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Perspective

Diversity in Clinical Trials: Breaking Barriers Increasing Inclusion - A Site Perspective

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Abstract

The lack of diversity within clinical research trials, particularly regarding ethnic minority representation, has been a widely reported issue for more than two decades [1,2]. The global COVID-19 pandemic further illustrated the discrepancy between ethnic minority disease burden and representation within clinical trials and highlighted the need for more inclusivity [3]. Regulating bodies, such as the Medicines and Healthcare products Regulatory Agency (MHRA) and the Food and Drug Administration (FDA) have subsequently released guidance, outlining recommendations for sponsors aimed at bolstering ethnic minority recruitment in clinical research trials. Following on from this, many sponsors and clinical research organisations have released their own white papers outlining barriers to clinical research participation and potential solutions. However, many of these white papers appear to remain as theoretical discussions rather than transforming into actions. This could be why despite the surplus of papers; there remains a challenge at the ground level with clinical research sites experiencing difficulties in recruiting and retaining diverse clinical research participants. This ongoing challenge represents the potential misalignment between the strategies theorised by the sponsor and key stakeholders and the pragmatism at a site level. Furthermore, diverse recruitment has rarely been defined, viewed and scrutinised from the perspective of a clinical research site who operate on the frontlines of clinical trial delivery. This paper outlines an actual approach taken by a clinical research site to combat the challenges of diverse representation within clinical trials at a research site level. We are convinced that increasing diversity in trials is possible through taking positive action and enriching the discussion around diversity. The arguments and practices showcased provide a blueprint for other institutions to adapt and adopt methods which have been proven to make a difference. We also provide feedback to Sponsors and key stakeholders from a site perspective on support required at a ground level.

Keywords: *Diversity in Clinical Trials; Hard to Reach; Site Strategy; Language Communication; Communication Barriers; Patient Satisfaction; Cost of Interpretation*

Background

The first global death from COVID-19 was registered on 9th January 2020, in Wuhan. By the end of December 2020, the estimated number of deaths had risen to more than 3,000,000 [4]. In the western world, ethnic minority patients were recognised as the most at-risk population; in the UK, the mortality rate for Black/Black British ethnic groups from COVID was reported as 225.4 per 100,000 population per year whilst the mortality rate for white ethnic groups was reported as 104.9 per 100,000 population per year [5].

COVID-19 has demonstrated the impact of ethnicity and deprivation on healthcare outcomes, in a stark, harsh and undeniable fashion. This has echoed in all corners of healthcare, including clinical research. The unique challenges faced by the sites during the pandemic were captured by Mitchell et al, alongside innovative solutions which enabled ongoing clinical trial delivery in the UK during those unprecedented times [3].

However, despite the UK industry showcasing its ability to adapt in ever changing circumstances, the delivery of diverse recruitment still fell short. Murali et al, conducted a recent systematic review and meta-analysis exploring the ethnic representation within UK COVID-19 trials. The results alarmingly revealed that the ethnic minority representation was approximately only 10% of the total COVID-19 population and was lower than the official figure reported by the Office of National Statistics of approximately 14% [6]. Similar underrepresentation is evident from figures reported from the US [7].

As a result, guidance aimed at Sponsors has been released by agencies including the Medicines and Healthcare products Regulatory Agency (MHRA) and the Food and Drug Administration (FDA). Subsequently, almost all major stakeholders have released their own white papers identifying and addressing potential challenges to clinical trial participation for individuals of ethnic minority.

One of the barriers identified was language and communication [8]. Overcoming language barriers to health care is a global challenge [9,10]. In the US over 24 million residents are unable to speak English fluently, with over 55 million residents speaking a language other than English [11]. The UK is also a diverse society with 7.9% of the population being from the Black and minority ethnic groups [12]. This is a heterogeneous group with different migration and settlement patterns, cultures, religions, and languages spoken. Research has identified more than 300 languages, excluding dialects, spoken by children at home in London and this indicates that London may be one of the most linguistically diverse cities in the world [13]. In this regard, the onus very much lies with the stakeholders, often clinical trials sponsors, who endeavour to provide trial related materials in the native language of potential participants in the hope to capture otherwise eligible participants [14].

Another recurrent barrier was identified as socioeconomic challenges and lack of adaptation for that challenge within clinical trial designs. Potential participants who are employed may be unable to commit to trial visits and those who are not employed or employed in a low-wage occupation may be unable to afford the travel to site. On a similar note, sites which are located a fair distance from potential participants may lose participants owing to the time required for travel. Trials which require procedures on a daily or relatively frequent capacity may also find certain groups of participants being unable to commit. As a result, sponsors and stakeholders should factor in travel and time reimbursements and are encouraged to review the locations of sites during the site selection visit [1,8].

Similarly, in a recent report by the Health Research Authority (HRA) exploring barriers to diverse representations within clinical research socioeconomic factors were recognised. The report positioned reducing costs to participants as a key recommendation in helping to address these barriers [15]. In addition, the employment of a hybrid model of traditional and decentralised clinical trial (DCT) model may allow for certain assessments and procedures to be conducted in a manner which significantly reduces the impact of clinical trials on the daily routine of patients [1,8].

In addition, almost all stakeholders will recognise the development of trust within the community as an integral component to increasing diversity within clinical research trials. Historic events such as the Tuskegee trials have led to the presence of deep mistrust in the ethnic minority community [1]. Stakeholders suggest various means to overcome this including trial staff being representative of the population they are treating, training of staff in cultural competence and initiatives to cultivate a relationship within the community including utilising community leaders [1,16].

The above barriers and potential solutions are a few of many examples put forward by sponsors and key stakeholders. Yet, despite this, ethnic minority participants remain underrepresented within clinical research trials.

The Birmingham FutureMeds team, including Site Director and Global Diversity Ambassador, Dr Khaled Ahmed, Associate Medical Director and Principal Investigator, Dr Tehmina Ahmed and Clinical Relations Specialist Samantha Bishop, have scrutinised the gaps between the solutions suggested by key stakeholders and the potential challenges faced by research sites in implementing such solutions.

As part of this, the team have delivered an initiative called '*Breaking Barriers, Increasing Inclusion'* to increase diverse and ethnic minority recruitment in clinical research trials. The site presents this initiative to provide an insight into the success resulting from the initiative and provide the successful strategies that can be emulated and scaled at other research sites nationally and beyond.

The site undertook this initiative to:

–Explore how to recruit participants from diverse groups

–Collate valuable information from site experience to understand any common themes or barriers diverse and ethnic minority groups have in taking part in trials

–Use the information collated to help support other sites in how best to recruit form diverse groups

–Plan for future studies where site could proactively recruit from diverse groups and share best practice to other clinical sites and by educating and raising awareness within the community

Provide further information to sponsors regarding diversity in clinical trials

New Contribution

To our knowledge this is the first paper where a research site has proactively taken strides into developing a site where diversity is at its core.

Method

The site undertook a thorough analysis of the barriers to clinical research for the underrepresented participant group. These key areas and the solutions implemented are described below:

1. Trust, Education and Access to Information

The establishment of international standards and regulations serve as a safeguard against exploitation in clinical research. However, historical exploitation remains at the core of the mistrust held within communities. To tackle this, education and dissemination of information is required. Yet, it is important to recognise that the ethnic minority population, despite having a higher disease burden in certain therapeutic areas, are more likely not to access or fully utilise healthcare services. Therefore, communication through primary care practices may not always reach this community group. Consequently, taking a community targeted approach and venturing outside of healthcare settings is vital in ensuring marginalised communities are reached.

2. Socio-economic circumstance

Clinical research studies do not come without their costs to participants. Within our research site's area of Handsworth (Birmingham), the unemployment rate is 52.7%, significantly higher than the national average of 25%. Of those individuals who are employed, the majority (56.3%) are within lower skilled occupations [12]. At a site level, we recognised the socio-economic burdens that could deter potential participants as 1) visits being conducted in working hours, 2) participants being required to travel to site and 3) site not having easy access to parking available.

3. Language and communication

Many of the marginalised communities remain excluded from research as patient materials are not available in their native language. Within Handsworth, this is a very significant issue; approximately 37% of participants do not speak English as their first language and many do not speak English at all [12]. In addition to this, we recognise that dialect may present a further issue. Many minority patients speak a language but of a certain dialect and so translated materials may not be enough or fit for purpose.

Following recognition of the above issues, we set out the following actionable items as part of the '*Breaking Barriers, Increasing Inclusion*' initiative:

1. Community events

- We identified different types of community events to attend allowing the team to represent clinical research in wide variety of arena's and to differing audiences. Each event type served a different purpose and combined to further the goal of attaining diverse representation within clinical research.

- Patient support groups, rehabilitation groups and patient awareness conferences: the team attended and presented at multiple patient group meetings and patient centred conferences. The aim of these events was to speak directly to relevant patient cohorts and raise awareness and increase engagement with clinical trials being delivered within the region. It would also enable the team to further their understanding of misconceptions within different communities and take a 'hot seat' approach in being able to answer questions directly from potential participants and deliver education and information.

- Community leader's events: the team presented at a regional faith forum meeting which was attended by leaders representing various faiths and backgrounds. The team have also attended various community leader events, some which have broadcasted on television. The aim was to develop collaborations with community leaders and enhance the trust of the team held within the community. We were hopeful that this approach would also help us to reach marginalised communities and individuals whom we may not have been able to interact with otherwise.

2. Raising awareness through media

- Facebook: The team launched a focused Facebook campaign to raise awareness of the clinical trials available locally.

- Radio: The team conducted an interview on a regional radio channel with a reach of up to 250,000 ethnic minority community members.

3. Establishing local and regional networks

- Patient ambassadors: the team has established partnerships with a number of patient ambassadors ranging from international Diabetes ambassadors to Healthy Minds ambassadors.

- Primary care practices and General Practitioners (GP's): the team worked closely with local and regional primary care practices to develop an efficient and effective recruitment programme.

4. Logistical considerations

- Translated patient material and interpreters: the team has identified the common languages spoken within the area. This information is then relayed to the sponsor for the potential provision of translated patient material.

- Provision of transport: The team provides the options of Taxis as a mode of transport for all participants following feedback from participant interviews. The team actively engages in discussion about socioeconomic considerations with sponsors at an early stage to ensure appropriate measures can be facilitated earlier in the ethical approval process.

Results

The first clinical research trial for which the '*Breaking Barriers, Increasing Inclusion'* initiative was implemented was a cardiovascular clinical research trial.

Overall, recruitment analysis for this trial has shown that one in four patients screened (25%) and subsequently one in five randomised (20%) are of an ethnic minority with site exceeding the overall recruitment target. When looking at the greater diversity cohort inclusive of other groups such as socioeconomic diversity, social class and educational diversity, sexuality and gender diversity groups, the number rises close to 50% of all patients randomized.

Further analysis of recruitment numbers reveals the greatest recruitment success has resulted from primary care practice partnerships. At the time of writing, FutureMeds Birmingham has partnerships with 35 local and regional primary care practices. These partnerships have resulted in 68 screens (47%) and 23 randomisations (16%).

Next, the use of Facebook campaigns has resulted in 21% of total screens which has led to the achievement of 15% of the overall randomisations for this cardiovascular trial. On the other hand, the radio interview did not culminate in any recruitment activity.

Finally, the presentations and talks undertaken at various community events, some in association with FutureMeds Birmingham ambassador partnerships, resulted in 2% of screens and led to 3% of the total randomisations achieved in this trial. In addition to this, these events resulted in further opportunities to speak in various forums, and this has led to an uptake in our pre-screening service by 120%.

At the time of writing this paper, the total number of trials where the initiative has been implemented stands at more than 20 with some trials showing ethnic minority recruitment as high as 65-70% with a retention rate of more than 90%. In addition, the Birmingham FutureMeds site undertook a rare disease (genetic screening) clinical trial for participants who identify as Black or Afro-Caribbean in which site was able to recruit more than 100 patients all of whom have been recruited through community outreach.

Due to the collective work on Diversity, FutureMeds Birmingham were nominated as a finalist for the Include Diversity award in Atlanta where Dr Khaled Ahmed Site Director & Global Diversity Ambassador was invited to present.

Discussion

Although, across the last few years, the international community has increasingly recognised the barriers to clinical research, the implementation of potential solutions remains focused at the level of the sponsor or clinical research organisations.

Little consideration is given to site-level solutions beyond the appropriate selection of sites. Yet, sites are the primary source of contact for potential participants into most clinical research projects and their activities at a ground level can greatly influence participant recruitment. At FutureMeds Birmingham, we have successfully shown that identifying barriers at a local level and implementing strategies to overcome these barriers can significantly improve diverse and ethnic minority recruitment and retention into clinical research trials.

The main success in recruitment overall, has been shown through partnerships with primary care practices. The use of healthcare physicians with whom potential participants have a long-standing relationship of trust, is an effective and well-known means to reducing barriers to clinical research.

However, we recognise that in utilising this approach we remain at risk of isolating the marginalised community who may not share an established relationship of trust with their healthcare practitioner or who may not utilise the healthcare services available to them [8]. Therefore, other avenues such as patient ambassadors, patient groups and community faith leaders should be sought out. Utilising these other potential trusted community pillars can serve as a means to reaching the marginalised communities and ensure a more inclusive recruitment practice.

Nonetheless, the recruitment of diverse and ethnic minority patients serves an important purpose beyond the clinical trial itself. Each participant recruited, creates a story and experience to be shared within the community. This positive anecdotal narrative can serve as a powerful tool in combatting the deep seated and long held stereotypes the ethnic minority community has regarding participation in clinical research. The ability for potential participants to speak to individuals who have been involved in clinical research is recognised as a strong and effective tool in reducing the barriers to clinical research.

Similarly, whilst the community events and radio interview did not yield immediate increase of recruitment numbers, they did provide a means of entry for those who were interested in clinical research. Perhaps more importantly, these events provided a means for initial potential participant contact; they provided the more sceptical individual access to information and provided an opportunity for them to ask questions of the team. During this interactive process, the team had the chance to address concerns and potentially correct long held stereotypes through informing and educating.

Therefore, these events and activities are imperative in tackling the barriers to clinical research by enabling the building of trust within the community in the long term.

In addition, integrating into the community has also allowed the team to gain valuable insight into understanding issues important to the community. An example of this includes the use of terminology like 'hard to reach communities' which is often used to describe ethnic minority communities within research. The team found an expression of dislike by many members of the ethnic minority community regarding the use of such terms and preference for terms such as 'marginalised' or 'underrepresented'. The team was then able to relay this message to the greater academic audience.

This example highlights the work yet to be done within the field of clinical research at a site level and beyond. As it stands, our initial phase of the 'Breaking Barriers, Increasing Inclusion' initiative has yielded promising results in improving diverse and ethnic minority recruitment into clinical research trials. Our next phase will be greatly focused on developing a deep understanding of the factors that matter to the diverse and ethnic minority patients and community.

At FutureMeds Birmingham, we hope to achieve this refined understanding in our next phase of 'Breaking Barriers, Increasing Inclusion' through participant and community focus groups. FutureMeds as a whole is targeting diverse groups across the sites which is inclusive of all diversity cohorts including socioeconomic diversity, sexuality and gender diversity, social class and educational diversity, disability diversity, caste system within ethnic minorities diversity and many more. In undertaking these activities, we hope to be able to greater understand the needs of the individual participant and tailor our approach to participant recruitment. We also hope to be able to disseminate these results to the academic community to enable change on a wider scale.

Nonetheless, we echo the findings of key stakeholders in limited sponsor support being a notable barrier at a site level in implementing solutions for improving diversity within clinical research [8]. The success of 'Breaking Barriers, Increasing Inclusion' initiative has been dependent upon the time commitment and energy expended by the site team in engaging with the participant and healthcare community. The groundwork which was laid in the initial cardiovascular trial was built upon across a period of time and is the key reason for the success of diverse recruitment in later studies.

However, the majority of this work has to be conducted by site staff in their own time. If these proven approaches are to be adopted by other sites, it is imperative that sponsor and key stakeholders provide adequate financial and material support to facilitate site staff activities.

In addition, whilst sponsors are forthcoming in providing translated trial materials, our experience suggests that the variation in dialect within native languages results in materials which are not understood by potential participant. Furthermore, whilst the conversation surrounding the use of translators for the consent process and scheduled visits are frequent, the requirement of translators for unscheduled contacts, particularly phone contact, presents a logistical barrier which has not yet been resolved. The use of services employed within emergency departments, such as language line, could present a potential solution to this.

Conclusion

We have shown that site led initiatives are successful in increasing recruitment and retention of diverse and ethnic minority participants in clinical research trials. However, most of the published site level solutions are derived from top level recommendations suggested by key stakeholders without recognition of the costs to individuals or research sites at a ground level.

We have shown that the successful delivery of initiatives like '*Breaking Barriers, Increasing Inclusion'* has its foundations rooted in the building of long-term relationships and trust within the community. This can often be time consuming and may therefore be seen as an 'extra-curricular' activity at a site level, often being driven purely through the team motivation and requiring work beyond the traditional working hours. For site led initiatives to become scalable and sustainable across the clinical research community, more needs to be done by Sponsors and CRO's to recognise and support sites in undertaking such activities. In alignment with this, the 2024 report produced by the Health Research Authority, found researchers cited resources to be one of the major barriers they faced in delivering good people-centred clinical research.

Competing Interests

Nil declared

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