Assessment of the Importance of Carer Quality of Life in Global Health Technology Assessments

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Introduction

Informal carers play a vital role in supporting patients, often at substantial personal, emotional, and financial cost. In high-burden developmental and degenerative conditions, carers frequently act as primary coordinators of care, facing a significant and sustained impact on their QoL.[1]

Carer QoL remains poorly represented in clinical trials and HTA frameworks. This can underrepresent the broader value of new technologies, potentially limiting access to therapies that can support improved patient and carer outcomes. A previous review of 422 NICE appraisals found carer QoL was included in the economic evaluation for only 12 TAs and 4 HSTs, covering indications including Alzheimer's disease, atopic dermatitis and Duchenne muscular dystrophy (DMD).[2] Furthermore, methodologies for quantifying carer QoL vary widely, including a range of generic and disease specific measures, with uncertainty on the number of carers affected,[2] and different approaches for modelling the QALY impact (including disutilities with specific health states and carer/family QALY loss due to patient death).

Objectives

This research examines how carer QoL is addressed by HTA bodies in six countries (Australia, Brazil, Canada, France, Germany, UK) and explores opportunities to strengthen its role in value assessments.

Method

A targeted review of national HTA guidelines and associated grey literature was conducted, followed by primary research using the Lightning Insights On-Demand Platform with recent former HTA stakeholders (n=6). Respondents were asked to assess the relevance of carer QoL, practical influence on decision-making, and approaches for quantifying the impact of treatment on carer QoL. Insights were analysed to identify gaps between formal guidance and real-world practice and key considerations for future evidence generation/value demonstration strategies.

Results

Figure 1: Formal guidance on carer QoL inclusion in HTA

Country	Inclusion in formal guidance	Excerpt from formal guidance	Considered by decision-makers during HTA
	✓	In circumstances where the beneficiaries of health or other relevant outcomes are broader than the treated patient population (e.g. community, **carers**, dependents), include these as supplementary analyses"[3]	Rarely
	✓	"Some diseases that severely affect children and the elderly impose significant limitations on family caregivers…In such cases, it is recommended to keep the base case without **caregiver utilities** and include them in an alternative scenario or in sensitivity analysis"[4]	Rarely
	✓	"An intervention aimed at patients may have **spillover impacts on informal caregivers due to changes in the level of care required by patients**. Depending on the target population(s) specified in the decision problem, any associated spillover beyond the targeted population(s), in terms of either costs or effects, should be addressed in a non-reference case analysis"[5]	Occasionally
	✓	"The evaluation of health outcomes identifies the relevant health effects from the point of view of the populations concerned (i.e. patients, healthcare system users and **informal caregivers**)…When the evaluated intervention has consequences on the health of other individuals, the population analysed may be extended to **caregivers**… [this] can be included in the supplementary analysis (not required by HAS)"[6]	Rarely
	✓	"Interventions can also have consequences for those indirectly affected, for example relatives and **carers**. If appropriate, these consequences can also be considered within the framework of the Institute's reports"[7]	Rarely
	✓	"It is helpful to have the perspective of patients or **carers** about how relevant the clinical outcomes and the standardised generic instruments for measuring health-related quality of life (as specified in the reference case) are to the disease or condition…For the reference case, the perspective on outcomes should be all relevant health effects, whether for patients or, when relevant, other people (mainly carers). The perspective adopted on costs should be that of the NHS and PSS"[8]	Often

Australia: PBAC guidance prioritises direct patient outcomes for economic evaluation, while carer outcomes are reserved for supplementary analyses.[3] HTA stakeholders note this may lead to "*inadequate representation*" of the overall clinical and economic value for a new medicine (particularly in therapy areas where a disproportionate burden is incurred by the carer, such as dementia). As a result, carer QoL is "*generally deprioritised*" and given low overall weight within assessments.

Brazil: Methodological guidelines recognise that some conditions impose high burden on carers, and failing to capture this may undervalue new treatments.[4] However, carer utilities are only considered in sensitivity analyses for specific patients (i.e., paediatrics, the elderly, cognitive impairments), while professional caregiver QoL is excluded. Brazilian HTA stakeholders confirm that carer utilities are rarely discussed, often due to limited/missing data and high uncertainty on the interpretation of carer QoL outcomes.

Canada: Canadian guidelines[5] stipulate that informal caregiver outcomes may only be reported in non-reference case cost-effectiveness analyses. Similarly, caregiver time and productivity impact is only included when assessing "*a broader societal perspective*". In practice, Canadian HTA stakeholders report minimal consideration of caregiver QoL, e.g., due to paucity of data, high levels of uncertainty on comparative analysis/matching of controls, and prioritisation of defining direct resource implications for the public payer.

France: HAS guidance[6] acknowledges the perspectives of informal caregivers, but sets no formal requirements for including carer QoL in HTA submissions. In practice, French HTA stakeholders report the TC routinely wishes to consider carer QoL, however this is inhibited through frequent lack of evidence. Common limitations include use of unvalidated scales (with no defined MCID for the target population), incomplete data and insufficient statistical power to support an incremental change vs. SoC.

Germany: IQWiG methods[7] acknowledge that treatments can have consequences for relatives/ carers, however, there is no clarity on the requirements for the measurement/ statistical analysis of carer QoL, and the role within assessments. German HTA stakeholder feedback confirms that carer QoL data "*remains optional and manufacturers are not expected to submit this*". Although carer QoL data could have an "*informal positive impact*", it has no formal impact on the assessment of patient relevant incremental value.

UK: NICE methods[8] state that evaluation should consider all relevant health effects "*for patients or, when relevant, other people (mainly carers)*". Although this suggests a potential high impact of carer QoL, HTA stakeholders report this is rarely achieved in practice, e.g. due to lack of data from pivotal trials (with reliance on *"estimates not based on clinical data"*), challenges mapping carer QoL outcomes to EQ-5D, and uncertainty in modelling carer utility/disutility.

Figure 2: Perceived importance of carer QoL when evaluating new health technologies vs practical influence of carer QoL on HTA outcomes

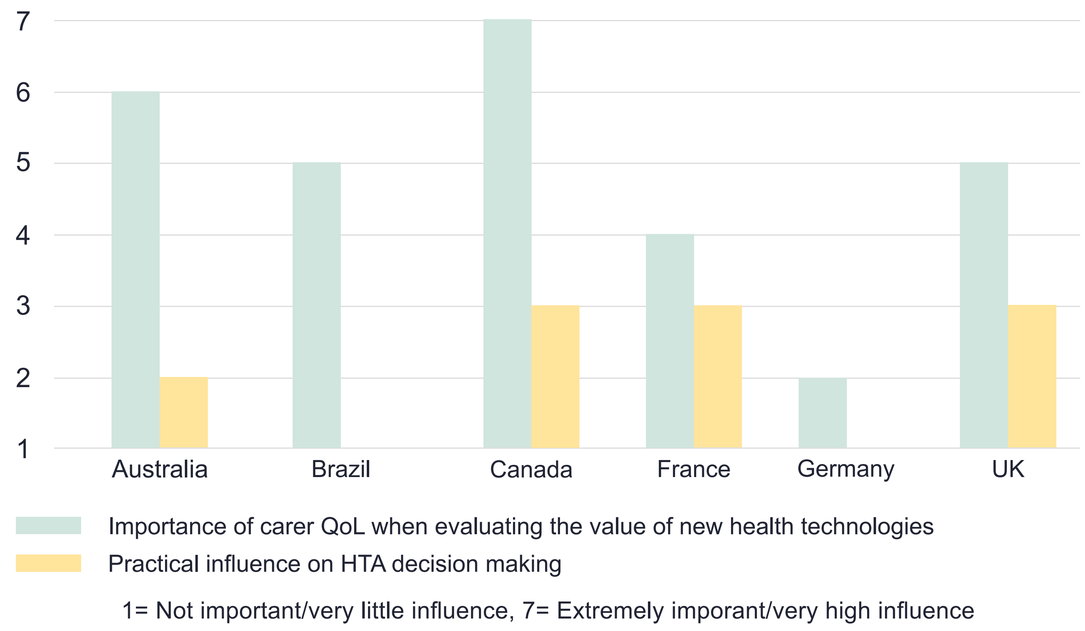
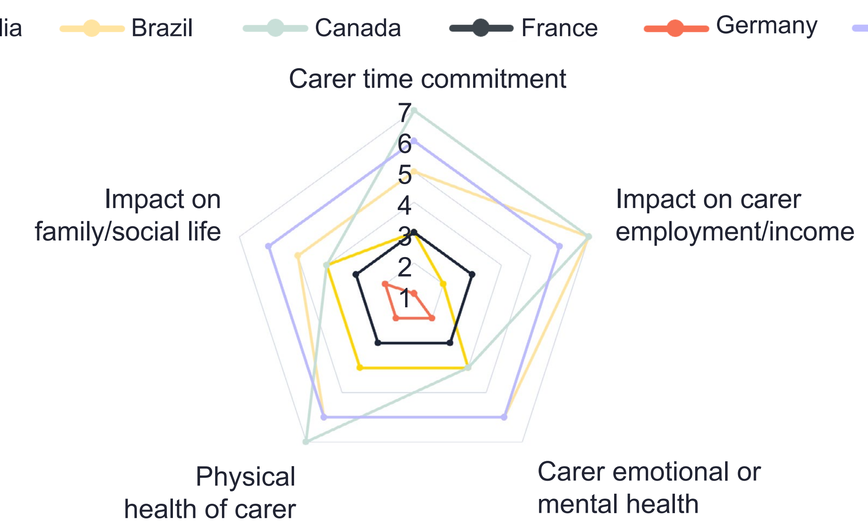


Figure 3. HTA stakeholder perceptions on the importance of carer QoL domains



Considering potential domains for evaluation of carer QoL, HTA stakeholders place the highest weight on physical health, time commitment and the impact on employment and income. Impact on family/ social life is generally rated as the least influential domain (given the heterogeneity in terms of family/ social norms and subjectivity in how these domains could be scored).

Conclusion and recommendations

Carer QoL remains inconsistently recognised across global HTA systems with most HTA bodies acknowledging the conceptual importance but lacking standardised frameworks for assessment. This means HTA authorities often have limited expectations as to what constitutes robust evidence on carer QoL, while manufacturers face ambiguity on how to design and position such data within clinical trials and HTA submissions.

Alignment is required between industry, patient/carer organisations and HTA authorities to inform country/region specific methods guidance for measurement of carer QoL in clinical trials, and requirements for relevant value demonstration in HTA frameworks. This must include a clear definition of the specific situations **where** carer QoL should be measured, alignment on **how** carer QoL should be measured, clarity on the optimal approach for **comparative analysis**, and agreement on the **optimal approach for modelling** carer QoL.

Figure 4: Key recommendations for the incorporation of carer QoL within HTA for new medicines

Requirements	Recommendations
Clear definition of specific situations where carer QoL should be measured	• A clear definition in HTA methods for conditions/patient types for which carer QoL is a relevant domain for evaluating the clinical/economic value • This should be based on the duration/progression of the disease, likely setting of care (i.e. >50% of long-term care outside a hospital/care facility) and likely dependency on informal/non-professional care
Alignment on how carer QoL should be measured	• A consensus position on validation requirements for metrics of carer QoL • As a minimum this should include construct validity, measurement of psychometric properties and confirmation of the MCID to demonstrate a 'meaningful change' in how the carer feels/functions • This should inform a 'battery' of validated metrics for carer QoL across therapy areas that will be recognised by HTA authorities
Clarity on the optimal approach for comparative analysis	• A clear definition within HTA methods on the appropriate approach(es) for comparative analysis of carer HRQoL if not available from a clinical trial (e.g., matched controls, general population data, individuals in 'full health') • Where 'utility' data is required, transferability of carer QoL data between disease areas should be considered

Clarity regarding the optimal approach for modelling carer QoL	• Clear guidance on the optimal approach for modelling carer QoL outcomes (and potential variation depending on the therapy area/product type). This should address:
	  • The appropriate duration for carer QoL measurement (e.g. between diagnosis and death or over a specific period)
	  • Whether carer utilities should be linked to patient's treatment or disease status
	  • Consideration of the number of carers likely to be impacted (e.g. based on the age and/or dependency level of the patient)
	  • Credible assumptions for how carer QoL changes over time depending on the progression of disease/impact of treatment)

Scan for abbreviations and references