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Closing the gaps in recruitment and retention in cancer trials: sufficient evidence but poor implementation

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One of the many impacts COVID-19 pandemic had on the UK healthcare environment was to highlight the disparities and inequalities present in the national setting in accessing healthcare and clinical trials.[1] If the challenges to design more inclusive, equal and effective trial recruitment strategies were known before the pandemic, what this historic moment did was to elicit a tangible effort in revolutionising these approaches: all the major national cancer trial funders started to demand that a solid plan for equality, diversity and inclusion, and patient involvement and engagement is in place at the trial design stage, with the support of the Innovations in Clinical Trial Design and Delivery for the Under-served (INCLUDE) roadmap scheme from the National Cancer Research Institute (NCRI), among others.[2]

By analysing the recruitment strategy of the BladderPath study, the article by Nanton and colleagues focuses mainly on the barriers to recruitment related to ethnicity and socioeconomic status (or deprivation), while providing potential approaches to address these and calling for national standardised schemes.[3] In terms of ethnicity-related barriers, it is pivotal to stress the fact that while cultural values, including lack of trust in the healthcare system and stigma around cancer, have been shown to impact the decision to participate in trials in some minority populations, the intention and willingness to take part in research does not vary between groups. Unsurprisingly, the underlying causes of ethnicity-related barriers are to be found within trial processes and staff practices.[4] Among the methods suggested to address this barrier and ensure a better ethnic representation in cancer trial recruitment, is the one of a systematic implementation of the National Institute for Health and Care Research (NIHR) Equality, Diversity and Inclusion (EDI) toolkit, a more attentive design of patient-facing material and enhancement of the cultural competency of trial staff.[5] In addition to this, Patient and Public Involvement (PPI) in research appears to be the fundamental tool that allows to take an appropriate action towards inequalities in health by ethnicity: only via a conversation with the representatives of the underserved communities can a targeted engagement be designed within the community settings, with community leaders and members, improving recruitment and retention in trials.[6] The UK Research and Innovation (UKRI) has also recently published the *Equality, Diversity and Inclusion Expectations Guide*, that serves as a beacon of light in the implementation of what is, too often, a tokenistic approach to PPI.[7] As a matter of fact, with oncology trial funders increasingly requesting a study-specific PPI plan, research teams often included PPI with the sole purpose of enhancing the success of their two times per day, with little or no attention to the core meaning of engaging with the patients, the public and, especially, the underserved populations. Outreaching strategies to engage with ethnic minority groups, associations and charities must be put at the forefront of the research pipeline during the trial design stage. Successful methods of collaboration with underserved communities must also transpose into appropriate financial recognition of such contribution, with many national cancer groups and institutes, such as Health Research Authority and NIHR now providing guides about payment for public involvement in care and research.

Of the utmost relevance is the discussion that Nanton *et al* provide about socioeconomic status as a barrier to recruitment and retention in cancer studies.[3] It is a common misconception and oversimplified interpretation of the demographic scene that ethnic minorities always relate with deprived conditions and low SES. Due to cultural norms and social distribution changing through

generations, there is mounting evidence that in the UK, some ethnic minority groups outperform white populations in selected parameters such as educational attainment and this confirms the data collected in the USA that indeed a low SES represents the main barrier to trial participation, regardless of the ethnicity.[8] It is therefore the research community's responsibility to address all trial design aspects that have a direct or indirect impact on the financial, social and professional sphere of the potential participants. The level of access and the cost of transports to attend trial appointments, the ability to understand the oral and written information before and during trial participation, the disruption to the participant's working patterns are only some of the aspects to be addressed when designing a trial and funders should require that such analysis is performed early in the pipeline of the study.

The combination of the ample evidence available from both UK and US settings, and the innumerable examples of toolkits and guides offered by nearly all major cancer research organisations now provide a fruitful ground for regulatory authorities to harmonise locally and globally on the methods to address the inequities in cancer trials. Furthermore, the next generation of cancer trials has now sufficient tools to appropriately broaden eligibility criteria, implement patient and public involvement and adapt staff representation and trial practices; while also having the opportunity to successfully design and validate assessment tools and indices of efficacy in closing the participation gaps once and for all.[9 10]

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