

The Inclusion of Utility Values for Carers and Family Members in HTAs: A Case Study of Recent NICE Appraisals in the UK

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BACKGROUND

- The inclusion of utility values for carers and/or family members in economic evaluations, where relevant, is encouraged but not enforced by many health technology assessment (HTA) agencies (Table 1).
- The National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK) promotes the inclusion of “all direct health effects for patients or, when relevant, carers” in its methods guide.¹
- “Carer” refers to a person who provides unpaid care by looking after a relative, friend, or partner who needs support because of ill health, frailty, or disability.¹

Table 1. Guidance on Inclusion of Carer and Family Member Utility in the Methods Guides of Selected HTA Agencies

HTA Agency	Statements From Methods Guide	Base Case / Scenario
NICE (UK)	Perspective on outcomes: all direct health effects, whether for patients or, when relevant, carers. ¹	Base case
SMC (Scotland)	The perspective on outcomes should be all direct health effects whether for patients or, where relevant, other individuals (principally carers). If appropriate data on utilities/QALYs for carers or other groups other than the patients affected is provided as additional evidence, this will need to be presented separately from the primary QALY analysis as it is outside the perspective adopted by the SMC. ²	Scenario
NCPE (Ireland)	All health effects accruing to individuals (QALYs, life-years gained, and so on) should be included in the outcomes for the reference case. The outcomes may include...other benefits such as nonresource effects that may accrue to other public sector agencies, patients or their carers as a result of a technology. ³	Scenario
CADTH (Canada)	The target population may include patients and their informal carers (i.e., unpaid carers). Researchers should consider any potential spillover impacts (such as due to changes in the level of care required by patients beyond those individuals for whom the interventions are being targeted). ⁴	Base case if carer is considered part of the target population
PBAC (Australia)	In circumstances where the beneficiaries of health or other relevant outcomes are broader than the treated patient population (e.g., community, carers, dependants), include these as supplementary analyses. ⁵	Scenario
ZiN (Netherlands)	The economic evaluation is carried out and reported from the societal perspective. All relevant societal costs and benefits, irrespective of who bears the costs or to who the benefits go, should be taken into account in the evaluation and reporting. ⁶	Base case
NoMA (Norway)	An intervention's effect on the HRQOL of a carer can be accounted for by showing relevant documentation. In essence, the same requirements are made for documentation of changes in the QOL of a carer as for a patient. The effects can be quantified in QALYs to be used in the cost-effectiveness ratio. The results of the analyses must be presented with and without the inclusion of effect on the carer's QOL. The central effect considered is how changes in the patient's HRQOL affects the HRQOL of the carer(s). If the intervention affects the life expectancy of the patient, the effects on the carer's QOL of the increased life expectancy in itself should not be taken into account. There are both ethical and methodological reasons for this. ⁷	Present with and without; base case unclear
HAS (France)	The population concerned can be extended to include other individuals when their health is affected by the interventions studied, even though they were not targeted. Examples include the positive effect of a vaccination programme for persons who are not vaccinated but are nevertheless protected and the negative effect of antibiotic therapies if antibiotic resistance develops. ⁸	Unclear
TLV (Sweden)	The health economic analysis should be done from a societal perspective. This implies that all relevant costs and effects from a treatment or disease should be considered, regardless of who they fall on (county council, municipality, state, patient, relative). ⁹	Base case

CADTH = Canadian Agency for Drugs and Technologies in Health; HAS = Haute Autorité de Santé; HRQOL = health-related quality of life; NCPE = National Centre for Pharmacoeconomics; NoMA = Norwegian Medicines Agency; PBAC = Pharmaceutical Benefits Advisory Committee; QALY = quality-adjusted life-year; QOL = quality of life; SMC = Scottish Medicines Consortium; TVL = Tandvårds-Läkemedelförmånsverket (Sweden); ZiN = Zorginstituut Nederland (Netherlands).

OBJECTIVE

- To assess the extent to which utility values for carers and family members have been included in the recent HTA appraisals and highly specialized technology (HST) evaluations by NICE published within the calendar year 2018.

METHODS

- The Technology Appraisal Guidance of the HTAs and HSTs completed and published by NICE in 2018 was reviewed to identify those including carer and/or family member utility weights.
- The following information was reviewed in identified appraisals:
 - The methods for estimation of carer and/or family member utility weights
 - The perspective of the analysis
 - Their inclusion in the base case or as part of a scenario analysis
 - Their impact on the incremental cost-effectiveness ratio (ICER) (where reported)
 - Comments in the technology appraisal (TA) guidance document

RESULTS

- Of the 58 appraisals completed in 2018 (56 HTAs and 2 HSTs), 3 included carer utility values in the economic evaluation (Table 2).
- Of the 3 appraisals that included carer disutilities, two evaluated therapies for multiple sclerosis and one for X-linked hypophosphatemia in children and young people.
- The inclusion of carer disutilities led to a negligible effect on the ICER in all 3 appraisals, and the appraisals were concluded with a recommendation for each treatment evaluated.
- In the 2 TAs, the inclusion of carer utilities was part of the base case, whereas in the HST, it was included as part of a scenario analysis.

Table 2. Details on the NICE Appraisals That Included Carer or Family Member Utility Values

TA ID and Process	Relevant Party and Analysis Information	Submission	Method and Sources of Estimation for (Dis)utilities	Comments in the Technology Appraisal Guidance Document
TA527 (MTA) ¹⁰	<ul style="list-style-type: none"> Carer NHS/PSS perspective Base case^a MS Impact on ICER: negligible All recommended 	Biogen submission (IFN β-1a and pegylated IFN β-1a) Merck Submission (IFN β-1a) Teva submission (GA) Assessment Group Model	Maximum disutility for a carer was 0.14, which was proportioned by EDSS score based on “average hours of care per patient per day” (based on a NICE assessment of treatments for Alzheimer's disease). ¹¹ Disutility estimates for a carer based on EQ-5D data collected in an online survey from the carers of patients with MS and estimated using UK general population preference weights. ¹²	The committee discussed the QOL for people with RRMS and the burden that their carers experience. The assessment group did not include disutility to carers in its base case because it had questioned whether this was consistent with the NICE reference case. The companies and the Department of Health did include disutilities to carers in their base-case analyses. The base cases in previous NICE TAs for MS (such as dimethyl fumarate and natalizumab) also included disutility to carers. The committee concluded that it would include disutility to carers when making its decision.
TA533 (STA) ¹³	<ul style="list-style-type: none"> Carer NHS/PSS perspective Base case MS Impact on ICER: negligible Recommended 	Roche submission (ocrelizumab) Assessment Group Model	Maximum disutility for a carer of 0.14 for the most severe health state (based on a NICE assessment of treatments for Alzheimer's disease), which was proportioned by EDSS score based on “average hours of care per patient per day.” ¹¹ Maximum disutility for a carer was 0.05 for the most severe health state, based on TA on daclizumab for treating RRMS (TA441) and expert opinion.	The company's economic model structure was based on advancing disability (EDSS states) but included disutility for relapses and carers.
HST8 (HST) ¹⁴	<ul style="list-style-type: none"> Carer NHS/PSS perspective Scenario XLH Impact on ICER: negligible Recommended 	Kyowa Kirin submission (burosumab)	A disutility estimate of 0.08 was used for a carer of patients in the moderate and severe health states up to age 18. The estimate was based on EQ-5D data for parental caregivers of children with activity limitations. ¹⁵	The committee noted that, because of the genetic nature of XLH, many adults with the condition will often be carers for other affected family members. The ERG noted that the company's approach of using a published disutility value was broadly reasonable, but the committee questioned the appropriateness of the disutility value. The committee concluded that it was important to consider carer burden in its assessment of burosumab, adding it would consider results including a quantitative estimate of carer burden. However, because the estimate provided was not robust, the committee would also consider the burden qualitatively.

^a Assessment Group provided two versions of the model. EDSS = Expanded Disability Status Scale; ERG = evidence review group; GA = glatiramer acetate; HST = highly specialised technology; IFN β-1a = interferon beta-1a; MS = multiple sclerosis; MTA = multiple technology appraisal; NHS = National Health Service; PSS = personal social services; RRMS = relapsing-remitting multiple sclerosis; STA = single technology appraisal; XLH = X-linked hypophosphatemia.

Table 3. Carer Disutility Values Used in NICE TA Submissions for MS^a

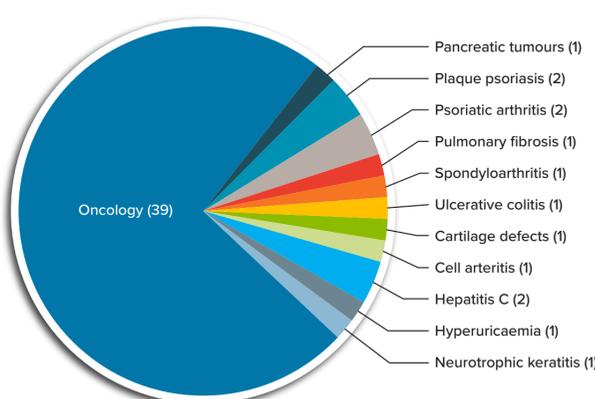
EDSS State	Approach Based on Acaster et al. ¹²		Approach Based on NICE TA127 ¹¹
	TA527 Merck Submission	TA527 Teva Submission and the Assessment Group Model	TA527 Biogen Submission ^b and TA533
0	0.002	0.002	0
1	0.002	0.002	0.001
2	0.045	0.002	0.003
3	0.045	0.002	0.009
4	0.142	0.045	0.009
5	0.160	0.142	0.020
6	0.173	0.167	0.027
7	0.030	0.063	0.053
8	0.095	0.095	0.107
9	0	0.095	0.140

^a In HST8,¹⁴ a disutility estimate of 0.08 was used for the carers of the patients in the moderate and severe health states up to age 18.

^b Used for the carers of both patients with RRMS and patients with secondary progressive MS.

- All 3 appraisals used values based on the literature:
 - In the TAs, which considered MS, the values were based on EQ-5D data for 200 caregivers and matched controls¹² or estimates for caregivers of people with Alzheimer's disease used in TA127 (referenced to TA111) (Table 3).¹¹
 - In the HST, which considered a rare disease causing significant skeletal deformities in children and lifelong disability and pain, the carer disutility values were based on EQ-5D data for parental caregivers of children with a limitation in school, play, or social activities.¹⁵
- In 2 of the 55 appraisals that did not include carer and/or family member utilities, the ERG and/or appraisal committee (AC) explicitly stated their preference for their inclusion.
 - TA534¹⁶: Stakeholders commented that the effect of moderate to severe atopic dermatitis on the QOL of families and carers should be taken into account. The AC acknowledged that there could be an effect on the QOL of families and carers, but there is a lack of evidence to support this.
 - HST7¹⁷: Patient experts stated that caring for someone who has immune deficiency affects all aspects of life for a carer and that improvements to the QOL of the carer occurred immediately after a successful treatment. The company included a scenario analysis including a disutility associated with bereavement after the death of a child, but the AC considered that this would not fully reflect the QOL benefit to carers after successful treatment. The AC acknowledged that a specific value could not be identified and concluded that improvements to carer-related QOL should be qualitatively taken into consideration in the committee's decision making.
- Of the 53 appraisals that have neither included nor commented on the inclusion of carer/family member disutilities, the majority were in oncology (39), followed by hepatitis C, plaque psoriasis, and psoriatic arthritis (2 each) (Figure 1).

Figure 1. Distribution of NICE TAs That Have Not Included/Commented on the Inclusion of Carer or Family Member Disutility Values (by Indication)



DISCUSSION

- Many health conditions have profound impacts on the QOL of informal carers and family members that may be alleviated by effective treatment. However, the inclusion of these benefits in economic evaluations is hindered by uncertainty about decision makers' attitudes toward their inclusion, issues related to how they may be incorporated into economic models, and the availability of suitable utility measures for carers/family members.
- As outlined in Table 1, HTA agencies (including NICE) generally encourage the inclusion of carer/family member QOL in economic evaluations when relevant. However, carer/family member QOL was captured in only 3 of 58 NICE appraisals published in 2018.
- Measurement of carer utility is challenging. Although generic PBMs such as EQ-5D have been used to measure carer utility, such instruments were not designed and may be inadequate for this purpose.^{18,19} Several QOL instruments are available for carers (e.g., Carer Experience Scale [CES]; Care-related Quality of Life [CarerQoL] instrument²⁰). However, these presently cannot be used to estimate utility weights (on a scale where 1 = full health and 0 = dead).
- Direct measurement (asking carers to value their current QOL using a preference-based method such as time trade-off or standard gamble) is likely to be impractical as the primary approach in most situations, and the results would reflect the preferences of carers rather than those of the general population (as required by most decision makers). Vignette valuation studies provide a possible solution given the lack of alternatives; however, their use comes with recognized limitations.²¹ The Extended QALY (E-QALY) measure (currently under development) may address this gap.^{22,23}
- Improving methods for estimating carer and family effects has been highlighted as an important area of future research by the second United States Panel on Cost-effectiveness²⁴ and others.²⁵ This gap in the availability of utility measures is a significant limitation to the inclusion of spillover effects for carers and family members in economic evaluations.

CONCLUSIONS

- Although the inclusion of carer and/or family member utility values is encouraged by some HTA authorities such as NICE, the evidence in recent appraisals suggests that there is still a lag in the practice for their inclusion in economic evaluations submitted for reimbursement. Therefore, it is likely that many appraisals fail to capture all benefits of the treatments being evaluated.

REFERENCES

See handout for references.

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