Carer health-related quality of life in health technology assessments:

Process recommendations for determining relevance, data collection and inclusion in health-economic models

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Objectives

The aim was to develop an asset agnostic internal process for justifying the inclusion of carers' health-related quality of life (HRQoL) and appropriately integrating their HRQoL within a cost-effectiveness health technology appraisal (HTA) framework when the impact on carers is believed to be important.

The primary focus was on HTAs to the National Institute for Health and Care Excellence (NICE) in England, although the process (or elements of it) may also be relevant to other markets where carer quality of life can be included in a HTA. For the purposes of this research a carer was defined as someone who provides unpaid support to someone they have an existing relationship with and who cannot cope without that support.

Method

Leveraging results from systematic literature reviews (SLR) [1, 2], more recent publications on carers' HRQoL in HTA[3, 4] and recommendations from NICE [5, 6, 7], process recommendations across three areas were developed:

1 How do we determine carer HRQol is relevant?

If deemed relevant

2 How/what carer HRQoL data should we collect and how should we validate it?

When collected

3 How should we include and report carer HRQoL in health economic models?

Results

Consider the potential impact of the intervention on carer HRQoL

1 **Is there an (expected) relationship between patient health and carer HRQoL? Is the intervention likely to change carer HRQoL?**
If there is no direct or indirect effect (e.g., through improved patient health) of the intervention on carer HRQoL, carer HRQoL will be equivalent in the intervention and comparator arms of a cost-effectiveness model

If question 1 is answered affirmative, consider including carer HRQoL in the HTA if at least one of the following questions is also answered affirmative:

2 **Has carer HRQoL been included (quantitatively or qualitatively) in previous NICE appraisals in the same indication?**

3 **Are there previous studies available in the literature describing carer HRQoL for the target patient population?**

4 **Is there a significant impact on carer HRQoL in this indication?**
Consider including carer HRQoL in the HTA if at least one of the following questions is answered affirmative:

- **3a.** Can you expect the presence of multiple caregivers?
- **3b.** Does a large proportion of the population use informal care?
- **3c.** Is the intervention indicated for paediatric patients?
- **3d.** Is the intervention indicated for a disease which is debilitating or progresses to the point of being debilitating?
- **3e.** Does the condition impose substantial impact on carer's work/social life/wellbeing?
- **3f.** Do specific carer support groups exist for this indication?

These factors are likely related to the volume of care (number of caregivers, proportion of patients with caregiver) and/or degree of impact on carer HRQoL (paediatric patients, progressive diseases).

5 **Are there studies/appraisals available describing carer HRQoL in related/similar indications?**

How should data be collected? Systematic literature review (SLR) is the first step to determine the appropriate source(s) of carer HRQoL data (utility values).

1. **If complete and robust values are available from SLRs / previous appraisals, they should be used and do not require supplementation.**
2. **If no values are available from SLRs / previous appraisals the generation of carer HRQoL data is required. The flowchart in Figure A can be used to inform the appropriate source of carer HRQoL data.**
3. **If values are available from SLRs / previous appraisals but they have limitations, they should be referenced (and may be used to inform part of the model or some scenarios) but likely require supplementation. See Figure B.**

FIGURE A | **No values available from SLRs / previous appraisals**

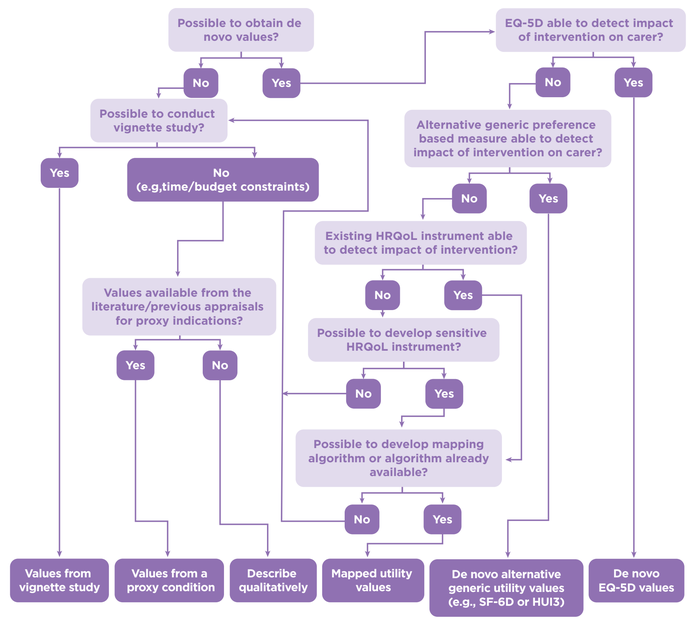
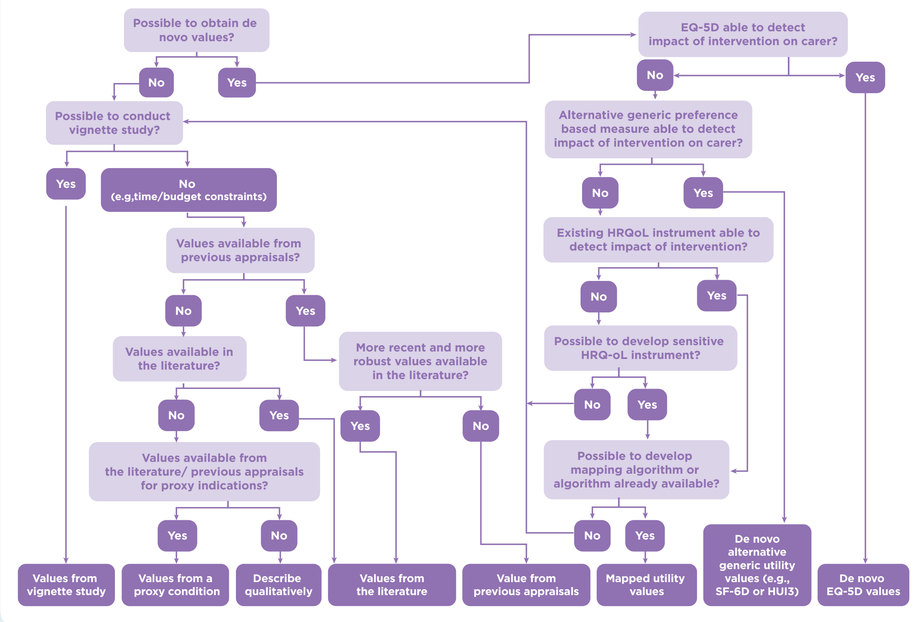


FIGURE B | **Limited values available from SLRs / previous appraisals**



What type of data should be collected

1. **What drives the impact of the intervention on carer HRQoL?**
   i.e., what is the causal pathway between the intervention and change in HRQoL
2. **Carer HRQoL values which can inform the health economic model**
   *By health state/intervention/clinical event/time**
3. **Number of carers per patient****
   *By health state/intervention/clinical event/time**
4. **Proportion of patients using informal care**
   *By health state/intervention/clinical event/time**
5. **Frequency of care**
   Number of days caring per week/month/year

* Depending on expected causal pathway and model type ** If unavailable, assume one carer

How should we include and report carer HQRoL in health economic models?

1 Determine causal pathway

A. Carer HRQoL is linked to patient disease severity: intervention improves patient health, which in turn improves carer HRQoL

B. Carer HRQoL is linked directly to the treatment: the intervention does not affect patient health but reduces the need for informal care (e.g., informal carers do not need to accompany patients to the hospital when the intervention is less invasive, such as subcutaneous vs. IV administration of the same product).

C. Carer HRQoL is linked to clinical (adverse) events: intervention leads to less adverse events, in turn reduces the need for informal care related to taking care of adverse events.

D. Carer HRQoL might be linked to other model parameters: for example, carer HRQoL might be different for institutionalized patients than for community-dwelling patients. An intervention might impact the probability of institutionalization, in turn affecting carer HRQoL.

2 Determine whether a de novo or existing model is required
If carer HRQoL has a large potential impact on the ICER and the causal pathway is not well-represented in an existing model or if implementing carer HRQoL in existing model is not possible, developing a de novo model is preferred.

3 Missing data and validating estimates
Missing information (e.g., number of carers per health state) can build upon assumptions informed by for instance clinicians and/or patient representatives.

4 Addressing uncertainty
Parameter uncertainty (standard errors around estimates) for carer HRQoL values should be included in the model like other parameters in univariate and probabilistic sensitivity analysis.
Structural uncertainty on the assumptions made related to carer HRQoL should be assessed using scenario analyses

5 Reporting
Critical assumptions and the methodology applied to collect carer HRQoL values should be clearly described and, if possible, validated by experts (clinicians, patients, carers) or previous estimates.

Conclusion

We recommend that the relevance of carer HRQoL to a HTA is established during early clinical development to best understand data needs and optimise data collection. We recommend, in order of preference, either collecting de novo EQ-5D values, using de novo alternative generic utility values, mapping carer HRQoL values to EQ-5D, conducting a vignette study, or using qualitative description where none of the above is possible.

Finally, we identified four main parameters to link carer HRQoL with (patient health, interventions, adverse events or other factors e.g., institutionalisation), recommending a de novo model if carer HRQoL has a large potential cost-effectiveness impact, or if the causal pathway is not well-represented or implementation unfeasible in an existing model.

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References

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