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Embedding equity, diversity and inclusion processes within clinical trials and health and social care research

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ABSTRACT

The lack of diverse and inclusive clinical research populations fuels health inequalities in the UK, and there is an urgent need to reverse this. This communication provides a practical framework for positive action to integrate equity, diversity and inclusion (EDI) processes into clinical research design, protocols and implementation and to establish accountable clinical research systems that are trustworthy to the public and accessible to diverse communities.

This framework is a consensus-based guide developed by the Equality, Diversity and Inclusion working group of the National Institute for Health and Care Research's (NIHR's) Clinical Research Network in North West London. This work involved analysing challenges to integrating EDI within the clinical research process, such as clinical trial protocols as directed by industry sponsors and National Health Service investigator teams. It aligns with the UK government's clinical research strategy and NIHR's INCLUDE project. It advises an interconnected approach to embedding EDI throughout the clinical research lifecycle. By following this framework, we aspire to guide clinical research towards a more equitable, inclusive and representative model that better serves the needs of all populations.

INTRODUCTION

Through the National Institute for Health and Care Research (NIHR), the UK and National Health Service (NHS) have invested heavily in clinical research to improve the nation's health and well-being. This investment has contributed significantly for providing innovative treatment, disease prevention and extending human life.[1 2] Effective clinical research, embedded in routine clinical practice, is key to improve patient outcomes, staff recruitment and retention, and institutional standards of care.[3]

However, clinical trial research has limitations. In the UK, populations with the most significant health challenges are often less able to benefit from clinical discoveries because they are not adequately represented in clinical research studies.[2 4–9]

Although progress has been made, particularly with the representation of white women in clinical trials, little progress has been made in involving ethnic minority groups within clinical trials.[5 9] Additionally, older adults, pregnant and lactating individuals, LGBTQ+ populations and people with complex health, diverse cultural needs and disabilities remain underserved and excluded from clinical trial research.[2] New drugs are often approved for public use on efficacy, safety and tolerability data from majority white male study populations. Therefore, comparatively, underserved groups experience less value from the trial outcomes.

Equitable, progressive clinical research studies must match the demographics of the disease burden under study, but this is yet to be prioritised.

Costs and consequences of failing to achieve diverse clinical trials and clinical research

The lack of diversity in clinical trials and research has significant consequences regarding public and individual health outcomes and financial costs. When certain demographic groups are under-represented, the generalisability of research findings to the broader population is compromised. This is particularly concerning for women, pregnant and lactating women, children, older adults, ethnic minority groups and people with complex health needs, as unique physiological and health characteristics can lead to distinct responses to investigational drugs.

Where access to treatments aligns with the populations included in clinical studies, inadequate representation limits access to effective medical interventions for certain demographics; for example, lack of safety data in children and pregnant women may exclude use in these populations.

As a result, evidence-based healthcare delivery for these groups is hindered, resulting in poorer outcomes. This has been historically acknowledged for groups actively excluded from clinical trials, such as pregnant women and children, given safety issues of drug investigation, limiting access to drug innovations in these groups. However, the exclusion and lack of enrolment of wider diverse groups limit the generalisability and application of novel drugs in real-world populations.

Lack of representation also has the potential to impede innovation and new discoveries. Diverse study participants enable the exploration of treatment effectiveness variation, crucial for understanding intervention safety and efficacy in under-represented populations, uncovering new biological insights and behavioural dynamics applicable to all groups.

The lack of attention to the diversity of phase 3 trial participants and potentially varied pharmacogenomic responses from earlier phase trials may also contribute to regulatory failure. When evaluated in 2014, only one in 10 drug trials entering clinical development at phase 1 advanced to the US Food and Drug Administration (FDA) approval.[10] Reasons included the lack of validated surrogate markers to demonstrate clinical impact and a lack of specific safety or efficacy data (later requested by regulators). Future approval success would be supported by earlier toxicology evaluation, biomarker identification, new targeted delivery technologies and adaptive trial designs;[10] in particular, given future expectations for clinical trials to have diversity plans.

The average research and development cost per drug product, including expenditures on failed trials, is estimated at US$1.1 billion.[11] Thus, it makes economic sense to consider drug response variability early in development.

A critical consequence of the lack of diversity and poor transparency is the erosion of public trust in the clinical research process and in the medical establishment.

Three recent examples stand out to demonstrate this problem

Clopidogrel

In August 2023, the NIHR reported that clopidogrel, a widely prescribed medication to prevent heart attacks (the UK's leading cause of death), may be ineffective for British South Asians.[12 13] This group was not represented in the clinical trials used for regulatory approval.[14–18] Clopidogrel's efficacy depends on the cytochrome P450 enzyme CYP2C19, and genetic polymorphisms in CYP2C19 can reduce its effectiveness.[19]

A study on 44 396 British Bangladeshi and Pakistani participants (UK Genes & Health cohort) found that 57% were intermediate or poor CYP2C19 metabolisers, with 13% carrying two loss-of-function alleles—higher than in European (2.4%) and Central/South Asian populations (8.2%). Among those diagnosed with acute myocardial infarction, 69% were prescribed clopidogrel, and poor metabolisers had a significantly higher risk of recurrent heart attacks (OR: 3.1; p=0.019). This highlights the need for clinical trials to prioritise diverse populations, integrating disease prevalence and pharmacogenomic data to prevent avoidable health inequities.

Assessment of kidney function in people of different ethnicities

Chronic kidney disease (CKD) is a global health issue with outcomes including end-stage kidney disease, cardiovascular disease and premature death. People of African or Afro-Caribbean heritage face greater risks, faster disease progression and more advanced presentations compared with white populations.[20]

Kidney function is typically assessed using estimated glomerular filtration rate (eGFR) calculated from serum creatinine levels via the modification of diet in renal disease (MDRD) or CKD-epidemiology (CKD-EPI) equations. Studies suggest higher creatinine production in people of black ethnicity, historically leading to adjusted eGFR values.[21] While this adjustment raises eGFR levels, it may delay CKD diagnosis, poorly recognise disease severity and limit access to care, such as transplant referrals or dialysis.[20]

In 2021, the National Institute for Health and Care Excellence removed ethnicity adjustments for eGFR from its guidelines, citing concerns over validity and acknowledging a lack of data for ethnic minorities in the UK and the USA.[21] Similarly, the American Society of Nephrology recommended discontinuing race-based eGFR estimation, introducing the race-free CKD-EPI creatinine equation and promoting cystatin C testing.[22]

Concerns persist about the reclassification of CKD diagnoses with race-free eGFR and its impact on treatment eligibility, especially for people of black ethnicity who may face barriers due to lower eGFR thresholds.[22 23] Limited guidance also exists for assessing kidney function in mixed-race individuals.

Progress requires research into true kidney function and disease outcomes in diverse populations to ensure accurate assessments, equitable management and prevention of health disparities.[23 24]

COVID-19 vaccine

The NIHR highlighted that, despite black, Asian and mixed-race communities experiencing higher risks of severe illness and death from COVID-19, their representation in COVID-19 studies was disproportionately low. Only 9.26% (57 661 participants) of ethnic minority groups were included in initial studies, with just 5.72% (1509 participants) in vaccine trials,[25 26] reflecting the broader historical under-representation in clinical trials.[2 5 7]

The lack of data for pregnant women further fuelled uncertainty around vaccine safety, contributing to confusion and hesitancy during the rollout to vulnerable groups.[27]

COVID-19 vaccine uptake among ethnic minority groups in the UK was significantly lower. In London, uptake during the first 6 months of the rollout ranged from 57 to 65% among black ethnic groups, compared with 90% in white groups, with lower rates in deprived areas. A government review identified vaccine hesitancy

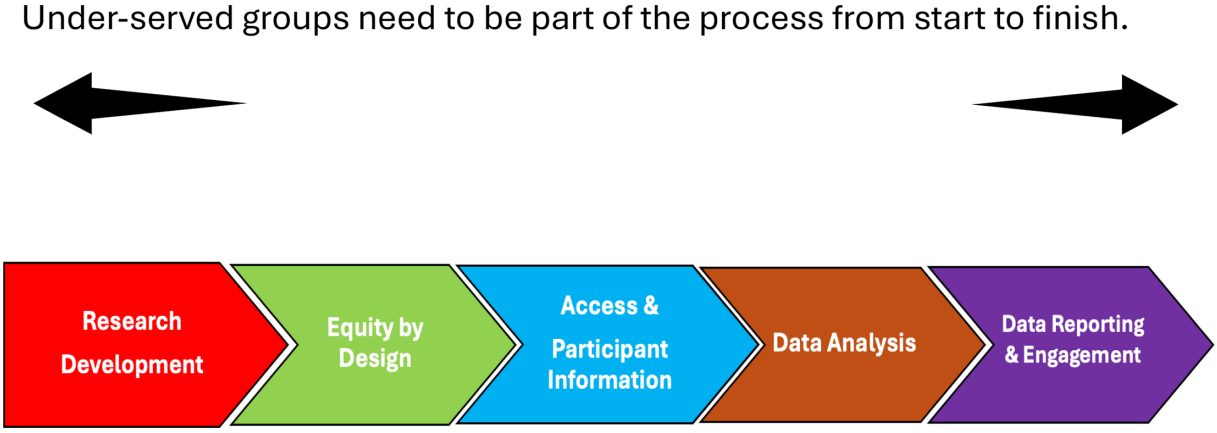

Figure 1 Visual integrating recommendations for embedding equity, diversity and inclusion into research processes across the research life-cycle.

as highest among black communities, followed by Bangladeshi and Pakistani groups, driven by a lack of trust in the vaccine. This hesitancy occurred despite these groups experiencing the highest COVID-19 death rates.[25 27]

In addition to its health-related impacts, the lack of diversity poses economic challenges. Better representation in clinical trials will reduce health disparities, leading to substantial cost savings for public healthcare systems. An economic analysis in the USA demonstrated the potential for billions of dollars in savings by addressing health disparities measured through life expectancy, disability-free life and years in the labour force.[28]

The costs and consequences of failing to achieve diversity in clinical trials and research are profound. From compromised healthcare delivery and limited access to treatments to economic implications and reduced trust in medical science, the need for inclusive and representative research practices is clear. Addressing these issues is vital for ensuring equitable healthcare and advancing medical knowledge for all populations.(figure 1)

The Future of Clinical Research Delivery

In the UK government's policy paper, The Future of Clinical Research Delivery: 2022 to 2025 implementation plan,[1] they describe an 'ambition to create a world-leading UK clinical research environment that is more efficient, more effective and more resilient, with research delivery embedded across the NHS'. It aspires for the UK to attract investment from all over the world, delivering cutting-edge clinical research. The vision outlines digitally enabled, proinnovation and people-centred clinical research to unleash 'the true potential of clinical research across the UK, addressing long-standing health inequalities and improving the lives of us all'.

Recently, the FDA released a communication outlining that all drug clinical trials must submit diversity plans to demonstrate the recruitment of representative trial populations for future FDA approvals.[4 5] This will act to shift priorities for clinical trial processes, and we understand that the UK Medicines and Healthcare Products Regulatory Agency will follow suit.[6] Our framework will help guide clinical trials to invest in more equitable, diverse and inclusive trial processes.

On the global stage, the UK continues to provide an incredible and unparalleled opportunity for industry investment to deliver cutting-edge clinical research and innovation, given our uniquely diverse population and research excellence via our accessible NHS universal healthcare system. Our framework for action helps facilitate the government's vision to encourage research investment in the UK, address long-standing health inequalities and translate NHS innovation and UK research globally.

Framework objectives and actions

This framework results from a collaborative effort to establish guidance for embedding equity, diversity and inclusion (EDI) principles into clinical research. It is designed to be a dynamic and evolving resource based on ongoing data and learning from the wider community (clinical, academic, public and industry). This work involved analysing challenges, at the North West London (NWL) network level, to integrate EDI within the clinical research process, for example, in clinical trial protocols as directed by industry sponsors and NHS investigator teams. The framework is targeted at clinical research teams, industry sponsors and academic investigators.

Key objectives include:

- To provide a practical framework for positive action in integrating EDI into clinical research design, protocols and implementation. Primarily to promote and enable the participation of underserved groups in clinical research.[2]
- Improve data quality and enable quality improvement data projects to collect granular data on the wider determinants of health within our local populations.
- Increase the proportion of clinical research staff from ethnic minority and other minoritised social, ethnic and disability backgrounds.

We aim to integrate measurable actions for all NHS research (see https://crnnwl.com/edi-framework-objectives-and-outputs/).

For example, we expect an update from studies post implementation to report on the following:

- The proportion of recruited underserved communities in the study population should include, but not be limited to, gender, ethnicity and complex health needs as defined by the EDI statement (within 12 months of study completion).
- Provide outputs from patient and public involvement and engagement (PPIE) and community engagement with underserved groups. For example, report on the proportion of community members agreeing to be contacted for research or postengagement survey or feedback results (within 24 months of study closure).
- How the study data are translatable to underserved communities—for example, was there sufficient participant representation within the study sample for the data to be immediately relevant and translatable to a diverse general population?
- For which groups are there a lack of data, and what limitations does this pose?
  - For clinical trials, this should be linked to phase I/II trial drug metabolism, pharmacokinetic and pharmacogenetic data, where applicable. Or is similar drug efficacy/safety data available in diverse populations? See clopidogrel case study.
  - If there is a low proportion of underserved groups (specifically women, pregnant individuals, ethnic minorities or groups with complex health needs), how do we progress to understand the data in this community? (At the point of data reporting for publication).

FRAMEWORK IN DETAIL

Please refer to Box 1 for the summary of framework with recommendations for embedding equity, diversity and inclusion into research processes.

Research development/patient and public involvement and engagement (PPIE).

Before clinical trial or research development, teams should understand the demographic and wider health determinant characteristics of the local population to which the research will be applied; specifically, demographics related to diversity criteria, but not limited to ethnicity.

- Data on the country of birth, first language and deprivation index (alongside ethnicity) can be used to understand barriers individuals and communities face in navigating access to and experiences of NHS healthcare. Current ethnic grouping (eg, white British/European/other, black African/Caribbean, Asian—Indian/Bangladeshi/Pakistani/Chinese/other) is reductive in nature, given that it prevents an understanding of wider characteristics associated with health inequality. Local and study population data assessments should be supplemented with country of birth, first language, disability, deprivation index and employment/profession.

Box 1 Summary of framework recommendations for embedding equity, diversity and inclusion into research processes.

We recommend research teams take the following steps:

1. *Foster collaborations for impact:* invest in diverse clinical research collaborations and partnerships, where appropriate, involving community organisations to codesign research and direct clinical innovation to reflect the needs of people who will benefit from it most. Early research design and grant applications should integrate leadership from the community, where community members are included as coapplicants with budgeted research costs.
2. *Local insight informs design:* analyse demographic data and wider health determinants of the local population to understand barriers faced by underserved groups and local opportunities. This can guide study recruitment and data-driven initiatives.
3. *Inclusive engagement:* engage in public-patient involvement and community engagement (patient and public involvement and engagement) activities, using community organisations (or trusted advocates) to promote health/research literacy and shape research priorities and study design. Aim to include community members from underserved groups as employed members of the research team or within steering groups.
4. *Effective communication:* develop culturally sensitive and translated patient information and innovative research engagement materials to ensure clear communication and informed consent. This requires specific funding investment and commitment from the outset. Consider plain language and visual/video formats for patient information and group consent processes where appropriate.
5. *Embrace complexity:* acknowledge that enabling inclusion and diversity in research participation involves embracing clinical, social and cultural complexity—use training to build skills in these areas.
6. *Accessible eligibility criteria:* regularly review eligibility criteria to ensure inclusivity and avoid inadvertently excluding underrepresented groups and those with complex health needs.
7. *Strategic recruitment:* use approaches to study recruitment that involve the following.
   - Widening recruitment and research delivery sites, operating research outside of 'office' hours and weekends to facilitate access.
   - Decentralised clinical trials.
   - Recruitment in sets and regular review of participant diversity.
   - Use of incentives and expenses.
   - Cap trial participant recruitment for the majority participant populations.
8. *Diverse research staff:* elevate the representation of research staff from ethnic minority and minoritised social, ethnic and disability backgrounds through promoting the NIHR investigator schemes and inclusive staff recruitment processes.
9. *Enhanced competency:* invest in research staff training to enhance cultural humility and skills in managing clinical complexity and different participants' needs.
10. *Informed data collection:* collect and analyse diversity data of study participants to identify disparities, including in outcomes and to inform improvement efforts and future innovations. Ensure participants understand why collecting anonymised diversity data is important and how their data are used to improve research.
11. *Engaged dissemination:* share research outcomes with community groups and NHS clinical teams, integrating their feedback into reports. Consider collaborative authorship groups during data

Continued

Box 1 Continued

publication, involving community members engaged in codesign or consultations.

12. *Shared progress:* collaborate with external stakeholders to exchange/share data, best practices and promote diversity, actively monitoring the integration of equity, diversity and inclusion principles.

- First language and literacy levels within the local population can also help guide public engagement strategies and how to provide patient information (for example, using different sources of visual media and developing patient information material in languages that the majority of diverse populations can understand). Additionally, knowledge of the targeted disease prevalence and related morbidity and mortality data for the local population.

Supplementary local population data can be sought from local trusts, the local authority and population health management from the Integrated Care Board, but this requires partnership working.

This approach will help to enable trials to be more inclusive and to direct clinical innovation to the communities who need it most. Every effort should be made to include participants from representative communities of the wider local population and from communities that the targeted disease impacts.

- Public-patient involvement and preclinical community engagement (PPIE) can strengthen interest and trust in the local community. Tailored, culturally competent engagement and study information can serve to recruit underserved groups when delivered in accessible formats and with suitable language.

We encourage PPIE and community engagement activities, involving the community, patients or research community champions and trusted advocates. This enables underserved communities to shape research priorities and study design. Early research design and grant applications should integrate community leadership, where community members are included as coapplicants with budgeted research costs.

The term 'trusted advocates' was recommended in the NHS *Good Practice Guide for engaging with under-represented groups,*[29] following qualitative research to understand the needs of some diverse, minoritised communities in the UK. It highlights that community members or peers working in research aim to represent the voices of under-represented groups but do not speak for them, highlighting the intersectionality and differences within under-represented groups across access, experiences and outcomes in health.

Trusted advocates or research champions can be included as experienced paid employees within the research team and recruited as staff members. Where this is not possible, they should be included as volunteers and in research steering groups. Their role includes helping to formulate the research question and inform protocol design, ethics applications, patient information, recruitment and data translation. The same principle applies to including skilled researchers from underserved groups to strengthen implementation.

Research design

Eligibility criteria

Industry sponsors and research teams should discuss eligibility and inclusion criteria with practising NHS clinicians before protocol development to ensure that criteria match the demographics and disease prevalence from clinic/hospital cohorts.

Clinical trials must enable eligibility criteria to be less restrictive, understanding that restrictive inclusion criteria may exclude diverse groups from the outset.[9 29 30] Sponsors and clinical research teams need to acknowledge the life and health complexity of under-represented groups and allow for this within their eligibility criteria, protocol design and staff training.

Ethnic groups that experience higher levels of inequality related to healthcare access, marginalisation and deprivation are more likely to have physical and mental health conditions that exclude them from specific trials. Physiological differences (eg, drug metabolism) among older people and different ethnic groups and differences in disease morbidity also need to be considered.[4 13 23 24]

A study protocol's eligibility criteria should be re-assessed at regular intervals during study recruitment to ensure that under-represented groups have not been excluded. This may require evaluation of the study design and research staff training to ensure they recognise these challenges during recruitment.

Research staff training

Improving researcher skills to manage patient, clinical and social complexity and cultural competency is essential. This requires dedicated research training either via locally tailored EDI training or the NIHR training modules on cultural competency.

Dedicated research training is also essential to enable clinical research practitioners to manage clinical challenges, understand how to manage and escalate care, and refer participants with complex medical and social issues. It is important not to exclude participants from diverse backgrounds because of complex clinical or social issues, as this restricts their involvement from the outset.

Recruitment strategy and research delivery

Five recruitment strategies are outlined

Widening recruitment and research delivery sites, operating research outside of 'office' hours and weekends to facilitate access

Considering protocol designs instructing participant recruitment and trial implementation at selected hospitals or clinical community sites that serve a high proportion

of diverse local communities. To improve access, consider operating flexible research consultations in the evenings and weekends, outside of regular working and school hours.

We acknowledge that central London teaching hospitals have infrastructures and staff skillsets to deliver and enable public access to high-quality research; whereas peripheral district hospitals often lack the infrastructure to support active research. Regions served by local district hospitals in NWL are often highly diverse; public engagement and recruitment in these areas can facilitate the recruitment of underserved groups to high-quality research in more convenient local locations. Recognising that underserved groups may experience deprivation and face challenges accessing research delivered in central London research facilities. As a minimum, transport costs should be covered for participant travel to research sites.

Decentralised clinical trials

The goal of decentralised trials or decentralised elements within trials is to make clinical trials easier for patients by reducing the need to travel to specific sites. Decentralised elements in clinical trials bring opportunities and new challenges not only for patient care, but also for ethical, legal and technical aspects of trial conduct.[31] To provide guidance for a harmonised approach, a task force was formed with experts from regulatory bodies, ethics committees, investigators, Good Clinical Practice Inspectors, patient organisations and healthcare professionals.[32] It addresses general principles in the conduct of clinical trials with decentralised elements within the European Union and European Economic Area.

Benefits of decentralised elements include accelerating patient recruitment, increasing participant diversity and engagement, gathering more diverse and applicable data sets and improving the reliability and accuracy of data. This approach has also been shown to increase participant retention and study effectiveness and enable drug innovation to market faster.[31–33]

Capping

Capping the trial participant recruitment of white UK majority groups should be considered.[34] Research and community personnel must be used to recruit participants from underserved groups and examine data on wider health determinants, including wider health determinants—country of birth, first language, deprivation index, disability, neurodiversity, migrant status and traveller status.[2]

Recruitment in sets

We encourage recruiting study participants in groups and reviewing the diversity of participants at regular intervals to understand where efforts are needed to improve diversity. For example, include approaches to recruiting staff in sets, e.g. recruiting 5 or more members of staff at a time rather than individually. This can help to immediately understand the lack of diversity and review efforts to improve this. Approaches in research recruitment could involve a diversity and inclusion review for every 5–10 participants recruited. We advise assessing participant characteristics based not only on ethnicity, gender and age but also wider determinants of health as outlined by NIHR[35].

Formalising the incentive process can be a way to build trust with underserved groups. The NHS Increasing Diversity in Research Participation document[29] highlighted that underserved groups criticised the lack of effective incentives for research participation or clarity around incentives.

Researchers can work with their trusted advocates to explore options for non-cash alternatives, which would incentivise their participants. Suggestions include food vouchers and access to local educational courses or family activities for participants with families.[29] The LOLIPOP study has had success in offering free comprehensive health checks aligned with the study design.[36] Financial incentives can make a significant difference in enabling people with financial hardship to get involved.

Researchers must cover all expenses incurred by participants and their carers to ensure they are not left out of pocket. Advice is outlined in NHS Increasing Diversity in Research Participation: A Good Practice Guide for engaging with under-represented groups.[29] Where possible, expenses should be paid at the end of each session.

Participant information, language translation and informed consent

Committed investment is needed in providing participant information sheets (PISs) to recruit participants from diverse communities. Data on the country of birth and first language and proactive community engagement can help to understand English literacy levels and what key languages represent minoritised ethnic communities in the local population.

We highly recommend that commercial sponsors invest in developing tailored and community-sense-checked patient information with dedicated funding.

Community engagement and data scoping outputs should involve understanding the relevant representative languages and cultures in the local patient population to direct the development of patient information. Patient information requires translation into relevant representative languages and culturally competent formats that are sense-checked with community members to ensure the study information is communicated with clarity and honesty. Alternatively, consider the role of trained research translators to help build trust and enable effective communication with participants who speak different languages and deaf communities. This also strengthens processes to receive informed consent from minoritised groups.

Culturally competent communication between underserved groups and research teams is essential to increase interest in research, provide patient information, ensure

informed consent and retain participants within studies. We should ensure good communication and trust are continued throughout the process of data translation.

Challenges with language translation

We acknowledge that medical and ethical information may be challenging to translate from English into languages from countries with high-context cultures. High-context cultures often have communication styles based on body language, tone and overall context, reflected in a native language. In contrast, low-context cultures (such as in Western Europe, the UK, the USA and other global North settings) are more explicit in verbal and written communication.

Given the similarities between the English language and Latin-derived languages and between conceptual contexts within these cultures, medical or ethical information is often understood to be more straightforward to translate. However, when translating study information from English to languages from Asia and Africa, care should be taken to ensure it is communicated and understood with equivalence.[29 37]

Data analysis

Analysis of wider determinants of health that are not restricted to ethnicity, gender and age must be included. We advise including data on country of birth, first language, Index of Multiple Deprivation/deprivation index as a minimum and broader data for white ethnic groups. We encourage researchers to collect data related to a lens of understanding health inequality. This aids data analysis on diversity characteristics of study participants to identify disparities, including in outcomes and to inform improvement efforts and future innovations.[38 39]

Participants must understand why collecting anonymised diversity data is important and how their data is used to improve research.

Interpretation of results and data translation

It is recommended that research and clinical trial data be fed back to the NHS clinical teams and community, particularly to the minoritised groups they impact where the results differ. This should be done before data are published in the public domain, and clinical and community stakeholder feedback should be incorporated into the translation of results and data reporting.

This can enhance public engagement and dissemination of clinical research and build trust with underserved groups. This can be achieved via focus group workshops with the community, facilitated by trusted advocates or via community-research open discussion forums.

Research teams should consider creating ‘collaborative authorship groups’ when reporting and publishing their research data. Which, alongside investigator, sponsor and academic authors, include key community organisations and trusted advocates that were involved in codesign, PPIE or within design and delivery consultations.

CONCLUSION

Fundamentally, research teams should involve diverse collaborations and partnerships, which promote trial processes that build public trust and engage with under-represented communities with honesty in meaningful ways. For example, at a basic level, this would involve ensuring PISs are communicated clearly (with cultural consideration and minimal jargon) and in the languages relevant to the local population. Research staff should include talent from diverse backgrounds with skills and training in cultural competency who reflect the local community they serve. Study participant recruitment strategies need to enable the inclusion of people with complex health and cultural needs and health determinants associated with health inequality. Prioritising data quality and understanding the wider health determinants of local communities is essential to drive innovation. It should guide clinical trial design, protocol development and implementation in a given setting.

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