Barriers to Participation of Diverse communities in Clinical Trials/research

There is an established evidence base exploring reasons for low participation of diverse groups in clinical trials and research studies some of which corresponds to barriers experienced in relation to Patient and Public Involvement in research. There is a large body of evidence that comes from clinical cancer trials (mainly US-based and less so in the UK). Other more recent condition-focused studies relating to Asthma and South Asian Communities as well as, mental health research participation and African-Caribbean communities in the UK and abroad, confirm these findings. Furthermore, there is also a considerable amount of discussion relating to the representation of diverse groups in clinical research being identified as an important component of strategies to reduce inequalities in healthcare.

Summaries of the main barriers identified:

**Increased cost of studies** – The addition of extra variables such as ethnic diversity of participants, which would require sub-group analysis, would mean that more subjects may have to be recruited into a trial – this would impact costs of the study.

**Structural racism** – Underserved populations can expect higher incidence rates (of cancer), worse access to prevention and screening, later diagnosis or treatment and reduced involvement in clinical trials and ultimately inferior survival rates. It is also unclear how many patients from diverse groups are explicitly offered participation in many studies.

**Attitudinal barriers** – researchers (along with the rest of society) may have unconscious bias or preconceptions about whether patients from certain groups are interested in participating in a study or not due to stereotypes or cultural myths.

**Language or Communication barriers** – for patients where English is not their first language. Often there is no guidance or resources for researchers to overcome this so those patients are automatically excluded from the study. Furthermore, ethics committee requirements to translate all written material in different languages can have little positive impact when many community languages are not generally used in a written form, or low levels of health literacy are not accounted for in the material.

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Mistrust of healthcare providers/anchor institutions – is often cited as the most common barrier to participation in trials for BME groups. Poor previous experiences and low satisfaction in a health care setting can often lead to patients not wanting to participate in a study. There is also fear around sharing or misuse of personal information and data protection issues.

Lack of understanding of the research process – in disadvantaged and marginalised communities can lead to them rejecting an invitation to participate. Roles for patient advocates and navigators could support the enrolment and compliance in the early stages of a trial to ensure retention of patients from underserved communities.

Lack of awareness – The lack of conceptual understanding of race, ethnicity and culture makes the recruitment of people from ethnic minority backgrounds appear more problematic to researchers.

Poor study design – Case selection biases that tend to structurally exclude BME patients and individuals with lower socioeconomic status, as they tend to have poorer health in general. Overly complex information containing jargon and consent forms can exclude potential participants from different backgrounds even when command of English is good.

Socioeconomic status – Decisions by patients to participate may be driven in part by socio-economic status. Loss of income (actual or perceived) or costs incurred by participation in research (due to more hospital visits) may deter participation.

Flexibility – Lack of flexibility around timing can prevent many patients from participating. Common reasons include Childcare, Carer responsibilities and employment in sectors that wouldn’t approve extra time off to attend follow up clinics.

Stigma – Different cultural/faith of patients can impact their perceptions of cancer, death and benefits of treatments through a clinical trial.

The above is not an exhaustive list but demonstrates the well-documented reasons for low participation in research from diverse groups.