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-imbursement" 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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HTA AND VALUE - A COMMENTARY

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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

defined as the health outcome achieved per dollar spent." This infers that a lesser weighting should be given to those elements of value which are not directly related to patients receiving the technology such as wider societal benefits.

Tunis and Eddy (3) introduced the concept of clinical and health policy decisions consisting of two critical components, namely evidence and then judgment. The evidence gathering component evaluates through a technical and scientific lens the benefits, harms, and costs between treatment options, while the second component represents judgment on the value elements themselves and addresses aspects such as personal preferences. It must be recognized that, if the quality of the evidence relating to the patient is poor or uncertain, then the judgment phase addressing wider benefits will be highly problematic.

Some elements of value need to be considered carefully in the context of an equity framework. An example is the use of the value element of a productivity gain. This will only be potentially realizable to someone who is in the work force and may disadvantage others such as children and the aged. Another example of an element of value that requires careful consideration is adherence to dosage regimens. If improved compliance is achieved through a new technology then, presumably, if relevant, it is also reflected in improved health outcomes. To add further value in the judgment phase simply for improved compliance may be seen to be double counting. Furthermore, factors that may be captured by a utility measure (which may include direct and indirect benefits to patients) and therefore included in a quality of life gain and form part of the evidence base should not be then heavily weighted in the final decision making requiring judgment.

There is clearly a divergence of opinion between decision makers and sponsors of new technologies regarding whether, and to what degree, broader aspects of value are taken into account in decision making. Sponsors generally believe that decision makers are too focused on the results from clinical trials and ignore additional benefits that a new technology may provide. However, as mentioned earlier often these "values" are not discrete entities but part of a "value framework" where interactions occur between value elements and care must be taken to ensure in these circumstances that the overall assessment of value is appropriate (e.g., helping to ensure no double-counting). That a divergence of opinion occurs indicates that greater transparency and information around the decision context is needed. If there is not an explicit acknowledgement of the potential of a certain value and how that was managed as part of the decision process then there will be an assumption that any such value(s) was not considered.

What the debate highlights is the need for sponsors of new technologies to broaden their horizons regarding the nature of clinical trials and what endpoints are being measured. To undertake a trial without a quality of life measure or some other patient relevant outcome, and base it only on a surrogate outcome that may be accepted by regulatory agencies, needs to be questioned. The methodologies used to identify and quantify the range of potential value elements needs to be advanced not only in clinical trials but in the postmarketing environment.

It must, however, be recognized that, even if all elements of value are considered and taken into account in decision making, this does not necessarily extrapolate into acceptance of "value for money." There is a risk that, if there is recognition of a wider range of values being considered by decision makers, then there will be an expectation that higher prices will be the result. That hypothesis is yet to be tested.

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HTA AND VALUE - AN INDUSTRY PERSPECTIVE

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The assessment of value within healthcare is undergoing a major transformation. Gone are the days when a new mechanism of action alone would be regarded as a high value innovation. Today, there is much more of an emphasis on what are the outcomes (i.e., mortality and morbidity benefits), how does this compare with the current standard of care and what is the impact to the usage of healthcare resources. This emphasis is quite understandable given the financial crisis we are experiencing with an ever growing and aging population that is placing considerable strain on the healthcare system.

There are few Eureka moments in science. Incremental innovation such as a new mechanism of action is vital for furthering the scientific understanding and fostering the development of future innovations, especially when it is linked to targeted patient populations and coupled with optimization of the disease management process. It should come as no