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2017



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Promoting Excellence in Health Services Research

Improving representation in trials: thinking more carefully about who should be in your trial

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Team effort



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Focus for today



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1. Helping to ensure trials involve the range of ethnic groups that they need to.
2. Moving beyond ethnicity.

In 2018 we teamed up with INCLUDE



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Trials Methodology
TMRP
Research Partnership



Witham et al. *Trials* (2020) 21:694
<https://doi.org/10.1186/s13063-020-04613-7>

Trials

RESEARCH

Open Access



Developing a roadmap to improve trial delivery for under-served groups: results from a UK multi-stakeholder process

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Abstract

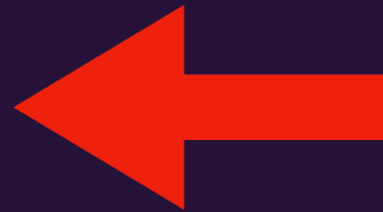
Background: Participants in clinical research studies often do not reflect the populations for which healthcare interventions are needed or will be used. Enhancing representation of under-served groups in clinical research is important to ensure that research findings are widely applicable. We describe a multicomponent workstream project to improve representation of under-served groups in clinical trials.

Methods: The project comprised three main strands: (1) a targeted scoping review of literature to identify previous work characterising under-served groups and barriers to inclusion, (2) surveys of professional stakeholders and participant representative groups involved in research delivery to refine these initial findings and identify examples of innovation and good practice and (3) a series of workshops bringing together key stakeholders from funding, design, delivery and participant groups to reach consensus on definitions, barriers and a strategic roadmap for future work. The work was commissioned by the UK National Institute for Health Research Clinical Research Network. Output from these strands was integrated by a steering committee to generate a series of goals, workstream plans and a strategic roadmap for future development work in this area.

Results: 'Under-served groups' was identified and agreed by the stakeholder group as the preferred term. Three-quarters of stakeholders felt that a clear definition of under-served groups did not currently exist; definition was challenging and context-specific, but exemplar groups (e.g. those with language barriers or mental illness) were identified as under-served. Barriers to successful inclusion of under-served groups could be clustered into communication between research teams and participant groups; how trials are designed and delivered, differing agendas of research teams and participant groups; and lack of trust in the research process. Four key goals for



THE INCLUDE ETHNICITY FRAMEWORK



[Key Questions and worksheets](#) >

[Background](#) >

[Appendix 1: Ethnic categories](#) >

[Appendix 2: Who developed the Framework](#) >

EXAMPLES

We have prepared some examples by applying the Framework to some existing trials. These examples are intended to be illustrative and not a definitive assessment of the trials. For the most part we were not involved with the trials so only had publicly available information with which to complete the worksheets. Moreover, doing this retrospectively rather than at the design stage is not ideal.

What is it?



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A 2-part tool to help trialists to identify the ethnic groups needed in a trial. The two parts are:

1. Four Key Questions
2. Worksheets to help you complete the questions.

Part 1 – Key Questions



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
Ensuring your trial is designed for all who could benefit


Key Questions. The starting point for all trials is to think about who the trial is for. The trial team then needs to do everything possible to make their trial relevant to the people to whom the results are intended to apply (often patients) and those expected to apply them (often healthcare professionals). This means thinking carefully during trial planning and design about who should be involved as participants.

The four questions below are intended to prompt trial teams to think about who should be involved as participants, and how to facilitate their involvement as much as possible. These questions should always be considered by trial teams in partnership with patient and public partners, including individuals from, or representing, groups identified in Question 1.

Note that: • 'Intervention' means the treatment, initiative or service being evaluated. • 'Comparator' means the what the intervention is being compared to. • 'Effective' means the intervention provides important benefits for people with the disease or condition that is the focus of the trial.

We recommend that trial teams use the worksheets to help them think through their answers to the four key questions.

-  **1. Who should my trial results apply to?**
Which groups in the community could benefit from the intervention if it was found effective, or benefit from not having it if it was found ineffective and/or harmful?
-  **2. Are the groups identified in Question 1 likely to respond to the treatment in different ways?**
How might the disease or cultural factors mean that some groups in the community respond to, or engage with, the treatment(s) being tested in different ways?
-  **3. Will my trial intervention and/or comparator make it harder for any of the groups identified in Question 1 to engage with the intervention and/or comparator?**
How might the intervention and/or comparator, including how they are provided, make it harder for some groups in the community to take part in the trial?
-  **4. Will the way I have planned and designed my trial make it harder for any of the groups identified in Question 1 to consider taking part?**
How might elements of trial design, such as eligibility criteria or the recruitment and consent process, make it harder for some groups in the community to take part?

 **THIS WORK IS PART OF THE LARGER NIHR INCLUDE PROJECT.**
• <https://sites.google.com/nihr.ac.uk/include/> • <https://doi.org/10.1186/s13063-020-04613-7>
For more information download our worksheets at www.trialforge.org

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1. Who should my trial results apply to?
2. Will the groups identified respond to the treatment differently?
3. Will the intervention itself make it hard for some groups to be involved?
4. Will the trial design make it hard for some groups to be involved?

Part 2– Worksheets



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Worksheets for thinking through factors that might affect ethnic group involvement in a trial

These worksheets are intended to be used by trial teams in partnership with patient and public partners to ensure that ethnic group involvement is considered at the trial design stage. Before completing the worksheets, the trial team **should have answered Question 1 of the INCLUDE Key Questions with regard to ethnic group involvement.**

The worksheet may cover issues that some trial teams already think about. The intention is that the worksheet will help to highlight issues consistently across trials for all trial teams, as well as raising some questions that may not be routinely considered at present.

Finally, while the worksheet asks trial teams to think about possible differences between ethnic groups, it is important to remember that there are also differences *within* ethnic groups, especially between generations and between men and women. No ethnic group is homogenous.

Worksheet 1

This worksheet provides some questions to guide your thinking about ethnic group involvement when answering Question 2 of the INCLUDE Key Questions.

Disease and cultural factors that might influence the effect of treatment for some ethnic groups

Disease	How might the prevalence of the disease vary between each ethnic group in the target population?	Response:
	How might the severity of the disease vary between each ethnic group?	Response:

Worksheet 2

This this worksheet provides some questions to guide your thinking about ethnic group involvement when answering Question 3 of the INCLUDE Key Questions.

Intervention and comparator factors that might affect how some groups engage with the intervention and/or comparator*

What	How might the intervention(s) and comparator limit participation of people from each ethnic group in the target population?	Response:
	How, and in what way, were people from each ethnic group involved in selecting or designing the trial intervention/comparator?	Response:
	Other factors to consider:	
Who	How might the person delivering the intervention/comparator limit participation of people from each ethnic group in the target population?	Response:
	Other factors to consider:	
How	How might the mode of delivery (e.g. telephone, video-call, face-to-face, in groups) limit participation of people from each of the ethnic groups in the target population?	Response:
	Other factors to consider:	
Where	How might where the intervention/comparator is delivered (e.g. hospital, general practice, local library) limit the participation of people from each ethnic group in the target population?	Response:
	Other factors to consider:	

Examples, guidance and videos



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Cultural	How might perceptions of the disease and social stigma around it be different for each ethnic group in the target population?	Response: SARS-CoV-2 is a new virus and it is not clear if there are different degrees of stigma among ethnic groups, or if stigma is different across ethnic groups. In Feb 2020 WHO updated the terminology used by some to describe the virus (e.g. 'Asian') and it is likely to stigmatise some Asian groups . Some UK politicians' remarks likely to stigmatise some ethnic groups.
	How might ways of describing the disease be different for each ethnic group?	Response: It is not clear if there are different ways of describing the disease across ethnic groups.
	How might cultural practices, beliefs and traditions influence the acceptability of, and adherence to, the treatment(s) for each ethnic group?	Response: All the trials are testing a vaccine that is already in use. These may come in capsule form, the capsule itself can contain animal products. religious beliefs may therefore prevent certain groups (e.g. Sikhs).

Appendix 1: Ethnic categories

As a team, we did a considerable amount of research around the way that data are categorised by ethnicity. We are aware that the language and terminology to do with characterising ethnic groups can be sensitive, due, in part, to the close tie-in to individual and group identity. We would welcome any feedback and suggestions that you may have at: info@trialforge.org

Both 'race' and 'ethnicity' are social constructs. Governments and institutions around the world tend to make use of one or both terms (or, when not in English, similar notions), for example, in census questions. The

Rough_Cut_BME.mp4



Examples



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RECOVERY
Randomised Evaluation of COVID-19 Therapy

 **PRINCIPLE**
Platform Randomised trial of INterventions
against COVID-19 In older peoPLE

Intervention

- What
- Who
- How
- Where
- When & how much

How might the intervention(s) and comparator limit participation of people from each ethnic group in the target population?

Response: All the interventions are drugs and the [content of medicine is a concern for Black, Pakistani and Arabic Muslims](#) (i.e. that the drug contains ingredients specifically designed to harm them in particular. Older people in most minority ethnic groups are more likely to believe that faith in God is needed more than medicine, a theme also recognised by younger members of those communities. Religious beliefs may prevent some groups (e.g. Sikhs) taking drug that include ingredients made from pigs; Hindus may have similar problems with ingredients derived from cows. Prednisolone and azithromycin tablets both contain magnesium stearate which may be of animal origin. Convalescent plasma is introduced as part of the main randomisation in part B – Jehovah's Witnesses will not accept blood products. Lopinavir-ritonavir is an HIV drug, and therefore issues could arise with association with HIV/AIDS in communities where these are still heavily stigmatised.

In summary, a lack of clarity about drug ingredients is likely to be a barrier to recruitment of many ethnic minority groups, especially older people who are those most likely to be affected by SARS-CoV-2.

Moving beyond ethnicity



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The TMRP Inclusivity Subgroup is now looking at Frameworks for:

1. People who have socio-economic disadvantages
2. People with cognitive disabilities.
3. People who are LGBTQIA+

Summary



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1. Many trials are not as diverse as they need to be.
2. INCLUDE and TMRP work can help.
3. Funders (NIHR especially) are taking this seriously.



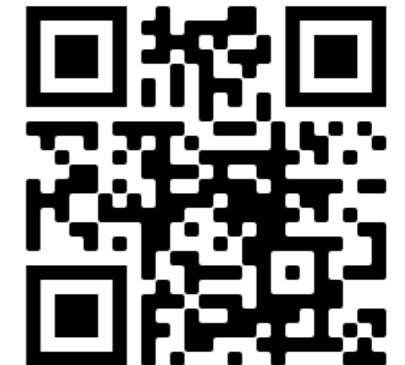
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