

QALYs: Some Challenges

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Introduction

In the preceding article, Weinstein et al. [1] explain the QALY concept, its methods, and their underlying assumptions. A number of interesting themes for discussion arise from this factual presentation. We restrict ourselves to addressing four issues that we deem particularly challenging.

As a general background for our selection of issues, we reiterate a basic point about valuation perspectives: Standard QALYs are meant to express the personal utility of health outcomes as judged *ex ante* and “on average” by the general public from behind a veil of ignorance about future health (so-called “decision utility”). Standard QALYs thus express value in terms of *ex ante* self-interest. There are, however, possible alternatives. First, health state utilities may in principle be elicited *ex post* rather than *ex ante*, i.e., from people who have or have had direct experience with the health states that are the object of the valuation (so-called “experienced utility”). Second, QALYs may be constructed to express society’s valuation of health outcomes when not only self-interest but also concerns for fairness are taken into account. The choice of approach depends on the question one wishes to answer, and the choice of health state valuation techniques depends on the choice of perspective.

The issues we address in the following reflect the above plurality in possible valuation perspectives and are in part independent of each other. One issue is intermethod variation in the estimation of *ex ante* health state utilities. A second is the existence of unwillingness to trade lifetime in elicitation of experienced utility. A third is the discrepancy between aggregate individual utility of health programs on the one hand and, on the other hand, societal valuations that include concerns for fairness. A fourth is a hitherto much overlooked distinction between healthy individuals’ valuations of states of illness (which is crucial in the conventional QALY procedure) and people’s valuations of treatment (valuations of health gains—including unintended side effects—or avoided health losses), which economic evaluation at the end of the day *should* be concerned with.

Among important issues that we do not address are discounting for time preference and attitudes to uncertainty. For discussions of these, readers are referred to earlier literature, e.g., [2,3]. Because we focus here on challenges to the QALY, we furthermore set aside concerns some hold that health should be valued for its impact on the range of exercisable opportunities open to people rather than on welfarist grounds [4].

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Bombardier et al 1982 (5). Health care personnel, patients, family.	Needs walking stick when moving about.	Needs supervision when walking.	Needs two assistants for moving about.
SG	0.85	0.64	0.38
TTO	0.78	0.41	0.11
RS	0.65	0.29	0.08

Figure 1 Differences between primary techniques in valuing health states. SG, standard gamble; TTO, time trade-off; RS, rating scale.

Variation in Health State Utilities

In cost-utility analyses of health technologies and programs, a variety of tools are used for valuing health states. In the health economics literature and in decision-making, results of analyses based on different tools are not infrequently compared with each other. For such comparisons to be helpful, different tools should yield much the same values for the same states. In fact, this is not the case. Typically, the standard gamble yields higher values than the time trade-off, which again yields higher values than the rating scale. Figure 1 gives an example [5]. For a later comparison, see for instance [6]. There are similar differences between multi-attribute utility instruments. Figure 2 shows an example [7]. Although evidence on this issue varies somewhat in the literature, the right-hand column of the table suggests that differences in valuations of states may have important consequences for the valuations of gains in health.

The problem of intermethod variation may in principle be alleviated by the development of algorithms for “cross-walking,” i.e., for “translating” utilities from a given tool to corresponding utilities according to other tools. Research to this effect is being conducted (among others by Dennis Fryback et al. at the University of Wisconsin); the reliability of cross-walking remains to be established. If its reliability and justification are unclear, then a question remains about the validity of the cost-utility tools.

Experienced Utility: Unwillingness to Trade Lifetime

To assess the actual benefits of a health-care program, a strong case can be made, that one needs quality of life information from people with experience with the health states involved in the program [8–10]. Nevertheless, when the standard gamble and the time trade-off are applied to patients and disabled people, many report zero willingness to sacrifice life expectancy to be relieved of their health problem [11–13]. The unwillingness to

	A: Crutches, light pain, unable to work	B: Difficulties moving about outdoors, some discomfort, able to do some work	U(A)-U(B)
EQ-5D (UK tto)	0.45	0.80	0.35
HUI 2	0.70	0.92	0.22
15-D	0.86	0.92	0.06

Figure 2 Differences between multiattribute utility instruments (Source: [7]). HUI, Health Utilities Index.

trade results in utilities of 1.0, which seems clearly unreasonable for states of less than full health. Arguably, the problem is that the time unit used in these studies—a full year—was too big. If one asks about willingness to sacrifice a month or a week or a day, there will presumably be a point at which any seeming “non-trader” will actually be willing to trade (George Torrance, personal communication). But even if this is true, two problems remain. One is in terms of policy relevance. If people with a considerable problem, for instance being dependent on a wheelchair for moving around, stated that they were willing to sacrifice only a month out of 10 years to be relieved of their problem, they would get a utility of 0.99. Would such a high number really be helpful for evaluating a program for getting them out of the wheelchair? The high number would also count against investment in preventive programs aimed at reducing the prevalence of conditions leading to wheelchair dependence. The other problem is in terms of meaning. The idea behind the standard gamble and the time trade-off is that the utility (value) of a health gain is reflected in people’s willingness to sacrifice to obtain it. But is willingness to trade a very small amount of distant lifetime necessarily an expression of willingness to sacrifice? We think it is possible for subjects to say that “Well, if you ask me about a month, then sure, I would be prepared to trade that off, but it would be without any feeling of sacrifice, since the time is so short and so distant.” If this is the psychology behind the response, it is hardly usable as an indication of value. Research into this issue is needed.

We believe that information about patients’ experienced quality of life is essential for economic evaluation of health interventions, but we think that the potential limitations of conventional utility measurement tools like the standard gamble and the time trade-off in patients and disabled people need to be carefully considered. We also are concerned that we know less about the experienced quality of life of people in various health states than is generally assumed when sensory deficits or mobility are taken as the key examples. Arguably, some of the gap, where there is one, between evaluations *ex ante* and from experience comes from those *ex ante* not anticipating adaptation; when cued to do so, the gap diminishes. Some of the gap may also reflect the objective loss of opportunity, which is not captured by experienced evaluations that have discounted certain opportunities. Also, adaptation may be less successful in those with, for instance, depression or traumatic brain injury compared to those with mobility problems [14].

Concerns for Fairness

As noted above, the standard QALY expresses value in terms of aggregate individual utility.

A question raised by many over the last 20 years is whether health benefits valued in this manner adequately represent *society’s* valuation of health programs for different groups of people when also concerns for fairness are taken into account. In our view, three particularly salient ethical problems have been identified.

The first problem arises from the fact that there is, in the standard QALY approach, no regard for the pretreatment utility level of the individuals concerned. Both ethical theory and public opinion in a number of industrialized countries suggest that, in setting priorities, society emphasizes how bad off the individuals would be if intervention did not take place [15–19]. That is to say, the worse off an individual would be without an intervention, the more highly society tends to value that intervention. This aspect of societal valuation is often referred to as an *independent concern for severity*. In quantitative population preference studies (e.g., by Peter Ubel et al. in the United States, Jeff Richardson in Australia, Paul Dolan et al. in the United Kingdom, Erik Nord in Norway), QALY gains to severely ill groups have been weighted two to 10 times more highly than gains to less severely ill groups (see reviews in [18,19]).

Second, the conventional QALY model implies that the value of an intervention is proportional to the beneficiary’s capacity to benefit. The model thus favors those with more treatable conditions and those with greater potentials for health—be it in terms of functioning or longevity. This is somewhat at odds with both ethical theory and public opinion, which suggest that it should not be held against people that they happen to have conditions for which there are no complete cures or that their remaining lifetime is somewhat limited [15–17,20–23]. The upshot seems to be that for groups with the same severity of illness, society does not wish to give strong priority to those whose health gains are greater over those whose health gains are smaller if the gains are substantial in both groups. The empirical preference studies mostly refer to prioritizing between groups with different potentials for improvements in quality of life. Nevertheless, in a qualitative study of public preferences in the United Kingdom, Dolan and Cookson [24] found the same reluctance to discriminate in situations where groups differed in terms of potentials for gaining lifetime (for instance 10 vs. 20 years). Their overall conclusion was that “50 years after the creation of the British National Health Service, people still seem to believe that there should be priority accorded to those in urgent need of medical attention. Whilst capacity to benefit does matter, it is a secondary consideration.”

The third problem is a special case of the second one. Valuing health gains in terms of QALYs means that life-years gained in full health—through, for instance, prevention of fatal accidents in people in normal health—are counted as more valuable than life-years gained by those who are chronically ill or disabled—for instance, by averting fatal episodes in people with asthma, heart disease, or mental illness. This conflicts with the idea of an equal right to protection of life by all, irrespective of their health condition, as long as they themselves have the desire to live [25,18] and also runs counter to results obtained in a study of public preferences for priority setting in the United States [26].

The concerns noted above may lead to considerable discrepancies between—on the one hand—rankings of health programs according to standard cost-per-QALY ratios, and—on the other hand—their ranking according to broader societal and political value judgments. We would argue that in much of the literature

of cost-utility analysis, the potential magnitude of these discrepancies has been insufficiently appreciated. There seems to be a need for greater recognition and acceptance of conventional cost-per-QALY ratios as only partial information about value for money in different areas of health care. In our view, the cost-per-QALY ratio of an intervention is a type of *productivity indicator*. It tells decision-makers how much—in this case, *health*—is produced per unit of resource used. Although this certainly is useful information, setting priorities in health care must be based on a wider set of considerations. The point is clearly recognized in the Institute of Medicine discussion of the ethical limitations of cost-effectiveness analysis in regulatory settings [27].

This said, one may ask whether there are ways of incorporating concerns for fairness formally in the QALY model. To this, we return in a later section.

The Ex Ante Value of Health States versus the Value of Interventions for People with Illness

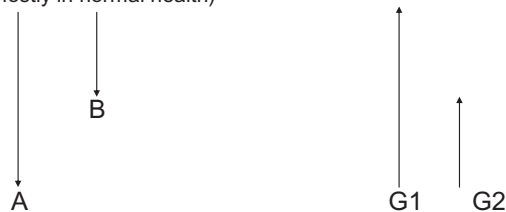
The fact that standard QALY calculations do not capture societal concerns for fairness does not imply that the calculations are flawed per se. In principle, they may still be valid estimates of what they purport to express, namely aggregate individual utility. In this section, however, we raise a more fundamental question, namely whether standard QALYs are constructed in a way that entails systematic underestimation of the individual utility of health gains when treatment potentials are somewhat limited. The hypothesis is based on three premises.

One is that, in the standard QALY procedure, there is no utility elicitation on *gains* in health resulting from interventions, even if such utility estimation is actually the aim of the procedure. For functional and symptomatic gains, there is only indirect valuation through ex ante preference elicitation (disutility judgments) on *states of illness* (health states) and subsequent subtraction of health state values from one another. The “subtraction procedure” is understandable on grounds of data collection feasibility: The number of possible changes is much higher than the number of possible states ($n/2[n - 1]$ possible changes if n states). It is nevertheless a proxy approach, which has not been discussed, let alone validated, in the health economics literature. For gained lifetime, there is no valuation at all of different numbers (quantities) of years gained, only of their quality. Also, this aspect of the QALY model lacks validation.

A second premise is that QALYs make no difference between comparisons of different outcomes for the same individual and different outcomes for different individuals with different potentials for health. Assume, for example, that wheelchair user A can be brought either to “dependent on crutches” or “full health,” whereas wheelchair user B can at best be brought to “dependent on crutches.” An intervention that takes both to “dependent on crutches” will score the same in terms of individual utility in the standard QALY model. This seems like a conflation of quite different valuation contexts, which may invoke quite different psychological issues and processes. For instance, for person A above, “the best (full health) will probably be the enemy of the good (crutches).” This is not the case for person B.

The third premise, related to the second, is that the value of gains in health needs to be understood in the light of two well-known aspects of human psychology. One is that value judgments depend on reference points (the individual’s point of comparison or “status quo” against which alternative scenarios are contrasted) and aspirations [28–30]. The other is that goods tend to have diminishing marginal utility (as a pure quantity effect, i.e., also when outcomes are certain).

States valued by community sample
(mostly in normal health)



Groups in state A with
different potentials

Figure 3 Valuing states versus valuing gains in health.

In the following, we argue that failure to take these two psychological mechanisms into account may lead standard QALY procedure to relate the individual utility of health care too strongly to the “size” of the health benefit that may be obtained.

Consider two states of disability, A and B. Standard QALY procedure is to let a random sample of the general population judge the badness (and goodness) of the states relative to full health. Assume that, from the sample’s typical reference point of “normal health,” A is considered to be twice as undesirable as B, and that, on average, people are willing to sacrifice 40% of their life expectancy to avoid A and 20% to avoid B. So A scores 0.6 on the QALY utility scale, whereas B scores 0.8, cfr Figure 3.

Now consider two groups of people, G1 and G2, who happen to contract two different illnesses. Both groups find themselves in state A (0.6). People in G1 can be restored to full health. For people in G2, that is not possible. But the best available medical technology can significantly improve their condition and raise them to state B (0.8).

The interesting question for cost-utility analysis is how highly the two *interventions*—leading to the two *changes in health*—are valued by those concerned. On examination, the following problem appears: According to the QALY “subtraction method,” the intervention for people in group G1 scores twice as much as the intervention for people in group G2 (0.4 vs. 0.2). But would people in group G2 necessarily value the help they could be given only half as much as people in group G1? From the position of being in full health, B is unattractive. But after onset of illness, the reference point of group G2 has changed, and so have presumably their aspirations. The most important concern may now be to achieve something better than state A. Furthermore, from the position of being in A and having B as the best possible outcome, B may appear more attractive than it did earlier. Perhaps, group G2’s valuation of help is not so much less than that of group G1 given the equality in the severity of the two groups’ condition and the reduced maximum health group G2 now has to accept. The method of subtracting one ex ante health state values from another misses this possibility.

Although the point we make here concerns the assessment of individual utility, it relates directly to our point in the preceding section about variability in potentials for health. If one demands mathematical consistency across the very different perspectives (anticipating a loss of health and being in diminished health and needing an intervention), consistency is obtained at the cost of devaluing the interest people who cannot be fully restored to health have in interventions that nevertheless improve their health.

The idea that the utility of health gains depends on reference points and health potentials seems relevant also with respect to

gains in life-years. Consider two groups, G1 and G2, with life-threatening conditions of different kind. Individuals in G1 can be restored to a normal life expectancy of, for instance, 20 years, whereas individuals in G2 can only be given a life expectancy of 10 years. Assume that all else is equal. Given their situation, i.e., given their having a risk of death as a reference point, the primary concern in both groups may be to avoid death in the near future and to at least get “some years.” This possible effect of the reference point may be strengthened by the general phenomenon of diminishing marginal utility: Even if there were no time preference, a prospect of 20 years is arguably unlikely to be considered twice as valuable as a prospect of 10 years. In short, although the two groups may value their potential gains differently, the two groups’ valuations will perhaps not differ as much as the difference in life-years, combined with conventional discount rates for time preference, might suggest.

The above reasoning—with respect to both functional improvements and gains in life-years—applies to utility assessments of health care *ex post* to illness. In principle, *ex post* feelings and valuations may be anticipated before illness. It is thus possible that nonproportionality between effect size and utility may be true also of individuals’ *ex ante* preferences for health care as expressed in preferences for health insurance.

It is a matter for empirical research to examine the questions we here raise. Some preliminary results from pilot studies were presented at the Philadelphia consensus workshop in November 2007 (publication forthcoming). Here, we restrict ourselves to noting a published study of preferences for priority setting in a series of focus group workshops with health administrators in different counties in Norway [31]. One of the issues concerned self-interest. Subjects were asked to think of two hospitals, A and B. Hospital A gave equal priority to patients with equal severity of illness, irrespective of the degree of treatability as long as the treatment effect was substantial. Hospital B gave priority to those with a greater potential for improvement. The subjects were reminded that they could not know what kind of illnesses they themselves might contract in the future and were then asked which hospital they would prefer to “belong to” if they were to think only of their self-interests as potential future patients. Of 51 subjects, 31 preferred hospital A (equal priority for people with different treatment potentials), whereas 20 preferred hospital B (priority according to treatment potential). The result is consistent with our reasoning above. Altogether, we feel—when we look across conditions and patients with different treatability and potentials—that to estimate the personal utility of interventions by looking simply at differences between *ex ante* health state values is an element of the QALY procedure that needs reconsideration.

Incorporation of Concerns for Fairness

In theory, the QALY model can be modified to incorporate the concerns for fairness noted earlier in this article and thus become a model of “equity adjusted QALYs.” One modification would be to count as 1 all gained life-years, even if they are in less than full health, as long as they are good enough to be desired by the individuals concerned [9]. Although agreeing with the underlying ethical premise, Johannesson [32] claimed that such an approach would lead to inconsistencies with individual preferences for health care. A response to this objection has been given elsewhere [33]. A second modification would be to place less weight on the duration of health benefits in comparisons of programs for patients with different life expectancies. This may, for instance, be done by discounting distant health gains more strongly than at the 3%–5% annual rate that is customary in conventional cost-

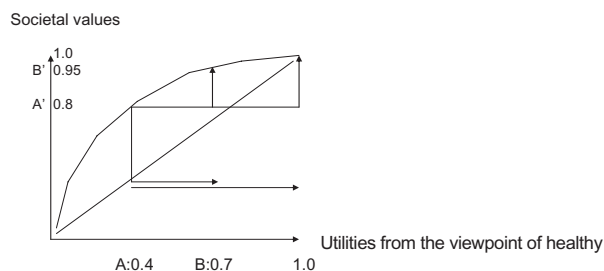


Figure 4 Valuing gains in functioning/quality of life: Transformation of Utilities (Source: [7], *cfr.* [9]).

effectiveness analysis, or by disregarding benefits that lie beyond a certain point in time. A third modification would be to add explicit equity weights [34], or—more specifically—severity weights and potential weights [9], to the quality of life weights of the conventional model. Alternatively, one may transform conventional utilities into societal values that incorporate concerns for severity of illness and reluctance to discriminate strongly against those with less treatable conditions and/or lesser potentials for health [7,9]. As can be seen in Figure 4, a transformation curve that is convex to the *y*-axis and has strong upper end compression can, in principle, accommodate both these concerns. For instance, in the figure, the curve transforms conventional utilities of 0.4 and 0.7 to societal values of 0.8 and 0.95. If one replaces utilities from the *x*-axis with the values from the *y*-axis, the value, for instance, of a cure of A relative to B increases from 2:1 to 4:1 (concern for severity), whereas the value, for instance, of taking someone from A to B relative to from A to healthy increases from 1/2 to 3/4 (concern for reduced potential). Some empirically based, tentative transformation functions of this kind for utilities from the Health Utilities Index, the EQ-5D, and other multi-attribute utility instruments have been published elsewhere [35].

The idea of incorporating concerns for fairness in a numerical valuation model may sound sensible but is not unproblematic. Some may feel that as long as the validity of the QALY as a measure of individual utility is in itself questionable, scarce intellectual resources should be devoted to resolving that issue before wider challenges are taken on. Others are concerned that incorporation of concerns for fairness may overload the model and perhaps make it more difficult to understand and less reliable [36–39]. Their preference is to leave it to decision-makers to take concerns for fairness into account informally in fair deliberative processes when dealing with the results of cost-effectiveness analyses.

As an alternative to elaborating the QALY to incorporate concerns for fairness, fair deliberative processes could be used to determine a range of cost-per-QALY thresholds according to context (rather than modifying the QALY itself). Such an approach could consist in establishing a set of “priority classes” to which treatments are assigned according to other criteria than cost-effectiveness (for instance, the severity of the condition, the lack of better treatment alternatives, or special end-of-life considerations). The more worthy of funding an intervention is considered to be according to such other criteria, the higher the class assignment. The higher the priority class, the higher the tentative cost-per-QALY thresholds would be. A considerable span of thresholds over the range of classes could be decided based on fair-minded people’s careful deliberations concerning societal values in priority setting. In the appraisal of new technologies, two kinds of assessment would be undertaken simultaneously and independently of each other (by different people).

One would be class assignment, again based on the deliberations of informed and fair-minded people. The other would be cost-effectiveness analysis. The result of the latter analysis would be compared with the relevant threshold, i.e., the one resulting from the independent class assignment.

Such a two-channel process would in theory remove the current primacy of cost-effectiveness considerations in economic evaluation, particularly if a large span was decided between the highest and the lowest cost-per-QALY threshold.

The choice of methods and procedures for incorporating concerns for fairness is an important practical issue for continued debate, as noted elsewhere in this issue [40]. The above possibilities are mentioned to indicate how complicated or uncomplicated modifications of the conventional QALY model would have to be and thus enlighten the debate.

But Figure 4 reveals a deeper problem. The societal values on the y-axis purport to indicate how important society thinks it is to treat people in state A compared to people in state B. In the example in the figure, the ratio is 4:1. On the other hand, according to the numbers on the x-axis, people in normal health have said that they view state A only as twice as bad as state B. In valuing *preventive* programs, it seems that the latter ratio is more relevant than the ratio resulting from the transformation.

Some will see this as a mathematical inconsistency problem. We see it differently. Prevention and treatment are activities that take place in different contexts, in which people—both patients and decision-makers—have different reference points, expectations, and feelings of obligation to others. Mathematical consistency in values and preferences is not necessarily to be expected across situations that differ on such issues.

This leads us to raise the question as to whether, in societal valuations of health programs, there may be a need to distinguish between valuations of preventive and curative programs. It is perhaps naïve to think that one single method of valuation is sufficient to inform priority setting in two so different contexts. Because conventional QALYs reflect the general public's ex ante judgments of the undesirability of different health states, one might say that they primarily speak to the challenges of setting priorities between preventive programs. When it comes to valuing and comparing interventions and treatment programs for people with different degrees of severity of illness and different potentials for health, the conventional QALY model may arguably have less to say and more sophisticated models may be required.

Final Remark

This article is based on the premise that formal valuation models may be helpful in increasing accountability in decision-making about resource allocation in health care. It is beyond the scope of this article to discuss exactly to which extent they can be helpful, including to discuss how sophisticated models can be made without becoming more mystifying than informative. We stress that whatever formal models analysts choose to use, results of formal evaluations should not be taken as final “answers” to resource allocations questions. Instead, they should always serve as *inputs* to further deliberations and fair decision processes [36,37]. This is also the official position of NICE and the Institute of Medicine report on cost-effectiveness in regulatory settings [41,27].

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