Editorial: On the Benefits of Modeling Using QALYs for Societal Resource Allocation: The Model Is the Message

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While moderating a debate at the recent ISPOR meeting in Athens, Professor Milt Weinstein suggested that maybe we should focus more on the "LY" (life-years) and less on the "QA" (quality-adjusted). I interpreted this comment to mean that health state utilities are only one element in the larger bioclinical models that are at the core of many cost-utility analyses. Typical disease-based cost-utility models also include intermediate end points to reflect disease progression, the probabilities of clinical events, and projected survival, as well as the cost elements. The focus of this quality-adjusted life-years (QALY) consensus development workshop was, however, on health state utilities—one element in the entire model. We have argued elsewhere that similar benefit-risk models, including health state utilities, could be very helpful in making regulatory approval deliberations more systematic and transparent [1]. In my view, the use of integrative, quantitative models to assist health-care decision-makers is more important than precisely how morbidity (i.e., health-related quality of life) is reflected in those models.

On the whole, these articles provide a fair and very useful representation of the current state of the debate about health state utilities and preferences in our field: namely, there remain several persistent and contentious issues—both about the theory and the practice. As noted, the ISPOR Consensus Development Workshop was motivated by the challenge that Nobel laureate Daniel Kahneman posed in his ISPOR address in 2005. He reprises that argument about human adaptability to illness in his contribution to this collection. Although these final Workshop articles did not resolve any of these issues, the Consensus Development Group should be congratulated on fashioning eight highlevel principles [2] that capture the state of the debate as well as a way forward, including the pragmatic next step of calling for the development of a reference method for estimating QALYs. In my view, this is a useful goal to pursue, but it will be helpful to keep in mind some higher level distinctions that were either implicit or unaddressed in these articles.

The Workshop articles did not explore two related foundational issues in any depth: 1) the use of the QALY in normative versus positive (or behavioral) economics; and 2) welfarism versus extra-welfarism as a basis for the use of the QALY in societal resource allocation.

Ex Ante versus Experienced Utility

First, the problem of whether to use ex ante versus "experienced" utility was addressed, though not resolved. The answer to this will depend on whether we are making normative societal

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10.1111/j.1524-4733.2009.00520.x

Lou Garrison has no conflict to declare.

resource allocation decisions or trying to understand or predict the behavior of patients. In any case, it is important to recognize that individual preferences change and adapt and that individuals are prone to errors and biases in decision-making under uncertainty [3]. One interesting suggestion in these articles is a kind of two-step procedure to inform those doing ex ante health state preferences about the ratings of patients based on experienced (i.e., ex post) utility. All of this raises an even more profound question: should we be asking "predictably irrational" people [4] about their preferences-either ex ante or ex post-when it comes to normative (rather than behavioral) analysis? Or should we be trying to determine what they would choose if they were rational, and use that for social decision-making? Mention is made of "equity-adjusted" QALYs. Maybe we should instead be considering "irrationality-adjusted" QALYs? The expected utility model that underlies cost-utility analysis provides a framework for overcoming some of these biases and irrationalities, but if the utility values themselves are biased, then the results can be misleading. Until we resolve the issue of which utilities are more rational and stable-experienced versus ex ante versus experience-informed ex ante-our best approach to social decision-making may be to develop a reference case method, as recommended here, that is consistent even if potentially biased. As fallible human beings making private decisions under constraints, we spend every day of our lives grappling with this question of what is truly in our best interest: public resource allocation decisions face the even greater challenge of aggregating those preferences.

Welfarism versus Extra-Welfarism

Second, when it comes to public resource allocation, where do we stand in using QALYs? The pragmatic proponents of QALYs would emphasize that no decision is, in fact, a decision, and that we have to make resource allocation decisions, so let's get on with it. There seem to be two poles in the use of the QALY—the UK and the US. Brouwer et al. [5] have recently provided a useful summary and description of the differences between welfarism and extra-welfarism that can help us to understand these poles. Although this area has its own controversies [6], the key issue seems to be that societies can choose to adopt policies that override "consumer sovereignty."

Among all health systems, the UK has the most developed and consistent approach to using QALYs in resource allocation. The basic principle—an extra-welfarist one—is that as a democratic society, the majority of British citizens have supported a set of public institutions that provide a national-level budget constraint for health (a "ring-fenced" budget) and the maximization of expected QALYs within that constraint. The reliance on the QALY and the cost-utility modeling under this system is understandable and logical. Of course, this is not to say that all citizens agree with this all of the time.

The United States is at the other pole: generally, QALYs and pharmacoeconomic cost-effectiveness analyses are not explicitly

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or consistently considered by either private or public payers. Being recommended by the Public Health Service Panel [7] for the "reference case" analysis, QALYs and cost-utility analyses show up primarily in academic publications and scientific meetings. At best, but importantly, this economic evidence can influence resource allocation implicitly through its impact on clinical practice guidelines. This can create norms of care, which in turn provide clinical, ethical, legal, and economic incentives that influence practice.

Welfare economics and the market failure paradigm have long provided a useful framework for understanding the special economics of health care. The welfarist view is grounded in consumer sovereignty and utilitarianism, and assumes that individuals vary in their preferences and generally have the best idea of what is in their best interest. Different preferences clearly mean different utility valuations: so, given the same information, different individuals would and do make different choices among health interventions and between health and other goods. Although health care is sometimes seen as a "merit good," for which individuals have preferences about other citizens' access to it, there is no fixed global budget for health or any specific percentage of GDP that is "right"—because it can easily change for many reasons. There is no constant value of the QALY that applies to all citizens: people make different choices.

Defining a Minimum Benefit Package

So what is the need for the QALY in such a "free-market" world? First, given the challenges of the biases and complexities in medical decision-making—as elucidated by Professor Kahneman—physicians, patients, and payers may find these costutility analyses to be useful decision support tools as they confront these difficult decisions. Second, if we posit that heath care is a merit good, and that we, therefore, care that our fellow citizens have access to some "minimum benefit package," then we will care about what is made available in that package. Admittedly, the current minimum in the United States is sketchy, implicit, unreliable, and sometimes even disgraceful; nonetheless, the safety net of Medicaid, emergency care, and cost-shifting via uncompensated care is a kind of implicit national health insurance [8].

Some major US reform proposals—from Enthoven's Consumer Choice Plan in 1978 [9] to the Emanuel-Fuchs voucher plan of 2005 [10]—include the definition of a societal minimum or universal benefit package. Presumably, cost-utility models (including QALYs) can provide a pragmatic tool for considering inclusions and exclusions to that package. Clearly though, just as in the UK, the vast majority of health sector spending (i.e., hospital and physician care) would be grandfathered in. In other words, the prospect of an Oregon Medicaid-type zero-based budget reconsideration of all medical services is probably not feasible practically or politically, so that changes to the list of covered benefits might only occur slowly over time, focusing on potential innovations. But with a more explicit national plan, the

United States would face—just as in the UK—the issue of whose preferences to use for the national coverage decisions. The UK has chosen to use the average health state preferences of the general population as the standard for comparison. Based on public finance theory, if an explicit minimum benefit package were adopted in the United States, then an interesting alternative would be to consider the preferences of the median or "swing" voter, who would in theory cast the deciding vote on the elements of the package.

To conclude, it is important to recognize that at either pole, we have to make social decisions—implicit, if not explicit—about resource allocation. In my view, the use of cost-utility models that use the QALY can be a pragmatic and necessary tool to improve these complex decisions—often made under conditions of considerable uncertainty and bias.

Source of financial support: Funding for the ISPOR "Building a Pragmatic Road: Moving the QALY Forward" Consensus Development Workshop was made possible in part by grant 1R13 HS016841-01 from the Agency for Healthcare Research and Quality. The views expressed in written conference materials or publications and by speakers and moderators neither necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the US government. Funding for this *Value in Health* special issue, "Moving the QALY Forward: Building a Pragmatic Road" was made possible in part by Contract No. HHSN261200800148P from the National Cancer Institute.

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