Assessing the Added Value of Health Technologies: Reconciling Different Perspectives

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A B S T R A C T

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.

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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 implicit “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
of therapy were also considered to be important. The opinions of patients and clinical experts were also quite similar in this example, although that may not be the case on all occasions.

In summary, there is a strong case for decision makers to be rethinking the notion of value in health care. Activities could include the exploration of differing weights for QALYs and further experimentation with stated preference approaches, such as DCEs, in real decision-making situations.

Aligning Manufacturers’ Research with Social Objectives

Research and Development in the Health Care Industries

Both the devices and pharmaceutical industries invest heavily in research. In Europe, the medical device industry employs more than 500,000 people and generates sales revenue of more than €95 billion per year [12]. Of this €95 billion, 8% is ploughed back into research and development each year, equivalent to around €7.5 billion and to one new European patent every 38 minutes [12]. The pharmaceutical industry spends nearly 17% of its sales income on R&D, equivalent to US $35,000 million for the US market and to €26,000 million in Europe. The average cost of researching and developing a new chemical or biological entity is constantly increasing and is estimated to be equivalent to €1059 million [13].

In times of resource constraints, when governments are struggling to keep health care budgets under control, however, it becomes crucial to discuss how much of the extensive investments in R&D made by the health care industries can be actually recuperated by placing new products on the market. The gap between the rates and pace of technological innovation and economic growth is likely to increase in the future. Thus, if access to health care is to be maintained in the future, manufacturers will have to align their research and development strategies so as to contribute to the maximization of the social objective of providing the best possible quality and sustainable care for the largest number of patients. This implies that manufacturers need to rethink their clinical development process and engage in early dialogue with payers and regulators, prior to investing large amounts of resources in clinical studies.

Rethinking Clinical Development Strategy

In the past, much research has been about pursuing a clinical hypothesis, rather than meeting an identifiable health need. One implication of this is that certain disease areas are over-studied and multiple technologies (e.g., molecules and devices) developed. Often, these generate a small incremental benefit (e.g., cancer treatment) while responding to the same patient group’s needs. However, products in other disease areas may be underdeveloped, with the potential of achieving bigger benefits in absolute terms. Cost-of-illness analyses, which estimate the economic burden of diseases together with their epidemiological burden, would be useful in identifying areas of unmet health needs where clinical research would have the potential to generate high returns [14].

For instance, urinary tract infection, a major health care concern that affects nearly 33% of healthy, sexually active women whose quality of life has been estimated as worse as that experienced by patients suffering from stroke and Alzheimers’ disease and exacerbated by its hidden and embarrassing nature [15], had an economic burden of equivalent to 3% of Italian health care expenditure in 2009, mostly paid for directly by patients as out-of-pocket expenses. However, it is currently not associated with a completely successful and effective treatment [16].

Second, the main emphasis in companies has been to design clinical studies to meet the needs of the regulators (e.g., Food and Drug Administration and European Medicines Agency). Most clinical trials have been designed as placebo-controlled, non-inferiority studies targeted at strictly defined patient populations, aimed at reaching high internal validity. In both the United States and Europe, however, there is a trend toward requiring studies...
that will be more useful to payers, clinicians, and their patients, that is, with a focus on external validity or generalizability.

In the United States, the American Reinvestment and Recovery Act established a Federal Coordinating Council for Comparative Effectiveness Research. This council defined comparative effectiveness research as the “conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in ‘real-world’ settings” [17]. It noted that the purpose of this research is to inform patients, providers, and decision makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research necessitates the development, expansion, and use of a variety of data sources and methods to assess relative effectiveness through developing standards on internal validity, generalizability, and timeliness.

In Europe, the EUnetHTA initiative was initiated in 2006 with a work program focusing on a pan-European “core model” for HTA in Europe, with initial reports on diagnostics, and medical and surgical interventions. The 2011 EUnetHTA work program includes research on pharmaceuticals and other technologies, reflecting a recent focus in Europe on the relative effectiveness of pharmaceuticals. The European Union High Level Pharmaceutical Forum was developed in 2005 to bring the European Commission, member states, representatives of the European Parliament, and a wide range of stakeholders together to examine challenges relating to providing information to patients on pharmaceuticals, pricing, and reimbursement policy, and relative effectiveness assessment. In its 2008 report [18], the forum adopted working definitions of efficacy, relative efficacy, effectiveness, and relative effectiveness. The report noted that the aim of a relative effectiveness assessment is to compare health care interventions in practice to classify them according to their practical additional therapeutic value.

One implication of this trend for manufacturers’ clinical development strategy would be to consider fewer placebo-controlled trials, more superiority studies, longer duration of trials, and measurement of end points of more interest to payers/patients. The development of more “pragmatic” controlled trial designs can serve these purposes. Pragmatic controlled trials are intended to maintain the advantages of randomization while examining outcomes in routine care. Pragmatic controlled trials also have the advantage to better inform economic analysis alongside clinical trials, which, if conducted on “pure” experimental studies, would measure incremental costs and outcomes under “ideal protocol-driven cost and efficacy,” conditions often not confirmed in real-world settings.

Generating evidence about new pharmaceuticals and devices is increasingly being seen as an activity that occurs throughout the entire product life cycle, rather than prelaunch for a one-off review at product launch. Drug regulatory authorities are exploring both early access and provisional access schemes, in which some studies about effectiveness and safety are conducted postlaunch. Similarly, HTA/pricing and reimbursement bodies are experimenting with evidence development including risk sharing that involves the collection of additional data postlisting. At the same time, concerns about safety have led to augmented postlaunch pharmacovigilance requirements. For many of these efforts, prospective observational studies have been the main vehicle for data collection.

Observational studies are particularly relevant for assessing medical devices. Devices are intrinsically different from drugs due to a number of important factors. These include the difficulty in gathering clinical evidence from randomized controlled trials, the effects of users’ learning curves, and different levels and depth of organizational impact. This can pose challenges in undertaking assessments to inform decisions about the uptake and diffusion of devices in clinical practice [19].

Engaging in Early Dialogue with Payers and Regulators
As previously mentioned, although regulatory agencies are increasingly looking for evidence of comparative effectiveness, there still is a gap between regulators and payers’ data needs. While regulators are often satisfied with placebo-controlled trials, or trials of short duration using intermediate or surrogate outcomes, payers commonly ask for head-to-head trials, trials of longer duration, and for evidence on final outcomes such as survival rates and/or patients’ quality of life (e.g., QALYs). Although manufacturers are traditionally focused on regulators’ requirements, being the ones necessary to get their technologies licensed, they must nevertheless equally be attentive to payers’ needs if they want to maximize the chances of their technologies being adopted in clinical practice. One possible way to reconcile regulators’ and payers’ views is for manufacturers to engage in early dialogue with payers before phase III trials.

In recent times, several pharmaceutical companies have formed advisory boards, consisting of experts in HTA, pharmacoeconomics, and health care management, to gather advice on how to better design phase III trials and/or how to better prepare their value proposition dossiers once phase III trials have been concluded. These efforts can undoubtedly provide manufactures with valuable advice on how to shape future market access strategies; they would be further enhanced if manufacturers could also seek advice directly from payers and/or HTA agencies.

In a recent article, Backhouse et al. [20] report on a pioneering effort by one technology developer to seek early dialogue with seven pricing and reimbursement agencies in five countries on their likely evidence requirements for a new oral treatment in development for patients with chronic plaque psoriasis. The questions concerned the most relevant design for the phase III trial, namely, the target population, the relevant subgroups of patients, the comparators, the outcomes of interest, the duration of follow-up, and how nonresponders would have to be considered. The results of this pioneering effort confirmed that requirements of payers are different and often more demanding than those deemed sufficient by regulators and, more importantly, showed that, overall, there was more convergence than divergence among the seven pricing and reimbursement agencies than in the advice provided to the manufacturer. More evidence is needed before concluding that this approach can actually make manufacturers’ R&D investments more efficient while satisfying at the same time both regulators and payers’ objectives. Perhaps a tripartite dialogue between manufactures, payers, and regulators would be more even useful [20]. Nevertheless, early dialogue may represent a way forward to maximize the social objective of providing the best possible quality and sustainable care for the largest number of patients who could benefit from it.

Increasing Patient Participation in HTA
As more innovative health technologies emerge on the scene, the decision-making process becomes rather complex and inevitably requires informed input by those who are mostly affected by the adoption of these innovations. This becomes particularly evident in the context of scarce resources where the risk of taking contentious coverage decisions increases rapidly [21]. The origins of patients’ involvement in health policy decisions can be traced back to the customer-centered public management philosophy and governance paradigm that has dominated public sector decision making from the early 1990s [22]. Under this paradigm, patients are not seen as passive recipients of information and of
decisions taken by others, but assume a role of an active, well-informed, and engaged interest group whose opinion is taken into consideration [23].

As a result of this general trend, HTA community’s interest for patient involvement has increased over the past decade. In 1998, a special issue of the International Journal of Technology Assessment in Healthcare was dedicated to the relationship between the consumer and technology investigating, among other issues, the patients’ perspective on the evaluation of health care and the driving forces behind their increasing involvement [24]. In the years to follow, numerous scientific publications explored the issue of the general public’s and patients’ involvement and the common emerging theme was that a greater effort must be made to involve patients and citizens in determining priorities, in evaluating the efficacy and cost-effectiveness of health care interventions, and, even more importantly, in using the results of these evaluations to make informed choices [25].

In 2005, the International Network of Agencies for HTA conducted a survey among its members to assess the involvement of consumers in HTA programs in different countries. The survey revealed great differences between practices adopted by HTA agencies. The most commonly reported approach to patient involvement included consultations with patient representatives/organizations during the formulation of the assessment. Four agencies (15%) reported providing training initiatives for patients, while almost all agencies prepared “simple language” guidance to make them more accessible [26]. The same year, Health Technology Assessment International established a designated group for patient and citizen involvement to promote ways in which patients’ needs, perspectives, and preferences could be incorporated into HTAs via the generation of robust evidence and fair processes.

In contrast to this rising interest, the empirical evidence generated over the past decade shows that the HTA community itself is divided about the actual purpose of (why) and appropriate methods (how) for involving patients in HTA [27,28]. Clarifying the why and how of patients’ participation in HTA is deemed necessary to explore more effective ways for incorporating patients’ input in assessing the value of innovative medical technologies.

Why Patient Participation in HTA?
There are at least three reasons that have been put forward to support the idea that patients’ views must be taken into consideration in HTA. The first is associated with the general definition of HTA and evaluation of health technologies and holds that a comprehensive assessment should take into account not only clinical efficacy, cost-effectiveness, and equity issues but also include patients’ views about satisfaction and acceptability of health technologies. Patients have unique knowledge about the technology that can and should inform an HTA [29]. The HTA community is well aware of the fact that there is frequently a gap between the perspectives and values of HTA practitioners and those of patients that could lead to unsatisfactory decisions. It has been repeatedly argued that scientific evidence produced by randomized controlled trials do not adequately reflect values of patients, their needs and desires, and cannot be used as the sole input to HTA. This reveals a need for broadening the evidence base on which the decisions are made by taking into account patients’ input [30]. The rise of so-called personalized-medicine further reinforces the need to involve patients in HTA.

The second reason for promoting greater patient involvement in HTA stems from the general epidemiological trend taking place in developed countries: a rather dramatic shift of acute to chronic diseases. With chronic forms of disease and disability, patients and their families play a more active part in health care and patients’ life style and behavior can dramatically influence the long-term prognoses of chronic conditions [24,30].

The third reason for greater patient involvement in HTA is concerned more with the decision-making process: involving patients increases transparency and openness in the public policy. Thus, patients’ involvement should emphasize a deliberative process through which normative assumptions underlying HTA are made more explicit [23]. As part of this, transparency about the influence of the patient perspective is essential. It is argued that, otherwise, HTA will have little chance of achieving its goals and it would also be hard to sustain public support for funding HTA if the public remains ignorant of its importance and relevance to them.

How to Effectively Ensure Patients’ Involvement in HTA?
Although most agree that the reasons highlighted in the previous section are strong enough to justify the effort needed to involve patients in HTA, the evidence suggests that there are several barriers to effectively doing so in practice [28]. The main obstacles stem from the following issues: 1) robustness of evidence on patients’ perceptions, 2) clarity on the type of patients’ input needed, 3) the knowledge base required for patients to make an effective input, and 4) lack of awareness of patients and their associations on potential involvement. Understanding and overcoming these barriers can greatly help identify strategies for how to effectively implement patients’ participation in the HTA process.

Identification and synthesis of information from patients raises a series of methodological questions and challenges [29]. The widespread barrier for patient participation in HTA is a belief that evidence collected on patients’ views is anecdotal and biased. Patient experiential information frequently requires different methodological approaches (e.g., focus groups and interviews) mainly qualitative in nature. This is in contrast with HTA being mainly influenced by the quantitative and positivism paradigm that emphasizes systematic reviews and the hierarchy of quality of evidence. Currently, there is little guidance on how to effectively collect the evidence, given the resource and time constraints faced by HTA bodies. To respond to this critique, it has been suggested that methods should be developed for gathering data on patients’ views. For example, in addition to more qualitative approaches, standardized tools could be employed, such as validated patient-report outcome measures. In the absence of relevant primary data, systematic reviews of existing secondary and primary studies on patients’ perspectives should be conducted. In this respect, particular attention should be given to developing tools to assess and synthesize qualitative studies [29].

The enhanced methods should also foster greater clarity on what type of information should be collected from patients. For example, patient input may include the following: preferences for health states, information about costs borne by the family in seeking/receiving care, views on the experience of care, involvement in the care process, and the convenience of different forms of treatment (e.g., oral medication vs. intravenous infusion, different dosing schedules).

To ensure an effective and relevant input into the HTA process, patients should have some knowledge about the basic concepts and terminology used in the assessment. In this respect, training opportunities for patients and their representatives should be promoted by both HTA bodies and associations themselves. For example, a patient decision aid has been recently developed for breast cancer patients on the basis of systematic literature review and primary data collected through qualitative study. The evidence collected suggests that patient decision aid allowed patients to access information, gain additional knowledge of their illness, and make shared treatment decisions and gave health care professionals a deeper insight into patient experiences.
of the disease [31]. Similar tools could be developed in other disease areas to allow for more informed and effective input from those experiencing the technology under assessment.

Finally, lack of awareness on the part of patients of the policy process and of opportunities for their involvement is frequently cited among the barriers to effectively include patients in HTA [26,32]. It is suggested that health care organizations and HTA bodies should engage in outreach activities to inform patients and their representatives of the possibilities to participate in HTA.

The above are just a few suggestions on how patients’ participation in the HTA process should be enhanced to accomplish meaningful and valuable input. It must be mentioned, however, that research offering insights into the effectiveness of different approaches is currently scarce [33].

In addition to identifying appropriate strategies for encouraging patients’ involvement, it is essential to clarify the phases of the HTA process in which patients’ input should be encouraged. Most commentators argue that patient involvement should be increased in all phases of HTA. This can be achieved by giving an opportunity to patients to become effective members of expert committees involved in 1) scoping of technology assessments, 2) commenting on draft reports and providing views on proposed recommendations, and 3) appealing the reimbursement/coverage decisions. However, a recent review shows that the extent to which patients are currently being involved in these three types of activities varies greatly across countries [25].

Discussion and Conclusions
In this article we have argued that to achieve universal access to innovative and costly technologies, the different perspectives of payers, manufacturers, and patients need to be reconciled. Although we have identified a number of possible initiatives, it is still not clear how such reconciliation would be achieved. It is important, however, to note that several initiatives are already taking place, in that manufacturers are engaging in more dialogue with payers and regulators, and some HTA programs are encouraging patient participation.

Indeed, the cornerstone to more progress is to develop and maintain an effective and efficient program for the comparative assessment of health technologies in a given jurisdiction. Drummond et al. [34] identified 15 key principles for the conduct of HTA for informing resource allocation decisions. These covered the structure of the HTA program (e.g., its level of independence, the methods for HTA (e.g., the incorporation of a broad societal perspective and the consideration of all types of clinical evidence), the processes followed (e.g., the involvement of stakeholders including patients), and the link with the decision-making process (e.g., the incorporation of different sets of values and the communication of findings to different constituencies).

A study of 14 HTA organizations showed that there was considerable variation in the acceptance and adoption of these principles across the various agencies [35]. Although in a later article, Drummond et al. [36] point to the challenges in making direct comparisons between particular HTA agencies, this research suggests that there is room for improvement in current HTA practice.

It can be argued that there are other interest groups, such as health care providers and general public, whose input should be considered as well. While we recognize their importance, we argue that the three perspectives chosen (patients, payers, and manufacturers) are the most important. In a public health care system, citizens are represented in principle by their democratically elected government, a third-party payer. Providers, however, are influenced by, and greatly dependent on, the coverage and reimbursement decisions made by the payer. Thus, while the three interest groups we focused on in our analysis are not the only players in the health care arena, we believe that reconciling their values is essential for ensuring access to innovation in health care.

Although all jurisdictions would benefit from an effective and efficient HTA (or comparative effectiveness) program, other initiatives may depend on the current focus of the health care system in the jurisdiction concerned. In many European countries, the organization of health care could be said to be “population focused.” That is, health care is financed through general taxation or social insurance and decisions about the availability of treatments are made on a collective basis. In these systems, there has been a growing interest in making reimbursement decisions on the basis of HTAs and, more recently, in value-based pricing [37]. These initiatives are likely to give manufacturers an incentive to more closely align their R&D with social objectives. As mentioned above, however, it is important to ensure, through adequate stakeholder involvement, that the values incorporated in processes such as HTA and value-based pricing do adequately encompass social values.

Other health care systems, in the United States and several middle-income countries in Asia and Latin America, could be said to be more “patient focused.” That is, patients play a direct role in determining the type of coverage they have and also make payments at the point of receiving care. In these jurisdictions, perhaps the main role of HTA and related efforts is to make patients more aware of the relative benefits of different health technologies so that they can make more informed choices. This can be reinforced by employing “value-based” insurance designs [38] and value-based formularies [39]. Here, the role of the payer is not to impose a particular set of values, but to be clear on which technologies should attract higher or lower co-payments and to facilitate more informed consumer choice, thereby increasing the alignment of patients’ and manufacturers’ values though a quasi-market.

Although different health care systems may require slightly different approaches, there are also linkages. For instance, Drummond and Towse [40] recently questioned whether, in the context of value-based pricing, the role of patient co-payments for pharmaceuticals should be reconsidered, with a view to encouraging more efficiency.

The points raised in this article also suggest an agenda for future research. This includes the testing, in a decision-making context, of some of the alternatives to QALYS. In addition, further research is required into the use of observational studies in the assessment of health technologies. Finally, some of the processes discussed above, such as the methods of increasing patient involvement in HTA and early dialogue between manufacturers, regulators, and payers, require more research so that they can be made as cost-effective as possible.

A reconciliation of payers’, manufacturers’, and patients’ perspectives on the value of health technologies presents several challenges, but it is not unattainable.

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