European Guidelines for Cost-Effectiveness Assessments of Health Technologies

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Health technology assessment (HTA) is becoming more challenging given the increasing need to assess and compare multiple and complex health technologies. In parallel, there is a realization that **more robust cost-effectiveness analyses** are needed to assess and compare the overall benefits and monetary value of various therapeutic options and health care interventions.

Some European Union (EU) member states have developed country-specific frameworks and recommendations to guide the post-licensing evaluation of new health technologies. There is however **significant variation amongst EU member states** regarding their respective recommendations with respect to economic evaluation**.** Some HTA agencies prefer to use Quality Adjusted Life Years (QALY) health outcome measure combined to acceptance thresholds, arguably for convenience or ease of use.

The ECHOUTCOME European project surveyed 1'300 respondents in Belgium, France, Italy and the UK, thus being **the largest survey ever undertaken to assess the theoretical assumptions of the QALYs**. The responses varied hugely across the population showing that the way people rate different medical outcomes is subjective to personal situations, and cannot be encapsulated exclusively by the QALY formula. **This European research concludes that the assumptions tested in the experiment invalidate the QALY as a suitable health outcome measure for making medical decisions** and allocating scarce resources. Further research is needed to assess the feasibility, reliability and validity of more flexible, clinically meaningful and robust methodologies.

These European cost-effectiveness guidelines should be considered as a step forward and as the new HTA methods of reference across EU member states towards establishing transparent HTA practices in Europe.

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Recommendation 1

Clear Distinctions Between Cost-Benefit, Cost-Effectiveness and Cost-Utility Analyses Should Be Established

A number of publications present costs per Quality Adjusted Life Years (QALY) analyses (cost-utility analyses) under the umbrella of "cost-effectiveness" analyses. This creates confusion between distinct approaches which do not share the same methodological assumptions. It is thus recommended to use the right original terminology to clearly distinguish the different methods, namely:

- *cost-benefit analyses:* health outcomes are expressed in monetary values
- *cost-effectiveness analyses:* health outcomes are expressed in clinical outcomes units
- *cost-utility analyses:* health outcomes are expressed in utility values

Recommendation 2

QALY Assessment for Healthcare Decision Making Should Be Abandoned

Based on the results of the largest experimental survey ever undertaken in Europe which tested the validation of QALY assumptions, the QALY indicator does not constitute a scientifically validated measure.

Then, given the overwhelming methodological limitations of the QALY indicator, and the major inconsistencies which irrefutably invalidate its use, the use of QALY indicators should be abandoned for healthcare decision making.

Recommendation 3

Cost-Effectiveness Analyses Should Be Expressed as Costs per Relevant Clinical Outcome

Valid cost-effectiveness analyses should use clinical outcomes as preferred consequences, relevant to the therapeutic area and usual medical practices.

In most cases, health priorities are expressed for one single therapeutic area. Then, cost-effectiveness analyses expressed as cost per therapeutic success would offer a potential robust alternative.
Making priorities across diseases represents a rare situation in public health. In such case, epidemiological outcomes could be used in cost-effectiveness assessments, such as cost per life years save, or cost per case avoided.

Recommendation 4

Cost-Effectiveness Analyses Should Be Validated With an Inter-Disciplinary Research Team

Cost-effectiveness research teams should be composed of clinical, economic, and methodological experts in order to ensure that study assumptions reflect medical practices, adequate costing assessments and robust methodological principles.
When necessary, experts in ethics or mathematics should join the research team.

Recommendation 5

Alternative Methodologies for Assessing Cost-Effectiveness Should be Explored on A Case-by-Case Basis

Because of the scientific complexity of situations raised by Health Technology Assessments, there is currently no single alternative paradigm to propose.

There is a spectrum of additional analytical techniques for assessing new technologies and healthcare interventions, which should be considered, on a case-by-case basis.

For example, the following analytical techniques could handle various outcomes including costs and health consequences in cost-effectiveness models (non limitative list):

Multi-criteria and Multi-dimensional Analyses, Bayesian Analyses, Neural Networks of Bayesian Networks, Simulation Techniques, Item Response Theory, Computer Adaptative Testing, Agent-based Modelling, Differential Item Functioning Cluster and Segmentation Analyses, Statistical Meta-analyses, etc.