

Tackling the lack of diversity in health research

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Background

High quality health research is central to evidence-informed healthcare. By assessing evidence on treatments, initiatives and different ways of delivering services and changing practice where appropriate, health outcomes are improved. But what if that evidence routinely ignores or forgets the needs and perspectives of many in our communities?

This is not an abstract question. A survey of Wellcome Trust data found that people of White British ethnicity were 64% more likely than ethnic minority groups to have participated in health research, even when accounting for socioeconomic status, age and sex (1). The proportionate representation of ethnic minority groups in health research has not improved in ensuing decades (2). There has also been underrepresentation of ethnic minorities in COVID-19 research, including randomised trials of potential treatments, and vaccination and vaccine research (3), despite the greater COVID-19 burden experienced by ethnic minorities. In addition, communities such as the elderly, (4) disabled (5), women (6), precarious status migrants (7), sexual minorities (8) and vulnerable populations (e.g. sex workers (9), homeless (10)) are also under-represented (or their health needs are understudied) in health research.

Who are the Under-served?

Under-served groups have been defined as people in society who are represented in health research at lower levels than would be expected from population estimates (11). These groups are often termed 'hard to reach', which may be related to a perceived difficulty in identifying and engaging with the target population or in some cases an unwillingness to engage. However the reality is that under-served groups are not hard to reach but instead seldom approached or heard, either through ignorance, lack of resource, or existing methods in how health research is done and by whom (12). There are however some challenges to engagement with under-served groups, which may include vulnerability of participants and risk of participation (e.g., a wish to remain hidden or concealed), mistrust of the research process (e.g. historic mistreatment of the Black community in medical research), and participant resource constraints (e.g. cost of childcare or transport) (13).

Under-served groups are not reflected in the volume or focus of health research. They may have greater healthcare needs, and there are important differences in how these groups respond to, or access, health and social care interventions and services compared with other populations (11). When thinking of under-served groups, health researchers typically focus

on core demographics such as ethnicity or age, but the notion of being under-served is more complex and includes context specific factors, which may be disease or study specific.

Under-served can be defined by demographic, social or economic factors, health factors, and/or disease-specific characteristics (11). For example, populations of working age are often under-served in research but may not be deemed under-served within other contexts. Notwithstanding obvious scientific and ethical repercussions of a lack of diversity in health research populations, the issue continues to be prevalent.

Health research needs to be more than just representative

Proportionate representation (i.e. research sample population reflects the population prevalence of the studied groups) in research helps ensure that results are applicable to the wider population. This is particularly important for patients and clinicians who make decisions on care from an evidence base that is informed by research (11). It is also important for researchers to understand how intervention responses may differ, and if implementation differs by target population.

But the external validity of research findings requires more than proportionate representation. For example within a trial, the inclusion of subgroups large enough to permit sufficient statistical power for subgroup analysis also requires consideration; and subsequent recognition that this may increase research costs. This is a prevalent issue within clinical research – A 2011 analysis of 86 clinical trials reported that only a small proportion (25%) of studies presented sex-specific results (14), and 64% did not provide any analysis by ethnic group.

As well as representing diversity with a sufficient sample size, there should be recognition that demographic characteristics that typically define under-served groups (e.g. age, sex, ethnicity, disease status) are in some sense proxy measures for underlying mechanisms (social and biological), experiences and behaviours that may explain differences or inequalities when compared to other groups (14). Therefore greater emphasis on collecting data on potential explanatory factors is required (14). This may include information on experiences relevant to the group of interest, such as racism (15) or homophobia, or social factors such as deprivation, or education. Moving beyond simply comparing population groups may help address the underlying structures or mechanisms that drive health inequalities.

Why are health research populations typically homogenous?

The dominant approach to health research, and in particular clinical trials, is to try and minimize bias and increase internal validity through the use of stringent inclusion criteria, and recruitment of homogenous study populations (14). It is likely to be quicker/cheaper to recruit a homogenous sample, and if researchers ask for supporting resource, funders may often not agree that it represents value for money. But beyond the current ways in which health research is set up, the barriers to increased representativeness of health research populations are arguably multi-layered, and operate at several levels.

Broader structural and logistical barriers to health and social care access interplay with barriers facing individuals from certain groups based on characteristics such as age, ethnicity, and sex. Such barriers are likely to be inherited by the health research environment where there is cross-over between health care and research teams, and where recruitment and study procedures are carried out by clinical staff. Trust is important in healthcare and levels of trust in both healthcare systems and health research have for example been found to be lower in some ethnic minority groups compared to the general population (16). This is thought to be in part rooted in historical abuses and racism, (17) and previous negative experiences of research and/or care (18). A lack of cultural knowledge and awareness (often termed cultural competency) amongst research staff, particularly those who lack exposure to working with a diverse group of participants, may also contribute to a negative experience of research participation and perpetuate existing inequalities in care (19).

A common theme within the evidence base is that many of the challenges and barriers concerning inclusion in health research are similar to those that influence the delivery and design of research more generally. For example barriers reported within clinical trial literature include language and communication issues (20) (e.g. for minority groups, or deaf or blind populations), poor access to research (21) (e.g. absence of information about trials for eligible individuals), eligibility criteria (21) (e.g. that unequally exclude people from underserved groups), or those who do not speak the majority spoken language), attitudes and beliefs (22) (e.g. a conservative attitude to risk taking), dearth of knowledge regarding clinical trials (23) (e.g. lack of understanding, knowledge, or information), and logistical and practical issues (20).

What researchers should consider when planning research to be inclusive of under-served groups

In a recent review on inclusion and diversity in clinical trials (24), we found 61 articles that reported strategies or interventions to overcome barriers to inclusion, or to improve diversity of trial populations. The main strategies with some evidence for their impact broadly coalesced into: the use of cultural competency training for researchers, forming and maintaining community partnerships, utilising a personalised approach with participants, using multilingual research staff and providing multilingual materials, increasing understanding and trust with target communities, communication focused strategies and common logistical issues. What is clear when reading through this list is there is no one-size-fits all approach. And it was also clear from our review, that in many cases a combination of interventions at different levels may be required (e.g. hiring multilingual research staff and establishing cooperative community partnerships). What then can we glean from this literature that researchers can enact practically?

Researchers need to start talking, and early, to the people they need to include in their studies, listen to what they say and adapt their designs accordingly. This will require more time and resources, from often already limited budgets, and therefore careful consideration of what populations need to be included or excluded and why, and what the impact (positive or negative) of excluding certain populations may be for the quality of the research and the populations themselves. This needs judgement: it is not always reasonable or possible to include every group in research. To help support this decision making process the UK National Institute for Health Research (NIHR) Applied Research Collaboration East Midlands have developed an Equality Impact Assessment (EqIA) toolkit (25).

For specific under-served populations, there are also guidelines to aid health researchers with decisions on who to include in their research. For example the INCLUDE Ethnicity Framework (www.trialforge.org/trial-forge-centre/include), a collaborative effort between the NIHR INCLUDE initiative, Trial Forge and the Medical Research Council (MRC)-NIHR Trial Methodology Research Partnership, is a toolkit to aid trial teams in how consider the ethnicity of the people who need to be involved in a trial, and how to facilitate their involvement. Facilitating involvement is arguably the hardest part. This requires implementation of interventions such as those detailed above, but with close consideration of the target population. In relation to supporting resources for this process, the Applied Research Collaboration East Midlands has also produced a toolkit and online training focused on improving participation of ethnic minority groups in research (26, 27) – see Box 1

for key principles the toolkit covers.

There is, however, a need to build and produce similar frameworks that consider a wider range of under-served groups and cover demographic features, social, economic and health factors, as well as diseases related characteristics (e.g. looked-after-children/children in care, people living in rural and remote locations, the visually/hearing impaired, prisoners etc.). The degree to which factors overlap for an individual (e.g. deprivation, ethnicity and age) – also needs attention.

Box 1. Good practice guidance for increasing participation of ethnic minority populations in health research (These principles apply to all under-served populations) Adapted from Farooqi et al. (26, 27).

Good practice guideline	Description
Consider the communities which the research needs to involve	Researchers should work to ensure that there is proportionate representation of ethnic minority (and all under-served groups where possible) groups, and that the research team are provided with the skills and tools to be able to achieve this.
2. Undertake effective patient and public involvement (PPIE) in research	Researchers should recognise how important PPIE is to conducting good quality health research and plan PPIE from the outset of the research, and have a strategy in place for how to achieve this.
3. Conduct effective recruitment in ethnic minority communities	There is a need for researchers to have sufficient knowledge of access and engagement strategies (and how they should be tailored to different population groups) to ensure effective recruitment of all populations who need to be involved.
4. Ensure cultural competence in the conduct of the research	All researchers who are engaging with patients should ensure their teams have undergone cultural competency training so that they can engage respectfully and effectively to people of all cultures, ethnic backgrounds, religions and other diversity factors.
5. Provide effective feedback to research participants	Findings of research should be communicated back to all communities involved (and not solely within the academic context), and be tailored to different population groups where required.

Policy changes may be necessary to support change

In the UK, specific policy on equality and diversity in health research is limited. The 2005 UK Research Governance Framework explicitly stated “The body of research evidence available to policy makers should reflect the diversity of the population.” In addition the framework also suggested researchers should take account of “age, disability, sex, sexual orientation, race, culture, and religion in its design, undertaking, and reporting.” However there was some regression in the later 2017 UK policy framework for Health And Social Care research, which makes no mention of equality and diversity needs in research. However, recent NIHR operational strategy has outlined a strong commitment to equality, diversity and inclusion across NIHR's research, systems and culture (28).

In the United States, the National Institute for Health (NIH) **require, through** legislation (NIH Revitalization Act of 1993) and policy, the inclusion of ethnic minorities and women in their funded research since the early 1990s. The impact of this mandate on the inclusion, analysis, and reporting of sex and ethnicity is mixed (14). The NIH stipulate the need for study populations to be representative, for due consideration to sex and ethnic group in study conception and design, and that sex and ethnic subgroup analyses are employed. Importantly, this legislation outlines key responsibilities for implementation of this policy for investigators, peer reviewers and ethics boards.

If we are to be serious about increasing diversity in health research in other countries, similar policy commitment may be required, but with closer monitoring from funders. In addition, encouraging the use of research sites with **good engagement and high recruitment** of under-served groups will ensure that health research is applicable, and that research is conducted in areas of greatest need and not just where successful investigators/research units are located/funded. And a focus beyond proportionate representation is required e.g. on issues such as measurement of underlying mechanisms and experiences, sufficient statistical power for sub-group analysis, and monitoring of diversity of public involvement and engagement.

Implementing policies will need funding. Funders (and grant reviewers) need to acknowledge that, initially at least, a commitment to tackling a lack of diversity is likely to make research slower and more expensive. For healthcare, one of the most important actions is to improve the inclusion of under-served groups in research. It is unethical to be content with the status quo: a renewed consideration of funding and policy support is needed to drive change and ensure existing inequalities are not perpetuated any longer.

Contributors and sources

All authors conceived the idea for the article and the recommendations that form the basis for the article. AR and KK led on drafting, editing and revising the content. All other authors contributed to editing the content, and all authors approved the final version and are accountable for all aspects of this work.

Conflicts of Interest

KK is a director of the University of Leicester Centre for Ethnic Health Research, trustee of the South Asian Health Foundation, and chair of the Ethnicity Subgroup of the Scientific Advisory Group for Emergencies (SAGE). AR, DB, AW, SP and ST declare no competing interests.

References

1. Smart A, Harrison E. The under-representation of minority ethnic groups in UK medical research. *Eth Health*. 2017;22(1):65-82.
2. Khunti K, Bellary S, Karamat MA, et al. Representation of people of South Asian origin in cardiovascular outcome trials of glucose-lowering therapies in Type 2 diabetes. *Diabet Med*. 2017;34(1):64-8.
3. NHS. COVID-19 Vaccine Research Registry Newsletter September 2021 2021 [
4. Cherubini A, Oristrell J, Pla X, et al. The Persistent Exclusion of Older Patients From Ongoing Clinical Trials Regarding Heart Failure. *Arch Intern Med*. 2011;171(6):550-6.
5. Spaul SW, Hudson R, Harvey C, et al. Exclusion criterion: learning disability. *The Lancet*. 2020;395(10223):e29.
6. Bierer BE, Meloney LG, Ahmed HR, White SA. Advancing the inclusion of underrepresented women in clinical research. *Cell Reports Medicine*. 2022;3(4):100553.
7. Fête M, Aho J, Benoit M, et al. Barriers and recruitment strategies for precarious status migrants in Montreal, Canada. *BMC Med Res Methodol*. 2019;19(1):41.
8. Egleston BL, Dunbrack RL, Jr., Hall MJ. Clinical trials that explicitly exclude gay and lesbian patients. *NEJM*. 2010;362(11):1054-5.
9. Silberzahn BE, Morris MB, Riegger KE, et al. Barriers and facilitators to retaining a cohort of street-based cisgender female sex workers recruited in Baltimore, Maryland, USA: results from the SAPHIRE study. *BMC Public Health*. 2020;20(1):585.
10. D'Souza MS, Mirza NA. Towards Equitable Health Care Access: Community Participatory Research Exploring Unmet Health Care Needs of Homeless Individuals. *Can J Nurs Res*. 2021:08445621211032136.
11. NIHR. Improving inclusion of under-served groups in clinical research: Guidance from INCLUDE project 2020 [Available from: <https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435>].
12. Routen A, Bambra C, Willis A, Khunti K. Hard to reach? Language matters when describing populations underserved by health and social care research. *Public Health*. 2022.
13. Ellard-Gray A, Jeffrey NK, Choubak M, Crann SE. Finding the Hidden Participant: Solutions for Recruiting Hidden, Hard-to-Reach, and Vulnerable Populations. *Int J Qual Methods*. 2015;14(5):1609406915621420.
14. Geller SE, Koch A, Pellettieri B, Carnes M. Inclusion, analysis, and reporting of sex and race/ethnicity in clinical trials: have we made progress? *J Womens Health*. 2011;20(3):315-20.
15. Powell RA, Njoku C, Elangovan R, et al. Tackling racism in UK health research. *BMJ*. 2022;376:e065574.
16. Schwei RJ, Kadunc K, Nguyen AL, Jacobs EA. Impact of sociodemographic factors and previous interactions with the health care system on institutional trust in three racial/ethnic groups. *Patient Educ Couns*. 2014;96(3):333-8.

17. On Racism: A New Standard For Publishing On Racial Health Inequities: Health Affairs Blog; 2020 [Available from: <https://www.healthaffairs.org/doi/10.1377/forefront.20200630.939347/full/#>].
18. Scharff DP, Mathews KJ, Jackson P, et al. More than Tuskegee: understanding mistrust about research participation. *J Health Care Poor Underserved*. 2010;21(3):879-97.
19. Masters C, Robinson D, Faulkner S, et al. Addressing Biases in Patient Care with The 5Rs of Cultural Humility, a Clinician Coaching Tool. *J Gen Intern Med*. 2019;34(4):627-30.
20. Rooney LK, Bhopal R, Halani L, et al. Promoting recruitment of minority ethnic groups into research: qualitative study exploring the views of South Asian people with asthma. *J Pub Health*. 2011;33(4):604-15.
21. Frew PM, Saint-Victor DS, Isaacs MB, et al. Recruitment and retention of pregnant women into clinical research trials: an overview of challenges, facilitators, and best practices. *Clin Infect Dis*. 2014;59 Suppl 7(Suppl 7):S400-S7.
22. Lee GE, Ow M, Lie D, Dent R. Barriers and facilitators for clinical trial participation among diverse Asian patients with breast cancer: a qualitative study. *BMC Women's Health*. 2016;16(1):43.
23. Byrne MM, Tannenbaum SL, Glück S, et al. Participation in Cancer Clinical Trials: Why Are Patients Not Participating? *Med Decis Making*. 2013;34(1):116-26.
24. Bodicoat DH, Routen AC, Willis A, et al. Promoting inclusion in clinical trials—a rapid review of the literature and recommendations for action. *Trials*. 2021;22(1):880.
25. NIHR ARC-EM. Equality Impact Assessment (EqIA) Toolkit [Available from: <https://arc-em.nihr.ac.uk/clahracs-store/equality-impact-assessment-egia-toolkit>].
26. NIHR ARC-EM. Increasing participation of Black Asian and Minority Ethnic groups in health and social care research 2019 [Available from: <https://arc-em.nihr.ac.uk/clahracs-store/increasing-participation-black-asian-and-minority-ethnic-bame-groups-health-and-social>].
27. Farooqi A, Jutlla K, Raghavan R, et al. Developing a toolkit for increasing the participation of black, Asian and minority ethnic communities in health and social care research. *BMC Med Res Methodol*. 2022;22(1):17.
28. NIHR. Best Research for Best Health: The Next Chapter 2021 [Available from: https://www.nihr.ac.uk/documents/best-research-for-best-health-the-next-chapter/27778#Embedding_equality_diversity_and_inclusion_across_NIHR's_research_systems_and_culture].