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

CLARITY (diabetic retinopathy) https://www.isrctn.com/ISRCTN32207582; https://www.journalslibrary.nihr.ac.uk/eme/eme05050#/abstract

The panel noted:

- The panel did not make specific comments regarding the ethnic groups needed by the trial.

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.

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General comments from the panel:

1. The trial targets both type 1 and type 2 diabetes. The distribution of participants across type 1 and type diabetes would need to be monitored to avoid one or other dominating in an unexpected way. The average age was 51, which perhaps suggests more type 2 than type 1.
2. The attention given to fertility in the eligibility criteria is likely to exclude many younger people and the implications of this for applicability need to be clear to the trial team.
3. The vision-related criterion suggests relatively mild vision impairment but perhaps this preferentially excludes some ethnic groups more because they present later and have greater problems by the time they present.
4. The trial team would need to carefully consider the language support that may be needed to ensure that members of the ethnic groups important to the trial can actually participate. This is particularly important because of the long list of exclusions linked to sexual issues. Consideration of both written translation and interpretation is needed.
5. The panel discussed payment/incentives and that these have an impact on behaviour in terms of engagement with the trial: £££ = 'I don't want to mess up their trial 'and FREE = 'I want to feel better'.
6. Younger people of all ethnicities, especially those under 18, are often excluded from diabetes trials. Whether exclusion is appropriate should be carefully considered by the trial team.
7. The panel recognised that interventions targeting people under the age of 18 may need to be different to those targeting older people and a single trial of both would therefore be inappropriate. Nevertheless, there was a belief that exclusion was often more related to a perceived difficulty with consent or ethical procedures rather than whether the intervention could benefit younger people.
8. Trial teams need to be aware that recruiting some groups may be easier than others and need to consider the possibility of trial spaces filling up before many from more diverse thence groups can join. Perhaps staged recruitment would be better to ensure that space remains for that diverse recruitment.

General comments from the panel:

9. The 'ability to give informed consent 'is open to prejudice. How is the judgement made and who are recruiters going to tell about the trial?
10. The design of trials needs to be made in light of the fact that some people will take additional treatments themselves. The trial should be transparent about other treatments, not something that can or can't be allowed. Need to find out what participants are also using as part of the trial research.

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.