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

**PMC70**

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

Lloyd A1, Bridges JP2, Johnson FR3

1Oxford Outcomes Ltd, Oxford, UK, 2Johns Hopkins University, Bloomberg School of Public Health, Baltimore, MD, USA, 3RTI Health Solutions, Research Triangle Park, NC, USA

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 preferences research such as conjoint analysis. METHODS: ISP0’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**

Schändler M1, Richardson J2

1Institute for Innovation & Valuation in Health Care (InnoVal-HC), Westbaden, Germany, 2Monash University, Clayton, Victoria, Australia

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 patients with dissimilar problems, and disregard characteristics of services except for cost-benefit assessment. In each group of patients additionally different analyses. 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.

**PMC72**

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

Marant C1, Spazak C2, Lorigo J1, Mavril A1, Van Ganse E1, Arnedt B1, Patrick DL2

1Institut Curie, Paris Cedex 05, France, 2Roche, Neuilly sur Seine, France

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 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). In the inter-indication comparison, a clear trend could not be determined for the effect size in the results in relation to the documenting methods used. CONCLUSIONS: If the legal conditions are satisfied and a consistent decision using cost utility analyses in one indication area is possible, the documenting method for utilities must be standardised. This could be directed indication-specific towards an optimum correspondence with the responsiveness of validated, disease-specific quality of life documenting instruments.

**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**

Dintzos CM1, Volz F, Seidl A2

1Institute for Quality and Efficiency in Health Care, Cologne, Germany, 2Materialwirtschaft und Wirtschaftswissenschaftliches Zentrum der Universität zu Köln, Köln, Germany

OBJECTIVES: The Institute for Quality and Efficiency in Health Care (IQWiG) assesses the benefit and costs of drugs by considering their affordability and reasona-
bleness from the insurers’ 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 investi-
gated, 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). In the inter-indication comparison, a clear trend could not be determined for the effect size in the results in relation to the documenting methods used. CONCLUSIONS: If the legal conditions are satisfied and a consistent decision using cost utility analyses in one indication area is possible, the documenting method for utilities must be standardised. This could be directed indication-specific towards an optimum correspondence with the responsiveness of validated, disease-specific quality of life documenting instruments.

**PMC74**

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

Baffet S1, Alfonsi A2, Florantin V1, Livrarroctow A1

1Institut Curie, Paris Cedex 06, France, 2Roche, Neuilly sur Seine, France

Conventional health economic tools are 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). 353 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 ana-
lyzed. The review showed a majority of studies in breast cancer with low level of evi-
dence 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), Q TWIST (Quality-Adjusted Time Without Symptoms and Toxic-
ity), QAPFEY (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-dimensional criteria comprising direct and indirect costs, efficacy and quality of life data integrating patient preferences; thresholds of resource availability need to be clearly defined according to treatment strategies and population sub-
groups (performance status, age, illness severity). This study underlines the need to develop tools for poor prognosis and raises the issue and necessity of economic rationality in the health care decisions in France. Although some countries have chosen arbitrations (QALY, Efficiency Frontier per pathology), France has not yet chosen a validated method for resources allocation.