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Healthy Policy Analysis

# Guidelines for Utility Measurement for Economic Analysis: The Brazilian Policy

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## ABSTRACT

*Introduction:* Health-related quality of life is expressed in utilities, also referred to as utility estimates or parameters. Considerations about the source and type of utility values are especially important in a modeling context, where the lack of transparency, including the lack of a hierarchy for utility data sources, is a major issue to any estimation and can potentially compromise model reliability.

*Objectives:* This document aims to present the first version of the Brazilian guidelines for utility measurement to support economic analysis.

*Methods:* A virtual workshop and a modified Delphi panel with 10 health technology specialists followed a rapid evaluation of 110 technical documents and indexed publications. The recommendations are based on the proposition that has received the most votes, although contentious issues are addressed in the suggestion or discussion. The rationale for the final decision is included in the text.

*Results:* The consensus includes 50 recommendations with the following topics: Transparency and Reliability, Model Design, Conditions Under Which Generic Questionnaires Are Not Sensible or Valid, Utility Evidence Hierarchy, Utility Data Searching, Modeling Utility Values, Extrapolating Quality Adjusted Life-Years for Models With Lifetime Horizons, Caregiver Utility, Utility Data Synthesis, Quality/Certainty of the Evidence, and Utility Estimates in End-of-Life Conditions.

*Conclusions:* The goal of this project is to create unified national standards for using utility metrics in economic analysis in Brazil. This set of recommendations is not obligatory, but it is meant to serve as a guide and lead to the development of better and more transparent economic models in the country.

*Keywords:* health economics, public health, public policy, quality-adjusted life-year, utility.

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## Objectives

In the Brazilian Public Health System, recommendations for the coverage and reimbursement of new medicines, devices, or equipment are centralized in a committee (National Commission for Technology Incorporation in the Unified Health System).[1] To be approved, the claimant must provide health technology assessments (HTAs). These include measures of safety, efficacy, effectiveness, and cost-effectiveness to substantiate the decision-making process. There is no restriction on the type of economic model that can be submitted for review. The recommendations are presented as legal documents and economic analysis guidelines.[2] This document discusses focus on the possibilities of the utility measures, without any reference to sources or methods or the selection of the best evidence for utility parameters. Health insurance plans in the private sectors have a similar process through an independent agency (National Regulatory Agency for Private Health Insurance and Plans) that is responsible for defining a mandatory list of procedures and medicines to be included in all plans.[3] Brazilian preference research was sparse in both the public and private sectors.

In this context, utility is a concept adopted from economics that refers to preferences for a specific health state or outcome. This preference (or weight) is usually based on a large group of people representing the general population.[4] Utility is a proxy of quality of life and reflects the preferences of individuals or society for any particular set of health outcomes. Utility expresses the health-related quality of life (HRQOL) in a single value scored on a scale anchored on 1 = “full health” and 0 = “death,” usually derived from “off-the-shelf” preference-based measures such as the EQ-5D questionnaire.[5,6] Some health states may be considered worse than death and given negative utility estimates.[7] Utilities

are used for informing cost–utility models and can sometimes be obtained from different sources; it is important to create a hierarchy when multiple estimates are available.[8]

In a cost–utility analysis, competing health technologies are compared in terms of their cost per "year in full health." The quality-adjusted life-year (QALY) is one such widely used measure that combines a person's life expectancy and the value of their HRQOL in a single estimate. The HRQOL can be expressed in utilities for an economic analysis.[4]

It is important to distinguish between the utility weights and the profiles or health states. The measurement process using multiattribute instruments starts by asking for a description of individual health states, called profiles. The selected profiles are converted to utilities compared with a table called the value set, which contains weights for each profile. These weights are usually collected from the general population (valuation process) and represent preferences for each possible health state.

In one Brazilian state, in 2011, value set was developed for the Short-Form Six-Dimension (SF-6D) instrument.[9] For 3-level version of EQ-5D (EQ-5D-3L), the value set was developed nationally in 2013.[10] Nonetheless, in the Brazilian HTA ecosystem, utility estimates based on Brazilian samples are limited. Considerations of the source and type of utility values are especially important in a modeling context, in which the lack of transparency, including the lack of a hierarchy for utility data sources, is a major issue for any estimation and could compromise model reliability. The absence of clear guidelines permits flawed modeling practices, given that an ad hoc evidence selection can result in cherry picking.[11] An extreme example of this practice would be feeding a model with data to uphold the owner's perspective, creating a false favorable impression of a particular technology.

In recent years, the process of decision making using cost–utility data in Brazil has improved.[12] Because of the lack of confidence in some economic models, the cost–utility models have a mixed impact on real-world judgments. Transparently built models can hopefully support better decisions for the rational use of health resources.

Few international guidelines[7,13-16] discuss how to select the best utility data from different perspectives in the Brazilian context. This document aims to present the first version of the Brazilian guidelines for a utility measurement supporting an economic analysis.

## Methods

A glossary of technical terms is available in Appendix 1 in Supplemental Materials found at https://doi.org/10.1016/j.vhri.2022.03.004.

As an initial step, a rapid review of the literature was conducted on July 6, 2020, based on an adapted search strategy available in Appendix 2 in Supplemental Materials found at https://doi.org/10.1016/j.vhri.2022.03.004 on the MEDLINE, EMBASE, and LILACS databases and the websites of The University of Sheffield, the Decision Support Unit of the National Institute for Health and Care Excellence (NICE), and the EuroQol Group. Additional individual search strategies were adapted for each recommendation to gather the main recommendations and debates previously published on utility measurement issues for economic analyses. Approximately 110 documents were reviewed.

The experts were selected based on their previous experience with utility measurement instruments or economic models. The external reviewer was selected for his experience with both topics. Another important criterion was to be a manager or member of the 2 incorporated sectors in Brazil: public health (Brazilian Public Health System) and insurance plans (National Regulatory Agency for Private Health Insurance and Plans).

The review results were synthesized in a brief report. Then, in October 2020, these findings were discussed during a 5-hour online workshop, in which 5 lectures were presented by international speakers followed by debates. The complete program is available in Appendix 3 in Supplemental Materials found at https://doi.org/10.1016/j.vhri.2022.03.004. The expert group included a wide range of stakeholders—including government representatives, industry, academic groups, international guests, and a patient representative—and regulatory agencies, including the private health sector (Appendix 4 in Supplemental Materials found at https://doi.org/10.1016/j.vhri.2022.03.004). An adapted Delphi panel[17] technique with 4 iterations was adopted for the construction of the final report. The draft report was sent to 10 representatives, who used it to write the final report and who are listed here as coauthors.

The recommendations are based on the proposal with the most approvals, but controversial topics are included in the recommendation or discussion. The text includes the rationale for the final decision.

## Results

### *Transparency and Reliability*

1. Attach a table with utility data sources and assumptions to the model or report submitted for appraisal.[18]
2. Include the primary source, not merely the economic model citation, in the data source references.
3. Explicitly present the model's base case (results obtained with an economic model with the main set of inputs and assumptions chosen).[14]

### *Model Design*

4. Preferably, present the results of cost–utility studies as an incremental cost-effectiveness ratio per QALY or as net benefits[19,20] for the appropriate time horizon, usually survival time.

**Rationale:** When data are collected with validated instruments, the QALY calculation allows us to reconcile the benefits observed in the survival expectation with the benefits observed in the HRQOL. The group considered this process essential to maintaining other modeling options, such as cost-minimization or the possibility of adopting different outcomes when the QALY was invalid or had significant limitations.

5. Preferably, use the EQ-5D-3L to collect the utility data for the health state values. Always use the same instrument for all utility inputs in the model.[11]

**Rationale:** Different instruments could result in vastly different utility values. Standardized instrument utilization could help in obtaining comparable results. The EQ-5D-3L is widely adopted and has Brazilian value sets with a large representative sample.[9,21,22] It is short and simple, and it is used in $>$ 90 countries.[23] The SF-6D also has Brazilian value sets and can be considered an option.[9] The use of different instruments in the same model is considered inadequate. It is essential to search the literature and to validate the EQ-5D-3L for the health state descriptions associated with the analyzed clinical condition.

**Table 1.** Proposed hierarchy for utility parameters.

| Proposed hierarchy for utility parameters. |
|---|
| A. Brazilian social preferences<br>Data collected using a validated measurement tool (EQ-5D-3L) and weighted using the representative social preferences of the general Brazilian population |
| B. Nonstandard instrument<br>B1 Data collected using a nonstandard instrument (ie, a generic instrument other than EQ-5D) but which is weighted using Brazilian social preferences<br>B2 Data collected using a nonstandard instrument (ie, a generic instrument other than EQ-5D) but which is weighted using non-Brazilian social preferences |
| C. Mapping<br>Mapping from a condition-specific instrument to EQ-5D-3L weighted using Brazilian social preferences |
| D. Other instruments<br>D1 Direct measurement patient preferences—time trade-off<br>D2 Direct measurement patient preferences—VAS<br>D3 Patient preferences obtained with any nonstandard instrument |
| E. Published data<br>Published utilities for which there is fully documented evidence of the preference elicitation method |
| F. Expert judgment<br>Elicitation of utility values for health states of interest |

EQ-5D-3L indicates 3-level version of EQ-5D; VAS, visual analog scale.

6. Patients experiencing the condition should report the health states (EQ-5D profile). Ideally, the clinical trial should collect data from a generic preference-based instrument (such as the EQ-5D-3L) with complementary information from a specific preference-based instrument for the condition or disease (such as the European Organisation for Research and Treatment of Cancer [EORTC] Quality of Life Questionnaire Core-C30). In the absence of clinical trial data, observational studies are an option.
7. For patients who are unable to describe their health status (eg, patients with cognitive impairments), an assessment of the patient's health status by her or his caregiver can be considered an adequate proxy.[14,24]
8. Whenever possible, prefer Brazilian value sets for calculating the utility weights for a health state.
9. All utility weights must have primary supporting evidence from reliable and reproducible data sources.[14]
10. Utility estimates can be selected from clinical trials, observational data sets, or systematic reviews, using the weights preferably obtained from a societal perspective (value set).
11. Prefer social weights to patient weights.[24]

**Rationale:** There is controversy about from which population utility weights should be derived. Most of the literature considers population preferences to be fair values reflecting societal preferences.[11] The general population represents a publicly funded healthcare system, considering the allocation of resources. Patient preferences (ie, weights allocated by patients with the condition of interest) may overestimate or underestimate the importance of the problems (utility weights). In contrast, only a patient can report the complete experience of having a health condition (health state), including functional status changes and the correct intensity of symptoms.[7]

Researchers should consider from which population they must generate utility parameters. The Brazilian EQ-5D-3L value sets are available from http://natsinc.org/wpress/euroqol/ *Tabela de Utilidades Brasil*. The SF-6D value sets can be found in Cruz et al 2011.[9]

## Conditions Under Which Generic Questionnaires Are Not Sensible or Valid

12. An alternative scenario is justified and provided if no validation is available for using a generic instrument, such as the EQ-5D, for the analyzed condition.
13. In the absence of utility data for a condition, adopting a similar condition could be an option.
14. Mapping is also an option as an alternative tool for obtaining utility data from other instruments, such as condition-specific data (eg, the EORTC).[15]
15. Demonstrate the model performance anytime a mapping model is applied.[25]

**Rationale:** Generic instruments, such as the EQ-5D-3L, cannot be included in clinical trials, only disease-specific instruments. Usually, these instruments do not generate utilities. The mapping objective is to predict generic utility based on other instruments that use algorithms constructed by applying 2 instruments for the same respondent (ie, crosswalks). Mapping increases model uncertainty and should be reserved for cases in which, after an extensive search, no generic data are available. The Nuffield Department of Population Health provides an updated database with mapping studies for estimating utilities, available at https://www.herc.ox.ac.uk/downloads/herc-database-of-mapping-studies.

16. When EQ-5D-3L estimates are not available or appropriate, options, since justified, include the following:
    - Other generic preference-based measures (such as the SF-6D and Health Utilities Index Mark 2)
    - Disease-specific preference-based measures of HRQOL with utility calculations (such as the EORTC Quality of Life Questionnaire Core-C30, Asthma Quality of Life Questionnaire, Functional Assessment of Cancer Therapy-Lung, or the Assessment of Quality of Life 7D Vision Instrument)[26]
    - Direct valuation of one's own health with the time trade-off elicitation technique or standard gamble
    - The visual analog scale, best–worst scaling, and discrete choice experiments
    - The EQ with "bolt-ons" (Bolt-ons are dimensions added to the core set of EQ-5D domains with the objective of improving content coverage and describing specific health problems that were not initially captured in a particular population.[27] Notably, the use of bolt-ons implies the use of value sets containing preference weights for the bolt-on dimension)
    - Express benefits only with a gain in life-years

**Rationale:** The EQ-5D-3L and many other preference-based instruments are not sufficiently sensitive to capture small changes in health status, utility in infants, vision/hearing problems, or severe cognitive and psychiatric disorders.[28]

## Utility Evidence Hierarchy

17. Always prefer the best health state utility evidence available or justify a different choice.
18. Choose the best evidence according to the model's base case characteristics.[29]

**Table 2.** Examples of relevant subgroups.

| Regarding the disease | Responding to treatment |
|---|---|
| | Stable |
| | Progression |
| | End of life |
| Type of treatment | Chemotherapy |
| | Hormonal |
| | Radiotherapy |
| Adverse events | Peripheral neuropathy |
| | Edema |
| | Febrile neutropenia |
| | Sepsis |
| | Hypocalcemia |

19. Assess the quality of the evidence based on the guidance given in Table 1.[16,29-31]
20. The preference for pooled utility data depends on the meta-analysis quality, such as heterogeneity (population, method, and instrument), anchoring (perfect health and death), and the quantity of missing data.

## *Utility Data Searching*

21. Although not without controversy, most experts consider utility data transferable between jurisdictions.[32] Prefer local data.
22. List all possible utility data necessary for modeling. Use a comprehensive search strategy, including clinical trials, cohorts, registries, surveys, and other economic studies.[8]
23. Adopt a rapid or full systematic review to identify the best unbiased data source for utility data.
24. Possible websites for locating valuable data include the following:
    - MEDLINE, Embase, LILACS, and Centre of Review Dissemination databases
    - Submissions to the Brazilian Committee (National Commission for Technology Incorporation https://www.conitec.gov.br), NICE (https://www.nice.org.uk/), and other HTA agencies
    - The EuroQol website (https://euroqol.org/search-for-eq-5d-publications/)
    - The Medical Expenditure Panel Survey (EUA)[33,34]
    - The School of Health and Related Research, The University of Sheffield (https://www.scharrhud.org/).
25. The search should include terms defining the health state (eg, "acute kidney injury") combined with keywords for utilities such as quality of life, health status, health status indicators, activities of daily living, health surveys, quality-adjusted life-years, treatment outcome, QALY, EuroQol, and EQ-5D-3L.[11,35,36]
26. Prioritize a search for utility data that have a greater impact on the incremental cost-effectiveness ratio.[11,35,36]
27. Run a sensitivity analysis using utility data confidence intervals.[11]

**Rationale:** It is essential to include the uncertainty inherent in utility estimation. For more information on how to generate confidence intervals, see Petrou et al.[37] In the absence of an available confidence interval, the best and worst available utility estimates are used. For the probabilistic analyses, use the values and parameter distributions that reflect the total utility uncertainty. One option is to use point estimates and confidence intervals from previous economic evaluations. Utilities extracted from a number of methods (eg, time trade-off or visual analog scale) or instruments (eg, EQ-5D, SF-6D). They cannot be directly compared.

28. Relevant subgroups are defined as age groups with different efficacy data, age strata, or disease stages.[7,36,38-40] See example in Table 2.
29. Include all severe or expensive adverse events that have an impact on HRQOL.[11]
30. Whenever possible, an economic analysis of diagnostic technologies should include the adverse effects of false-positive tests, such as increased anxiety or depression.[41]

## *Modeling Utility Values*

31. Baseline mean utility data are never equal to full health (utility = 1), irrespective of the measure.

**Rationale:** The baseline of full health overestimates the effects of avoiding events or conditions. Patients have disutilities related to age and comorbidities that should be considered. "Condition-free" utility data should be estimated from the target population; mean health state utility values (HSUVs) represent comorbidity utility effects at the mean age of the utility study population.[4]

32. If age-specific utility data are not available, they should be estimated using age-specific population norms.[11] The Brazilian population norms are available at the NATS website http://natsinc.org/wpress/euroqol/-#Normas Populacionais EQ-5D-3L.
33. The multiplicative method (observed mean utility/baseline mean utility) can be used to calculate the utility effects, particularly for concurrent clinical events.[11]

**Rationale:** For concurrent events (eg, stroke and renal failure), the global effect should be calculated by multiplying the utility estimate in the absence of an event by the product of the ratios of the utility estimate for the individuals with the clinical events to the HSUV for individuals who do not experience the clinical events (the multiplicative method).[11]

34. Include utility estimates in the deterministic and probabilistic sensitivity analysis.[11]
35. Options for individual mean utility or function-based utility estimates depend on the availability and quality of data.[11]
36. All utility data should be discounted by 5% for each year of the patient's estimated survival (the official Brazilian discount rate).[2]

## *Extrapolating QALYs for Models With Lifetime Horizons*

37. Assumptions must be transparent.
38. The model should have a survival time compatible with the disease survival data (historical cohorts). Evaluate the data by a visual inspection of the mean estimates of the model predictions and from the historical cohorts.
39. The internal fit should be checked with an adjustment based on the fit to the observed data, for example, by indicators such

as the Akaike information criterion and Bayesian information criterion.

**Rationale:** Modeling data are often initially based on short-term clinical trial probabilities of health conditions in intervention/comparative groups. Given that most models include a lifetime perspective, it is necessary to extrapolate data using statistical models that must follow good practice recommendations.[7]

### Caregiver Utility

40. Include the impact on caregiver utility data in a model only when the quality of life of close relatives is clearly affected.[14] Include caregiver utility data only as a scenario analysis, in which it should be added to patient utility data.
41. Do not include the impact on HSUV for professional caregivers.
42. Clearly describe the impact on caregivers of the QALY impact to maintain model transparency.

**Rationale:** Some diseases cause significant limitations for family caregivers, mainly if the diseases affect children and elderly people. If spillover effects are not measured, the actual technology benefit can be underestimated.[42,43]

### Utility Data Synthesis

43. There are controversies regarding the meta-analysis of utility data; nevertheless, systematic reviews are essential sources of unbiased utility data.
44. A meta-analysis should be conducted only when the studies have similar populations, the same instrument to measure, and the same preference weights.[44]
45. When multiple, good-quality sources for utility data are available, a synthesis of the pooled data could reflect more accurate estimated and confidence intervals.[37]
46. Describe the methods used to combine the utility data. Preferably, give greater consideration to random-effects meta-analyses given that variations between the samples are not solely derived from random errors.[37]

### Quality/Certainty of the Evidence

47. Assess the quality of the data underpinning the utility data source with validated instruments, such as the Risk of Bias 2[45] for clinical trials and ROBINS-I[46] for cohorts.
48. Use different instruments depending on the study design (clinical trial, cohort, or direct valuation of the patient's health).
49. When the data quality of data is assessed, essential topics that should be covered are adequacy of the sample size, precision of the utility value, the response rate, follow-up losses, and missing data.[11] Avoid the common mistakes described in Table 3.

### Utility Estimates in End-of-Life Conditions

50. No recommendations are given for adopting differential weights for end-of-life health conditions.

**Rationale:** There is some debate in the literature about using the QALY as a rule for deciding efficiency in palliative care. It is necessary to be careful using the QALY at the end of life, given that these values can have small gains between interventions.[47-50] A recent integrative literature review concludes that the QALY might be more valuable in informing decisions among palliative care treatments if specific domains are included in the evaluation.[49] Quality of life or capability instruments specific to palliative care can be added to generic instruments such as the EQ-5D-3L when generic instruments lack dimensions essential to healthcare in end-of-life conditions. The authors also suggest integrating the valuation of time in a nonlinear way into the QALY framework.

### Guideline Application

This document is primarily designed for HTA experts and researchers, HRQOL researchers, and health economists and secondarily to public and private decision-makers. The document is not intended to govern but to help experts select the best utility parameter, either by a literature search or by primary fieldwork.

Many uncertainties and gaps occur in the existing evidence. Appendix 4 in Supplemental Materials found at https://doi.org/10.1016/j.vhri.2022.03.004 lists the recommendations for future research and the facilitators of and barriers to the implementation of these guidelines.

## Conclusions

This work aims to build harmonized Brazilian national standards for using utility measurements in economic analyses. This set of recommendations is not mandatory, but it is intended to provide guidance and to lead to the country's development of better and more transparent economic models. Although much knowledge has been shared on cost–utility analyses and utility measurements, numerous controversial points remain on various topics.

The consensus from the discussion group diverged from the other international guidelines for 2 items. The more controversial topic was maintaining the possibility of using outcomes other than the QALY for the economic models. Most participants considered several instances in which the use of the QALY would not be adequate and situations in which simple economic models, such as cost-minimization, could be helpful.

Another controversial topic was that the group considered that particular end-of-life criteria should not be recommended given that the EQ-5D-3L lacks essential dimensions for evaluating palliative care and the evidentiary support is not robust.[47-51]

The inclusion of caregiver utility data as a model input was a topic of interest. All participants agreed that it was a fundamental topic to be included in the discussions. A recent systematic review[52] concluded that reporting caregiver utility values in economic models was still not routine. Although foreseen in several technical manuals and the NICE British Agency documents, most NICE models do not evaluate these caregivers' effects even for diseases with recognized impacts, especially regarding the mental health of caregivers.[52]

One controversial topic was raised in the discussion, because it is valid for summarizing different utility values in a meta-analysis. For instance, although widely adopted in a range of conditions, Peasgood and Brazier[44] state that the "variability of utility scores by elicitation methods generates a problem for pooling values through a meta-analysis." Regarding this and other issues, the literature[11,44,53] is favorable to pooling the data only if it is homogeneous (population and instrument), highlighting that the best techniques for meta-analyses require further study. Petrou et al[37] published a comprehensive practical guide to conducting a meta-analysis of utility parameters.

**Table 3.** Common errors in utilities measuring.

| XXX |
|---|
| A lack of or insufficient literature review |
| Choosing the most favorable evidence ("cherry picking") |
| Lack of transparency regarding inputs and sources |
| The chosen utility estimate did not match to the sources. |
| The comparator had no benefit (even a placebo has a positive effect). |
| The respondent group reaching "perfect health" (utility = 1) |
| Do not include utility losses as a result of intervention`s adverse effects |
| Using a variety of instruments inside the same model (SF-6D, HUI, and the EQ-5D-3L) |

EQ-5D-3L indicates 3-level version of EQ-5D; HUI, Health Utilities Index; SF-6D, Short-Form Six-Dimension.

There are a variety of reasons why preferences differ from jurisdiction to jurisdiction. Local data are, without a doubt, the finest evidence for utility estimates. According to the literature, the hierarchical table offered the best possible solutions. According to an assessment[54] of ISPOR Good Research Practices Economic Data Transferability Task Force, 60% of international guidelines provide no recommendations on utility transferability between jurisdictions. The rest were categorized as having high or low transferability.

Finally, the prioritization proposal remains a live document open to broad discussion. In practice, it is not easy to summarize, with prioritization criteria, in 1 table the many possibilities for quality and confidence assessments of the utility data. Many criteria addressing internal and external validity can have different combinations; only trained experts can judge complex examples. The sensitivity analysis should consider any potential differences in utility estimates. The document's intention is not to be prescriptive, but only to suggest some methodological preferences.

Limitations of the document include the lack of a presentation because of the COVID-19 pandemic, which could have reduced the interaction between participants. The small number of experts in patient preferences and outcome research limited the discussion of the more complex issues.

National best practices for measuring quality of life for economic analyses can help Brazil and other Latin American countries more appropriately measure the impact of new technologies on patient quality of life.

## Recommendations for Additional Reading

- DSU NICE Utilities TSD series (http://nicedsu.org.uk/technical-support documents/utilities-tsd-series/)
- Pharmacoeconomics 2017 volume 35, supplement issue 1: Estimating Utility Values for Economic Evaluation Harvard Center for Risk Assessment (http://www.hcra.harvard.edu/)
- Brazier J, Deverill M, Green C, Harper R, Booth A. A Review of the use of health status measures in economic evaluation (https://doi.org/10.1177/135581969900400310)
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