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Assessing the Added Value of Health Technologies: Reconciling Different Perspectives

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ABSTRACT

Providing universal access to innovative, high-cost technologies leads to tensions in today's health care systems. The tension becomes particularly evident in the context of scarce resources, where the risk of taking contentious coverage decisions increases rapidly. To ensure economic sustainability, the payers of health care think that the benefits from the use of the new technologies need to be commensurate with the costs. Therefore, many jurisdictions have programs of health technology assessment, which often results in restrictions of access to care, either through complete refusal to reimburse the technology or its restriction of use to only a subset of the eligible patient population. However, manufacturers feel that they should be adequately rewarded for their innovations and require sufficient funds to invest in further research. Finally, patients perceive these technologies to have added benefits, and so they are concerned when they are denied access. If sustainable access to health care is to be maintained in the future, approaches are needed to reconcile these different perspectives. This article explores the approaches, in both methods and policy, to help bring about this reconciliation. These include rethinking the notion of social value (on the part of payers), aligning manufacturers' research more closely with societal objectives, and increasing patient participation in health technology assessment.

Keywords: comparative effectiveness, health technology assessment, patient participation, quality-adjusted life-year.

Introduction

Providing universal access to innovative, high-cost technologies leads to tensions in today's health care systems. Many of these tensions arise from the fact that the main actors in the health care sector have different perspectives on the value added by health technologies. For example, the payers of health care feel that the benefits from the use of the new technologies need to justify the costs. Therefore, many jurisdictions have programs of health technology assessment (HTA), which often results in restrictions of access to care, either through complete refusal to reimburse the technology or its restriction of use to only a subset of the eligible patient population. The central notion of value in these assessments is the cost per quality-adjusted life-year (QALY). (A similar concept to the QALY, the disability-adjusted life-year is used in assessments carried out in developing countries.)

However, manufacturers feel that they should be adequately rewarded for their innovations and require sufficient funds to invest in further research. They feel that the restrictions on the use and price of health technologies resulting from HTAs limits their sales potential and ultimately the profits from which future research has to be funded. Manufacturers, however, sometimes set research priorities on the basis of the pursuit of a research hypothesis, as opposed to developing new technologies that meet unmet social need.

Finally, patients, and the clinical professionals who act as their agents, perceive the value of health technologies in terms of the benefits that these confer to the individual, irrespective of the costs falling on society more broadly. The characterization of these benefits may or may not be fully reflected in QALYs. Therefore, patients are concerned when they are denied access because of inadequate value for money, as expressed through the incremental cost per QALY gained.

If sustainable access to health care is to be maintained in the future, approaches are needed to reconcile these different perspectives. This article discusses three general strategies for achieving this. In the next section, we discuss ways in which payers might rethink the notion of value, including alternatives to the QALY. Then, we discuss how health technology manufacturers might align their research and development more closely with social objectives. Finally, we discuss how the participation of patients and their representatives in HTA might be increased, so that patients' perceptions of the various treatment benefits can be more closely aligned with those of payers.

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Rethinking the Notion of Value in Health Care

Growth of HTA

Faced with the rising costs of health care, governments and other payers in many jurisdictions have introduced programs of HTA. Increasingly, the assessments of the costs and benefits of new treatments, in comparison with existing care, have become "hardwired" into the decision on whether to reimburse the new technology.

The detailed methods of HTA vary from jurisdiction to jurisdiction, but a common approach is to express the benefits of treatments in terms of QALYs gained. (A similar concept to the QALY, the disability-adjusted life-year has been adopted by the World Health Organization and is widely used in assessments carried out in developing countries) [1].

Comparisons are made between health technologies in terms of their incremental cost per QALY gained as part of the reimbursement decision. In some countries, such as the United Kingdom, there is an explicit "threshold" of incremental cost per QALY gained beyond which the new technology will not be approved for reimbursement [2].

Problems with QALYs

Because the QALY reflects the added years of life and the improved quality of life resulting from treatment, it could be argued that it is a reasonable measure of health gain. But is it a reasonable measure of social value? In cost-benefit analysis, the form of economic evaluation most closely aligned to classical welfare economics, the benefits are measured by the sum of individuals' willingness to pay. This approach, however, has not been extensively pursued in the health care field because of the practical and emotional problems in assigning values to life and death.

There are two main reasons why the QALY may not adequately reflect social value. First, given the blunt nature of some of the instruments used to assess changes in quality of life, it is possible that these will not reflect all the aspects of treatments that individuals care about. For example, QALYs are unlikely to be sensitive enough to detect differences in the side-effect profile of alternative treatments, or differences in convenience resulting from different forms of administration (e.g., oral medication vs. intravenous infusion).

Sometimes, health technology organizations compensate for this in their decision-making procedures. For example, in an assessment of treatments for metastatic breast cancer in the United Kingdom, the National Institute for Health and Clinical Excellence (NICE) eventually recommended two available taxanes (taxotere and taxol) on the basis of evidence submitted by patient groups that the drugs had different side-effect profiles. It therefore determined that the choice of taxane should be at the discretion of the patient and her physician (J. Mossman, personal communication, March 5, 2012).

Also, in its technology appraisal of quick-acting and long-acting insulin analogues, NICE recommended that these more costly medications could be used if the patient could not tolerate frequent injections [3]. Both these decisions, however, resulted from the discussions that took place in the Appraisal Committee, rather than from the analysis of cost per QALY gained.

The second reason why the QALYs gained may not adequately reflect social value relates to the way in which the QALYs are normally aggregated in the technology appraisal. Each gain in QALYs is treated as being equally valuable, no matter whether the gain arises mainly from life extension or improved quality of life. In addition, QALYs are valued the same no matter who receives them.

While this approach could be viewed as egalitarian, it can also be questioned. First, simple aggregation of QALYs requires that the quality-of-life scale on which they are based has strict interval properties. That is, a gain of 0.1 QALYs is valued the same whether the patient's health state (on a scale from 0 to 1) is improved from 0.2 to 0.3 or from 0.8 to 0.9.

Some surveys suggest that improving the health of an individual with a very serious health condition may be valued more highly by the general public than improving the health of someone who is already reasonably healthy [4,5]. This notion is reflected in the supplementary guidance given to the NICE Appraisal Committee in the assessment of treatment for "end-of-life" conditions. If the therapy is for a small patient population with a life expectancy of less than 24 months and when the therapy adds 3 months or more to life expectancy, the committee can consider that the QALYs gained should be weighted greater than unity if this means that the therapy could be approved given NICE's cost-effectiveness threshold [6].

Therefore, it is possible that for some health treatments and technologies, appraisals based on health gain (expressed in QALYs) may deviate from those based on social value. This is illustrated in Figure 1 [7]. The technologies in cluster A have no special characteristics to suggest that perceptions of social value are highly positive or negative. Therefore, they may be reliably appraised on the basis of their incremental cost per QALY. Technologies in cluster B, however, while having a cost per QALY lower than the threshold, have a perceived low social value. Therefore, they may not be reimbursed, despite being "cost-effective" by current criteria. Examples could be the surgical removal of tattoos, or treatments for male impotence. However, society may wish to reimburse technologies in cluster C, despite the fact they are *not* cost-effective. Examples here could be end-stage cancer treatments and drugs for rare diseases.

Alternatives to QALYs

Three alternatives to QALYs have been proposed. First, one could leave the main clinical outcomes in their natural units and let the trade-offs between them be made by the committee. This is the approach suggested by the Institute for Quality and Efficiency in Health Care in Germany [8]. To date, there is not enough experience with this approach to provide an assessment of its feasibility and usefulness.

The second approach would be to revert to providing estimates of willingness to pay through contingent valuation. This approach is now well established as a research methodology in the health care field [9] but has not, so far, been widely accepted by decision makers.

The third approach would be to conduct discrete choice experiments (DCEs) to explore individuals' valuations of the various attributes of treatments. This approach has also established itself as a research methodology [10] and is now attracting the interest of decision makers. DCEs enable several attributes of treatment to be valued relative to one another. These can include not only clinical outcomes but also convenience and duration of treatment.

Mühlbacher et al. recently conducted a DCE for the (German) Institute for Quality and Efficiency in Health Care (IQWiG) on treatments for hepatitis C, considering both patients' and clinical experts' opinions [11]. Levels of achievement for various attributes of treatment were considered, including treatment efficacy, treatment duration, frequency of injections, the probability of adverse effects and their duration. The highest weight was given to the main clinical attribute, probability of sustained virological response, by both patients and experts, although other attributes