

The Use of QALYs in Clinical and Patient Decision-Making: Issues and Prospects

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Background

Decision-makers utilize the results of economic analysis in a wide range of settings that include governmental agencies, managed care, and other health-care payers [1,2]. A cornerstone of such analysis is the quality-adjusted life-year (QALY), which is formed by the arithmetic product of quantity and quality of life. The expansion in use of economic evaluation by health agencies has mirrored the growing recognition of the usefulness of health-related quality of life (HrQoL) as an important indicator of outcome of disease treatment among clinicians and patients [3–7]. This information has a dual use in that it informs both clinicians and health economists in the evaluation of treatment options. The use of the QALY as a health outcome measure for groups of patients is fairly clear for payers, managed care, and governmental organizations who seek to make decisions that maximize the value of health-care spending in terms of health outcomes achieved through the most efficient use of limited resources. Nevertheless, the importance and need to bring QALYs into the wider decision-making process of clinicians and patients is more controversial.

For the purposes of this article, it is assumed that economic evaluation of health-care interventions by national reimbursement or other health-care decision-making bodies is largely a given, although there clearly are health-care jurisdictions in which this is not the case. Nevertheless, in a global marketplace, the requirements of dominant health-care jurisdictions are likely to influence the behaviors of other stakeholders across the world community. Hence, the influential role of cost-utility analysis (CUA) as part of an information toolkit for high-level decision-making is unlikely to be radically altered in the next 5 to 10 years. Central to CUA is the need for an outcome measure that combines the effects of health interventions on mortality and morbidity into a single index—the QALY. Critical to the computation of QALYs is the assessment of the impact of morbidity, represented through the measurement of HrQoL from data gathered in clinical trials and observational studies. Although these same data are applied in the economic evaluation of new health technologies, they may also be used in other non-economic applications, for example, in monitoring health status in individual patients, or in measuring population health or the impact of therapies in clinical studies.

Different health jurisdictions permit or require different forms of HrQoL measurement in the economic evaluation of health technologies. Some stipulate that the weights used to value

HrQoL states are social preferences that reflect the views of the general population. Others are open to the use of values derived from patients or others directly affected by the health technology. The question as to whose values do (or should) count is a matter for local arbitration within the decision-making framework of specific societies and their individual health-care systems. Ultimately, it is a political choice. It is not (and should not be) determined by health economists or other single stakeholder groups. For the purposes of this article, it is sufficient to note that the quality-adjustment factor used in computing QALYs can emanate from several sources and may or may not represent the views of the patient or those who care for them.

It is worth briefly reflecting on both “decision-maker” as an attribute of an individual or set of individuals and “decision-making” as an activity undertaken by members of that set. High-level policy that shapes the development of health-care programs is clearly distinct from the day-to-day delivery of care to patients. Decision-making activity in support of the former is more likely to make use of economic evaluation than is the case in the latter. Policy formation is informed to some extent by aggregated measures of costs and benefits. Individual clinicians may contribute to those data but more often are faced with decisions that are made in relative ignorance of the wider societal-level picture. A decision by a clinician to admit a patient to hospital for treatment, or to provide innovative therapy or embark on diagnostic investigations is likely to be taken with minimal reference to the evidence of any economic evaluation (should it exist). Conversely, health programs are more likely to be formulated with regard for evidence of effectiveness and cost-effectiveness of such interventions when applied to population subgroups, occasionally to whole populations.

This article addresses a number of related issues that stem from a more widely drawn interpretation of the QALY in which its status as a composite measure of health benefit is recognized, but where its role is not wholly contained within or limited to a cost-effectiveness framework. Under what circumstances is QALY-based information of value to decision-makers such as clinicians and other staff with direct responsibility for patient care? Is the QALY in its present format useful for the comparison of health outcomes within a given therapeutic area? How might the value to clinicians and patients of QALY-based information and its application in low-level decision-making be enhanced? And finally, what obstacles need to be overcome in extending the uses and usefulness of the QALY to noneconomist health-care decision-makers?

QALYs and Decision-Making

Taking the QALY as a given part of economic evaluation and a fundamental component of CUA, it is an open question as to

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whether the QALY is useful to health-care decision-makers outside that reference space. The question might be more widely posed in respect of the general role of economic evaluation in health-care decision-making. Is there a universal benefit that derives from its use across all levels of decision-making or is that benefit restricted to specific applications? Here, it is more useful to see the QALY simply as a summary measure of health benefit intended in the first instance for use in one specific application but potentially of value in other settings. To address its wider usefulness requires the consideration of 1) the type of decisions that are made by those charged with the responsibility of planning, managing, allocating resources, and delivering health care; 2) the organizational level at which such decisions are made; and 3) the role of individuals and groups of individuals within that organization. Figure 1 displays how the application of QALYs might (from a theoretical standpoint) extend across different types of decision-makers. The columns list decision-making segments in a health-care delivery system, and the rows represent the type of measurement/focus of interest.

This matrix helps to identify a set of potential users within sectors within a health-care system or organization and the different levels at which QALY-based information might be used for different forms of observation and measurement. Cells that are shaded black exemplify situations in which a QALY is currently unlikely to be of relevance—for example, in government-level decisions made with respect to individual patients. Cells that are left unshaded indicate situations in which QALY-based information might have potential for practical decision-making, for example, those made by provider units in respect of individual patients. Cells that are partially shaded indicate a mixed assessment of QALY potential. Entries for some cells only exist from a theoretical point of view because no practical use for QALYs can be envisaged at the present time. For example, in informing decisions about individual patients, it is relevant to consider patient-specific data on quality and quantity of life rather than QALYs based on aggregated data that incorporate a societal

perspective on the value of any health benefits. Further study would be required to test the comprehensiveness of the decision set described in Figure 1 and it is included here only by way of illustration.

We note that the literature regarding patient involvement in health treatment decision-making is expanding with the increased sophistication and access to information about health-care alternatives [8,9]. Research regarding improved effectiveness of the patients' participation in their own health decisions through the use of HrQoL and quantity of life measures have involved treatments for cancer [3,10–13], hepatitis C [14], heart failure [15], dialysis [16], Parkinson's disease [17], and sickle cell anemia [18]. The application and relevance of HrQoL and QALY measures to clinicians is expanding and it is possible to find examples that report the use of QALYs in a range of conditions such as heart failure [19], diabetes [20], and oncology [4–7]. The use of cost-effectiveness analyses that incorporate QALY outcomes to supplement formulary decisions is also increasing in managed care pharmacy [2–21].

Two characteristics of the QALY are important when it comes to identifying potential uses and users. First, the QALY is a generic measure which means that for some clinicians, it will be seen as lacking the specificity that is required in daily practice. Second, the weighting system used to compute the quantity × quality product is most often calibrated in terms of social preferences—not those of the patient or other beneficiaries of treatment. Hence, the criticism that the value attached to quality of life may be determined by wholly disinterested and ill-informed third parties. This represents a more significant challenge to those who advocate for the wider use of the QALY as a measure of health outcome.

The QALY's constituent elements (HrQoL and survival) separately provide information in measuring outcomes. For example, if a choice is to be made between two therapies in oncology, if one has a 60% chance of survival to 5 years and the second has an 80% survival rate, and if survival were the only choice

Form of measurement	Level of aggregation	Users of QALY – based health outcomes data				
		Patient	Individual provider	Provider groups	Employer /insurers	Government
Observing health status	<i>Individual patients</i>					
	<i>In groups of patients</i>					
	<i>In whole populations</i>					
Comparison with normative reference data	<i>Individual patients</i>					
	<i>In groups of patients</i>					
	<i>In whole populations</i>					
Measuring change over time	<i>Individual patients</i>					
	<i>In groups of patients</i>					
	<i>In whole populations</i>					

Figure 1 Users and uses of health outcomes data. Black—quality-adjusted life-year (QALY) is unlikely to be relevant to decision-making by user. Gray—QALY may (or may not) be relevant to decision-making by user. Unshaded—QALY is likely to be relevant to decision-making by user.

criterion, then the latter would be preferred to the former as it maintains the patient's existence for longer. When viewed solely in terms of quantity of life (survival), one therapy dominates the other. Nevertheless, such a comparison wholly discounts any quality of life differential. By opting to use QALY-based information, the HrQoL component would be given a status that is absent when only survival is used to differentiate treatment options. The relevance of such considerations in patient-centered decision-making is more common in therapeutic areas such as oncology where trade-offs between life expectancy and the quality of the time that remains are particularly salient. It is for this reason that standardized measures of HrQoL are more numerous and have been in widespread use for longer.

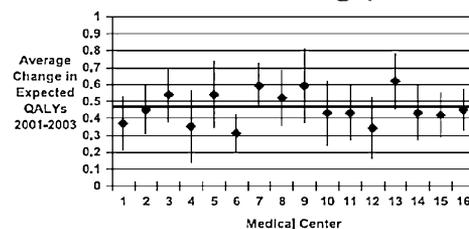
For the clinical decision-maker working within a given therapeutic area, there sometimes can be little to encourage them to use the QALY as a measure of health benefit. Where there is no differential effect on survival and a decision is to be made between (say) two alternative surgical procedures, for example, in fixing a fractured femur, any marginal HrQoL outcomes would be the principal driver in accounting for any QALY differences. What then would be the practical value for the orthopedic surgeon who is invited to see the wider potential use of QALY-based information in setting priorities outside of his specialist area? What is to be gained for him or his patients from this more generalized measurement of outcomes?

Despite all this, there does seem to be some scope for a wider management role for the QALY quite apart from its primary application within cost-effectiveness analysis. For example, one recently reported an application that demonstrated the use of QALYs in the valuation of quality improvement in diabetes management [22]. The Diabetes Risk Factor Control (a disease management program) [22] used a QALY-based metric to examine performance in terms of delivering improved outcomes to patients with diabetes by adopting appropriate monitoring and treating strategies for those patients. Historically, most diabetes-related quality measures have focused on multiple process measures that have not been empirically linked to improved outcomes, or on single risk factor levels typically represented as percents of patients in "control." As such, not only does typical monitoring and measurement not enable decision-makers to consider the value associated with a decision to allocate resources to the care of patients with diabetes compared to allocations in other clinical areas, but it also does little to inform the allocation of resources across multiple diabetes care management options. A summary measure based on a standard metric has the potential to greatly improve decision-making. Figure 2 exemplifies the use of expected mean change in QALYs gained as an index of performance in 16 Kaiser Permanente Medical Centers.

Although providers and patients are interested in separately incorporating information on HrQoL and quantity of life in treatment decision-making, improving the relevance of the QALY as a composite measure to these groups of users involves promoting its interpretability. The QALY was developed to inform top-down decision-making processes through the medium of CUA. Nevertheless, a different practical and theoretical underpinning is needed if it is to have relevance to patients and clinicians. Some attempt is necessary to bridge that gap and adapt QALY measures to render them more applicable in the clinical setting. This could involve methods that place HrQoL measures in the hands of the patient and clinician at the point of decision-making, thereby generating QALY results that are relevant to the clinical situation.

The apparent lack of consensus among HrQoL instrument developers, methodologists, and health economist weakens the case for accepting the QALY as a standard metric. Criticism is

Real-world Exemplars – I Clinical Decision Making (Diabetes)



Mean change in QALYs across Kaiser Permanente Medical Centers

Source : Schmittiel et al, Predicted Quality-Adjusted Life Years as a Composite Measure of the Clinical Value of Diabetes Risk Factor Control, *Medical Care* Volume 45, Number 4, April 2007, 315–21.

Figure 2 Clinical decision-making in diabetes. QALY, quality-adjusted life-year.

played down or circumvented. So for example, although it is generally acknowledged that different utility elicitation methods yield different quantitative estimates, there is no agreement on which of these variants constitutes the preferred method—or indeed whether any such choice exists at all. Observations of this sort tend to be dismissed but in so doing entirely miss the point that the existence of a standard method would be consistent with a mature QALY technology. A similar argument can be made regarding the selection of a reference source for the values themselves. The preference for social values over patient (or caregiver) values is contingent on the belief system of the QALY user. For non-economists, the discounting of patient values is hard to understand or tolerate.

Moving the QALY forward

There is a need to develop evidence of the importance of the independent usefulness of the disaggregated QALY components and to decouple what are essentially technical issues around the valuation of health status. The mechanics for collecting patient-based HrQoL assessments have been presaged in the UK National Health Service with the requirement from 2009 for pre and postsurgery measurement of health status in selected procedures [23]. Embedding such data within national health information systems should make for an easier interpretation of QALY-based information. Assimilating HrQoL into routine clinical practice will assist the longer-term development of other uses for those same data.

The routine use of HrQoL in operational and clinical contexts will itself help move the QALY forward. Including it as part of the process of delivering care would change the way people regard decisions that are based on it. But there needs to be some sort of recommendation about which HrQoL system to use because continuing debate about the choice of system creates a significant problem, confusing the process of understanding and undermining attempts to show how HrQoL data might be creatively exploited. Going back to decision-makers and asking them what might be useful and in what context is an important first step in achieving real change. Getting decision-makers to accept this tool means ensuring that they have some experience with it. This is an educational prerequisite and starts with getting an understanding of how HrQoL can be used in patient-level decision-making. In moving the QALY forward, it may be helpful to consider approaches such as the transtheoretical model (TTM)

of change, developed by Prokaska [24,25]. The TTM model has been successfully applied in studies of patient decision-making [26]. The TTM model proposes that we think of decision-makers as being in different stages in their potential ability and interest to use QALYs. For example, patients are probably unaware that QALYs exist and although providers may be aware of them, they may be skeptical or perplexed by them. Different strategies and educational efforts are needed based on the TTM stage in which individual currently resides.

Conclusions

There are merits in the use of the QALY within the mainstream of decision-making concerned with questions of resource allocation within patient populations, but the boundaries of practical usefulness are only slowly evolving. For a more generalized adoption of the QALY as a component in decision-making beyond its traditional economic evaluation hinterland, several things must happen. To go beyond cost-effectiveness applications that explicitly legitimize the QALY requires a concerted effort to rigorously evaluate the use of QALYs in a variety of decision-making situations. Such evaluations would include those that consider both the perceived quality of decision-making process and as well as their final results. We need to improve our understanding of the extent to which decision-makers would utilize information based on QALYs. That is an issue that seems ripe for investigation. The paucity of evidence that bears on this issue suggests that this is an unknown area. To make progress here, we have to do more than assert that there is a ready audience for this kind of information. Investigating the issue and identifying the value to real-world clinicians and patients is the proper way to proceed. ISPOR should take a leadership role in this educational process, so that good practice and guidance in delivering the technology for applying QALYs would follow.

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