

Expert advice on the EQ-5D-5L valuation set for England: process and questions

Background

The Office of Health Economics (OHE) was granted funding by the National Institute for Health Research's Policy Research Programme to create a EQ-5D-5L valuation set for England. This valuation set was made available in 2016 (Devlin et al. 2016) and published 2 years later (Devlin et al. 2018a). In collaboration with NICE, the Department of Health and Social Care (DHSC) commissioned its Policy Research Unit in Economic Evaluation of Health and Care Interventions (EEPRU) to quality-assure the methods used to create the 5L valuation set (see appendix A for more information on DHSC and NICE). EEPRU raised serious concerns about the data quality and the statistical modelling and concluded that the 5L valuation set is not fit for purpose (Hernandez et al. 2018). EEPRU recommended that a new study, including both data collection and modelling, should be done to develop a new 5L valuation set. The authors of the existing valuation set disagree with EEPRU's criticisms and have published a response defending their methods (Devlin et al. 2018b).

Adopting a 5L valuation set that does not adequately represent the preferences of the public in England risks making inappropriate decisions about allocation of public resources. But creating a new valuation set would be time-consuming and expensive, so careful due diligence must be exercised before recommending this course of action. Accordingly, NICE and DHSC are seeking expert advice to guide our next steps. This process will not involve duplicating EEPRU's rigorous assessments, but should establish whether there are ways to overcome the issues identified by EEPRU.

In the interim, NICE continues to use the 3L valuation set (NICE, 2018).

Overview of proposed process

This work will be managed by NICE, overseen by DHSC, and funded by the EuroQol Research Foundation. To ensure the process is independent, the EuroQol group will transfer the funds to NICE as an unrestricted grant. NICE and DHSC will select internationally respected academic experts. We will provide the experts with the relevant documents and models. We will ask each expert independently to provide written responses to a list of questions set by NICE and DHSC. The experts will have the opportunity to ask questions of the valuation set authors and EEPRU, and to ask those groups to share analyses. The experts' reports will be made available on the NICE website and, although the advice is non-binding, it will be used to inform future policy decisions at NICE and DHSC.

Objective

Regarding **data quality**, we request advice on whether:

1. The existing data are likely to represent the preferences of the public in England adequately, and are suitable for informing health and social care policy decisions in England (including NICE evaluations); or
2. The data quality concerns are insurmountable, such that new data collection is required

Regarding the **model specification**, we request advice on whether the existing model is suitable for informing health and social care policy decisions in England (including NICE evaluations). If the experts believe it is not, we will ask them to suggest alternative model specifications

Details of proposed process

Selecting experts

We will select internationally respected academic experts who have not been involved in creating the valuation set or in EEPRU's quality assurance. Experts must hold sufficient technical skills, be independent and impartial, and have built reputations that ensure their views hold substantial weight. EEPRU and the EuroQol

group will have the opportunity to suggest experts; the final selection will be made by NICE and DHSC.

We plan to consult 4 individuals with expertise in measuring stated preferences (particularly time trade-off and discrete-choice experiments), as well as expertise in statistics, Bayesian modelling and econometrics.

This work falls under NICE's [Policy on declaring and managing interests for NICE advisory committees](#); experts will be required to complete the [Declaration of interests form](#).

NICE and DHSC are content for the nominated experts to call on the expertise of their research groups for specific technical support (such as running the model). If this happens, all contributing individuals should complete the declaration of interests form and their input should be acknowledged in the expert's report. The principal expert contracted to NICE is responsible for answering the questions set by NICE and DHSC. The report's conclusions and recommendations should reflect the principal expert's opinions.

Independent evaluation

Each expert will be provided with the relevant materials:

1. the EQ-5D-5L valuation set publications by Devlin et al. (2016 and 2018a) and Feng et al. (2016 and 2018)
2. papers describing the protocol used in the valuation study (EQ-VT version 1.0), concerns about the quality of data gathered with that protocol and potential interviewer effects, and subsequent changes to the protocol: Ramos-Goñi et al. 2017, Ramos-Goñi et al. 2018, Shah et al. 2015, Stolk et al. 2019
3. the EEPRU report, the response from the valuation set authors and the counter-response from EEPRU
4. a short briefing document from the valuation set authors to accompany the coding script
5. a list of the additional analyses conducted by the valuation set authors but not published

6. a list of the additional analyses conducted by EEPRU as part of the quality assurance exercise, but that are not detailed in the EEPRU report
7. an unpublished analysis of interviewer effects in the England valuation study
8. the raw data and statistical code (in R and WinBUGS) for the published valuation set.

The questions for the experts are shown in Appendix B.

The experts' advice should be based on the reports and briefing documents listed above and the responses to clarification questions (see below). The data and model are available for reference should they want to use them, but it is not expected that the experts will replicate the analyses conducted by EEPRU nor that they will run substantial new analyses.

In order to ensure independence of advice, we request that experts do not discuss their findings or recommendations with each other.

Clarification

Experts are encouraged to ask clarification questions of the valuation set authors, EEPRU, NICE and DHSC. If the experts believe that a specific analysis would be informative they should ask the valuation set authors and EEPRU whether the analysis has been done and request the results. All questions and requests should be put in writing and sent to NICE, who will pass them on to the valuation set authors and/or EEPRU. To help with logistics, we request that the experts send all requests and questions to NICE on a pre-agreed date. The valuation set authors and EEPRU will commit to responding by a pre-agreed date. The questions and answers will be shared with all experts, to ensure that they have all the relevant information.

Reporting

Each expert will submit a draft report to NICE containing their responses to the questions posed. NICE and DHSC will arrange a discussion with each expert to discuss their draft. The aim of this discussion is to clarify the report; experts will not be asked to alter the substance of their advice. The draft report will be shared with

EEPRU and the valuation set authors to provide an opportunity to identify any factual inaccuracies. The draft report will be shared with EuroQol for information.

Each report will acknowledge that the work was funded by an unrestricted grant from the EuroQol Research Foundation.

Interpretation

NICE and DHSC will consider the reports carefully but the advice is non-binding; indeed, we anticipate that there might not be consensus amongst the experts' recommendations. The reports will help NICE to update its position statement on the 5L valuation set. Any substantial change in NICE's position would be subject to public consultation. When NICE releases a draft update to our position statement for consultation, we will also publish the final reports, declarations of interest, clarification questions and clarification responses on the NICE website for consultees to review.

Responsibilities

NICE and DHSC will be responsible for:

- managing contracts and invoices
- selecting experts
- providing experts with relevant materials (see items 1–7 in the section titled 'Independent evaluation')
- co-ordinating interaction between experts, valuation set authors and EEPRU
- publishing the expert reports, clarification questions and clarification responses on the NICE website.

The Office of Health Economics (OHE) will be responsible for:

- providing experts with the raw data and statistical code (in R and WinBUGS) for the published valuation set (see item 8 in the section titled 'Independent evaluation'); this will be done under a data sharing agreement between the OHE and each expert.

EEPRU and the valuation set authors will commit to:

- responding to clarification questions and requests for existing analyses within the specified timeline
- reviewing the draft reports in order to identify any factual inaccuracies within the specified timeline.

The EuroQol Group will:

- provide the funding for this work, transferred to NICE as an unrestricted grant.

References

- Devlin *et al.* 2016. [Valuing health related quality of life: An EQ-5D-5L value set for England. Technical Report 16.02, Health Economics & Decision Science, University of Sheffield](#) [online]
- Devlin N *et al.* 2018a. Valuing health-related quality of life: An EQ-5D-5L value set for England. *Health Economics* 27(1): 7-22.
- Devlin N *et al.* 2018b. [Response to: Quality review of a proposed EQ-5D-5L value set for England](#) [online].
- Feng *et al.* 2016. [New Methods for Modelling EQ-5D-5L Value Sets: An Application to English Data, OHE Research Paper 16/02](#) [online]
- Feng Y *et al.* 2018. New methods for modelling EQ-5D-5L value sets: An application to English data. *Health Economics* 27(1):23-38.
- Hernandez Alava M *et al.* 2018. [Quality review of a proposed EQ-5D-5L value set for England](#). EEPRU report [online]
- NICE 2018. [Position statement on use of the EQ-5D-5L valuation set for England](#) [online]
- Ramos-Goñi JM *et al.* 2017. Quality Control Process for EQ-5D-5L Valuation Studies. *Value in Health* 20(3):466-473.
- Ramos-Goñi JM *et al.* 2018. Handling Data Quality Issues to Estimate the Spanish EQ-5D-5L Value Set Using a Hybrid Interval Regression Approach. *Value in Health* 21(5):596-604.
- Shah K. *et al.* 2014. [Improving the quality of data collected in EQ-5D-5L valuation studies: a summary of the EQ-VT research methodology programme](#). 31th Scientific Plenary Meeting of the EuroQol Group, Stockholm, Sweden [online]

Stolk E. *et al.* 2019. Overview, Update, and Lessons Learned From the International EQ-5D-5L Valuation Work: Version 2 of the EQ-5D-5L Valuation Protocol. *Value in Health* (22), 23-30.

Appendix A: Background information on the Department of Health and Social Care and NICE

The Department of Health and Social Care (DHSC) is the department of the UK government responsible for providing strategic direction for the NHS and the wider health and social care system by creating national policies and legislation. The DHSC carries out some of its work through arms-length bodies such as NICE, Public Health England and NHS England. Several of these bodies use the EQ-5D to inform policy decisions about health and social care in England. The DHSC manages the Policy Research Unit in Economic Evaluation of Health and Care Interventions (EEPRU), which conducted the quality assurance of the EQ-5D-5L valuation set for England (Hernandez *et al.* 2018).

NICE is accountable to DHSC and receives most of its funding directly from the department. But operationally NICE is independent of government and NICE guidance is developed by independent committees. The way NICE was established in legislation means that our guidance is officially England-only. However, we have agreements to provide certain NICE products and services to Wales, Scotland and Northern Ireland. Since 2008, NICE's preferred measure of health-related quality of life in adults has been EQ-5D. [NICE's position statement on use of the EQ-5D-5L valuation set for England \(updated November 2018\)](#) applies to all guidance-producing programmes at NICE that use cost–utility analyses.

Appendix B: Questions for experts

Please ensure that your answers are succinct and use language that is comprehensible by a non-specialist. Your report will be published on the NICE website. If members of your research team provide technical support to you when answering these questions, please acknowledge their input in your report and ensure they submit a declaration of interests form.

Some questions are deliberately open-ended. Please answer as comprehensively as possible in the time available. If you would have liked to do further analysis but were unable to do so, please describe the further analysis briefly and explain why it would be informative.

Data quality

1. Are the data used to develop the valuation set likely to reflect the preferences of the public in England adequately?

Explanatory note: concerns have been raised about interviewer effects, whether the respondents understood and engaged with the task, and the number, nature and distribution of possibly inconsistent responses in the time trade-off (TTO) data. There is a lack of scientific consensus about how to define an 'inconsistent response' in TTO tasks, a question that we do not seek to resolve. Instead, we request advice on whether the data quality issues raise concerns about the validity of the data set.

Modelling

2. Considering the model that informs the published 5L valuation set:
 - a. Is there evidence of convergence failure? If so, please comment on the strength of this evidence and the implications for the validity of the model.
 - b. Is it possible to achieve convergence (e.g. by changing the model parameters or specifications, or by estimating a model based on only TTO or discrete-choice experiment data instead of a hybrid model)?
3. The valuation set authors state that "modelling does not assume that all TTO responses are 'accurate'. The modelling approaches were selected to reflect

the characteristics of the data, following careful assessment of individual respondent level data”. They state that the modelling methods also account for interviewer effects (see page 4 of Devlin et al. response to the EEPRU report and the unpublished analysis of interviewer effects). Does the modelling approach chosen by Devlin et al. (2018) and Feng et al. (2018) adequately account for the characteristics of the data?

4. Are there particular choices in the model that cause you concern? Please provide your rationale, specific recommendations for alternative approaches and, where possible, supporting evidence (for example, outcome of sensitivity analyses performed by the valuation set authors or EEPRU). Please also explain the magnitude of your concern – are any issues grave enough to mean that the model should not be used to inform health and social care policy decisions in England? In particular, please consider the 4 concerns raised in the EEPRU quality assurance report, listed in the table.

Table 1. Issues raised by EEPRU and sources of further detail.

Issue	EEPRU report	Devlin et al. response	Devlin et al technical appendix	EEPRU counter-response
A. The approach to handling valuations of +1	Section 3.3	-	Page 9	Paragraph 4a
B. The approach to heteroscedasticity and heterogeneity	Table 3.1 and section A2.1	-	Pages 10-11 and 16	Paragraph 4b
C. The possible conflict between the distributional assumptions for the TTO and discrete choice experiment parts of the models	Table 3.1 and section A2.1	-	Page 11	-
D. The prior distributions in the model: whether they are well-justified, how informative they are, and how sensitive the model results are to them	Sections 3.2.1 and A2.2	Pages 12 and 14	-	Paragraph 4c

Conclusions and recommendations

5. In your opinion, should health and social care policy decisions in England (including NICE evaluations) use utility values derived using the 5L valuation set for England?
6. If the answer to question 5 is NO:
 - a. What action do you recommend to create a 5L valuation set that would be suitable for informing health and social care policy decisions in England (including NICE evaluations)? Please be explicit about whether you believe new data collection is required or if you recommend different modelling approaches of the current data set.
 - b. In the interim, whilst the actions specified above are being done, should health and social care policy decisions in England be based on the existing 5L valuation set for England?

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