

CLINICAL TRIALS WORKSHOP

# Health Equity through Clinical Research — Meeting the Challenge of Inclusion

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## Abstract

Representativeness is perhaps one of the most important requirements in medical research, especially for health disparities research. Representativeness is necessary for the study findings to apply to all members of the population without selection bias. Here we detail the multiple approaches to ensuring representativeness that were developed in the HANDLS (Healthy Aging in Neighborhoods of Diversity across the Life Span) study. (Funded by the National Institute on Aging Intramural Research Program, National Institutes of Health; ClinicalTrials.gov number, [NCT01323322](https://clinicaltrials.gov/ct2/show/study/NCT01323322).)

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Editor

## Introduction: Rationale and Justification for Health Disparities Research

*What has been will be again, what has been done will be done again; there is nothing new under the sun.* — Ecclesiastes 1:9.

Despite this well-worn biblical verse, many were shocked by the tremendous health disparities bared by the coronavirus disease 2019 (Covid-19) pandemic. The grim age-adjusted mortality rates for non-Hispanic American Indians, Alaska Natives, and non-Hispanic Blacks graphically underscore the need for research on the health of racial and ethnic groups, health disparities, and health equity, as do the substantial decrements in life expectancies for these groups and Hispanic Americans.<sup>1,2</sup>

The inextricable linkage between social factors and socially determined environmental exposures was discerned as early as the 1700s. Bernardino Ramazzini described social and environmental risk factors for breast cancer among nuns and the risk of specific conditions linked to occupations in the *De Morbis Artificum Diatriba (Diseases of Workers)*.<sup>3</sup> He focused on vulnerable women, marginalized groups, laborers, and the working class at risk due to their poor residential circumstances and, especially, toxic occupationally related environmental exposures.<sup>4,5</sup> Pott's observations linking cancer to youth, occupation, and soot exposure were the first descriptions of chemical carcinogenesis and, perhaps more importantly,

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the role of a socially induced, economically driven harm on a health disparity that led to social policy reforms.<sup>6</sup> Likely related to his early experiences in medicine during the German typhus epidemic in the mid-1800s, Rudolf Virchow saw medicine as a social science. He identified the connection between risk of infection and poverty, poor housing, and low education, among other social determinants of health.<sup>7</sup> Sadly, Virchow would have experienced déjà vu had he been practicing in March 2020. Clearly, the call for expansion of research on health disparities, health of different racial and ethnic groups, and health equity is well-justified. What is not as clear are tangible, feasible, and practical methodologies and requirements for overcoming the barriers for research in this challenging area.

Representativeness is perhaps one of the most important requirements in medical research, especially for health disparities research. There are fundamental scientific reasons for studying representative and diverse samples of the population. Representativeness is necessary for the study findings to apply to all members of the population without selection bias. Similarly, diversity is necessary because it provides researchers access to the full spectrum of possible variability in the outcome and therefore expands our understanding of the processes under study. Moreover, representativeness and diversity improve the likelihood for replication under differing conditions, a requirement too infrequently met in contemporary literature. With these considerations in mind, we established the HANDLS (Healthy Aging in Neighborhoods of Diversity across the Life Span) study.<sup>8</sup>

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## HANDLS Study Design

HANDLS is a longitudinal epidemiologic study examining the interaction of race and socioeconomic status (SES) on age-associated health disparities among a socioeconomically diverse cohort of Black and White residents of Baltimore, Maryland.<sup>9</sup> HANDLS deploys novel research tools such as mobile medical research vehicles (MRVs) to improve participation rates and retention among urban, poor, and non-White research participants. The scientific objectives are to disentangle the effects of race as a cultural construct and SES on risk factors for morbidity and mortality, incidence and progression of preclinical disease, and the development of health disparities. HANDLS's operational goals include enhancing training opportunities in epidemiology, aging, and health disparities research for students pursuing careers in public health, enhancing participation of non-White

investigators and Historically Black Colleges and Universities in clinical research, contributing to building research capabilities at these institutions, and developing and disseminating effective community-based methods of recruiting and retaining non-White and socioeconomically diverse participants in clinical research.

The study design (Fig. 1) is a factorial cross of age (seven age bands 30 to 64 years of age), sex, race, and SES operationalized as household incomes below or above 125% of poverty defined by the 2004 Health and Human Services guideline.<sup>10</sup> From 2004 to 2009, participants were recruited as an area probability sample of 13 neighborhoods (contiguous census tracts) identified as likely to fill the design cells. We recruited a fixed cohort of participants in two phases. In the first phase, interviewers selected one or two eligible persons per household by doorstep screening using a computer-generated probability selection method. Once successfully recruited and consented in the home, participants completed household surveys and a 24-hour nutritional intake interview.<sup>11</sup> We suspected that medical mistrust and lack of community facilities were the greatest barriers to research participation. This guided us to use MRVs as community-based research platforms (Fig. 2). In phase two, participants were invited for in-person examinations at the MRVs parked in their neighborhoods. Examinations included collecting blood and urine specimens for laboratory testing and biospecimen banking, medical histories and physical examinations, and other measures described in our protocol.<sup>8</sup>

We accrued 3720 participants (Fig. 1), of whom 2198 self-identified as Black (59%) and 1522 as White (41%); 1535 (41%) participants had household incomes below 125% of the poverty level and 2185 (59%) above the poverty level. We accrued approximately equal numbers of participants in each race by poverty group except for White adults with household incomes below 125% of the poverty level. We have reexamined this fixed cohort every 4 to 5 years since 2009.

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## Challenges and Solutions in HANDLS

There are many publications that document the barriers and challenges that make the conduct of health disparities and health research on marginalized groups difficult.<sup>12,13</sup> Three years before initiating the epidemiologic phase of the study, we performed a pilot study on a convenience sample.

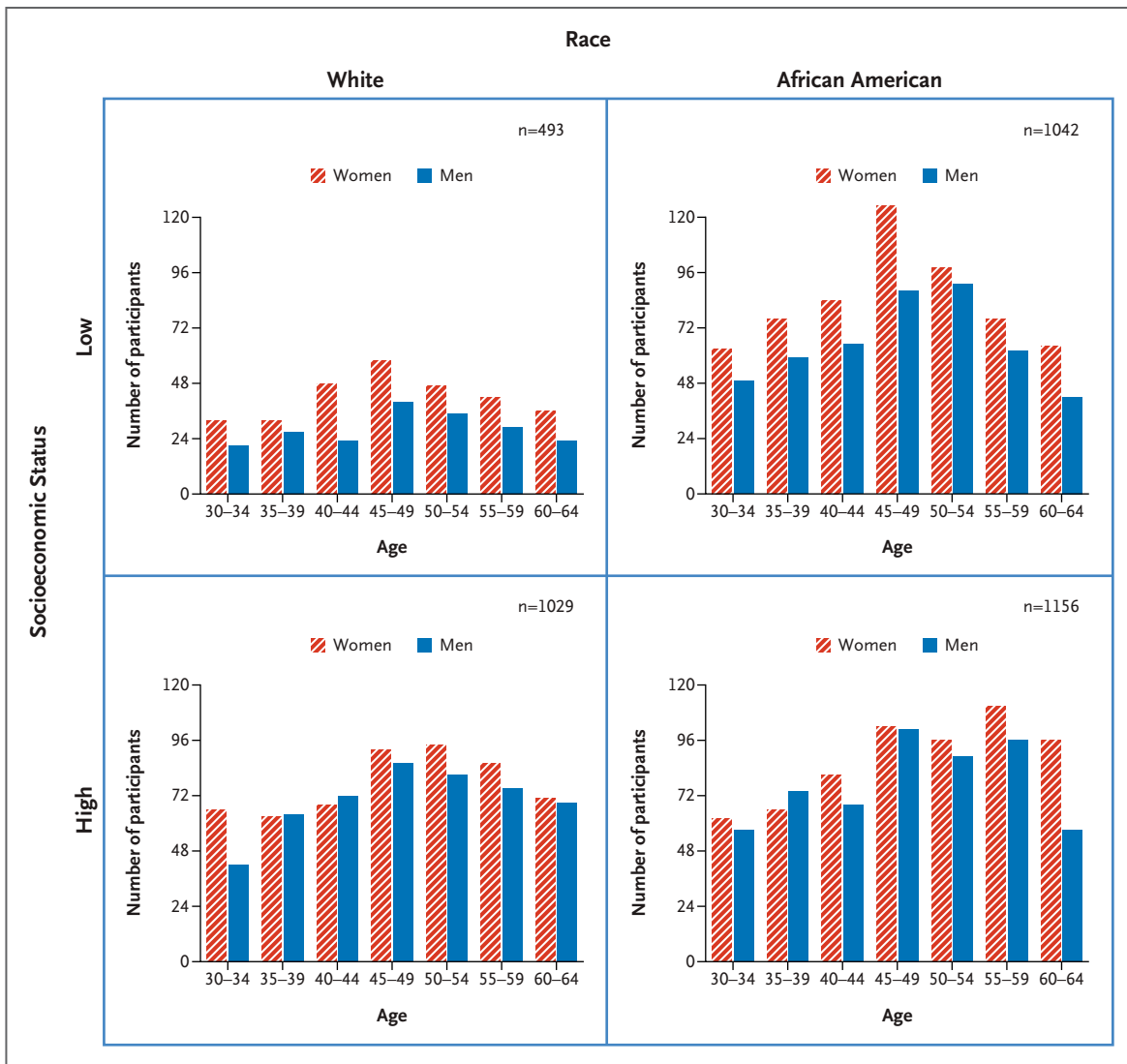
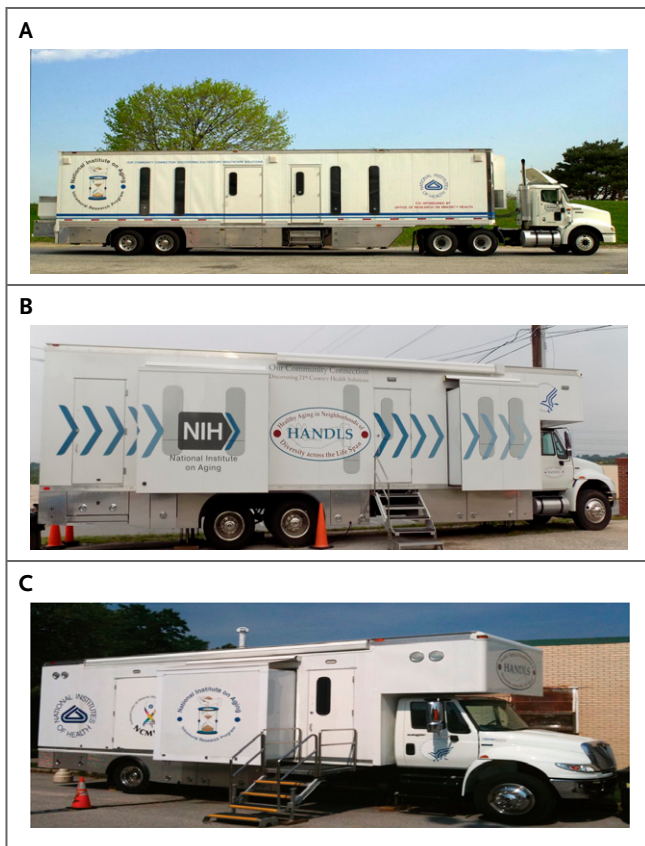


Figure 1. Design and Participant Accrual for the HANDLS (Healthy Aging in Neighborhoods of Diversity across the Life Span) Study, 2004 to 2009.

The pilot study included many measures ultimately adopted for the epidemiologic study phase and, importantly, provided us with the opportunity to get to know Baltimore residents, their neighborhoods, and the everyday problems impeding research participation. This was the basis for the theoretical framework that we developed to inform our methods (Fig. 3). The pilot study was also an opportunity to test whether the measures we elected to collect were acceptable to community participants, particularly physical examinations and biospecimen collections. We empaneled a community advisory board (CAB) composed of study participants and members of neighborhood leadership groups, including tenants' associations, church health ministries, and

collaborating researchers. Study investigators, including the principal investigators, study manager, and other staff, made multiple presentations to the CAB and other city stakeholders to facilitate discussions about Baltimore health disparities and the need for research in Baltimore communities. In addition to discussions with governmental officials at state, federal, and local levels, these presentations provided feedback about making the study suitable, reducing neighborhood-specific barriers, and topics relevant to community members.

As part of our theoretical framework (Fig. 3), we identified three domains central for facilitating recruitment and



**Figure 2. Mobile Medical Research Vehicles.**

Panel A shows Medical Research Vehicle (MRV)-1, a 50-foot customized trailer divided into three functional areas: bone density and cardiovascular sonography, physical examination, and physical and cardiovascular performance. Panel B shows MRV-2, a 43-foot customized self-propelled truck divided into functional areas for participant interviews, cognitive testing, and audio and vision testing. Panel C shows MRV-3, a 45-foot customized self-propelled truck divided into three functional areas: a two-seat participant area for collecting blood and saliva samples, a sample processing area, and a physician consultation office.

retention of racially diverse and socioeconomically disadvantaged cohorts: individual, community, and researcher and scientific research.<sup>14</sup> Individual barriers included mistrust, behavioral and social factors, multimorbidity, and personal biases. Community barriers included concerns about the benefits of research, the fear of exploitation, neighborhood safety, and lack of exposure to medical research. Researcher and scientific domain barriers included personal bias, staffing, lack of direct benefit from hypothesis-driven research, absence of community membership, and knowledge.

As proposed solutions (Fig. 3), we prioritized developing multilevel interdigitating strategies to address mistrust and personal bias. Acknowledging the validity of mistrust was the first step. Mistrust was deeply rooted among Black people in Baltimore. It was also present among low-SES White Baltimore residents. In 1999 — before the enactment of the Affordable Care Act — this climate of mistrust was driven by long-standing racial discrimination and in equal measures by the extremely inadequate health care access available for non-White and poor urban residents. Many have also posited that trust is a social determinant of health because mistrust is associated with poor health outcomes inextricably bound with ineffective physician-patient relationships, substandard treatments, low engagement in health care systems, and failures to access preventive care, ultimately contributing to health disparities.<sup>15-17</sup>

We deployed numerous strategies to prove ourselves trustworthy to the community and to familiarize ourselves and our staff with the community. Prior to the start of the study, we hired several study staff members so that they would learn firsthand about Baltimore and become the face of the future epidemiologic study. As we were conducting the pilot studies, they also used our MRVs as health screening sites during widely attended Baltimore community events. These community contacts facilitated discussions that led to useful community-based suggestions, including the preference for monetary compensation for participation and assistance with health care access. We tailored HANDLS to provide an immediate direct benefit. Compensation is one immediate benefit, but we also provide medical referral and navigation, social service, and tailored health education. Our consistent attendance at Baltimore City events and at neighborhood and tenants' association meetings over several years demonstrated our commitment to become active citizens in the community. Most importantly, it provided a forum for active listening with community members about Baltimore health disparities and the gaps in our knowledge about how to reduce them.

Before deploying our recruitment teams across the city, they were specifically selected and at times race matched with the neighborhoods from which they would recruit. The principal investigators educated the recruitment staff on the study and the potential barriers they would face — mistrust and personal bias, particularly. They were also educated about the potential benefit of research participation and the specific benefits associated with the HANDLS study. Not only did we ensure the diversity of the study recruiters but we also intentionally recruited a racially

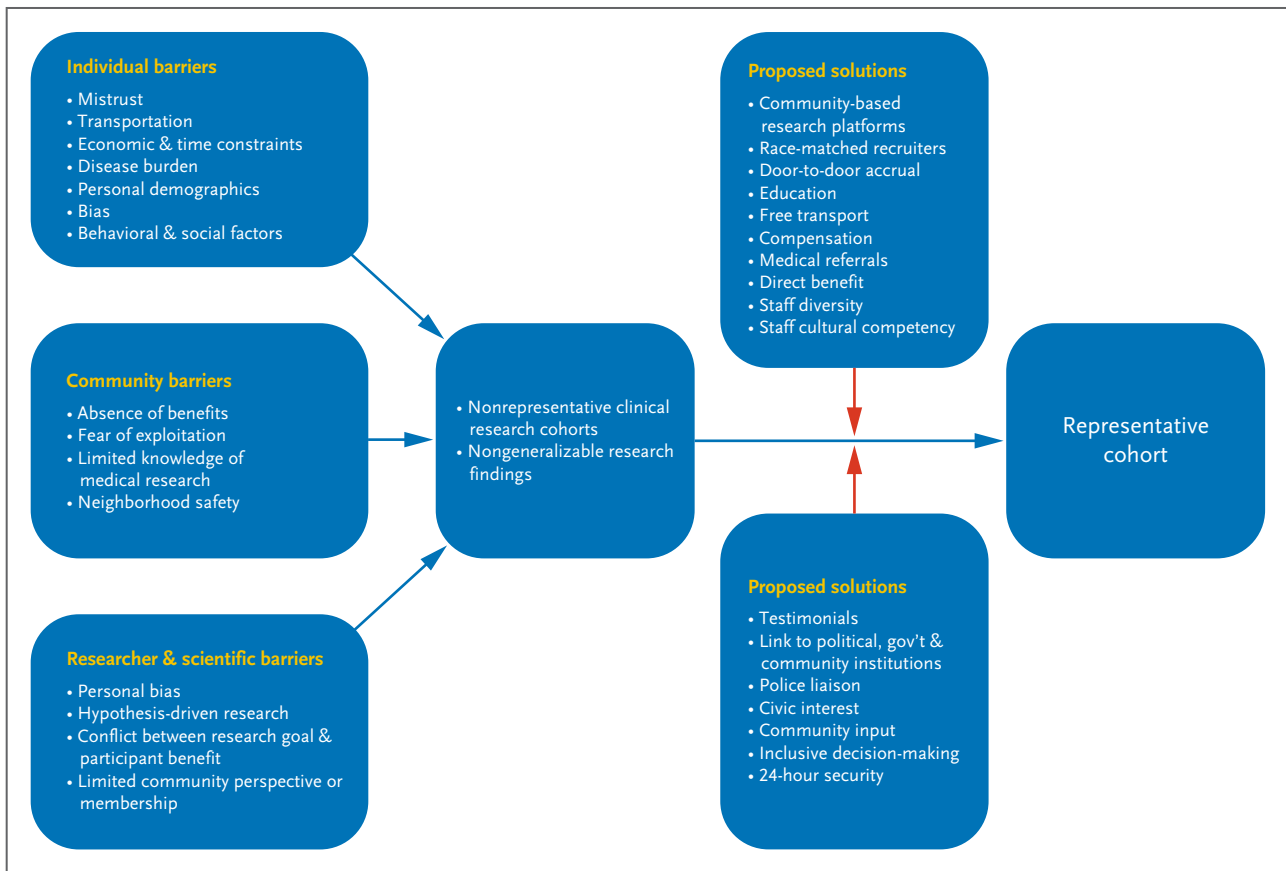


Figure 3. Theoretical Framework.

diverse, emotionally intelligent clinical and basic science research staff. We also made some unusual decisions on hiring. For example, rather than selecting a nurse as the clinical study manager, we selected a psychiatric social worker so that we had the competency within the staff to help participants navigate entitlement programs and mental health resources. We also hired a door-to-door insurance salesperson with no health care or research experience as our community coordinator because we believed that the unique skill set acquired going door-to-door throughout the city was better preparation to surmount the community-based obstacles that we expected to face.

The focus on mistrust and personal bias was paramount for staff selection and preparation. Our custom cultural competency/proficiency training focused on understanding structural and medical racism and examining our own ethnocentric views and biases. The central focus of our now-18-year cultural competency series was to instill cultural humility to help staff re-center and perform self-evaluation

of existing biases that could impede their roles in conducting this research. The first trainings covered general concepts of diversity in terms of race, ethnicity, and social class, and specific facets of African American culture, low-SES White population cultural perspectives, and Baltimore-specific issues. The course also provided background on historical contexts that influence non-White and marginalized and medically underserved persons' views of health care services and biomedical research. In addition, we designed the course to introduce cross-cultural communication techniques and discuss how ethnocentrism, bias, prejudice, and stereotyping influence interpersonal relationships with persons from a culture other than one's own. The trainings were valuable not only for White staff members but also non-White staff members who felt empowered by the open discussions of these issues and recognized their own privilege and potential bias conveyed by their educational advantage and medical research positions. The yearly commitment to education in this sphere has been crucial to constant staff introspection on these



issues. It prepared staff to navigate our participant relationships across the power imbalance. Importantly, it provided a useful context for responding seamlessly to contemporary societal upheavals such as the pandemic and the murder of George Floyd. Most importantly, we believe that this knowledge helped prove our trustworthiness to our participants. This HANDLS core value implemented in 2002 has been validated by recent work citing the need for health care providers to prove themselves to be worthy of trust to improve health and ameliorate health disparities.<sup>15,16</sup>

We have learned that advancing from mistrust to trust is critical in conducting inclusive clinical research. We accomplished this also by tailoring our research program to always provide an immediate direct benefit at multiple levels. Compensation is one immediate benefit, but we also worked to exceed participants' expectations by our outstanding medical referral network through which they accessed primary and specialty care through private practitioners and at Baltimore medical institutions. During the 2008 recession, which had a devastating impact on HANDLS participants, our nurses, as part of the study visit and upon request, aided in job hunting, application completion, and submission because many of our participants were on the wrong side of the digital divide. We also publish a quarterly newsletter, "[The Healthy Journey](#)," which focuses on relevant health education topics and reports our findings to HANDLS participants. During the height of the pandemic, the newsletter became a biweekly to monthly update on the Covid-19 pandemic, prevention measures, vaccine development, and economic resources available to combat the widespread unemployment and food insecurity experienced by our participants.

We also built trust through the informed consent process. The informed consent process required modifications to address issues of trust and transparency. We analyzed all study documents for readability using the Flesch-Kincaid Readability Scale.<sup>18</sup> The informed consent documents required by the institutional review board had reading levels that far exceeded what we predicted were the average reading levels for those we wished to recruit. Therefore, we wrote and produced a series of videos that provided an overview of the study and its rationale, including a tour of the MRVs and a detailed description of the tests and procedures that comprise the study. We used these videos as part of our presentations to community organizations and when participants came to the MRVs for their examination visits (<https://www.youtube.com/user/NIAsHANDLS>). The HANDLS team also distributed information packets that

included documentation of institutional review board approval, letters of support from legislators, study descriptions, and neighborhood site maps.

This study also faced internal obstacles related to structural racism in medicine and biomedical research and the fact that health disparities research is often undervalued in research-intensive environments. In 1997, at the time of study conception, few understood the intrinsic value and importance of this research. With these facts in mind, in addition to scientific goals, operational goals were developed to acknowledge the presence of structural racism within medicine and biomedical research that continues to contribute to the nationwide dearth of physicians and researchers from non-White and marginalized groups. Our operational goals included the enhancement of training opportunities in epidemiology and health disparities research for students pursuing careers in public health. Additionally, we planned to enhance the participation of students, investigators, and institutions from underrepresented groups in clinical research to contribute to building research capabilities at Historically Black Colleges and Universities using the HANDLS study and resulting data as a platform for these researchers to advance their scientific careers. To date, the study continues to be successful in meeting these operational goals.

Safety arose as an issue for participants and staff. The principal investigators listened carefully to design a two-part strategy to address these concerns. The first was to establish an ongoing dialogue with the Baltimore Police Department (BPD), district commanders, and community affairs police officers. The study was explained to the police commissioner and local community affairs police officers, which garnered support and provided important insights about the communities into which we would be sending field staff and deploying the MRVs for examination visits. The police also provided perspectives about neighborhood safety from community members as well as the safety issues that might be faced by participants walking through the neighborhoods to the vehicles for each census segment. The BPD included our deployment sites into their regular patrol routes. Providing safety for participants and staff also required that we train our staff members on personal and property safety and actively follow crime trends and statistics throughout the city. This was particularly important for staff so they could avoid inadvertently signaling neighborhood or gang allegiances. The second part of the strategy was providing 24-hour security surveillance at the MRVs by the HANDLS security staff, who were viewed not only as security staff but also as

research study staff. The principal investigators and the logistics manager provided tailored training on clinical research overall, the specifics of the HANDLS study, and cultural competence, and provided them answers to frequently asked questions about our presence in the neighborhood. Because they are frontline staff on-site and responsible for participant pickup when transportation provided a barrier to participation, it was essential that our security staff could speak knowledgeably about the study and understand selected aspects of clinical research.

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## Conclusion

Our approach to health disparities research takes advantage of the breadth of the field spanning from the social determinants of health contextualized by environmental stressors to molecular and genomic factors. We believe applying this biosocial approach will facilitate understanding the multifaceted interplay of factors that lead to health disparities and guide pathways to eliminate them.<sup>19</sup> As we illustrated (Fig. 3), we faced considerable individual, community, and scientific barriers in our path to examine a representative cohort. We had few a priori models upon which we could base our methods. Consequently, it was most useful to foster a spirit of empirical research while pursuing our goal in a flexible manner. Solutions to problems in recruiting and retaining participants depend on contributions from staff at all levels, often challenging preconceived notions. We monitor the efficacy of our proposed solutions as an acknowledgment that we must change our methods as time, participants, and communities change. What worked then may not work today; what works today may not work tomorrow. This is crucial in our efforts to minimize barriers to participation.

Social determinants of health contribute most of the risk for premature mortality.<sup>20</sup> Research strategies to promote improved health outcomes cannot rely solely on technological aspects of basic biomedical research. Building solutions to health disparities and achieving health equity requires focus on and comparable funding of investigations into the social determinants of health, unequal treatment in health care settings, and the pervasive influence of adverse psychosocial environmental factors.<sup>20</sup>

Acknowledging pervasive inequities,<sup>21</sup> it is incumbent on medical practitioners to focus national attention on this area of research. It is also important to note that it will take time and experience to overcome the dearth of understanding on

how to conduct research on health of non-White and marginalized groups and health disparities. This is a particular gap for researchers not from underrepresented groups who have been encouraged by the increased funding to enter the field without the specific scientific expertise, experience, or engagement with the communities they seek to study. Although it is useful to have additional researchers attacking this multidimensional area of research, the off-target outcome at times disenfranchises long-standing, committed expert scholars, many of whom are from underrepresented groups in medicine and biomedical research.<sup>22,23</sup> While everyone with ideas, interest, and commitment is welcome, it is essential that researchers engaged in health disparities research, the health of racial and ethnic groups, and health equity commit for the long term by engaging with the communities they study and learn from and work in concert with those who have trailblazed this area of research.

Addressing health disparities requires shifting the research paradigm from disease to focusing on health and the societal factors that drive poor outcomes. Both Ramazzini and Virchow understood that we must integrate medicine and science into the social and economic spheres of life to address the problems of the most vulnerable in society. Health disparities research is difficult and at times frustrating because it is inextricably entangled with politics and policy. Nevertheless, it is up to us to press forward to eliminate the barriers to health disparities research and health equity at this critical juncture. As the Greek physician and anatomist Herophilus wrote, “When health is absent, wisdom cannot reveal itself, art cannot manifest, strength cannot fight, wealth becomes useless, and intelligence cannot be applied.” We as a nation cannot afford to fail to meet this century’s challenge to reap the promise of equality for every American.

## Disclosures

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Author disclosures are available at [evidence.nejm.org](https://evidence.nejm.org).

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