Improving diversity in research and trial participation: the challenges of language

The COVID-19 pandemic has brought into focus issues of health inequality and the disproportionate disease burden experienced by ethnic minority communities, compared with the population as a whole.[1] High-quality research is the basis for an evidence-based approach to the delivery of health care. It is widely accepted that some subgroups of patients might respond differently to interventions due to genetic, social, and cultural factors.[2] Therefore, diversity within study cohorts is crucial to ensure research is generalisable,[3] benefits all of society, and does not perpetuate existing inequalities.

In some demographically heterogeneous countries, such as the UK, national funding bodies have issued guidance that aims to promote equality within research.[4] The aim of improving representation in research involvement is to improve on the current status quo, and is scientifically justified in light of differential disease risks and ethically justified given differences in access to care. However, issues of feasibility and knowledge gaps hamper efforts to achieve this improved representation.

An important under-researched area in the context of diversity is methods to accommodate the language needs of under-served ethnic minorities, some of whom might have low first language literacy, health literacy, or English language proficiency (in majority English-speaking societies, such as the UK). Engaging a substantial proportion of such groups to make the recruited sample more representative of the target population is unlikely to be easy or cheap. Simply translating a document into a heritage language is unlikely to be an effective solution for this complex challenge. Such an approach is impervious to working with communities to facilitate sustained understanding and enhance trust.

Defining the scale of this issue is difficult. A review on telehealth interventions for type 2 diabetes, a condition for which ethnic minority groups are over-represented and experience poorer outcomes, found that only two-thirds of included trials reported the ethnic composition of participants.[5] Language and socioeconomic variables were not routinely described, making it difficult to compare characteristics of the recruited sample with the target population and to examine within-group and between-group differences (where language barriers are present for some but not all ethnic groups). These findings suggests the need to improve reporting practices to disambiguate language barriers from cultural factors.

In establishing a need for translation, and other related support in the planning stage of a trial, it is important to distinguish trial contexts where language is required solely as part of the informed consent process (an ethical imperative for all research participants) and trial contexts where language is part of the intervention. Use of the same word or the direct translated equivalent word might convey differing concepts.[6] Communicating symptom experiences such as pain can differ across languages, and if these form part of the intervention or outcome assessment, comparisons are likely to be affected. Despite the ethical issues, there are some contexts where there could be meaningful grounds for exclusion based on language proficiency (eg, the nature of the intervention is different when offered in different languages), but this would need to be justified.

There are gaps in current knowledge of the most effective methods to inform best practice guidance aimed at more inclusive recruitment to clinical trials centring on language. To address these gaps, the following points are proposed for researchers considering language translation in clinical trials. First, language-specific information for the target population (eg, proficiency in English and other languages) alongside ethnicity information should be considered at the trial conceptualisation phase.[7] More accurate and detailed data on first language literacy in diverse populations can better assess demand and lead to a more accurate cost-benefit analysis of providing language translation as part of clinical trials. Second, matters of inclusion need to be considered at all stages of the research process, from initial research focus through to implementation, addressing key barriers from previous literature that limit participation.[8] Third, robust translation methods should be employed (eg, forwards and backwards translation with input from multiple translators and clinical reviewers).[9] Where possible, in the written mode, emphasis should be placed on achieving

conceptual equivalence, with appropriate readability levels, assessed via end-user testing.[10]

Improving access and promoting diversity in research is a priority for governments and funders seeking to reduce health and socioeconomic disparities.[7] However, strategies promoting inclusion cannot be overburdensome and limit the feasibility of carrying out research. Pragmatic approaches are needed to ensure that research is open to a broader participant base, without undue participant exclusion decisions being made due to the non-clinical criterion of language barriers and with additional resources available to support the inclusion of ethnic (including linguistic) minorities. Once an intervention or therapy has shown efficacy at a population level, targeted approaches, where there is greater scope for tailoring of interventions, could be successful.

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