

COMMENTARY

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Achieving equitable recruitment through inclusive protocol design: lessons learned from the ILANA study

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Abstract

The importance of conducting inclusive research is well-established, yet recruiting a sample which reflects the distribution of a disease or condition within a target population has proven elusive for many trialists. We draw on our experiences of achieving inclusive recruitment through the intentional protocol design and delivery in the ILANA (Implementing Long-Acting Novel Antiretrovirals) study to highlight some tangible steps that could be extrapolated to trials to aid inclusive recruitment to research and produce findings which can contribute to tackling health inequities. These include the importance of meaningful public involvement from start to finish, drawing on existing data to determine appropriate targets, factoring targets into analysis plans through pre-specified analyses and triangulation with qualitative data, and making targets mandatory (rather than aspirational) through a range of strategies. We believe ILANA offers a proof of concept for trialists seeking to radically improve representation and conduct more equitable RCTs that engage all those who could benefit.

Keywords Health equity, Inclusive recruitment, Public patient involvement, Randomised trials, HIV

Background

The importance of conducting inclusive research is well-established [1]. Consequently, funders, regulators and researchers are increasingly focused on addressing underrepresentation in health and care research [2, 3]. Yet recruiting a sample which reflects the distribution of a disease or condition within a target population has proven elusive for many trialists [4–9]. In this

commentary, we draw on our experiences of achieving inclusive recruitment through the intentional protocol design and delivery in the ILANA (Implementing Long-Acting Novel Antiretrovirals) study to highlight some tangible steps that could be extrapolated to trials to aid inclusive recruitment to research and produce findings which can contribute to tackling health inequities.

ILANA was a 12-month, non-randomised, longitudinal implementation science study evaluating the delivery of long-acting injectable cabotegravir and rilpivirine (CAB+RPV) in six clinics and decentralised community settings in the UK (ClinicalTrials.gov identifier: NCT05294159; detailed information on study design is available within the published protocol [10]). CAB+RPV represents a paradigm shift in HIV treatment as the first ever long-acting, injectable antiretroviral regimen, removing the requirement to take daily pills [11]. It is a recommended option in treatment guidelines

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in high-income countries on the basis of its efficacy and safety across three large phase III clinical trials [12–15]. Participants on CAB+RPV LAI overwhelmingly preferred it to daily oral therapy and reported significantly higher treatment satisfaction [16–19]. However, these trials underrepresented women, racially minoritised people, and older people aged ≥ 50 at 25%, 28% and 18%, respectively [12–15], compared to our national and global populations of people living with HIV. Globally in 2023, 53% of adults (aged ≥ 15 years) living with HIV are women and 26% are aged 50 and older [20, 21]. In England in 2023, 33% of all adults (aged ≥ 18 years) seen for HIV care were women, 49% were racially minoritised people, and 51% were aged ≥ 50 years [22]. Observational cohorts have not closed this gap, with a recent scoping review identifying that only 19% of participants in 51 CAB+RPV studies were female [23].

This lack of representation is a long-standing problem in HIV clinical research. Women, racially minoritised people and older people living with HIV are underrepresented across treatment, vaccine and cure trials [4, 24, 25], meaning varying intervention outcomes as a result of biological and/or social differences are often not identified until they have been adopted into clinical practice. For example, although HIV treatments are similarly efficacious across age and gender categories, women and older people have been reported to have higher susceptibility to side effects with some antiretrovirals [26–29]. A range of social factors has meant that racially minoritised people are often at greater risk of poorer treatment outcomes compared to white people [30, 31], indicating that more research is needed into treatment strategies which can support people to overcome structural barriers to optimal treatment outcomes. Finally, the widespread exclusion of women and others who are pregnant or breast/chest-feeding from HIV drug trials has also meant that a large scale, uncontrolled experiment with heightened risk occurs whenever new drugs are licensed and prescribed to women or other people who conceive on drugs in the absence of safety or efficacy data [32]—as was the case when the antiretroviral dolutegravir was rolled out as first-line treatment across many low- and middle-income countries [33, 34].

Given these research gaps, we considered it vital that any further research into CAB+RPV LAI ensured adequate representation of underserved groups, particularly as implementation outcomes like feasibility and acceptability may be influenced by differences in socio-demographic and contextual factors that can vary significantly across population groups. A key innovation of ILANA, therefore, was the implementation of mandatory inclusion targets for sites to recruit a sample of at least 50% women, 50% racially minoritised people, and 30%

aged 50 years or older. In addition, use of contraception was not an eligibility criterion for the study, and shared decision-making between clinician and participant was stipulated with the option to continue in the study if a pregnancy occurred. Various practices, such as travel reimbursement and flexible appointment hours, to support a positive research experience and promote retention, were also employed.

ILANA's inclusive recruitment targets were exceeded in the final sample, which included 53% female participants, 70% racially minoritised participants and 40% participants aged 50 years or older [35]. Retention at study end was high (89.5%), with only 3/12 participants withdrawing for non-medical reasons [35]. Pre-specified subgroup analyses identified statistically significant differences in the feasibility (primary endpoint) and appropriateness (secondary endpoint) of CAB+RPV injections between women and men and Black and non-Black participants, indicating that additional support strategies are needed to facilitate equitable outcomes for these groups [35]. One ILANA participant became pregnant during the study and chose to withdraw after receiving one further injection; the pregnancy resulted in a healthy live birth [35].

The ILANA study has been highlighted as a good practice case study by the World Health Organization [36], and has demonstrated that equitable recruitment is achievable within HIV research. It has also allowed us to develop an approach that will form the basis of future studies within the SHARE Collaborative for Health Equity (<https://shareresearch.org.uk/>). We believe that our approach provides a useful 'proof of concept' that could, and, we argue, should, inform the design and delivery of randomised controlled trials (RCTs). Below we outline the key principles of our approach, how this was implemented within ILANA and explore ways it could be scaled up for RCTs.

Meaningful public involvement from start to finish

Central to ILANA's design was the meaningful involvement of people with lived experience of HIV at every stage of the research process. We aspire to meaningful involvement through adherence to national guidance, such as the UK Standards for Public Involvement in Research [37], as well as our own guidelines on community involvement [38]—co-produced with SHARE's remunerated community advisory board of people with lived experience of HIV. The CAB provides strategic oversight to our research, and includes groups under-represented in health research such as women, LGBTQ+ and racially minoritised people. In addition, BK, a member of our CAB and co-author of this commentary, was engaged as a research collaborator for ILANA to enable

greater involvement in the study design and delivery. Her involvement shaped key decisions around research questions, protocol design, ethical implications, study promotion and dissemination. For instance, she reworded the consent forms and attended the ethics board meeting with the chief investigator and effectively defended aspects of the protocol.

When considering inclusion of underserved groups in trials, it is vital that representatives from these groups are meaningfully involved in the study design and delivery in a way that goes beyond encouraging participation within their networks. Without their involvement, inclusive recruitment targets are unlikely to be achieved, and even if they are, exclusionary research practices could result in tokenism, inequitable retention and negative experiences which deter people from participating in future research [39]. To avoid this, an overall commitment from the study team to foster an inclusive research environment is essential for promoting equitable recruitment and retention [40]. Crucially this means a recognition that inclusion is the work of all study team members (not only those who have minoritised identities and/or are the most junior members of the study team) [39]. The study team should continually reflect on their identities and positionalities, and how these influence power dynamics and whose voices are heard within the research process [40].

In collaboration with public patient involvement and engagement (PPIE) representatives appropriate to the study, the study design should be carefully considered and co-designed. This should include consideration of how recruitment practices and eligibility criteria may inadvertently exclude underserved groups, and how study materials and processes may be inaccessible or exclusionary to those who experience material and social disadvantage and discrimination, leading to inequitable retention [39, 41, 42]. For example, in ILANA, child-care costs and travel costs were met to support retention, and interview participants noted that appointments offered outside of work hours (in line with routine clinical practice) were crucial for their ability to maintain the increased appointment schedule required of CAB+RPV and remain in the study [35]. Dissemination strategies should treat participants and people affected by the study results as the central audience for research findings [43, 44]. Key to this process is recognising that genuinely inclusive research may require greater effort, time and resource, but these efforts are imperative if we are to avoid simply reproducing inequity [39, 40].

Determining appropriate targets

Determining appropriate recruitment targets for ILANA relied on an evaluation of prior research on CAB+RPV with respect to inclusion and representativeness. We were aware that pre-registrational clinical trials of CAB+RPV LAI underrepresented women, racially minoritised people and older people living with HIV, as outlined above. At the time of developing the study, we knew that 31% of people seen for HIV care in England were women, 46% were from racially minoritised communities, and 42% were aged 50 or older [45]. We also anticipated that these proportions would increase since people living with HIV are an ageing population and declines in HIV incidence among predominantly white, gay, bisexual and other men who have sex with men were not being observed among other groups [46].

As well as improving representativeness, it was important for us to understand how sociodemographic factors might lead to differences in our outcomes of interest. Based on international CAB+RPV LAI studies [47–49] and evidence on the social circumstances of people living with HIV in the UK, we theorised that differences in gender, ethnicity and age may result in differing perceptions of feasibility, acceptability, and appropriateness of CAB+RPV among people living with HIV in the UK. A 2022 national survey of people living with HIV in the UK found that older people, women and racially minoritised people were less likely to share their HIV diagnosis with others [50]. Women and heterosexual men living with HIV (whom are more likely to be from a racially minoritised background [22]) also reported higher rates of feeling ashamed of their HIV status, sometimes described as 'self-stigma' [50]. Concerns about preserving confidentiality of HIV status and self-stigma may result in greater preference for long-acting injectable treatment due to the greater discretion around treatment use and removal of the daily reminder of HIV status created by daily pill-taking [15]. Conversely, higher rates of unemployment and poverty among women and Black African people with HIV in the UK [50], increased caring responsibilities among women [51], and lower health-related quality of life among older people with HIV [50] may negatively influence feasibility, acceptability and appropriateness of a treatment which requires two-monthly clinic attendance and has a more rigid schedule than oral medication [52]. These factors could affect treatment success if they lead to challenges with adherence.

Triallists should seek to understand, insofar as possible, who is affected by the health issue of interest and where gaps exist in the data, in order to determine which groups it is appropriate to target, and to what extent. The NIHR INCLUDE and PROGRESS-Plus frameworks offer useful guidance for determining which underserved

populations may be relevant to focus on in the context of your trial [53, 54]. In some cases, for example where there is disproportionately high risk and low uptake of healthcare among a particular group, it may be justifiable to focus a study specifically on that group. Trustworthy, publicly available data on disease prevalence, severity and progression disaggregated by a range of socio-demographic factors may not be available for all conditions and contexts [55–58]. However, we would argue that, in many cases, this is a poor justification for inaction. A recent commentary in the academic journal *Trials*, providing guidance on determining the proportions and diversity of ethnic groups to be included in a trial, advocates for the adoption of a minimum default position based on census data where epidemiological data is not available [55]. This approach offers a pragmatic course of action for other sociodemographic factors where there is reasonable grounds to believe they may influence trial outcomes. Triallists can also improve data availability and advance scientific knowledge of a condition by collecting more extensive socio-demographic data; in ILANA, we included measures of socioeconomic deprivation (such as food, financial, and employment insecurity), caring responsibilities and disability, as well as clinical and other demographic information [35]. Crucially, given that socio-demographic data in medical records are often incomplete or inaccurate [59, 60], this data was reported by participants themselves within their baseline surveys rather than derived from the medical record.

Factoring targets into analysis plans

Consideration must also be given to how targets should be factored into trial analysis plans. In ILANA, we pre-specified analyses based on gender, ethnicity and age since we anticipated that these factors may influence differences in outcomes. As described above, we found statistically significant differences in implementation outcomes based on gender and ethnicity [35]. Aspects of the study design (small sample size, and non-randomisation due to the nature of the study) meant these findings needed to be interpreted with caution and limited our ability to explore associations statistically. Combining the survey findings with our qualitative interview findings that identified particular factors that may influence outcomes (such as autonomy and flexibility in employment, concerns about attending new treatment settings and having one's HIV status exposed to more people) and the broader research literature increased the plausibility that these findings indicate real differences in outcomes. In our dissemination, we have emphasised that inclusive recruitment has increased the representativeness of our overall findings, while subgroup analyses offer insights that warrant further investigation. The ILANA findings

underline the need for further research to investigate the types of support that can better facilitate CAB+RPV use, as well as supporting the development of alternative long-acting regimens which may overcome some of the challenges around CAB+RPV use. Sites involved in the study have already adapted their services based on the study findings, for example, by offering more out-of-hours appointments.

Subgroup analyses pose challenges for interpretation, and yet, such analyses are often the best evidence we have of the potential effects of interventions on health equity [61]. Disaggregated results and analyses are also important for patients—if individuals are being advised to participate in a study or use a drug or intervention because their sex, gender, ethnicity, age, or some other factor which places them at higher risk of poorer outcomes, they will want to see any differential effect represented in the results. While powering statistical analysis for subgroups is complex and may not always be feasible, descriptive findings from subgroup analyses can still offer useful insights—particularly for hypothesis generation for future studies—and sufficient power may be achieved through meta-analyses of pooled studies of the same intervention. Petticrew et al. (2012) offer useful guidance on how to develop and interpret subgroup analyses from an equity perspective [61]. Explanations about subgroup analyses for participants should be carefully developed in collaboration with PPIE representatives to manage expectations of what information these analyses can provide and maintain trust in the research process.

Including targeted subgroups in randomised trials is essential when differing effect sizes are anticipated across groups, as it helps reduce bias and improves representativeness. Balanced randomisation methods, such as minimisation or stratification, support subgroup analysis by ensuring even distribution of key characteristics/groups across treatment arms. This reduces variability and confounding, enhancing the statistical power to detect true differences or interactions. By improving comparability, these methods make subgroup findings more reliable and interpretable, leading to more accurate conclusions about treatment effects in diverse populations [62, 63]. Additional techniques for monitoring representation include pre-specifying interim analyses to see how well-represented sub-groups are across trial arms and tracking missing data by subgroup throughout the duration of the trial. Finally, sensitivity testing through per-protocol analyses can give a sense of factors influencing adherence. Combining these with longitudinal qualitative data collection can provide further explanation and potentially allow for adaptation and rectification as the trial is ongoing.

Making targets mandatory, not aspirational

The innovative aspect of ILANA's approach was making our recruitment targets mandatory, rather than aspirational. This underscores our conviction that research that is not inclusive is harmful and more wasteful than inclusive research that takes the time and care to build in inclusion.

Enforcing our targets was achieved through a range of strategies. Firstly, we carefully selected sites based on our knowledge of their patient cohorts—these sites were then invited to complete detailed feasibility assessments for the study, including which (if any) of the targets (gender, race and ethnicity and age) they considered achievable at their site. Sites had increased motivation to engage as ILANA was a portfolio adopted study, meaning they can use it as evidence of research activity to support future National Institute of Health Research funding applications [64]. We excluded sites that were unable or unwilling to commit to the targets. The targets were written into multiple sections of the protocol [10], reinforcing their importance within the study—particularly as failure to achieve targets would be recorded as a deviation. Recruitment overall and disaggregated by each target were closely monitored, and bi-weekly reports on progress towards each target were sent to all sites. An internal deadline for recruitment was set earlier than the funder deadline, creating in-built flexibility if sites needed more time to recruit. Where sites were struggling to recruit for certain targets, our Chief Investigator (CO) and community research collaborator (BK) engaged with the clinic and local patient groups to inform them about the study and promote recruitment. As a last resort, sites were capped, and competitive recruitment was applied where necessary.

While capping is usually used to avoid recruitment imbalances which may result in confounding [65], in ILANA we used caps to restrict sites from recruiting an excess of participants that do not contribute to meeting the inclusivity targets—for example, one site was told they could not continue to recruit men as they had already filled 50% of their allocated sample with male participants. There was initial resistance from sites regarding capping, but it also increased motivation to recruit targeted groups and ultimately capping was only required for two sites. Competitive recruitment, as opposed to allocated recruitment, usually means each site recruits participants until the overall sample size is reached [66]. In the context of ILANA, it meant that, following ethics amendment, study slots could be redistributed between sites when one site was finding it challenging to meet the target for a particular group and another was confident they could overrecruit for this target to ensure the overall

target was met for all groups. Ultimately, with redistribution, we were able to achieve the overall targets across all sites, and two out of six sites also achieved all three targets at site level.

Many of these techniques could be applied to trials. Sites could be chosen based on the demographics of their patient cohorts and similarity with settings where interventions are most likely to be introduced, should they be adopted into routine care. Research readiness and past enrolment rates, while important, were a secondary consideration in our study in order to avoid biasing selection to more experienced, specialist sites with less representative patient cohorts. Targets can easily be written into protocols. Capping and competitive recruitment are already regularly used within commercial trials where sites are struggling to recruit. Combined with integrated PPIE throughout the research and other innovative and well-established approaches to inclusive research [67–69], we have an opportunity to produce findings that can be used to meaningfully tackle health inequities.

But for trialists to be able and willing to seize this opportunity, the incentives and infrastructure to support these actions need to be in place. Funders and regulators who understand the value and impact of delivering inclusive research are making changes to their processes to ensure diversity and inclusion are required rather than 'nice to have' [2]. They also need to ensure mechanisms are in place to prevent the drive for greater inclusion resulting in unethical recruitment practices [70, 71]. A crucial aspect of this will be recognising that for inclusion to be done well and ethically, more time and resources will be required for study design and delivery, and this needs to be translated into adequate funding for inclusive research [72].

Conclusion

Our experience with ILANA offers a proof of concept for trialists seeking to radically improve representation and conduct more equitable RCTs and studies that engage all those who could benefit. We hope this also provides inspiration to funders and regulators seeking practical examples of inclusive research that can be scaled up. We encourage further work in exploring the implications of mandatory target setting and delivery within RCTs and welcome opportunities for collaboration on this important topic.

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Authors' contributions

This commentary was conceptualised by RH, MS, and CO. The original draft of the manuscript was written by RH, and critical revisions for important intellectual content were conducted by all authors. All authors approved the final manuscript.

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Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

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