

HEALTH EQUITY COLLABORATIVE

### DRIVING DIVERSITY AND INCLUSION IN HEALTH CARE RESEARCH AND ACCESS

THE TOOLS FOR DISMANTLING STRUCTURAL AND SOCIAL INEQUITIES FACED BY UNDERSERVED COMMUNITIES



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# CONTENTS

1.	Introduction	3
2.	Health Care Equity and Awareness	4
	a. Components of Health Care Equity and Awareness	4
	b. Developing an Equitable Health Care System	4
	c. Components of a Culturally Competent Health Care System	6
3.	Lack of Inclusion and Diversity in Clinical Trials	7
	a. Barriers to Equitable Access to Clinical Trials and Solutions	8
	b. Transforming Clinical Trials Through Data Management and Digitalization	9
4.	Innovative Technologies and Shifts in Health Care Emerging from COVID-19	11
5.	Infrastructural Developments Required to Adapt to New Trends in Health Care	12
6.	Conclusion	14
7.	References	15

### **1. INTRODUCTION**

A significant gap exists between the standard of health care currently available and accessible to the masses and the standard of care the U.S. is capable of providing. This results largely from negligence on the part of health care facilities to incorporate known enhancements into their health care systems and trial protocols. A vicious cycle of substandard care follows when limited infrastructure is combined with archaic care systems that are not updated frequently enough. This causes a deterioration in the quality of care within health care organizations.

In any health care establishment, the six major goals of reform should be safety, efficacy, timeliness, efficiency, equity, and patient-centeredness.<sup>1</sup> All these factors work together to build the foundations for a holistic health care system for all citizens. Of these six factors, equity is the most commonly overlooked since some providers may be oblivious to the health disparities existing within their patient populations or may not have adequate data to analyze these differences. Some also mistakenly assume that equity will naturally catch up when the other five goals are accomplished.

'Equity' refers to health care that does not compromise in quality due to personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status. This is not to be misperceived with 'equality,' which refers to the equal distribution of care to ensure that each person receives the same share. Health care inequity needs to be identified, the pain points need to be assessed, and the root causes should be rectified. These inequities could raise moral, ethical, economic, and even legal issues. Morally and ethically speaking, providers often struggle with time limitations, care coordination, and a constrained clinical support system, which leads to subpar and less desirable care. Bias claims and violation of civil rights of patient protection regulations could pose a legal problem for providers, as well as a decline in overall quality and a rise in expenditures.





## 2. HEALTH CARE EQUITY AND AWARENESS

#### a. Components of Health Care Equity and Awareness

Health care equity can be broken down into two components: horizontal and vertical equity.<sup>2</sup> Horizontal equity refers to people with equal needs being treated equally, and vertical equity refers to people with greater clinical need having more access to health care than people with lesser needs. However, vertical equity is often disregarded by policy makers, which leads to unequal determination of equity and to patients not receiving the quality of care they deserve and need.

Racial and ethnic minority groups such as African Americans, Hispanics, and Native Americans, people belonging to a low socioeconomic status, and vulnerable populations, have a higher risk of chronic disease, disease complications, and disabilities. They also gain access to the health care system after reaching an advanced stage in their disease. Additionally, they also exhibit greater chances of re-hospitalization for exorbitant illnesses such as congestive heart failure (CHF). African Americans also display twice the rate of premature births as compared to Caucasian individuals, which calls for a greater demand for neonatal intensive care. These analyses shine light on how sustainable health care resource allocation could serve as a path to reducing health care expenditures.

In conclusion, health care equity affects not only resource allocation and health care expenditure, but also, and perhaps most importantly, patient satisfaction. Therefore, it is crucial to increase health care equity awareness in any hospital or clinical care setting so as to eliminate injustices and bias and achieve a more comprehensive and inclusive reform of the health care system.

#### b. Developing an Equitable Health Care System

Building an equitable health care system does not come without its challenges. Factors including political complications, the controversial history of race, lack of clear data, and other common misconceptions regarding the nature of existing inequities can impact reform efforts. If, for a particular condition, there are a large number of undiagnosed cases, this could lead to a discrepancy in storing and analyzing health care data. Diagnosis is socially patterned, and disease presentation can vary by social groups. People also might have different definitions for the 'need of treatment.' Further, non-universal health care systems, such as the U.S. system, could have limited access to medical databases, which do not include people without insurance coverage. This can lead to gaps in the data recorded.

However, the task of designing an equitable health care system is not unattainable. Steps that can be taken include increasing awareness among providers and decision makers, ensuring unbiased access to preventive and curative health services, maintaining real-time patient data and laboratory information to diminish ambiguity in clinical decisions, instituting evidence-based guidelines, improving efficiency and harmonization at many levels of care, eliminating variations in care that might arise due to financial considerations, increasing and improving education regarding the nature of existing inequities and devising appropriate action plans to reduce or eliminate them, developing a 'culturally competent' health care system which can provide patients with effective and equitable care, guaranteeing health care accountability by keeping abreast of any updates and tracking changes in the system, and all-in-all focusing on amalgamating equity initiatives with overall quality improvement.

Managed care plans, integrated health care systems, and hospitals all over the U.S. are collecting data on race and ethnicity to identify inequities and set an action plan in motion. Managed care plans such as Medicare and Medicaid, have managed to achieve this through federally funded collaborations.<sup>3</sup> The Centers for Medicare and Medicaid Services (CMS) require these plans to submit data on patients' ethnicity as well as the principal language they speak to create a database that would help establish inequities and create programs in culturally competent services. In addition to federally funded programs, Medicare and Medicaid have also performed externally-funded projects to gather data on these parameters to prepare Health Plan Employer Data and Information Set (HEDIS) reports to combine and present these

data. Private insurance companies such as Aetna have also stepped forward in their endeavor to diminish inequities in the health care system. Aetna's CEO and chair authorized the collection of race and ethnicity data in 2001, which started off in the District of Columbia and later expanded to 47 states.<sup>4</sup> Starting in 2004, several health organizations such as Aetna, Kaiser Permanente, and others collaborated with the Agency for Healthcare Research and Quality (AHRQ) to reduce disparities and improve the quality of data collection. Lastly, the Health Research and Educational Trust, an affiliate of the American Hospital Association, developed a toolkit for collecting information on race, ethnicity, and primary language in hospitals with the help of the Commonwealth Fund, which was a consortium of six hospitals and health systems, including Henry Ford, Kaiser Permanente, Massachusetts General Hospital, Northwestern Memorial Hospital, Parkland Memorial Hospital, and the University of Pittsburgh Medical Center Health System.

Once this data is collected, it is then used to develop ways to circumvent and diminish inequities in the system. The Health Resources and Services Administration (HRSA) established the Health Disparity Collaboratives among some regional community health centers to enhance the quality of care for underserved communities by determining their impact on chronic illnesses such as diabetes, hypertension, asthma, and depression. Some key components of this initiative include unanimous decision making, updates to the clinical systems, redesigning the delivery system, and reorganizing the health care system to be inclusive of senior partnerships, clinical veterans, and evolving community partnerships.

#### c. Components of a Culturally Competent Health Care System

A lack of equal access to health care is another reason for health inequity in an organization. There are large differences between the percentage of access to usual care between Hispanics (23%) and Caucasians (33%), as well as between African Americans (24%) and Caucasians (42%). Unequal access to health insurance is one of the primary reasons for this difference. Around 52% of uninsured Americans are either Asian American, Hispanic, Native American, or African American.<sup>5</sup> Apart from health insurance, other contributors to this discrepancy include financial limitations, inadequate numbers of providers in some localities, time constraints regarding appointments, and restricted availability of culturally sensitive services. One possible solution is the formation of alliances and partnerships with local communities, faith-based organizations, and local health systems. Another effective way to increase access to health care for underserved communities is setting up financial incentives and payment structures for providers.

Establishing a culturally competent health care system is an indispensable step towards achieving health equity and improved quality of care. Inclusion of translation/ interpretation services can help enhance communication and decrease misunderstanding between people who speak different languages. Employing a culturally diverse clinical staff can help people from different communities feel represented. Training this staff on cultural sensitivity and awareness would facilitate cross-cultural interface. As described previously, entering into partnerships with community health workers can provide improved access to care. Integrating culturally sensitive messages in health advertising can expand knowledge, while changes in administrative procedures and working environments to better suit the needs of underserved communities can promote inclusion and improve communication between providers and patients.



### 3. LACK OF INCLUSION AND DIVERSITY IN CLINICAL TRIALS

The current clinical trials landscape is another area in the health care sphere that lacks diversity and inclusion. Ensuring individuals from diverse backgrounds are part of clinical trials is key to advancing health equity. Clinical trials are research studies conducted in humans with the goal of evaluating safety and efficacy of medical, surgical, or behavioral interventions. For this reason, the participants in clinical trials should represent the patients that will use the medications, vaccines, or medical devices that are being evaluated for safety and performance.

However, this is often not the case given that racial and ethnic minorities and other groups are underrepresented in clinical research. For instance, during the COVID-19 pandemic, older adults, pregnant women, children, and racial and ethnic minorities have been found to be affected in different ways due to clinical trial disparities. This current difference in impact illustrates why it is crucial to encourage developers of medical products to include diverse populations to assess the risk-benefit profiles of these products across all groups.

In the U.S., minority ethnic and racial groups form approximately 40% of the population - however, 75% of the 32,000 participants in the trial of 53 novel drugs approved by the U.S. FDA in 2020 were Caucasian.<sup>6</sup> Such over-representation of Caucasian participants is in stark contrast to the disproportionate burden of chronic illness in racial and ethnic minorities, for whom clinical trials could be life-saving treatments. This is also concerning given that people of different race, age, and ethnicities may respond to certain medical products differently. For this reason, multifarious factors such as age, biological sex, disabilities, chronic comorbidities, geographical location, race, gender identity, ethnic background along with their intersectional ties all become important components of medical decision making while developing medical drugs and conducting clinical trials.

Historically, patient population diversity and inclusion initiatives have generally been considered a luxury rather than an imperative. Calls for reform have not had the momentum needed to bring about real change. There have been many worthy initiatives in this space, but they have fragmented and fallen short. For instance, every year, the U.S. Food and Drug Administration (FDA) issues a Drug Trials snapshot report. In 2019, only 26% of clinical trial participants were the age of 65 or older, 72% were Caucasian, 18% were Hispanic, 9% were African American, and 9% were Asian.<sup>7</sup> During the same year, the FDA also introduced draft guidance to enhance the diversity of clinical trial populations, encouraging trial teams to broaden their eligibility criteria, use adaptive clinical trial models, and consider enrollment challenges that potential participants may face.



#### a. Barriers to Equitable Access to Clinical Trials and Solutions

Overall, the initiatives in this arena have occurred in silos without significant collaboration, which has prevented them from yielding broadly sustainable results or scalable solutions. There are various barriers to participation in clinical trials including access. eligibility, enrollment practices, and negative beliefs, norms, attitudes, and medical mistrust from the participants. These are substantial challenges – and yet, they are modifiable. Diversity and inclusion need to be considered at different levels, including the clinical trial sites, sponsors, and the patient levels. For this reason, proposed interventions so far have primarily targeted patient, provider, and system-level change. For instance, at the sponsor and site levels, there is a lack of patient advocacy, a fear of delaying the trial, and as a consequence, the fear of increasing the cost of conducting the trial. From the investigator or clinical research staff perspective, the eligibility criteria often limit enrollment. For this reason, thorough examination of the eligibility criteria could lead to expanding the clinical trial to make it accessible to a larger population of participants.

Typically, participants and patients are recruited from the same sites repeatedly. This is partly a result of trial teams not opening research naïve sites in locations that may hold more diverse patient populations. One effective solution to this limitation is to lessen institutional bias that directly results in a lack of diverse cultural understanding, and to increase the diversity of staff at the site. Further benefit can be derived from improving staff education on clinical trials by including acknowledgment of historical trauma from unethical trial practices. Encouraging formal training for clinical trial staff on cultural humility, implicit bias mitigation, recruitment strategies to facilitate accrual of underrepresented communities, developing culturally sensitive educational materials, and leveraging multimedia platforms to disseminate these materials can also aid in making the conduct of clinical trials more inclusive. Moreover, to overcome the lack of resources and benefits that minority groups face as barriers to participating in clinical trials, researchers could be encouraged to pay for study-related expenses such as transportation, childcare, and hotel stays. If the nature of the study allows, they can be conducted in community-based medical centers and clinics, and not just limited to academic centers which may be far from where people reside. Such grassroots community involvement can also be promoted by increasing outreach to minority communities through places of worship, community events, and other venues.

Sponsor companies must be open to change, and patient engagement is key to achieving diversity and inclusion in the clinical trials arena. For instance, the sponsors can consider engaging with diverse patient communities even before having the protocol developed, reaching out to research naïve sites and arming trial teams with training around inclusive language and behavior, and offering translation or interpreter services. Moreover, the sponsors can evaluate protocols with a thorough assessment of the patient burden to determine if steps can be taken to reduce the secondary and tertiary endpoints, potentially opening the pools of study participants. Additionally, a lack of diverse voices at sites and biopharmaceutical companies makes it challenging to understand the very patients they wish to enroll and eventually treat. This is where the importance of both acknowledging and understanding cultural competencies comes into play. This cannot be achieved through training courses alone. It can only be achieved by having those voices represented at sites and companies.

It is important to qualify the value of diversity to the science of biological variability, health care, and social justice. Engagement of and bidirectional feedback between stakeholders, including community, government, and pharmaceutical companies, can promote meaningful partnerships to foster trust, co-create strategies and solutions, and pursue change for collective impact. Leveraging partnerships among academia, community, government, and industry can be particularly effective. The biopharmaceutical industry, as the manufacturer of novel therapeutics and clinical trial sponsors, is well positioned to promote clinical trial diversity through modifications to protocol design, eligibility criteria, and study enrolment practices.

Additionally, there are no harmonized requirements for data collection. There is an inherent lack of data standards that result in inconsistent data analysis. The interoperability of clinical data is vital to quality and sustainable health care. Developing the infrastructure required for the collection and disaggregation of health care data can help minimize this issue.

## b. Transforming Clinical Trials Through Data Management and Digitalization

Digital health interventions (DHIs) have become a global priority to health equity and accessibility. DHIs are computer and smartphone applications that receive, store, process, and communicate health care-related data. DHIs focus on integrating information management technology into health care, personalized medicine, mobile health, wearable devices, telehealth, and telemedicine. However, to date, few countries have managed to fully implement the infrastructure required to sustain a holistic digital-based health care system that enables and fosters secure exchange of patient information, interoperability and data quality, drug safety, scalability, inclusiveness, and equity.<sup>8</sup>

An initial step to targeting health equity from a digital approach is ensuring effective data aggregation at both remote and brick and mortar health establishments, which could include data digitalization, improved storage, and disaggregation. Patient data should be attained in such a way that it can be categorized by race, ethnicity, primary language, sex (including orientation and gender identity), disability status, age, social determinants of health, and other sociodemographic characteristics. For consistent and accurate patient health data to be collected uniformly, clinical terminologies, unique identifiers, and data standards, with regards to data in demographic variables, must be established and, eventually, internationally harmonized to promote data interoperability and optimal use in the health care ecosystem. Moreover, if such wide-reaching interoperable personal health records are made easily accessible, understandable, and controlled by patients – to the extent that patients have the option to add personalized notes about their health and current records, restrict or provide access, and review upon request, health care data can be controllable on the patient-end, improving accuracy and nurturing health equity from several verticals.

Effective organization of patient demographic, non-demographic, and personal health data is a critical step in optimally enrolling patients in decentralized clinical trials to promote a diverse study population while improving clinical trial quality. The inclusion of socioeconomic data in such a digital portfolio may also assist study sponsors in designing trials that incorporate strategies to mitigate barriers of inclusion, whether access to digital technologies, transportation, language, or other factors. The transformation of electronic health records may also enhance minority patient retention in decentralized trials by facilitating the pairing of suitable study staff with patients, potentially improving communications and trust. Improving diversity in clinical trials is a primary step to bridging the health disparity gap by providing minority groups additional confidence on novel therapies and access.

In addition to enhancing clinical trial diversity, another health equity vertical impacted by data digitalization is the allocation of health care resources. Collection of demographic and non-demographic variables are critical for localizing regions of inequitable care and improving the effectiveness of health care-based infrastructure development. If regions of health inequity can be localized and assessed based on the demographic and socioeconomic information, then appropriate strategies for expanding diversity and inclusion may be employed. Forms of resources that may be optimized by data digitalization are public health and economic security grants, health care establishments, personnel, and equipment. Figure 1 depicts ways in which DHIs may overcome the aforementioned barriers to health equity and inclusion.<sup>9</sup>

#### FIGURE 1: DIGITAL HEALTH INTERVENTIONS TO OVERCOME HEALTH SYSTEM CHALLENGES



### 4. INNOVATIVE TECHNOLOGIES AND SHIFTS IN HEALTH CARE EMERGING FROM COVID-19

COVID-19 has unveiled the magnitude of health care disparities in the U.S., which cost an estimated \$42 billion in productivity and \$93 billion in excess medical fees annually, as well as innovative health technologies that have proved essential in adapting to and combatting COVID-19; in particular, DHIs.<sup>10</sup> DHIs can be tailored for a patient population based on demographic data to account for cultural complexities and other barriers such as mobility and scheduling constraints, which can make access to health care services expensive or unattainable.

During the early stages of COVID-19, digital health technologies were used for predictive models and analytics, supporting health care organizations and policy makers in decision-making when developing appropriate mitigation and resource allocation strategies based on data points collected in certain regions of the U.S. These data points include the number of COVID-19 cases and deaths; the severity, momentum, and direction of COVID-19 transmissions; the amount of resources present, disbursed, and/or required (ICU beds, PPE, vaccine allocations, etc.); and other environmental factors that enabled models to better understand and predict the pandemic's behavior. Such predictive modeling tools, based on machine learning, have displayed certain drawbacks given that artificial intelligence (AI) systems have not been put through a similar training regime as staff at local health care facilities.<sup>11</sup> AI is currently being used by health care administrators, clinicians, and payers – meaning a lack of implicit bias training or unfair prejudice may trickle down into all aspects of the health care ecosystem, should there be a dependence on data generated from AI. There are additional layers of complexity that should be challenged by regulators and policy makers when developing AI's ability to take into consideration biases and unfairness in clinical decision-making.

COVID-19 limited patient access to traditional health care, exacerbating access to care disparities in all communities. This acted as a catalyst in the development and adoption of digital health technologies, while supporting the case that the current health care system has not optimally utilized its resources in ameliorating health equity. Between March and July 2020, the rate of physicians conducting virtual patient consultations rose from 9% to 80%.<sup>12</sup> This 71% increase in virtual consultations represents growth in just one segment of the digital health industry. Such a rapid shift towards digital patient-centric health care presents an unparalleled opportunity to increase patient engagement and accessibility, improve the pace and quality of health care management and outcomes, and reduce health care costs and inequities. COVID-19 has also facilitated the expanded use of digital health technologies via the Centers for Medicare & Medicaid Services' reimbursable telehealth codes for 2021 – however, the duration of this regulatory adjustment is uncertain.

Data from McKinsey & Company's June 14, 2021 COVID-19 Consumer Survey displays the following consumer uses of telemedicine by percentage of visits: visits to a psychologist or psychiatrist (63%), visits to a health clinic at a pharmacy or retail store (30%), visits with a pediatrician for my child (29%), non-annual/routine visits with a primary care physician (24%), routine visits with a primary care physician (23%), visits to an urgent care center (21%), annual wellness visits with a primary care physician (17%), visits with a gynecologist for non-pregnancy or non-maternity care (17%), and visits to a specialist (16%).<sup>13</sup>

From a provider perspective, in 2019, 27% of health care executives had invested in automation technologies including AI and digital technologies. A survey by Deloitte in 2020 measured physicians' perspectives on such technologies, finding that physicians expect digital health would save time and resources (73%), improve accuracy in diagnosis (42%), patient experience (33%), preventative measures (32%), personalized care (25%), and improve risk stratification of patients (22%). With regards to primary care physicians, a positive impact is expected on clinical quality (40%), on patient experience (42%), on patient engagement (39%), and on physician-patient relationships (35%).<sup>14</sup>

This range and level of use and interest from all stakeholders, including patients, providers, and health care administrators, combined with the fact that at least 85% of minority groups in the U.S. own a smartphone and between 90% and 95% have access to household internet, demonstrates the potential for digital health to be widely adopted across all communities, as long as resources are deployed to facilitate access to virtual care and current reimbursable telehealth codes are expanded and extended beyond COVID-19.<sup>15</sup>

### 5. INFRASTRUCTURAL DEVELOPMENTS REQUIRED TO ADAPT TO NEW TRENDS IN HEALTH CARE

In order for such technologies to be sustainably and safely employed and adopted at the scale required to expand national access to health care beyond COVID-19, there are infrastructure requirements that must be considered.

Although keeping up with industry and technology proves daunting, the FDA recognizes the urgency of regulatory oversight in digital health. In 2017, the FDA published a Digital Health Innovation Action Plan (DHIAP). In the years since, FDA investment in digital health regulation has continued to expand.<sup>16</sup> A critical component to the DHIAP is a Precertification Program for digital health technology developers. This program is being developed to improve the safety and efficacy of digital health technologies while streamlining their complex commercialization process to rapidly expand user access. The precertification program would achieve this streamlined process by leveraging manufacturer and patient-input data; leveraging real-world clinical, post-market, and performance data; and establishing and monitoring a breadth of KPIs tailored towards digital health technologies while keeping up with the agile software development cycles.<sup>17</sup>

For the FDA and other governmental agencies to manage and process the vast and growing amount of data associated with the precertification program and the regulation, use, and maintenance of digital health technologies, the U.S. requires digital infrastructure capable of immense data collection, management, and disaggregation as well as an extraordinary ability to establish and adapt to standards, both in technological development and in data collection and reporting.<sup>18</sup> Accordingly, one of the FDA's 2021 budget allocations serves to recruit technical experts to ensure the integrity and safety of data and IT systems, make data management more holistic, and improve FDA's capacity to evaluate and recognize third party auditors or certifiers to complement rapid digital transformation within the health care ecosystem. In 2019, HHS' regulatory framework for digital health proposed changes to insurance systems to facilitate reimbursement for digital health services, including a digital health formulary and Centers for Medicare and Medicaid Services adding virtual patient monitoring to reimbursement codes.<sup>19</sup>

Significant plans and phases of infrastructure development are underway to support a digital transformation. However, without additional regulatory oversight, shifts in policy, or corresponding infrastructure development, digital health care's impact on society may lead to alarming results, including payers' incapacity to identify robust digital health platforms, risks to users' private health data, misleading physician and patient decision-making, and an increase in health disparities.<sup>20</sup> The following figure from the TGA's Digital Health Agency (DHA) outlines seven components of a sound and scalable digital health strategy as well as infrastructure developments required to target each component.<sup>21</sup>



#### FIGURE 2: TGA DIGITAL HEALTH PRIORITIES (Australian DHA, 2018)21

TGA's model for national digital health transformation presents infrastructural considerations that are rooted in ease of data collection, personalization, and disaggregation, ultimately providing accurate health metrics and analytics that trickle down into all arms of health care to optimize clinical and health care innovation, quality, equity, and access.

Currently, it is difficult to accurately realize the potential cost-savings of a digital health transformation in the U.S. Limited research has been done on the cost-effectiveness, utility, minimization, consequence, and benefit analyses of digital health investments compared to traditional methods of managing information in health care systems.<sup>22</sup>

The World Health Organization's Recommendations on Digital Interventions for Health System Strengthening reinforces that inequities may be mitigated should inequity be monitored during DHIs implementations and that DHIs propose a solution for promoting equitable access to care.<sup>23</sup> Despite the clear potential DHIs and digital transformations have to drive affordability, diversity, and inclusion in health care, further research is required on behalf of all stakeholders to conclude long-term costs, value, and sustainability of a digital health transformation.

### 6. CONCLUSION

The many root causes of health disparities in the U.S. require systemic changes to mitigate income inequality and provide access to resources in an equitable manner. Such causes require cross functional collaboration from policy makers, state, and local governments as well as grassroots-organizations. Such policies would require ground level solutions for equitable access to clinical trials and health care; grant funding for community-based health care services; reimbursement strategies for digital health formularies to expand access to care and inclusion in decentralized clinical trials; the issuance of guidance for stakeholders on encouraging diversity; and developing a decentralized and equitable health care ecosystem.



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