Ethnic minority representation in trial of cardiometabolic disease

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Disclosures

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Impact of underrepresentation of ethnic minority groups in research

Health difference across ethnicity may reflect different disease pathologies and response to treatments (Hussain-Gambles et al., 2004; Nazha et al., 2019).

Differences in effective doses of treatments: lower doses of Warfarin are required to be effective in Asian patients (3.4mg) compared to white (5.1mg) patients.

Culture and behavioral norms can shape patients' experience of navigating a complex healthcare system. Patients from an Asian background were among the least satisfied with aspect of care (Race Disparity Audit, 2019).

Implications: National evidence based guidelines may confer greater benefits to particular communities, particularly those who have helped shape the underpinning research.
Prevalence of T2 diabetes higher in ethnic minority groups

- Prevalence of type 2 diabetes is approximately three to five times higher among ethnic minority groups than the White British group
- Diabetes diagnosed 10-12 years earlier in ethnic minority groups

HSE 2004
Paul S et al. Diab Obes Metab 2017;19:1014-1023
Differences in the risk of cardiovascular disease across ethnic groups: UK Biobank observational study

- 502,539 participants from UK Biobank.
- Three-point major adverse cardiovascular events (3P-MACE) as outcome.
- Higher CVD risk in South Asian individuals was independent of all sociodemographic, lifestyle, environmental and clinical factors.
- Black individuals generally had similar or lower CVD risk compared to white Europeans.

Razieh et al., (2022) Nutr Metab Cardiovasc Dis
Ethnic minority representation in diabetes trials

Twenty-year trends in racial and ethnic enrolment in large diabetes randomized controlled trials
405 RCTs included for analysis
Increase in trends ethnic minority enrolment for diabetes RCTs

BIPOC = Black, Indigenous, and People of Colour

Exploring ethnic representativeness in diabetes clinical trial enrolment from 2000 to 2020: a chronological survey

• 405 trials

• 78 single-country trials (69 in the USA and nine in the UK) and 327 multi-country trials.

• Non-white enrolment under-represented in majority of trials:
  • US Trials 29.0%
  • UK Trials 12%

• Temporal trends of increase in non-white participation-no significant trends in US or UK trials

• Non-white groups under-enrolled in US (62.3%) and UK (77.8%) Trials

• 6.4% of all trials provided subgroup results or explored effect modification by ethnicity.

Li et al. Diabetologia 2022;65:1461-1472
Inclusion of Under-Represented Racial and Ethnic Groups in Cardiovascular Clinical Trials

- 153 RCTs with 1,138,683 patients were included (1986-2019)
- Only 56% reported race/ethnicity. (99% reported sex)
- Average % of Non-White ethnicity was 20% and did not change from 1986 to 2019.
- “These trials would ‘under-represent’ the Non-White population in many diverse countries such as the USA”

Vilcant et al. Heart, Lung & Circulation 2022;31:1263-1268
Hispanic representation in diabetes cardiovascular outcomes trials (CVOTs)

- 10 of 13 CVOTs with primary study results published January 2008 to October 2018.
- Compared Hispanic/Latino representation to Hispanic adults with diabetes in NHANES.
- Hispanics/Latinos comprised 18.5% of trial subjects, which was similar to the proportion of US adults with diabetes who identify as Hispanic (18.2% in 2015).
- BUT Trial participants were younger, more likely to be female, and more obese than US Hispanics/Latinos.
- US Hispanics/Latinos differ from participants in diabetes CVOTs, limiting generalisability of trial findings.

Kelley et al. BMJ Open DR&C 2019;7:e000656
Representation of people of South Asian origin in cardiovascular outcome trials of glucose-lowering therapies in Type 2 diabetes

• 12 studies included.

• Among the 8 for which South Asian representation could be reliably estimated, 7 under-represented this group relative to the 11.2% of the UK diabetes population estimated to be South Asian.

• “Clinicians should exercise caution when generalizing the results of trials to their own practice”.

Khunti et al., (2016) Diabetic Medicine
A Roadmap for Increasing Enrollment of Underrepresented Populations in Heart Failure Clinical Trials

- **Patient level**
  - Patient advocates and advisory boards
  - Culturally sensitive approaches

- **Community level**
  - Engagement in community settings such as churches and barbershops

- **Sponsor and investigator level**
  - Deliberate site selection
  - Broad inclusion criteria
  - Diverse site PIs and research staff
  - Research staff able to engage participants in multiple languages

- **Federal and regulatory level**
  - Changing research paradigm and incentive structure

DeFillippis JAMA Cardiol 2022;7:540-548
Promoting inclusion in clinical trials

Opportunities to improve inclusion

- Cultural humility and competency training
- Building community partnerships
- Taking a personalised approach
- Multilingual materials and staff
- Communication specific strategies
- Increasing understanding and trust
- Tackling logistical barriers

Bodicoat et al. Trials 2021;22:880
Capacity Building - Training programmes

"I did learn new terminology and develop a greater understanding. I thought the self-awareness aspect was interesting"

"The course offered many eye-opening moments and clearly demonstrated the need for cultural competence being embedded in organisations, healthcare and research"

https://ethnichealthresearch.org.uk/
Equality Impact Assessment Toolkit

- A process designed to improve equality analysis, practice and outcomes
- Toolkit has now been developed consisting of:
  - comprehensive training
  - a directory of useful resources
  - ongoing advice and guidance through webinars

https://ethnichealthresearch.org.uk/
Summary

- Much scope for improvement in ethnic minority recruitment
- Better monitoring of participation
  - Improve the recording and reporting of participation
  - Encourage proportionate representation across protected characteristics
- Further development and evaluation of strategies to increase participation
- Increased investment is needed
  - Highlighting the benefit of delivering more inclusive research
  - Capacity building for researchers/research teams
Thank you

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