stakeholders who can do so:

- *Government research agencies*: The National Cancer Institute, for example, awarded $23 million to establish four Telehealth Research Centers of Excellence ("TRACE") that will, among other things, establish an evidence base of telehealth approaches to cancer care as well as identify and address disparities in their access and use.[32,33]

- *Professional associations*: The American Medical Association consulted clinical and technical experts (including device manufacturers and the FDA) to develop criteria to determine which automated blood pressure measurement devices have been validated for clinical accuracy.[34] It is now funding an independent third party to determine which devices meet those criteria and making the list publicly available at https://www.validatebp.org/.[35]
- *Academic institutions*: Howard University has established the 1867 Health Innovations Project to support the innovation and adoption of digital health technologies that address the needs of medically underserved communities.[36] To achieve this goal, it seeks to collaborate with a variety of other stakeholders, including technological, government, academic, business, and health. It is initially concentrating on, among other technologies, mobile apps, wearables, sensors, and AI.[36]

None of these stakeholders should be overlooked when considering possible sources of evidence and all of them can carve out roles that will support the evaluation and adoption of digital technologies.

Equity

Health equity has been defined as "the state in which everyone has a fair and just opportunity to attain their highest level of health"[37] or, more completely and pointedly, "[t]he state in which everyone has a fair opportunity to attain full health potential and well-being, and no one is disadvantaged from doing so because of social position or any other socially defined circumstance."[38] It is, or should be, however, common knowledge that the benefits of the US health system are not equitably distributed among its citizens. Specific subpopulations, including racial and ethnic minorities, people with lower socioeconomic status, people without a high school diploma, the elderly, people with disabilities, LGBTQ+ people, and people living in rural areas all face higher barriers to care, resulting in poorer health outcomes and higher mortality.[2,39] Attaining equity is one of the most important challenges to the US health care system. CTA-EXCITE conference participants consistently and repeatedly emphasized both the importance of equity in the development of DH and the opportunities for new technology to help alleviate health disparities. They also stressed that DH could potentially exacerbate inequities and could not be allowed to do so.

One of the most important ways that DH can help achieve equity is by increasing access to health care and health information. People living in rural areas, for example, can use patient portals, telehealth conferences, and remote monitoring to overcome problems with transportation and lack of providers. The growth of real-time language translation apps provides greater accessibility of health information to people who do not know or have difficulty with English.[40] AI technology can improve accessibility for people with disabilities through, e.g., real-time transcription and captioning services for people with hearing-impairments[40,41] or smart readers that can record text and generate speech for people with visual impairments.[42] DH technology can further improve health care for people with disabilities by better capturing and analyzing information about their function in various contexts to assist health care providers in adopting a more holistic approach.[43]

Besides improving access to care, DH can help advance health equity through its capabilities to:

- close communication gaps between patients and providers
- increase patient engagement in understanding and managing health
- improve providers' abilities to tailor services

- improve decision-making of both consumers and providers
- facilitate health surveillance and interventions[2,39]

Responses to the COVID-19 pandemic illustrate many of the ways that DH can reduce disparities. The elderly population, for example, rapidly adopted telehealth during the pandemic, with Medicare primary care visits conducted through telehealth increasing from less than 1% to greater than 43% of visits in a manner of months.[44] Similarly, as the number of people affected by depression and anxiety increased during the pandemic, more people, including many in historically marginalized communities, turned to DH apps and other platforms to meet their mental health needs.[45] Latinx smartphone users were even more likely than White smartphone users to use a health app and a vast majority of Latinx patients indicated interest in doing so.[45] Interestingly, while the use of telehealth has diminished overall with the decline of the pandemic, it is remaining at elevated levels for those with mental or substance abuse disorders.[46] This observation suggests that telehealth is meeting previously unmet needs of those stigmatized populations. DH technology also contributed to addressing public health needs during the pandemic as officials used mobile apps to track spread of the virus and to notify people who appeared to have been exposed to it.

Although DH technologies have enormous potential for transforming our health care system to reduce inequities, they also have the potential to exacerbate disparities. In fact, evidence has rapidly accumulated that the well-known "digital divide," between those who have access to technology, broadband, and knowledge and those who do not, has resulted in a corresponding "digital health divide" -- people without adequate technology access cannot benefit from DH development to the same extent as others. Because the digital divide disproportionately affects many groups who also face barriers to obtaining health care, inequities are compounded.

For example, about half of Black and Latinx workers have limited or no digital skills.[47] Despite the rapid growth of telehealth during the pandemic, more than 40% of Medicare patients lack high-speed Internet services in their home.[48] People with lower incomes are also more likely to lack broadband access at home.[49] People with less than a high school diploma use the Internet at a substantially lower rate than do college graduates.[49] Younger people and White people of non-Hispanic ethnicity are more likely to use DH tools.[2,39] Each of these disparities reflects societal inequities that have been embedded for many years.[49,50]

There is no simple solution, no single solution to the digital divide because the causes are many and complex. The following sections address the three aspects of the digital divide most often mentioned at the CTA-EXCITE conference as affecting use of DH technologies: broadband Internet availability and adoption, digital literacy, and health literacy (including digital health literacy). If the full potential of DH technologies to advance health equity is to be achieved, these three factors are indispensable prerequisites and existing gaps in them must be closed.

Broadband availability. While there are other barriers to broadband adoption and use, an initial prerequisite is obviously the physical availability of broadband through infrastructure. Broadband availability is particularly critical because it affects so many other social determinants of health: employment, income, education, access to transportation, and access to health care, among others.[51] As one commenter observed about unconnected rural communities, "[they] can't start or run a modern business, access telemedicine, take an online class, digitally transform their farm or research a school project online."[52]

When discussing "broadband" availability, speed is highly relevant. The Federal Communications Commission is still using a definition of broadband from 2015 that is less than one-fourth the speed of what is considered broadband today (although the FCC has recently proposed updating this standard[53]).[54,55] Under the newer definition of broadband (download of 100Mbps and upload of 25Mbps), 64.4% of rural households have broadband available compared to 98.5% of urban households,[56] indicating a continuing gap between urban and rural areas in terms of availability.

It is important to note, however, that the *number* of households without broadband availability is nearly the same in rural and urban areas – 12 million in rural and 10.2 million in urban.[56] Much of the seeming discordance in the statistics is due to a lower rate of uptake in urban areas: only 74% of the urban households where broadband infrastructure is available have subscriptions, compared to around 91% of the rural households with availability.[56] Those with lower income (one of the most important factors), higher age, or lower educational attainment are less likely to adopt broadband.[57] Even after accounting for differences in these and other factors, Blacks, Hispanics, and Native Americans are also less likely to be connected.[57,58] The racial differences are greater in dense urban areas, where Black households are twice as likely as White households to lack connection.[58] Some of the problems in dense urban areas may still be infrastructure related: multi-dwelling units may have capacity constraints because of shared bandwidth limitations, poor wiring or other equipment, and high peak demand.[58]

Improving and expanding the availability of broadband and internet services has been a high priority for the federal government for several years. In just the past few years, it has made more than $425 billion available for broadband and digital equity through various pieces of legislation.[58–60] The funding is targeted not just at expanding broadband infrastructure but also at improving internet affordability and adoption, among other goals.[58] Experience with programs specifically aimed at reducing the costs of internet connection, in particular, exposes the continuing barriers to adoption besides infrastructure and affordability.

The FCC's Affordable Connectivity Program,[61] which provides a discount of up to $30-$75 per month toward internet service for eligible households, as well as a $100 one-time discount on a tablet, laptop, or desktop, has been used by less than 40% of eligible households, for example.[62,63] Barriers to using the program identified through interviews with eligible households include: limited awareness of the programs; lack of information around eligibility, applications, and installation; lack of trust about costs and sharing personal data; and structural limitations such as language barriers or complex housing situations.[64]

Digital literacy. Another factor that likely contributes to the disappointing performance of programs aimed at economic barriers is the lack of digital literacy. Low digital health literacy is one of the most significant obstacles in achieving telehealth equity.[65] Digital literacy can be defined as "a person's ability to use, access, evaluate, and communicate across digital platforms"[66] or, to focus more on context, "being able to make use of technologies to participate in and contribute to modern social, cultural, political and economic life."[67] Both definitions emphasize skills in using technology, which are an essential aspect of meaningful accessibility. Although extensive digital skills are usually not needed to use DH tools like wearables and tracking devices, other DH tools may require more sophisticated abilities to navigate and take advantage of the benefits they offer. Having a high level of health literacy does not guarantee the same level of digital literacy -- even individuals with high levels of health literacy often have low self-efficacy in their abilities to find and assess the quality of online information.[68]

While the lack of digital literacy is widespread – in 2019, one-third of US workers lacked basic digital skills needed to participate successfully in the modern economy – it disproportionately affects people of color.[60] According to the National Skills Coalition, half of Black workers and more than half of Hispanic workers have limited to no digital skills.[47]

Health care professionals are not exempt from this problem. Although research regarding health care providers' digital literacy levels is not robust, what exists points to gaps:[67] 30%-70% of health workers are estimated to be unable to use digital technology.[69] Disparities in DH technology use also exist within health care professions: survey data from four southern states, for example, indicated that Hispanic clinicians were only one-third as likely to use telehealth as other clinicians.[39]

Health providers' (as well as their staffs') digital literacy is essential to capturing the promise of DHTs.[69] Even administrative work, like ensuring that EHRs are complete, accurate, and secure, can negatively affect patient health if not achieved.[70] Wearables and monitors are common and patients who use them will expect their health care providers to know how to access and use the data they contain.[70] As health care delivery systems become increasingly more digital and sophisticated, health care providers must be ready to participate in and manage them or they risk contributing to inequities.[39]

The lack and inequitable distribution of digital skills are not just individual issues but also societal problems -- and largely require societal solutions. Public investment in closing the digital skill divide is more than justified simply by the economic benefits for workers, businesses, and the economy, even apart from ethical considerations.[71] Workers would benefit by being able to attain higher-paying jobs that require higher levels of digital skills; businesses would benefit through increased productivity associated with having a more skillful workforce and improved employee retention; society would benefit by the positive spillover effects such as increased tax revenue and the boost to the economy provided by workers' increased purchasing power.[71]

Some of the more specific steps that might be taken to increase digital literacy include: (a) increasing access to larger display screens because many people can access the Internet only through their small screen smartphones, which increases users' cognitive loads and makes skill acquisition more difficult; (b) providing technical support for updates and repairs; and (c) increasing training opportunities in a flexible manner, including outreach to target populations.[49] Increasing the digital literacy of the covered populations is one of the objectives of the Digital Equity Act, and states must measure and develop plans to advance digital literacy in the covered populations.[72] The National Telecommunications and Information Administration provides digital literacy content and best practices at DigitalLiteracy.gov. Free training materials are available not only at the government site but also at websites from non-profit organizations like Connected Nation.[63,73]

Health literacy. The US Department of Health and Human Services, in its *Healthy People 2030* initiative, defines "personal health literacy" as "the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.[74,75] It also has added a definition of "organizational health literacy" to incorporate more of a public health perspective and also to emphasize that organizations have a responsibility for improving health literacy: "the degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others."[74,75] The concept is important because it focuses attention on societal and community actions that can improve health literacy even if they do not change individuals' abilities

and knowledge.[75,76] Examples might include making translations available or ensuring that reading materials concerning health care are not at too high a level.

Low health literacy contributes to health inequities and is more prevalent in vulnerable populations.[76] More specifically, health literacy is lower among the elderly, Black and Hispanic populations, the medically underserved, people with limited English proficiency, and people with lower incomes or educational attainments.[76] Many of the most commonly-cited estimates of health literacy levels in the US are outdated, being derived from the 2003 National Assessment of Adult Literacy survey.[76,77] At that time, around 65% of the population was at an intermediate or higher level of health literacy proficiency (e.g., able to determine what time a person can take a prescription medication based on information on the drug label that relates the timing of medication to eating), while 22% performed at a basic level (e.g., able to explain why it is difficult for people to know if they have a specific chronic medical condition, based on information in a one-page article about the medical condition) and 14% at a below basic level (e.g., able to identify what is permissible to drink before a medical test, based on information in a clearly written pamphlet).[77] People with basic or below basic health literacy would be expected to struggle with using an over-the-counter drug label to identify three substances that could interact with the drug to cause a side effect.[77]

Unsurprisingly, lower health literacy levels are associated with poorer health outcomes and increased health care costs but the range of health consequences is remarkable.[2,68,76] People with low health literacy have more difficulty adhering to preventive behaviors and have poorer self-care. They are more likely to miss appointments with health providers. They are more likely to have delayed diagnoses. They have more difficulty adhering to health intervention requirements. They are more likely to unnecessarily use emergency care, more likely to be admitted to a hospital for an extended stay, and more likely to be readmitted for avoidable reasons. As noted above, they have more difficulty reading and interpreting drug labels. They are less likely to use DHTs and less likely to consider them useful.[78] As our health care system continues to move towards a model in which patients use DH technologies to take a greater role in their own disease management and preventive behaviors, disparities will grow even larger unless vulnerable populations are able to develop increased levels of health literacy.[68]

The federal government for some time has recognized the importance of health literacy in addressing health inequities. In 2010, the Office of Disease Prevention and Health Promotion published a *National Action Plan to Improve Health Literacy*,[79] explicitly acknowledging that health literacy is critical to achieving the country's health goals. The *Healthy People 2030* initiative includes six objectives related to health literacy.[80] Although the objectives largely pertain to communication goals for provider/patient interactions, they do include increasing the health literacy of the population as well.[80,81] The CDC offers links to health literacy best practices and a number of other supportive materials on its health literacy website.[74]

DH app developers have an important role to play in increasing health literacy because too many DH apps are less than ideal for people with low health literacy.[50,68] Developers should consider health literacy at all stages when designing an app but certainly in designing their user interfaces. Some recommendations include:

- using plain language and short sentences
- making information available in the user's preferred language (link to an online translator) and channel of communication
- using culturally appropriate language
- using bullets and icons in text[68,74]

The Office of Disease Prevention and Health Promotion offers a research-based guide to help designers develop intuitive health websites and digital tools that can be easily accessed and understood by all users.[82] The guide is intended for anyone involved in creating online health content, regardless of their discipline -- writers and editors, content managers, digital strategists, user experience strategists, web designers, developers, and others.

Digital health literacy (or ehealth literacy). Digital health literacy is a concept that intersects both health literacy and digital literacy and can be defined as "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."[83] As with health and digital literacy, the definition focuses on skills and purposes. Some sources advocate that digital health literacy also includes being able to add your own health-related content and keep it secure.[84]

The abilities to find and to critically evaluate online health information are two of the key skills comprising digital health literacy. Participants at the CTA-EXCITE conference spoke of the widespread use of "Dr. Google" and how patients are using internet sources to provide informal second opinions. The amount of information available is overwhelming. Google reported almost eight billion results for a search for "cancer" in November 2023; a search for "acute lymphocytic leukemia" produced around 47 million results. Navigating these sources in search of reliable and relevant information provided at an appropriate reading level from a trusted source is a critical ability and one that not enough people in the US possess.

Research into digital health literacy's impact on health outcomes is still at a relatively young stage[85] and the terms "digital health literacy" and "digital literacy" are not infrequently confused or used interchangeably. There is evidence, however, that higher digital health literacy is associated with better health outcomes.[84] For example, US college students with higher digital health literacy were shown to be more likely to follow COVID-19 safety measures and more willing to get the COVID-19 vaccine.[86] Veterans with uncontrolled hypertension who used patient portals to refill prescriptions for two years or more were more likely to achieve control at follow-up than those who did not.[87] Conversely, CMS has noted that older adults' low digital health literacy has resulted in gaps in their care.[65]

It does seem clear, however, that optimal digital health literacy cannot be achieved without health literacy, digital literacy, and accessible connectivity.[88] Thus, many of the disparities observed for digital and health literacies are observed for digital health literacy as well, including by age, by race/ethnicity, by educational attainment and by income.[85]

As with health literacy, several of the *Healthy People 2030* initiative's goals relate to digital health literacy, including increasing the proportion of the population that uses digital technology to access their EHRs or to communicate with their health care provider.[89,90] The National Library of Medicine offers a free digital health literacy curriculum on its website that includes materials advising how to find online health information that is trustworthy.[91] Additionally, an earlier CTA report on *Advancing Health Equity Through Technology*,[2] produced in partnership with the Connected Health Initiative, provides a number of recommended strategies to improve digital health literacy health literacy that are directed to a wide variety of stakeholders. A few of the points most relevant to DH solution developers include:

- Develop culturally competent digital health tools.
- Ensure adequate language interpreter access is included in consumer-facing digital health tools.

- Track digital health access and use to ensure digital health solutions are appropriately serving the whole community.
- 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.
- Develop technologies designed for people with different levels of digital competency and assistance needed in using these tools (such as those with disabilities).
- Ensure that design, engineering, data, and clinical teams properly evaluate health equity factors (e.g., mitigating potential bias) from the earliest stages of development.

Bias can unintentionally be built into DH tools in several ways. The section of this paper addressing AI goes into more depth about how to avoid building-in bias.

In summary, many of the people and groups who suffer inequities in our health care system are also disproportionately disadvantaged by having poorer access to and difficulty using DH services. As our health care system becomes more and more reliant on DH tools and technologies, those vulnerable groups could be further excluded and their inequities augmented. All stakeholders involved with developing, using, selecting, and paying for DH solutions must examine their actions through an equity lens to ensure that DH fulfills its potential to alleviate disparities and not to increase them.

Data Privacy

"Health data sharing only moves at the speed of trust, and right now it's slow-going"[92]

As noted previously, the digital health transformation, with the development and adoption of new technologies, is making available extensive amounts of health and health-related data. The scope and complexity of these data are unprecedented and provide unique opportunities for medicine and public health. Digital health and health-related data sources include not only EHRs and clinical notes, but also lab values and test results, imaging studies, genetic tests, and pharmacy records, as well as data from wearable devices, social media posts, internet searches, and even financial records, among others.[93,94] The ability to combine and analyze all these types of information holds the prospect of improving the quality and personalization of medical care, advancing and enhancing medical research, and reducing health care costs.[93] In terms of public health, the data could result in more accurate assessments of diseases and pathogens as well as better understanding of patients' exposures, susceptibility, and behaviors; these improvements in understanding could in turn be used to develop more effective interventions and policies directed at disease prevention.[95]

All of these social goods, however, are contingent on the relevant data being available to potential users. Because the ultimate sources of the data are patients and consumers, the availability of the data depends on those individuals' willingness to share them. That willingness to share is affected by a number of factors, perhaps the most important of which is peoples' positions regarding the importance of privacy of their PHI. Numerous studies have identified data privacy and security as critical factors in willingness to share information and the observation is true across many types of populations.[94,96,97] Furthermore, while the particular circumstances and context of the information-sharing can affect many individuals' willingness to share, there is evidence that a majority of patients make sharing decisions based primarily on their core beliefs about privacy rather than context.[97]

Individuals value privacy for numerous and varied reasons. As an initial matter, privacy can be considered "a fundamental right, essential to autonomy and the protection of human dignity, serving as the foundation upon which many other human rights are built."[98] By controlling who has access to their personal information, individuals are able to exert some degree of power over others who might use the information to their detriment. It is not difficult to understand why people would be distressed about others learning of, for example, the severity of their depression or anxiety, their use of injected drugs, their history of treatment for sexually transmitted diseases or sexual dysfunction, or other sensitive material.[99] Apart from providing the potential for discrimination in various forms, the reputational impact of data breach could be substantial and long-lasting – not only for the individual but also for the entity whose actions or inactions resulted in the public availability of the information.

It is an unfortunate reality that fear of discrimination in employment and insurance based on PHI is a substantial concern for patients.[100] Patients are particularly reluctant to share genetic information,[96] and most US patients would decline genetic testing because of the fear that the results could be used by employers or health insurers to discriminate against them.[101] (Although the federal Genetic Information Nondiscrimination Act of 2008 ("GINA," Pub. Law 110-233) prohibits covered health insurers and employers from discriminating based on genetic information, other types of insurers (e.g., life, disability, long-term care) and smaller employers have no such restrictions under GINA.) The fear of discrimination is not limited to genetic information, however. Around 60% of respondents to a recent survey of 1000 patients conducted for the American Medical Association indicated they were "very" or "extremely" concerned about PHI in general being used in a discriminatory manner, including to exclude them from insurance coverage or employment.[102,103]

The U.S. Supreme Court's decision in Dobbs v. Jackson Women's Health Organization, overruling Roe v. Wade and resulting in the loss of Constitutional protection for reproductive rights, also brought to prominence another strong motive for maintaining privacy. For women in states that have enacted severe restrictions on reproductive rights, apps that gather information on menstrual cycles, for example, or include geolocation data could provide an evidentiary basis for criminal prosecution. The collected information does not have to be obviously health-related to create this risk. The national retailer Target famously developed an algorithm that could accurately identify customers who were highly likely to be pregnant as well as their estimated due dates.[104,105] The algorithm was based not on health data but on demographic information and individuals' retail product purchasing patterns. Target did nothing illegal but customers were considerably disturbed and upset about such private information becoming "public" and the basis for focused marketing efforts.[104,105]

Some commenters have pointed out what appears to be inconsistency in how our society regards privacy of different types of sensitive information – notably, differences between health information and financial information. Many consumers actually consider their financial data to be more sensitive than their health care information.[97] Despite this higher sensitivity, however, consumers have widely accepted conveniences like ATMs, which require sharing financial data, providing personalized identification, and electronic communication with financial networks that may be world-wide. Consumer reluctance to share sensitive health data thus seems oddly excessive, the argument goes.

This comparison may be inapt, however. As an initial matter, federal law has provided a number of protections for consumers' financial data for decades through the Financial Services Modernization Act of 1999 (also known as the Gramm-Leach-Bliley Act, privacy provisions codified at 15 USC §§ 6801-6809, 6821-6827). The Act limits how banks and companies providing many other types of financial products

and services can collect and disclose customers' personal financial information and also requires these financial institutions to maintain safeguards to prevent others from accessing the information.[106] These protections could be considered roughly analogous to HIPAA's regulation of health care providers and payers and their treatment of specified types of PHI, however, and would not explain the differing consumer attitudes. The distinction is that much of the discussion about health data privacy focuses, not on the providers and payers covered by HIPAA, but on companies who obtain access to data through non-traditional means such as apps and social media and who are not covered by HIPAA. The ATM analogy does not involve financial information accessed through non-traditional means.

As highly as individuals generally value privacy, however, they often are willing to share PHI in particular contexts. One of the main factors they consider is the *use* to which the PHI is going.[94,96] If sharing PHI will benefit the sharer, or perhaps the community, then people are more likely to provide access.[92,94] Thus, people are inclined to share PHI for the purpose of research but are much less willing if the use is commercial.[94,96,97] Sharing that will enable health self-management or peer-to-peer information exchange is also more likely to prompt participation.[94,96] Apps that measure health markers like physical activity or blood pressure, for instance, can facilitate patients' ability to manage their health and may cause them to be more interested in data sharing, particularly with other individuals in similar situations.[94]

The *identity* of the data user, a closely related concept, is also usually an important consideration. Patients' primary physicians and their associated institutions top the willingness-to-share hierarchy, while organizations not associated with patients' health care are less favored, and businesses like pharmaceutical or digital technology companies also suffer by comparison.[92,94,97] In general, however, patients have become less and less willing to share their health data with any large organization, including research organizations, employers, commercial companies, and government.[92] This reluctance is consistent with the earlier observation that people are more willing to share information when they will directly benefit and less willing when others plan to use the information for their own benefit.[92]

The *type* of information to be shared is additionally a common factor. People are less willing to provide genetic information compared to other health information,[96] for example, and sensitive information, especially if it has a stigma attached, leads to reluctance to share.[94,96] In general, the most common barriers to willingness to share PHI are the fear of data misuse and the fear of a data breach/loss of confidentiality.[94,96]

Taken as a whole, the factors above associated with willingness or reluctance to share PHI illustrate the importance of trust as a facilitator. The presence of trust can enhance willingness to share while patient mistrust leads to data suppression.[94,96] Patients who share PHI are putting themselves in a position of vulnerability and have expectations about how their data will be used and by whom; if those expectations are not met, trust can break down.[94] As participants in the CTA-EXCITE conference cautioned, trust is difficult to earn and easy to lose.

One important note of caution in interpreting these studies about willingness to share – patients' attitudes about privacy, as measured by instruments such as surveys, often conflict with patients' actual behaviors. Patients often do share more private information than their stated willingness would suggest.[96] Although this "privacy paradox" has been studied primarily in the settings of social media and e-commerce,[96] it may apply in others as well.

As noted above, development of trust can be facilitated by robust data protection. Although HIPAA is one federal source of health data protection, it is not as broad as many consumers may think. For one thing, it applies only to specific "covered entities," mostly health care providers and insurers. HIPAA requirements to safeguard data usually do not apply to companies that may obtain health information through apps, social media, wearables, or other emerging digital technologies. Such companies often can legally share and sell users' health data without the users' knowledge or consent.[45]

Thus, at the present time, DH technology may present a sort of mixed blessing. DH technology was unquestionably critical in providing health care during the COVID-19 pandemic by enabling telemedicine visits and remote monitoring, as well as by supporting patients through apps. At the same time that apps were expanding health care access and otherwise helping meeting patient needs, however, some were also collecting and selling sensitive health information. Consequently, to provide one example, data brokers have been able to obtain and offer for sale information on patients with depression, ADHD, and bipolar disorder, among other mental health diagnoses, along with associated demographic data, zip code, credit score and net worth, and religion.[45] Providers of internet search services can store users' health-related searches and social media can obtain patient information from hospital websites.[107]

Although HIPAA may not apply to such practices, other federal laws may. The Federal Trade Commission ("FTC"), in particular, has brought a number of high-profile actions against entities that it alleges have engaged in fraudulent, deceptive, or unfair trade practices with respect to PHI. Most of the alleged violations involve commercial companies' failures to keep the commitments they made to consumers about their data sharing and protection practices and failure to notify users that their PHI has been shared. The penalties assessed against the companies have included:

- monetary fines[108,109]
- refunds to customers[110]
- prohibitions on sharing users' PHI with any third party for advertising purposes[109,111]
- requirements to tell users how their PHI will be used and obtain their affirmative consent before sharing their PHI with third parties for any non-advertising purpose[109–111]
- notifying affected users about the disclosure of their PHI[109,111,112]
- deletion of improperly-obtained information[108]
- instructing any third party that received improperly-shared data to destroy it[109–112]
- deletion of any algorithms developed using improperly-obtained data[108]

Developers of DH products potentially used by minors also should be particularly aware of specific privacy protections for children's data promulgated by the FTC in Title 16 CFR Part 312 (implementing the Children's Online Privacy Protection Act of 1998 ("COPPA"), 15 USC §§ 6501-6505). These regulations address issues relating to the collection, use, and disclosure of children's personal information as well as data retention and deletion requirements, among others. In the specific digital health information space, the FTC brought an action alleging COPPA violations by the owner of a weight loss app who marketed it for use by children.[108] In the more general children's personal information space, the FTC has brought COPPA actions against some of the largest digital companies in the US, imposing fines up to $170 million.[113,114] The FTC does provide on its website a model six-step plan for complying with COPPA.[115]

Separate from government charges, users themselves are able to bring privacy violation suits directly against companies. As one example, to resolve Facebook user claims of data privacy violations related to Cambridge Analytica's collection of data on 50 million users without their knowledge or consent,[116]

parent company Meta Platforms entered into a $725 million settlement, the largest recovery ever in a data privacy class action.[117,118]

Finally, some state laws also provide legal protections for health information. States that have enacted data privacy laws taking effect in 2023 include California (expanding the reach of the California Consumer Privacy Act of 2018), Virginia, Colorado, Connecticut, and Utah, with several other states' data privacy laws taking effect over the next two years.[119] While the state laws share several common features, their particular provisions differ -- meaning that DH product developers need to determine which laws apply to them and what they must do to comply on a state-to-state basis that is constantly changing and possibly in conflict. Because of this patchwork regulatory environment, 51 tech company CEOs sent an open letter to Congress asking for "a comprehensive consumer data privacy law that strengthens protections for consumers and establishes a national privacy framework to enable continued innovation and growth in the digital economy."[120] The letter emphasizes that consumer trust and confidence in privacy protections are essential elements and that consistent legal and regulatory requirements facilitate both consumer understanding and business innovation.

Unfortunately, although some new federal privacy bills have been introduced into Congress over the last few years to establish additional protections, most notably the American Data Privacy and Protection Act in May 2022, they do not appear to have the necessary legislative support at this time to move forward.[121] To address this gap, various entities have offered advice on lessons learned,[122] promulgated privacy guiding principles,[123] or suggested codes of conduct[124] to guide companies. The CTA's guiding principles, for example, are:

- Be open and transparent about the personal health data you collect and why
- Be careful about how you use personal health data
- Make it easy for consumers to access and control the sharing of their personal health data and empower them to do so
- Build strong security into your technology
- Be accountable for your practices and promises[123]

The non-profit Center for Democracy and Technology and industry group Executives for Health Innovation, have together gone one step further – they have developed the framework for a neutral, independently-run, self-regulatory program to oversee the data use policies and procedures of participating companies.[125] The program endorses the concept that, in the absence of suitable federal legislation, the private sector carries the clear burden of creating and using a regulatory model that will give consumers confidence that their PHI will be protected.[125] That regulatory model incorporates a third-party independent entity (BBB National Programs) to establish accountability through mechanisms like auditing members' privacy policies and practices and providing a pathway for investigating consumer complaints.[125,126] Importantly, the model takes a broad view of health information, including not just clinical information but also any data that advertisers could use to learn or infer about a person's health status. The framework also prohibits companies from trying to associate "de-identified" data with any particular person or device.

In contrast to most digital technology companies, clinicians and health systems are generally covered by HIPAA and must develop compliant privacy notices and processes. The points above nevertheless have value for these stakeholders in helping establish a useful mindset about privacy. Indeed, the primary advice to these stakeholders that emerged from the CTA-EXCITE conference was to adopt a way of

thinking: privacy should be viewed as part of "safety" and approached with the same rigor and attention.

Consumers and users are other stakeholders who need to take responsibility for protecting their PHI. They should make themselves aware of the privacy practices of digital health companies and social media and be ready not to use or participate in platforms with inadequate safeguards and limits. They should consider any health information they post online to be public. For additional information and concrete steps to take, consumers can consult government websites (e.g., for the FTC,[127] for the Office of the National Coordinator for Health Information Technology[128]) or materials from trusted privacy organizations.

Artificial/Augmented Intelligence

The last main theme that participants at the EXCITE/CTA conference repeatedly discussed, and the subject of the second CTA conference, was "AI" – shorthand for "artificial intelligence" or "augmented intelligence," depending on one's perspective. DHTs that utilize AI have the potential to substantially improve health care on both patient and population levels, reduce administrative burdens and costs, increase the pace of research, and create new cures.[129,130] They also hold the risk of negatively affecting health care instead by producing worse outcomes, propagating biases and inequities, and increasing costs.[130] The question of how to maximize the positive potential impacts and minimize the risk of harm is a vibrant discussion that is also pressing as the technologies are exploding and projected to add $13 trillion to global economic output by the end of the decade.[131]

As an initial matter, experts do not agree on a single definition of AI. It probably is best regarded as an umbrella term referring to computers or other technologies that seem to simulate intelligent human behavior, including learning, making decisions, and making predictions.[129,132,133] The term "augmented intelligence" emphasizes that AI is a tool that should be used to enhance human capabilities rather than to replace them. Two other frequently-referenced terms include (1) machine learning ("ML"), which refers to AI technology that provides "the ability to learn and change without providing/programming an explicit model for mapping input to output," and (2) large language models ("LLMs"), which are trained on vast amounts of text data in order to translate, summarize, generate text, and answer questions (one example would be OpenAI's GPT series).[132] There are many other AI technologies and CTA has published standard definitions for reference.[132]

This section is divided into two subsections, one reviewing AI's historical uses and future potential in health care and one examining its most critical challenges.

Historical uses and future potential. Although AI has dominated headlines only recently, technologies utilizing AI in various forms have been applied to health since the 1970s, at least in limited form.[134] Not until the late 2000s, however, did advances in computer science, probability, mathematics, and computational power begin coalescing to give rise to machine learning capabilities and the rapidly expanding vista that we see today. As of October 19, 2023, FDA had identified more than 690 Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices marketed in the US,[135] and the actual number of marketed devices is likely far higher.

The great majority (around 80%) of these devices are intended for use in radiology (e.g., detecting breast cancer or hidden fractures), but the field of specialties is broad, including cardiology, hematology,

neurology, microbiology, pathology, and gastroenterology, among others.[133,135,136] FDA has approved one AI technology that is intended to function autonomously – an algorithm that analyzes images of the retina to screen for diabetic retinopathy and indicate whether the patient should be referred to an eye specialist.[137,138] Otherwise, none of the devices is intended to substitute for a doctor's diagnosis or interpretation; rather, they are intended to serve as additional tools for the practitioner. FDA has not yet authorized any device that uses generative AI (AI capable of generating text, images, or other media) or is powered by LLMs.[135]

The range of possible AI applications in health care is almost unlimited. For patients, technologies like ML, natural language processing, speech recognition, and chatbots will increasingly be incorporated into wearables and apps to provide advances in health monitoring, disease prevention and self-management, and medication management, among other areas.[133] Administrators/payers, another key user group, are already using algorithms for scheduling, billing, and identifying potential health billing fraud and extending them to functions such as automating reimbursement coding, making prior authorization decisions, and possibly assessing physician competence.[133] Such uses may not be implemented without constraints, however. Effective in 2024, for example, CMS is substantially limiting Medicare Advantage plans' use of proprietary algorithms to deny beneficiary claims based on medical necessity.[65] Separately, UnitedHealth Group is facing a class action brought by beneficiaries alleging that it is illegally using an algorithm to deny rehabilitation care to seriously ill patients in its Medicare Advantage plans.[139]

In the clinical research environment, AI tools are being used to identify and screen potential clinical trial participants,[140,141] examine clinical trial data in greater depth and review data integrity,[142] and monitor patients for adverse events.[140] For more basic science research, neural networks and machine learning can accelerate drug discoveries, genomics, and disease prediction.[133] AI can advance public health aims as well -- machine learning and geospatial pattern mining can enable air and water pollution detection as well as epidemiologic analysis and contact tracing.[133]

The greatest potential benefits of AI, however, probably accrue to clinicians and our health care system generally. One of the largest problems our health care system has been confronting is a shortage of qualified health care workers, including physicians; this situation has become even more dire because of the pandemic and clinician burnout. The Association of American Medical Colleges estimates that, just ten years from now, the US will have a shortage of between 54,100 and 139,000 physicians with the most severe scarcities occurring in primary care and in rural areas.[143] Two demographic factors are largely driving this shortage – the aging of the population (people older than 65 years are projected to increase by 45% by 2033) and the expected retirement of 40% of current physicians over the same period, with burnout likely to accelerate retirements even more.[143–145]

The causes of health worker burnout are complex -- a number of societal, cultural, structural, and organizational factors contribute -- but excessive workloads and administrative burdens are chief among them.[146] Burnout also disproportionately affects women and health workers of color because of continued inequities among social determinants of health.[146] AI-enabled technologies can both reduce administrative burdens and relieve clinician workloads and therefore help address worker shortages by increasing efficiency.

Continued AI integration into diagnostic imaging, for example, can enhance both the efficiency and accuracy of radiologists, pathologists, dermatologists, and cardiologists, among other specialties, by identifying and calling to attention possible important findings, as well as by classifying images into different priority levels for clinician review.[133,147] By identifying cases that need less attention, the DHT

provides more time for clinicians to focus on the more complex ones.[147] Incorporating chatbot generative capabilities into the tools to also draft notes or reports for clinicians to review could also further improve efficiency and relieve administrative burdens.

Interactive AI-enabled conversational systems, like Alexa or Siri, could perform searches of EHRs at clinician spoken request and perform functions like summarizing recent medical history or providing relevant lab values, freeing time for more cognitive tasks.[133] Physicians who are overwhelmed with a large number of patient inquiries could ask an AI chatbot to draft responses. AI also can help relieve alert fatigue by using more complex models to better identify when alerts are needed, as well as by adapting to reflect clinician use patterns (e.g., identifying which alerts the clinician ignores and subsequently reducing their incidence).[133]

Whether such interactive tools could actually replace clinicians as opposed to assist them is a matter of great debate. On one side are those observers who argue that most clinical jobs "require much more cognitive adaptability, problem solving, and communication skills than a computer can muster."[133] Additionally, this line of reasoning goes, humans have unique qualities that cannot be supplanted -- "the capacity to love, to have empathy, to care and express caring, to be generous, to be brave in advocating for others, to do no harm, and to work for the greater good and advocate for justice,"[148] or, as one conference participant noted, "a chatbot can't hold your hand."

At least one recent study, however, suggests that AI has already achieved being perceived as, not only empathic, but more empathic than human doctors.[149] In the study, health questions from a social media forum were answered by both a physician and a chatbot, then a blinded panel rated the answers. Answers from the chatbot were four times as long as physician responses and 45% of them were judged to be "empathetic" or "very empathetic" as opposed to around 5% of the doctors' answers. The chatbot answers were also of significantly higher quality. While some clinicians have responded to these results with alarm, others have reacted with great optimism about the burden-lifting potential of AI.

Whereas physicians are already under severe time constraints and overburdened, including with patient questions and data, chatbots have essentially infinite time. In communication exchanges they therefore can provide longer and more detailed answers, simulate empathy, and follow up on any patient comments or questions even if they seem off-point, thereby validating the patient. As previously noted, AI also can be trained to translate answers to overcome language barriers, and to answer at a designated reading level then adapt based on the level of patient questions and responses. Chatbots could, at a minimum, draft answers to patient questions for clinicians to review, saving hours a day in some cases.

As technology continues to improve, chatbots will be capable of appearing more than just empathetic in written responses. Algorithms are being trained on detecting emotional cues in written language and facial expressions[150] and will be able to provide them to users through human facial avatars, for example.

Expanding on communicative skills, AI-enabled technologies could also take part in the informed consent process for treatments or clinical trials. An exchange could begin with a chatbot and continue for as long as the patient or potential participant desires, even days to weeks, before the clinician re-enters the process to answer any questions and confirm understanding. Patients may actually prefer to start with a non-human chatbot because they would have less fear of seeming to be ignorant and little chance of embarrassment.

Challenges. The uses above are a fraction of what AI-enabled technologies will be able to achieve. Nevertheless, while DH tools and technologies have tremendous promise to help alleviate health system inequities, they also carry the risk of inadvertently incorporating and magnifying societal biases. AI-enabled DHTs can absorb biases in three main ways: (1) using (for training, testing, and validation) data sets that do not accurately represent the population; (2) using data that themselves reflect biases in the health care system or in clinical decision making; (3) through human choices made during the design, development, and use of these systems.[151] AI products need to be thoughtfully and carefully developed and employed in order to avoid these problems.

Lack of representation. Because health care is not equally accessible to various groups (e.g., racial minorities, immigrants, people at lower socioeconomic levels), any collection of health data based on routinely kept health records like EHRs will reflect who is able to obtain health care, not the true diversity of our society.[151] Furthermore, as a consequence of the digital divide, data from mobile phone apps, social media, or other digital sources will also manifest the inequities inherent in their use. Algorithms that rely on such biased data will often lack sufficient input about the underrepresented groups to provide accurate output.

The same observation applies to data from clinical trials. Patient populations in clinical trials seldom accurately represent the real-world population. FDA has been highlighting the importance of diversity in clinical trials for decades, beginning in the 1980s with a guidance emphasizing the value of including elderly patients in drug trials.[152] Women are now substantially more represented in trials than when they were often excluded because of concerns about hormonal variations that do not appear to have held up to scientific scrutiny.[152,153] Despite progress, however, racial and ethnic minorities are still significantly underrepresented in clinical trials in the US. According to US Census data, approximately 40% of the US population in 2020 was racial and ethnic minorities (14.2% Black, 7.2% Asian, 18.7% Hispanic).[154] That same year, only around 25% of patients in new drug trials were minorities (8% Black, 6% Asian, 11% Hispanic).[155] The elderly were also underrepresented.[154]

Diversity in clinical trials is critical for understanding safety and effectiveness because different subgroups of patients may respond differently to a given treatment. ACE inhibitors, for instance, do not seem to be as effective in lowering blood pressure in Blacks as they are in Whites.[156] Genetic differences can influence responses. Moreover, underrepresentation of racial and ethnic minorities is particularly problematic because those populations often have higher rates of chronic diseases, many of which are targets of the interventions being studied.[154] When clinical trials are not diverse, the lack of data for subgroups may result in important variances not being detected. Some of the concern about using data from clinical trials conducted outside the US relates to the representativeness of the research population and uncertainty about how well the results will transfer to US patients

Fortunately, because these shortcomings are known or can be anticipated and are relatively quantifiable, DHT developers can take steps to enrich their data sets to provide additional information about less represented subpopulations.[157]

Inherent biases. More difficult to adjust for are biases in the data points themselves that manifest inequities arising from existing practices, institutional policies, and societal norms.[151] Clinical decision making, for example, can demonstrate biases, whether conscious or unconscious, against disfavored groups.[158–160] Disparities in diagnoses or treatments can lead to disparities in outcomes and will be reflected in the data – not because data are lacking but because of the inequity of the systems from which the data are collected. Biases recorded in clinical notes may be more subtle but present

nonetheless. One study of over forty thousand history and physical notes in the EHRs of an urban academic medical center found that negative descriptors were 2.54 times more likely to be present in Black patients' records compared with White patients after controlling for sociodemographic and health characteristics.[161] Any LLM being trained on such records will almost certainly be affected by this discriminatory pattern.[151]

Design and development choices. The data chosen for training and validation are not the only potential source of bias. Each stage of the product lifecycle, from conception to post-marketing, involves decisions and choices, from who is included on the team to identifying the targeted users and designing the user interface.[157] All of these decisions potentially can introduce bias or help to alleviate it.

Decisions made in creating an algorithm are particularly important and can introduce bias in unintended ways. As one example, most US insurers and health care systems use some sort of risk prediction tool to identify patients with complex health needs and relatively high risk who would benefit from receiving additional health resources.[162] The algorithms generally work by reviewing past data to predict future health care needs. One of the most popular tools purposely excluded race as a factor to consider in the algorithm, utilized medical expenditures as the measure of past and future needs (health care costs and health needs are highly correlated), and was well-calibrated in that predicted costs were similar for Blacks and Whites at any given level of risk. Despite these positive characteristics, however, the algorithm identified Black patients to receive additional resources substantially less often than White patients at the same level of health.

The explanation is that Blacks had lower health care costs than Whites at any given level of health. Although the reasons are unclear, possibilities include that (a) patients in lower socioeconomic groups are known to encounter more barriers in obtaining health care and there is a correlation between race and socioeconomic status,[163] and (b) characteristics of the health care system's interactions with Black patients, whether through not inspiring trust, communicating poorly, or making biased assumptions, result in their lower utilization of health care. Because the algorithm used cost as a surrogate measure for health needs rather than an actual measure of health status, it imported all of these factors into its predictions with the result that Black patients were discriminated against.

The detail of this example is intended to illustrate at a granular level how seemingly reasonable decisions made in the product design process can inadvertently incorporate or even exacerbate existing inequities. Unless developers adopt a methodical and comprehensive approach to consider the possibility of bias at all stages of the product life cycle, from conception to post-marketing, such outcomes are likely to recur.

Several models and frameworks are available to help guide developer processes in a deliberate and broad manner. Abràmoff et al., for example, have proposed a framework based on the Total Product LifeCycle approach to medical devices that includes equity considerations for each of the six lifecycle stages.[164] Leslie et al. have set forth a list of health inequality risks and corresponding means of prevention and remediation at the clinical, institutional, and societal levels.[151] Suresh and Guttag examine the general ML model development process step by step, identifying several types of bias, the stage at which they may enter the process, illustrative examples, and implications.[157] Finally, the American National Standards Institute and CTA have jointly set voluntary standards regarding practices for identifying and managing bias that represent current common practices.[165] Just as with the evidentiary evaluation frameworks discussed earlier, these models are useful both for DH developers and for users who want to evaluate AI-enabled technologies. Developers should anticipate that potential

users will be familiar with the models and ask them about the specific steps they took to avoid building in bias.

Transferability. Conference participants also expressed concern about transferability – whether an AI-enabled DH tool would perform in their specific systems the same way it performed in other systems. One characteristic of static models in health care is poorer performance over time because of changes in the environment and targets.[133] Similarly, predictive models may not generalize well from training to implementation because of different populations or practice patterns – a phenomenon known as dataset shift.[166]

Dataset shift did appear to occur with a popular analytic tool for predicting which hospital patients are at high risk for sepsis.[167,168] The model had not been externally validated and perhaps became commonly used because it was embedded in the developer's widely-adopted EHR software.[168] The first published study to attempt to externally validate the model found that, in a large academic health system, it performed substantially below the levels achieved by the developer and also created a large clinician burden of alert fatigue.[167] After other reports of inconsistent outcomes, the developer subsequently re-engineered its model -- changing the data variables it used, changing its definition of the onset of sepsis, and recommending that users train the model on data from their own health care system before using it in order to avoid dataset shift.[168]

As mentioned above, passage of time results in changes in patient populations, practice patterns, and other variables that a static algorithm will be less and less well-fitted for – resulting in reduced performance. One method of addressing this challenge is to periodically refresh the model; another method is to use a continuously-learning ("adaptive") algorithm that automatically incorporates additional information over time. In either case, however, monitoring the model's performance in the real world setting will be needed to maintain or confirm continuing function.[169]

Transparency. The example above, where hospitals and health systems widely clinically adopted an analytic tool before it had been adequately validated and before they truly understood how it worked, leads to the challenge of transparency, sometimes referred to as the "black box" issue. The black box metaphor refers to the difficulty of explaining, or even understanding, how a complex algorithm (using ML as opposed to rules-based programming) arrives at its output prediction or decision. Some users may embrace it because of its perceived utility while others may remain more cautious about the unknown harms it may impose.

In a health care setting, those possible harms include death. If inputs cannot be traced to algorithmic outputs, then it becomes impossible to determine how harm may have been caused and, perhaps more importantly, how to prevent it in the future.[136] Moreover, because of the possibility of systematic biases being incorporated into algorithms, the unknown harms could include methodical discrimination against vulnerable individuals and populations. Nevertheless, as pointed out in the National Academy of Medicine's ("NAM") report, *Artificial Intelligence in Health Care: The Hope, the Hype, the Promise, the Peril*:

> "If society, lawmakers, and regulatory agencies were to expect every clinical AI system to provide an explanation of its actions, it could greatly limit the capacity of clinical AI developers' use of the best contemporary AI technologies, which markedly outperform older AI technology but are not able to provide explanations understandable to humans."[133]

If clinicians and health care systems are not able to understand the connections the AI model has made, however, then their adoption of the technology will have to be based on trust. For that trust to be developed, there must be transparency. The NAM describes transparency in three domains: data, algorithmic, and performance.[133] AI developers can provide significant information about the datasets used to train and validate the model and how they are processed, for example. The same applies to the model's performance measures. Information about the architecture of the model – what the pieces are and how they fit together – can be made available.[133] The algorithm might be less transparent and the degree of transparency may depend on who the user is, the type of algorithm, whether proprietary intellectual property is involved, the degree and type of risk posed by the model, and similar factors.

Transparently providing this sort of information can help assure potential users that the technology was thoughtfully and carefully developed and can be trusted. Publication in a peer-reviewed journal of the results of a clinical trial using the technology would also help cultivate user trust. Candid dialogue among relevant stakeholders is likely necessary to more fully outline the specific transparencies that would be both feasible and meaningful.

The NAM succinctly summarized the overall situation as follows:

> AI systems will generally make people more efficient at what they are already doing, whether that is good or bad…. Machine learning relying on observational data will generally have an amplifying effect on our existing behavior, regardless of whether that behavior is beneficial or only exacerbates existing societal biases.[133]

It is everyone's responsibility to ensure that the amplifying effect is beneficial.

Conclusion

This white paper began by asking what are the most important factors that need to be considered to provide a stable and sustainable approach to the development and adoption of impactful digital health technologies that improve patient outcomes and/or health system efficiencies with the support of payers, expert end-users, and patients. The brief answers seem to be: (1) Evidentiary Requirements: DH technologies provide a wide variety of value propositions to a number of stakeholders. In order to obtain third-party payer coverage, DH developers should be ready to provide clinical evidence commensurate with the risk the technology may pose to patients. For products intended to provide treatments, that evidence likely entails at least one randomized clinical trial. Developers should also be prepared to provide budget impact statements. (2) Equity: DH technologies have the ability to help eliminate many of the inequities in our health care system. In order to prevent them from exacerbating those inequities, however, affordable high-speed internet access must extend to all people and gaps in health literacy and digital literacy levels must be closed. (3) Data Privacy: Many of the benefits of DH solutions depend upon patients being willing to share their personal health information, but patients have grown wary of sharing because of well-publicized breaches that have occurred. There are substantial gaps in legal protections for PHI and all stakeholders will need to take steps to strengthen consumer trust. (4) Artificial/Augmented Intelligence: AI-enabled DH technologies have the most potential to transform our health care system for the better. They amplify both positive and negative aspects of our health care system, however, and developers need to carefully and methodically consider the many ways that bias could be built into their digital solutions and provide as much transparency to potential users as possible.

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