Some Fundamentals of HTA

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Abstract

The article describes the main characteristics of Health Technology Assessment and the chief disciplines contributing to it, with emphasis on HTA's role as an aid, rather than a substitute, for thought, and as a help for decision makers at senior levels in identifying and prioritising their options. HTA can be as complex or as simple as anyone wishes, but should always serve the needs of decision makers having a responsibility and accountability for their decisions. HTA should be as complete, impartial and professional as the context permits. Evaluating evidence; taking account of complex ethical issues of effectiveness, efficiency and equity (fairness); transparency; context-dependency; using deliberative and participative procedures; and not letting the perfect become the enemy of the merely good; are all hallmarks of good HTA.

Keywords: Effectiveness; Efficiency; Health insurance; Fairness; Context - sensitivity; Deliberation; Scope ; HTA ; Cost-effectiveness analysis; Social value judgments

Introduction

Getting right the questions to which a Health Technology Assessment (HTA) might provide helpful answers lies at the heart of good HTA. HTAexists to help decision makers make better recommendations or to take better decisions that will directly impinge on the healthcare system and the people it serves. Many such interventions are clinical, in personal or public health, but others come in variety, such as those affecting service organizations, client behaviour, workplace health and safety, and financing arrangements. The object is to identify those that work better than others. The critical question is plainly what counts as 'working better'?

If you grant that seeking answers to questions such as, 'does it work better than other interventions?', 'for whom does it work better?' and 'at what cost does it work better?' are all reasonable questions to ask of such interventions, especially ones that are paid for by third parties such as public or private insurance agencies, and that the answers are of interest and importance to patients and their families; the professionals, both clinical and managerial, who serve them; the third-party payers; manufacturers of medicines and medical devices; and regulators and others, such as employers, who can affect the environment that helps to determine the health of the public, then you are well on the way to understanding what HTA is about. Some basic questions are clear, as are the people commonly referred to as 'stakeholders'.

What Is 'It'?

The 'it' in the questions is not merely pharmaceutical in nature. A health technology intervention can, as stated at the beginning, take many forms. Depending on the form, the scientific nature of the discipline needed to answer the question will be shaped. A clinical intervention will typically require both clinical knowledge of the condition being treated (or prevented) together with existing treatments, and

epidemiological skills to examine the impact the intervention is likely to have on outcomes of interest (broadly speaking, 'health'). Epidemiological and statistical skills will be needed to assess impacts system-wide rather than just individual ones. Assembling and evaluating clinical and epidemiological evidence from documented studies requires skills in both searching and summarizing the literature in ways that detect bias and incompetence without introducing any in the process. Appreciating whether evidence generated elsewhere at another time, in another context and for various other purposes is relevant in an HTA requires skills in health services research and comparative healthcare studies. Assessing costs and measuring benefits adds economics as an additional discipline, required if efficiency is to be a part of the HTA.

It is immediately obvious that HTAis, of necessity, a multi-disciplinary and multi-professional activity. Sometimes additional disciplines will be needed: ethics to help analyses the distributional and fairness issues that may arise; management science to assess the feasibility of managing the introduction or removal of an intervention; politics and religion to help address issues that might arouse from the use of a technology that affects sensitive matters of public policy. And many others could be added [1].

Not all these types of expertise will always be needed. Which ones are needed depends on the question, and the question needs to come from those whom HTA is designed to help: the decision makers and those involved in the decision making process. HTA is normally used at a rather high level of decision making: not at the bedside but at the level at which, for example, the concern is whether to add, modify or remove an intervention from those covered by public or private insurance benefits package. It follows that the scope of any HTA is context-dependent, depending on the circumstances of the case, the country, the available wealth, the existing patterns of care, the available skills, the longer-term plans for building a healthcare system that is as universal and comprehensive as is judged to be achievable [1,2] judged, not by outsiders, nor the World Health organization, nor major philanthropies, nor even the 'experts', but by people with local responsibility and local accountability.

What Does 'Working Better' Mean?

The very first task in any HTA is to establish the question as precisely as one can. This normally entails identifying one or more interventions that can affect health for the better; settling what is meant by 'health'; deciding the criteria for choosing between the interventions (cost-effectiveness, equity, sustainability, religious proscriptions, etc.); various speeds of implementation; identifying potential gainers and losers; evaluating what other services will necessarily be forgone as a consequence of a decision to spend, or might now be possible as a consequence of withdrawing a service; making interpersonal comparisons between ethical claims to benefit; deciding who will be consulted and otherwise involved in the decision making process; identifying any training needs required for conducting the analysis and for implementing its results; and conveying the recommendations to board level authorities, clinical professionals, managers, organized patient groups and the general public [3].

Only Efficiency?

An efficient allocation of health care resources exists when it is impossible to increase health outcomes for some patients without reducing outcomes for others. The Figure illustrates how choices about the services to be provided (or not) in a national healthcare system (NHS) can be considered in terms (at least initially) of their impact on health [4,5]. Imagine a bookshelf of healthcare interventions; each intervention is a book, and each is ranked by height according to its effectiveness. 'Effectiveness' here means the expected health gain in Quality-Adjusted Life-Years (QALYs) or averted Disability-Adjusted Life-Years (DALYs) generated per £1000 of NHS spending, estimated empirically. The most effective intervention (the tallest book) is positioned on the left, and the less effective ones stretch away on the right. The fatness of each book represents the estimated cost of providing the intervention. This fatness is a combination of several things the cost of a specific technology, such as a drug the costs of associated procedures (other medicines, diagnostic services, community services, etc.) for as

long as the treatment continues; and the estimated number of people using the intervention [1-3]. The area of each book's spine thus measures the anticipated expenditure on each intervention [Figure 1].

To maximize the impact of health spending on health, the decision-maker ought to select the first book on the left and then add books (further interventions) along the shelf until the money runs out. At that point, all the interventions included will be effective, and only the most effective of the effective ones will have been selected. The only services to be offered will therefore be those to the left of the 'budget limit' line. The least cost-effective intervention that is included defines the effectiveness-cost 'threshold' t. If turned upside down, this effectiveness-cost threshold becomes the cost-effectiveness threshold used in many countries.

So why are all effective interventions not to be provided? It is not because they are ineffective. On the contrary, all the interventions on our bookshelf are effective; one would have to go a long way to the right before hitting a zone of clinical iatrogenesis (zero productivity). The trouble with the ones not being used is that they are not effective enough. The benchmark test for including further interventions is the cost-effectiveness of the least cost-effective intervention that is included. This cost-effectiveness is the impact per £1000 that has to beaten. For purposes of prioritisation, what needs always to be demonstrated in assessments of clinical productivity is relative (rather than absolute)effectiveness.

The threshold and the budget are intimately linked. This is because what determine the threshold are the productivity of the interventions (their impact on health) and the size of the budget. If healthcare managers complain that the Ministry approves interventions that cannot be afforded, the model tells us that either (a) the threshold is too generous, or (b) the budget for the NHS is too small. Or it may, of course, be that government policy is inconsistent, giving the impression of wanting to spend more but not providing the necessary funding.

It is possible for the system in practice to be supporting inefficient interventions: ones that ought to have been on the right hand side of the yellow vertical in the Figure. In such cases, t is an unreliable benchmark. It will be necessary to make estimates of the procedures most likely to be displaced in order to establish whether to take on a new intervention. Suppose, for example, that the health lost through squeezing mental health services in order to accommodate new cancer treatments was larger than the health gained from the cancer treatments.

But, being efficient is not the only good served by HTA.

Beyond The Basics?

The foregoing contains the logical essence of efficiency in deciding what services shall be provided. In practice, many of its informational requirements will have to be met by reasoned judgments. Many of the elements of an HTA are rich in terms of social value judgments: the budget available will depend upon priorities established between alternative uses for resources inside and outside health care; the measures of outcome (like lives saved, QALYs and DALYs) are deeply imbued with social values that give meaning to some concept of health and that may vary according to whose life is likely to be affected (like babies, children, adults, the elderly, the mentally ill, informal family carers, people with multiple morbidities); the likely consequences of a decision for the distribution of the burdens of sickness and of health care expenditures the acceptability of degrees of risk under conditions of uncertainty[6,7]. There are also other kinds of judgment that are often required: how good or complete the research evidence; what the balance should be between quantitative and qualitative evidence; how transferable the results obtained in one study in another are to the country in question; how competently the systematic reviews and research summaries have been done; how acceptable the necessary changes are in affected persons' political and financial interests; how willing the professional groups are who are essential to implementation.

An Aid To Thought, Not a Substitute For It?

It is a mistake to think of HTA as an algorithm that requires no input from its users. HTA is better seen as way of thinking about settling priorities in health care. It offers agendas for consideration and judgment. Social values permeate all aspects of both. Decisions are not merely 'technical', let alone scientific. Moreover, uncertainty abounds, and all decisions require the exercise of judgment about the quality of the evidence, the difficulty of implementation, the value of the outcome, the value of what is forgone as resources are committed to specific purposes, the merits of openness and transparency, the rightness of reaching outside the health and finance ministries for example, by utilizing school resources in diagnostics for children. Specific measures of health such as the QALY or the DALY may or may not be good proxies for 'health' in some contexts. More complex criteria may be required. Two further common criteria concern the distribution of health benefits (QALYs or DALYs) and the impact the intervention has on exposure to out-of-pocket costly healthcare needs. Other value-laden issues include how much risk or uncertainty about the evidence can be tolerated; whether future costs and benefits ought to be discounted (reduced in current value) at the same general rate as is used elsewhere in the public sector; how much information (some of which may be claimed to be commercially confidential) should be shared with stakeholders, including journalists and the general public; whether the right technologies have been selected for investigation to start with and for use as comparators; how to negotiate clashes between criteria when they occur; where to look to find out what values the public and its constituents have; and a host of social value judgments regarding the processes of decision-making such as: choice of stakeholders; the nature of their involvement, if any, in decision-making; ways of minimizing bias; opportunities to appeal against decisions; the public nature and openness of committee and other meetings and the accessibility of their minutes; the frequency of revisiting past decisions as circumstances and knowledge change. One of the advantages of HTA is that it explicitly identifies each of these matters as worthy of consideration and deliberation. The ultimate test is whether changing the benefits package increases expected health, with any health losses compensated by the gains [8,9].

Conclusion

Deliberation is a thoughtful and careful way of reaching a conclusion or deciding something. It is not precipitous and discourages rushed judgments. It involves the focused evaluation of alternatives, weighing their pros and cons, especially when there are a lot of unknowns. Deliberation can be a learning process learning about the evidence and learning from other people about perspectives on the question that had not previously occurred to one. In deciding or advising on policy it requires a kind of 'round table' at which significant interests and expertise are represented.

Deliberation can be a means of suppressing the arbitrary and subjective self-interest of the participants in a decision- making process. It should be a means of achieving an impartial state of mind in which people of good will restrain any selfish personal and professional concerns in pursuit of a wider, or deeper, idea of the social good: one that is not simply the sum of the preferences or prejudices of those participating in the debate. Deliberation enables decision-makers to reflect on, discuss openly and possibly revise their beliefs about a problem. Is this our top priority? Who loses most if we do such-and-such? Do we believe the scientists? Can we trust the economists? Have we got the balance between rival assertions right? Have we inferred correctly from the evidence?

HTA is a way of opening minds and informing them in useful and practical ways. It invites anyone to judge later whether whatever was done was reasonable and defensible, and enables analysts and policy advisers to identify early what will be the key issues to resolve and the most important evidence to seek out. It will be as broad in scope and as detailed in depth as is fit for purpose. It should never prescribe a perfect approach when a merely good one will suffice.

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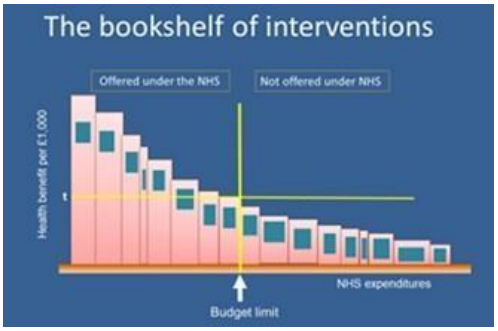

Figure 1 : The bookshelf of interventions.