THE INTERSECTION OF RWE, HEALTH EQUITY, AND HTA: A STRUCTURED LITERATURE REVIEW OF HEALTH POLICY AND METHODOLOGICAL GUIDANCE

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INTRODUCTION & OBJECTIVE

HTA/HEOR has a key role in reducing inequity in healthcare between populations and social groups

RWE is a key source of information to feed into HTA/HEOR

Understanding health inequities in real-world populations is dependent on RWE

The objective of this literature review was to identify and assess the interplay between RWE, health equity, and HTA/HEOR, for the promotion of equitable access to healthcare and improved patient outcomes.

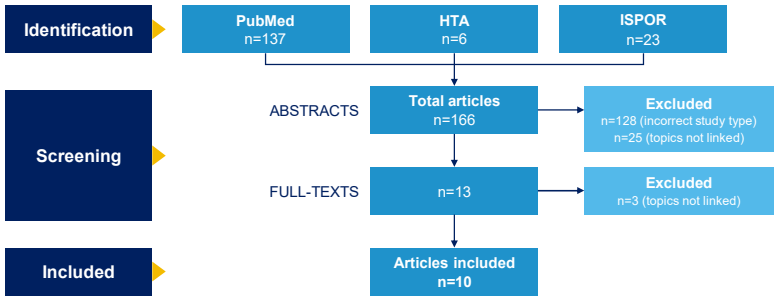
METHOD

- Search terms for health equity/inequity, RWE and HTA/HEOR were used to search PubMed and the ISPOR Presentations Database on 3rd June 2025, with no date or language restrictions.
- Methodological guides for French, German, Italian, Spanish, and UK HTA were also retrieved from agency websites.
- Articles were assessed according to pre-defined inclusion criteria:
  1. Policy document, methodological guidance, or systematic literature review;
  2. Discussing the combined topics of HTA/HEOR, health equity and RWE.

RESULTS

LITERATURE REVIEW

- Nine published articles plus the NICE HTA manual health inequalities update were relevant for inclusion.[1-10]
- NICE is the only HTA agency of the scope countries which provides guidance on how RWE can be used to provide data on health inequalities for inclusion in HTA evaluations.[7]
- Other HTA agencies consider RWE and/or health equity in decision-making; however, the concepts are not linked in current methodological guidance.



KEY THEMES

1 RWD is an important source of evidence for identifying and assessing populations with health inequities in HTA

- RWD can provide evidence on health inequities across social demographics for special consideration in HEOR/HTA.[4,8] Methodological efforts are ongoing to provide robust data sets, for example:
  - Identification of data gaps in electronic health records to inform future improvements in data quality.[6]
  - Integration of enhanced individual-level demographic data into administrative claims databases.[10]
  - Linkages of large payer claims databases to cancer registries.[2]
  - Bayesian Improved Surname Geocoding (BISG) methodology to improve race/ethnicity completeness in oncology RWE.[3]
- Other uses for RWE in addressing inequity in access to health technologies may include monitoring RWE on inequities post-launch, alongside other data on clinical effectiveness and long-term safety.[8]

2 RWE sources have a number of limitations; there is a need for best practice guidance on how to integrate RWE, health equity and HTA

- Example barriers to optimal use of RWE in HTA and improvement of health equity:
  - Limited availability of longitudinal/population level data.[4,8]
  - Electronic health records or claims data lacking information on social determinants of health.[4]
  - Vulnerable groups excluded from claims datasets (e.g., uninsured).[4]
- Examples of best practice:
  - Development of guidance to inform the selection of optimal real-world data sources, and documentation of the strengths/limitations of RWE for exploring health equity research questions.[4]
  - Alignment of key stakeholders around the definition of equity-relevant variables and populations of interest, to support efficient prioritisation of data collection and enrichment.[4]
  - Investment in data generation/analyses (RWE) to understand differences in outcomes/risks between populations.[1]

3 Measures and methodologies such as QALE and DCEA can use RWE to incorporate health equity analysis into HTA

- For NICE to consider health inequalities due to disease severity in economic evaluations, QALY shortfall can be calculated and applied as a decision modifier, to assign a higher QALY weighting for more severe conditions.[7]
  - QALY shortfall can be calculated based on the difference in the QALE (measure of life expectancy and HRQoL) of a person with and without a particular disease at a given age.
  - QALE requires real-world public heath data on epidemiology and quality of life.[5]
- DCEA is used in economic evaluations to synthesise evidence on health inequalities across social groups.[7]
  - Manufacturers submitting to NICE may use DCEA to show the potential impact of a new technology on health inequality, where there is evidence of a significant burden of health inequalities in the eligible population.
  - RWE provides the source of health inequalities data.

4 RWE is particularly important to address health inequities in rare diseases, including HTA assessments of cell and gene therapies

- Health inequities due to social determinants of health can be significantly compounded for people with rare diseases due to additional barriers to diagnosis, treatment, and support.[4,9]
- The cost of cell and gene therapies, often indicated for treatment of rare diseases, can affect patient access, further impacting health equity in these populations.[9]
- The incorporation of RWE into HTA assessment of these novel therapies, and the continued evolution of HEOR methodologies to improve access for patients with rare diseases is essential.[9]

CONCLUSIONS

- The use of RWE and the incorporation of health equity considerations into HTA is an evolving area.
- Increasing acceptance of RWE by HTA agencies provides more evidence to decision makers to make informed decisions, which in turn can aid health equity.
- Harmonisation of evidence requirements across HTA agencies is a key consideration to ensure equitable access to healthcare.

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ABBREVIATIONS

DCEA, distributional cost-effectiveness analysis;
HEOR, health economics and outcomes research;
HTA, health technology assessment;
ISPOR, the professional society for health economics and outcomes research;
NICE, National Institute for Health and Care Excellence;
QALE, quality-adjusted life expectancy;
QALY, quality-adjusted life year;
RWD, real-world data;
RWE, real-world evidence;
UK, United Kingdom.

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