Structured Expert Elicitation in Global HTAs: Acceptance and Application

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Background and objectives

In health technology assessment (HTA), evidence regarding the parameters used in economic evaluation, such as long-term outcomes, target population, or transition probabilities, is often limited, uncertain, or entirely unavailable (1,2).

Structured expert elicitation (SEE) provides a formal, systematic, and transparent approach for obtaining informed judgments from subject-matter experts on these uncertain quantities, translating their knowledge into probability distributions suitable for use in healthcare decision making (2,3).

As a result, SEE has been increasingly recognized by HTA bodies as a method for addressing gaps in empirical evidence, by improving the transparency of model assumptions, and mitigating biases and lack of robustness associated with consultation from experts.

Despite growing recognition, the use of SEE in HTA submissions remains inconsistent, partly due to uncertainty around its acceptability, methodological expectations, and the practical guidance available to applicants.

In 2024, ISPOR published best practice guidelines and recommendations to support the appropriate design and implementation of SEE protocols within HTA (3).

This research aimed to evaluate how SEE is currently perceived and accepted across different HTA bodies, and to explore how SEE methods are applied, including how SEE is used to gather insights to support HTA submission.

Methods

Analysis of the literature was performed to explore: 1) acceptability of SEE method use in HTA evaluations and 2) explicit guidance set by HTA authorities, with a specific focus on the following eight markets: England, Germany, France, Australia, Brazil, Japan, Canada, and the USA.

To ensure a focus on healthcare decision making, searches used the MEDLINE® database, accessed via PubMed®, and an algorithm designed using broad keywords for "expert elicitation" for publication retrieval. The search was adapted according to each market of interest and was limited to the last 3 years and English language publications (Table 1). Publications retrieved were included on their use of SEE methods, with exclusions applied to methodological papers (Figure 1).

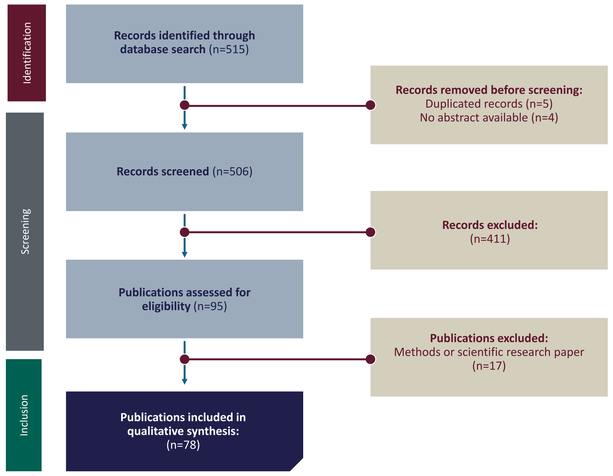
Since peer-reviewed publications may not fully capture HTA authorities' published guidance on SEE methods, targeted hand-searching of methodological guidelines published by relevant authorities (NICE, England; G-BA, Germany; HAS, France; PBAC, Australia; CONITEC, Brazil; CDA-AMC, Canada; ICER, USA) was undertaken through each authority's public website (4-11).

Real-world evaluation of supporting SEE evidence was further assessed via additional systematic analysis of HTAs undertaken by each market authority within the period of April 1st, 2023–2026. Screening for relevance from full texts of HTAs and reports was conducted, and case study examples identified for further evaluation of SEE methods used, insights generated, and HTA outcome. Three case studies were used for the purpose of this research: Crysvita® (burosumab), Vyvgart® (efgartigimod alfa), and Welireg® (belzutifan).

Table 1: Search terms for systematic literature review

Synonyms for "expert elicitation"	Geography/HTA authority-specific terms							
	England	Germany	France	Australia	Brazil	Japan	Canada	USA
"Structured expert elicitation"	NICE	G-BA	HAS	PBAC	CONITEC	Chuikyo	CDA-AMC	ICER
"Delphi method"	National Institute for Health and Care Excellence	Federal Joint Committee	Haute Autorité de Santé	Pharmacy Benefits Advisory Committee	Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde	Central Social Insurance Medical Council	CADTH	Institute for Clinical and Economic Review
"Delphi consensus"	Technology appraisal	Benefit assessment	Commission de la Transparence	Public summary document		MHLW	Reimbursement review	
"Delphi consensus method"	Health technology assessment	Gemeinsamer Bundesausschuss	Transparency Committee			Ministry of Health, Labour and Welfare	Health technology review	
"Modified Delphi"	NICE appraisal	Arzneimittelmarkt-Neuordnungsgesetz				C2H		
"Modified Delphi method"	NICE	G-BA				Center for Outcomes Research and Economic Evaluation for Health		
"SHELF"	National Institute for Health and Care Excellence	Federal Joint Committee						
"Sheffield Elicitation Framework"		Benefit assessment						
"Cooke's classical method"		Gemeinsamer Bundesausschuss						
"Cooke's classical"								
"MRC reference protocol"								
"IDEA protocol"								
"IDEA"								

Figure 1: Identification of publications via MEDLINE database



Results

Wider systematic review retrieved a total of n=506 publications, of which n=95 noted use of SEE methods. SEE was predominantly used to establish clinical guidelines (27%), as well as defining treatment pathways (18%), clinical outcomes (15%), and patient populations (11%) (data not shown).

When determining real-world application of SEE during HTA, targeted literature searching revealed 87.5% (n=7/8) of HTA authorities indicated SEE evidence to be acceptable, with formal guidance on use and/or appropriate methods published by 50% (n=4/8) of authorities (Table 2).

Searches of England's published NICE technology appraisals revealed 8.4% (n=17/203) had mentioned use of SEE methods; 1.8% for Germany's G-BA benefit assessment (n=6/331); 1.0% for Australia's PBAC assessment (n=4/384); 2.0% for Brazil's CONITEC published reports (n=4/204); 12.5% for Japan's C2H reports (n=4/32); and 0.7% for Canada's CDA-AMC reports (n=2/279) (Figure 2).

SEE used during HTA was predominantly for semi-quantitative validation, informing analysis for economic models (e.g., health state transitions, health resource utilization, patient adherence, and treatment discontinuation), long-term outcomes (including survival rates, clinical endpoints, mortality/morbidity), and defining target populations. Of all assessments identified (N=25), and after removing duplicates, n=7 assessments were in orphan/rare disease, n=6 in metabolic disorders, n=6 in oncology, n=4 in autoimmune disease, and n=2 in neuromuscular and renal disorders (Other) (Figure 3).

It was not possible to identify whether formal SEE evidence was submitted for evaluations when assessing retrievals for France (n=182). Retrievals for the USA were excluded due to the lack of acceptability and formal guidance published by HTA authorities.

Detailed analyses from select case study examples noted Delphi consensus as the primary methodology for SEE and used for semi-quantitative validation. Derived insights and HTA outcomes for each case example are presented in Table 3.

Due to rarity and uncertainty within the therapeutic areas of these case examples, SEE use appeared to support gathering insights for defining treatment pathways (n=3) and target populations (n=2), as well as supporting economic analysis (n=1) and evaluating clinical outcomes/patient quality of life (QoL) (n=2).

Table 2: Acceptability and formal guidelines published by HTA authorities

	Markets of interest							
	England	Germany	France	Australia	Brazil	Japan	Canada	USA
Acceptability of SEE evidence	✓	✓	✓	✓	✓	✓	✓	×
Formal guidelines published	✓	×	✓	✓	✓	×	×	×

Figure 2: HTA evaluations where SEE methods used†

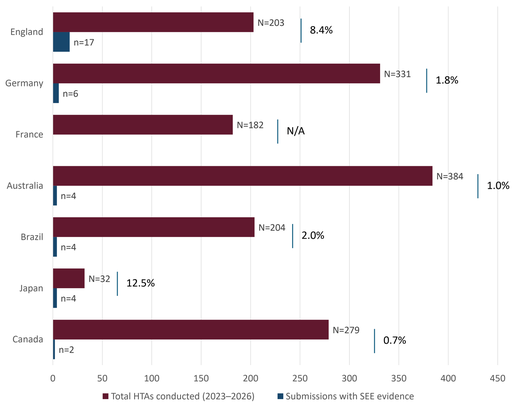


Figure 3: Therapeutic areas for SEE methods

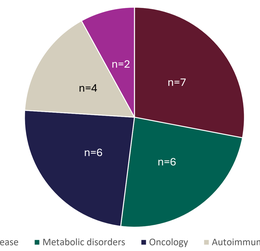


Table 3: Case study insights and HTA outcomes†

	Case study examples with SEE evidence		
	Crysvita (burosumab)	Vyvgart (efgartigimod alfa)	Welireg (belzutifan)
	Treatment of X-linked hypophosphatemia	*Treatment for antibody-positive gMG*	*Treating tumors associated with von Hippel–Lindau disease in renal cell carcinoma*
England	Recommended	Not recommended	Recommended (CDF)
Germany	No added benefit	No added benefit	No added benefit
France	-	-	-
Australia	-	-	Recommended
Brazil	Not recommended	-	-
Japan	-	-	-
Canada	Recommended	Recommended	Recommended
SEE evidence topics	• Economic modeling • Clinical outcomes • Treatment pathway	• Defining target populations • Current standard of care • Patient QoL	• Defining target populations • Treatment pathway

† Retrievals for the USA were excluded due to the lack of acceptability and formal guidance published by HTA authorities.

Conclusion

The possibility of negative outcomes due to uncertainty means that SEE methods are playing an increasingly important role, providing vital insights to support market access and HTA submissions. Many markets in this study demonstrate acceptability for SEE during HTA evaluation; however, there remains a gap in formal publication of guidelines.

Based on the literature, SEE methods are predominantly used to support semi-quantitative validation of topics such as defining target populations, clinical outcomes, treatment pathways, and clinical guidelines, particularly where document evidence is lacking or incomplete. Yet case study examples demonstrate that, despite use of supporting SEE evidence, there is no apparent correlation with SEE use and positive HTA outcome.

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Abbreviations

C2H – Center for Outcomes Research and Economic Evaluation for Health

CADTH – Canadian Agency for Drugs and Technologies in Health

CDA-AMC – Canada's Drug Agency

CDF – Cancer Drugs Fund

Chuikyo – Central Social Insurance Medical Council

CONITEC – Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde

G-BA – Gemeinsamer Bundesausschuss

gMG – Generalized myasthenia gravis

HAS – Haute Autorité de Santé

HTA – Health technology assessment

ICER – Institute for Clinical and Economic Review

IDEA – Investigate, Discuss, Estimate and Aggregate

MHLW – Ministry of Health, Labour and Welfare

MRC – Medical Research Council

N/A – Not applicable

NICE – National Institute for Health and Care Excellence

PBAC – Pharmacy Benefits Advisory Committee

QoL – Quality of life

SEE – Structured expert elicitation

SHELF – Sheffield Elicitation Framework