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Preference-Based Assessments

The Feasibility and Validity of Preference-Based Quality of Life Measures With Informal Carers: A Think-Aloud Study



Carol McLoughlin, PhD, Ilias Goranitis, PhD, Hareth Al-Janabi, PhD

ABSTRACT

Objectives: A range of preference-based quality of life (QoL) measures have been proposed for use with informal carers. Qualitative evaluation of validity and feasibility of the measures is an important step in understanding whether measures will work as intended. At present, little is known about the performance of different types of preference-based QoL measures with informal carers. The objective of this study was to qualitatively assess the feasibility, content validity (including face validity), and acceptability of 5 QoL measures (the Carer Experience Scale, CarerQoL-7D, ASCOT-C, ICECAP-A, and EQ-5D-5L) with informal carers.

Methods: A total of 24 “think-aloud” interviews were conducted with a cross-section of carers of adults in the United Kingdom. This think-aloud process was followed by semistructured discussion to probe issues of validity and feasibility in more detail. The interview data were transcribed, coded to identify the frequency of errors in completing the QoL measures and thematically analyzed to study the validity, feasibility, and acceptability of the measures.

Results: Few errors (3%-7% per item) were identified in completing each of the measures with little distinct pattern. Most participants found the measures to be concise, clear, and relevant. Challenges included relevance, context, time period, missing items, multiple questions, and response options. Informal carers generally expressed a preference for using a care-related QoL measure.

Conclusions: Existing preference-based QoL measures have encouraging validity and feasibility within a mixed sample of informal carers, with minor challenges raised. These challenges ought to be considered, alongside the decision context, when administering QoL measures in this context.

Keywords: cognitive interview, content validity, informal care, mental health, outcome measurement, qualitative research.

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Introduction

The measurement of informal carer quality of life (QoL) in economic evaluation is important in assessing the value of health and social care interventions.^{1,2} Inclusion of informal care (also referred to as unpaid/family care or caregiving) is highlighted in a number of health technology assessment guidelines.³ A range of preference-based QoL measures have been proposed for use with carers,⁴ focusing on different concepts, including “health-related” QoL (HRQoL), “care-related” QoL (CRQoL), and “general” QoL (GQoL) or wellbeing. At present, little is known about the relative performance (ie, validity and feasibility) of preference-based QoL measures with these different conceptual foundations.

HRQoL is a concept that has been applied in different ways,⁵ with most measures focusing on physical functioning (eg, pain and mobility) and to a lesser extent mental functioning. The EQ-5D, a commonly used HRQoL measure with patients, is also used to measure carer spillovers effects⁴ and value carer outcomes within economic evaluation.⁶ HRQoL measures have the

advantage of consistency with patient outcomes (enabling the aggregation of outcomes from an intervention across both patients and carers). They are also consistent with using an economic evaluation to inform health-maximizing resource allocation decisions. However, HRQoL measures were often developed with patients rather than carers in mind⁷ and do not focus on attributes relevant to the caring role, which might impact on informal carer's QoL.⁷

CRQoL tools measure the experience and impact of caring and emphasize aspects of caring, such as relationship quality, fulfillment, and control.⁷ CRQoL outcomes can be used in cost-consequence analyses and for cost-utility analysis of carer interventions. In the latter case, although CRQoL states are not directly valued on the 0 (death) to 1 full QoL scale outcomes can be weighted to generate scores on the same numerical scale.^{8,9} General QoL instruments measure QoL in a broader sense (rather than focusing on health- or care-related aspects) and include aspects such as relationships, stability, and enjoyment. GQoL measures such as the ICECAP instruments (which measure

capability to achieve key functionings in life) can be used in studies where there is an interest in measuring the impact of interventions on QoL or wellbeing in a broader sense.¹⁰

There is an emerging quantitative literature on the validity of different preference-based QoL tools with informal carers, with studies of HRQoL measures conducted with carers in dementia, autism, stroke, rheumatoid arthritis, mental health, and long-term disability.¹¹⁻¹³ Studies of validity of CRQoL measures and GQoL measures with carers have been conducted in end of life,¹⁴ general population samples,¹⁵⁻¹⁷ and dementia.¹⁸ This body of research indicates encouraging construct validity but limited evidence to support the responsiveness of preference-based QoL measures with carers.

To date, there is a smaller *qualitative* literature on the validity of QoL measures with informal carers, with qualitative studies of validity mainly limited to carers of people with dementia.^{19,20} Qualitative studies enable an in-depth exploration into how and why respondents arrive at their answer when completing a QoL measure, allowing for aspects such as content validity, face validity, feasibility, and acceptability to be investigated; therefore, researchers can be confident that measures are capturing what they are intending to capture.²¹ The aim of the present study was to qualitatively assess the feasibility, content validity, and face validity of CRQoL, HRQoL, and GQoL measures with family (informal) carers.

Methods

Concurrent cognitive (think-aloud) interviews, with a semi-structured follow-up discussion,^{22,23} were used to assess the

measures. Cognitive interviewing enables an in-depth exploration into the process respondents use to arrive at their answer when completing the measures, providing insights into the feasibility of completing the measures and aspects of content validity.²⁴⁻²⁶ The semistructured follow-up discussion was used to further probe aspects of content (including face) validity, and feasibility. When assessing content validity for QoL measures, the goal is to ascertain if the items of each measure are relevant and important²⁷ to the respondents and to gauge whether there are additional areas of interest that are not covered in the existing measure.²⁷ Furthermore, assessment of content validity can provide evidence “that the conceptual framework, content of items and overall measurement approach are consistent” (p.1263, Brod et al²¹). Face validity looks at whether a measure appears to be valid and acceptable to users.²⁸ When assessing face validity for QoL measures, the goal is to ascertain if the dimensions of a measure are comprehensive and if they adequately reflect the perspective for the population of interest. The feasibility of a QoL measure can also be described as the measure’s ease of completion.^{29,30} It provides evidence that the measure is practically usable in the relevant context. Face validity can be thought of as a nested concept within content validity.³¹

Five instruments were included in the study (see Table 1³²⁻³⁶). Three CRQoL measures were selected as there had been no head-to-head comparison of the available measures across multiple conditions. The EQ-5D and the ICECAP-A were selected as prominent examples of a HRQoL measure and generic preference-based measure of wellbeing. This approach mirrored earlier work on the validity and responsiveness of the 5 instruments.¹³

Table 1. Measures of QoL used in this study.

Measure	Conceptual basis	Items
Carer Experience Scale (CES) ³²	Care-related QoL	Activities outside caring Support from family and friends Assistance from organizations and the government Fulfillment from caring Control over caring Getting on with person you care for
CarerQoL-7D ³³	Care-related QoL	Physical problems Having support Financial problems Daily activities Mental health problem Relational problems Having fulfillment
Ascot-carer ³⁴	Care-related QoL	Occupation Control over daily life Looking after yourself Personal safety Social participation Space and time to be yourself Feeling supported and encouraged
EQ-5D-5L ³⁵	Health-related QoL	Mobility Self-care Usual activities Pain/discomfort Anxiety/depression
ICECAP-A ³⁶	General QoL (capability wellbeing)	Stability Attachment Autonomy Achievement Enjoyment

CES indicates Carer Experience Scale; QoL, quality of life.

Table 2. Topic guide for the semistructured portion of the interview.

Topic	Stem question(s)
Face validity	Do the questionnaires reflect the way caring impacts on your life?
Content validity	Are there any aspects of caring that impact on your life that weren't covered in the questionnaires?
Feasibility	How clear did you find the instructions? How did you find how the questions were phrased? Were the response options available appropriate? Were there any questions you found difficult to answer for any reason?
Acceptability	Which is your preferred measure and why?

Sampling

Participants were identified through earlier survey and focus group work with informal carers.^{13,37} The focus of this work was predominantly with adult informal carers of adults with dementia, stroke, or mental health conditions. Within the sample frame of carers expressing a willingness to be contacted for follow-up research, a purposive sampling strategy^{38,39} was used to ensure carers in a range of circumstances across clinical areas were recruited. Participants were sampled to generate diversity in relation to recipient condition (dementia, stroke, and mental health condition), relationship to the care recipient (spouse, parent, and adult child), gender, age, rural/urban area of residence, length of time in the caring role, and level of burden as indicated by the number of hours per week spent providing care. Each participant who met the sampling criteria was sent an invitation to participate in this study, along with an information sheet and consent form (by email or post). Participants were then contacted by telephone to confirm an interview location and date. We sought to recruit approximately 25 participants, based on sample sizes used in previous studies with similar aims, to investigate how people complete different QoL measures.^{40,41} The final sample size was informed by thematic saturation as judged by analysis of field notes (ie, extensive repetition of similar findings).

Interview Conduct and Data Collection

To minimize burden, each participant was given 3 of the 5 QoL measures in a random order and were asked to verbalize their thoughts on each QoL measure without interference from the interviewer (CM).^{25,42} The interviewer was undertaking this study as part of a PhD and did not know the participants. Field notes were written to reflect on the process and aid interview conduct.

Face-to-face interviews took place over a 6-month period between May and October 2018 at a location convenient to participants (participants home, a university room, or a neutral venue of the participants' choice). To help participants familiarize themselves with the think-aloud techniques, a warm-up "window-counting" task was initially completed. Participants were not interrupted unless they paused for a few seconds at which point the researcher asked them to keep thinking aloud. Semi-structured probes were then used to explore participant's views on the validity and feasibility of the QoL measures²¹ (Table 2). All interviews were digitally recorded and transcribed verbatim.

The cognitive interview process was piloted with 3 members of a lived experience advisory panel.⁴³ This included individuals who had experience of caring for people with stroke, dementia, or mental health problems. Panel members were asked to complete a think-aloud warm-up exercise and 3 QoL measures, followed by a

clarifying discussion and semistructured interview and feedback session.

Data Analysis

The think-aloud portion of the interview was coded to reflect whether each item response on each measure resulted in an error or struggle. Four categories of error/struggle were identified in general comprehension (understanding of question); temporal comprehension (appropriate time period considered); decision process (relevant decision about question); and response process (maps desired response to question without error).^{44,45} A representative sample of 6 think-aloud interviews were initially coded by the 3 authors. Final error coding was based on consensus and discussion of any discrepancies.

A thematic analysis of the semistructured follow-up discussions was used to derive themes related to content validity (including face validity) and feasibility of the 5 QoL measures completed by participants. "Open" codes were developed to reflect how the emerging results related to the research questions in a way most closely related to grounded theory. Following independent open coding of a subset of transcripts by 2 raters, discussion among the research team, and close reading of the remaining transcript and field notes, a formal (axial) coding framework⁴⁶ was developed. The axial coding framework organized open codes in a structured way underneath psychometric concepts. Coded material was synthesized through a descriptive account juxtaposing quotes from multiple interviews under common codes. An explanatory account was then created to structure the data by theme. The trustworthiness of the thematic analysis was supported by a clear audit trail through coded transcripts, descriptive accounts and an explanatory account, regular team discussions on coding, field notes, and the use of direct quotes. In the explanatory account, the data were structured by the themes,⁴⁷ and "patterns of association"⁴⁶ were developed to explain how participants felt the measures captured their QoL issues. These themes were broader and more interpretive than the categories and subcategories, and they were linked with the psychometric concepts under investigation. Data management was undertaken using NVivo 12 qualitative data management software. The study was reviewed and approved by University's ethical review committee (14-1444) and the NHS Health Research Authority (IRAS 206161).

Results

In total, 24 interviews were conducted with 15 female and 9 male informal carers. 10 participants were caring for a parent, 8 were providing care for their adult child, and 6 were caring for a spouse (Table 3).

Think-Aloud Analysis

The items of each measure were completed without error the majority of the time. Error rates ranged from 3.3% (2 errors on 60 segments [a segment is generated when each participant completes an item]) on the EQ-5D-5L through to 6.7% (4 errors on 60 segments) on the ICECAP-A (Table 4). Overall, from 440 segments, there were 2 comprehension errors, 4 temporal errors, 5 decision errors, 12 response errors, and 9 segments categorized as a struggle.

There were 3 items where multiple respondents made an error. On the CES fulfillment item, 3 decision errors were made, with these participants seemingly giving a socially desirable answer (Table 5). On the EQ-5D-5L pain item, 2 temporal errors were recorded, with participants basing their answer on a general time frame, or the “bigger picture,” rather than the present moment. Similarly, in the CarerQoL-7D, 2 participants made a response error on the support item. Participants also verbalized their frustration with the limited number of response options available.

Semi-Structured Interview Findings: Content Validity

Following analysis of the semistructured follow-up discussions, 4 themes were developed to explain the overlapping challenges raised by respondents in relation to content validity. These themes were: “relevance,” “context,” “capturing a moment in time,” and “missing items.” Table 6 reports challenges raised in relation to specific measures.

Most participants did not raise any concerns about whether items in the measure were relevant, although some felt the brevity

of the measures meant they were lacking in nuance. Some participants struggled to see the relevance of particular items and the focus of the questionnaire being on them and how they have adapted to their role as a carer:

It's more geared to someone who's the primary carer whereas I realize that the situation I'm in, I mean I queried that specifically when I was approached in the first place. (Filial carer, dementia).

Several participants expressed their desire to provide context to the answer they gave when completing the measures. This would allow them to elaborate on their answers and provide personal experiences to enrich the meaning of the questions:

I've been through so much and you can't put it in one question, do you know what I mean? (Filial carer, dementia)

Each of the measures completed by participants asked them to think of their “current situation” when selecting their answer. Most participants were able to do this. However, some participants struggled with this instruction. They commented on the variability inherent in providing care and how it is difficult to measure the fluctuations:

What actually fits on this week might not fit next week. There's quite a variation. (Parent carer, mental health)

Some participants also commented that answering the measures based on the current situation did not allow them to provide an answer that covered their overall experience of caring. Additionally, some participants selected their answer based on a past moment in time or their historical experience of caring.

Most participants felt the measures were comprehensive, and no major factors related to caring and their QoL were missing. However, some issues were raised, with one carer highlighting the need to assess how they engage with the care recipient's services:

... the integration between your role as a carer and the professional services that the person is receiving...one of the worst aspects is the lack of communication. (Filial carer, dementia).

Another participant talked about how guilt can be attached to the caring role and how none of the questions focused on what the participant has done to improve the care recipient's situation, instead focusing on the assumption that the care recipient's condition was worsening. Two participants who had noted the importance of financial impacts on their QoL commented on the lack of items relating to finance in the measures.

Semistructured Interview Findings: Feasibility and Acceptability

The participants' views on the feasibility of each measure is described below under the themes of format and clarity, multiple questions, and response options. The section finishes by reporting the participants' preferred measure.

None of the participants had any issues with the length of the measures and, indeed, 1 participant compared them favorably with the “30-page forms” they routinely needed to complete. Most participants found the instructions given for each measure to be clear and did not have any problems with the instructions. Some participants had language issues with specific items on individual questionnaires (Table 6). Although 1 or 2 participants pointed out the need for more clarity, most participants found the language used in the measures clear and easy to understand:

Table 3. Characteristics of the sample (N = 24).

Participant characteristics		n (%)
Location	South England	4 (18)
	Midlands	9 (37)
	North England	9 (37)
	Scotland	2 (8)
Sex	Male	9 (38)
	Female	15 (62)
Highest level of education	Not known	3 (12)
	GCSE (or equivalent)	6 (25)
	A-Level	4 (17)
	Degree	11 (46)
Years caring	Not known	5 (21)
	<10	11 (46)
	11-20	3 (12)
	>20	5 (21)
Lives with care recipient	Yes	12 (50)
	No	12 (50)
Care recipient condition	Dementia	7 (29)
	Mental health condition	6 (25)
	Stroke	2 (8)
	Other	9 (38)
Carer – recipient relationship	Parent – (adult) child	8 (33)
	Spouse - spouse	6 (25)
	(Adult) Child - parent	10 (42)

GCSE indicates General Certificate of Secondary Education.

Table 4. Number of errors and struggles per measure.

Measure	Item	Judged problems				Struggles
		Comprehension	Temporal	Decision	Response	
CES n = 16 error rate = 6.3%	Activities outside caring	0	0	0	1	0
	Support from friends & family	0	0	0	0	1
	Assistance from orgs & government	0	0	0	1	2
	Fulfillment from caring	0	0	3	0	0
	Control over caring	1	0	0	0	0
	Getting on with the person you care for	0	0	0	0	0
CarerQoL-7D n = 16 error rate = 5.4%	Problems with combining care tasks with daily activities	0	0	0	1	0
	Support with carrying out care tasks, as needed	0	0	0	2	1
	Fulfillment from carrying out care tasks	0	0	1	0	0
	Relational problems with the care receiver	0	1	0	0	0
	Problems with physical health	0	0	0	0	0
	Problems with mental health	0	0	0	1	0
	Financial problems due to care tasks	0	0	0	0	0
ASCOT- Carer n = 16 error rate = 4.5%	Occupation in valuable or enjoyable activities	0	0	0	0	1
	Space and time to be yourself	0	0	0	0	1
	Feeling supported and encouraged	0	0	0	1	1
	Control over daily life	0	0	0	1	0
	Social contact with people you like	0	0	0	1	0
	How well you look after yourself	0	1	0	0	0
	How safe you feel	1	0	0	0	0
EQ-5D-5L n = 12 error rate = 3.3%	Usual activities	0	0	0	0	0
	Pain/discomfort	0	2	0	0	0
	Mobility	0	0	0	0	1
	Anxiety/depression	0	0	0	0	0
	Self-care	0	0	0	0	0
ICECAP-A n = 12 error rate = 6.7%	Love, friendship, and support	0	0	0	1	1
	Enjoyment and pleasure	0	0	0	1	0
	Being independent	0	0	1	0	0
	Feeling settled and secure	0	0	0	1	0
	Achievement and progress	0	0	0	0	0

Note: n = 12 for ICECAP-A and EQ-5D-5L because these were used in alternating interviews, whereas the CES, CarerQoL-7D, and ASCOT-Carer were used in n = 16 interviews.

CES indicates Carer Experience Scale.

I like the fact that they're very ordinary words and they're not laden with technicality... there aren't any language barriers in that respect. (Filial carer, dementia).

Although participants did not find the wording challenging in general, some participants were confused by items that asked about >1 concept in a single question. This challenge occurred across a number of the measures (Table 6).

Most participants found the response options available in the measures to be appropriate. However, others struggled to select an answer from the given options. Conversely some participants thought the response options were too similar to choose between them. Participants discussed the importance of providing context to their answers or picking different options at different moments in time (see earlier sections).

When asked directly which of the measures they preferred, 7 participants (29%) indicated that they felt the ASCOT-Carer measure best captured their QoL as a carer, 6 (25%) indicated the CES, and 3 (13%) indicated the CarerQoL-7D. These measures were all presented 16 times during the interviews. Participants often justified their preferred measure in terms of it being the most comprehensive (see Table 6 for specific comments about individual measures). No participant chose the EQ-5D-5L (from the 12 times it was presented) and 1 participant chose the ICECAP-A (from the 12 times it was presented), because a bereavement

meant they found it difficult to answer questions directly related to their caring role. Five participants could not choose between the measures they completed or they had no preference.

Discussion

This study investigated how a range of preference-based QoL measures performed with informal carers, using qualitative methods to study aspects of content (including face) validity, as well as feasibility and acceptability. In terms of feasibility, the error rate on the think-aloud exercise ranged from 3.3% to 6.7%, with infrequent challenges in relation to the understanding of certain terms, the time frame, and the number of response options. In terms of content validity, the measures were generally perceived to be relevant and sample an appropriate set of items, with a desire to add context and ensure relevance of items for some carers.

Overall, the results showed the 5 QoL measures to be relevant and feasible to most participants. This may be because the QoL measures had either qualitative work built into their development (as with the CES, ICECAP-A, and ASCOT-Carer) or had been extensively tested since development. Error rates were in line with think-aloud studies using similar measures,⁴⁸ and there were few obvious trends across the measures. For the EQ-5D, challenges were raised in terms of the relevance of usual activities, self-care

Table 5. Example quotes relating to think-aloud errors.

Measure	General comprehension	Temporal comprehension	Decision process	Response process
Carer Experience Scale	<i>That I'm coping. That I'm not at the stage where I can't cope. Sometimes I feel I can't cope.</i> (Spouse carer, "control" item)		<i>Obviously, I suppose I have to say I do because he is my son.</i> (Father, CES "fulfilment" item)	<i>I can do few of the other things I want to do. The demands of the cared for are quite high.</i> (Parent carer, "activities outside caring" item [selected "some"])
CarerQoL		<i>... the big picture. Sometimes it's ok, and sometimes it's not ok.</i> (Parent carer, "relational problems" item)		<i>No to most of it, just the stress caused by this everlasting trying to cut back. So, do I put in there no and ring stress? I think I will because I don't really have a mental health problem, but stress can get bad.</i> (Parent carer, "mental health" item [selected "no"])
ASCOT-Carer	<i>Well, I did have a break in in the house last year which shook me a bit, no I feel as safe as I want, I mean it was just a one off.</i> (Parent carer, "safety" item)	<i>I was hospitalized last year you know.</i> (Filial carer, "self-care" item)		<i>I feel that I have adequate social contact with people. It varies between "adequate" and "I would like more."</i> (Parent carer, "social contact" item [selected "some" and "adequate"])
ICECAP-A				<i>I think that's most on this one.</i> (Filial carer, "feeling settled and secure" item [selected "none"]) <i>I'm able to be independent in many things. Yes, I can run the car, I can go shopping, this sort of thing... Yes, quite a few things. So, I'm able to be independent in a few things.</i> (Spouse carer, "being independent" item, selected "I am able to be independent in a few things")
EQ-5D-5L		<i>I'm going to go with moderate, just depends.</i> (Parent carer, "pain/discomfort" item) <i>I bashed my knee, does that count? It's a temporary slight pain. Generally, no.</i> (Filial carer, "pain/discomfort" item)		

CES indicates Carer Experience Scale.

and mobility and the measure was not selected as the preferred measure. In contrast, challenges related to CRQoL measures included the language in some terms (such as assistance or relationships) and the formatting of the measures. Furthermore, the CRQoL measures were regularly selected as the preferred measure.

Some issues raised during the work are relevant to preference-based quality of life measures more generally (and their use with patients and members of public). These include challenges relating to the time frame, missing items, double (composite)

questions, and number of response options that were raised during the interviews. Indeed, the challenge of composite questions is consistent with findings of other think-aloud work^{19,24} and an inherent difficulty in assessing a complex concept in a brief set of items.

Some challenges may be more likely to occur when using preference-based QoL measures with carers. This includes a feeling that participants wanted to provide context to the answers, given the interpersonal dynamic of the caring role, and that items

Table 6. Quotes illustrating measure-specific issues related to content validity, face validity, feasibility, and acceptability.

Measure	Feasibility	Face/content validity	Acceptability
Carer Experience Scale	Issues raised included multiple concepts (1) and language (2). (1) <i>Assistance from organizations and the government, oh that's a nasty one. Organizations like where she goes now, we get lots of support. Lots and lots of support. The government help, yes, but the council help absolutely no. How can I answer that when some are excellent, and some are rubbish?</i> (Parental carer, bone disease) (2) ... <i>the government, does that mean the NHS? Define your terms, organizations...Alzheimer's? Government, social services?</i> (Filial carer, dementia)	Issues raised included relevance (7) ... <i>because he's my son it doesn't sound right fulfilment. if he was a three-year-old ... and you'd seen him learning to read a book... and you'd done it with him ... you would get some fulfilment from that wouldn't you. But at 32 and 33 years of age ... it's not the same ... if anything it's only gone worse not easier. And I'm not sure fulfilment is the right word.</i> (Parent carer, learning difficulties)	Chosen as preferred measure by 6/16 participants ... <i>rather than like social contact and having support or leisure time, it's actually having control over what I do</i> (Spouse carer, brain disease)
CarerQoL	Issues raised included instructions (3), language (4), and response options (3) <i>Certainly, your expansions with italics are useful because it is helping someone think about what does it really mean.</i> (Filial carer, dementia) (4) ... <i>that's all negative isn't it. Relational problems with the care receiver, he/she is very demanding, he/she behaves differently, we have communication problems.</i> (Parent carer, mental health condition)	Issues raised included timeframe (8) and missing items (9) (8) ... <i>now what do I put here, you know what opportunity cost is don't you? And that's high but I don't have financial problems yet and this is supposed to be a current.</i> (Filial carer, dementia) (9) <i>Well, I don't know. Were you particularly interested in where the support was from? You asked about friends, families, neighbors, and acquaintances but you didn't ask about the authorities. You haven't asked about the statutory bodies.</i> (Parent carer, mental health condition)	Chosen as preferred measure by 3/16 participants ... <i>it's getting down to the nitty gritty realism</i> (Filial carer, dementia)
ASCOT-Carer	Issues raised included response options and multiple concepts (5) (5) <i>What I'm hesitating over with the feeling supported and encouraged is I'm not sure where that might come from. ... within the family, definitely not enough... I am quite well supported... by the care home ... from the health service ... almost none, the family doctor's fantastic when you can get hold of them, ...that's what I'm hesitating over with that one.</i> (Daughter carer, dementia)		Chosen as preferred measure by 7/16 participants ... <i>it encourages me to express what's going on in my head</i> (Filial carer, dementia)
ICECAP-A	Issues raised included multiple concepts (6) and language. (6) <i>I would not have linked those 3 together personally because very often support does not come with friendship or love. I mean I think I can have quite a lot of love, but not necessarily so much of the other. So, I'm not quite sure where to put my tick.</i> (Parent carer, bone disease)	Issues raised included relevance (10) (10) <i>I never envisaged my lifestyle would be picking someone off the floor, feeding them, trying to keep them clean and all the rest of it, it goes with caring.... So...achievement and progress well, it's sort of fairly irrelevant I think, it's just a case of struggling by from day to day.</i> (Spouse carer, brain disease).	Chosen as preferred measure by 1/12 participants

continued on next page

Table 6. Continued

Measure	Feasibility	Face/content validity	Acceptability
EQ-5D-5L		<p>Issues raised included relevance (11,12)</p> <p>(11) ...see usual activities... I've never had usual activities in the way most people would who have a normal child and whose child has grown that's 45...they're visiting children, grandchildren, but we don't have ... the same as everybody else...It's not really relevant. (Parent carer, bone disease)</p> <p>(12) I mean there might come a time when some of these things are relevant, self-care and mobility. (Parent carer, bone disease)</p>	Chosen as preferred measure by 0/12 participants

relevant to some participants might not be relevant to others. For example, carers may see HRQoL items as less relevant to evaluating their lives than patients' lives. Furthermore, carers in primary and secondary caring roles face different challenges,⁴⁹ and this may affect the perceived relevance of some CRQoL items. These are issues that should be considered when administering these measures and designing measures in the future. Overall, there was a clear preference (when pushed) for the CRQoL measures, which various participants mentioned as capturing different information to that captured by the EQ-5D-5L and ICECAP-A, engaging them as a carer, and looking at the real issues for carers.

Given the relatively low error rate overall, researchers can be confident that carers will generally find the measures relatively easy to complete, clear, and relevant in research studies. The decision to use a particular instrument for carer outcomes within economic evaluation will be dictated by a number of considerations in addition to the evidence on the validity of the tools. A HRQoL measure such as the EQ-5D-5L may be preferred if the focus of the decision maker is on generating evidence about health effects or the HRQoL measure is already used for patients in the study, thus making it simple to sum patient and carer outcomes and estimate quality-adjusted life-years (QALYs). Although our findings suggest the EQ-5D-5L is largely completed without problems, quantitative evidence suggests the EQ-5D-5L may be less sensitive than measures based on GQoL or CRQoL.¹³ This leads to a concern that the sole use of a HRQoL measure may "miss" key aspects of the value of an intervention, such as psychosocial and relational benefits.

The use of CRQoL measures in economic evaluation brings both opportunities and challenges. CRQoL measures are likely to be of particular relevance in settings where decision makers are open to considering nonhealth effects of interventions. Researchers could potentially use a CRQoL measure alongside an HRQoL measure for the carer. This is unlikely to create much additional burden for the carer because the decision has been made already to collect data, and CRQoL measures are brief relative to other survey methods. A greater challenge is how to present and use the CRQoL data. One option is to present the CRQoL outcomes alongside the HRQoL outcomes (for both carer and patient) in a disaggregated cost-consequence analysis.⁵⁰ Another option would be to use the CRQoL data alongside an exchange rate to generate QALY-equivalent data^{8,9} and use these as methodological sensitivity analyses in the economic evaluation. This method would enable CRQoL outcomes for carers to potentially be aggregated with

HRQoL outcomes for patients and show, for example, how the cost-effectiveness of the technology changes when a CRQoL measure replaces a HRQoL for carers. A third option is to use CRQoL as the measure of outcome for carers either in an economic evaluation of a health technology for carers⁵¹ or to capture the spillover.² This would entail a different "evaluation identity" for carers compared with patients within economic evaluation.⁷ The approach to including CRQoL data in the economic evaluation would depend on a range of factors, including the objectives and guidance from the decision maker³ and the importance of carer effects in the specific context.

In this study of validity and feasibility of 5 measures with carers, there are some limitations worth highlighting. Some participants (n = 16, 66%) who completed the cognitive interviews had already completed the 5 QoL measures twice through earlier survey work with informal carers.¹³ This means that each of these participants had some level of familiarity with the outcome measures. Also, the informal carers were initially identified by NatCen in 2016. As such, the sample (interviewed 2 years later) did not include carers who are relatively new to the role nor in some caring roles that might affect carers lives differently. Finally, some elements of content validity, such as whether the experiences of caring were reflected in the measure, were not fully explored. Future studies in this area could build upon patient-reported outcomes guidelines^{31,52} for wording and conceptualizing this issue.

Establishing the validity and acceptability of an outcome measure is an ongoing process.²⁷ Different findings, for example, in relation to which items of QoL are considered important, may be generated in relation to informal care for children or for people with more physically disabling conditions. However, rather than exclusively focusing on psychometric evidence, a future priority is to identify and address barriers to including carer quality of life outcomes more routinely in evaluative research. This may include, for example, how to: (1) collect carer outcome data in trials and registries,⁵³ (2) better identify carers,^{54,55} (3) generate estimates of spillovers in carers and family networks from limited QoL data,^{56,57} and (4) present carer outcomes alongside patient outcomes for different decision-making contexts.

In conclusion, existing preference-based QoL measures appear to have encouraging content validity and feasibility within a mixed sample of informal carers. Minor challenges were raised, which ought to be considered when administering, designing, and refining preference-based QoL measures in this context.

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