An introduction to carer burden in health technology assessment

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Executive summary

What is carer burden and why is it important?

Many patients, and especially those with neurological conditions, rely on informal or family caregivers, imposing a burden on caregivers.

Spillover effects are impacts of a disease and treatment on the welfare of people other than the patient and are measured through the impact on Health-related Quality of Life (HRQOL) or the impact on costs.

This burden is often not adequately accounted for in Health Technology Assessments (HTAs), potentially undervaluing innovative treatments that can reduce caregiver burden.

Where and how carer burden is considered in HTA

The guidelines of many HTA agencies state that carer health-related quality of life can be included in assessments.

However, in practice, carer burden is included in a minority of HTA admissions and is less likely to be included in assessments which principally impact length of life.

Carer QOL is most commonly included in assessments for neurodegenerative diseases. Case studies show that including carer QOL can result in a more favourable ICER.

Best practice for industry and HTA bodies

Carer burden is most likely to be considered for products with high intensity and long duration of care. However, in instances where either duration is long or intensity is high, the context for including carer burden should be explored.

Data on carer quality of life should be collected for the relevant patient population, disease area and country.

Implications of the modelling approach should be carefully considered and justified. Results should be presented disaggregated for patients and carers.

Next steps and future opportunities

More routine, disease-specific collection of carer burden in clinical trials, especially but not limited to neurological and musculoskeletal indications.

Routine inclusion of carer burden as a value element in HTA submissions.

Given the relatively inconsistent methods, industry is a key stakeholder to collaborate with in the development of global HTA guidelines around the measurement and incorporation of carer burden in HTA.

What is carer burden and why is it important?

Where and how carer burden is considered in HTA

Best practice for industry and HTA bodies

Next steps and future opportunities

The impact on informal carers can influence whether a new treatment is approved

What is it?

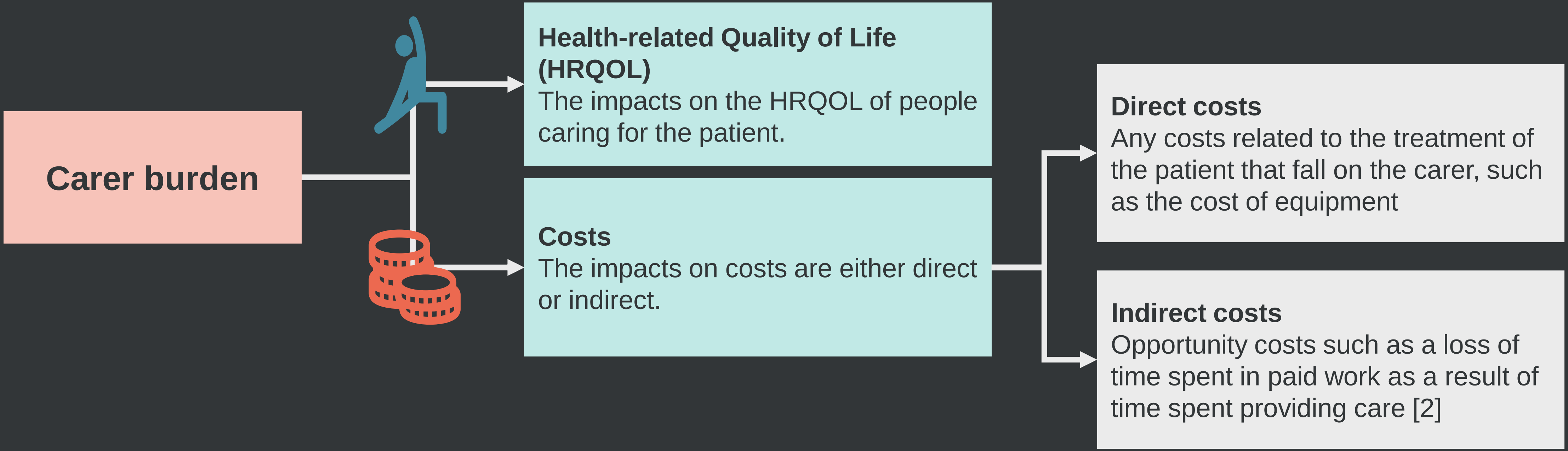
- Informal care means providing unpaid care for a dependent you have a social relationship with.
- Providing informal care can have significant negative effects on:
    - Health-related quality of life (HRQOL) e.g. by causing stress and hence psychological costs.
    - Financial costs e.g. lost income from taking time out of paid employment.

Why is it important?

- Society would prefer to minimise the burden on informal carers.
- Ignoring carer effects in HTA* will lead to resource allocation decisions that are not optimal from the point of view of society as a whole.
    - Even HTA agencies that only consider patient and health system effects should consider impacts on carer HRQOL because these can lead to higher demand for health and social care from carers and therefore higher costs.

*HTA (health technology assessment) is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its life-cycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system [1].

Carer effects can be classified into health-related quality of life effects and cost effects



Carer burden

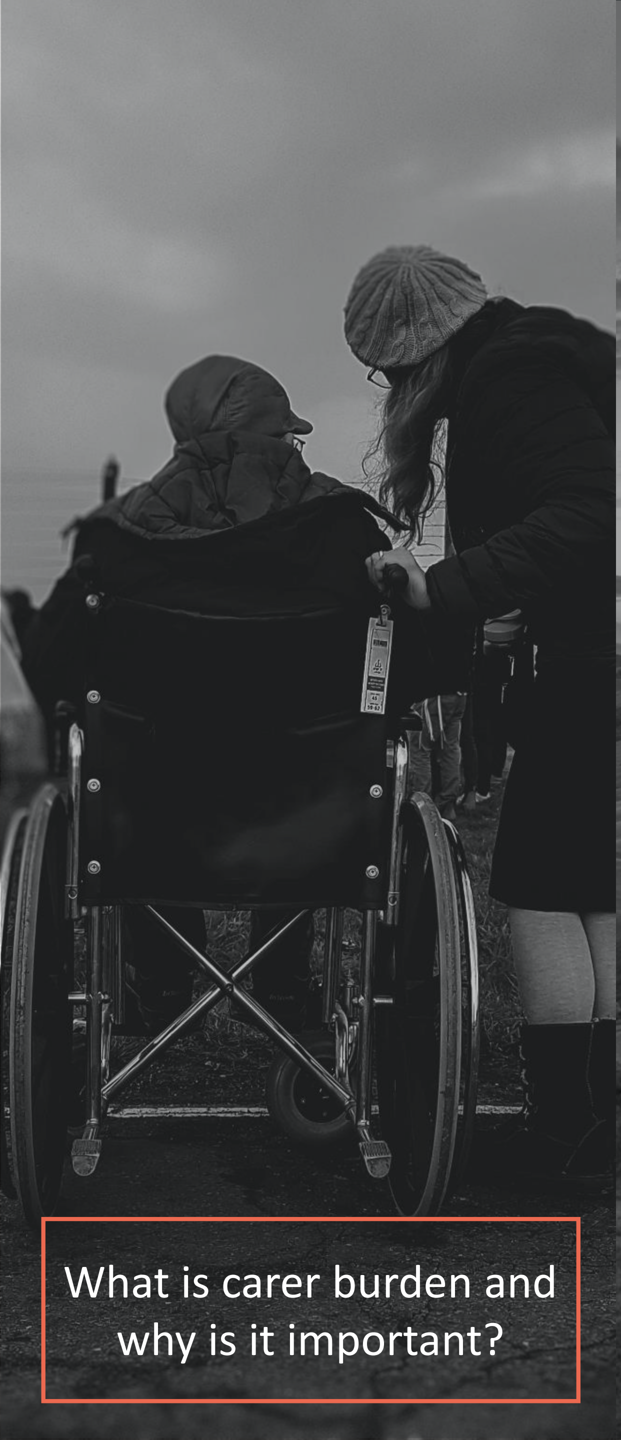
Health-related Quality of Life (HRQOL)
The impacts on the HRQOL of people caring for the patient.

Costs
The impacts on costs are either direct or indirect.

Direct costs
Any costs related to the treatment of the patient that fall on the carer, such as the cost of equipment

Indirect costs
Opportunity costs such as a loss of time spent in paid work as a result of time spent providing care [2]

- Treatments may also affect people who care *about* the patient but not necessarily *for* the patient, in which case they are called family effects [2]. Here we focus on carer or caregiving effects.
- There are other ways in which diseases and treatment can impact informal carers [3], but here we focus on carer HRQOL and costs as these are the two main domains of effects for HTA.



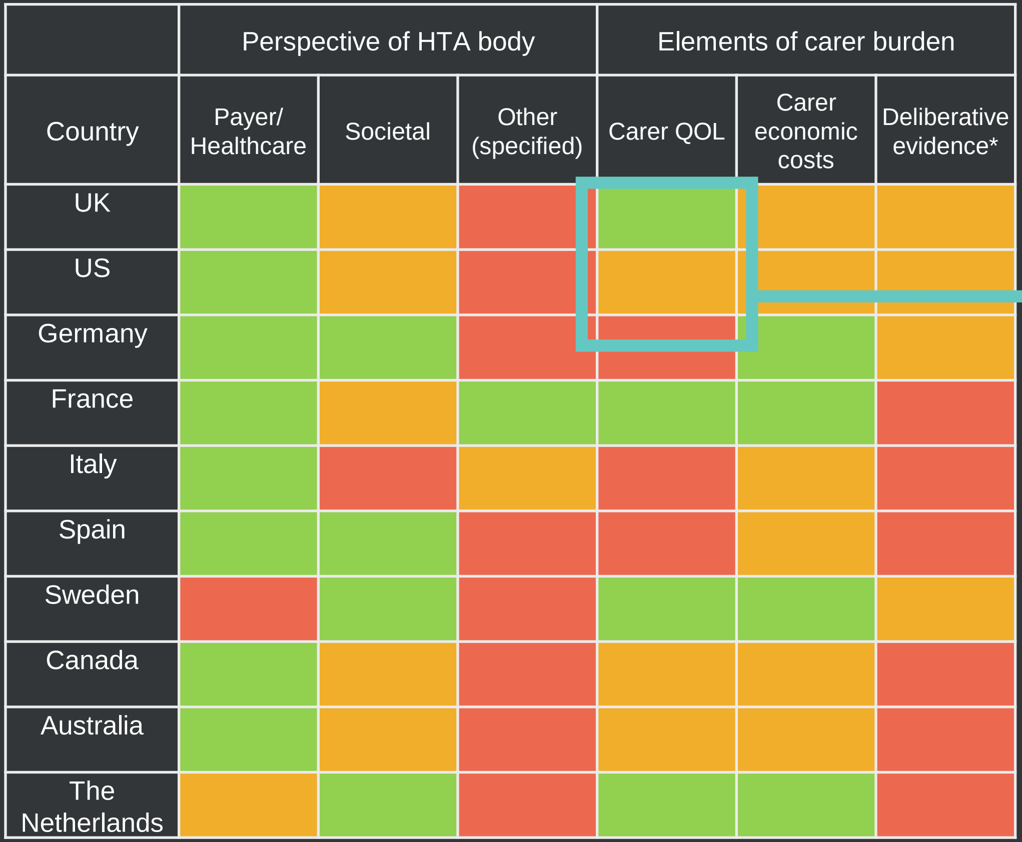
What is carer burden and why is it important?

Where and how carer burden is considered in HTA

Best practice for industry and HTA bodies

Next Steps and Future Opportunities

The guidelines of many HTA agencies state that carer HRQOL can be included in assessments



	Perspective of HTA body			Elements of carer burden		
Country	Payer/ Healthcare	Societal	Other (specified)	Carer QOL	Carer economic costs	Deliberative evidence*
UK	🟩	🟧	🟥	🟩	🟧	🟧
US	🟩	🟧	🟥	🟧	🟧	🟧
Germany	🟩	🟩	🟥	🟥	🟩	🟧
France	🟩	🟧	🟩	🟩	🟩	🟥
Italy	🟩	🟥	🟧	🟥	🟧	🟥
Spain	🟩	🟩	🟥	🟥	🟧	🟥
Sweden	🟥	🟩	🟥	🟩	🟩	🟧
Canada	🟩	🟧	🟥	🟧	🟧	🟥
Australia	🟩	🟧	🟥	🟧	🟧	🟥
The Netherlands	🟧	🟩	🟥	🟩	🟩	🟥

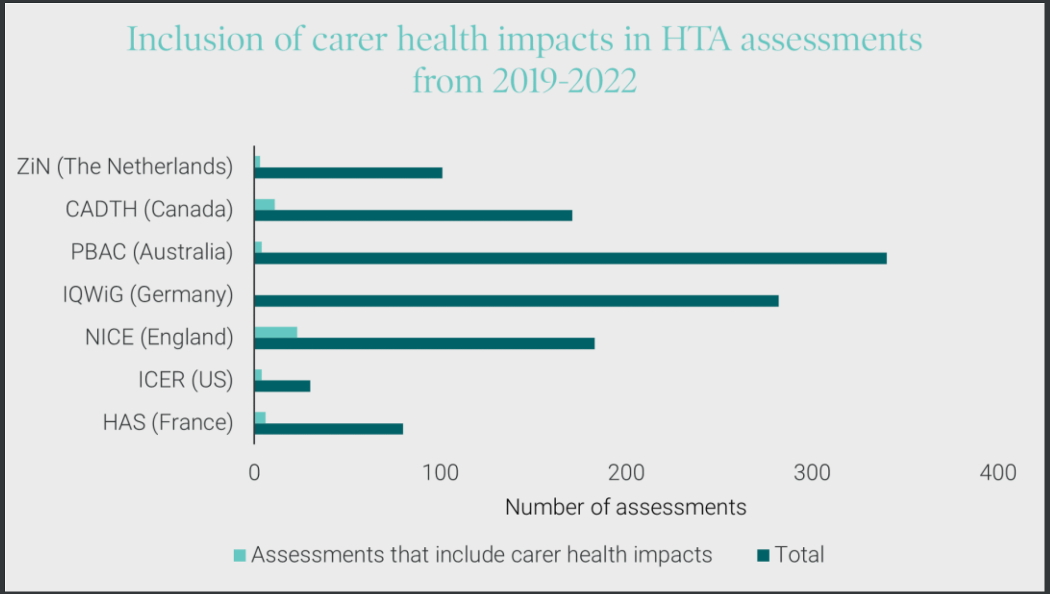
🟩 Reference case
🟧 Non-reference case/ supplementary
🟥 Not specified

Countries differ on how carer burden can be included in economic evaluations. For example whether it's included in the base/reference case or as a sensitivity analysis [4].

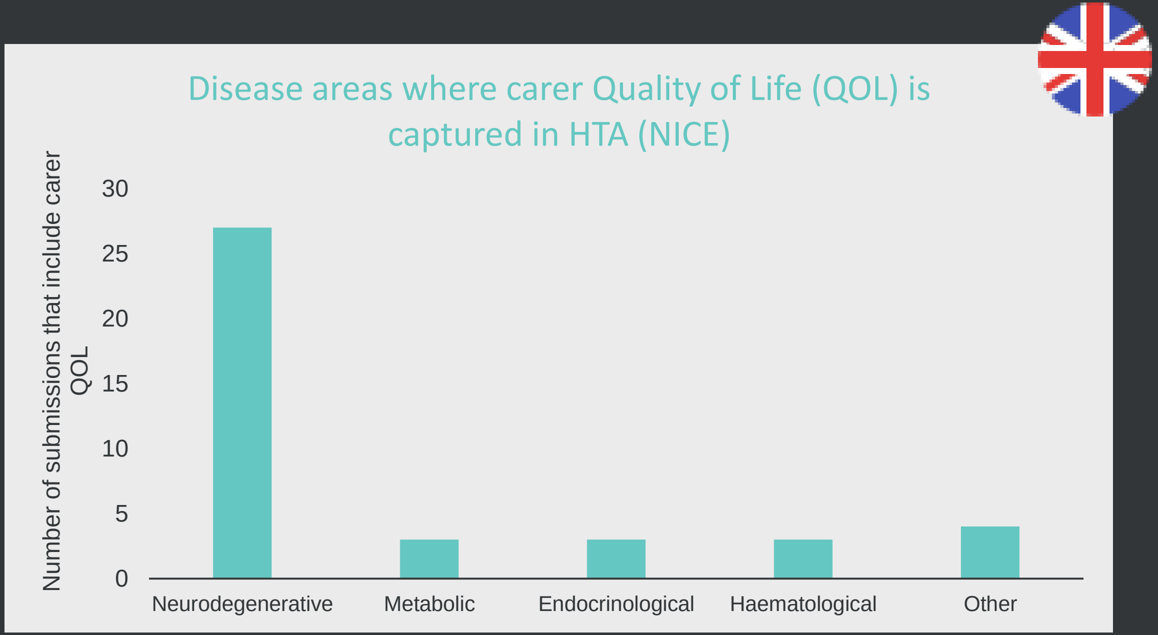
UK: "For the reference case, perspective on outcomes should be all relevant health effects, whether for patients, or, when relevant, other people (mainly carers)." [5]

US: "Specific scenario analyses (including one using a modified societal perspective that incorporates estimates such as productivity losses, caregiver burden, and other indirect costs) and subgroup analyses are conducted when appropriate." [6]

Carer HRQOL is included in a minority of HTA submissions, with variation across countries and disease areas



Analysis performed by OHE (OHE data on file)



Analysis performed by OHE (OHE data on file)

This analysis summarises the number of HTA assessments where carer QOL was included within the submission (in the modelling or other assessment methodology). For all countries, the analysis reviewed completed assessments from 01/2019 to 04/2022. PBAC and CADTH assessments are further filtered to those that have received recommendation and reimbursement approval respectively.

This analysis summarises the number of NICE (England) HTA assessments where carer QOL was included within the submission (in the modelling or other assessment methodology) from 2000 to April 2022.

ZiN (The National Health Care Institute), CADTH (The Canadian Agency for Drugs and Technologies in Health), PBAC (Pharmaceutical Benefits Advisory Committee), IQWiG (Institute for Quality and Efficiency in Health Care), NICE (The National Institute for Care and Excellence), HAS (French National Authority for Health).

Quantitative evidence informs (and is supplemented by) deliberative discussions

ICER (US) appraisal committees discuss and vote on the impact on caregivers and family through a deliberative approach.

[6] ICER Value Assessment Framework, 2020

IQWiG (Germany) permit qualitative research methods to be used to explore and understand the experience of relatives.

[7] IQWiG General Methods v6.1, 2022

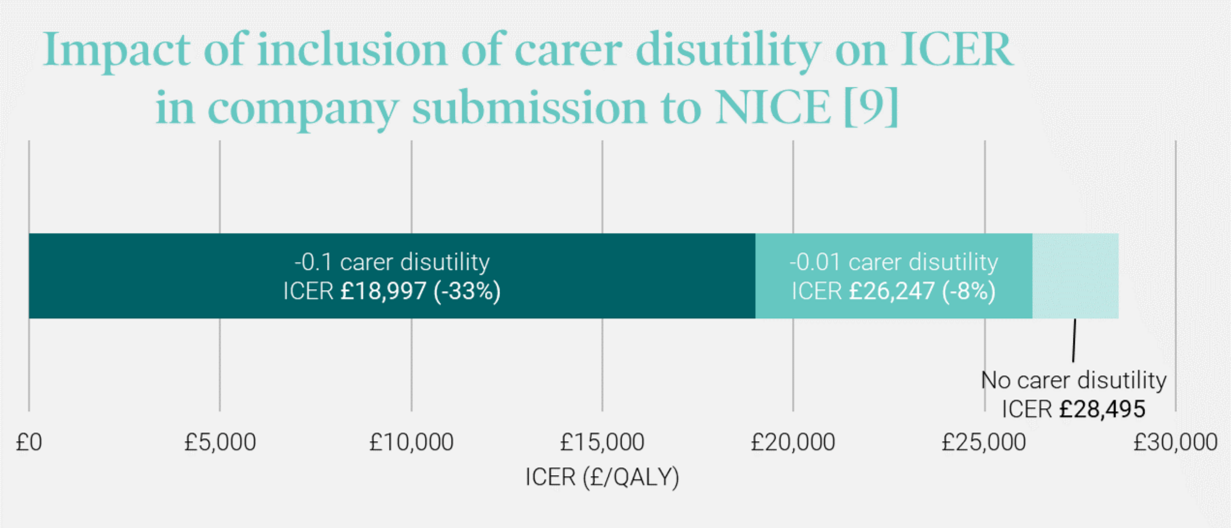
NICE (UK) require evidence to demonstrate that the condition is associated with a substantial effect on carer’s HRQOL, and how the technology affects carers.

[5] NICE health technology evaluations: the manual, 2022

The SBU (Sweden) suggest including a description on how costs and effects are distributed among different stakeholders.

[8] SBU Medical and Social Science & Practice, 2022

Considering carer burden in HTA can change the perceived value of a treatment



Impact of inclusion of carer disutility on ICER in company submission to NICE [9]

Disutility refers to the reduction in the carer's HRQOL as a result of caring and the extent to which this changes when the patient's health changes [4]. A lower disutility implies a smaller impact on the carer's HRQOL as a result of caring and therefore has a smaller impact on the ICER.

In their economic opinion on dupilumab for atopic dermatitis in children [10], HAS concludes that taking into account carer utility significantly lowers the ICER

> "Without taking into account the usefulness [*sic*] of caregivers, the RDCR reaches around €42,221/QALY (+77%) all other things being equal"*

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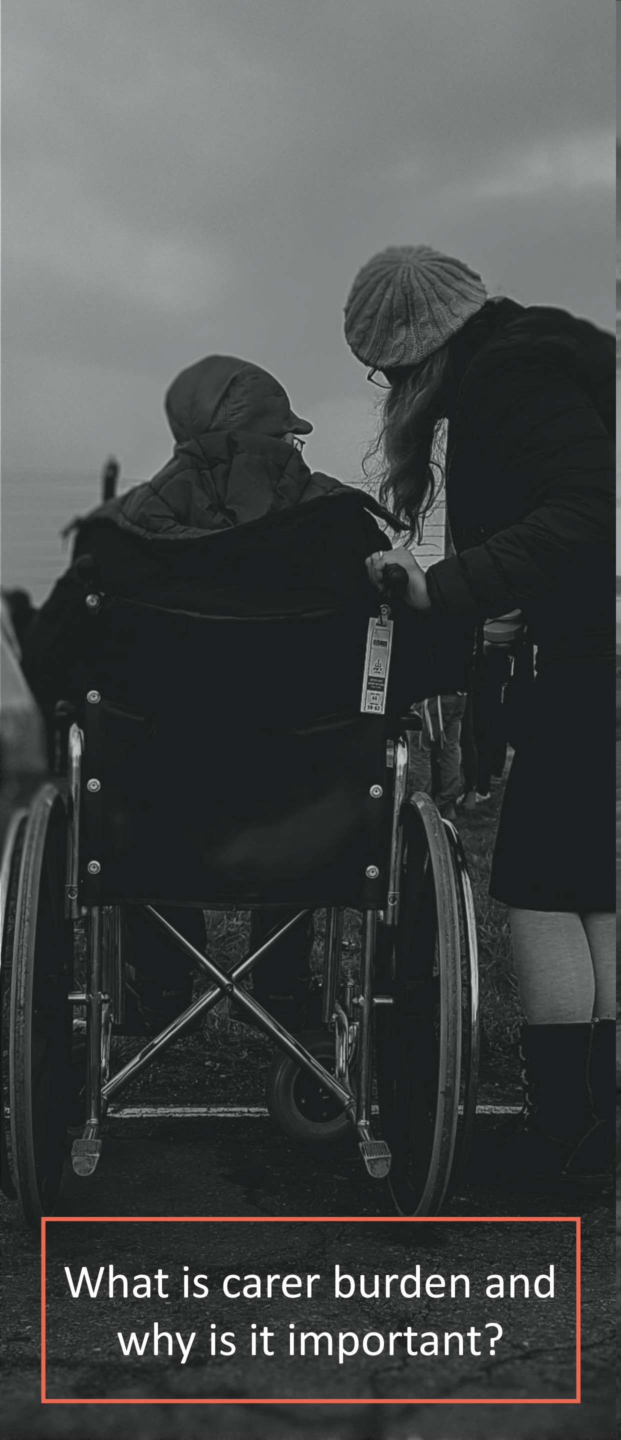
*"Usefulness" is the machine translation of "l'utilité" but utility is the more appropriate translation. RDCR stands for "ratio différentiel coût-résultat" defined as incremental cost-outcome ratio in the English translation. The outcome is QALYs so RDCR is equivalent to ICER.

A recent academic review highlighted a general paucity of evidence around carer’s HRQOL, and where such data are available, inconsistencies in how it is modelled. [4]

⚠ The overall paucity of carer HRQOL data means that assessments for one indication may use carer HRQOL data from a different disease area. [4]

⚠ Even where disease-specific carer HRQOL data is available, it may be modelled differently between different appraisals, or critiqued differently by different HTA bodies. [4]



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Best practice for industry and HTA bodies

Next steps and future opportunities

Carer burden is greatest in higher intensity, higher duration conditions, and therefore the effort of collecting data on carer burden is more justified in these circumstances

	Short duration	Long duration
High intensity	**SOME RELEVANCE** *Acute but limited duration: e.g. cancer treatments*	**HIGH RELEVANCE** *Intense chronic conditions: e.g. childhood neurological conditions, dementia, muscular dystrophy, paraplegia*
Low intensity	**LOW RELEVANCE** *Transitory conditions: e.g. respiratory illnesses*	**SOME RELEVANCE** *Less intense chronic conditions: e.g. Type 1 diabetes, cystic fibrosis. This category may also represent family effects or bereavement effects*

The intuitive relevance of "higher intensity, higher duration" burden appears to be supported by the greater likelihood of inclusion of carer burden in the HTA submissions with these characteristics. In particular, we see that long-term neurological conditions are disproportionately represented among NICE submissions that considered carer burden (refer to slide 8, right hand-side chart).

Consideration of carer burden could be improved by adopting these 6 recommendations for industry and HTA bodies [4]

🪙 📄 ✍ 🖩 Clearly justify whether, and why, carers' HRQOL is included in the economic evaluation .

🪙 📄 ✍ 🖩 Where possible, provide evidence of carer's HRQOL for the population under consideration .

🪙 📄 ✍ 🖩 If carers' HRQOL is informed by data from a different disease area and/or country, justify its use and discuss its limitations.

🪙 🖩 Where cross-sectional data informs carers' HRQOL, justify the choice of external data used to derive comparisons.

🪙 🖩 Carefully consider the implications of the modelling approach and be explicit about the assumptions made.

🪙 🖩 Present disaggregated results for patients and carers, using sensitivity analysis to include/exclude carers .

✍ Qualitative carer burden
🖩 Quantitative carer burden
🪙 Relevant for cost-effectiveness HTA systems
📄 Relevant for non-cost-effectiveness HTA systems

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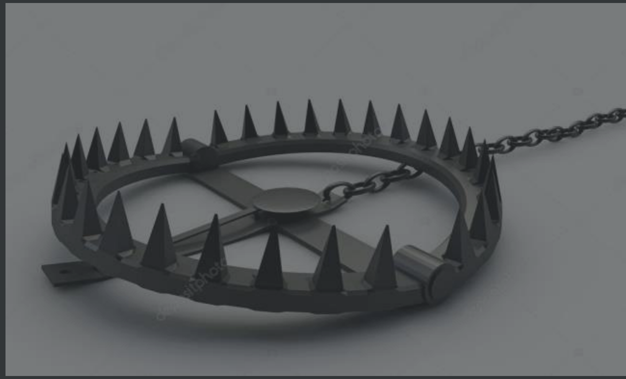
It will be important to recognise potential ethical implications of different approaches to considering carer burden

Extending patient survival can also mean extending the burden on carers. In some circumstances, especially where treatment extends survival without dramatically improving functioning, this extended carer burden can outweigh the value of survival gains to patients and lead to a recommendation *against* life extending treatments. OHE refers to this tension between patient and carer value as the Carer QALY Trap. This Carer QALY Trap means that consideration of carer burden in HTA will not *always* improve the value of new treatments. It will be important to understand the relative balance of patient gains and carer burdens with life-extending treatments.



When carer burden is expressed in terms of direct or indirect monetary losses, such as lost income or foregone societal productivity, it can mean that less value is assigned to conditions that impact lower-income, unemployed, or retired carers. For this reason, many HTA bodies see differences in value based on patient or carer productivity as unfair and tend to exclude it from consideration. England, Germany, and France, for example, do not consider productivity losses in their base case analysis. Agencies in the Netherlands, Sweden, and Spain, however, are more open to consideration of productivity losses [11]. This highlights ethical challenges in how to account for the direct and indirect costs to informal carers in a fair and equitable manner.

Next steps

- More routine, disease-specific collection of carer burden in clinical trials, especially but not limited to neurological and musculoskeletal indications.
  - HTA bodies want to see carer burden measured in the same way as the impact on patients. Therefore, despite some limitations, OHE recommends using EQ-5D to measure carer burden.
  - Best practice for collecting carer burden in clinical trials includes collecting data from the relevant disease area and country and collected at multiple time points.

- Routine inclusion of carer burden as a value element in HTA submissions.
  - Early HTA interaction can be leveraged to align on the measurements and methods to incorporate carer burden within HTA.
  - Disease areas where the carer burden is high intensity or long duration can particularly benefit from early HTA and scientific consultation to assist the acceptance of carer burden in submissions.

Future opportunities

- Given the relatively inconsistent methods, collaboration with stakeholders, representing patient groups, academia, HTA decision makers and industry, can be carried out to develop HTA guidelines around the measurement and incorporation of carer burden within HTA.
    - This may include promoting consideration of spillover effects *beyond* carer burden, including the impact of a disease on family members other than carers.
    - It may also include consideration of the *process* of treatment on carers, independent of patient health outcomes.

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