Which ethnic groups should be in the trial and at what proportion?

PANDA (depression) https://www.isrctn.com/ISRCTN84544741; https://doi.org/10.3310/pgfar07100

The panel noted:

- Broad inclusion of ethnic groups across the trial population (because all ethnic groups are susceptible to depression) was raised during the discussion.

The panel concluded:

- The panel did not reach a conclusion with regard to particular percentages for different ethnic groups.

Where a panel cannot reach a conclusion, STRIDE suggests adopting the following default inclusion position:

- The minimum target for **inclusion of the specified ethnic groups should be at the same proportion as is found among the population of people with the condition targeted by the trial.** The proportion is dependent on the intended reach of the applicability of trial results. A trial intending national reach should aim for national ethnic proportions by disease. A trial with more local reach could aim for proportions in its local area.

Where **disease data by ethnicity do not exist, or cannot be obtained,** STRIDE suggests adopting the following default inclusion position:

- The minimum target for **inclusion of the specified ethnic groups should be at the same proportion as is found in the most recent census data**. The proportion is dependent on the intended reach of the applicability of trial results. A trial intending national reach should use national census data. A trial with more local reach could aim for census proportions in its local area.

General comments from the panel:

1. Trial teams need to consider that the starting point of patients may differ by ethnicity. For example in some South Asian groups individuals are often using alternative remedies, herbal remedies for example. If these do not help then they will eventually seek medical help. If health professionals treat the person as though this is their first attempted treatment it is likely that the person will go away feeling they have been ignored. Their situation is already more advanced because they have already exhausted a range of alternative remedies. This is not their first presentation.
2. Trials teams need to be aware that mental health diagnoses are themselves stigmatised and contested, which compounds problems for individuals who also come from ethnic minority backgrounds.
3. Sertraline can be harder to come off and has some stigma around it particularly among younger people as a drug that has withdrawal problems if switching from it to something else. It is unclear whether this is also a perception held across ethnic groups.
4. Trial teams needs to consider how people view research. People from minority groups are more likely to think of research as them being experimented on and without their consent based in historical examples of exactly that and people have long memories.
5. Non-health issues (e.g. the UK's Windrush scandal) also influences health-care decision-making now. Why would minority groups want to help a system that is always using them?
6. Research is also seen as being very elitist also an issue the people of colour. Researchers themselves are often not very representative of society as a whole.

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General comments from the panel:

7. Researchers need to be open to all people and trials should be targeting x% from this group and y% from that group and stopped if they don't meet those targets. There needs to be a consequence for not working to improve the diversity of trials. While having targets linked to ethnicity in trials is likely to increase ethnic diversity in trials (which is needed) these targets may themselves come across to some individuals in ethnic minority groups as ethnic minority people being used again to further someone else's career, usually white researchers. This perspective is linked to direct experience by many ethnic minority individuals of insufficient effort being put into then ensuring that everyone that needs the treatment or an intervention can engage with it and receive that treatment or intervention.
8. Building trust and effective, honest communication about what greater ethnic diversity in a trial may mean for those communities once the trial is complete will be important. Simply saying to potential participants that the trial has targets may do as much harm to trust as it does good.
9. The conversation with an individual to discuss possible involvement in the trial needs to be open and explain exactly what will happen and what the potential benefits are. What will you get? What is the offer?

NB. Completed by Shaun Treweek, University of Aberdeen, based on a discussion with an external panel brought together for this purpose as part of the STRIDE project (https://www.abdn.ac.uk/hsru/what-we-do/research/projects/stride-supporting-recruitment-and-retention-improvements-for-diverse-ethnicities-283). None of us was involved in this trial, we did not discuss the information below with the trial team.

Given the above, the information below may not be a proper reflection of what the trial team itself may have considered the ethnic groups needed by their trial. The information is therefore intended to be illustrative, not definitive.