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## Editorial

## Reflection on Black and Ethnic Minority Participation in Clinical Trials

Z. Iyizoba-Ebozue <sup>\*1</sup>, A. Fatimilehin <sup>†1</sup>, P. Mbanu <sup>‡2</sup>, S. Adeleke <sup>‡2</sup><sup>\*</sup> Department of Clinical Oncology, Leeds Cancer Centre, Leeds, UK<sup>†</sup> Department of Clinical Oncology, The Christie NHS Foundation Trust, Manchester, UK<sup>‡</sup> Department of Clinical Oncology, Guy's & St Thomas' Hospital, London, UK

Cancer treatments have developed significantly over the past century, primarily due to clinical research. Clinical trials, and the knowledge gained from them, offer patients the opportunity to receive life-changing therapies and live longer than before. We must ask ourselves, how representative of our diverse community are the trials we do? This is particularly important as the evidence from these trials is applied to a diverse community. Past studies have also shown that genetic disparities associated with race can affect response to treatment or the disease process [1,2]. Therefore, unless there is an adequate representation of Black and ethnic minority people in clinical trials, it is difficult to infer that the results of these studies apply to them. According to Godden *et al.* [3], the odds of being in a cancer trial were 30% lower for ethnic minorities than their White counterparts. This inequality in representation might indicate that Black and ethnic minority people are not fully benefiting from scientific advances in health care. Their lack of participation also impacts the robustness of our studies.

### Under-representation of Black and Ethnic Minorities in Clinical Trials

The ongoing pandemic has highlighted the lack of representation of Black people in clinical trials in the UK. According to data released by the Office of National Statistics, COVID-19 death among Black African males and females was 2.4 and 1.7 times higher than in their White counterparts [4]. Yet, participation of Black and minority ethnic groups in clinical trials for developing the vaccines was 5.7%, whereas these groups represent 13.8% of the population [5].

Published ethnicity data in UK clinical trials remain scarce due to the lack of an obligation to record and report

ethnicity in clinical research studies in the UK [6]. However, this is beginning to change with the introduction of the Innovations in Clinical Trial Design and Delivery for underserved groups (INCLUDE) project [7]. Ethnicity data in clinical trials are more available in the US as the Food and Drug Administration Safety and Innovation Act of 2012 [8] requires demographic representation in clinical trials. However, even in the USA, participation among the Black population in clinical trials remains poor. A review of demographic participation was published in 2019 in the USA using data submitted for oncology drug approval to the Food and Drug Administration from 2008 to 2018. White, Asian, Black and Hispanic patients represented 76.3%, 18.3%, 3.1% and 6.1% of trial participants, respectively [9]. However, in the UK, the proportion of Black patients included in clinical trials may well be less than in the USA, given the lack of drive that encourages more participation from this group of patients.

The reasons for the under-representation of the Black population in clinical trials are multifactorial. Szczepura [10] classified the challenges in access to health care by ethnic minority populations into four groups: (i) extrinsic, (ii) organisational factors, (iii) intrinsic or (iv) personal factors. Extrinsic factors include language difficulties in a population whose first language is not English. Healthcare professionals involved in clinical trials may find the additional time required in these situations an added burden. Screening potential trial patients against an ever-growing list of eligibility criteria is complex and sometimes challenging. Other obstacles to participation include distance to treatment centres and low social-economic status [11]. Higher social-economic status has been shown as a statistically significant predictor of involvement in oncology trials [12]. Intrinsic factors include a lack of education on the importance of clinical trials and an inherent distrust of institutions due to racial discrimination. Black communities have been subject to historic scandals linked with clinical trials, such as the Tuskegee syphilis study of untreated syphilis in Negro males [13], unethical experiments by

Author for correspondence: P. Mbanu, Department of Clinical Oncology, Christie NHS Foundation Trust, 450 Wilmslow Road, Manchester, M20 4BX, UK.

E-mail address: [Peter.mbanu1@nhs.net](mailto:Peter.mbanu1@nhs.net) (P. Mbanu).

<sup>1</sup> Joint first authors.

<sup>2</sup> Joint last authors.

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James Marion Sims and the cases of multiple medical experimentations in Africa [14]. These historical racial abuses under the umbrella of clinical trials have hindered the participation of Black patients.

## Lack of Opportunities for Ethnic Minority Clinicians in Academia

A diverse clinical academic workforce is vital in driving innovation and excellence in research and teaching. It is also crucial to train doctors to practice in a culturally diverse environment and research health issues specific to under-represented communities. Academics are tasked with implementing research agendas and training the next generation of researchers [15]. However, recruitment and retention within clinical academia affect certain demographic groups disproportionately, and minority ethnic clinical academics are under-represented [16]. This hinders the development of a positive and inclusive medical culture.

In 2019, ethnic minority groups accounted for 22% of lecturers, readers and senior lecturers in medical schools, but only 14% of medical professors [17]. In the academic years 2016–2019, of the total 19 868 PhD funded studentships awarded by UK Research and Innovation (UKRI) councils collectively, 245 (1.2%) were awarded to Black or Black Mixed students [18]. Ethnic minorities are under-represented among UKRI fellows and principal investigators [19], reflecting similar findings in US funding differentials among African American or Black principal investigators [20]. Existing barriers that have been identified include, lack of funding, training opportunities, unsupportive culture, lack of mentors and limited role models [21,22]. There is a disparity between talent and opportunities for ethnic academic clinicians. Even though there are talented clinicians from minority ethnic groups, the gap in opportunity in academia, which is not fairly distributed, hinders them from flourishing.

Data-driven accountability is crucial, and we must capture and monitor the recruitment, career progression, experience and achievements (including funding awards) of academics and researchers from ethnic minority groups. We need to establish a supportive culture for clinical scholars, whereby soft skills can be learned to thrive and succeed in an academic environment. Positive peer interaction helps reduce feelings of isolation and fosters a sense of belonging [22]. Educational mentorship programmes that provide one-on-one mentoring by experienced investigators, group-based skill-building workshops, support for conducting pilot studies and accessing funding opportunities/grants need to be established to help the career advancement of Black, Asian and Minority Ethnic (BAME) academics.

## Lack of Funding for Ethnic Minority-related Research

Funding and grant allocation is an essential part of the research we do. The need to increase the participation of

ethnic minorities is often highlighted, but the factors affecting access to the necessary funding to improve this are complex and poorly investigated. The role of funding organisations and pharmaceutical companies in funding many clinical trials is significant, as they determine which studies to support and which to reject. Pharmaceutical companies run on achieving the financial goals of their shareholders. As a result, they may be more inclined to recruit a homogenous trial cohort and choose investigation sites with higher enrolment, which may not necessarily serve large numbers of patients from ethnic minority groups [23].

The inclusion and exclusion criteria for trials could also indirectly impact the funding of diseases that affect minority groups. People from ethnic minority groups may be more likely to have comorbidities such as chronic kidney disease and HIV, rendering them ineligible for trials [24,25]. For example, patients with lower creatinine clearance levels should be considered for inclusion if the study drug does not require renal clearance. Healthy HIV-positive patients with a low risk of developing AIDS could also not be automatically excluded.

Scientists from minority groups are more likely to centre their research interests on areas that benefit their community [26]. To achieve trial outcomes that reflect the diversity of our communities, research funding would need to be distributed more fairly. The diversity data from the UKRI councils covering the financial years 2014–2019 showed that White principal investigators had been awarded higher grant amounts than their ethnic minority counterparts in that period [19]. This result reflects a more considerable inequality when we consider that White applicants are usually around five-to six-fold more than those from ethnic minorities [19,27]. Diversity grant data released by the largest independent funder of cancer research in the UK, Cancer Research UK (CRUK), from 2017 to 2019 showed that researchers from ethnic minority groups applying for a CRUK fellowship are less likely to be funded than their White peers [27]. Their data show that the differences are most marked in the interview process, where 28% of fellowship applicants from ethnic minority groups are unsuccessful compared with 16% of their White counterparts [27].

Given that these results from CRUK are statistically significant and coupled with the fact that ethnic minority applicants make up only about 20% of the total number of interviewees, one wonders whether there is a need to improve the diversity makeup of the interviewing panels to ensure diversity and inclusion in their decisions. It is also crucial that the individuals who sit on the review committees and the leadership boards of our research funding organisations are diverse individuals who look more like the society they belong to. These individuals drive the research agenda and need to be diverse to ensure well-balanced decision making for the trials we run. This is essential for the fund allocations in today's studies and influential in shaping future generations of medical research. Diversity data on the leadership board of research funders should always be available publicly.

## Conclusion

Diversity is essential in enhancing innovation in all walks of life, both in medicine and outside the field of science [28,29]. There is a need to foster greater inclusivity and diversity in cancer research to reflect and better serve the needs of our diverse patient population, improve ethnic minority patients' trust in our health system, access to health care and increase participation in research [30]. To allow targeted and measurable improvement in cancer research, mandatory diversity and demographic records in clinical trials are crucial. The availability of high-quality demographic data will enable us to identify what needs to be done so that our trials reflect the community they are recruited from, and the result applies to all. To improve recruitment, we need to educate ethnic minority groups on the importance of engaging in clinical trials. Establishing good financial incentives for organisations that promote diversity and equality and enhance funding opportunities for ethnic minority research is also essential. Moreover, academic mentorship programmes for clinical academics of ethnic minority backgrounds will foster diversity. Achieving diversity in clinical trials and research is both good science and a moral duty.

## Conflicts of interest

The authors declare no conflicts of interest.

## Author contributions

PM is the guarantor of integrity of the entire work. ZI-E, AF, SA and PM were responsible for study concepts and design. ZI-E, AF, SA and PM carried out the literature research. ZI-E, AF, SA and PM prepared the manuscript. ZI-E, AF, SA and PM edited the manuscript.

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