PCR113

Embedded Qualitative Interviews – Guidance and Practice by Major HTA Bodies

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BACKGROUND

- Health technology assessment (HTA) bodies increasingly recognize the importance of incorporating the patient experience into decision-making[1]
- Embedded qualitative interviews can provide in-depth insights into treatment impact and patient experience not captured by quantitative measures
- The use of qualitative research in HTA, particularly from clinical trials, is not consistently defined across HTA guidances[2]
- Understanding how qualitative evidence is guided and applied in HTA is important to support more consistent, patient-centered decision-making

OBJECTIVE

To examine how HTA methods guidance incorporates qualitative research on patient experience within clinical trials and assessed whether such guidance is reflected in the use of qualitative evidence in recent HTA assessments

METHODS

Part 1 – Review HTA Methodologies

Objective:

Identify how HTA bodies incorporate and recommend the use of qualitative patient experience data in methodological guidance.

Approach:

A targeted review of the most recent publicly available methodological guidance (as of December 2025) was conducted across major HTA agencies.

References to qualitative research and patient experience data were identified, along with any recommendations for their inclusion in submissions.

HTA Bodies Reviewed:

North America:

- Institute for Clinical and Economic Review (ICER; U.S.)
- Canada's Drug Agency (CDA) / Agence des médicaments du Canada (AMC) (Canada)
- Institut national d'excellence en santé et en services sociaux (INESSS; Canada)

Europe:

- National Institute for Health and Care Excellence (NICE; England and Wales)
- Danish Medicines Council (Medicinrådet; Denmark)
- Scottish Medicines Consortium (SMC; Scotland)
- Norwegian Medicines Agency (NoMA; Norway)
- Federal Joint Committee (G-BA; Germany)
- Haute Autorité de Santé (HAS; France)
- Institute for Quality and Efficiency in Health Care (IQWiG; Germany)
- Zorginstituut Nederland (ZiN; Netherlands)
- Swedish Dental and Pharmaceutical Benefits Agency (TLV; Sweden)
- Agenzia Italiana del Farmaco (AIFA; Italy)

AsiaPacific:

- Pharmaceutical Benefits Advisory Committee (PBAC; Australia)
- Ministry of Health, Labour and Welfare of Japan (MHLW; Japan)

Part 2 – Review Applications by HTA Bodies

Objective:

Evaluate how qualitative patient interview data is incorporated in HTA submissions and reflected in final HTA assessments

Approach:

Identify HTA agencies from Part 1 whose methodological guidance explicitly references the use of qualitative patient experience data

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Conduct a targeted literature search to identify drugs with published in-trial qualitative patient interview data (2023-2025)

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For identified drugs, retrieve corresponding HTA assessments from selected HTA bodies

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Review HTA documents and sponsor submissions (where available) to evaluate whether qualitative interview data was included

RESULTS

Part 1 – HTA Guidances Mention of Qualitative Research

Among the 15 HTA bodies, 3 agencies (NICE[3] , CDA/AMA[4] , IQWiG[5]) incorporated PQS and/or AQS in their assessments (Figure 1)

Explicit Qualitative Methods Referenced (n=3)

Three HTA bodies (NICE[3] , CDA/AMA[4] , IQWiG[5])	explicitly describe qualitative research as a method that can be used in HTA
NICE[3]	outlines how qualitative evidence can inform patient experience, treatment acceptability, and equity considerations.
CADTH–CDA/AMC[4]	describes how qualitative studies can capture patient perspectives and preferences and can be formally analyzed and synthesized.
IQWiG[5]	provides a clear description of qualitative methods, including interviews and focus groups, and how they can complement quantitative data.

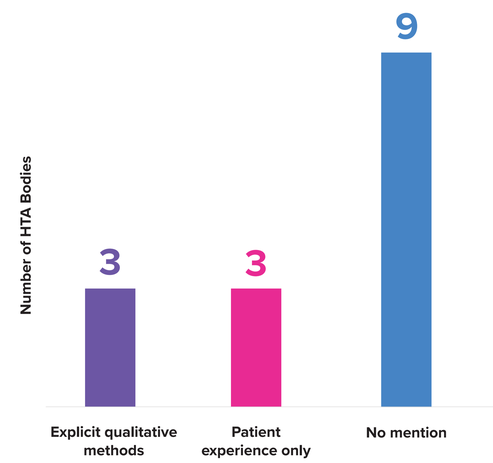
Explicit Qualitative Methods Referenced (n=3)

Three HTA bodies (SMC[6], INESSS[7], Medicinrådet[8])	recognize patient experience as important for decision-making but do not provide specific guidance on qualitative research methods

No mention (n=9)

Nine HTA bodies (ICER[9], GBA[10], TLV[11], NoMA[12], HAS[13], ZiN[14], AIFA[15], PBAC[16], MHLW[17])	did not explicitly reference qualitative research or provide guidance on its use within their HTA guidances

Figure 1. Recognition of Qualitative Research in HTA Guidances



Part 2 – Use of In-Trial Qualitative Interviews in HTA Assessments

Across NICE, CADTH–CDA/AMC, and IQWiG, only 1 of 5 submissions included in-trial qualitative interview evidence (NICE: efanesoctocog alfa).

Evidence was presented within a separate Summary of Information for Patients (SIP) a plain language document developed by the sponsoring company as part of the NICE submission to support patient engagement.

Within the patient-based evidence (PBE) section, the sponsor summarized both published and newly collected qualitative insights on living with hemophilia A, including findings from semistructured qualitative interviews conducted with patients in the XTEND-1 study.

Drug	Therapeutic area	Qualitative evidence included in HTA submission
Mirikizumab	Crohn's disease	No
Idecabtagene vicleucel	Multiple myeloma	No
Efanesoctocog alfa	Hemophilia A	Yes, included as a separate document (SIP) submitted by the sponsoring company as part of the NICE submission.
Tirzepatide	Weight loss	No
Vimseltinib	Tenosynovial giant cell tumor (TGCT)	No

CONCLUSION

Use of qualitative research in HTA remains limited and inconsistent across agencies.

Only a minority of HTA bodies explicitly reference qualitative methods, with most either focusing on patient experience broadly or not mentioning it at all.

Even when included (e.g., NICE), qualitative evidence is often embedded in supplementary documents rather than systematically integrated into core assessments.

Develop clearer, standardized HTA guidance on the role, evaluation, and use of qualitative evidence to better inform decision-making.

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ABBREVIATIONS

AIFA, Agenzia Italiana del Farmaco; AMC, Agency for Healthcare Research and Quality; CDA/AMA, Canadian Drug Agency/Agence des médicaments; HTA, Health Technology Assessment; ICER, Institute for Clinical and Economic Review; IQWiG, Institute for Quality and Efficiency in Health Care; INNESS, Institut national d'excellence en santé et en services sociaux; MHLW, Ministry of Health, Labour and Welfare; NICE, National Institute for Health and Care Excellence; NOMA, Norwegian Medicines Agency; PBAC, Pharmaceutical Benefits Advisory Committee; PBE, Patient-Based Evidence; PQS, Patient Qualitative Studies; SIP, Summary of Information for Patients; SMC, Scottish Medicines Consortium; TLV, Tandvårds- och läkemedelsförmånsverket; XTEND-1, Extension Study 1.

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