Addressing the gap for racially diverse research involvement: the King’s Model for Minority Ethnic Research Participant Recruitment

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Abstract

Background

Ethnic minorities (EM) are still underrepresented in research recruitment. Despite wide literature outlining the barriers, enablers and recommendations for driving inclusion and diversity in research, there is still little evidence for successful diversity in research participation, which has a direct impact on the quality of care provided to ethnically diverse individuals.

Methods

In the light of the Covid-19 pandemic and the key public health need to address the disparity in care provided to non-white populations, we applied the recommendations made by Ocloo and Matthews (2016) on diverse engagement in PPI groups to promote inclusive research recruitment.

Results

Our results demonstrate a significantly higher recruitment of EM populations to studies, when compared to recruitment in years 2017–2020.

Conclusions

Enriched by additional recommendations based on our experiences during the Covid-19 research recruitment drive, we propose the King’s Model is used to support ethnically diverse research recruitment. Further evidence is needed to replicate our findings, although this preliminary evidence provides granular details necessary to address the key unmet need of validating clinical research outcomes in non-white populations.

Background

It is widely evident that research participation varies greatly among different ethnicities. This has a direct effect on the healthcare experiences and the extent to which personalised medicine can be applied patients of ethnic minorities. Principle 13 of the Declaration of Helsinki stresses the importance of providing access to research to the underrepresented groups The reports of this issue being identified dates as far back as the 1980s [1] and yet, there is little evidence for effective addressing of this concerning disparity. In 2012, the Department of Health in the United Kingdom (U.K.) conducted a Delphi consensus exercise and published the Leeds Consensus Statement outlining principles for research on ethnicity and health. The recommendations for future priorities included identification of effective ways of reducing inequalities and further research on models for involving minority ethnic communities in research [2], seemingly setting the path for improvement.
Three years later, the Royal College of Physicians (RCP) in the U.K. highlighted the importance of research availability to all patients, identifying this to be beneficial not only to patients, but also to the National Health Service (NHS) Trusts and their staff [3]. This need was then echoed in the Care Quality Commission inspection framework for NHS Trusts in 2018, although relatively little has been done in practise to address the issue.

Nevertheless, some key pieces of work have been completed in the meantime, such as the identification of barriers and enablers for enrolment of diverse populations [4–6], which identified that healthcare organisations should place a greater emphasis on empowerment and addressing equality and diversity in their involvement strategies and aim to reduce institutional racism [7].

Despite this work and a wide literature existing concerning the need for the inclusion of ethnic minorities (EM) in research [8], a recent report demonstrates that little effort has been made to promote diversity in research and in real terms, where diverse populations are available, research recruitment remains largely limited to white Caucasian, middle class, educated individuals [9]. In addition, a pre-pandemic systematic review investigating researcher reported strategies for non-white recruitment into clinical trials in the United Kingdom highlighted that limited strategies have been employed to increase recruitment among ethnic minorities [10]. Despite studies looking into language barriers in research and how these can be addressed [11], relatively little has been done to promote research for those who speak adequate English and who do not participate for various reasons, including unawareness of research taking place. It is also important to highlight that in direct comparison, there are little differences in willingness to participate in research among Caucasian and non-white participants, highlighting the need to ensure access to health research for all groups [12].

With the recent SARS-CoV-2 (Covid-19) pandemic, and the rate of severe infections and mortality being higher among EM populations [13, 14], ethnically diverse recruitment to research became the key need which simply had to be addressed [15]. Given the diverse population residing in South-East London and within the catchment area of King’s College Hospital, we applied the recommendations proposed by Ocloo and Matthews (2016) which focus around enabling power and decision making among the patients and the public in designing, planning and co-producing healthcare, in the current piece of work. We aimed to increase EM recruitment into medical research though closer and multi-layer involvement of wider groups of individuals in promotion of research participation.

This article outlines a novel, holistic approach to addressing the current glaring gap in research recruitment diversity, applied in a real-life, people-based setting. We applied the herewith proposed model to research studies conducted at King’s, and the aims were to (i) observe an increased recruitment to Covid-19 studies among EM populations and (ii) explore the feasibility of implementation of the model to future research participation strategies.

**Methods**
Where available, we inspected diversity in retrospective research recruitment to studies conducted at King’s College Hospital NHS Foundation Trust within the period of 2017 to 2020, across a number of specialities including neurology, stroke, cardiology and palliative care. We then applied the Model outlined in Fig. 1 to a research recruitment drive for four of the key Covid-19 studies, given their public health urgent need status. We implemented items from the proposed Model starting in September 2020 and analysed the data in September 2022, despite that some studies such as COVID-CNS were still open to recruitment at the time of analyses. As the model outlines, we conducted local (in hospital) action as well as a community outreach.

**Local action**

Our local action focused around increasing research awareness, internally in the hospital and involving all hospital stakeholders in promoting research and addressing misconceptions that the public may have around research. We identified that conversations, meetings, seminars and creating electronic resources are imperative to driving diverse research participation from within the hospital. We therefore began with highlighting the issue to the senior management to create a line of dialogue during smaller departmental meetings as well as senior management meetings. We also initiated meetings focused on diverse recruitment strategies and invited key professionals who are already have a track record of working on this issue.

**Community outreach**

We targeted the local community groups including churches, schools and colleges and youth centres, to identify local champions. Once these were identified, we held webinars for local population, which featured a multi-disciplinary panel to increase the awareness and dispel any misconceptions that the audience may have had. In light of the Model being employed for the Covid-19 studies, we also organised a Vaccine Awareness Day with key staff manning stalls open for public to visit. Stemming from our local action, we recorded a series of videos featuring ethnic minorities patient ambassadors and increased our social media presence, ensuring that the local reach is intensified and that the key hashtags and localisation services are utilised.

**Implementation of the Model – the MAADE scheme**

During implementation of the King’s Model, we observed some key drivers of success. For example, it was essential that were aware of the current ethnic breakdown of our research participant to aid more targeted action. In addition, we consulted with the local champions on the way we presented research information to ensure that it is indeed acceptable to the general public. We also maximised the availability of research to accommodate for those who cannot attend research clinics within the normal working time. For example, our SIREN clinics were open beyond the usual 9am-5pm working hours to ensure that
participants could attend the study visits without having to take time off work. It was also important to ensure that the drive for recruitment was a Trust-wide initiative, rather than just singular teams. To achieve this, we collaborated with the Communications department to increase the visibility of the Recruitment Strategy on the Trust Intranet and all our electronic resources. Lastly, in line with the strategy proposed by the Clinical Research Network (https://www.nihr.ac.uk/documents/participant-in-research-experience-survey-pres-202122/31768), we aimed to ensure that the participants have been satisfied with their research experience. This included communication and distribution of newsletters, as well as accommodation of any changes to their visits (permissible within the study protocols) and distribution of the results, where available. As a result, we propose the MAADE as a guide for implementation of the King’s Model.

**Results**

Baseline findings indicated a low rate of minority ethnic recruitment specifically in interventional studies. The findings show that the recruitment of EM subjects, especially to interventional studies, has been problematic, with an average EM recruitment being as low as 6.4% despite a diverse catchment area for King’s College Hospital (see Table 1) in years 2017–2020. It is also demonstrated that EM participation had been highest in the non-commercial observational studies. Following application of the King’s model, we found that that the percentage of recruitment of EM participants to both interventional and observational studies was higher compared to where the King’s Model was not employed (see Table 2), although this difference was not tested for statistical significance. In addition, initially in this report we focus on Covid-19 studies in this period.

Chosen research workforce were empowered to apply the various enablers of the King’s Model (Fig. 1) as was seen to be appropriate in specific research settings in the clinic. Recruitment data was collected from central records kept by the King’s Research and Innovation department. A health inequalities oversight group provided advice when required.

<table>
<thead>
<tr>
<th>Study type</th>
<th>N of reviewed studies</th>
<th>N (%) white participants</th>
<th>N (%) BAME participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-commercial interventional and observational</td>
<td>37</td>
<td>629 (69.8%)</td>
<td>272 (30.2%)</td>
</tr>
<tr>
<td>Commercial interventional</td>
<td>19</td>
<td>73 (93.6%)</td>
<td>5 (6.4%)</td>
</tr>
</tbody>
</table>
Table 2
Recruitment of ethnic origin breakdown across the following Covid-19 priority studies after the King’s Model had been applied

<table>
<thead>
<tr>
<th>Study type</th>
<th>N (%) white participants</th>
<th>N (%) BAME participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIREN (non-commercial observational)</td>
<td>345 (70.6%)</td>
<td>144 (29.4%)</td>
</tr>
<tr>
<td>PHOSP-COVID (non-commercial observational)</td>
<td>148 (59.0%)</td>
<td>103 (41.0%)</td>
</tr>
<tr>
<td>COVID-CNS (non-commercial observational)</td>
<td>75 (40.8%)</td>
<td>49 (59.2%)</td>
</tr>
<tr>
<td>NOVAVAX (commercial interventional)</td>
<td>187 (83.9%)</td>
<td>36 (16.1%)</td>
</tr>
</tbody>
</table>

Conclusions

This work outlines the premises of the King’s Model for Minority Ethnic Research Participant Recruitment, based on the work undertaken at King’s College Hospital since 2020. Prior to the initiation and implementation of the King’s Model, we had performed a rough signposting of the current landscape of the ethnic minority (EM) population participation in research trials within the Trust using existing research databases among different research delivery units, where data on race identification was available for use and disclosure. Robust data was only available in selected research and when looking at commercial interventional studies, it was clear that within the four research delivery units, representing 78 patients, while 93.6% were White Caucasian, only 6.4% were EM. Similarly, when considering non-commercial studies, from a total pool of 901 participants, recruitment of EM participants was higher at 30.2%, but still significantly lower when considering the local catchment area, where non-white individuals make up, respectively, 42%, 46% and 50.7% of the total population in Lambeth, Southwark and Croydon [16–18].

The data was a board reflection in line with the recent studies published from our group in trials related to Parkinson’s disease (PD) as an exemplar. A detailed survey of clinical trials in PD from 2017 to 2021 showed a shocking lack of recruitment of EM subjects to clinical trials [9]. In another study from our group, a concerning lack of analgesia was reported in black PD subjects with pain compared to white Caucasian PD subjects with pain [19].

This had led to our initiative to improve the research participation of EM patients in clinical trials and we selected out four high profile Public Health England studies: SARS-CoV2 immunity and reinfection evaluation (SIREN, IRAS ID: 284460), Post-hospitalisation COVID-19 study (PHOSP-COVID, IRAS: 285439), COVID-19 Clinical Neuroscience Study (COVID-CNS, UKRI/MRC (MR/V03605X/1), and A Phase 3, Randomised, Observer-Blinded, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1™ Adjuvant in Adult Participants 18–84 Years of Age in the United Kingdom (NOVAVAX, IRAS: 288793). The first three are non-commercial, observational Urgent Public Health England studies and the latter being a vaccine trial taking place at King’s College Hospital.
The King's Model was initially used in the first stages of Covid-19 research projects, with PHOSP-COVID and SIREN being the first two targeted studies. Given the vaccination hesitancy among non-white populations [20], the model was also utilised with the Novavax interventional trial and at a later stage, with the observational COVID-CNS study. The implementation of the individual items outlined in the Model was conducted simultaneously to increase reach and ensure that the drive for diverse recruitment was in focus both locally and in the community. Consequently, our local recruitment, as outlined in Table 2, represents higher numbers of EM participation, compared to the studies where the Model was not utilised.

The application of the King’s model led to a significant increase in research participation among non-white populations during the Covid-19 pandemic at King’s and is currently utilised in further research as part of the NIHR-led Reset and Restart programme, which aims to make the research portfolio delivery achievable and sustainable within the resources and capacities of the current NHS settings.

Broadly, the action taken to address this key unmet need has been divided into (1) within-hospital steps and (2) Community outreach.

**Within-Trust action**

We employed a multi-level engagement in order to reach all levels of the hospital staff and as a result, patients across all specialties, to ensure that all patients at King’s were aware of the currently offered portfolio of studies. More importantly, we ensured that all the staff at King’s were not only aware of the research portfolio but were actively engaged in promoting research. This was facilitated by engaging senior management to ward staff. We felt it was especially important to engage leaders of EM background to increase relatability among both EM staff and patients.

**Community Outreach**

Education and dialogue are imperative to creating a trust rapport which allows the public to take part in research. It was felt that engaging local communities in the dialogue is key to widening the public involvement, participation and understanding of research, outside of a hospital setting. We therefore formed a close collaboration with the local church leaders and community champions. Additionally, we had organised a series of webinars for the local community which were attended by a multi-specialist and disciplinary panel to answer any questions and address any concerns about research that the members of the local community have. We found that engagement drive through social media played a key role, especially in terms of getting through to the younger populations.

On reflection, the initiative, whilst successful, highlighted a fundamental unmet need when addressing research recruitment imbalance among the ethnic minority populations: the under-resourcing. Healthcare centres such as hospitals and general practices are in dire need of providing more resources to enable promotion and engagement of ethnic minority populations in research and more widely, decision-making regarding health management. It is therefore imperative that the budget being used to utilise such models
as the King’s Model is carved out, given that as demonstrated by our initiative, it leads to a significant improvement in addressing the gap which has been highlighted by numerous publications, including Lau et al (2022).

**Future directions (studies)**

From this novel initiative, we have shown that the disparity in ethnic minority inclusion in research can be addressed through methods such as the King’s Model. We have also found that whilst addressing this disparity in research, the need to support communities financially with resources is essential to ensure outreach is successful. The King’s Model, when resources are available, proposes a real-world working approach when utilised.

An example of a currently ongoing study utilising the King’s Model is the PD-Ballet study (NCT04719468) utilising a ballet-based dance intervention to aid motor and non-motor symptoms of Parkinson’s disease. Despite the niche type of the intervention which may be alien to many cultures (Asian for instance), following utilisation of the King’s Model, the study recruited across multiple ethnicities and the final demographics will be available at study completion.

In light of the proposed Model, we recognise that there are a number of factors which may influence the implementation and effectiveness of such a model. We therefore propose the MAADE scheme (Fig. 2) which outlines the key factors for consideration in long term planning when employing the King’s Model. For example, by constant Monitoring of the research participation ethnic breakdown, we will be able to reassess and revisit the initial aims and refocus, if the Model does not yield the desired outcomes. The King’s Model, as a whole aims to lead to a greater Acceptability of research participation across different ethnicities, and therefore a constant insight into the assumptions and flawed beliefs held by people of different ethnicities will allow to shift focus to topics which may make the most difference. In addition, where possible, it is important to assess the accessibility of research to the potential participants. For example, people who are carers or work long or unsociable hours may be less likely to take part in research due to their availability. It is therefore important to consider whether the research studies on the portfolio make provisions for monetary or otherwise reimbursement for participation, or flexibility around study visit attendance. It is also important that there is an active Drive to implement the King’s Model within the Trust, and that those who eventually decide to take part in research have a positive Experience and are likely not only to participate in further research, but also encourage participation within their communities.

**Conclusion**

In this report, we are proposing a scheme of work called the King’s Model for Research Participation Recruitment, which aims to offer a holistic approach to the key unmet need that clinical research is facing currently in the form of lack of ethnically diverse study participation. In addition, we also propose the
MAADE scheme which allows to identify the key factors to be considered for effective implementation of the King's Model.

It is too early to see if the King’s Model is replicable in all aspects of the NHS, let alone other healthcare bodies, however further research should focus on the implementation of the King’s Model and its efficacy on a wider scale. Reports regarding disparities in representation of ethnic minority populations in research have been highlighted over the past decades and have become more paramount following the Covid-19 pandemic. The King’s Model provides a world-first novel approach in addressing this gap, and supports the need for further work to ensure ethnic minority populations are represented in research at all levels, to ensure participation in research is truly universal for all.

Abbreviations

COVID-CNS - COVID-19 Clinical Neuroscience Study

EM – ethnic minorities

NOVAVAX - A Phase 3, Randomised, Observer-Blinded, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1™ Adjuvant in Adult Participants 18-84 Years of Age in the United Kingdom

PD – Parkinson’s disease

PHOSP-COVID - Post-hospitalisation COVID-19 study

SIREN - SARS-CoV2 immunity and reinfection evaluation

Declarations

Ethics approval and consent to participate

All participants in the analysed studies consented to taking part in the research studies and signed Participant Informed Consent Form for the individual projects.

Informed consent was sought by trained research staff and conducted in accordance with Good Clinical Practice Guidelines and the Declaration of Helsinki. All research methods were carried out in accordance with Good Clinical Practice Guidelines and the Declaration of Helsinki. Where participant ethnicity data was reviewed, all experimental protocols were approved by the Research Ethics Committees in England.

Consent for publication

Not applicable

Availability of data and materials
The datasets analysed during the current study are available from the corresponding author on reasonable request.

**Competing interests**

Authors do not report any competing interests.

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**Authors' contributions**

Conceptualisation: AP, KRC, JEO; Data analysis: AP, MAQ, AM; Supervision: KRC, CG, AG, JEO; Writing – Original draft: AP; Writing – Review and Editing: AP, KRC, YHL, AM, MAQ, SOD, KL, MA, AG, SB, AL, OA, AMM, JEO. All authors read and approved the nal manuscript.

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**References**


Figures
<table>
<thead>
<tr>
<th>Approach</th>
<th>Specific actions</th>
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<tr>
<td>Local (in hospital)</td>
<td>Engagement of senior management in conversations</td>
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<tr>
<td></td>
<td>Engage key professionals in meetings</td>
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<td></td>
<td>Engage all hospital stakeholders ranging from security and cleaning to consultants in seminars</td>
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<td>Video of management and clinical stakeholders to engage ethnic minorities</td>
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<td>Community Outreach</td>
<td>Webinar for local population by a multi-specialist and disciplinary panel</td>
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<td>Communication with local champions</td>
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<td>Social media presence about vaccine facts and dispel fake news</td>
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<td>Engage with NIHR (South London ARC)</td>
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<td>Vaccine awareness day</td>
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<td>Video of ethnic minorities patient ambassadors</td>
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**Figure 1**

An outline of the proposed actions as part of the King's Model for Research Participation Recruitment
Figure 2

The MAADE Scheme for effective implementation of the King's Model.