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Boosting and broadening recruitment to UK cancer trials: towards a blueprint for action

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ABSTRACT

Recruitment and retention in cancer trials are long-standing issues, exacerbated by the COVID-19 pandemic. The UK National Institute of Health Research and leading clinicians have emphasised the urgency to achieve and surpass prepandemic levels of participation.

Data from a recent UK trial demonstrated the impact of COVID-19 and highlighted factors that limited recruitment. In response to this worldwide problem, studies have identified strategies for remediation at the levels of funding, the research environment, study design and trial team-related aspects, yet evidence of progress is lacking. Equality, diversity and inclusivity have become central to UK health and social policy during the 2000s. The need for greater inclusivity in trials has become a particular concern for cancer researchers and funders in the UK and in the USA, in recognition of potential bias in results. In the UK trials, the lack of standardised recording of ethnicity data renders interpretation difficult and caution is required in comparisons with the USA.

Recently, the focus of concern has shifted away from the impact of deprivation and low socioeconomic status on trial participation. Barriers created by these factors and their frequent intersection with ethnicity should not be overlooked.

The UK has adopted an advisory approach to broadening recruitment, publishing policy documents, guidance and toolkits. In the USA, by contrast, action on inclusion is increasingly mandated. Within the UK paradigm, the cancer research community is strongly encouraged to adopt a coordinated approach towards standardised digital data collection and embed and evaluate innovative, cocreated, locally relevant strategies.

INTRODUCTION

Recruitment and retention in cancer trials are long-standing issues, yet more salient since the COVID-19 pandemic. The need to achieve and surpass prepandemic levels of participation has been forcefully argued by the UK National Institute of Health Research (NIHR)[1] and strongly endorsed by leading clinicians.[2]

Equality, diversity and inclusivity (EDI) have risen to the forefront of UK health policy and in wider political spheres since the turn of this century.[3] In parallel, the importance of greater inclusivity in trials has become an increasing focus for cancer researchers and funders. Disparities in cancer incidence and outcomes reflect more general health disparities underpinned by social and economic inequalities.[4] Ultimately, under-representation of minorities in trials risks compounding this inequity—broadening participation to include those groups currently largely absent, and boosting participant numbers, are both critical in mitigation and to establish external validity of results.

A body of literature now exists on barriers to inclusion and potential remedies, yet evidence of progress remains scant, notwithstanding the impact of COVID-19. Here, we consider recruitment pre-COVID-19 and during the COVID-19 pandemic from our own experience of a UK randomised trial, the BladderPath study.[5] We identify barriers to progress, including the lack of standardised data on trial participants' socioeconomic status (SES) and ethnicity, and contrast the approaches to inclusivity adopted in the UK and the USA. Finally, we suggest a coordinated approach of systematic digital data collection, urge the implementation of current guidelines and recommend innovative recruitment strategies for consideration by the cancer research community.

RECRUITMENT DURING THE COVID-19 PANDEMIC

In the UK, recruitment to cancer trials was largely suspended during the first 5 months of the COVID-19 pandemic as staff were redeployed; this has been slow to regain momentum as sites endeavour to restore

patient services. This delay is particularly disappointing after the success in the UK in recruiting to both vaccine trials and COVID-19 therapy trials. To facilitate these trials, administrative processes were streamlined and fast-tracked in parallel. These lessons and successes have not been carried over into postpandemic, non-COVID trials.[6] While the major and long-lasting impact of the pandemic is evident, boosting recruitment and retention has long been an aspiration of triallists and funders alike.[2] Missed targets undermine the validity of findings and waste the costly time and resources required to set up and conduct studies. Some trials are inherently easier to recruit to than others and unrealistic expectations based on optimistic and simple methods of prediction are also unhelpful.[7–9] Despite such concerns, detailed data on recruitment to randomised controlled trials are elusive. Reviews have largely included cancer trials alongside studies focused on other conditions and the variability of recruitment data reported in reviews, such as discontinuation rates, percentage of eligible patients recruited, and percentage of target recruitment achieved, contribute to a lack of clarity over the extent and nature of recruitment challenges pre-COVID-19.[7 10–12]

Our recent feasibility BladderPath trial,[5] with a target of 150 patients, was severely affected by the pandemic. Recruitment was paused at the 16 participating sites for 5 months between April and August 2020 and not all were able to resume non-COVID research during the remainder of the recruitment period. Recruitment resumed between September 2020 and October 2021 in 11 of the 16 sites.

While 78% of the total number of 143 participants were recruited pre-COVID-19 (July 2018–March 2020), 9 of the 16 sites recruited the remaining 22% in the months from September 2020 to December 2021 when the impact of COVID on services and staff was still severe.

Table 1 illustrates recruitment pre-COVID-19 and post-COVID-19 suspension.

Evidently, COVID-19 was not the only factor impacting on recruitment. Six of the 16 sites stopped recruitment before the beginning of the first lockdown in March 2020 as shown in the table. Four of these did not resume post suspension. During the pre-COVID-19 period considerable variation in recruitment between sites was apparent. One site, the highest recruiting overall, achieved a maximum of 7 patients during 1 month; of the other 10 sites open before March 2020, 9 did not recruit any patients and 1 site recruited one. Reasons for this variation included staff absences, Trust restrictions on trials, lack of flexible study processes, lack of involvement of general practitioners and difficulties for local principal investigators and research nurses in engaging clinical staff due to the prioritisation of front-line patient care.

INCLUSIVITY

The UK NIHR, concerned at the inequality of access to cancer trials, reported a drop of 60% in the numbers of patients participating in trials during the pandemic and has highlighted the need to regain and surpass prepandemic levels, encouraging triallists to address known barriers.[6] Investigations in the UK and worldwide have

Table 1 Recruitment pre-COVID-19 and post-COVID-19 suspension

Site no.	Accrual pre-COVID-19	Recruitment stopped prior to COVID-19	Did site reopen?	(Re)opened in	Accrual post-COVID-19
1	7	N	Y	November 2020	1
2	25	Y	Y	September 2021	0
3	20	Y	Y	October 2021	4
4	3	N	Y	September 2020	1
5	25	N	Y	May 2021	4
6	5	Y	N		
7	17	N	Y	October 2020	9
8	3	Y	N		
9	1	N	N		
10	0	Y	N	Closed	
11	0	N	Y	September 2021	1
12	1	N	Y	May 2021	3
13	2	N	Y	August 2001	5
14	1	Y	N		
15	2	N	Y	November 2020	2
16*	0	N	N/A	October 2020	1

*Site opened after reinstatement of recruitment. NB: Site numbers relate to order of opening.

identified challenges with funding, the research environment (including complex regulatory requirements), study design and trial team-related aspects.[13–15] Adaptive trial designs have been introduced to increase the efficiency of trials in terms of numbers of participants needed,[16] and use of resources; however, they do little to address the more fundamental challenges of inclusion and representation of diversity.

Strategies proposed to improve inclusion and representation have included methods to widen geographical access to trials through the use of digital technology. This has its own challenges such as the need to improve broadband infrastructure in rural communities where high-speed mobile and full fibre broadband are lacking. Among disadvantaged rural populations, affordability and sometimes lack of digital skill create further barriers. The urgency and importance of reducing this 'digital divide' has become a priority for local government and councils; multilevel approaches are recommended in order to achieve solutions.[17]

Among other strategies for inclusion are the introduction of patient navigators; these are, in theory, independent people that provide personal support to people receiving healthcare or participating in a clinical trial. In the UK, the role is usually carried out by the clinical research nurse. In addition broadening eligibility criteria, overcoming potential recruiter bias in favour of a narrow section of the population and simplifying the consent process and participant opt out strategies[13 14 18] Patient and public involvement (PPI) too has been shown to have a positive impact on recruitment and retention rate.[19]

Recently, there has been a shift of focus towards the representation of a range of population groups in trials, reflecting wider societal trends including increasing recognition of health disparities. Consequently, broadening participation has become a priority for funders. As well as the clear moral imperative for inclusivity, a narrow recruitment pool results in a potential bias of outcomes with implications for the spectrum of cancer trials; early phase drug trials in particular, require wide genetic and genomic variation to determine tolerability and efficacy among different populations.[20] Psychosocial and psychoeducational interventions also require evaluation in relation to social demographic and cultural characteristics.[21] In the USA, particular attention is being paid to the recruitment of ethnic minority populations in research studies to identify factors determining specific susceptibilities, and to the retention of minority group patients to achieve equity of outcome.[22]

In the UK, while 'inclusion' in theory applies to those with the nine 'protected characteristics' identified by the 2010 Equality Act[23] and now generally termed 'underserved', particular emphasis has also been on under recruitment from ethnic minority populations.

DATA GAP: ETHNICITY

Data on ethnic patterning of cancer incidence, prevalence and survival are available in the UK through Cancer Registries, the Office for National Statistics (ONS) and Cancer Research UK, although with certain caveats. The Hospital Episode Statistics database records ethnicity of patients admitted to hospital. As yet, ethnicity data are rarely recorded in cancer trial recruitment statistics and may be poorly documented in-patient records rendering accurate assessment of levels of under-representation problematic.

Norms and practices regarding ethnicity data collection are to some degree anomalous. Ethnicity is classified as personal data under General Data Protection Regulation. Researchers are required to state if these data are to be collected in applications to National Health Service (NHS) research ethics committees and to provide a rationale. Health records in primary and secondary care largely include ethnicity data, although these are frequently inconsistent. From 61.8 million individuals registered with a primary care practice in England, 51.5 (83.3%) had at least one ethnicity recorded in General Practice Data for Planning and Research. Approximately 12% of individuals had at least two conflicting ethnicity codes in primary care records.[24]

Funding bodies and the government committed to inclusion, now emphasise the importance of ethnicity reporting and the UK Government (GOV.UK) recently published standards for ethnicity data collection linked to Action 6 of it 's Plan for Inclusive Britain.[25]

An investigation of the extent to which recruitment of minority groups in clinical cancer research reflected prevalence of cancer in the population identified 30% lower odds for a member of a minority ethnic group with cancer participating in a trial than a white person, after adjusting for disease, age and gender, with variations between ethnic groups.[26] However, this report expressed frustration at the inadequacy of trial ethnicity data collection which limited the study's ability to determine participation levels in relation to prevalence.

In 2021, Blood Cancer UK, in a comprehensive review of barriers to recruitment, attempted to bring together statistics on under-representation across the range of cancer trials.[27] The report cited the ProtecT study in which 1% of the 1643 participants were black men; a figure that appears startlingly low given the increased risk of prostate cancer among men of Black Caribbean and Black African ethnicity.[28] With so few black participants, the ProtecT trial conclusion (that monitoring with deferred treatment is safe) may not apply to the entire patient group, especially as, in addition to increased risk, black men may have more aggressive disease. Nevertheless, without a baseline of the ethnic composition of the total number of men out of the 2664 eligible for inclusion, the true implications of the 1% figure are difficult to determine.

Of the limited data available, one recent review of trials undertaken between 2014 and 2021 involving

patients with multiple myeloma, reported significant under-representation of non-white patients in early phase studies (p<0.010) which was particularly marked in relation to population prevalence (p<0.0001).[29]

Discussions of under-representation in the UK frequently cite evidence from American trials, where Hispanic and black participation has been markedly low.[30 31] Comparison with the experience of France, also a former European colonial power, may be more informative. However, the ideological underpinning of the French state prohibits data collection on ethnicity in any public context, except in areas of health research where specific ethics committee permission must be sought. While cancer researchers in France have argued the importance of comparative data on different population groups, there is a perceived mismatch between collection of these data and French values and concepts of equality.[32] The utility of an Anglophone comparator for the UK is clear, nevertheless there is a danger in overextrapolation from the USA context to the UK, given the different historical experience and composition of minority populations.

Factors identified as underlying the lack of ethnic diversity among trial participants largely overlap with those that account for low recruitment[14–16 18]; for example, studies in the USA have highlighted a lack of trust in health services as a barrier to uptake which may also be relevant in the UK.[33 34] People of African, Asian and Caribbean heritage experienced worse outcomes from the COVID-19 pandemic in terms of morbidity and mortality; hence, continued poor recruitment may be a reflection of increase in disaffection in the light of this disparity.[35]

Cultural barriers, including stigma surrounding cancer, have been shown to influence decisions around participation among some minority populations.[36] However, there is compelling US evidence that while participation varies between groups, willingness to participate does not and that the major barriers are those relating to trial processes and staff practices.[12 37] No comparable UK-based studies have been identified to date. Nonetheless, evidence from a review of UK non-cancer studies has shown how the complicated consent process and lengthy and complex patient information materials, aimed at safeguarding patients, can act as a deterrent to participation.[38] In addition, negative assumptions and lack of cultural understanding among recruiters may lead to a reluctance to approach patients from minority groups. An additional factor underlying lack of diversity may be the priorities of hospitals themselves. Hospitals in areas of high deprivation and high levels of diversity (which are often correlated) will tend to be under higher service pressures than hospitals in less deprived areas which may therefore be more able to offer trial recruitment. Trials are not part of NHS targets and hence Trusts have an incentive to prioritise other areas where there is a risk of financial penalty for failure. While Trusts do not receive direct payments via the NIHR for trial recruitment, Trusts may be more supportive of simple trials than more complex ones.

DATA GAP: DEPRIVATION

Disparities in cancer trial participation have been linked with disparities in overall experience of healthcare that affect those in 'underserved groups', including those of low SES.[20 34] Deprivation has long been associated with poor health outcomes, particularly apparent in certain cancers. While deprivation is mentioned in the NIHR guidance, the term appears to have largely disappeared from discussions within the UK health research agenda, now focused on EDI. In the USA, the American Society of Clinical Oncology (ASCO) and the Association of Community Cancer Centres 2020 recommendations for expanding the participation of underserved individuals in cancer clinical trials highlight the importance of sharing aggregate data on 'racial' and ethnic diversity, but make no mention of deprivation, disadvantage or social class.[39]

This is concerning. First, it risks those at the lower end of the socioeconomic scale continuing to be underrepresented and underserved.[40] Second, it suggests a conflation of ethnicity with disadvantage and deprivation, an oversimplified analysis of the position of ethnic minorities in society. In the UK, certain ethnic minorities (Chinese, Indian) outperform white populations on a number of parameters including educational attainment, and within-group variation is wide though most ethnic minorities are however over-represented compared with white populations in the most deprived decile.[41] Barriers to inclusion clearly exist across minority groups but these may not all be shared. Cultural norms evolve over generations and as minorities improve their socioeconomic position. While all minorities, particularly those who are Black or Asian, experience bias, conscious or otherwise, or direct discrimination, not all face barriers that relate to deprivation or social and economic disadvantage. In the USA, evidence is mounting that not only are differences in outcome more attributable to SES than 'race', but that low SES is the major barrier to trial participation.[42 43] Despite a universal healthcare system in the UK, there are often hidden costs in trial participation as well as other barriers associated with deprivation, such as educational deficit and poor access to transport. For those on low pay, taking time off for hospital visits may incur direct loss of income if, for example, on a zero hours contract. For example, 16.4% of the population of England is described as functionally illiterate and the UK government website recommends public information to be written at the population average reading age level of 9 years.[44] Additionally, patients may be non-native English speakers, potentially compounding literacy issues. Furthermore, public transport outside of metropolitan centres is notoriously poor and often expensive.

The impact of low SES on access to trials should not be underestimated or overlooked. It is important that those delivering interventions to broaden and boost recruitment are mindful of the heterogeneity of potential participants within ethnic minority categories and are aware of and develop strategies to address barriers that relate specifically to SES, for example, financial pressures

of caring responsibilities and transport issues. NHS research ethics committees are guided by the principle of data minimisation, that is, the collection of only those data necessary for the purposes of the research, although where the relevance of SES is demonstrated, research ethics committees will agree to the inclusion of postcode in the dataset.

In both the USA and the UK, minority populations with cancer generally have worse outcomes than white patients.[30 45 46] The extent to which this is driven by different underlying pathology (eg, the known increased risk of aggressive prostate cancer in black men) or socioeconomic factors is impossible to assess without adequate representation in trials from all sections of society. In the bladder cancer setting, the same issues may apply to female patients.

In addition, patients with cancer are highly likely to suffer from comorbidities. Among patients with four common cancers in the UK, up to two-thirds suffered from at least one comorbidity from a list of 14 long-term conditions. The odds of having a comorbidity, and the probability of multiple comorbidities, were highest in patients from the most deprived areas.[47]

BROADENING ELIGIBILITY

Broadening eligibility criteria and addressing the challenges to participation experienced by patients with cancer living with long-term conditions is important in terms of understanding variation in tolerability and efficacy in the presence of other illnesses and treatments and would do much to promote inclusivity.

Patient safety is generally cited as the rationale for narrow recruitment. It has been argued, however, that inclusion criteria that are too restrictive both exclude patients in greatest need and exacerbate disparities in cancer treatment and outcomes. Researchers at the Fred Hutchinson Cancer Centre (USA) have advocated a move away from limiting recruitment to those they term 'Cancer Olympians' that is, those most likely to do well.[48] As cancer researchers, perhaps we should all be wary that much of our evidence to date may be based on these Cancer Olympians.

At the same time, in the USA in 2021, the National Cancer Therapy Program (CTEP) issued a memorandum emphasising a commitment to broadening eligibility criteria in clinical trials in general, in order to increase diversity of participants. The memorandum draws attention to the specific CTEP Broadened Eligibility Criteria Guidance based on two sets of recommendations made by ASCO and Friends of Cancer Research in relation to a range of criteria. The first of these included, for example age, HIV infection and prior and concurrent malignancies. The second, washout periods, concomitant medications, prior therapies, laboratory reference ranges and test intervals, and performance status. A proposal for the removal of psychiatric illness as an exclusion criteria was also mooted.

The CTEP guidance recognises the possible need for modifications in relation to specific protocols or particular drug developments, however, the guidance firmly advocates the provision of a scientific or clinical rationale in such instances such as the requirement of specific biomarkers.[49]

In the UK, by contrast, more attention has been given to the recognition of barriers to participation and how these might be overcome than to widening eligibility.

STRIVING TO CLOSE THE GAPS

The impact of COVID-19 on cancer care and cancer trials has been profound. There is now a shared sense of urgency to recover from this impact and a renewed ambition to extend participation. This is essential to ensure generalisability of findings with regard to new diagnostic pathways, treatments and interventions.

Crucial to a more nuanced approach to trial inclusion is accurate and detailed record keeping. The US National Institute of Health has led the way in terms of requiring the collection of ethnicity data in all clinical trials,[50] although the response has not been universal.[51 52] The collection of SES data, though advised by the Federal Drug Administration (FDA), remains more limited.[53] In the UK, regulatory authorities have not yet mandated the collection of ethnicity and SES data and the former are particularly lacking. The CONSORT reporting checklist for two-arm randomised controlled trials includes 'demographic and clinical data for each group' yet provides no detail as to how these data should be described.[54] Nonetheless, such data are essential for the measurement of improvements in inclusion and, ultimately, the measurement of outcomes.

In June 2022, the US House of Representatives, in response to slow progress in increasing diversity, passed legislation mandating sponsors of phase 3 drug trials to submit an action plan to the FDA.[52] Action plans are required to include goals for recruitment according to demographic grouping and proposed steps towards achievement. These measures have been cautiously welcomed, although there are questions around enforcement and the failure to address the root causes, as well as a call for financial support from the FDA for relevant infrastructure development at trial sites.[55]

In the UK, by contrast, the approach to promoting inclusivity is facilitatory: the NIHR has developed an EDI strategy[56] and has published 'INCLUDE,' an ethnicity framework and roadmap focused on trials.[57] In addition, the NIHR's Research Design Service has produced an EDI toolkit.[58] The toolkit provides resources and guidance relevant to the full range of health-related research, promoting cultural sensitivity and competence in trial staff and increased diversity in staff recruitment. The NIHR also supports the Centre for Ethnic Health Research[59] in developing training and resources on inclusion. A recent paper under the 'Trial Forge' umbrella[60]

has made four key recommendations on how to broaden trial participation:

- Ensuring eligibility criteria and recruitment pathways do not limit participation in ways you do not intend.
- Ensuring your trial materials are written with inclusion in mind.
- Ensuring trial staff are culturally competent.
- Building Trust in partnerships with community organisations that work with ethnic minority groups.

Advocacy groups such as Blood Cancer UK have undertaken the development of ethnicity toolkits and training specifically related to cancer.[27]

Evidence on the utilisation of the guidance and toolkits, and evaluation of effectiveness, is currently limited. The requirement by NIHR funding streams for the inclusion of an EDI strategy within grant applications may go some way to ensuring take up of guidance, although this should be linked to a further requirement for the collection of ethnicity and SES data. A requirement for inclusion in the final report of a discussion of the implementation and effectiveness of the strategy, including identification of any specific local challenges or solutions, may be a start in providing such evidence.

MOVING FORWARDS

Opportunities for cancer-related data sharing offered through digital technology are immense.[61] Electronic patient records include ethnicity data using ONS standard ethnicity classification[41] and patient postcodes that can be classified in terms of deprivation indices.[62] These can be recorded by local trial teams for all eligible patients and can be used to measure inclusivity. The proportion of the population selecting more than one ethnicity in the 2021 UK Census rose to 10.1 from the 8.7% figure in 2011[41]; hence, it will be increasingly important that consenting patients are offered the opportunity to identify multiple ethnicities from the ONS list. They may also self-define, as the online census now allows. The reason why these data are needed should be explained verbally and questions invited. Data can be collated and reported with monthly accruals, with ethnicity data aggregated for non-participants.

Genetic exploration in multiethnic populations is already technically and statistically challenging and the identification of tumour tissue samples in biobanks as of dual or multiple ethnic origin will add to these challenges. Nevertheless, as these heterogeneous sample volumes grow, they may be important in the exploration of intrapopulation and interpopulation patterning of the mutations implicated in variations in disease incidence, pathology and drug response.[63] In the future, artificial intelligence may play a large part in improving ethnic diversity in health data, for example, by creating equitable multiethnic polygenic risk scores.[64]

At a national level, collection of deidentified ethnicity and postcode data for those eligible and for those recruited, via a standardised electronic proforma available via a central repository, would also provide a sound basis for the evaluation of progress. Datasets with both ethnicity and postcode data linked to indices of multiple deprivation[65] would help to unravel the relationship between ethnicity and other sociodemographic factors.

Funding applications should include recognition of the particular challenges faced by some sites in terms of recruitment and trial delivery. Funders should be urged to acknowledge these and be prepared to allocate additional resource to support participation from sites in areas which include postcodes with high levels of deprivation.

As well as improved access to clinical trials in cancer centres, the lack of trials available in rural areas can be addressed through investment in the research networks, for example, the NIHR Clinical Research Network, with staff working between sites.

In addition, further development of joint working between cancer centres providing treatment and rural hospital or community services undertaking assessment and/or monitoring, will improve patient access to trials. The rapid development of liquid biopsy approaches to cancer diagnosis and monitoring, whereby biospecimens can be posted at ambient temperature to a central analytical laboratory,[66] may facilitate trial participation in settings that lack a broad portfolio of laboratory assays.

During proposal and protocol development and during preparation of study materials, known barriers to participation can be discussed within the study team with particular regard to the views of PPI representatives and addressed where possible. The UK 5 Standards for PPI emphasise the need for diverse representation in PPI activities (Standard 1: Inclusive Opportunities)[67] Just as patient navigators may facilitate inclusivity in the recruitment of trial participants, PPI navigators may also be required to achieve the same for trial design, development and management.

Researchers are encouraged to engage with local groups and organisations and build rapport in order to increase participation. Eligibility criteria should be as inclusive as is realistic. Mandatory patient information materials can be supplemented with more ‘patient friendly’ summaries, a measure introduced into the BladderPath study at the suggestion of our trial co-ordinator and developed in collaboration with our PPI representatives. Innovative digital approaches to recruitment and data collection[68] are also recommended.

At local level, a strategy for optimum and inclusive recruitment can be developed with the trial coordinator or a member of the study team with specialist knowledge of EDI resources and, where possible, PPI representatives.[19] In addition to the ‘Trial Forge’ recommendations, strategies should be responsive to factors such as trial type, site recruitment systems and staffing, local geography and population characteristics.

The pressures of frontline clinical work, even more apparent since the start of the COVID-19 pandemic, may limit the enthusiasm of clinical staff for highlighting and discussing trials with patients. A dedicated member

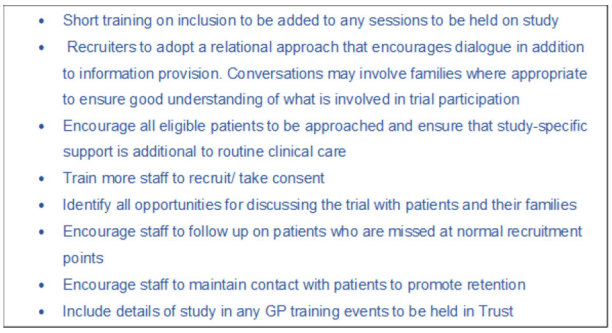

Figure 1 Strategy suggestions for local teams to boost and broaden recruitment.

of the trial team must work to build relationships with local teams to set realistic targets, recognise unmodifiable barriers to recruitment (eg, trials competing for staff resources), identify potentially modifiable barriers and cocreate possible solutions.

A number of pragmatic strategies to boost and broaden recruitment to clinical trials for consideration by local teams are suggested in figure 1.

Strategies aimed specifically at broadening participation offer a range of activities that trial and local teams may consider; these are collated from the literature[27 58 60] and from the discussion above, with examples shown in figure 2.

EVALUATION

In terms of boosting recruitment, measurement of uptake against numbers invited and against a target set by the site will provide a broad measure of increase in accrual rate. Without an established baseline, the evaluation of the success of strategies in terms of broadening participation is problematic. Although imprecise, an estimation of target numbers of participants from the groups of interest based on local population statistics and cancer prevalence data, would provide a benchmark by which to measure progress.

Local research networks should make such data more accessible so as to embed this notion (or even expectation) at the preaward study design stage.

Regular review at trial management meetings will indicate whether strategies are working. Where shortfall or high attrition is identified, the relevant guidance and checklists can be consulted regarding the introduction of adjustments or new actions.

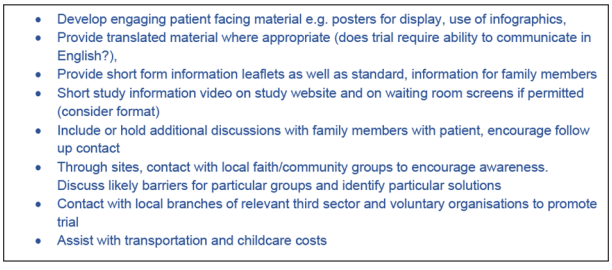

Figure 2 Strategy suggestions for trial and local teams to broaden study participation.

CONCLUSION

As well as good will and commitment, these measures require time and funding; both are limited resources. Nonetheless, time and funding are essential if the ambition to boost and broaden participation in trials is to be achieved.

Extending survival and improving quality of life of patients with cancer depend on robust results from well-conducted, sufficiently powered trials. Disparities across groups in society are multifactorial; nevertheless, increased inclusivity in recruitment and recognition of variations in pathology, presentation and experience are essential to the development of improved diagnostics, treatments and care pathways, enabling better and more equitable outcomes for all.

A data-driven, multilevel approach combining current guidance with the centrally and locally developed strategies discussed above, offers the potential to meet the twin challenges of boosting and broadening recruitment—too important to ignore.

IMPLICATIONS

The NIHR has itself highlighted the urgency of increasing cancer trial participation beyond pre COVID-19 levels and the importance of inclusivity.[6] As the major public funding body for research in the UK, the NIHR is suited to take the lead role in this endeavour enhancing its work in this vital area of research practice. First, this challenge will involve initiating and coordinating the development of the infrastructure and reporting processes required. Second, it will require active support from the NIHR for the implementation and evaluation of the recommendations and strategies identified. Lastly, in addition to individual recruitment targets set by trial statisticians, we encourage the NIHR to build on the guidance regarding inclusion it now offers and to set standards to provide a benchmark against which progress in representation can be assessed.

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