Do Health Technology Assessments (HTA) consider racial health inequalities? A case study of NICE HTAs for chronic kidney disease, hypertension and diabetes

Steady J D Chasimpha, Henry Swales, Rhiannon Green, Anne L Wilson

Maverex Limited, Newcastle upon Tyne, UK

HPR61

01 BACKGROUND

- Heath technology assessments (HTA) rely primarily on evidence from clinical trials to inform the clinical and cost-effectiveness of new technologies.
- Clinical trials may not always have appropriate representation of diverse racial and ethnic groups nor address important treatment variations that may exist in certain subpopulations for conditions in which racial and ethnic differences are well established[1,2].
- Lack of patient diversity in clinical trials has implications on generalisability of results to the target population[3].
- HTAs are increasingly being considered as a tool to address health inequalities by evaluating the impact of new technologies on different population groups, including use of real-world evidence (RWE).
- Chronic kidney disease (CKD), CKD-related complications, hypertension and diabetes have a high intertwined burden on the NHS and well-documented racial/ethnic inequalities in prevalence, progression and mortality[4].
- However, it is unclear to what extent HTAs for CKD, hypertension and diabetes consider racial and ethnic inequalities.

02 OBJECTIVE

- We assessed the extent to which pivotal trials and RWE used in HTAs for CKD (and related complications), hypertension and diabetes include racially diverse populations, and whether HTAs explicitly consider the health inequality impacts of guidance on racially diverse populations.

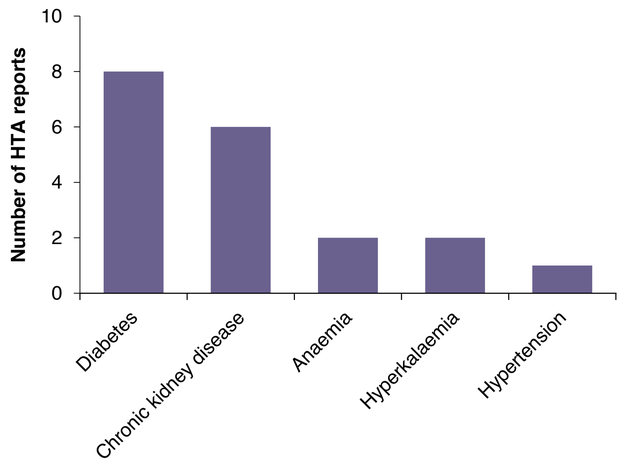
03 METHODS

- We conducted a targeted review of the National Institute for Health and Care Excellence (NICE) website to identify published HTA documentation for CKD and related complications (e.g. anaemia and hyperkalaemia), hypertension and diabetes for the period between 1 January 2010 and 31 May 2025.
- Data were extracted on:
  - racial composition of pivotal trials and whether subgroup analyses were performed
  - conduct of RWD studies and racial composition of RWD studies
  - whether race was raised as an equality issue at scoping stage or committee/guidance development stage in the NICE Equality Impact Assessment (EIA), and during consultation.

04 RESULTS

- A total of 19 HTA reports* were identified covering CKD (n=6), hypertension (n=1), diabetes (n=8), anaemia (n=2), and hyperkalaemia (n=2). The HTAs included total of 46 pivotal clinical trials. Of these, race was reported in 57% (n=26) of the trials with 52% (n=24) of trials reporting granular racial data in the HTA.

Figure 1. Number of HTA reports by disease area (n=19)



- Overall (N=34,161), 68.5% of the trial participants were white compared with 20.2% Asian, 7.4% Black or African American, and 3.9% mixed or other races.
- For CKD (n=13,219), 60.4% of trial participants were white, 31.3% Asian, 4.5% Black or African American, and 3.8% mixed or other races.
- Among diabetes trial participants (n=8,551), 71.1% were white, 17.2% Asian, 4.3% Black or African American, and 7.3% mixed or other races.
- Subgroup analyses by race were reported in HTAs for only 30% (n=14) of the trials.
- Only 3 HTA reports (2 Diabetes and 1 Hyperkalaemia) included RWE studies, and 1 report described the race of the participants.
- 79% (n=15) of the HTA reports included an EIA at Scoping stage; 63% (n=12) of HTA reports included an EIA at committee/guidance development stage; and 53% (n=10) of HTA reports included both documents.
- 42% (n=8) and 37% (n=7) of HTAs raised race/ethnicity as an equality issue in the EIA at scoping and committee/guidance development stage, respectively.
- Consultees raised race/ethnicity equality concerns in 53% (n=10) of HTAs, with comments relating to the trial patient composition, racial/ethnic groups having a higher prevalence of condition, poorer outcomes, and issues with current standard of care.

Trial patient composition

> "I have concern in the recruitment of patients from these studies (most in the US) will be from groups with medical coverage, motivated and white Caucasian populations. Hence their baseline type 1 diabetes management is likely to be good."
>
> HTA807

Higher prevalence of condition

> "Kidney disease disproportionally impacts people from deprived communities and ethnic minority groups."
>
> HTA1035

Issues with current standard of care that can be overcome with new technology

> "Current treatment of sub-cutaneous erythropoietin requires the patient to have a fridge, be willing and accepting of a home treatment and have the confidence and support to administer their own treatment - in my experience this is more challenging in patients on low incomes, those where English is not their first language and if they are elderly, live alone and have dexterity problems. A tablet form would aid treatment for these groups."
>
> HTA807

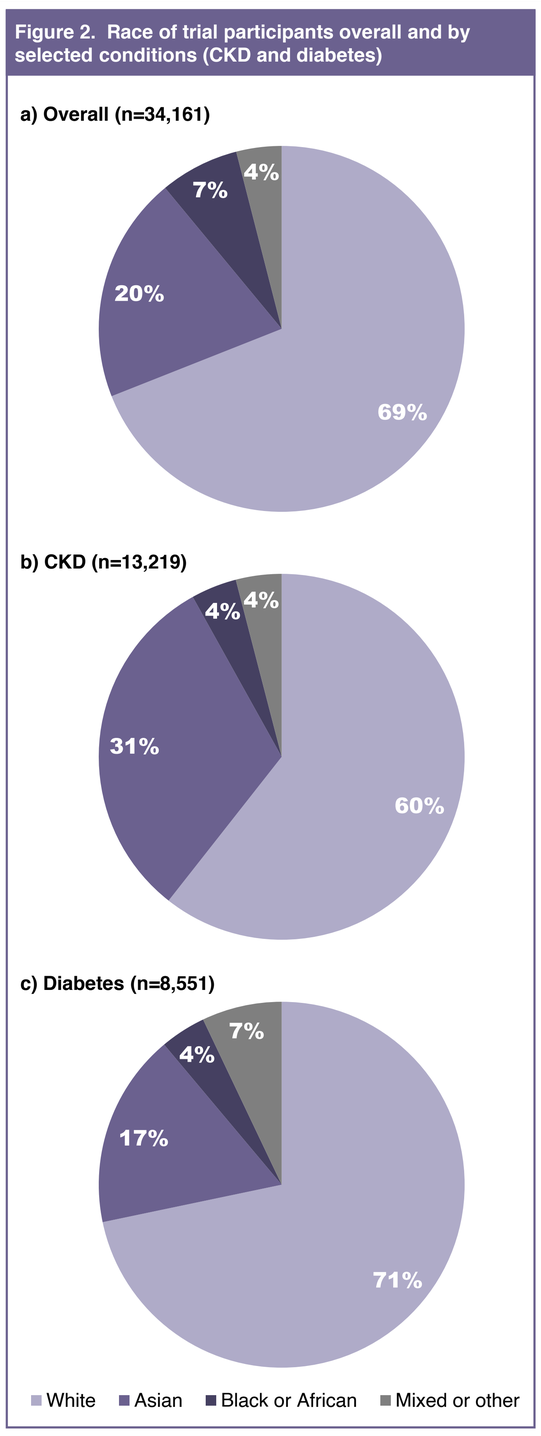
Poorer outcomes

> "People from BAME communities are more likely to progress faster towards kidney failure and less likely to receive a kidney transplant."
>
> HTA809

Access/uptake of new interventions

> "Insulin pump usage is significantly lower in the black community. If no action is taken to understand why and respond to it, there is a risk this trend would continue through to hybrid closed loop usage."
>
> HTA943

Figure 2. Race of trial participants overall and by selected conditions (CKD and diabetes)



05 DISCUSSION AND CONCLUSIONS

- **NICE conducts HTAs with due regard to equality, systematically assessing impacts on protected characteristics such as race/ethnicity and ensuring recommendations do not marginalise any group[5].**
- **This study highlights significant representation of racial minorities in clinical trials used in HTAs for CKD (and related complications), hypertension and diabetes largely in line with the racial composition of CKD and diabetes patients in the UK[6,7].**
- **Whilst acknowledging differential disease prevalence and outcomes, and access to technologies by race/ethnicity, most appraisal committees did not consider these equality considerations relevant to the appraisals.**
- **Strengthening incorporation and reporting of diverse populations and integrating RWE are critical steps for equitable health technology evaluation.**

Abbreviations

BAME – Black, Asian and Minority Ethnic; CKD - chronic kidney disease; EIA – Equality Impact Assessment; HTA - health technology assessment; NICE - National Institute for Health and Care Excellence; NHS - National Health Service; RWE - real-world evidence; US – United States

References

1. Chatters, R. *et al.* (2024) Exploring the barriers to, and importance of, participant diversity in early-phase clinical trials: an interview-based qualitative study of professionals and patient and public representatives. *BMJ Open* doi:10.1136/bmjopen-2023-075547; 2. Camidge, D. R. *et al.* (2021) Race and Ethnicity Representation in Clinical Trials: Findings from a Literature Review of Phase I Oncology Trials. *Future Oncology* https://doi.org/10.2217/fon-2020-1262; 3. Wallace, N. *et al.* (2023) Underrecording and underreporting of participant ethnicity in clinical trials is persistent and is a threat to inclusivity and generalizability. *Journal of Clinical Epidemiology* **162**, 81–89 4.; Mathur, R. *et al.* (2018) Ethnic differences in the progression of chronic kidney disease and risk of death in a UK diabetic population: an observational cohort study. *BMJ Open* **8**, e020145; 5. Evidence on health inequalities | Tools and resources | NICE health technology evaluations: the manual | Guidance | NICE. https://www.nice.org.uk/process/pmg36/resources/support-document-health-inequalities-15313210669/chapter/evidence-on-health-inequalities (2022); 6. Diabetes. *NHS England Digital* https://digital.nhs.uk/data-and-information/publications/ statistical/ health-survey-england-additional-analyses/ethnicity-and-health-2011-2019-experimental-statistics/diabetes; 7. 27th Annual Report - data to 31/12/2023. *UK Kidney Association* https://www.ukkidney.org/audit-research/annual-report/27th-annual-report-data-31122023.

*Included HTA reports

TA1035, TA942, TA809, TA807, TA775, TA1009, TA943, TA924, TA877, TA622, TA583, TA572, TA418, TA390, TA599, TA623, TA358, TA937, TA448.

maverex