



TRIAL FORGE

STRIDE 

Supporting Recruitment & retention
Improvements for Diverse Ethnicities

Design considerations for including diverse ethnic groups in surgery trials

This document summarises findings from the INCLUDE Ethnicity Frameworks completed for the STRIDE project. The identified challenges have been organised into the five main Office for National Statistics ethnicity categories: White, Mixed/Multiple ethnic groups, Asian/Asian British, Black/African/Caribbean/Black British, and Other ethnic groups. The intention is to support trial teams working in cancer, cardiovascular diseases, diabetes, maternal and infant health, mental health, smoking cessation, COVID, surgery, and dental health. By consulting these summaries, teams can quickly see the key challenges they may need to consider when designing inclusive trials and enabling participation from people across diverse ethnic backgrounds. Where a challenge is relevant to more than one ethnic group, it appears under each applicable heading. The challenges span factors such as cultural beliefs, practical concerns, and aspects of trial design.

Mixed/Multiple ethnic groups

By Band Sleeve (bariatric surgery)	
Trial registration document	
INCLUDE Framework	
Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • There is some evidence that BMI cut-offs for categories of obesity should vary by ethnic group based on risk to future health. Generally this evidence finds that the BMI cut-off considered to represent obesity are lower for non-White groups than the 30 used for White individuals (The National Institute for Health and Care Excellence, 2013). • Risk of diabetes from obesity was higher in Black and Asian ethnic groups than in White, especially for women (NHS Digital, 2017). • Obesity can be seen as a symbol of affluence and success in some traditional, non-Western societies. • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support. This means that individuals from ethnic minority communities may present later than their white counterparts, which is likely to lead to increased complications and poorer health outcomes (NHS England, 2018). • The requirements for pre-operative programs can disadvantage some across all ethnic groups because of e.g. weight loss requirements, mandatory appointments and physical activity requirements (Taylor et al., 2019). • Ethnic minority patients report lower satisfaction and less positive experiences of care overall (Pinder et al., 2016). • All interventions need close follow up and more surgical procedures are not uncommon. Bands in particular need many visits to hospital for band adjustment (up to 7 in the first year from the protocol) and this may affect participation from some members of some the ethnic groups where transport and ability to leave work are problems. • The criterion 'Committed to follow-up' could, in principle, be used consciously or unconsciously to exclude some ethnic groups depending on how it is interpreted. It could, for example, be used as a proxy to exclude individuals where the next stage of the trial process, consent, is considered likely to be difficult for reasons of language, health literacy or other non-clinical reason. • If written material is a key part of the information provision for the trial this is likely to limit participation of individuals from any ethnic group with low literacy levels. If recruiting staff can speak the same language as the potential participant, this problem may be mitigated. Even with translation, older people from some ethnic groups do not read the language they speak.

Asian/Asian British

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Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • There is some evidence that BMI cut-offs for categories of obesity should vary by ethnic group based on risk to future health. Generally this evidence finds that the BMI cut-off considered to represent obesity are lower for non-White groups than the 30 used for White individuals (The National Institute for Health and Care Excellence, 2013). • Risk of diabetes from obesity was higher in Black and Asian ethnic groups than in White, especially for women (NHS Digital, 2017). • Obesity can be seen as a symbol of affluence and success in some traditional, non-Western societies. • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support. This means that individuals from ethnic minority communities may present later than their white counterparts, which is likely to lead to increased complications and poorer health outcomes (NHS England, 2018). • The requirements for pre-operative programs can disadvantage some across all ethnic groups because of e.g. weight loss requirements, mandatory appointments and physical activity requirements (Taylor et al., 2019). • Ethnic minority patients report lower satisfaction and less positive experiences of care overall (Pinder et al., 2016). • All interventions need close follow up and more surgical procedures are not uncommon. Bands in particular need many visits to hospital for band adjustment (up to 7 in the first year from the protocol) and this may affect participation from some members of some the ethnic groups where transport and ability to leave work are problems. • The criterion 'Committed to follow-up' could, in principle, be used consciously or unconsciously to exclude some ethnic groups depending on how it is interpreted. It could, for example, be used as a proxy to exclude individuals where the next stage of the trial process, consent, is considered likely to be difficult for reasons of language, health literacy or other non-clinical reason. • If written material is a key part of the information provision for the trial this is likely to limit participation of individuals from any ethnic group with low literacy levels. If recruiting staff can speak the same language as the potential participant, this problem may be mitigated. Even with translation, older people from some ethnic groups do not read the language they speak.
Only reported in Asian/Asian British participants	<ul style="list-style-type: none"> • In some Asian groups (e.g. Pakistani) older women may look to their husbands or other male family member for guidance; discussions about participation will need to explicitly consider this. • Written consent may limit participation of some groups (e.g. South Asians) who may prefer verbal discussion to written documents (NIHR, 2023). • Individuals in some ethnic groups (e.g. South Asian women) are more likely to want to involve family in decisions and this may limit their ability to take part if this cannot happen (Grewal et al., 2005).

Black/African/Caribbean/Black British

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Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • There is some evidence that BMI cut-offs for categories of obesity should vary by ethnic group based on risk to future health. Generally this evidence finds that the BMI cut-off considered to represent obesity are lower for non-White groups than the 30 used for White individuals (The National Institute for Health and Care Excellence, 2013). • Risk of diabetes from obesity was higher in Black and Asian ethnic groups than in White, especially for women (NHS Digital, 2017). • Obesity can be seen as a symbol of affluence and success in some traditional, non-Western societies. • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support. This means that individuals from ethnic minority communities may present later than their white counterparts, which is likely to lead to increased complications and poorer health outcomes (NHS England, 2018). • The requirements for pre-operative programs can disadvantage some across all ethnic groups because of e.g. weight loss requirements, mandatory appointments and physical activity requirements (Taylor et al., 2019). • Ethnic minority patients report lower satisfaction and less positive experiences of care overall (Pinder et al., 2016). • All interventions need close follow up and more surgical procedures are not uncommon. Bands in particular need many visits to hospital for band adjustment (up to 7 in the first year from the protocol) and this may affect participation from some members of some the ethnic groups where transport and ability to leave work are problems. • The criterion 'Committed to follow-up' could, in principle, be used consciously or unconsciously to exclude some ethnic groups depending on how it is interpreted. It could, for example, be used as a proxy to exclude individuals where the next stage of the trial process, consent, is considered likely to be difficult for reasons of language, health literacy or other non-clinical reason. • If written material is a key part of the information provision for the trial this is likely to limit participation of individuals from any ethnic group with low literacy levels. If recruiting staff can speak the same language as the potential participant, this problem may be mitigated. Even with translation, older people from some ethnic groups do not read the language they speak.
Only reported in Black/African/Caribbean/Black British participants	<ul style="list-style-type: none"> • Black women have less concern about being overweight but they recognise the health risk being overweight poses (Shoneye et al., 2011). • Weight gain after surgery appears higher in some ethnic groups than others (e.g. Black individuals), which may affect willingness to take part (Medicine, 2018). • Obesity may not reduced quality of life as much in African Americans than White individuals, meaning they are less likely to take up an offer of bariatric surgery (Newsweek, 2014).

Other ethnic groups

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Challenges	
Reported across several ethnic backgrounds	<ul style="list-style-type: none"> • There is some evidence that BMI cut-offs for categories of obesity should vary by ethnic group based on risk to future health. Generally this evidence finds that the BMI cut-off considered to represent obesity are lower for non-White groups than the 30 used for White individuals (The National Institute for Health and Care Excellence, 2013). • Risk of diabetes from obesity was higher in Black and Asian ethnic groups than in White, especially for women (NHS Digital, 2017). • Obesity can be seen as a symbol of affluence and success in some traditional, non-Western societies. • Health literacy is low among some ethnic groups, and this is a known barrier to seeking healthcare support. This means that individuals from ethnic minority communities may present later than their white counterparts, which is likely to lead to increased complications and poorer health outcomes (NHS England, 2018). • The requirements for pre-operative programs can disadvantage some across all ethnic groups because of e.g. weight loss requirements, mandatory appointments and physical activity requirements (Taylor et al., 2019). • Ethnic minority patients report lower satisfaction and less positive experiences of care overall (Pinder et al., 2016). • All interventions need close follow up and more surgical procedures are not uncommon. Bands in particular need many visits to hospital for band adjustment (up to 7 in the first year from the protocol) and this may affect participation from some members of some the ethnic groups where transport and ability to leave work are problems. • The criterion 'Committed to follow-up' could, in principle, be used consciously or unconsciously to exclude some ethnic groups depending on how it is interpreted. It could, for example, be used as a proxy to exclude individuals where the next stage of the trial process, consent, is considered likely to be difficult for reasons of language, health literacy or other non-clinical reason. • If written material is a key part of the information provision for the trial this is likely to limit participation of individuals from any ethnic group with low literacy levels. If recruiting staff can speak the same language as the potential participant, this problem may be mitigated. Even with translation, older people from some ethnic groups do not read the language they speak.

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