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

PCM70
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 the field, not least 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 for 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.

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), Wiesbaden, 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: the comparison of 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 been also increased questioning of the value basis of the QALY. Should ‘utility’ incorporate an individual or social perspective (like the person years lost (PYL)), could economic values revert to the earlier concept of hedonic, rather than preference / utility (i.e., subjective well-being), but, perhaps most fundamentally, can QALYs be abstracted from other values relating to the distribution of benefits between patients with dissimilar problems, and disregard characteristics of services except which they cost? Which utility, social well-being (SWB), etc? Apart from normative concerns, there are an increasing number of empirical studies on societal preferences for health care resource allocation, indicating that the QALY maximisation hypothesis must be considered as falsified. The broad range of documented ‘contextual’ variables implies that an uniform ‘social value’ of a QALY does not exist, and suggests that projects designed to determine the dollar value of a QALY will either fail or mislead policy.

PCM72
DEVELOPMENT OF THE ACCEPT© QUESTIONNAIRE TO ASSESS ACCEPTABILITY OF LONG TERM TREATMENTS: QUALITATIVE STEPS
Marcelli C1, Spakot C1, Longin J1, Van Gasse E1, Arnoldi E1, Patrick DL1, Majo Valun1, Lyon, France, 2Registre-Cancer, Lyon, France, 3Pfizer-Wehrheim Hospital, Bron, France, 4University of Washington, Seattle, WA, USA
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 conducted on biomedical 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.

RESULTS: In the test version, items generated for each concept identified were organized into 6 sections: drug characteristics, duration, constraints, side-effects, efficacy and global acceptability of treatment. Except a few items that were modified or deleted following patients’ suggestions and some minor modifications in the answer choices, the questionnaire was globally very well accepted, easy to complete, and considered relevant and appropriate by patients. The pilot version of the ACCEPT© questionnaire contains 32 questions divided into the same 6 sections as the test version. CONCLUSIONS: The comprehension tests confirmed the existence of the previously hypothesized concept of treatment Acceptability. The ACCEPT© questionnaire will allow the Acceptability of a great variety of long-term treatments to be assessed, while being a specific instrument making sense to each individual.

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
Dirkx CM1, Volz F, Siedl A2
1Institute for Quality and Efficiency in Health Care, Cologne, 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 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 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 con-
trasts 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 corre-
spendence with the responsiveness of validated, disease-specific quality of life docu-
menting instruments.

WHICH HEALTH ECONOMIC APPROACHES FOR WHICH DECISION-MAKING SUPPORT IN METASTATIC CANCER? A LITERATURE REVIEW AND FRENCH EXPERT OPINIONS
Buffet S1, Alfonso A2, Florinetti P1, Livrario C1
1Institut Curie, Paris Cedex 05, France, 2Roche, Neuchâtel sur Seine, France
OBJECTIVES: 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-
yzed. 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), QTWST (Quality-Adjusted Time Without Symptoms and Toxic-
ity), QAPFYs (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 sub-
groups (performance status, age, illness severity). This study underlines the need to develop tools for poor prognosis and raises the issue of an 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.