

HTA AND VALUE - A COMMENTARY

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The notion of value, in the evaluation of the clinical and cost-effectiveness of therapeutic interventions, was the subject of discussion at the HTAi Policy Forum in February 2013. A summary of its discussions and conclusions is published in this issue of the journal. This commentary considers the implications of the proposal that health technology assessment (HTA) agencies should include, in the value proposition, wider societal costs and benefits as well as incorporating innovative promise.

It is a gloomy, but inescapable, fact that no nation seeking to provide its citizens with universal health care has sufficient resources to meet every need. Decisions about priorities have to be made; and the core mission of HTA is to give healthcare payers the tools by which these decisions can be explicitly, and transparently, reached (1).

For the report from its meeting in Barcelona (2), the HTAi Policy Forum had a wide-ranging discussion about the elements of how HTA agencies should assess “value” in health care. The Forum accepted, rightly in my view, that value to both the patient (in terms of both quality and quantity of life), and to the healthcare system (both costs and savings), are paramount. Problems arise, however, where attempts are made to extend the concept of “value” to non-healthcare benefits including benefits to carers and families, and broader benefits to society. Even more contentious is the notion that innovative “promise,” possible future benefits over and above those demonstrated from the results of clinical trials, should also be assigned “value.”

Widening the evaluation of the benefits of new interventions, to encompass informal caregivers, has obvious attractions. The spouse or offspring of patients with, for example, dementia may suffer both materially and psychologically as a consequence of the care they give to their affected family mem-

bers. So should not the benefits that they derive also be included in the “value proposition” of new interventions? The problem with this is that virtually all chronic diseases place burdens on patients’ informal caregivers, whether it be because of epilepsy, malignant disease, schizophrenia, or arthritis. Leaving aside the difficulties of assigning benefits, costs, and savings to the endeavors of the army of informal caregivers, the inevitable consequence will be to reduce the incremental cost-effectiveness ratios of many new interventions. This will have one (or both) of two consequences: it will either leave the healthcare system to meet the inevitable opportunity costs; or cost-effectiveness thresholds will have to be reduced.

Taking account of wider societal costs and benefits, although again superficially attractive, also poses difficulties. For example, taking account of what economists call “productivity losses,” the consequences of sickness absence from work or long-term unemployment, is not straightforward. The majority of people with chronic conditions are elderly and are not (in the pejorative language of economists) “economically active.” Moreover, productivity gains, in the absence of full employment, are illusory because as one person leaves the workforce, due to illness or death, an unemployed person will get a job. With seasonally adjusted unemployment rates in the European Union and United States currently at 12.2 percent and 7.5 percent (respectively), the inclusion of productivity gains is, therefore, highly questionable.

Although I am pleased that it does not appear to have been discussed by the Forum in Barcelona, there is one school of economic thought that has suggested that the “value proposition” should also take into account future healthcare costs. In other words, a cost-effectiveness analysis of saving the life of a child, age 10 years, should, on this premise, include the average healthcare costs that he or she will incur over the next 60 or more years.

Including innovative “promise” in assessing the value proposition of new interventions is another facet that might

be desirable but is, in my view, probably undeliverable. It is sometimes possible to predict, with reasonable confidence, that a new intervention is likely to have profound benefits over and above those of its initial licensed indication(s). The new family of thrombin inhibitors is a case in point. Initially licensed for the prevention of venous thromboembolism it was likely, even then, that they would also be effective in the prevention of cerebral emboli in people with non-valvular atrial fibrillation. There are few other recent interventions where such predictions can be made with any degree of confidence; and the concept of “pro-imburement” is, therefore, likely to be impossible to operationalize (3).

Incentivizing innovation might be better achieved by progressive (or “adaptive”) licensing. Under such an arrangement, a new device or pharmaceutical could be marketed (with very strict provisions about its use) after the completion of its phase 2 studies and at a modest price. If its promise were fulfilled, or bettered, at the end of its “real world” observational phase of development, a price increase would be triggered so as to give the manufacturer a reasonable return on investment. Although the Policy Forum did, briefly, include the notion of progressive licensing it is one that deserves more extensive discussion at a future meeting.

The report gives only cursory attention to the issue of social values. If HTA is to assist healthcare decision makers about whether or not particular interventions should be provided, then it needs to take account of societal preferences in the way that resources are used. Adopting a purely utilitarian approach, and emphasizing the importance of efficiency, may also give rise to conclusions that many would find morally offensive. For example, utilitarianism may do little or nothing to resolve problems of inequalities due to socio-economic or ethnic factors. This is another area where the Policy Forum could make an effective contribution to the methodological evolution of HTA.

The HTAi Policy Forum has more than fulfilled the ambitions its creators had when it was established, under the leadership of Chris Henshall, all those years ago. It can be expected to continue to do so in the years ahead.

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There is an expectation that the value of a new technology will be considered by decision makers in determining whether to provide subsidy. What constitutes the elements of value and how these may be weighted is not transparent, however, and further work needs to be done to determine the circumstances and mechanisms of their application. In the end, judgment will still be needed even if greater formalization of the value construct is developed.

While the terms “value” and “value for money” have been used in the context of health technology assessment (HTA) for many years, the outcomes of the recent HTAi Policy Forum indicates that there is not yet a universal acceptance of what constitutes value and how it should be addressed in the assessment of new technologies. The introduction of cost-effectiveness analysis by third-party payers during the early 1990s (Australia) and by other agencies in the early part of this century has seen the term “value for money” become the framework of decisions. However, even before the introduction of this approach, statements were being made by health planners and policy makers of the need to consider outputs from health expenditure. For example in 1978, the then Minister of Health in Australia, the Hon Ralph Hunt said “whatever decisions are taken will reflect the Government’s determination to get more value for the dollars spent on health care.” With the ever increasing demand for, and costs of, health care, the definition and assessment of value has taken on a new energy and is the subject of the feature article in this edition of the *Journal* (1).

The INAHTA definition of HTA includes the consideration of the medical, social, ethical, and economic implications of the development, diffusion, and use of a health technology in health care. As such, HTA is well placed to consider the value proposition from a wider social and health system perspective rather than solely from a patient perspective. However in considering the issue of value there are certain questions that need to be addressed, namely: What is value? To whom is the technology of value? How is it measured and quantified? How are the various elements of value weighted in any decision context? Porter (2) has stated that “achieving high value for patients must become the over-arching goal of healthcare delivery with value