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Editorial: Moving the QALY Forward or Just Stuck in Traffic?

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This Special Issue summarizes an ISPOR Consensus Development Workshop held in November 2007 on methods for estimating and applying quality-adjusted life-years (QALYs) [1–7]. Participants were charged with the agenda of "Moving the QALY Forward," with the primary objective of seeking consensus on how to define and refine the QALY. The authors analyze the underlying assumptions, offer critiques of QALY methods, and propose alternative approaches. Although the contributions provide a reasonable overview of the current state of QALYs, they confirm several rather unfortunate truths. First, the scientific foundations of conventional QALYs remain unsatisfactory—being essentially unchanged since their inception. Second, many practitioners and policymakers remain content to apply QALYs uncritically and unapologetically for the purposes of health-technology assessment (HTA). As a consequence, one must conclude that the prospects for moving the science and practice of QALYs forward are discouraging.

It is remarkable that three decades of QALY research have yielded so little substantive methods development. This lack of progress is particularly discouraging in light of the rapid international growth of HTA and increased attention to comparative effectiveness issues in the United States. Rather than moving HTA science and practice forward, QALY research appears to be stuck in a methodological traffic jam.

Unsatisfactory Theory

It is clear that strong institutional demand exists for a simple, intuitive metric for assessing health status across a broad range of applications that can be applied with little explanation or technical expertise. Most participants at this Workshop seemed to agree with Smith et al. [1] that "the lack of a simple better measure as an alternative makes the QALY an indispensable tool." The simplicity of the QALY as a universal health-care metric certainly has lead to its broad acceptance, but it comes at the cost of several limiting assumptions. The significance of these assumptions generally are poorly understood, or simply ignored, among practitioners and policymakers despite the assumptions' repeated failure in careful tests of validity and reliability.

Apart from Kahneman's [4] suggestion that we abandon any attempt to measure utility and leave health evaluations entirely to the judgment of a small group of experts, Nord et al. [3] offer the only serious critique of conventional QALYs in this collection. Their concerns include well-known empirical and conceptual deficiencies such as inconsistencies among values obtained from standard-gamble, time-trade-off, and visual-analog-scale elicitation formats and linearity assumptions that violate diminishing marginal utility. It is not surprising to survey researchers that health-state utility values are influenced by the elicitation format. Because the context provided in the elicitation format matters, the best strategy is to elicit preferences with formats that mimic the policy-relevant context as closely as possible. Other preference-elicitation methods such as conjoint analysis or discrete-choice experiments offer opportunities to simulate a more realistic clinical decision context [8].

Even if QALY researchers were to adopt better measurement methods, any resulting improvements would be meaningless if users insist on linear, additive utility. One of the fundamental principles of economics is diminishing marginal utility, which requires that values be nonlinear. Marginal values of a given commodity decrease as quantities already consumed increase. Health is not exempt from this virtually universal principle, yet standard HTA practice ignores the fundamental nonlinearity of preferences. A significant movement forward would be to acknowledge and embrace evidence of preference nonlinearities in everyday QALY applications.

Uncritical Practice

Weinstein et al. [2] acknowledge that "the conventional QALY remains a powerful conceptual tool" and that "the conventional QALY retains an important role in health care decision making." Nevertheless, moving the science and practice of QALY research forward requires going beyond orthodoxy. Researchers must help decision-makers identify circumstances where the benefits of relaxing QALY assumptions or considering alternative approaches justify at least a modest increase in analytical complexity. For example, nowhere in this special issue is there mention of the approach adopted by the Institute for Quality and Efficiency in Health Care (IQWiG) in Germany. IQWiG is playing an increasingly important role in HTA thinking, and has concluded that QALYs are both unethical and unconstitutional within the context of the German health system [9]. Such a strong rejection in Germany of the QALY approach to HTA is an interesting exception to the common assumption that conventional QALYs are essential to prudent allocation of health care resources.

A Poor Prognosis

It is clear that I share Nord et al.'s [3] view that, in view of the limitations of the conventional QALY model, "more sophisticated models may be required." Unfortunately, because decision-makers clearly have a strong revealed preference for simplicity, various proposed improvements to QALY measurement have remained in the pages of academic journals. Decision-makers' demand for a simple solution to HTA has forced investigators with an interest in policy-relevance to devote scarce research resources to lower priority topics. For example, Lipscomb et al. [5] discuss challenges in translating health-state descriptions from one health-related quality of life instrument into another. Although this certainly is a practical concern, it is of secondary importance in the QALY research agenda. The highest priority research problem is not how to describe health states, but how to

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obtain a valid utility estimate for any particular description. Similarly, several articles in this issue devote considerable attention to equity considerations. There is little likelihood that equity considerations will be neglected in health-care decision-making. However, our understanding of public decision-making suggests that there are considerable grounds for concern that equity will dominate decisions and that consideration of *efficiency* will be neglected.

QALY research and practice reflect a general consensus that health-care decisions are fundamentally different than other public investments. Thus, HTA deviates from common economic evaluation practices in virtually every other area of societal decision-making. One wonders how much longer the particularism enjoyed by health-care stakeholders will survive in the competition for increasingly scarce public resources and the relentless rise in health-care costs.

The entrenched state of the practice in HTA and devotion to the QALY leaves serious researchers in an awkward position. We all should have an interest in developing more valid indicators of health outcomes that will improve the efficiency of health-care spending. On the other hand, proposed improvements in QALY methods are not likely to have much traction with decision-makers until researchers are able to document a significant—perhaps dramatic—misallocation of health-care resources as a result of the distortions introduced by using an oversimplified health index.

How to Move Forward

Despite the wide acceptance of QALYs among health economists, nearly all nonhealth economists view the concept and implementation of this metric with considerable skepticism. Moving the QALY forward requires taking such outside skepticism regarding the HTA status quo more seriously. The research agenda should include several important questions, such as:

1. What lessons can be learned from 50 years of economic research in Europe and the United States on optimal public investments?
2. What lessons can be learned from the ongoing German experiment to apply a completely different approach to HTA?
3. What is the cost in money and human suffering of allocating scarce societal resources using QALYs?
4. How can users be trained to accept and implement more valid, if somewhat more complicated, approaches to HTA?

Traffic jams are a consequence of poor planning, perverse incentives, and inefficient use of scarce resources. Similarly, the lack of movement in health-technology traffic signals a failure to resist incentives to endorse simplistic approaches to HTA and to demand that health care decision makers take their responsibility to the commonweal seriously enough to adopt more valid methods.

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