

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

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V1 13/3/2023 Trial Forge

Trial: PROPELS

Type 2 diabetes

PROPELS (type 2 diabetes) <https://www.isrctn.com/ISRCTN83465245>;
<https://www.journalslibrary.nihr.ac.uk/hta/hta25770>

The panel noted:

- **South Asian, Black African and African Caribbean individuals** must be involved because the disproportionate Type 2 diabetes disease burden borne by them.

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. What is meant by South Asian needs to be defined by the trial team.
2. The increased prevalence and disease burden of type 2 diabetes is widely recognised for South Asians but other ethnic groups with increased burden such as Black African and African Caribbean should not be forgotten.
3. Interpretation of BMI by ethnicity is not straightforward. BMI thresholds vary by ethnicity and there are certainly different thresholds for South Asian participants. Using BMI as an eligibility criterion is best avoided for this reason.
4. In trials where ethnicity is considered likely to have an effect on outcomes, stratification by ethnicity should be considered.
5. 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.
6. 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.
7. 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 requires consideration of both written translation and interpretation.

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.