Exploring The Role Of Patient Experience Data And Patient Involvement In HTA

HTA141

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OBJECTIVES

- This study aims to provide an overview of the use of patient experience data (PED) in health technology assessment (HTA), the role of patient representatives in HTA appraisals, and current opinions on the role PED should have in HTA

METHODS

- A targeted literature review was conducted in Embase to identify research exploring the use of PED in HTA and patient inclusion in appraisals
  - Inclusion criteria
    - Population of interest: No age limit
    - Outcomes of interest: i) How PED is currently used in assessments and guidelines?; ii) How PED should be used in the assessments and guidelines?; iii) How patients are included in appraisals?; iv) How patients should be included in appraisals?
    - Studies of interest: Methodological papers/studies, systematic reviews, opinion pieces, editorials, guideline documents, discussion papers
  - Exclusion criteria: Literature not including an outcome of interest
  - Limits: English only, All countries, 2008-Onwards
- HTA guidelines in Europe were also evaluated to explore the role of PED

RESULTS

- A total of 1008 articles were identified throughout the targeted literature review; In total, 41 articles met the inclusion criteria (Figure 1).
- A total of 6 HTA guidelines from German (IQWiG), France (HAS), England (NICE), Italy (AIFA), Spain (RevalMed-SNS) and European Union (EUnetHTA) were reviewed (Table 1).
  - In Germany, patient-reported outcomes (PRO) data has a key role in driving benefit assessment based on morbidity and health-related quality of life (HR-QoL).
  - In France, PRO has a limited role in HTA assessments due to frequent rejection of PRO data owing to stringent evaluation methodology
- How PED is currently used in assessments and guidelines and how PED should be used in the assessments and guidelines:
  - Guidelines are mostly lacking regarding the use of PED in HTA dossiers and regarding how PED should be used in decision-making
  - In several articles, authors call for guidelines and increased use of PED in HTA to improve decision-making and stimulate patient-centered healthcare
- How patients are included in appraisals and how patients should be included in appraisals:
  - Current HTA systems lack resources to fully engage patients in decision making; in many countries, it is common to include patient representatives in the appraisal process.
  - Payers consider PRO evidence in their decisions, but such evidence is usually considered complementary to clinical and safety endpoints. Besides QoL data for utility assessment, PED data seems to have a very limited formal role in HTA decision-making
  - To perform the appraisal process, PED should be used alongside expert value judgement
  - HTA assessments should be more patient centric by encouraging patient participation in HTA processes, incorporating patient reported measures in the development of 'value frameworks' & incorporating patient preferences in assessments of health technologies

CONCLUSIONS

- **There is a common perception in the literature that PED deserves a more prominent place in HTA and that patients should be seen as partners in appraisals. However, in most countries it appears that HTA bodies struggle with how to include PED in the HTA process, given the lack of clear direction in available HTA guidelines. This lack of direction likely impacts the PED inclusion in HTA submissions.**
- **More research and guidance on PED inclusion and patient involvement in the HTA decision-making framework can stimulate patient centricity in HTA**

Figure 1. Literature Review – PRISMA Flow Diagram

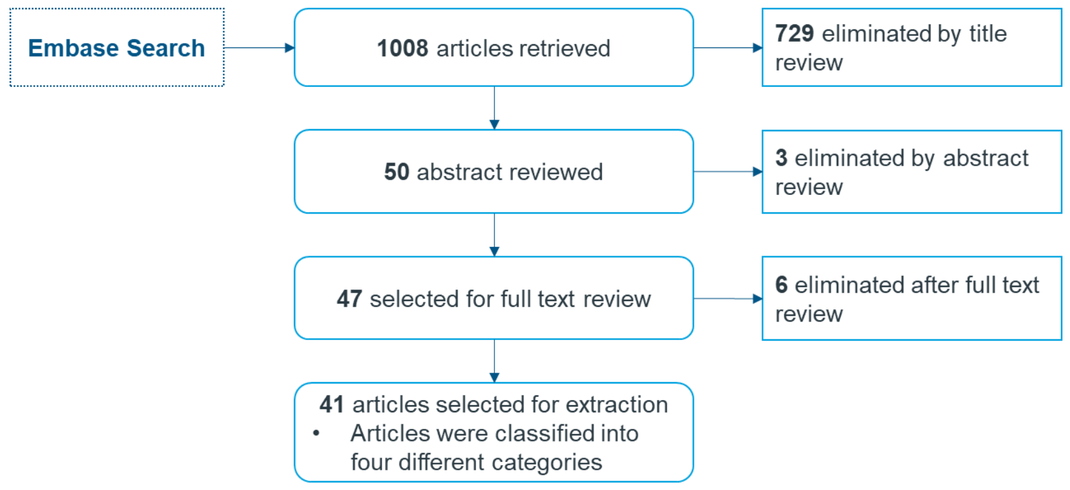

Table 1. PED used in HTA guidelines

HTA Body Country	Content
IQWiG Germany	Detailed guidance on the relationship between PED and benefit of a new drug; the G-BA (federal joint committee) then uses this assessment as a basis for its conclusion without offering specific frameworks on how the assessment is conducted
HAS France	It notes the impact of QoL benefit on ASMR*. QoL data is discriminatory in the transparency committee evaluations if the findings are based on a rigorous methodology: objective and clinical relevance threshold pre-specified in the protocol, double-blind conditions, management of multiplicity of the analyses, appropriate analysis frequency, time and duration, few missing data
NICE England	It's technology appraisal guidance indicates that QoL data are needed to inform utility in the economic analysis. PRO has a key role in deriving utility values for cost–effectiveness analysis using EQ-5D-3L value set
AIFA Italy	Issued guideline for the compilation of the dossier to support the request for reimbursement and pricing. It set out new criteria for the price negotiation procedure between the AIFA and the marketing authorization holder to establish the price for a medicine to be reimbursed by the National Health Service. This document did not discuss PED and only references UK's approach. Inclusion of PRO data in payer decision-making is currently determined on a case-by-case basis
REvalMed-SNS Spain	It does not provide guidance on how collection of types of PED will be implemented
EUnetHTA European Union	Issued recommendations on HRQoL data collection noting that objective measures are insufficient to fully demonstrate the relative benefit of a medicinal product

*ASMR is a scale used in France to rank each drug compared to existing treatment

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