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Dimensions and Attributes Used in QALY Instruments: A Systematic Review

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Abstract: Economic assessment is highly important in healthcare decision-making process. The quality-adjusted life-year (QALY) concept provides a rare opportunity to combine two crucial aspects of health, i.e., mortality and morbidity, into a single index, in order to perform cost-utility comparison. Recently, the Coronavirus disease 2019 (Covid-19) pandemic challenged all healthcare systems and recommended measures (e.g., confinement, social distancing) that produced negative effects on population's health. To correctly assess this impact of the virus, it is important to use the most relevant QALY instruments. Hence, understanding their characteristics and development process is a key point. In this aim, we conducted a systematic review and 40 studies were selected after searches done in four databases: Medline EBSCO, Scopus, ScienceDirect, and PubMed. The search procedure ended on June 18, 2020. We mainly focused on the type of instrument developed, the number and the nature of dimensions and levels used, the elicitation method and the model selected to determine utility scores, and the instrument and algorithm validation methods. Results show that studies dealing with the development of specific instruments were motivated by inappropriateness of generic instruments in their field. For the dimensions' and levels' selection, item response theory, Rasch analysis and literature review were mostly used. Dimensions and levels were validated by methods like the Loevinger H, the standardised response mean, or discussions with experts in the field. The time trade-off method was the most widely used elicitation method, followed by the visual analogue scale. Random effects regression models were frequently used in determining utility scores.

Keywords: QALY; utility; impact; instruments development; economic assessment.

1. Introduction

In the face of growing demand for health services, public and private agencies are increasingly interested in the cost-effectiveness of programs (Brazier and al., 1998). Since then, the quality adjusted life year (QALY) has grown in popularity and is used as a measure of benefit in the economic evaluation of health programs and technologies around the world (Mavranezouli and al., 2013). In its method, QALY combines the duration (mortality) and quality (morbidity) of life in a single measure. Quality of life, characterized by a utility value between 0 and 1; where 0 represents death and 1 represents perfect health, is determined by instruments that can be generic or specific. The purpose of these instruments is to reflect respondents' perceived health, which is an important factor in health and therefore a measure of effectiveness (Brazier and al., 1998; Brazier and al., 2020; Chen and Ratcliffe, 2015; Mavranezouli and al., 2013). Recently, the Coronavirus disease 2019 (Covid-19) pandemic challenged all healthcare systems and recommended measures (e.g.,

confinement, social distancing) that produced negative effects on population's health as regards to HRQoL. To be able to correctly measure the impact of this pandemic on people's quality of life, instruments must be adapted/created in order to fully take accounts of all adverse consequences ensued from this disease.

However, in order to be usable in cost-effectiveness studies, the tools must meet several essential criteria. Thus, the development of these instruments is done in several stages to ensure their reliability and validity. These steps, which are common to both generic and specific instruments, are generally described under 3 aspects: development, validation of psychometric properties and measurement (Mulhern and al., 2012; Netten and al., 2012). It is therefore essential, with a view to developing, using, or adapting an instrument, to master its creation process in order to identify the context in which it is applicable. The purpose of this systematic review is to analyze the different phases of the development of the tools used in QALY calculation in different countries. More specifically, it will determine the dimensions and levels used in the different QALY tools and specify how these attributes/dimensions as well as the utility scores were obtained. Next sections present the methodology used for the systematic review, the results and the discussion.

2. Method

2.1. Research strategy

The databases consulted were Medline EBSCO, Scopus, ScienceDirect (Elsevier), and PubMed. Grey literature searches were also conducted via Google Scholar, and various health-related websites. The bibliographic references of the selected articles were used as a source to find other relevant studies. The keywords used in the different databases were 'QALY', 'quality adjusted life year', 'instrument', 'multi-attribute', and 'utility'. Using the Boolean operator 'AND', combinations were made to refine the results and get closer to the type of study requested. There was no restriction on the publication date and only publications in English or French were considered. Searches were conducted in English in the databases mentioned above. The search ended on June 18, 2020.

2.2. Selection of studies

In accordance with the literature search protocol, the selection of studies was based on the following criteria:

Studies published in French or English;

Studies describing the development of QALY measuring instruments;

Studies addressing the general population or specific patient groups.

Studies dealing with draft versions of instruments that have been subsequently modified, using a QALY instrument without a description of dimensions and levels, using instruments that do not measure health utilities, and dealing with the paediatric population were not included.

The selection of studies was done in 2 steps. First a group of 2 reviewers made the first selection after reading the titles and abstracts. The selected articles were then read in full and only those that met the inclusion criteria were selected. In case of disagreement between the 2 evaluators, the reason for this disagreement was submitted to an arbitrator who decided. At each stage a kappa coefficient was calculated. Data extraction was done by one evaluator and then validated by the second.

2.3. Data analysis

Data extraction was performed using a form structured around the instrument development process. Thus, the main information we wanted to collect relates to the 3 aspects of instrument elaboration: development, validation and measurement. Among other things, we were interested in the target population, the type of instrument developed, the number and nature of dimensions and levels, the elicitation method and model used in the determination of utility scores, and the methods used to validate the tool and the algorithm. The analysis of the quality of the studies was done with the COSMIN grid (Mokkink and al., s. d.).

3. Results

3.1. Selection of studies

A total of 4264 studies were found through our various searches. At the end of the different filtering processes, 44 articles were fully read. Figure 1 describes the PRISMA flowchart and shows the details of the selection of studies. At the first stage of selection, 2740 works were not retained because they did not meet the inclusion criteria. A kappa coefficient equal to 0.37 was obtained. In the second stage of selection, 4 studies were excluded. A kappa coefficient of 0.65 was found at this level and the arbitrator had to intervene to decide between disagreements related to 2 studies. This review thus consists of 40 studies dealing with the development of 42 preference-based instruments for the purpose of QALY calculation.

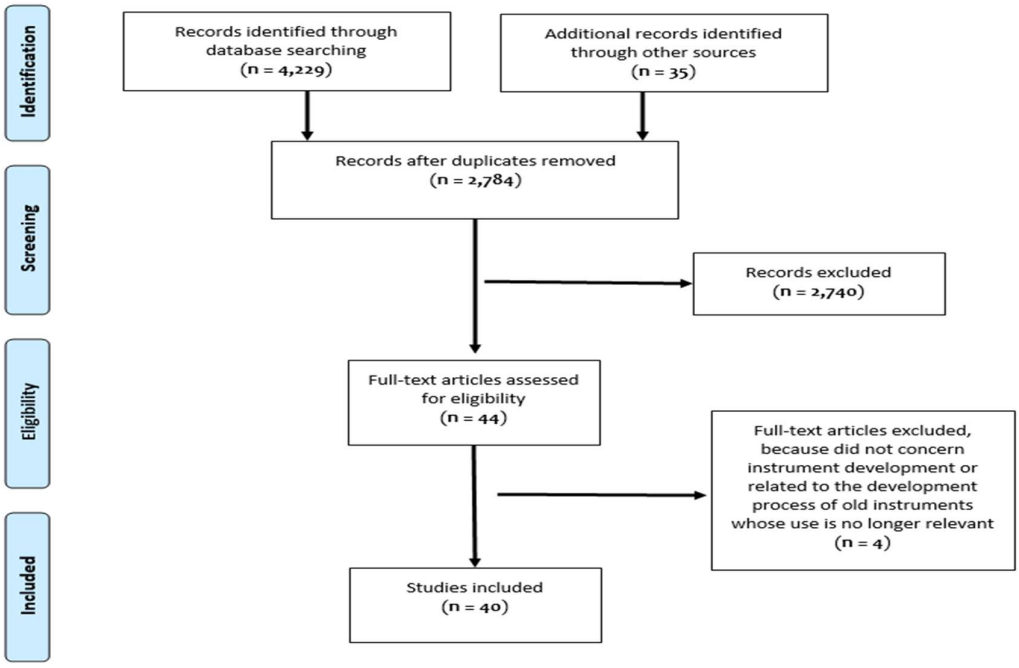

Figure 1. PRISMA flowchart, June 18, 2020.

3.2. Characteristics of the selected studies

The studies included in the systematic review all concern the development of a tool based on individual preferences for use in a cost-effectiveness evaluation. Of the 40 studies that met the inclusion criteria, 11 dealt with the development of generic instruments and the remainder (31) were dedicated to the development of specific instruments. The exclusive countries of application of these studies are Canada (n=3), United Kingdom (n=19), United States of America (n=4), Australia (n=4), Holland (n=3), Spain (n=1), Finland (n=1), England (n=1), and South Korea (n=1). The rest of the studies were carried out simultaneously in several of the above-mentioned countries (n=3). The specific instruments developed refer to a wide variety of areas related to neurological disorders (n=6), respiratory problems (n=4), social care and dependency (n=4), diabetes (n=3), bladder (n=2), cancer (n=2), musculoskeletal disorders (n=2), menopause/flushing (n=2), sexuality/fertility (n=2), vision/glaucoma (n=2), digestive function (n=1), and prostate (n=1). All studies were published between 1998 and 2020.

3.3. Instrument development

The development of preference-based tools comes into play to provide a mean of measuring preferences in a field where such instruments are non-existent or to overcome the problem of unsuitability of already existing tools (sensitivity problems, tool not based on preferences, etc.) (Hawthorne, 2009; Herdman and al., 2011; Oppe and al., 2016). Thus,

in order to allow for a better allocation of available resources, various generic as well as specific instruments have been developed. 42 instruments make up this review, 24 of which are the result of improvements to existing instruments and 18 of which were developed *de novo*.

Less than a quarter of the studies constituting this review concern the development of generic instruments. Thus, 11 studies address the development of 11 generic instruments that are well known in the evaluation community. Table A1 in Appendix A provides an overview of the dimensions and levels covered by the different generic instruments identified, while Table A2 in Appendix A identifies the different methods used in the different phases of the development of the generic instruments.

More than half of these studies (n=6) describe the improvement of a pre-existing tool because of limitations noted in its use. This is the case of Hawthorne (2009), Seiber and al. (2008) et Richardson and al. (2012) which deal with the development of parsimonious tools from AQoL and QWB respectively. To do so, they suggested switching from original versions to AQoL-8, AQol-7D and QWB-SA, respectively. Hawthorne (2009) thus retains 8 items through an iterative process of entering and removing the items proposed in the AQoL model. This process is repeated until all possible combinations of items are examined. Richardson and al. (2012) propose to increase the sensitivity of AQoL to sight-related difficulties and disabilities. Vision-related Quality of Life (VisQol) is thus added as a dimension to AQoL-6D. Seiber and al. (2008) explain the implementation of the QWB-SA, derived from the Quality of Well Being (QWB) and is a tool that offers the same properties as the latter while being less time consuming and easier to use. This is also the case of Herdman and al. (2011b) and Brazier and al. (2020) who, to alleviate concerns about the sensitivity of precursor instruments, introduce EQ-5D-5L and SF-6Dv2 respectively. The main changes were provided in the nature of the severity levels in different dimensions, leading to an increased number of possible combinations from 243 to 3,125 for EQ-5D-5L and from 18,000 to 18,750 for SF-6Dv2. For this purpose, a literature review on the response scales and interviews with native speakers of the different target languages and experts were conducted. In addition, the exploratory factor analysis (EFA), confirmatory factor analysis (CFA) and Rash's analysis made it possible to retain the elements relevant to the new tools. These techniques were also used in the development of ReQol-UI and CORE-6D.

The 15D is the instrument that covers the most dimensions, followed by the HUI3, the AQoL-7D and the HUI2. The ReQol-UI records the fewest dimensions. All instruments record dimensions related to symptoms and discomfort, physical sensations and pain. Only three instruments (AQoL-8, AQoL-7D and CORE-6D) do not record dimensions on mobility/ambulation. Five and seven instruments have dimensions related to mental function and anxiety/depression respectively. Fertility and sexual activity are only considered in HUI2 and 15D, respectively. The number of levels per dimension varies between 3 (HUI2 and CORE-6D) and 7 (AQoL-7D). Only two instruments are interested in psychological well-being/happiness. Fertility and sexual activity are only considered in HUI2 and 15D respectively. The number of levels per dimension varies between 3 (HUI2) and 7 (AQoL 7D).

Among the authors who were interested in specific instruments (n=31), most (n=22) raised as a problem the inadequacy of existing tools due to their lack of sensitivity or their psychometrically invalid nature in the field concerned. Others (n=9) simply developed an instrument because of the non-existence of a measurement tool or the fact that existing tools are not usable in economic evaluation because they are not based on individual preferences. Table A3 in Appendix B shows the dimensions and levels used in the various specific instruments.

Thus, several studies (n=14) specify that a literature review of old instruments and exchanges with professionals and/or patients helped in the selection of dimensions and levels. In addition to these resources, more than half (n=17) of the studies state that they used empirical methods such as factor analysis, Rasch analysis, standard psychometric

criteria and differential item functioning (DIF) in the selection of the dimensions and levels shown in Table A3.

3.4. Psychometric validation

Following the selection of the items to make up the instrument, it is subjected to qualitative and quantitative tests to ensure its reliability, consistency and validity (internal and external) (Bédard and al., 2013; Slocum-Gori and Zumbo, 2011).

Among the 11 generic instruments, the method used to test the validation of dimensions and levels is provided for only 5 tools (see Table A2). Thus, Hawthorne (2009) tested the unidimensionality of the descriptive system as well as the degree of homogeneity using item response theory (IRT) and Loevinger's H coefficient, respectively. Herdman and al. (2011b) asked participants to assess the interpretability and plausibility of the instrument. Using sub-samples, Brazier and al. (2020) et Seiber and al. (2008) used the DIF and the test-retest respectively. In addition, the latter tested the impact of the questionnaire administration method on the scores obtained. Sintonen (2001) stated that for its validation, the 15D was compared to other instruments such as the Nottingham Health Profile (NHP), the 20-Item Short Form Health Survey (SF-20) and the EQ-5D.

Regarding the validation of specific instruments, about one third of the instruments (n=10) were provided with their validation method (see Table A4 in Appendix B).The two versions of the DHP (DHP3 and DHP5) were validated by collecting the opinions of professionals in the field after presenting them with the results of the item selection. The sensitivity of OAB-5D and EORTC-8D was tested using the standardised response mean (SRM) on random samples from the initial database as well as on an independent sample of patients. The validity of the ASCOT was tested by comparing it with other tools such as the EQ-5D and the General Health Questionnaire (GHQ-12). This was done using the Chi-square test and the analysis of variance. A comparison with other instruments was also performed for the DUI and P-PBMSI using the Cohen criterion, Spearman's correlation and Pearson's correlation. A patient group test-retest was used for the validation of the CAMPHOR, the Menaupose specific health quality of life questionnaire and the RSUI to assess the reliability and validity of the construction of these instruments. Finally, the IIEF was validated following confirmation of the consistency of the ordinal structure of its dimensions.

3.5. Measuring utility scores

The final step in the process of creating a preference-based instrument is the measurement of individual preferences. This involves assigning a utility score to the different possible health states described by the instrument. To do this, the questionnaire is filled out by a sample of individuals and finally a conversion algorithm is used to convert the responses to the questionnaire into a utility score (Brazier and al., 1998; Fauteux and Poder, 2017; Neumann and al., 2000).

In this exercise, almost two thirds of the instruments in this work used the preferences of individuals from the general population (n=29) compared to less than one third that used patient preferences (n=8). Only 4 instruments were valued by both parties. Thus, more than three quarters of the elicitations of the selected health states were made by interviews (n=33) and just 3 instruments were evaluated through remote methods (online survey, postal mail). In addition, 82% of the studies provided information on the number of participants, and of these, 96% provided details on the characteristics of the participants. However, just 45% of the studies (n=18) stated that the sample used was representative of the target population.

For the generic instruments, the time trade off (TTO) was the most used method (n=4) followed by visual analogue scale (VAS) (n=3), standard gamble (SG) (n=1) and discrete choice experiment with duration (DCEtto) (n=1). Only one study used a hybrid method combining VAS and SG. To provide utility scores for all the possible states, the additive regression model was used for AQoL-8, 15D, QWB-SA and CORE-6D; the conditional

logit for SF6-Dv2 and the multiplicative model for CAT-5D-QOL, HUI2 and 3 and AQoL-7D. The random effects model was used for ReQol-UI.

The models, once estimated, are validated to ensure the reliability of the results obtained. For the AQoL-8 the preferred model was the one that produced closest utility scores to the original instrument (AQoL) and the highest degree of correlation with it. For CAT-5D-QOL, a comparison of its scores with those of the HUI3 allowed to select the best specification. For the SF6-Dv2, heterogeneity was tested and the 15D had its preferred model selected using correlation analyses with different samples. As for AQoL-7D, the analysis of its ability to discriminate between the general population and patients allowed its model to be validated. The analysis of the specification of the different models used (significance of the coefficients, mean absolute error, root mean standard error, etc.) made it possible to validate the best model for CORE-6D and ReQol-UI.

In terms of the elicitation methods used for specific instruments, it is noted that TTO has been the leading method. Indeed, more than half (n=16) of the 31 instruments concerned were valued by this method. Only a few studies exclusively used a DCE (n=3), VAS (n=1) or best worst scaling (BWS). A mixed method was preferred by 6 studies, 3 of which used VAS and SG, another used TTO and VAS.

In order to estimate the utility scores of the various remaining combinations, the authors use different models such as random effects models (n=10), simple ordinary or generalized least squares (n=6), multiplicative models (n=2), conditional logit or maximum likelihood models (n=7), and multivariate models (n=2). Most of these different models proved their validity by the consistency of the model judged through its specifications (R^2, root mean square error, SRM, sign and significance of the coefficients, AIC and BIC criteria, etc.) (n=15). Five studies made comparisons either with other instruments or with scores obtained with a population other than the one used in the initial study.

4. Discussion

This work addressed the main steps in the development of a preference-based measurement instrument. The development of new tools or the modification of existing ones requires an understanding of the different phases involved in the development of measurement tools. These phases are generally development, validation and measurement. The studies considered in this review are those that met the various inclusion criteria. Thus, 40 studies were selected, tracing the development of 42 preference-based tools for use in economic evaluations.

At the time of study selection, rigour in methodology or the amount of information available was not a criterion for inclusion. For example, during data extraction, several studies did not provide information on important aspects of the tool development process such as the sampling strategy or the method of recruiting participant samples. In view of these aspects, it seems likely that biases may remain in the measurement of the utilities or in the algorithms derived from this information. Moreover, only 45% of the studies claim to have used a representative sample of the target population in their work. This raises the question of the external validity of the various tools. Therefore, additional steps could be taken to ensure the operationality of the instrument or to provide a confidence interval for the results obtained. Sensitivity analysis is one such step. It thus makes it possible to account for the degree of stability or variability of the result provided. However, of all the studies selected, few were listed as having performed a sensitivity analysis (n=3).

Nevertheless, the average quality of the studies constituting this review is acceptable and allows a clear description of the process used. Table A5 in Appendix C presents the quality of the different studies regarding the COSMIN grid, which allows an evaluation of the quality of the studies according to different criteria (content validity, consistency, reliability of the tool, etc.). Four levels of response are allowed, ranging from "very good" to "inadequate" depending on the criteria assessed. Table A5 provides the proportions of responses provided at each possible level of response and for the different criteria in the grid. On average, 55% of the various criteria assessed were rated as "very good" and 38%

were rated as questionable or undetermined. Only 6% of the criteria were rated, on average, as inadequate.

5. Conclusion

This systematic review on the development of preference-based instruments identified the steps required to develop an instrument to measure QALY. This work thus provides an understanding of the process of developing preference-based tools. Most of the studies that have focused on the development of specific instruments have been done because of the verified inadequacy of generic tools in some areas. A great diversity was observed in the different methods used in the different parts of the development of the tools. Rasch analysis, TTO, and random effects models were predominantly used in instrument development and measurement.

Appendix A: Generic instruments

Table A1. Dimensions and levels retained in the generic tools.

	AQoL-8	AQoL-7D	CAT-5D-QOL	EQ-5D-5L	SF-6Dv2	15D	HUI2	HUI3	QWB-SA	ReQoL-UI	CORE-6D
Breathing						X					
Speech/Communication						X		X	X		
Listening/Hearing						X		X	X		
Vision						X		X	X		
Eating/Nutrition						X					
Sleep/Vitality						X					
Symptoms and discomfort/Physical sensations/Pain	X	X	X	X	X	X	X	X	X	X	**X**
Usual Activity/Daily Activities			X	X	X	X					**X**
Mobility/ Ambulation			X	X	X	X	X	X	X	X	
Autonomy/Control/Dependence	X	X							X	X	
Self-care				X			X			X	
Dexterity			X					X			
Excretion						X					
Social relationship	X	X			X				X		
Mental function		X				X	X	X		X	
Anxiety/Depression	X			X	X	X			X	X	**X**
Psychological well-being/Happiness						X				X	
Self-confidence										X	
Loneliness										X	**X**
Mental health (other)						X					
Mood/Emotion							X	X			**X**
Terror/Fear											**X**
Humiliation											**X**
Suicidal idea											**X**
Adaptation		X									
Sexual activity						X					
Fertility							X				
Number of dimensions (items)	4 (8)	7 (26)	5 (25)	5	6	15	7	8	5	2 (7)	**6**
Number of levels by dimensions	NA	5,6,7	4	5	5,6	5	3,4,5	5,6	NA	5	**3**

Table A2. Methods used during the different phases of development of generic instruments.

Instruments	Method of choice of dimensions and levels	Validation method	Elicitation method	Model used	References
Assessment of Quality of Life-8 (AQoL-8)	Iterative process of entering and removing potential items in the AQoL model until all possible combinations are analyzed.	Loevinger H (homogeneity)	Time Trade Off (TTO)	Multivariate linear regression	Hawthorne (2009)
Assessment of Quality of Life (AQoL)-7D	Literature review and focus group; factor analysis; structural equation modeling; logical considerations.	Non applicable	TTO	Multiplicative regression model	Richardson et al. (2012)
Computerized adaptative testing quality of life 5 dimensions (CAT-5D-QOL)	Item Response Theory	Non applicable	Standard Gamble (SG)	Multiplicative regression model	Kopec et al. (2015)
EuroQol 5 dmensions (EQ-5D-5L)	Literature review	Patients were asked to assess the interpretability and plausibility of the instrument.	Visual analogue scale (VAS)	Non applicable	Herdman et al. (2011a)
Short Form 6 dimension (SF-6Dv2)	Exploratory and confirmatory factor analyses; Rasch analysis; literature review; expert opinion.	Differential item functioning (DIF) on sub-samples.	Discret choice Experiment with duration (DCEtto)	Conditional logit	Brazier et al. (2020) Mulhern et al. (2020)
15 dimensions (15D)	Factor analyses; patient surveys; instrument user feedback.	Multi-method multivariate matrices based on empirical measurements of the dimensions of 15D, NHP, SF-20 and EQ-5D.	Visual analogue scale (VAS)	Additive model	Sintonen (2001)
Health Utilities Index 2 & 3 (HUI2-HUI3)	General population survey: the importance the public places on each attribute was considered.	Non available	Visual analogue scale (VAS); Standard gamble (SG)	Multi-attribute multiplicative model	Horsman et al. (2003)
Quality of Well Being Self-Administered (QWB-SA)	Inputs from the QWB.	Test-retest; test the impact of the administration mode on total scores.	Visual analogue scale (VAS)	Additive model	Seiber et al. (2008)
Clinical Outcomes in Routine Evaluation 6 dimensions (CORE-6D)	Rasch analysis	Non available	TTO	Additive model	Mavranezouli et al. (2013)
Recovering Quality of Life utility index (ReQoL-UI).	Literature review, interviews, factor analyses and IRT	Non available	TTO	Random effects models	Keetharuth et al. (2020)

Appendix B: Specific instruments

Table B3. Dimensions and levels retained in specific tools.

Instruments	Number of dimensions/items	Nature of dimensions	Number of levels per dimension/item
Alzheimer's disease (AD-5D)	5	Interpersonal environment, Physical, Self-functioning, Memory, Mood.	4
Cerebral palsy-specific 6 dimensions (CP-6D)	6	Social well-being and acceptance; Physical health; Communication; Pain and discomfort; Manual ability; Sleep.	5
Amyotrophic Lateral Sclerosis Utility Index (ALSUI)	4	Speech and swallowing; Eating, Dressing and bathing; Leg function and Respiratory function.	5 / 6
Multiple Sclerosis Impact Scale 29 (MSIS-29)	8 items	Problems with your balance, Being clumsy, Limitations in your social and leisure activities at home, Difficulties using your hands in everyday tasks, Having to cut down the amount of time you spent on work or other daily activities, Feeling mentally fatigued, Feeling irritable, impatient or short tempered, Problems concentrating;	Non available
Prototype Preference-Based MS Index (P-PBMSI)	5	Walking; Fatigue; Cognition; Mood; Work.	3
Epilepsy-specific preference-based measure (NEWQOL-6D)	6	Worry about attacks; Depression; Memory; Concentration; Stigma; control.	4
Rhinitis Symptom Utility Index (RSUI)	5	Stuffy/blocked nose, Runny nose, Sneezing, Itchy/watery eyes and Itching nose/throat.	10
Chronic obstructive pulmonary disease (COPD)	3	COPD ; Non-serious exacerbations ; Serious exacerbations.	3
Cambridge Pulmonary Hypertension Outcome Review (CAMPHOR)	4	Social activities, Travelling, Dependence and Communication.	2 / 3
Asthma Quality of Life (AQL-5D)	5	Concern; Short of breath; Weather and pollution; Sleep; Activities.	5
Adult Social Care Outcomes Toolkit (ASCOT)	8	Personal cleanliness and comfort, Accommodation cleanliness and comfort, Food and drink, Safety, Social participation and involvement, Occupation, Control over daily life, Dignity.	4

Dependency 6 dimensions (DEP-6D)	6	Eat, Incontinence, Personal care, Mobility, Housework and Cognition/mental problems.	3 / 4
Aberrant Behavior Checklist Utility Index (ABC-UI)	7	Mood; Distractible; Aggressive; Impulsive; Speech; Social; Movements.	3
Index of capability for older people (ICE-CAP-O)	5	Attachment, Security, Role, Enjoyment and control.	4
Diabetes Health Profile 3 (DHP-3D)	3	Mood, Social limitations, Eating.	4
Diabetes Health Profile 5 (DHP-5D)	5	Mood, Social limitations, Eating, Hypoglycaemic attacks, Vitality.	4/5
Diabetes Utility Index (DUI)	5	Physical ability and energy, Relationships, Mood and feelings, Enjoyment of diet and Satisfaction with management of diabetes.	3 / 4
Overactive Bladder 5 dimensions (OAB-5D)	5	Urge, Urine loss, Sleep, Coping, Concern.	5
King's Health Questionnaire (KHQ)	5	Role limitation, Physical limitations, Social limitations/family life, Emotions, and Sleep/energy.	4
Quality of Life Questionnaire for Cancer 30 (QLQ-C30)	8 items	Trouble taking a long walk, Limited in doing either your work or other daily activities, Have you had pain, Have you felt nauseated, Were you tired, Difficulty in concentrating on things, Did you worry, Has your physical condition or medical treatment interfered with your social activities.	Non available
European Organization for Research and Treatment of Cancer (EORTC-8D)	8	Physical functioning, Role functioning, Social functioning, Emotional functioning, Pain, Fatigue and Sleep disturbance, Nausea, Constipation and Diarrhea.	4 / 5
Health Assessment Questionnaire for arthritis (HAQ)	5 items	Stand up from a straight chair, Walk outdoors on flat ground, Get on / off toilet, Reach and get down a 5-pound object (such as a bag of sugar) from just above your head, Open car doors;	Non available
Dupuytren's contracture (DC)	8	Joint #1: index finger, PIP joint; Joint #2: index finger, MCP joint; Joint #3: middle finger, PIP joint; Joint #4: middle finger, MCP joint; Joint #5: ring finger, PIP joint; Joint #6: ring finger, MCP joint; Joint #7: little finger, PIP joint; Joint #8: little finger, MCP joint.	3
Menopause specific health quality of life questionnaire	7	Hot flushes, Aching joints/muscles, Anxious/frightened feelings, Breast tenderness, Bleeding, Vaginal dryness and Undesirable androgenic signs.	3 / 5
Flushing Symptoms Questionnaire (FSQ)	5 items	Redness of skin, Warmth, tingling, Itching and Sleep difficulty	4 / 5

Sexual quality of life questionnaire (SQOL-3D)	3	Sexual performance, Sexual relationship and Sexual anxiety.	4
International Index of Erectile Function (IIEF)	2	Ability to Attain and maintain an erection sufficient for satisfactory sexual performance.	5
Glaucoma Utility Index (GUI)	6	Central and near vision; Lighting and glare; Mobility; Activities of daily living; Eye discomfort; Other effects of glaucoma and its' treatment	4
Visual Function Questionnaire–Utility Index (VFQ-UI)	6	Near vision activities, Distance vision activities, Vision-specific social functioning, Role difficulties, Dependency, and Mental health.	5
Short Bowel Syndrome-specific quality of life scale (SBS-QoL)	6	Diet, Eating and drinking habits; Diarrhoea; Fatigue/weakness; Mobility and self-care/everyday activities; Leisure activities/social life; Emotional life.	2
International prostate symptom score (IPSS)	2	Obstructive symptoms; Irritative symptoms.	3

Table B4. Methods used during the different phases of development of generic instruments.

Instruments	Method of choice of dimensions and levels	Validation method	Elicitation method	Model used	References
Alzheimer's disease (AD-5D)	Factorial analysis; Rasch analysis	Non applicable	Non applicable	Non applicable	Nguyen et al. (2017)
Cerebral palsy-specific 6 dimensions (CP-6D)	Factorial analysis, Rasch analysis.	Non available	DCE with duration (DCEtto)	Conditional logit, mix logit	Bahrampour et al. (2019)
Amyotrophic Lateral Sclerosis Utility Index (ALSUI)	Non available	Non available	VAS; SG	Multiplicative model	Beusterien et al. (2005)
Health Assessment Questionnaire for arthritis (HAQ), Multiple Sclerosis Impact Scale 29 (MSIS-29), Quality of Life Questionnaire for Cancer 30 (QLQ-C30)	Rasch model, basic psychometric criteria, clinical expert opinion	Non available	TTO	Random effects model	Versteegh et al. (2012)
Prototype Preference-Based MS Index (P-PBMSI)	Rasch analysis, threshold graph, WHO International Classification of Functioning, Disability and Health.	Comparison with other instruments; Cohen criterion; Spearman and Pearson correlations.	VAS	Simple linear regression	Kuspinar et al. (2014)

Epilepsy-specific preference-based measure (NEWQOL-6D)	Exploratory factor analysis, Rasch and psychometric analyses, DIF	Non available	TTO	Generalized least squares regression	Mulhern et al. (2012)
Rhinitis Symptom Utility Index (RSUI)	Literature review, interviews with patients and experienced clinicians	Test-retest, comparison of RSUI with other indicators of disease severity	VAS; SG	Multiplicative model	Revicki et al. (1998)
Chronic obstructive pulmonary disease (COPD)	Non available	Non available	TTO; VAS	Linear mix model	Cho et al. (2015)
Cambridge Pulmonary Hypertension Outcome Review (CAMPHOR)	Percent affirmation of items; logit location in Rasch analysis	Test-retest	TTO	Moindres carrés ordinaires ; modèle à effets aléatoires.	McKenna et al. (2008)
Asthma Quality of Life (AQL-5D)	Non available	Non available	TTO	fixed-effect model	Yang et al. (2011)
Adult Social Care Outcomes Toolkit (ASCOT)	Literature review on old instruments; empirical analysis	Comparison with other measurement tools	TTO; DCE; BWS	Multinomial logit model	Netten et al. (2012)
Dependency 6 dimensions (DEP-6D)	Non available	Non available	TTO	Random effects regression model	Rodríguez-Míguez et al. (2016)
Aberrant Behavior Checklist Utility Index (ABC-UI)	Factor and Rasch analyses, consultation with clinical experts	Non available	TTO	Maximum likelihood with random effects	Kerr et al. (2015)
Index of capability for older people (ICECAP-O)	iterative interviews until convergence	Non available	best-worst scaling (BWS)	Conditional logistic regression	Coast et al. (2008)
Diabetes Health Profile 3 & 5 dimensions (DHP-3D; DHP-5D)	Exploratory factor analysis; consultation with professionals in the field; Rasch analysis.	Validation by professionals in the field	TTO	Generalized Least Squares with Random Effects	Mulhern et al. (2017)
Diabetes Utility Index (DUI)	Non available	Comparison with other tools	VAS; SG	Simple linear regression model	Sundaram et al. (2010)
Overactive Bladder 5 dimensions (OAB-5D)	Factorial analysis; Rasch analysis	Standardised response mean (SRM) method	TTO	Ordinary least squares; random effects model "one-way error components".	Young et al. (2009) Yang et al. (2009)
King's Health Questionnaire (KHQ)	Relevance of quality of life, percentage of items completed, face and construct validity of items, score distribution and responsiveness.	Non available	SG	Random effects models	Brazier et al. (2008)
European Organization for Research and Treatment of Cancer (EORTC-8D)	Factorial analysis, Rasch analysis, expert opinion	Standard Mean Response (SRM)	TTO	Multivariate regression model	Rowen et al. (2011)
Dupuytren's contracture (DC)	Non available	Non available	DCE	Conditional logit	Gu et al. (2013)

Menopause specific health quality of life questionnaire	Focus group sessions with patients, literature review, expert opinion, standard psychometric criteria	Test-retest reliability, face validity, construct validity and convergent validity.	TTO	Random effects models	Brazier et al. (2005)
Flushing Symptoms Questionnaire (FSQ)	Rasch analysis	Non available	TTO	Ordinary least square	Young et al. (2010)
Sexual quality of life questionnaire (SQOL-3D)	Psychometric criteria	Non available	TTO; DCE; Ranking	Ordinary least squares and random effects model; Ordered logit	Ratcliffe et al. (2009)
International Index of Erectile Function (IIEF)	Non available	Consistency of IIEF ordinal structure	TTO	Non available	Stolk et Busschbach (2003)
Glaucoma Utility Index (GUI)	Review of existing instruments on vision and glaucoma; advice from experts in the field	Non available	DCE	Conditional logit regression model	Burr et al. (2007)
Visual Function Questionnaire–Utility Index (VFQ-UI)	Rasch analysis, expert opinion.	Non available	TTO	Multivariate regression	Rentz et al. (2014)
Short Bowel Syndrome-specific quality of life scale (SBS-QoL)	Factor analysis and item performance analysis, expert opinion	Non available	LT-TTO	Random effects model	Lloyd et al. (2014)
International prostate symptom score (IPSS)	Factorial analysis	Non available	TTO	Non available	Kok et al. (2002)

Appendix C

Table C5. Analysis of the quality of studies using the COSMIN grid.

Authors	Very good	Adequate	Doubtful/Undetermined	Inadequate
Hawthorne (2009)	57.89%	-	31.58%	10.53%
Kopec et al. (2015)	57.89%	-	26.32%	15.79%
Herdman et al. (2011a)	42.11%	-	47.37%	10.53%
Brazier et al. (2020)	57.89%	-	42.11%	-
Mulhern et al. (2020)	42.11%	-	31.58%	-
Sintonen (2001)	57.89%	-	36.84%	5.26%
Horsman et al. (2003)	47.37%	-	47.37%	5.26%
Seiber et al. (2008)	47.37%	-	42.11%	10.53%
Richardson et al. (2012)	57.89%	-	36.84%	5.26%
Nguyen et al. (2017)	47.37%	-	42.11%	5.26%
Mulhern et al. (2017)	57.89%	-	36.84%	5.26%
Young et al. (2009)	52.63%	-	42.11%	5.26%
Yang et al. (2009)	52.63%	-	42.11%	5.26%
Burr et al. (2007)	57.89%	-	42.11%	-

Netten et al. (2012)	84.21%	-	10.53%	5.26%
Rodríguez-Míguez et al. (2016)	63.16%	-	26.32%	10.53%
McKenna et al. (2008)	63.16%	-	31.58%	5.26%
Rowen et al. (2011)	57.89%	-	31.58%	10.53%
Bahrampour et al. (2019)	36.84%	5.26%	52.63%	5.26%
Mavranezouli et al. (2013)	57.89%	-	36.84%	5.26%
Versteegh et al. (2012)	57.89%	-	26.32%	15.79%
Beusterien et al. (2005)	57.89%	-	36.84%	5.26%
Brazier et al. (2005)	57.89%	-	36.84%	5.26%
Brazier et al. (2008)	63.16%	-	31.58%	5.26%
Cho et al. (2015)	52.63%	-	42.11%	5.26%
Gu et al. (2013)	42.11%	-	57.89%	-
Kerr et al. (2015)	63.16%	-	36.84%	-
Kok et al. (2002)	36.84%	-	52.63%	10.53%
Rentz et al. (2014)	52.63%	-	36.84%	10.53%
Kuspinar et al. (2014)	94.74%	-	5.26%	-
Lloyd et al. (2014)	42.11%	-	47.37%	10.53%
Mulhern et al. (2012)	42.11%	-	52.63%	5.26%
Ratcliffe et al. (2009)	47.37%	-	47.37%	5.26%
Stolk et Busschbach (2003)	52.63%	-	36.84%	10.53%
Young et al. (2010)	57.89%	-	36.84%	5.26%
Yang et al. (2011)	57.89%	-	36.84%	5.26%
Coast et al. (2008)	57.89%	-	42.11%	-
Sundaram et al. (2010)	63.16%	-	31.58%	5.26%
Revicki et al. (1998)	36.84%	-	42.11%	21.05%
Keetharuth et al. (2020)	57.89%	-	36.84%	5.26%

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