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

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, not least the much wider use of stated preference measures
such as conjoint analysis. METHODS: ISPOR’s Patient Preference Conjoint Analysis
Working Group convened a team to develop a new taxonomy to characterise the dif-
ferent 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 meas-
ures 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 that 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 differ-
ences in methods and also the different uses of data.

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,
TTTO, etc.), should the QALY be replaced by the healthy-year equivalent (HYE)—is
there additive separability between health states; are valid QALY league tables achiev-
able. 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
trading off time and money)? Should economic values rever to the older 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 when
measuring utility, social well being (SWE) or value. Apart form normative concerns, there are an increasing number of empirical
studies on societal preferences for health care resource allocation, indicating that the
QALY maximization hypothesis must be considered as falsified. The broad range of
documented ‘contextual’ variables implies that a uniform ‘social value’ of a QALY
does not exist, and suggests that projects designed to determine the dollar value of
QALY will either fail or mislead policy.

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 vari-
ables alone. Our objective was to develop a generic Acceptability measure assessing
how patients balance out between advantages and disadvantages of long-term treat-
ments. It could be used in future adherence studies. METHODS: A literature review
was performed using medical databases using keywords related to acceptability, per-
ceptions, 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 organ-
ised 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. CONCLU-
SIONS: The comprehension tests confirmed the existence of the previously hypothe-
sised acceptability concept. The ACCEPT© questionnaire will allow the Assessability
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 CO-PROFIT B-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 reasona-
bleness from the insuran’s 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
(exremely) wide scatter related to the documenting. Depending on the documenting
method, indication-dependent trends are suggested for effect size and direction of
QALYs. RESULTS: The studies identified showed that the variation 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-
structs 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-
ponsiveness 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
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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 methodo-
logical 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 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-
ty), 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 multidimension criteria comprising direct and indirect costs,
efficacy and quality of life data integrating patient preferences; thresholds of resource
availability 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 proper progression and raises the issue of economic rationality in the health care decisions in France. Although some countries
have chosen arbitrations (QALY, Efficiency Frontier per pathology), France has not
eyet chosen a validated method for resources allocation.