NATIONAL ACADEMIES Sciences Engineering Medicine

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The Use of Race and Ethnicity in Biomedical Research: Community Perspectives Public Session

PUBLIC BRIEFING BOOK

March 14, 2024

VIRTUAL MEETING

Public Session, March 14 (2:00 PM – 4:30 PM ET)

Webcast Link: https://www.nationalacademies.org/event/41882_03-2024_the-use-of-race-and-ethnicity-in-biomedical-research-meeting-4

NATIONAL ACADEMIES Sciences Engineering Medicine

The Use of Race and Ethnicity in Biomedical Research

Meeting 4: March 14, 2024

Table of Contents

Agenda

Committee on the Use of Race and Ethnicity in Biomedical Research: Community Perspectives

Public Session

March 14, 2024

PURPOSE AND OBJECTIVES

- Learn about community perspectives on race and ethnicity in biomedical research by listening to community members and research participants.
- Understand community viewpoints on how race and ethnicity are or are not being used appropriately in biomedical research.
- Include suggestions from community groups about how race and ethnicity should or should not be used in biomedical research.

THURSDAY, MARCH 14, 2024

2:00 – 4:30 pm ET

OPEN SESSION

Webcast Link

Community Perspectives on the Use of Race and Ethnicity Data in Health Research

Session Objectives:

- Understand experiences from community groups about the collection and use of race and ethnicity data during different phases of community-based participatory research, including:
  - learning about the research goals, building partnerships, designing the study, participating in research, and learning about the results and benefits to the community.
- Learn from community members and research participants about current research practices involving race and ethnicity that should be continued, stopped, or modified.
- Listen to what changes related to the use of race and ethnicity in research community members may want to see and discuss possible ways to implement those changes in biomedical research practices.

2:00 – 2:05 PM ET — **Welcome**
M. Roy Wilson, *Committee Chair*
President Emeritus
Wayne State University

2:05 – 2:10 PM — **Introduction to the Session**
Margaret Moss, *Session Moderator*
Professor and Associate Dean for Nursing and Health Policy
Katherine R. & C. Walton Lillehei Chair in Nursing Leadership
University of Minnesota School of Nursing

2:10 – 2:25 PM — **Level-setting Opening Talk**

Ella Greene-Moton
Administrator
Community Based Organization Partners, Community Ethics Review Board
President
American Public Health Association

2:25 – 2:40 PM — **Q&A with Opening Speaker**

2:40 – 2:45 PM — **Introduction to the Panel**

Matthew F. Hudson, *Session Moderator*
Director of Cancer Care Delivery Research
Prisma Health

2:45 – 3:30 PM — **Panelists' Opening Remarks**

Jamil Rivers
Founder
The Chrysalis Initiative

Audie Atole
Conservation Officer
Jicarilla Apache Nation

Gladys Vega
Chief Executive Officer
La Colaborativa

Donald Adams, Jr.
Assistant Director of Design Innovation
University of Illinois System, Office of Medicaid Innovation
Patient Engagement Advisory Panelist
Patient Centered Outcomes Research Institute

Danurys "Didi" Sanchez
Senior Research Staff Associate
Taub Institute for Research on Alzheimer's Disease and the Aging Brain
Columbia University Irving Medical Center

Sela Panapasa
Associate Research Scientist, Research Center for Group Dynamics
University of Michigan

3:30 – 4:15 PM — **Panel Discussion – Race and Ethnicity Considerations throughout the Research Process**

- Community involvement in study design
- Knowledge that researchers should have prior to data collection
- Questions at the time of recruitment
- Data management and stewardship
- Benefit sharing and post-participation communication
- Recommendations that community members have for the committee

4:15 – 4:25 PM **Reflections on the Panel Discussion**

Eliseo Pérez-Stable
Director
National Institute on Minority Health and Health Disparities (NIMHD)
National Institutes of Health (NIH)

Monica Webb Hooper
Deputy Director
National Institute on Minority Health and Health Disparities (NIMHD)
National Institutes of Health (NIH)

4:25 – 4:30 PM **Closing Remarks**

4:30 PM ***Adjourn***

Study Information

NATIONAL ACADEMIES Sciences Engineering Medicine

Committee on the Use of Race and Ethnicity in Biomedical Research

Study Sponsors: Doris Duke Foundation, Burroughs Wellcome Fund

Project Background

The Doris Duke Charitable Foundation has asked the National Academies of Sciences, Engineering, and Medicine to generate a report that guides the scientific community on the use of race and ethnicity in biomedical research, including identifying current research practices that are not grounded in rigorous scientific method and may ultimately exacerbate inequities in healthcare delivery and patient outcomes.

Statement of Task

An ad hoc committee of the National Academies of Sciences, Engineering, and Medicine will assess the current use of the social constructs of race and ethnicity in biomedical research and provide recommendations to guide the scientific community in the future use of race and ethnicity in biomedical research.
More specifically, the committee will:

- Document and evaluate how racialized group and ethnic categories are currently being used in biomedical research (e.g., as a descriptor, to stratify data, to apply race norming, to infer differences between groups due to environmental and social impacts), including describing consequences and contributions to health inequities in current clinical practices;
- Identify the circumstances in which it is appropriate to use the social constructs of race and ethnicity in biomedical research, for example in studying the health effects of racism, and the circumstances in which race and ethnicity should not be used to inform inferences;
- Review existing guidance for researchers on the use of race as a variable in biomedical research.

Based on its review of the literature and other expert input, the committee will develop a report with its findings, conclusions, and recommendations for entities such as researchers, funders, publishers, scientific and medical societies, health systems, and industry regarding:

- The use of race and ethnicity in biomedical research, including identifying current practices that should be continued, stopped, or modified;
- Policy changes to reform the use of race and ethnicity in biomedical research, with specific attention to the practice of race norming or race correction;
- Implementation strategies to help enhance the adoption of best practices across the biomedical research community.

The committee's work will focus on the use of racialized group and ethnic categories across the spectrum of biomedical research, including the development of clinical prediction models and other clinical decision tools. Related topics in the provision of clinical care, such as inequitable access to health care and racism in care delivery, are beyond the scope of this study.

Timeline

The committee will meet at least 5 times between October 2023 and July 2024, with the report being set to release in October 2024.

Project Website: https://www.nationalacademies.org/our-work/the-use-of-race-and-ethnicity-in-biomedical-research

Committee Membership

M. Roy Wilson, M.D., M.S. (Chair)
Wayne State University

Allison Aiello, Ph.D.
Columbia University

Efrén J. Flores, M.D.
Massachusetts General Hospital

Carmen Guerra, M.D., M.S.C.E.
University of Pennsylvania

Elizabeth Heitman, Ph.D.
University of Texas Southwestern Medical Center

Matthew F. Hudson, Ph.D., M.P.H.
Prisma Health

Husseini K. Manji, M.D.
Oxford University

Amy Moran-Thomas, Ph.D.
Massachusetts Institute of Technology

Margaret Moss, Ph.D., J.D., RN
University of Minnesota School of Nursing

Elizabeth O. Ofili, M.D., M.P.H.
Morehouse School of Medicine

Neil R. Powe, M.D., M.P.H., M.B.A.
University of California, San Francisco

Aliya Saperstein, Ph.D.
Stanford University

Roland Thorpe, Jr., Ph.D.
Johns Hopkins Bloomberg School of Public Health

Shyam Visweswaran, M.D., Ph.D.
University of Pittsburgh

Genevieve L. Wojcik, Ph.D.
Johns Hopkins Bloomberg School of Public Health

Ruqaiijah Yearby, J.D., M.P.H.
The Ohio State University

Study Staff

Sarah Beachy, Study Co-Director, RaceInBiomedResearch@nas.edu
Samantha Schumm, Study Co-Director
Joseph Tumfour, Associate Program Officer
Lydia Teferra, Research Associate
Ashley Pitt, Senior Program Assistant
Clare Stroud, Senior Board Director, Board on Health Sciences Policy
Francis Amankwah, Senior Program Officer, Board on Health Care Services
Ronique Taffe, Program Officer, Board on Population Health and Public Health Practice
Ben Weston, NAM Fellow

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Committee on the Use of Race and Ethnicity in Biomedical Research

Committee Member Biographies

M. Roy Wilson, M.D., M.S. (chair), is a physician, researcher, healthcare leader, and author. His 20-year history as leader of universities with budgets of $550 million to $1.8 billion is hallmarked by his successful efforts to expand access for underrepresented minorities, improve graduation rates, increase extramural funding, and execute ambitious fundraising campaigns. Dr. Wilson is chancellor emeritus of the University of Colorado Denver and Health Sciences Center and president emeritus of Wayne State University; he also served as deputy director of strategic scientific planning and program coordination at the National Institute on Minority Health and Health Disparities at the NIH. Previously, he was dean of the School of Medicine and Vice President for Health Sciences at Creighton University; president of the four-campus Texas Tech University Health Sciences Center; and dean of the medical school, president, and chair of the board of directors of Charles Drew University of Medicine and Science. He completed medical school and an ophthalmology residency at Harvard Medical School.

Allison Aiello, Ph.D., is the James S. Jackson Healthy Longevity Professor of Epidemiology at the Mailman School of Public Health and the Robert N. Butler Columbia Aging Center, where she leads a new program in Biosocial Science of Aging and Health Equity. Previously, Dr. Aiello led the Social Epidemiology Program as Professor of Epidemiology at the Gillings School of Global Public Health and became the Deputy Director of the National Longitudinal Study of Adolescent to Adult Health (Add Health) in 2021. She was awarded the 2019 Carol Rowland Hogue Award for Outstanding Mid-Career Achievement in Epidemiology from the Society for Epidemiological Research for her achievements. Dr. Aiello's research focuses on identifying the processes by which health inequities in aging emerge across the life course, with the goal of uncovering points of intervention. Her research program has focused on some of today's most pressing and complex health exposures and conditions, including socioeconomic inequalities, biological aging, Alzheimer's disease, immunity, and susceptibility to infectious diseases. She received her Ph.D. in epidemiology from Columbia University with distinction and was awarded the Anna C. Gelman Award for outstanding achievement and promise in epidemiology.

Efrén J. Flores, M.D., is an Associate Professor at Harvard Medical School and serves as faculty in Thoracic Imaging at Massachusetts General Hospital (MGH), where completed his Diagnostic Radiology residency and fellowship. Dr. Flores is a nationally recognized health services researcher focused on understanding health disparities and advancing health equity among historically underserved racial and ethnic minority communities. He has served in several leadership roles at MGH, including his current role as Vice-Chair for Radiology Diversity Equity, and Inclusion (DEI), and as the founding Director of the Radiology Inclusion and Systemic Equity (RISE) Center. Dr. Flores is recognized as a national thought leader in health disparities research as evidenced by numerous awarded grants, invited presentations

nationally, and peer-reviewed publications. His health equity work is guided by the overarching goal of fostering trust and a sense of belonging. In recognition for his work, Dr. Flores was selected as one of the inaugural NAM Scholars in Diagnostic Excellence in 2021, and he currently serves on several institutional and national committees, including as Co-Chair of the Health Equity Committee for the Radiological Society of North America and as Associate Editor of Health Equity for the Journal of the American College of Radiology.

Carmen Guerra, M.D., M.S.C.E., is the Ruth C. and Raymond G. Perelman Professor of Medicine at the Perelman School of Medicine at the University of Pennsylvania. She is also the Vice Chair of Diversity and Inclusion for the Department of Medicine, and the Associate Director of Diversity and Outreach for the Abramson Cancer Center (ACC) where she leads Community Outreach and Engagement, including a Genentech-funded Cancer Clinical Trials Ambassador Program that promotes clinical trial awareness through peer-to-peer education. A general internist trained in epidemiology and a health equity researcher, Dr. Guerra has designed and evaluated interventions to increase access to cancer screening and cancer clinical trials for underserved populations. Dr. Guerra serves on the American Cancer Society's Guideline Development Group and is an author of the American Cancer Society's current colorectal, cervical, and lung cancer screening guidelines as well as the current HPV vaccination guidelines. In recognition of her contributions, Dr. Guerra received the American Cancer Society's St. George Medal in 2017, the Association of Community Cancer Centers Research Award in 2022, and the American Society of Clinical Oncology Excellence in Health Equity Award in 2023. She is also a member of the advisory board of Guardant Health, a company developing blood tests for colorectal cancer, and is the US Deputy Chair of the Health Equity Workgroup of the Multicancer Early Detection Consortium.

Elizabeth Heitman, Ph.D., is Professor in the Program in Ethics in Science and Medicine and Department of Psychiatry at the University of Texas Southwestern Medical Center in Dallas, Texas. Her work focuses on cultural aspects of ethics in clinical medicine, biomedical science, and public health, particularly international standards of research ethics and education in the responsible conduct of research (RCR). Dr. Heitman teaches research ethics and RCR across UT Southwestern through the Center for Translational Medicine and Graduate School of Biomedical Sciences, and she leads ethics education for two NIH training grants on cardiovascular health disparities, Obesity Health Disparities PRIDE and the Jackson Heart Study Graduate Training and Education Center at the University of Mississippi Medical Center. Dr. Heitman co-directs a Fogarty International Center-sponsored research ethics education program with Eduardo Mondlane University in Mozambique and is an advisory committee member for similar programs in Colombia and the Caribbean. She is a National Associate of the US National Research Council and has been chair or member of eight US National Academy of Sciences programs in research integrity education in the Middle East, North Africa, Indonesia, and Malaysia. In 2015-16 she co-chaired the NASEM Committee on Gene Drive Research with Non-Human Organisms.

Matthew F. Hudson, Ph.D., M.P.H., is the Director of Cancer Care Delivery Research (CCDR) at Prisma Health (Greenville, South Carolina), and Professor of Medicine at the University of South Carolina School of Medicine Greenville. Dr. Hudson conducts and oversees research on patient, provider, and organization-based interventions improving cancer care outcomes and patient well-being. Dr. Hudson served on multiple National Institute of Minority Health and Health Disparities study sections designed to augment workforce diversity. Dr. Hudson's own research examines racial differences in pain reports and management experiences among patients with cancer. Dr. Hudson served the Patient Centered Outcomes Research Institute (PCORI) as a member of their Patient Engagement Advisory Panel; he also

co-authored the PCORI report, Equity and Inclusion Guiding Engagement Principles. Dr. Hudson received his Ph.D. from Dartmouth College, M.P.H. from the University of California at Berkeley, and B.A. from the University of San Francisco. Dr. Hudson also received a certificate from the National Cancer Institute's Multilevel Intervention Training Institute (MLTI), and subsequently served MLTI as a small group junior faculty member.

Husseini K. Manji, M.D., is Co-chair of the UK Mental Health Mission and a visiting professor at Oxford University. Previously, Dr. Manji was Global Head of Science for Minds at Johnson & Johnson (J&J), where he led a global team to discover and develop new therapeutics for major neurologic, psychiatric, and pain-related diseases with a high unmet need for effective treatments. Dr. Manji's research has helped to conceptualize severe neuropsychiatric disorders as genetically influenced disorders of synaptic and neural plasticity and led to the investigation of key novel therapeutics. The major focus of his research has been the investigation of disease- and treatment-induced changes in gene and protein networks that regulate synaptic and neural plasticity in brain and behavior disorders. Before joining J&J, Dr. Manji was Director of the Mood and Anxiety Disorders Program, the largest research program of its kind in the world, at the National Institute of Mental Health. His work led to approval of the first novel antidepressant mechanism in decades, SPRAVATO (esketamine) nasal spray for adults with treatment-resistant major depressive disorder, by the U.S. Food and Drug Administration, Canada, and the European Commission. Dr. Manji is a member of the National Academy of Medicine. He also serves on the scientific advisory boards of the Dana Foundation and of Vanna Health.

Amy Moran-Thomas, Ph.D., is Associate Professor of Anthropology at the Massachusetts Institute of Technology and a faculty member in the program in History, Anthropology, and STS (Science, Technology, and Society). She is interested in how social perspectives on design can contribute to producing more equitable technologies. Her work combines insights from ethnographies of science and medicine; material histories of design; and STS perspectives on health and environment. Her essays helped draw attention to longstanding racial biases encoded in color-sensing medical devices and catalyzed clinical reexaminations of the pulse oximeter, including recent FDA hearings that led to new safety advisories. Prof. Moran-Thomas' writings have appeared in publications such as New England Journal of Medicine and Wired. Her first book, Traveling with Sugar: Chronicles of a Global Epidemic (2019), offers an anthropological account of diabetes technologies in use and the lives they shape in global perspective. Research and writing were supported by the Mellon-American Council of Learned Societies (ACLS), the Wenner-Gren Foundation, and the Rachel Carson Center for Environment and Society and received five book awards, including the Wellcome Foundation's Medal for Anthropology as Applied to Medical Problems. Professor Moran-Thomas received her Ph.D. in Anthropology from Princeton University in 2012.

Margaret Moss, Ph.D., J.D., RN, is an enrolled member of the Mandan, Hidatsa, and Arikara Nation in North Dakota. She is currently Professor and Associate Dean for Nursing and Health Policy at the University of Minnesota, School of Nursing. She holds both Nursing and Juris Doctorates. She has been a nurse for 34 years and an academic for 23 years across four universities. Previously at the University of British Columbia (UBC), she was a Professor in the Faculty of Applied Science, School of Nursing (20%) and Director of the UBC First Nations House of Learning (80%). During this time, she served as Interim Associate Vice President Equity & Inclusion at UBC (2022). Dr. Moss sat on the American Academy of Nursing Board of Directors in 2021-2023, is a new member of the National Academy of Medicine (2022) and is a member of the National Academies Board on Population and Public Health. Dr. Moss was a

committee member on the recent consensus report (2023) *Federal Policy to Advance Racial, Ethnic and Tribal Health Equity*. She wrote an award-winning text, *American Indian Health and Nursing* (2015) followed by *Health Equity and Nursing* (2020). She co-led the development and launch of the *UBC Indigenous Strategic Plan* (2020) and was a consultant on the *In Plain Sight Report: Addressing Anti-Indigenous Racism in Healthcare in BC* for the Minister of Health (2020). Dr. Moss was named an Inaugural member of the *Forbes 50 over 50 Impact list 2021.* She was a RWJF Health Policy Fellow, staffing the US Senate Special Committee on Aging, and was a Fulbright Chair at McGill University-Montreal, QC, Canada.

Elizabeth O. Ofili, M.D., M.P.H., is a Professor of Medicine at Morehouse School of Medicine and a practicing cardiologist with Morehouse Healthcare in Atlanta, Georgia. She serves as Chief Medical Officer for Morehouse Choice Accountable Care Organization, a Center for Medicare and Medicaid Services Shared Savings Program, which includes Federally Qualified Health Centers across the state of Georgia. Dr. Ofili is a nationally and internationally recognized clinician scientist with particular focus on cardiovascular disparities and women's health. In 2002, as president of the Association of Black Cardiologists (ABC), she led the initiative to implement the landmark African American Heart Failure Trial (AHEFT), whose findings changed practice guidelines for the treatment of heart failure in African Americans. Dr. Ofili is the Founder and Chief Executive Officer of AccuHealth Technologies Inc./Health 360x™ a patient-centered platform for population health management and clinical trial diversity. Dr. Ofili is the immediate past Chair of the Board of the Association of Black Cardiologists. She serves as Chair of the Board of Directors of Alliant Health Group, a nonprofit Quality Improvement Organization. Dr. Ofili is a principal investigator (PI) in the National Research Mentoring Network and contact PI of the Coordination and Evaluation Center for the NIH Faculty Institutional Recruitment for Sustainable Transformation (FIRST) Program for Inclusive Excellence. She serves as PI of the Amgen-sponsored African American Heart Study, multi-PI of the Georgia Clinical and Translational Science Alliance, and contact PI of the Research Centers in Minority Institutions Coordinating Center. She serves in advisory roles for Amgen's Rise program and the Bristol-Meyers-Squib-Pfizer alliance initiative. Dr. Ofili has received many awards for her contributions and is an elected member of the National Academy of Medicine. Dr. Ofili graduated with distinction from Ahmadu Bello University School of Medicine in Nigeria and received an M.P.H from Johns Hopkins University.

Neil R. Powe, M.D., M.P.H., M.B.A., is Chief of Medicine at the Priscilla Chan and Mark Zuckerberg San Francisco General Hospital and the Constance B. Wofsy Distinguished Professor at the University of California, San Francisco. He also serves as the Chief Science Officer for the Commonwealth Fund. Dr. Powe led the National Kidney Foundation-American Society of Nephrology Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Diseases that led to elimination of race from estimation of kidney function. As member and now chair of the Journal of the American Medical Association Oversight Committee, he provided important decision making regarding a podcast on structural racism. Dr. Powe is a member of the National Academy of Medicine and has served on previous National Academies consensus study committees. Among his honors are the Herbert W. Nickens Award for Promoting Justice in Medical Education and Health Care Equity from the Association of American Medical Colleges, the Diversity Award from the Association of Professors of Medicine, the John M. Eisenberg Award for Career Achievement in Research and the Robert J. Glaser Award from the Society of General Internal Medicine, the David Hume Memorial Award from the National Kidney Foundation, the 2021 John Phillips Memorial Award for Distinguished Contributions in Clinical Medicine from the American College of

Physicians, and the Cato Laurencin Lifetime Research Award from the National Medical Association. Dr. Powe holds an M.D. and M.P.H from Harvard, and at the University of Pennsylvania, he completed residency, was a Robert Wood Johnson Clinical Scholar, and earned an M.B.A.

Aliya Saperstein, Ph.D., is the Benjamin Scott Crocker Professor in human biology and a professor of sociology at Stanford University. Her research focuses on the conceptualization and measurement of race/ethnicity and the consequences of these methodological decisions for studies of stratification and health disparities, including in the field of precision medicine research. Her work has been published in *Science*, the *Proceedings of the National Academy of Sciences*, *American Journal of Sociology*, *and* the *Annual Review of Sociology,* among others*.* Dr. Saperstein has been a Visiting Scholar at Sciences Po and the Russell Sage Foundation. Her scholarship has been honored with multiple articles awards as well as the Early Achievement Award from the Population Association of America. Saperstein has a Ph.D. in sociology and demography from the University of California-Berkeley.

Roland J. Thorpe, Jr., Ph.D., is a Professor in the Department of Health, Behavior, and Society, Founding Director of the Program of Men's Health Research in the Hopkins Center for Health Disparities Solutions, and Director of the Johns Hopkins Alzheimer's Disease Resource Center for Minority Aging Research at the Johns Hopkins Bloomberg School of Public Health. Dr. Thorpe is a social epidemiologist and gerontologist whose research focuses on how social determinants of health impact health and functional outcomes among men across the life course. Dr. Thorpe serves as principal investigator (PI) on several NIH-funded grants and is a multiple PI of the Artificial Intelligence/Machine Learning consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD). Dr. Thorpe is the inaugural Associate Vice Provost for Faculty Diversity at Johns Hopkins University. He is a Fellow of the Gerontological Society of America and the Academy of Behavioral Medicine Research. Dr. Thorpe earned a bachelor's in theoretical mathematics from Florida A&M University, a master's in statistics, and a Ph.D. in clinical epidemiology with a graduate minor in gerontology from Purdue University. He received postdoctoral training in health disparities and gerontology from the Division of Geriatric Medicine and Gerontology at the Johns Hopkins School of Medicine. Dr. Thorpe is a member of scientific advisory boards, including the National Center for Health Statistics Board of Scientific Counselors, and is the editor-in-chief of *Ethnicity & Disease*.

Shyam Visweswaran, M.D., Ph.D., is a professor and Vice Chair of Clinical Informatics in the Department of Biomedical Informatics at the University of Pittsburgh. His research broadly focuses on computerized clinical decision support driven by machine learning; patient-specific modeling, in which statistical models are tailored to the characteristics of the patient at hand and optimized to perform well for that patient; and the development of statistical machine learning methods for causal discovery using electronic health record data, molecular data, or both. His current research focuses on cataloging clinical algorithms that incorporate a person's race and ethnicity and developing computational methods for understanding the effect of race and ethnicity on model bias. He holds an M.B., B.S. degree (M.D. equivalent) from the Jawaharlal Institute of Post-Graduate Medical Education and Research in Pondicherry, India, an M.S. degree in Physiology and Biophysics from the University of Illinois at Urbana-Champaign, and a Ph.D. in Intelligent Systems (artificial intelligence) from the University of Pittsburgh. He completed his neurology residency at Boston University.

Genevieve L. Wojcik, Ph.D., is an Assistant Professor of Epidemiology at the Johns Hopkins Bloomberg School of Public Health. As a statistical geneticist and genetic epidemiologist, her research focuses on

method development for diverse populations, specifically understanding the role of genetic ancestry and environment in genetic risk in admixed populations. Dr. Wojcik integrates epidemiology with statistical and population genetics to better understand existing health disparities in minority populations, as well as underserved populations globally. In 2021, she was the recipient of one of NHGRI's Genomic Innovator Awards (R35). She is a long-standing member of multiple NHGRI consortia focused on diverse populations, such as the Population Architecture using Genomics and Epidemiology (PAGE) Study and the PRIMED consortium. Prior to her faculty appointment, Dr. Wojcik was a postdoctoral research scholar at Stanford University in the Departments of Genetics and Biomedical Data Science. She received her Ph.D. in Epidemiology and M.H.S. in Human Genetics/Genetic Epidemiology from the Johns Hopkins Bloomberg School of Public Health and her B.A. in Biology from Cornell University. She was recently a member of the National Academies Committee on the Use of Race, Ethnicity, and Ancestry as Population Descriptors in Genomics Research, which published its report in 2023.

Ruqaiijah Yearby, J.D., M.P.H., is the inaugural Kara J. Trott Professor in Health Law at the Moritz College of Law, Professor in the Department of Health Services Management and Policy at the College of Public Health, and a faculty affiliate of the Kirwan Institute for the Study of Race and Ethnicity at The Ohio State University. An expert in health policy and civil rights, Professor Yearby has received over $5 million from the National Institutes of Health (NIH) to study structural racism and discrimination in vaccine allocation and from the Robert Wood Johnson Foundation to study the equitable enforcement of housing laws and structural racism in health care. She was a keynote speaker for the 5th Annual Conference of the ELSI Congress and has served as a reviewer for NIH, the Swiss National Science Foundation, and the Wellcome Trust. Yearby is on the editorial board of the American Journal of Bioethics and is a Committee Member for the U.S. Department of Health and Human Services, Secretary's Advisory Committee on Human Research Protections. Her work has been published in the American Journal of Bioethics, American Journal of Public Health, Health Affairs, and the Oxford Journal of Law and the Biosciences.

Public Session Information

Community Perspective on the Use of Race and Ethnicity in Biomedical Research

March 14th, 2024

Speaker Biographies

Donald Adams, Jr., M.Ed., is the assistant director of design innovation for the University of Illinois System, Office of Medicaid Innovation. Before he began his current role, he led the workforce learning and development team for the Provider Assistance and Training Hub (PATH) Program at the University of Illinois School of Social Work. Adams has over 20 years of instructional design, teaching, training, and learning and development experience, providing and overseeing workforce learning and development solutions for state and nonprofit agencies. Adams is one of 14 research ministry ambassador facilitators IRB certified and trained by and under the authority of Pastors4PCOR, a collaborative of researchers, churches and health professionals in the South Side and South Suburbs of Chicago. As a member of a research engagement team, Adams engages and trains faith-based community members in developing skills to survey their communities for health and well-being topics for research. Adams believes in and supports PCORI's vision that "patients and the public have information they can use to make informed decisions that reflect their desired health outcomes." Adams believes engagement and involvement in the health research ministry allows advocacy opportunities. Adams holds a master's degree in education, concentrating in curriculum and instruction from the National College of Education, National Louis University; and an advanced certificate in online teaching, a nationally recognized Blackboard Exemplary Course Program from Governors State University.

Audie Atole, M.L.S., is a Conservation Officer at the Jicarilla Apache Nation. He received his Master's in Indigenous Peoples Law, where he developed a strong foundation in Native American Law for non-lawyers who deal with contracts, negotiations or any other issues that demand knowledge of Native American policy, regulation, or business practice. As a Conservation Officer, he is tasked to patrol the lands and waters of his state day and night. In addition to enforcement, the conservation officer educates the public about wildlife and wildlife management, conducts wildlife surveys, captures "problem animals," investigates wildlife damage to crops and property, assists in wildlife relocations and helps to develop new regulations.

Ella Greene-Moton is the President of the American Public Health Association. Ella Greene-Moton has an extensive background in Public Health Advocacy, Public Health Policy, Community-Based Participatory Research (CBPR), and programming, spanning over the past forty plus (40+) years in the City of Flint and surrounding areas. In addition, specific efforts in public health ethics have focused on providing an awareness at the community level,

developing, and elevating the community voice and advocating for community inclusiveness at the State and National Levels. Her areas of expertise include facilitating community /academic/practice partnership building and sustainability; developing, managing, and evaluating community-based projects; and training programs for graduate students, community members, as well as middle and high school students partnering with community-based organizations, schools, and public health agencies. Ella joined the Flint Odyssey House, Inc. Health Awareness Center in 1995 and served as its Assistant Director from 1998-2005. She served from 2006-2019 as a Community Education Coordinator and "Bridge" at the Center for Public Health and Community Genomics, at the School of Public Health – University of Michigan - Ann Arbor. She currently serves as the Community Based Organization Partners (CBOP) Community Ethics Review Board (CERB) Administrator and the Executive Consultant and Co-Chair of the Flint/Genesee Partnership, Health in Our Hands project. She also serves as an Independent Community-Academic Consultant working with other academic institutions nationally that are engaged in Community Based Participatory Research (CBPR) with their local communities. On the State, regional, and national levels, Ella is a member of the Michigan Public Health Association, the immediate past Affiliate Representative to the Governing Council of the American Public Health Association, and member of the Great Lakes Public Health Coalition.

Monica Webb Hooper, Ph.D., is Deputy Director of the National Institute on Minority Health and Health Disparities (NIMHD). She works closely with the Director, Dr. Pérez-Stable, and the leadership, to oversee all aspects of the institute and to support the implementation of the science visioning recommendations to improve minority health, reduce health disparities, and promote health equity. Dr. Webb Hooper is an internationally recognized translational behavioral scientist and clinical health psychologist. She has dedicated her career to the scientific study of minority health and racial/ethnic disparities, focusing on chronic illness prevention and health behavior change. Her program of community engaged research focuses on understanding multilevel factors and biopsychosocial mechanisms underlying modifiable risk factors, such as tobacco use and stress processes, and the development of community responsive and culturally specific interventions. Her goal is to contribute to the body of scientific knowledge and disseminate findings into communities with high need. Before joining NIMHD, Dr. Webb Hooper was a Professor of Oncology, Family Medicine & Community Health and Psychological Sciences at Case Western Reserve University. She was also Associate Director for Cancer Disparities Research and Director of the Office of Cancer Disparities Research in the Case Comprehensive Cancer Center. Dr. Webb Hooper completed her doctorate in clinical psychology from the University of South Florida, internship in medical psychology from the University of Florida Health Sciences Center, and her Bachelor of Science from the University of Miami.

Sela Panapasa, Ph.D., is an Associate Research Scientist at the University of Michigan. Sela conducts research that examines the role socio-demographic change plays in the health and well-being of island populations across the life course. In her early research she studied family

support and intergenerational exchanges among aged Pacific Islanders living in the US and Pacific region. These works examined change among elderly living arrangements and headship status as a response to demographic and socioeconomic shifts from modernization and development. Her current research will establish baseline information to address and eliminate health disparities among Native Hawaiian other Pacific Islanders living in the United States (funded by the National Cancer Institute and National Center for Minority Health and Health Disparities). She is also reviewing the quality of health data resources in the US Territories (funded by the US Department of Interior) and working with these governments to improve the use of these data to measure disease processes and health concerns. Her interests include family demography, race, and ethnicity, measuring health disparities and comparative studies.

Eliseo J. Pérez-Stable, M.D., is Director of the National Institute on Minority Health and Health Disparities (NIMHD) and Principal Investigator in the National Heart, Lung, and Blood Institute at the National Institutes of Health (NIH). Dr. Pérez-Stable's research interests have centered on improving the health of racial/ethnic minorities and underserved populations, advancing patient-centered care, improving cross-cultural communication skills among health care professionals, and promoting diversity in the biomedical research workforce. Recognized as a leader in Latino health care and disparities research, Dr. Pérez-Stable has spent more than 30 years leading research on smoking cessation and tobacco control policy in Latino populations in the United States and Latin America.

Jamil Rivers is the Founder of the Chrysalis Initiative. The Chrysalis Initiative was born from Jamil's experiences offering guidance to women on how to thrive with breast cancer, even as she was actively receiving chemo herself. At only 39 years old, Jamil was diagnosed with metastatic breast cancer de novo. The determination to fight and survive for her family launched her into vigorous research to understand and contend with breast cancer. The extensive research Jamil undertook along her own journey became the foundation of a lifelong commitment to exploring and enacting optimal and comprehensive breast cancer care. Jamil went on to participate in numerous community health events which facilitated the design and funding of two metastatic clinical trials. This afforded her the opportunity to meet with leadership within the PA governor's office and congressional leaders in D.C. She became an advocate, using her knowledge base and experiences to help advance legislative policy, medical research, and customize support to better meet the needs of individuals who have breast cancer (particularly metastatic), Black patients and other disparate groups. Jamil is Board President of METAvivor Research and Support, Inc. She is a Young Advocate Alum, Board Member of Living Beyond Breast Cancer and Advisory Chair of the Knowledge is Power: Understanding Black Breast Cancer series. She is a policy science and health equity advocate and metastatic advisory committee member with Susan G. Komen.

Mrs. Danurys (Didi) Sanchez, M.S., is currently a Senior Research Staff Associate at the Taub Institute for Research on Alzheimer's Disease and the Aging Brain at Columbia University Irving Medical Center. For the past fifteen years, she has been the Project Manager of a longitudinal

study on memory and aging, the Washington Heights-Hamilton Heights-Inwood Columbia Aging Project (WHICAP), a community-based longitudinal study of aging and dementia which began enrolling patients in 1989 and has followed more than 8,000 older adults residing in Northern Manhattan, NYC. Didi has led initiatives to engage the Spanish-speaking and African American community in Alzheimer's Disease research, dissemination, and education on brain health. As she became more involved in community education, her focus shifted to the limited knowledge of value-based advance care planning and barriers and access to end-of-life care throughout the target communities. After working for more than two decades as a Project Research Manager, Danurys saw a need for establishing an organization that centered community-led approach to building and fostering equitable relationships between medical and research institutions and community stakeholders. Communities for Responsible Bioethics, LLC, was founded in March 2021 to increase knowledge of how bioethical principles impact end-of-life decision-making and can guide communities to shape initiatives that have the possibility of improving their clinical standard of care and overall well-being. Earlier this year, Didi graduated from the master's program in Bioethics at Columbia University's School of Professional Studies and endeavors to improve communication on end-of-life decision-making between physicians and patients through an ethical framework based on trust, professionalism, and compassion.

Gladys Vega is the Chief Executive Officer off La Colaborativa. Gladys Vega has dedicated more than three decades of service to the City of Chelsea and La Colaborativa, which she joined in 1990 – just two years after its founding. Gladys was born in Puerto Rico and came to Chelsea with her family at the age of nine. Since that time, she has made a lifelong commitment to the community in which she was raised. Being a mother of two has deepened her commitment to building a better future for families throughout the region. During her tenure at La Colaborativa, Gladys has assumed increasing levels of responsibility with each passing year, as she moved from receptionist to community organizer to Assistant Executive Director and ultimately Executive Director. She has led La Colaborativa in the Executive Director role since 2006. Gladys is a groundbreaking community organizer and advocate, working relentlessly and fearlessly to ensure the Latinx immigrant community has a voice in determining how it's needs and concerns are addressed. She believes that empowerment of the individual leads to empowerment of the community and that social action is the vehicle an empowered community can use to achieve its goals. Gladys is the architect of nearly all La Colaborativa's programs, initiatives, and community organizing campaigns. Her leadership has resulted in expanded rights for immigrants, low-income families, tenants, workers, youths, and people of color across Massachusetts. Gladys is recognized as one of the region's most prominent and important community leaders, receiving citywide, statewide, and national accolades for her leadership. When the COVID-19 pandemic created overlapping public health, unemployment, housing, and hunger crises in Chelsea and surrounding areas, Gladys's leadership positioned La Colaborativa at the forefront of state and local efforts to meet the tremendous needs of Latinx residents across Massachusetts. Her advocacy earned national coverage from the Atlantic Monthly, as well as local coverage in The Boston Globe, CBSN Boston and others.

Committee on the Use of Race and Ethnicity in Biomedical Research

March 14, 2024
2:00 PM – 4:30 PM ET

Speaker Guidance
Community Perspectives on the Use of Race and Ethnicity in Biomedical Research

BACKGROUND AND CONTEXT

As part of the information gathering phase of their work, the Committee on the Use of Race and Ethnicity in Biomedical Research would like to learn more about community perspectives on the use of race and ethnicity in biomedical research.

COMMUNITY PERSPECTIVES ON THE USE OF RACE AND ETHNICITY DATA IN HEALTH RESEARCH

Session Objectives

- Understand experiences from community groups about the collection and use of race and ethnicity data during different phases of community-based participatory research, including:
    - learning about the research goals, building partnerships, designing the study, participating in research, and learning about the results and benefits to the community.
- Learn from community members and research participants about current research practices involving race and ethnicity that should be continued, stopped, or modified.
- Listen to what changes related to the use of race and ethnicity in research community members may want to see and discuss possible ways to implement those changes in biomedical research practices.

Questions for community members and research participants:

1. Describe your experience with the collection and use of race and ethnicity information in biomedical research. In your experience, how have you seen race and

ethnicity being *collected and used* in biomedical research?

2. Is your race and ethnicity being captured in the way that you think it should be? Do the categories offered as options reflect you as an individual? Does using race or ethnicity improve the research?
3. Do you have concerns about the way race and ethnicity is captured and used? If so, what are those concerns? Do those concerns cause you to think differently about participating in research?
4. How could researchers capture intersectionality, or intersectional identities, better?
5. What do you think a clinician or researcher wants to know when they ask you your race and ethnicity? What do they think the information would be used for? Does that motivate you to participate or not?
6. What do you think about transparency of the data researchers are collecting and what it will be used for? Would you want to know how race and ethnicity inform biomedical research? Are you curious about who will have access to your data?
7. What would you like your researcher to know about your community?
8. What are the gaps between researchers and community participants on this issue? What can be done to reduce that gap?
9. What would you like to see from the committee in terms of recommendations? What could be the impact of those recommendations?

Questions for researchers:

1. What is the motivation for using race and ethnicity in health research? Does collecting race and ethnicity data improve the research or health outcomes?
2. What are the gaps between researchers and community participants on this issue? What can be done to reduce that gap?
3. How could social or political biases affect the research process of your study?
4. What are ways that researchers could improve questionnaires that participants fill out related to their race and ethnicity?

Background Materials

Links to Additional Resources

Community Perspectives on the Use of Race and Ethnicity:

- Borthwick et al. (2023). How should communities be meaningfully engaged (if at all) when setting priorities for biomedical research? Perspectives from the biomedical research community https://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-022-00879-5
  (Please see page 25 for article)

- Galinsky et al. (2019) Surveying Strategies for Hard-to-Survey Populations: Lessons From the Native Hawaiian and Pacific Islander National Health Interview Survey https://pubmed.ncbi.nlm.nih.gov/31415207/

- Gilmore-Bykovskyi et al. (2022). Traversing the Aging Research and Health Equity Divide: Toward Intersectional Frameworks of Research Justice and Participation https://pubmed.ncbi.nlm.nih.gov/34324633/

- Lee (2023). Reliability and Validity of Self-Reported Vascular Risk Factors: Hypertension, Diabetes, and Heart Disease, in a Multi-Ethnic Community Based Study of Aging and Dementia https://pubmed.ncbi.nlm.nih.gov/37483004/

- Lett et al. (2022). Health Equity Tourism: Ravaging the Justice Landscape https://pubmed.ncbi.nlm.nih.gov/35150324/

- Odedina et al. (2023). Building healthy populations one community at a time https://pubmed.ncbi.nlm.nih.gov/37464033/
  (Please see page 40 for article)

- Panapasa et al. (2014). Community-Based Participatory Research Approach to Evidence-Based Research: Lessons from the Pacific Islander American Health Study https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4156312/

- PCORI Engagement Resources https://www.pcori.org/engagement/engagement-resources

- Jamil Rivers: The Chrysalis Initiative https://thechrysalisinitiative.org/

BMC Medical Ethics

RESEARCH

Open Access

How should communities be meaningfully engaged (if at all) when setting priorities for biomedical research? Perspectives from the biomedical research community

Josephine Borthwick[1,3], Natalia Evertsz[2] and Bridget Pratt[3,4*]

Abstract

Background There is now rising consensus that community engagement is ethically and scientifically essential for all types of health research. Yet debate continues about the moral aims, methods and appropriate timing in the research cycle for community engagement to occur, and whether the answer should vary between different types of health research. Co-design and collaborative partnership approaches that involve engagement during priority-setting, for example, are common in many forms of applied health research but are not regular practice in biomedical research. In this study, we empirically examine the normative question: should communities be engaged when setting priorities for biomedical research projects, and, if so, how and for what purpose?

Methods We conducted in-depth interviews with 31 members of the biomedical research community from the UK, Australia, and African countries who had engaged communities in their work. Interview data were thematically analysed.

Results Our study shows that biomedical researchers and community engagement experts strongly support engagement in biomedical research priority-setting, except under certain circumstances where it may be harmful to communities. However, they gave two distinct responses on what ethical purpose it should serve—either empowerment or instrumental goals—and their perspectives on how it should achieve those goals also varied. Three engagement approaches were suggested: community-initiated, synergistic, and consultative. Pre-engagement essentials and barriers to meaningful engagement in biomedical research priority-setting are also reported.

Conclusions This study offers initial evidence that meaningful engagement in priority-setting should *potentially* be defined slightly differently for biomedical research relative to certain types of applied health research and that engagement practice in biomedical research should not be dominated by instrumental goals and approaches, as is presently the case.

Keywords Ethics, Priority-setting, Engagement, Participation, Patient and public involvement, Biomedical research, Genomics research

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Introduction

Community engagement is a core feature of participatory health research, and there is growing agreement that it is essential for all health research, from biomedical to applied forms [1]. As Nunn et al. affirm, it is estimated that by 2025, nearly two billion people worldwide will have had their DNA sequenced and this creates a global imperative for engagement in genomic research [2]. Community engagement is now encouraged, or even mandated, as a key element of all health research, including 'traditional' non-participatory health research, by research institutions and funding bodies [3–5]. For example, it was a required component of applications to the second and final round of funding for the H3Africa Consortium, which supports genomics research in Africa [6]. Many high-profile genomics research initiatives have made public statements about the importance of involving the community [2]. Community engagement is also increasingly required by international biomedical research ethics guidelines [5–7].

Arguments have been made that it is *ethically* essential to undertake some form of engagement in health research because it is central to showing respect for communities and the traditions and norms that they share, increases the chances that research will improve health outcomes, builds public trust, enhances prospects for justice, and facilitates better stewardship of resources [1]. Where engagement is undertaken as shared decision-making throughout the research process, it facilitates self-determination because those who are significantly affected by the selection of health research priorities and the translation of the evidence generated by their investigation are included in discussions and decision-making about them [8]. Such engagement also promotes cognitive and epistemic justice and maximizes the social knowledge generated to identify and solve complex problems that impede health and well-being [8]. It is seen as a key means to ensure that research projects ask the 'right' questions—namely, those that are responsive to urgent community-identified needs—and create 'better' knowledge that uses and reflects a diversity of knowledge systems and is shared beyond peer-reviewed journals and academic conferences [9].

Yet debate continues about when, how, and for what purpose engagement should be performed in health research, and whether the answer should vary between different types of health research. Several types of ethical goals have been attributed to community engagement in health research: instrumental, intrinsic, and transformative. Engagement can advance intrinsic goals like building a sense of inclusion or demonstrating respect [3]. Engagement activities can further purely instrumental goals such as facilitating smooth research operations, augmenting the efficiency of study recruitment, or gaining community 'buy-in' [4, 10]. It also has "the potential to redress past harms; compensate for or resolve existing differences in power, privilege, and positionality; [and] allow for marginalized voices and experiences to be represented in the production of scientific knowledge" [4, p. 257].

Who is engaged can vary considerably based on how the "community" is defined. A community can be defined based on geography; shared experiences, characteristics, or ethnicity; or special interests or goals [3]. In health research, communities are often related to the nature of the research activity, e.g., the geographical area or illness group a given study involves. Engagement activities then frequently include patients, carers, and/or the broader public. However, depending on how the relevant community is defined, ministries of health, ethics committees, policymakers, international organizations, the media, and universities may be engaged as well [3].

What constitutes community engagement in health research practice also varies dramatically along a spectrum from shallow and tokenistic engagement to deeper and more meaningful engagement. Engagement takes different forms, ranging from raising community awareness of research projects, to consultation on certain parts of research projects, to community representation throughout the entire research cycle, to long-term and authentic partnerships [11]. Where these forms of engagement fall on the spectrum largely relates to the *stage of the research cycle* at which engagement occurs, and the *level of participation* they afford to those engaged. Goulet contends that the earlier 'non-elites' enter the process, the higher the quality of their participation. In the health research project context, this means entry during grant writing and priority-setting comprises deeper participation than, for instance, when communities enter during data collection or analysis [12].

Even so, the quality of communities' participation is not exclusively determined by when they enter into the research process. A range of levels of participation exist, with some more "active, deliberative, and influential" than others [13, 14]. Informing refers to generating awareness and understanding within host communities about what research is and about already defined research projects that are being undertaken with them. The outputs of decision-making in research projects are shared with community members; they do not give their input and are not involved in making the decisions. Consulting is a particularly common form of engagement in health research [3, 15]. Community members are asked to give their input (e.g., feedback, suggestions, critiques) on aspects of research projects but with no guarantee that those who decide will use or

consider the information they provide. There is broad consensus that they can potentially be consulted about a wide variety of health research activities, including protocol development, research conduct, access to data and samples, and the dissemination or publication of research findings [16]. Often, their consultation occurs through specifically established bodies such as community advisory boards.

Collaborative partnership, on the other hand, means involving community members in decision-making throughout health research projects. This is consistent with growing emphasis on practicing engagement in health research as the co-construction of knowledge or co-design. Taking such approaches means researchers jointly construct knowledge with communities: all parties design and conduct research together in ways that achieve the purposes of both sets of actors [17]. Community members are part of assessing what local health problems should be the focus of the research; planning, conducting and overseeing the research; and integrating the research into the health care system [18]. These approaches thus share many similarities with community-based participatory action methodologies. A key point of difference between them and other forms of engagement is the balance of power. Consulting and informing do not entail community members' participation in decision-making, whereas collaboration does.

A key matter to investigate is whether the type of health research is ethically significant in specifying what engagement should entail—namely, when, how, and for what moral purpose engagement should be performed. A spectrum of health research disciplines exists, ranging from basic science, clinical, and genomics research to more applied types like public health, health services, and health policy research. It has been suggested that types of applied health research place a greater emphasis on meaningful engagement with communities [5]. Co-design and participatory action methods are not regular practice in genomics or other types of biomedical research [2]. Questions have been raised by researchers as to whether co-design methods are even possible in biomedical research, which, unlike public health or health services research, requires more specialised and technical knowledge [19]. A scoping review investigating public involvement in human genomics projects found their involvement was highest at the stage of "implementation and management" (19/32), while the stages of engagement with the lowest number of initiatives reporting involvement were "funding" (1/32) and "identifying topics" and "prioritization" (4/32)" [2]. Similarly, a recent realist review showed that the collaborative partnership thread of community engagement is less common in biomedical research. Instead, where engagement with instrumental goals and approaches dominates [20]. Thus, biomedical research potentially seems less suited and/or inclined to adopt more meaningful forms of engagement, but this does not necessarily mean they aren't nonetheless ethically ideal.

This paper investigates what form of community engagement (if any) ideally belongs in biomedical research priority-setting. We empirically examine the question: should communities be engaged when setting priorities for biomedical research projects, and, if so, how and for what purpose? Biomedical research is defined as encompassing *basic science, clinical*, and *genomics* research. Basic science and clinical research have traditionally fallen within the biomedical research category. Over the past few decades, genomics has also become a central and cohesive discipline of biomedical research [21]. Research priority-setting refers to defining the research topic and study questions for individual health research projects or programs. It does not encompass defining a set of global, national, or institutional research topics that should receive priority funding and implementation. This study's focus on priority-setting reflects the moral importance of engagement from the beginning of research projects. Communities' early engagement equates to deeper participation and enhances the responsiveness of research priorities. It means community members are part of making a greater number of decisions about a given study, including those that determine the direction of the entire research project. Without engagement from priority-setting, researchers may ultimately miss the needs deemed of high import and urgency by communities [22]. Research has shown that patients, based on their lived-experience, prioritize different topics than experts [23]. Despite this, in practice, communities concerningly often do not participate in the priority-setting stage of biomedical research projects [2]. Our study's focus, however, is not meant to suggest it is sufficient to engage communities in the priority-setting stage of health research projects alone.

We conducted in-depth interviews with 31 members of the biomedical research community from the UK, Australia, and African countries who had engaged communities in their work. Both genomics and clinical research have become increasingly globalised since the 1990s [24, 25]. As such, the recruitment of interviewees spanned both high-income countries and low- and middle-income countries. African countries were selected to provide a low- and middle-income country perspective due to the growth of clinical and genomics research initiatives requiring community engagement on the continent. The UK and Australia were selected to provide a high-income country perspective because engagement in health research is established in both countries. Since "patient

and public involvement" in health research has been a feature of UK policy for longer and is widely adopted by UK research funders [26], it was also thought that UK interviewees might have different ideas and experiences related to what comprises ideal engagement in biomedical research priority-setting than Australian or African interviewees. We analysed interview data thematically and report four main themes in the paper: the value of engagement, pre-engagement essentials, ideal goals and models of engagement, and barriers to engagement in biomedical research priority-setting. We conclude by considering whether our findings suggest community engagement in priority-setting should occur but look different for biomedical research relative to applied health research, should occur and look the same, or should not occur.

Methods

Study methods and sample

We performed 31 semi-structured interviews with basic science, clinical, and genomics researchers who had engaged communities in their work (27 interviewees) and community engagement experts who were embedded in biomedical research (4 interviewees).In-depth interviews were chosen as the primary method to explore the research question because they allow for the rich details of key informants' experiences and perspectives to be gathered. All procedures were performed in accordance with the National Health and Medical Research Council of Australia's *National Statement on Ethical Conduct of Human Research*.

The sampling strategy used a mix of purposive and snowball methods. To recruit Australian interviewees, we identified potential candidates systematically through a structured search, targeting five universities in Australia with high-calibre biomedical/genomic institutes. We approached sixteen Australian researchers via email and interviewed eight. Five did not respond, and three did not believe their experience to be relevant to the research question. Another three interviewees were identified via snowball sampling.

To identify UK and African interviewees, we initially employed a similar strategy targeting UK and African universities, but it was very difficult to tell from academic profiles in those countries whether individuals had experience with community engagement in biomedical research. Across the UK and Africa, not many academics advertised that they did community engagement. As such, we revised the sampling strategy to target biomedical consortia and institutions that we knew were supportive of and/or funded by entities that require community engagement and that funded/employed UK and African biomedical researchers: the Sanger Institute (UK), the US National Institutes of Health, and the H3Africa Consortium. The Sanger Institute was chosen because its researchers spanned basic science, clinical, and genomics research and it has links to Wellcome Trust, which have funding requirements for community engagement. H3Africa was selected because it is a large consortium of genomics researchers spanning the African continent and its funding made community engagement a required component of applications [6, 27]. The NIH was chosen because its researchers were likely to have done community engagement to secure funding[1] and it was easy to find UK and African scientists through their website. We identified the websites of NIH centres for biomedical research and searched their staff directories for UK and African professors/group leaders. At all three institutions, senior researchers were approached, with the rationale being that they could refer on junior research team members as potential interviewees. In total, we approached 195 UK researchers and interviewed seven. Another thirteen were identified via snowball sampling, of whom three were interviewed. We approached 63 African researchers and interviewed three. Another 24 were identified via snowball sampling, of whom seven were interviewed. The low success rates reflect that many potential interviewees declined due to being overburdened with clinical responsibilities during the Covid-19 pandemic.

Study inclusion and exclusion criteria are described below (Box 1). All interviews were conducted remotely. Sampling continued until no new information emerged and saturation was achieved.

In total, our 31 interviewees came from the UK, Australia, Kenya, South Africa, Malawi, Nigeria, Uganda, and Burkina Faso. Eighteen women and thirteen men were interviewed. Interviewees' work spanned basic science (4), clinical (13) and genomics (17) research. Three interviewees had experience with both clinical and genomics research. Interviews' duration was approximately 40–75 min. 22 interviewees had experience with community engagement in priority-setting. Of those, nine were from Australia, three were from Africa, and ten were from the UK.

Data collection and analysis

We conducted semi-structured interviews according to the technique of *thick description* [28]. Thick description

[1] The NIH is supportive of community engagement overall and has formalised it into their strategy for improving research translation. See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5582944/; https://www.niehs.nih.gov/news/assets/docs_a_e/community_engagement_efforts_at_nih_examining_best_practices_to_bridge_community_and_research_agendas_508.pdf; https://ncats.nih.gov/engagement; https://datascience.nih.gov/community-engagement.

Box 1 Interview inclusion and exclusion criteria

Inclusion criteria
Members of the biomedical research community who have experience with community engagement in their home country and/or overseas contexts
English-speaking
Ability to be interviewed remotely (i.e., Phone call, Zoom, Skype)
Over the age of 18
Exclusion criteria
Researchers or others involved in performing other types of health research
Non-English speaking
Participants who are unable to be interviewed remotely
Under the age of 18

means that questions for interviewees are open-ended and attempt to draw out interviewees' experiences and views. In keeping with in-depth interviewing techniques, explanatory probes (such as asking "why" and "could you tell me more about that") were also used to elicit richer details and clarificatory probes were employed to generate a better understanding of interviewees' comments [29]. The interview guide used in this study is provided in Box 2 below.

Interviews were transcribed verbatim and thematic analysis of interview data was undertaken in the following five phases: initial coding framework creation, coding, intercoder reliability and agreement assessment, coding framework modification, and final coding of entire dataset [30, 31]. Two coders (NE and JB) independently examined six transcripts and identified categories and subcategories. They then developed an initial coding framework together and discussed that framework with BP. Using the initial coding framework, NE and JB next undertook an iterative process of coding a transcript, assessing intercoder reliability and agreement, and modifying the coding framework [30]. Here, a "negotiated agreement approach" was adopted, whereby NE and JB separately coded a transcript, compared their codings, and then discussed their disagreements in an effort to reconcile them and arrive at a final version in which as many discrepancies as possible were resolved [31]. Six transcripts were co-coded. Across the six transcripts, coders ultimately agreed with proposed inclusion/exclusion of codes 100% of the time. Where a coder identified codes that the other had not, agreement to include JB's codes occurred 92% of the time and agreement to exclude occurred 8% of the time, and agreement to include NE's codes occurred 89% of the time and agreement to exclude occurred 11% of the time. During this process, the coding framework was modified, discussed with BP, and finalised. NE then applied the final coding framework to recode the African interviewee transcripts, and JB applied it to recode the UK and Australian interviewee transcripts. All data was coded using NVivo software. From this analysis, four main themes emerged: the value of engagement, pre-engagement essentials, ideal goals and models of engagement, and barriers to engagement in biomedical research priority-setting.

Results

The value of engagement

Most interviewees strongly affirmed there is value for community engagement when determining priorities for biomedical research projects: *"communities should be engaged in the conceptualisation [of research]…at the time of planning, communities at the table bring in their own perspective." – African interviewee (06).* Interviewees described four reasons for why engagement should occur in priority-setting– epistemic value, community ownership, equity, and responsiveness (see Table 1). Interviewees across all geographical contexts (Africa, the UK, Australia) strongly affirmed that the epistemic knowledge held by community members is a critical resource for any priority-setting exercise in biomedical research. According to one UK interviewee (01), *"… the people who have the best knowledge of those problems are the people that live with particular conditions or challenges that the research is trying to benefit."*

Box 2 Interview guide

What kind of biomedical research (basic science, clinical, or genomics) do you do?
Have you have engaged communities in biomedical research agenda setting? Why have you chosen to do so?
Should communities be engaged in biomedical research priority-setting? Why or why not?
What do you think community engagement in should ideally look like in biomedical research priority-setting? Who should be engaged and how?
In your experience, what is important to ensure people can raise their voices equally and be heard when engaging communities in biomedical research priority-setting?
In your experience, what barriers exist relating to meaningfully engaging communities in biomedical research priority-setting?
Is there anything you would like to share about meaningful engagement in biomedical research priority-setting that you haven't already spoken about during the interview?

Table 1 Reasons for community engagement in biomedical research priority-setting

Reason	Example quote
Epistemic value	*"… questions which, because we're not patients we don't think of them in the same way whereas the patients have questions or problems that they think need addressing which we don't necessarily think about from a medical point of view."—UK interviewee (10)* *"I think people with lived experience… I think academics, particularly in things like genomics; we have this interest in following things that are shiny, and kinda cool. Sometimes we may lose sight of the real reason as to why we are undertaking these sorts of activities. I think by having consumer involvement in research design, we can still be aspirational about the outcomes of research. So we can still have our…head in the clouds, but it keeps out feet on the ground and really grounded in lived experience, and the reality of these conditions that we are researching."—Australian interviewee (05)*
Community ownership	*"So they're owning it… if you plan with them and you end up developing what they need, you're not gonna ask them, you're not gonna force them to use it, be it knowledge, it's information or be it a product, it's theirs and they use it."—African interviewee (08)*
Equity	*"…we don't actually engage with consumers and with communities who are supposed to benefit from it from the beginning. And to me it's just another way that equity and inequity kind of slips into our research, that no matter how much we say this research is good and it's gonna benefit people, unless we actually have the people who it's supposed to benefit with onboard at the beginning it's actually going to harm them more than it's gonna help them."—Australian interviewee (05)*
Responsiveness	*"In an ideal world as I said I think it is important that when a researcher decides to come up with their research idea, before actually develops their proposal, they should go to the community to find out whether that research idea will actually translate into solving a health problem that is there."—African interviewee (02)*

However, a minority of interviewees expressed concern about carrying out community engagement during biomedical research priority-setting under specific *unsafe* circumstances. Some interviewees worried that community engagement in particular countries or generally could put individuals from certain patient communities at risk of harm. According to an African interviewee (07),

> *" [I] think the reason why we decided to leave them out it's because homosexuality is illegal in the country, right, it's not accepted and so sometimes if you actually involve such individuals in the [HIV] research study sometimes you put them at risk. The same with sexual, we call them sex workers yeah."*

Where a sub-group within a patient community experiences stigma or a patient community experiences a stigmatised illness, it may be ethically appropriate to instead engage family members, or individuals who are close to them, or to not engage them at all. An interviewee from Africa (07) provided an example,

> *"I've been involved in some psychiatric genomic research as well, we know that psychiatric patients in Africa are completely marginalised right…How do you engaged those people right? Who carriers their voice? Now you can do beautiful community engagement around psychiatric illness, and we've tried right, we've even engaged patients with schizophrenia… but to get them to really help you set research priorities is, is you know what's quite a different kettle of fish and so what often happens is you engage their family members…"*

Interviewees further highlighted that, in other contexts, it may not be culturally safe for communities to engage with researchers. As one Australian interviewee (08) described,

> *"…what I am seeing is this reflex to, really rapid, I would say, quick and dirty relationship being formed, and then expected that a letter of support will be written, without the research being properly discussed with anyone beyond the leadership of a particular organisation. So, what that means is, there has often not been sufficient community consultation".—Australian interviewee (08).*

Where a "loose threads" or tokenistic approach to engagement is taken, there is insufficient planning, inadequate time for engagement, and limited engagement occurs, often random, one-on-one communication. For example, one member of a research team speaks to one person within an Aboriginal organisation. This is not representative of a community and can reinforce unequal power dynamics within a community. Such practices may cause more harm to communities than benefit.

They are often a product of a research economy, where funders require evidence of community engagement, but pay little attention to the depth of engagement. Where there is no funding for community engagement in priority-setting, and/or no requirement (or expectation) from funders to *meaningfully* engage communities when determining research priorities.

Pre-engagement essentials

Interviewees identified two components that comprised *pre-engagement essentials:* defining the community and building foundations. These should be achieved *before* attempting to engage a community in biomedical research priority-setting.

Defining the community

First, defining the community with whom to engage was thought to be essential in biomedical research priority-setting. Interviewees described two overlapping ways of defining the community that are common to biomedical research: *communities of people who live with a certain disease* and *communities defined by geographical boundaries*. The latter was more commonly described by African interviewees and the former by Australian and UK interviewees. Some interviewees also explained that they used geographical boundaries to define a patient community, as some diseases or genomic conditions are more prevalent in certain areas.

Building foundations

Four main types of foundations were thought to be essential to have in place before meaningful engagement can occur in biomedical research priority-setting: environmental, relational, collective and individual (see Table 2). Of these, none were specific to biomedical research relative to health research broadly, with the exception of genomic literacy. Genomic literacy means those engaged have a base level of understanding of genomics concepts and terms. Interviewees believed such literacy is critical to the success of genomics research priority-setting discussions involving community members. In instances where there is not an existing level of genomic literacy, efforts should be made to educate the community.

When the community of interest is defined by geographical boundaries or is marginalised, being embedded in the community is an especially important relational foundation. Identifying and obtaining the support of community gatekeepers (i.e., individuals or groups who have significant influence in the community) is a key first step to build relational foundations with such communities. Gatekeepers can facilitate access to members of geographical communities through different stakeholder groups, including local leaders and community health workers, civil society organisations, local government health committees, and/or community advisory boards. Identifying gatekeepers or community leaders is also important because they may have a *"a bigger understanding of the health needs at a national level, or they can be able to advise what the implications are at, at the national level and if it fits within their planning at that level"—African interviewee (04).*

Ideal goals and models of engagement in biomedical research priority setting

Interviewees described two models of engagement in setting biomedical research priorities that correspond to different ethical goals: *empowerment* and *instrumental*. Interviewees cautioned against tokenistic engagement at all costs. Some interviewees believed that if engagement is not evident from research conceptualisation, it can be tokenistic:

> *"You know, having a fully developed and finalised document that they wave under a community advisory group's nose. That really just doesn't cut it. If it's not involvement from the start, it's tokenistic and it's insulting"—Australian interviewee (05).*

Having empowerment goals means community engagement assists with breaking down power disparities between community members and biomedical researchers. Several interviewees believed the ideal engagement model to achieve this goal is where communities' initiate engagement and set research priorities, as this action can facilitate power sharing in the relationship. According to African interviewee (01), *"An ideal would be the communities reaching out to researchers to tell them what they want researchers to do. It wouldn't be researchers engaging communities about the research researchers want to do."* The interviewee further noted that, while the *community-initiated model* is "ideal", self-aware and mobilising communities are rare.

Other interviewees felt empowerment goals are best furthered when research priorities arise out of synergistic relationships between communities and researchers. The *synergistic model* is embodied in an *"approach of action-based research where we would engage people at the start, and co-design research programs"* (Australian interviewee 08). In this model, community members were commonly described as "partners" and as critical members of the research team. Priority setting comprises a two-way process that requires both researchers and community members to identify research priorities. Where communities alone set priorities and design research, the potential for research to actually address those priorities is constrained, as the methods to address their priorities is limited to the community's experience or imagination. Similarly, where researchers set priorities completely in isolation from those who have lived experience with a disease, they may favour inappropriate priorities and methods. Several interviewees reflected that community engagement is most powerful when it fosters an exchange of perspectives and knowledge.

Having instrumental goals means community engagement helps ensure that research reflecting priorities identified by researchers is more feasible. Here, researchers initiate engagement and approach a community with a research idea before they develop a research proposal. Engagement either functions to assess whether the community believes the research idea addresses a priority and, if so, to refine the idea, or it primarily functions to

Table 2 Foundations for meaningful engagement

	Example quote
Environmental	
Time	*"Engagement to me and what I've seen like working with Aboriginal and Torres Strait Islander communities and an amazing colleague who works in Indigenous health, it's actually longer and it takes a lot more time than people think it does. And so I was like yeah, we'll do it in three months, and it's like no, no you need eighteen months to make sure you're doing this right."—Australian interviewee (04)*
Organisational support and governance frameworks	*"I think community engagement does require a governance framework to be successful. Community engagement is one activity that occurs within the space of a research project in the space of collaboration. So I do think the governance framework is an essential foundation for the community engagement to occur."—Australian interviewee (08)*
Funding requirements for community engagement	*"… So the NIHR which is the National Institute for Health Research in the UK so a bit like the NIH in the States, so it has a PPI [patient and public involvement] mantra and agenda. So in order to secure fundings from them you have to show adequate PPI."—UK interviewee (10).* *"…that model is not around developing a suite of policies and standards, but a framework that funded research projects must adhere to, and agree to these policies if they are going to be funded. And that is around community involvement, community renumeration if appropriate and involved in publications if appropriate. So all those sorts of standards surrounding best practice in consumer involvement."—Australian interviewee (02)*
Relational	
Embeddedness/existing connections to the community	*"well really since the late eighties or mid-eighties so a really, really long time… what I have realised is that you can only do this kind of sustained research (on dementia) if you have a relationship with a community."—UK interviewee (08)* *"If you create that kind of enduring infrastructure coproduced with the community, then you have an infrastructure to identify to work with community to work with the relevant people and the community itself can identify who are the right people to be talking to about the questions which they see of, which the community identifies to be of value…"—UK interviewee (08)*
Diversity amongst the research team	*"So I think you have to, you have to be mindful of where your, your power dynamics look like in terms of—and even the kind of people you're sending out, you know the, if you're trying, and some of these things are unavoidable you know you might have a research group that is predominately white but they, you'll engage for whatever reason with a different audience and already there's a dynamic there which you have to accept that…you might not get successful engagement."—UK interviewee (01)*
Obtaining gatekeeper support	*"What we do initially is to identify the key members of the communities who can influence the community members in making decisions. And it's those people are usually the traditional rulers, village heads, opinion leaders. Sometimes we even involve the politicians, and the political office holders who have a strong hold in the communities. So the idea is to them first and when they get to the communities and they speak to them it's easy to convince the members of the communities because these people are known to them, they are not strangers, they also believe that these people are interested in their wellbeing so these are the people that we think should be the stakeholders in the communities."—African interviewee (03)*
Trust	*"So due diligence is very important, it's very important to build trust, for people to understand what you're doing, who you are what you're going to do you won't have problem."—African interviewee (04)*
Fair processes	*"I think at the end of the day you want to make sure there is a fair playing field so the researchers and communities are working together in harmony, there is communication happening… transparency should be there as well; accountability as well…"—African interviewee (02)*
Collective	
Self-mobilising	*"I think it would have to be a community that is so critically aware of itself and of, of what is missing, you know what needs to be addressed to reach to that level, and it has to be a self-mobilising community… that is a really empowered community."—African interviewee (01)*
Individual-researchers	
Understanding of community context	*"But in Nigeria I won't mix male and female in Northern Nigeria, in Southern Nigeria it's not an issue. Women speak up, men don't override you know but in Northern Nigeria I won't do that because when males and female are mixed up females won't speak and then culturally you shouldn't mix male and females."—African interviewee (08)*

Table 2 (continued)

	Example quote
Experience with/literacy in community engagement	*"I would be interested in community engagement expertise becoming like, your biostatistics, or your statistician. It's a given requirement that you consult with a community engagement specialist for any research that involves communities. And they contribute to the formulation of your research in terms of your objectives, your aims and your hypotheses. They help with the formulation of your ethics application, and they facilitate your approach with engaging to community. Because guess what? A lot of biomedical researchers are not necessarily skilled at engaging with communities. It is a different skill set."—Australian interviewee (08)*
Communication skills	*"… I think it comes back to as researchers we need to do better with communication, and I think it's putting onus on people saying that they don't know enough, they need to learn more, we actually need to be clear with what we communicate and how we communicate and the way we do."—Australian interviewee (11)*
Attitudes (respect for communities, recognition of value of community expertise, open-mindedness to different points of view)	*"…my research is led by people who see a value in community engagement and they've had a really great experience with consumer advocates as well and really found that they can give great insights and interpretations, even of the data like as we're writing it up and putting together the manuscript."—Australian interviewee (09)*
Individual-community	
Able to take a broad perspective	*"…necessary people who have a broad enough perspective to kind of be able to represent the community as a, as a bigger community…" African interviewee (09)*
Research literacy, including genomics literacy	*"…somebody who's, who knows enough about what you're doing to contribute but also understands the scientific processes a bit."—UK interviewee (02)*
Known status within the community	*"So the first thing for someone to be a community consultant… they need to be known within the community those people who have a say within the community, that is one thing."—African interviewee (06)*
Communication skills and compassion	*"So they'd also need to be good communicators, they would need to be compassionate you know all those sorts of things that you would look for, for somebody who truly represents a community."—African interviewee (05)*

refine a researcher-initiated idea with the community. The former approach is described by an interviewee*:*

> *"Before the researcher develops their research protocol, they should go to the communities and find out whether that particular research idea will address the priority that the communities that will be involved have. The researcher should have input from the communities at that point and then from there then they, the researcher, can draw up the research proposal and then you know, submit it for review and all that."—African interviewee (02).*

In contrast, another interviewee suggests the latter approach

> *"We've identified this problem in the community, for example, from preliminary reports we are seeing that there is a high level of maybe of schistosomiasis, it's a common disease that is prevalent in communities here that really along the shores of the lakes … we tell them what kind of plan we have as the design as of the study in our mind that this is what we want to do … And then ask them for their opinions, is it feasible; do you think it's going to be beneficial to the community"—African interviewee (04).*

Generally, instrumental goals were more commonly described as achieved through consultative models of engagement, where community members provide "input" and "information" and are "asked for opinions".

Irrespective of whether interviewees believed that meaningful engagement should facilitate empowerment or instrumental goals, they collectively thought consideration of diversity, bringing out voices, and the nature of the engagement space are necessary in biomedical research priority-setting. Engagement of patient and geographic communities should ensure diversity in terms of what demographics are represented and, in geographic communities, what community roles are represented. Interviewees highlighted that ensuring there is ethnic diversity in biomedical research is important to capture issues affecting unique genomics populations.

Engagement should also be designed to draw out different voices, with a particular focus on marginalised voices. Interviewees describing several strategies to do so when engaging in person such as providing those engaged with background materials and pre-readings in advance; breaking into smaller groups of people with similar life-experiences; using deliberative, individualised communication; and making the engagement mirror an informal

meeting. The latter reflects that "formal and structured" engagement processes can make community members uneasy, an observation more commonly reported by African interviewees.

In some circumstances, online engagement methods were recommended. The diaspora of a patient community can be reached through online engagement methods (i.e., online discussions). When considering online engagement methods, interviewees highlighted that it is important to be aware that this can disadvantage some individuals from being able to participate as they may have limited access to the necessary tools to participate (i.e., computer, internet access).

In relation to space, interviewees felt that the space chosen for engagement can influence which voices are the loudest, and which voices are missing from priority setting process. They believed that the researchers should ideally go to the community and use safe community spaces that are not imbued with exclusionary norms. Interviewees from Africa more commonly reported on the impact of cultural norms in spaces for engagement.

Barriers to and challenges within engagement

Interviewees identified environmental, relational and individual barriers to engaging communities in setting priorities for biomedical research projects (see Table 3) and challenges that arise when doing so. Certain challenges—undefined communities, literacy, bias, and sidelining—were unique or more likely to occur in relation to engagement in genomics or biomedical research than applied health research. Interviewees reflected that one of the biggest challenges for exploratory genomics work can be the identification of the community:

> *"The biggest challenge with genomics research is that it's still a developing area and some terms you can't identify a community or who you need to engage with kind of until you start understanding what's going on".—Australian interviewee (11).*

Efforts to build genomics literacy also come with challenges

> *"So one of our challenges in genomics is of course that we don't have a vocabulary and a language for genomics in many of our African settings. So that has been interesting in itself and as part of this bigger project that I'm involved in…people are actually looking at words and concepts…and how they can try and make it more accessible and also more culturally sensitive"—African interviewee (05).*

Biases can arise in biomedical research priority-setting due to disease-based lobbying from different stakeholder groups and government bodies. This can result in priorities being selected for funding that are not always priorities that the community deems most important. Rare diseases can be sidelined in biomedical research priority-setting in favour of diseases that are slightly more common within a geographic community in order to address the needs of a greater number of people. But, as one interviewee affirms, "*I think you also can't always go well if it's common you have to call it a priority and if it's rare you ignore it."—African interviewee (09).* Priority-setting for rare diseases is also affected by the number of different rare disease groups competing for money. In some instances, the *"really emotive, or effective advocacy groups"* (Australian interviewee 01), may get more funding. This was not identified as a "good or a bad thing", but the interviewee cautioned it is important to be aware of these factors. Other interviewees highlighted strategies to manage bias such as (1) undertaking fair processes that achieve transparency and accountability and (2) understanding a given community and ensuring a diversity of participants from it. These strategies were not discussed in relation to disease-based lobbying but may be relevant to dealing with it.

Certain barriers varied by location or country context. Australian and African interviewees more commonly described barriers created by unsupportive local funding structures. In contrast, achieving adequate community engagement is often required and supported by UK funding agencies. Barriers related to unfair power dynamics, especially those grounded in coloniality, were reported more often by interviewees from Africa. They commented that an impact of biomedical research funding coming from the global North to the global South means the global North holds more power over the global South, and therefore controls the narrative and elevates voices of "those they want to hear". This can be hugely disempowering.

Stigma associated with different diseases was also commonly reported by interviewees from Africa as affecting the scope of community engagement in biomedical research. Living with certain illnesses can be hugely stigmatising for community members, and they are, therefore, often excluded from engagement generally and during priority-setting processes.

Discussion

Whether the type of health research is ethically significant in specifying what engagement should entail is a key question to investigate. This study gathered empirical evidence that can help inform an answer. We interviewed biomedical (largely clinical and genomics) researchers and community engagement experts embedded in biomedical research from Australia, the UK, and several

Table 3 Barriers to meaningful engagement

	Example quotes
Environmental	
Lack of resourcing/funding	*"Sometimes the budgets are so tight that to do a heap of engagement and workshops and surveys, or whatever it may be to gain community input is a barrier."—Australian interviewee (01)* *"Ideally, we would have that approach of action-based research where we would engage people at the start, and co-design research programs. I would love to have the opportunity to do that, but I think it is challenging in terms of the way that our funding structure is set up."—Australian interviewee (05)*
Lack of organisational support	*"I am also talking about the organisation, and the executive of the organisation, because the group leader and the researcher can end up being in a very compromised position, if what they are doing is not actually supported by, resourced, understood, invested in by the organisation at the executive level."—Australian interviewee (08)*
Funding bodies control the agenda	*"…but you see the problem is who sets the agenda? You know sometimes it has something to do with funders or sponsors of research, they are the ones sometimes who are trying to set the agenda because I think most of our local researchers decide to develop proposals based on some cause that come from you know the sponsors or the funders like the NIH have a call for this particular topic, right, and then you know a researcher from a developing country would decide to draw up a proposal to respond to that cause."—African interviewee (02)*
Laws	*"One of the barriers for participation in that research was that a number of the members of the communities said, "can you guarantee that, as researchers, that the genomic data you collect will not be used by the police or the government for law enforcement of other reasons?" And you know what—the researchers couldn't guarantee that. They actually couldn't. Because the law states that the police can have access if they request it. Right. Now that is a huge problem if you are a member of a community that is the victim of system, sustained racism for generations and is still going."—Australian interviewee (01)*
Relational	
Mistrust	*"… we've also come across you know communities thinking that, that we are doing something as an ill will to their health and also there have been communities that can think there is some sort of black magic involved… social ways of thinking and cultural perspective is something that has to be taken into account."—UK interviewee (12)*
Unfair power dynamics	*"…this is context specific to biomedical research, would often come from the North with the global South, that's the context most of the time and that's because of the money involved in this research is huge and we don't get to take that in our local context. And that you see that in a lot of examples continue to talk about the difference and reflections, but one of the things I think happens also when you have a global North engaging with a global South there's the power to write the narratives tend to be written by the global North."—African interviewee (08)*
Stigma	*"I mentioned the examples of psychiatric patients, people with, with diseases that attract superstitious, or superstition so cleft lip palate for instance you know that, that general, generally people think about that as being devil's disease…discrimination and inequality within communities is a huge barrier to meaningfully engaging those that are discriminated or marginalised…"—African interviewee (07)*
Individual	
Researchers unsupportive of meaningful engagement / have low levels of literacy in engagement	*"the training and researchers have, traditionally, hasn't had anything to do with how to interact with the public or participants. It has just been how to analyse the data and produce publications."—Australian interviewee (02)* *"I think sometimes there can be a reticence to include the community because, 'they just won't understand,' you know? It is a quite a paternalist perception though, isn't it?"—Australia interviewee (05)*
Target population not wanting to engage	*"some people just don't like interacting with their healthcare system. Usually men of my age. I don't know why that is but you know most men my age never see their GP so they ain't gonna engage with you. And that's why diseases like prostate cancer don't probably get as much attention as breast cancer."—UK interviewee (10)*
Burden of participation	*"Because a lot of the time, when you want to talk to people. If we are talking about people who are part of the genetic and undiagnosed rare disease community, many of them are struggling day-to-day to be living with what it is they are living with. Maybe they have a family member who has got a condition. So to then be asking them to spend extra time, to be involved with agenda-setting and participating in research, and all of those kind of things, I think that can be a challenge as well."—Australian interviewee (05).* *"There a huge under-representation of ethnic minorities and there's a huge under representation of poorer and lower socioeconomic classes. Cos they can't take time off from work, they're not really interested, they've got no spare money."—UK interviewee (10)*
Previous negative experiences with researchers	*"I think certainly their experiences of not being listened to make them quite reticent to actually talk."—UK interviewee (02)*
Bias	*"… and so you do get these weird sorts of things which certainly I think would impact on, on something like if you used a patient support group to lobby you could get very biased lobbying, and priority setting you know which wouldn't necessary be to everybody's benefit"—African interviewee (09)*

African countries to obtain their perspectives on whether community engagement should occur in priority-setting for biomedical research projects and, if so, how and for what purpose.

The researchers we interviewed strongly affirmed that engagement should occur as early as the priority setting phase of biomedical research projects, except under circumstances where engagement puts individuals or communities at risk of harm, and the risk cannot be mitigated. Their endorsement of early engagement is consistent not only with literature on engagement in applied and participatory health research [8, 32–35] but also with literature on engagement in genomics research [36, 37], in biomedical research [20, 38], and international biomedical research ethics guidelines [5, 39]. For instance, Ogurin et al. propose a four-stage model for community engagement in genomics research, where the first two stages include the process of conceptualising and defining the research question. Their model was developed based on interviews and focus groups with biomedical researchers, community rulers, opinion leaders, community health workers, and prospective research participants in Nigeria [36].

Study participants' reasons for endorsing engagement during biomedical research priority-setting (see Table 1) also align with the findings of prior studies that speak to the value of early engagement in health research—namely, responsiveness, epistemic benefits, and community/local ownership or self-determination [8, 32, 40–42]. However, these and other studies identify reasons to value engagement that were not voiced by study participants here, including building relationships, opening doors, making those engaged feel valued, and giving them competence and confidence [32, 41]. This perhaps reflects the fact that our interviewees did not include those who had been engaged in health research.

Although most interviewees felt strongly that engagement should occur in biomedical research priority-setting, they gave two distinct responses on what ethical purpose it should serve. Some proposed engagement should have *transformative* goals, whereas others suggested *instrumental* goals. Both ethical goals have previously been described in the research ethics literature on engagement [4, 43] and debate continues over whether or not transformative goals should apply to engagement in health research. In this study, interviewees proposed two overlapping models of engagement as the ideal means to achieve empowerment goals: community-initiated and synergistic. The community-initiated model aligns more with Arnstein's "citizen control" level of participation, whereas the synergistic model corresponds more closely with collaborative partnership and co-design approaches [14, 18]. Thus, the two models call for different levels of participation for those engaged.

In accordance with these findings, existing literature on engagement in genomics research also supports its being empowering and synergistic. May et al. purport that the techniques of community-based participatory research, which emphasise true partnership, should be applied in genomic science [44]. They affirm that such techniques can empower communities and can provide meaningful strategies to build trust, especially where underrepresented groups are engaged [44]. Watson et al.'s conceptual model for engagement in genomics research calls for an approach of "collaborative decision-making, facilitating dialogue, balancing power" that encompasses the priority-setting phase [37, p. 1]. Similarly, literature on participation [45–47], engagement in health research priority setting [19, 41], community-based participatory research [32], and co-design in health research [35, 48] all purport that transformative goals, collaborative partnership, and shared-decision-making are ideal or necessary to achieve more meaningful engagement.

In contrast, other interviewees in our study felt that engagement in biomedical research priority-setting should seek to achieve instrumental goals using a consultative model. Their views are consistent with some of the existing ethics literature on what engagement should look like in biomedical research [15, 49, 50], though that literature does not discuss the priority-setting phase specifically. In relation to genomics research, including priority-setting, Ogurin et al. also argue for meaningful community engagement as a way to ensure the success of a research program [36].

Although no consensus existed amongst interviewees on what the ethical goal(s) and model of community engagement should be in biomedical research priority-setting, identifying instrumental goals and consultative models as ideal is perhaps less common than in many forms of applied health research, which tends to associate meaningful engagement with empowerment goals and co-design/synergistic models. Thus, this study offers initial evidence that meaningful engagement in priority-setting should *potentially* be defined slightly differently for biomedical research relative to applied health research. Empowerment and instrumental goals achieved by community-initiated, synergistic, or consultative models may each comprise meaningful engagement in biomedical research priority-setting, though more research is needed to further assess this, both conceptually and empirically (as discussed further below in relation to study limitations). Future work should determine whether robust ethical or philosophical arguments can be made for defining meaningful engagement more broadly in biomedical research. It should also consider whether the different goals and approaches should apply under different circumstances of biomedical research priority-setting. If

they should vary by context, it is necessary to determine when/where different goals and models should be used, i.e., what contextual factors demand certain goals and models of engagement. Future research could usefully further investigate the rationale for why the community-initiated or synergistic model should be used to advance empowerment goals in biomedical research priority-setting and which (if either) is better at achieving them in practice. In this study, for example, epistemic arguments were made by biomedical researchers for relying on the synergistic model.

It is also important to note that our interviewees' endorsement of empowerment goals and models contrasts with much current biomedical research practice, where the collaborative partnership thread of community engagement is less common and instrumental goals and approaches dominate [20]. Thus, this study offers initial evidence that engagement in biomedical research priority-setting, and more broadly, should not be dominated by instrumental goals and approaches. A different balance may be ethically appropriate than what is currently practiced.

Our study identified several individual and collective qualities of researchers and community members, as well as relational and environmental essentials to build if biomedical researchers want to engage meaningfully with communities in priority-setting. Our study also identified numerous personal, relational, and environmental barriers to assess for (and address) before commencing and/or during engagement. Many of these foundations and barriers are not specific to engagement in biomedical research or during the priority-setting phase. They have been identified in previous work on engagement in health research priority-setting [51, 52] and in the wider literature on participatory development and participatory health research [32, 53–57]. However, certain barriers are likely to be more common in certain country contexts. This study suggests funding structures that are unsupportive towards engagement in priority-setting are more common in African countries and Australia relative to the UK. Unequal power dynamics and stigma were emphasised more strongly by African interviewees as barriers to engagement, which is unsurprising given the context in which much health research occurs and has historically occurred in Africa (with the global North providing funding to the global South and controlling the agenda).

Some of the challenges identified in this study are unique to engagement in *genomics* research: identifying the community and genomic literacy. This result is support by the findings of Manafo et al. and Stauton et al., who affirm that "defining 'community' is challenging and can depend on the particular social, cultural and geographical context in which the [genomics] research takes place." ([58, 59], p. 2).

It is critical to acknowledge the main limitations of this study. First, this study did not solicit the voices of research participants or their communities on whether, how and for what purpose they should be engaged in biomedical research priority-setting. As a matter of epistemic justice and democratizing knowledge within the ethics field, this is a key group to focus upon in subsequent research on this topic. Second, while interviewees spanned basic science, clinical, and genomics research, few respondents to our recruitment efforts were basic scientists. This perhaps reflects the fact that community engagement in such research is less common and thus there were not as many researchers who met our inclusion criteria. Future ethics research should also solicit the views of basic science researchers on the topic of community engagement in biomedical research priority-setting. Such research could also potentially seek out the perspectives of biomedical researchers who have not engaged communities in their work. Although this study only sought the views of those researchers with some community engagement experience, other biomedical researchers would still have views about whether community engagement should happen in priority-setting or not, though they would not be grounded in actual engagement experience. Third, interviewees were recruited from Australia, several African countries, and the UK only. While engagement in biomedical research is increasingly common in these countries, there are other countries where engagement is frequently occurring in biomedical research, including non-English speaking countries and countries in other regions. Future research should capture their views as well.

Conclusions

Our study shows that members of the biomedical research community support engagement in biomedical research priority-setting. However, interviewees did not demonstrate consensus on what ethical purpose it should serve or how it should be done. Some conveyed support for engagement to promote empowerment via co-design and community-initiated approaches, which are more common in forms of applied health research. Others endorsed a more instrumental consultative approach that is consistent with current biomedical research engagement practice. This finding suggests that how meaningful engagement in biomedical research priority-setting is defined should *potentially* look different to engagement in applied research priority-setting and that engagement should be undertaken differently to current practice. Going forward, there is still much more ethics research to do to further explore whether community engagement

in priority-setting should look different in biomedical research relative to applied health research.

Abbreviations

CIOMS	Council for International Organizations of Medical Sciences
NIH	National Institutes of Health
UK	United Kingdom
UNAIDS	Joint United Nations Programme on HIV/AIDS

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Author contributions
BP conceived of the study: its topic, aims, and methods. JB and NE were primarily responsible for recruiting interviewees, conducting interviews, and undertaking thematic analysis, though BP oversaw and contributed to both data collection and analysis. BP and JB were responsible for writing the first draft of the paper and revising the work critically for intellectual content. NE revised the paper critically for intellectual content. All authors gave final approval of the version to be published.

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Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This study was approved by the Melbourne School of Population and Global Health (MSPGH) Human Ethics Advisory Group (HEAG) at the University of Melbourne (Ethics ID: 1749720.5). Written informed consent was obtained from all interviewees. All procedures were performed in accordance with the National Health and Medical Research Council of Australia's National Statement on Ethical Conduct of Human Research.

Consent for publication
Not applicable.

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BP is a member of the editorial board (Associate Editor) of *BMC Medical Ethics*. NE and JB have no competing interests to declare.

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Building healthy populations one community at a time

Folakemi T. Odedina, Rafaela Alves Pacheco & Marcia C. Castro

Tailored community engagement led or co-led by the community can build trust with underserved communities to deliver health equity.

Health equity is achieved when everyone can attain their full potential for health and wellbeing (Table 1). Often referred to as social justice in health, achieving health equity requires building healthy populations one community at a time.

Unfortunately, the opportunities to build healthy populations are not distributed equally from one community to another. Differences in population health between diverse communities can be due to inequalities, injustices, social determinants of health, racism, discrimination, segregation, and lack of diversity in the health and biomedical research workforce (Fig. 1).

To foster optimal health for all, these health disparity factors can only be addressed effectively when the communities affected are fully engaged in developing solutions for their community health. Community engagement is widely recognized as the key to building trust and a requirement for an effective academic–community partnership.

Trust is a cornerstone of fostering health equity in diverse communities and is therefore fundamental to building healthy populations. Trust is relational, it takes time to earn, and is not automatic or given immediately, especially in communities that have been historically marginalized or minoritized.

Trust and engagement frameworks

Several frameworks have been developed to build community trust and guide engagement, especially of minoritized and marginalized communities[1–4] (Fig. 1). Dave et al.[2] proposed five determinants of trust: (1) authentic, effective and transparent communication; (2) mutually respectful and reciprocal relationships; (3) sustainability; (4) committed partnerships; and (5) communication, credibility and methodology to anticipate and resolve problems. Trust is a key requirement for community engagement, which can be delivered through community-based participatory research[3], a gold standard for fostering health equity in diverse communities.

Community-based participatory research is an approach to research in which all stakeholders are involved in the decision-making process, and comprises four components: partner characteristics (such as motivation, cultural identities and personal beliefs); partnership structures (such as partnership values and norms); shared resources; and relationships among partners (which include trust, participatory decision making and conflict management)[4].

More recently, the Assessing Community Engagement (ACE) conceptual model[5] was developed to center community engagement and engagement principles. The ACE model proposes the following core principles: co-equal, co-created, ongoing relationships, shared governance, multi-knowledge, equitably financed, culturally centered, inclusive, bidirectional and grounded in trust. Using this framework, health equity can be achieved through transformed health systems that includes strengthened partnerships and alliances; expanded knowledge; improved health; healthcare programs and policies; and thriving communities.

Regardless of which model of trust and engagement is adopted, a well-defined community with shared characteristics must be identified, sustainable solutions should be sought within the community, and the project be led or co-led by the community. Two examples of effective community engagement approaches include the community living lab and the primary care delivery model.

Community living lab

An actionable model of trust and engagement is the 'Community Living Lab Learning Health System', which integrates the principles of a Living Lab[6] and a Learning Health System (Table 1). A living lab is a system and environment for building a future economy using real-life user-centric innovation to co-create products, services and societal infrastructures. A successful living lab depends on systems thinking, a functional environment (an environment that works to its full potential for the benefit of the community), real world (without manipulation), innovation, trust, engagement, inclusive research, actionable research

Table 1 | Key terms and concepts in health equity research

Concept	Description
Health equity	The absence of unfair, avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically or geographically or by other dimensions of inequality (such as sex, gender, race, ethnicity, disability or sexual orientation).
Trust	Willingness of a party to be vulnerable to the actions of another party based on the expectation that the other will perform a particular action important to the trustor, irrespective of the ability to monitor or control the other party[13].
Social determinants of health	Nonmedical factors that influence health outcomes. They are the complex conditions in which people are born, grow, work, live and age, and the wider set of forces and systems shaping the conditions of daily life. Examples include income, education, occupation, gender equity, racial segregation, housing quality, food security, and access to basic infrastructure (WHO social determinants of health; https://go.nature.com/42CobrG).
Community engagement	A process of working collaboratively with groups of people who are affiliated by geographic proximity, special interests, or similar situations with respect to issues affecting their wellbeing[14].
Living lab	An innovation platform that brings together all stakeholders at the earlier stage of the innovation process to experiment breakthrough concepts and potential value for both the society and users that will lead to breakthrough innovations[6].
Learning health system	A health system in which internal data and experience are systematically integrated with external evidence, and that knowledge is put into practice.

and sustainability. A community-driven living lab learning health system includes: academic-community leaders committed to a culture of continuous learning and improvement; evidence-based interventions guided in real time; real-time improvement of decision-making through the use technology to share new evidence; inclusiveness of all members of the learning team; continuous improvement through the use of data and shared experiences; and continuous assessment of outcomes to refine processes and training.

In 2020, the Mayo Clinic Comprehensive Cancer Center (MCCCC) and the American Legion Post (ALP) 197 partnered to co-create a community living lab learning health system. The MCCCC serves the people and communities in its regional, geographically adjacent catchment areas in Arizona, Florida, Rochester and across the Midwest. Before 2020, most of the MCCCC's community outreach and engagement activities focused on health systems and episodic outreach programs in diverse communities.

The MCCCC Community Outreach & Engagement Office and Programs partnered with The American Legion for community-based learning health systems. The MCCCC–ALP197 partnership provides access to comprehensive cancer resources, education, amenities, and clinical trials for Black populations. ALP197 is located in Duval County, Health Zone 1, a region with a large population of Black people, with higher levels of poverty, lower level of educational attainment, and higher rates of multiple chronic conditions compared to other health zones in the area.

The Community Living Lab Learning Health System took two years of engagement and trust to build, including collaborative evidence and data gathering; partnership building; investing in a physical presence in the community; community training and empowerment; education and outreach; and dissemination of program progress. The Learning Health System received US$1.5 million from the Department of Defense to strengthen and expand the system to other American Legion Posts. The ALP197 health system is led by Veterans, which builds trust, especially with Black residents. A physical community space was needed to provide access to residents, increase reach, and increase enrollment of people from underrepresented groups in the research registry.

As the Community Living Lab Learning Health System expands across Florida, the expected long-term outcomes are wide-ranging. They include: expanded access for prostate health services in Black communities; improved trust with targeted populations; improved access to prostate health-related education and navigation services; enhanced knowledge and awareness of clinical trials in underrepresented and underserved communities; increased reach and enrollment of Black men in clinical trials; an expanded community hub for prostate cancer disparity and community engagement research activities; an expanded research training hub for underrepresented minority scientists and cancer advocates; and a community platform that will foster the immediate dissemination of prostate cancer scientific discoveries to the Black community.

Primary care delivery model

Another model of trust and engagement leverages primary healthcare. The Sustainable Development Goal (SDG) 3, good health and wellbeing, includes universal health coverage (target 3.8). This target cannot be achieved without a strong primary care platform. Community-based primary care delivery is a powerful tool to improve healthcare access, quality and equity. Such programs often rely on primary care teams (including community health workers) who provide care in a defined geographical area through regular home visits. Community health workers often live in the same area where they work, which helps to build and sustain trust in the actions of the public health team.

Community health workers have had notable successes in improving health equity, especially in low- and middle-income countries such as China, Costa Rica and Brazil. The "barefoot doctors" program in China provided intensive training to young peasants in anatomy, bacteriology, midwifery, birth control, maternal and infant care, and other specialities[7]. After training, they worked in rural areas providing basic healthcare. This low-cost program contributed to improving health outcomes and increasing life expectancy, especially among the poorest communities. The barefoot doctors also inspired the Alma-Ata Declaration in1978, which identified primary healthcare as the key to equitable health for all.

Costa Rica has one of the highest life expectancies at birth in the Americas thanks to its community-based primary healthcare program that relies on multidisciplinary teams, which include a doctor, nurse assistant, medical clerk, community health worker, nutritionist, psychiatrist and pharmacist, integrated within the community[8]. To promote equity, the program was first introduced in rural areas, and later expanded into urban areas. The program contributed to reducing overall mortality, as well as maternal, child and infant mortality.

Family health strategy

In Brazil, the 'family health strategy' is the platform of primary care delivery[9]. Teams consist of one physician, one nurse, one nurse assistant and up to six community health workers. Community health workers operate in a defined geographical area, the same as where they live, and

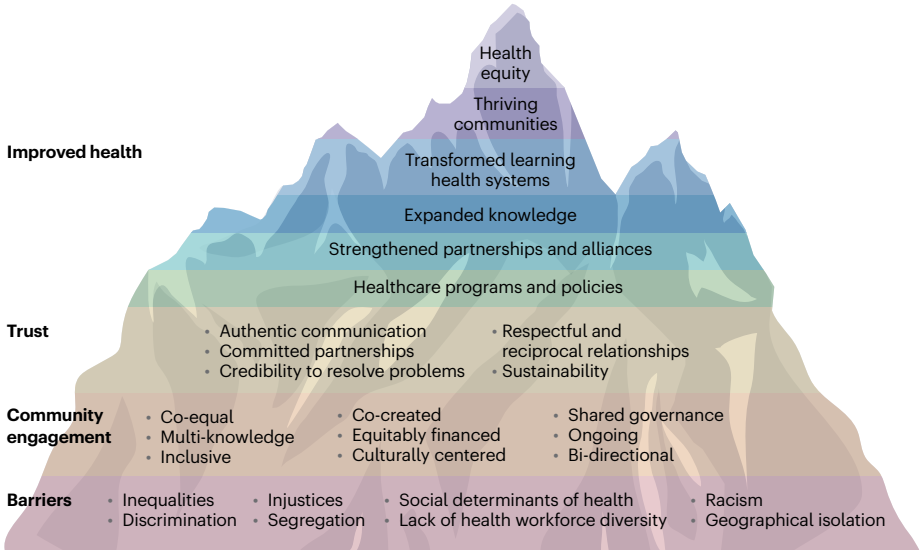

Fig. 1 | The health equity mountain. Strategies to improve the health of underserved communities must come from within those communities, with an understanding of barriers to healthy behavior, inclusive principles of community engagement, and authentic approaches that build trust.

serve as a bridge between health units and the local population. The family health strategy has contributed to declines in infant mortality, avoidable hospitalizations and avoidable mortality, and better and more equitable access to health[10].

In each of these examples, trust in community health workers is crucial for the success of the program. The equity lens of community-based primary care delivery also empowers often underserved and unheard communities. The Brazilian unified health system (known as SUS) has community participation as part of its foundational principles[11]. Health councils and health conferences regulate community participation. Primary healthcare is delivered through the family health strategy, which ensures integrated care to populations of a defined territory through multi-professional teams, including community health workers[10].

The family health strategy focuses on the reference territory and may include interventions that focus on the individual person, the family, on the community. This enables health interventions that promote community empowerment, a model that has inspired other health systems, such as the UK National Health Service (NHS). Valuing community engagement is also one of the competencies of family and community medicine in Brazil and the entire Ibero-American region[12]. Community engagement requires an understanding of the geographical and cultural characteristics of a community, the local lifestyle, and the leadership and socio-institutional organization of the community. The goal is to work with the community to guarantee individual, family and community care.

The importance of the model of primary healthcare was highlighted during the COVID-19 pandemic. Despite failures of the Brazilian government, the SUS and the family health strategy had pivotal roles in some localities, averting an even worse outcome[12]. Family health strategy teams continue to conduct household visits, providing information, explaining the importance of masks, clarifying questions, and organizing information sessions in churches and other community spaces to respond to questions and demands from the community. This was critical considering the propagation of fake news, including the use of unproven medicine to treat COVID-19, such as chloroquine.

Tailored approaches

Trust and community engagement are crucial to build healthy populations and achieve health equity for all. There is not one size that fits all. Approaches are context specific, so what works for one community, will not necessarily work in another. Therefore, approaches must be tailored to each community. There are several models of community trust and community engagement that can be adopted or adapted, but the most important step is to follow the lead of the community. From the onset, the community must be at the table with equal power to make the right decision for their community. If the problem is in the community, the solution for healthy populations will come from the community.

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Competing interests

The authors declare no competing interests.