**Author’s response to reviews**

**Title:** Functional health state description and valuation by people aged 65 and over; a pilot study

**Authors:**

Riaan Botes (r791970@hotmail.com)

Karin Vermeuelen (k.m.vermeulen@umcg.nl)

Adelita Ranchor (a.v.ranchor@umcg.nl)

Erik Buskens (e.buskens@umcg.nl)

**Version:** 2  **Date:** 02 Oct 2017

**Author’s response to reviews:**

Reviewer reports:

Paul Kind (Reviewer 1): Functional health state description and valuation by people aged 65 and over; a pilot study

My thanks to the authors for taking previous comments into account and I appreciate that they have made some efforts to respond to them. However, there remain some critical elements that still need attention.

1. Distinguishing QoL HrQoL and capabilities

It would be really much better if the introductory section of the manuscript avoided reference to what is/isn't meant by capabilities, HrQoL or anything else. You would be strictly speaking rather more accurate if you acknowledged that there is some uncertainty about how to identify/describe/value the benefits of health/social care interventions in the elderly - especially when it comes to economic evaluation. The opening statement is fine in that respect. Leave out the window-dressing though.

Authors’ response:

The authors appreciate the feedback of Professor Kind and have attempted to address the critical issues identified in the subsequent comments. We performed an extensive rewrite of the issues identified and, where possible, we have provided explanations for our reasoning and attempted to clarify or correct unsatisfactory statements.
The corrections and references to lines in the rebuttal relate to the corrected, clean version of the paper.

The references in the rebuttal do not correspond with the references in the manuscript, since the rebuttal do not include the complete text and the referencing software assigns new reference numbers.

Regarding the concerns as stated in point number 1, we removed some of the text relating to extensive descriptions and included statements to clarify the reason for the study. We subsequently removed the following text.

Also, specific interventions like physiotherapy, home care and personal care workers have been shown to positively influence health related domains of the EQ-5D and wellbeing dimensions of the ICECAP-O questionnaires.

The opening paragraph now reads:

Aging is a progressive process of deterioration, comprising physical and mental domains. It constitutes loss of ability to maintain and function at previous levels of achievement. Moreover, aging is a personal process that includes both positive and negative experiences [1]. Quality of life (QoL) is one popular outcome measurement used in assessing the effects of aging on what people judge to be important in their lives. It is, however, a contentious subject, since some are of the opinion that i) the elderly population should generate the health descriptions and valuations relating to QoL, while others consider that ii) the general population should provide these health descriptions and valuations [2-4]. Furthermore, the methods and procedures used to determine QoL have yet to be standardized, thus raising issues of the accuracy and applicability of elderly health state descriptions and valuations [5,6].

Lines 77 - 83 remain entirely opaque. I simply do not understand the confused text here - even after several readings. Please imagine that you are describing this for the benefit of one of the subjects in your feasibility study and try again.

Authors’ response:

We removed this section of the text (Lines 77-83) to avoid confusion and increase the coherence of the text:

The capability approach advocates the idea that every individual entertains real projections about being or doing something. The two major components of this approach, functioning and capabilities, are one’s achieved doing and being (functioning) and one’s ability to achieve a certain level of functioning (capabilities). In terms of health and quality of life (QoL),
capabilities refer to functional aspirations, while functioning refers to achieved health and QoL aspirations. People, whether on an individual or social level, utilize resources to attain levels of functioning important to them.

Lines 101 - 104 belong in the discussion section. They are a statement of belief that lacks substance.

Authors’ response:

The authors reviewed the statement in line 101 -104 and decided to remove this statement completely, since there is reference to utility, resource allocation, and optimizing the benefits that is probably not within the scope of this paper.

This following part of the text was removed: Potentially, using the capability approach, either as a single measure, or together with a standard utility measure could provide a more comprehensive insight in elderly health states and their valuations. These insights could guide public policy as well as health policy makers in allocating resources, and optimising the benefits in terms of health and functioning.

Please check statement in Lines 107 - 109.

First we aim to study the feasibility of allowing elderly, from South-Africa and the Netherlands, to use both questionnaires to report on their own health and QoL. Ultimately to provide appropriate information on quality of life for use in a future study among elderly.

You are not "allowing" you are administering questionnaires

This is a feasibility study - it does not provide definitive information on QoL, it is reporting on methods.

Authors’ response:

The proposed change was adopted, and the aims of the study were adapted to try and enhance the coherence of the article.
The present pilot study aimed to determine the feasibility of two distinct components. First, our aim was to determine which of the two methods for elucidating health-state valuations would be appropriate for the elderly, that is, whether to use a visual analogue scale (VAS) or apply the Time Trade Off method (TTO).

Second, we wished to study the feasibility of administering the EQ-5D+C and a generally accepted functioning questionnaire (CAF) to elderly people both from South Africa and the Netherlands.

Line 110 - 112

Secondly to determine whether of the two methods to elucidate health state valuations, i.e., using a visual analogue scale (VAS) or applying the Time Trade Off method (TTO), would be appropriate for the elderly.

WHICH of two methods …

Authors’ response:

“Whether” was changed to “which.” Line 98

2. EQ-5D+C

EQ-5D+C is not as variously described in the manuscript

* a standard utility instrument

* a well-known and validated questionnaire

Firstly, EQ-5D can be represented in several formats - descriptively in terms of its individual dimensions or as a summary index. In this latter format responses to the EQ-5D components are scored using one of several different methods. ONE approach is to use utility weights and this type of scoring is primarily intended to provide a quality-adjustment factor when computing QALYs. It has absolutely nothing to do with HrQoL in any other context and certainly not when
it comes to measuring patient self-reported health status. I must insist that this "utility" definition is corrected.

Authors’ response:

The authors acknowledge and agree with the facts as stated above. The aim of the pilot study was to use the EQ-5D+C to describe the individual dimensions of the elderly. We have now explained in more detail that we included this questionnaire in order to investigate whether the elderly could understand and complete the questionnaire, which contains domains involving HRQoL to a large extent. More importantly, we used the EQ-5D+C to extract descriptive information regarding individual health conditions. References to the concept of utility have been removed.

Lines 76-78:

Typically, the EQ-5D describes health status in terms of health-related quality of life (HRQoL) domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression [7].

Lines 84-87:

An instrument like the EQ-5D incorporates HRQoL to a large extent into the valuation and descriptive capacity, while the capability approach incorporates non-health aspects such as attachments, role, security, control, and enjoyment, which will influence health and, ultimately, overall well-being [8,9].

Lines 116-118:

The purpose of the inclusion of these questionnaires was to extract descriptive information regarding the individual domains of the EQ-5D+C and the CAF.

Secondly, if EQ-5D+C is indeed a "validated" questionnaire then please provide some/any evidence to support this description. Furthermore, please note that there is at least one other published paper in HQLO relating to EQ-5D+C which was compared against EQ-5D in elderly people. This paper concluded both the EQ-5D and the EQ-5D+C were responsive to changes in the MMSE, with the EQ-5D performing slightly better.
Authors’ response:

The authors realize that the statement can be construed as misleading, and we therefore altered the text to indicate that the questionnaire used was an extended version of the original EQ-5D. The main motivation for utilizing this version was from Reference 22 in the manuscript.

The altered text now reads, Lines 170-178:

We used an extended version (EQ-5D+C) of the standard EQ-5D that included “cognitive functioning” as an additional attribute [10]. The standard EQ-5D classification system developed by the EuroQol Research Foundation (https://euroqol.org/) describes health status according to five attributes: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each attribute has three levels: “no problems” ("1"), “some problems” ("2"), and “severe problems” ("3"). Health state descriptions are constructed by choosing one level for each attribute (e.g., the best health state is represented by 11111). The non-standard EQ-5D+C is similar to the EQ-5D, but with a 3-level cognition attribute added, Appendix D.

Lastly, the nomenclature EQ-5D+C is mostly likely an invented one as there is absolutely no mention of it on the EQ-5D website (www.euroqol.org). I strongly urge that you contact them to ask for advice on this matter.

EQ-5D is probably better described as a generic measure of health-related quality of life with the capacity of being represented as a single index score. BTW it should be noted that the 0-100 VAS rating of self-assessed health status is an integral part of EQ-5D.

Authors’ response:

The authors realize that the EQ-5D+C is not a well-known adapted version of the EQ-5D questionnaire but nevertheless have decided to include this version of the questionnaire, since the cognition domain might be of importance to the elderly population. The main reference to this version stems from three references found in the literature (Reference 23-25).

Please see lines 178-181:

Of specific relevance to the elderly are health aspects such as vision and hearing, and in particular cognition [11] [12,13]. The addition of the cognition domain makes the EQ-5D+C of
specific importance to the elderly, since aging is to a degree associated with a decline in cognitive ability.

Please note also that references 2 and 7 are identical. One should be deleted.

Authors’ response:
Double referencing has been addressed and double-checked.

3. CAF

Whilst appreciating that this is effectively a work in progress and presumably part of PhD development I find it very concerning that it should have a pivotal role in a study (even a feasibility study) without apparent documentation regarding its provenance.

In particular I am troubled by some aspects of its design, for example, dimension 1 (Attachment) is described as

Feelings of love, affection, companionship and friendship from your partner, family, friends and pets

I find it troubling that all these sources are conflated and even designated as such.

Something needs to be said about development/testing of this questionnaire, if only to refer to other separate work relating to it.

In addition, there must be something in the manuscript relating to the (presumed) translation of the questionnaire from Dutch / Afrikaans / English ??

Authors’ response:
The authors endeavored to address the issues above with the addition of specific text relating to the conception, translation, and design of the CAF questionnaire.
The CAF questionnaire included the attachment, enjoyment, security, role, and control attributes, with five response categories possible. Inspiration for the development of the CAF came from the work performed by Grewal and colleagues [14]. They embarked on a 2-stage analysis, first, to determine factors that contribute to the quality of elderly informants’ lives and, second, to identify the attributes of quality of life. From this study, 5 attributes emerged: Attachment, Enjoyment, Security, Role, and Control. Appendix B summarizes the aspects that contribute and determine these attributes.

Coast and colleagues investigated this matter further by doing qualitative and quantitative work on these five attributes [15]. The qualitative work focused on the design of a measurement instrument, while the quantitative work focused on the validation of the measurement instrument. Ultimately, an instrument to determine the effect of health and social care interventions was presented, while mentioning the potential of the instrument in the economic evaluation of interventions [15].

The work performed by Grewal and colleagues to determine qualitative attributes important to the elderly was utilized, since these attributes fit into the theory of the capability approach [14]. An extract from the research done by the authors summarizes what was done:

“This paper reports an attempt to determine attributes for a new index clearly focusing on quality of life for older people rather than health or other influences on quality of life. In-depth interviews were conducted with 40 purposively selected informants aged 65 and over in private households to explore their views about what is important to them in terms of quality of life. Data were analysed using Framework qualitative analysis. Initial discussions tended to concentrate upon factors influencing quality of life including activities, relationships, health, wealth and surroundings. Further probing and analysis suggested five conceptual attributes: attachment, role, enjoyment, security and control.”

Subsequent literature suggests that the non-health-related attributes of attachment – enjoyment, security, role, and control – are unique and can possibly be an alternative or at least contribute to current healthcare interventions designed for the elderly [16].

The validity of a questionnaire, which includes the attachment, enjoyment, security, role, and control attributes, was also tested in a Dutch setting, with positive results [13].
The original version of the CAF questionnaire was constructed in English (Appendix C), to be utilized in South Africa, while the English version was translated into Dutch by a specialist translator and one of the authors of the paper (AR).

4. Valuation method(s)

There is a great deal of confusion in the text about the number/selection of health states used. Line 187 cites the same 10
Line 192 list 9
Line 200 cites 18 (the same as in group #1) - really?
Line 203 we are back to 10 listed states
This is a mess. It might be better handled by providing the information in tabular form.

Authors’ response:

The authors clarified the issues associated with the valuation of health states and included the following text to indicate the valuation procedure.

For the South African sample Line 212 -236:

The TTO technique required the respondents to value how much time in health state 111111 (full health) was equivalent to 10 years spent in a target state. Target states represent different levels of decline in HRQoL. Thus, a typical TTO valuation task would involve a hypothetical trade-off between length and quality of life. The TTO process, utilized in our study, provides the elderly respondents with options to choose from, rather than subjectively reasoning and cognitively determining the point of indifference. The chosen TTO exercise provided elderly respondents with a less cognitively burdensome alternative.

The target states were 112112, 212111, 111221, 212121, 133113, 212321, 333211, 323331, and 333333. Only 9 health states were valued for the TTO exercise, since health state 111111 was given as the comparison full-health state.

The VAS method requires ten health states, 111111, 112112, 212111, 111221, 212121, 133113, 212321, 333211, 323331, and 333333, rated on a visual analogue scale, typically ranging from 0
(worst off) to 100 (full health). They were asked to state which of the two techniques was the easiest to complete in terms of understanding the task that had to be completed, and also the cognitive burden of the task. Upon investigating the results from the first group, it was decided to continue only with the VAS valuations in group two and group three.

The second group was asked to value and describe ten EQ-5D+C health states using a visual analogue scale. The health states chosen were 111111, 112112, 212111, 111221, 212121, 133113, 212321, 333211, 323331, and 333333.

The third group was asked to complete the questionnaire pertaining to functioning (CAF) that they were currently achieving and also to value ten health states using a VAS: 11111, 21114, 12335, 55555, 11245, 44433, 11122, 11312, 33333, and 33544.

For the Dutch sample Line 249-255:

The elderly respondents completed the CAF and EQ-5D+C questionnaires and again three subgroups, dependent, semi-dependent, and independent respondents, completed 10 hypothetical health state valuations, for each questionnaire using a VAS.

The health states were identical to the health states that were valued in the South African pilot study. Health states 111111, 112112, 212111, 111221, 212121, 133113, 212321, 333211, 323331, and 333333 for the EQ-5D+C, while health states 11111, 21114, 12335, 55555, 11245, 44433, 11122, 11312, 33333, and 33544 were valued for the CAF questionnaire.

The so-called TTO procedure given in the Appendix is non-standard and you will need to find suitable references to justify its selection - how/why did you choose it?

TTO normally involves an interview situation in which respondents iterate through choices before reaching an indifference point. This departure from conventional TTO must be clarified for the reader.

Authors’ response:

The authors appreciate this comment and have provided the following explanation and references in Lines 209-218:
Previous studies have shown that TTO techniques place a great cognitive burden on respondents, since they require a high degree of abstract reasoning [17]. Taking this into consideration, the decision was made to utilize a simplified version of the TTO exercise [18].

The TTO technique required the respondents to value how much time in health state 111111 (full health) was equivalent to 10 years spent in a target state. Target states represent different levels of decline in HRQoL. Thus, a typical TTO valuation task would involve a hypothetical trade-off between length and quality of life. The TTO process, utilized in our study, provides the elderly respondents with options to choose from, rather than subjectively reasoning and cognitively determining the point of indifference. The chosen TTO exercise provided elderly respondents with a less cognitively burdensome alternative.

How were health states selected for valuation study?

Did you choose any that were already published in the literature - if not, then you missed a chance to say something about how robust your results are in fact.

Authors’ response:

The authors decided that, since this is only a pilot study and the values will not necessarily be compared to other studies, the health states should be selected randomly to reflect a selection of varying health states across the spectrum of the best and the worst health states.

Line 243-247:

The health states were chosen randomly to reflect the better and worse-off states associated across the spectrum of the two questionnaires. Care was taken, however, to include the health states that represented full health and worst possible health. Only ten health states per questionnaire were included, so as not to impose a heavy cognitive burden on the elderly respondents [17].

More critically, the SA study included a form of TTO whereas this was dropped from the Dutch follow-up. This is an absolutely critical part of your research material and MUST be properly accounted for in the manuscript. Respondents did not like TTO (or preferred VAS) so we excluded it from the 2nd study is not acceptable. Others need to be able to learn from your experience. You need to explain this choice process. You may reject this criticism, but if you do
then I must insist that you remove all reference to TTO from this paper since it neither contributes any useful information nor are any results properly reported.

Authors’ response:

We do appreciate the fact that the TTO exercise was not reported on. One of the aims of the study, however, was to investigate the method that should be applied to extract health-state values from the elderly respondents. We did include the comments from the South African respondents to substantiate our claims that the VAS method was preferred by the elderly respondents, which was why we decided to discontinue the TTO exercise in the subsequent valuation tasks. The text in lines 259-267 reads:

Seventy percent of the respondents from the SA sample indicated that they preferred the VAS method as compared to the TTO. Exemplary comments from the respondents with regard to the task were:

“The TTO exercise placed a heavy cognitive burden on me”; “I feel the TTO exercise is too difficult to complete”; “the VAS is much easier to complete”; and “I feel the TTO exercise might not provide accurate results.” Based on the fact that respondents complained about and failed to complete the TTO exercise, it was decided to continue using the VAS in group two and group three in the South African study, and in all groups in the Dutch study.

5. Results

Mean VAS scores are presented as decimals when in fact they come from a 0-100 rating scale. The reported numbers therefore should be in this range too. There is no reason whatsoever for this "rescaling" since no TTO data are presented in this paper.

Frequencies are presented as %. The numbers are small and should be shown as such - 6 people may be 60% but you can safely leave this to the reader I think

Authors’ response:

Both the rescaling and the percentages were removed from the text and the tables.
Is there an error in Table 3 for the SA value for 55555 (value given is 0.06) which is WAY out compared to everything else

Authors’ response:

The authors acknowledge that this was indeed a mistake made when the data was transferred into table format: The correct value is 36. Please see table 3 and line 276 for the correction. Furthermore, we have gone on to double-check the results to ensure no other mistakes were made when data was transferred from text into table format.

You might wish to consider a Friedman test (non-parametric) on the ranking of CAF state values across the samples.

Authors’ response:

We appreciate the advice of Prof. Kind and will certainly consider using the Friedman test when applying the methods from this study to a larger sample of elderly respondents.

For the purpose of this study, however, we decided to simplify the ranking method, that is, ranked by health state, to indicate that the elderly respondents evaluated the health states logically and consistently. Adding to the notion that the VAS method is appropriate for the valuation task.

You choose to present health state values in graphical form but you might want to state how the rank order of states in Figure 1 was determined (sorted by one subgroup probably) and that the Dutch semi group displays a single marked divergence from the other subgroups.

Authors’ response:

The data was ranked from better to worse health states in order to simplify and enhance the comprehensibility of the tables. That is why, after considering Prof. Kind’s remarks, the decision was made to convert the data presented in Fig. 1 into table format in order to enhance uniformity. Table 2 now includes the values of the EQ-5D+C questionnaire that ranked health states from better to worse-off health states.
6. Spelling

A couple of spelling errors - notably SATES instead of STATES.

Please check more carefully

Authors’ response:

Spelling errors have been corrected and the entire text checked again by a language editor.

All in all, some further (minor) revisions are needed.

Danan Gu (Reviewer 2): The format of Appendix E might be incorrect. I am not able to open it.

Authors’ response:

The format of the Appendix was checked and will be reloaded with the final version of the paper.

If improvements to the English language within your manuscript have been requested, you should have your manuscript reviewed by someone who is fluent in English. If you would like professional help in revising this manuscript, you can use any reputable English language editing service. We can recommend our affiliates Nature Research Editing Service (http://bit.ly/NRES_BS) and American Journal Experts (http://bit.ly/AJE_BS) for help with English usage. Please note that use of an editing service is neither a requirement nor a guarantee of publication. Free assistance is available from our English language tutorial (https://www.springer.com/gb/authors-editors/authorandreviewertutorials/writinginenglish) and
our Writing resources (http://www.biomedcentral.com/getpublished/writing-resources). These cover common mistakes that occur when writing in English.

Reference List


