with the framework of Maslow’s hierarchy of needs. In conclusion, Maslow’s hierarch-
y of needs was partially supported by the WHOQOL-BREF.

**PMC70**

**CLASSIFYING PATIENT REPORTED OUTCOMES: DEVELOPMENTS IN THE FIELD SUGGEST A NEW TAXONOMY**

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**OBJECTIVES:** The FDA proposed the term ‘patient reported outcomes’ in 2001 which grouped concepts such as quality of life (HRQL), satisfaction and preference together in terms of their role in regulatory approval. Since then there have been notable developments in this field, but not the much wider use of stated preference methods such as conjoint analysis. **METHODS:** ISPOR’s Patient Preference Conjoint Analysis Working Group convened a team to develop a new taxonomy to characterise the different approaches used to capture patient based data. A thorough review of different patient reported methods was undertaken, and based upon discussion and further expert review, a taxonomy of methods based was developed. **RESULTS:** Several groups of methods emerged from the review which reflected both the underlying data that the method produces and also the audience of the data—regulators, payers, policy makers and decision makers. Group 1 (Classic PRO) includes different psychometric approaches, commonly based upon Likert scale responses. This group includes measures of HRQL, symptoms and treatment satisfaction. Group 2 (Stated preference) describes ordinal methods including conjoint analysis (discrete choice, graded pairs) and willingness to pay methods. Group 3 (Cardinal utility) describes cardinal methods of capturing health outcomes often used in economic evaluation. Each group of methods also has naturally different audiences. **CONCLUSIONS:** The FDA’s simple classification of measures as PROs does not reflect the diversity and applications of patient reported data. The proposed taxonomy we believe reflects important differences in methods and also the different uses of data.

**PMC71**

**THE EVOLVING HEALTH ECONOMICS EVALUATION PARADIGM AND THE ROLE OF THE QALY**

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The quality-adjusted life year (QALY) is a unit of measurement which combines the length and quality of life in a way which reduces the number of dimensions which must be taken into account in an economic evaluation. In simple cost utility analysis (CUA), the problem of allocating scarce resources is reduced to two steps: ranking projects by their cost per QALY and deciding upon a threshold cost per QALY above which projects will not be funded. Over time there has been increasing dissatisfaction with the perceived excessive simplicity of the approach. Partly this has arisen over technical questions which instrument should be used to measure QALYs (the SG, TTO, etc.), should the QALY be replaced by the healthy-year equivalent (HYE)—is there additive separability between health states; are valid QALY league tables achievable. However there has also been increased questioning of the value basis of the QALY. Should ‘utility’ incorporate an individual or social perspective (like the person trade-off (PTO) or economic rationality in the health care decisions in France. Although some countries yet chosen a validated method for resources allocation.

**PMC72**

**DEVELOPMENT OF THE ACCEPT© QUESTIONNAIRE TO ASSESS ACCEPTABILITY OF LONG TERM TREATMENTS: QUALITATIVE STEPS**

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**OBJECTIVES:** Patient-Reported Outcomes (PRO) are routinely used to measure disease severity, perceived treatment impact, or patient attitude toward treatment. However, adherence can only partially be explained by clinical and these PRO variables alone. Our objective was to develop a generic Acceptability measure assessing how patients balance out between advantages and disadvantages of long-term treatments. It could be used in future adherence studies. **METHODS:** A literature review was performed on medical databases using keywords related to acceptability, perceptions, motivations and barriers linked to treatment, allowing the initial conceptual model of Acceptability to be developed. Exploratory interviews were performed with 5 pharmacists and 18 patients. They were recorded, transcribed word-for-word and systematically analysed in order to complete the initial conceptual model. Items of the ACCEPT© questionnaire were generated in French for each concept identified, using patients’ words. The resulting test version was tested for relevance and comprehension with 5 patients, and revised accordingly; the new version was tested on a second set of 5 patients and revised to create the pilot version of the ACCEPT© questionnaire.

**PMC73**

**DIFFERENT STUDY RESULTS OF UTILITIES IN RELATION TO THE DOCUMENTING METHOD USED AND THE GUARANTEE OF LEGALLY COMPLIANT IQWIG RECOMMENDATIONS WITHIN THE FRAMEWORK OF COST-BENEFIT ASSESSMENT**

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**OBJECTIVES:** The Institute for Quality and Efficiency in Health Care (IQWIG) assesses the benefit and costs of drugs by considering their affordability and rationality from the insurants’ viewpoint. IQWIG forwards its assessments to the German Federal Joint Committee (G-BA) in the form of recommendations, which may be used in establishing ceiling prices for drug innovations. Within the framework of its methods proposal, IQWIG does not negate an intra-indication-related application of QALYs. However, depending on the methods applied and the target populations surveyed, different results can be generated for evaluating states of health. No international standard exists for a preferred method. **METHODS:** After performing a systematic literature search to identify studies in which various methods for documenting benefit were applied and different target populations were investigated, selected studies are presented, whose incremental cost-utility-ratios have an (extremely) wide scatter related to the documenting. Depending on the documenting method, indication-dependent trends are investigated for effect size and direction of QALYs. **RESULTS:** The studies identified showed that the variations in methods for documenting QALYs even within the same intervention trial considerably reduces its comparability. It is also not easily possible for decision-makers to make a decision based on these results. The documenting methods used clearly create different constructs that apparently display different levels of responsiveness in the same indication (e.g. rheumatoid arthritis, sleep apnoea, macular degeneration, oral anticoagulation).

**PMC74**

**WHICH HEALTH ECONOMIC APPROACHES FOR WHICH DECISION-MAKING SUPPORT IN METASTATIC CANCER? A LITERATURE REVIEW AND FRENCH EXPERT OPINIONS**

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Conventional health economic tools were not adapted to the very specific problems of metastatic cancer treatment. The objective of this study was to analyze the methodological tools used in published economic evaluations for metastatic breast cancer (empirical studies) and for all metastatic cancer treatments (methodological studies). Results of a systematic literature search (Medline, Embase, Cochrane Library, Pascal, HTA databases) since 1990 were completed by expert interviews (oncologists, health economists, decision-makers). 535 abstracts were screened and 80 selected, excluding: clinical trials with no economic analysis, alternative treatments to chemotherapy, early stages of cancer, any metastatic cancer with no specific and/or original methodology and/or endpoints. According to a pharmacoeconomic quality checklist, 37 were analyzed. The review showed a majority of studies in breast cancer with low level of evidence and only two prospective studies. More than half of the studies were cost-utility analyses. Endpoints combine quality of life and other indicators: QALY (Quality-Adjusted Life Years), QTW (Quality-Adjusted Time Without Symptoms and Toxicity), QAFPEY (Quality-Adjusted Progression-Free life Years), QADs (Quality-Adjusted Days of life). We did not find any specific criterion to the metastatic state. Experts recommend the use of multi-dimension criteria comprising direct and indirect costs, efficacy and quality of life data integrating patient preferences; thresholds of resource allowance should be defined according to treatment strategies and population subgroups (performance status, age, illness severity). This study underlines the need to develop tools for poor prognosis and raises the issue of economic rationality in the health care decisions in France. Although some countries have chosen arbitrations (QALY, Efficiency Frontier per pathalogy), France has not yet chosen a validated method for resources allocation.