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View of health technology assessment from the swampy lowlands[1] of general practice

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This article seeks to comment on the approaches to health technology assessment (HTA) outlined in the four main country studies in this volume. It is written from the perspective of a general practitioner working in an inner city area in the United Kingdom and argues that, from the point of view of the clinician, HTA delivers considerably less than it promises. The problems center on the inevitability of judgment by both politicians and clinicians and the conflicting foundations of these judgments. Within political decision-making, the needs of the population inevitably outweigh the needs of the individual; within clinical decision making, the opposite is the case. Attempting a scientific rationality, HTA struggles with the impossibility of holding the balance between the two. These difficulties are further compounded by the implications of ever-increasing expectations of perfect health and the effects of multinational commercial pressures.

Keywords: Health technology assessment, General practice

From my perspective as a general practitioner, with no direct research experience, who has been working in a deprived urban area for more than 25 years, health technology assessment (HTA) promises much. The potential of HTA is almost dangerously self-evident with its aspiration to analyze and summarize the available evidence in relation to both clinical science and cost-utility and to provide recommendations that will make it possible for both clinicians and politicians to perform in ways that are both rational and economic. Unfortunately, on closer acquaintance, HTA often seems to deliver much less than it promises. Patients attend general practice with problems and symptoms that are confused and ill-defined and, in this context, it is very difficult to locate the point at which one can translate one's deliberations into the clear rational light of HTA. Nonetheless, in some circumstances, the impact of HTA has been enormous and of undoubted benefit. The most obvious examples occur where a treatment that is cheaper and easier than others is shown to be unequivocally better, as in the case of early mobilization for the treatment of acute back pain. This intervention has no monetary costs and the advice is easily given, although it may be much less easy to follow. The situation with almost all pharmaceutical interventions is vastly much more difficult, even where there is clear evidence of benefit, as in the prescription of statins for those with ischemic heart disease. The drugs are an increasing financial burden on society; they have significant side effects and may cause more harm than good to individual patients, even if the reverse is true for populations taken as a whole. The need to take medicaments erodes a patient's confidence in their health and can undermine their self-esteem and ability to cope with the demands of work or family (3). Many patients need to take several different drugs for single or multiple conditions with an increasing chance of suffering harmful interactions or side effects. Each patient is offered a balance of risks and benefits; there are no absolutes and no guarantees. On this closer examination and from my perspective, I begin to have a sense of fault lines running through the whole endeavor of HTA.

FALLING BETWEEN STOOLS

HTA seems to have many different potential functions, and different stakeholders have widely differing expectations of

what it can deliver. These multiple views include HTA as:

- a participant within scientific dialogue and debate;
- a tool for changing and improving clinical practice;
- a device to inform and enable rationing;
- a means of reducing health inequalities;
- a basis for decisions on resource allocation.

The first of these presumes an objective rationality, producing, in the words of the French study, "comprehensive and up to date scientific and technical information," but all the others must incorporate normative and value-laden judgments about the nature of both health and society, and about what constitutes a good life. These judgments will be different in the context of each different view and as a result, the outputs of HTA become fragmented and dissipated.

Furthermore, as the Dutch study points out, objective rationality even within science is always illusory and it is better to be explicit about the assumptions that underpin deliberations rather than to seek to conceal them behind a facade of rationality. However, I would argue that HTA can only be useful to clinicians and politicians if it strives to maximize its rational, objective, and scientific content and positions itself clearly at an explicit distance from the activities, judgments, and decisions of practitioners and policy makers. As the study from England and Wales argues, "evidence on its own makes no decisions," and it is essential that the distinction between the processes, which this study labels as assessment and appraisal, are not blurred. The Swedish study draws a similar distinction between a descriptive scientific assessment and one that is normative and political. The distinguishing feature of HTA is that it seeks to combine evidence about effectiveness and cost into a single useful tool; but, how much is it about effectiveness and how much about cost? The answer seems to vary in different contexts. The Dutch study defines HTA as seeking to describe the economic, organizational, social, and ethical impacts of a given health technology. However, several of the studies lament the paucity of attention given to the social and ethical impacts and the over-riding ascendancy of the economic aspects. In clinical practice, and perhaps particularly in general practice where we spend so much time listening to extraordinary stories of the detail of particular lives, the social and the ethical will always overshadow the economic. By marginalizing the importance of the social and the ethical, HTA renders itself marginal to my everyday practice.

INEVITABILITY OF CLINICAL JUDGMENT

Well-founded information will always be useful within any clinical encounter but the usefulness has limitations. The most obvious of these is the sheer volume of information. There are now many more guidelines and summaries of evidence available to me than I have time to read, let alone assimilate (4). The much more serious limitation is that no evidence is absolute and every decision remains a gamble in the face of a range of probabilities and possibilities. Most patients understand this—perhaps most explicitly in relation to cigarette smoking. Despite the simplistic rhetoric of almost all health promotion literature, patients are aware that every decision to stop smoking, or to continue, is a gamble—admittedly against differing odds. This is well understood because almost everyone has personal knowledge of at least one heavy smoker who has lived to a respectable old age and a fit nonsmoker who has died tragically young. No one situation guarantees a particular outcome. All health professionals know that the same gamble underpins almost every treatment decision. This understanding is less accessible to ordinary patients, because it is obfuscated by the difficulty of medical science. The risks of illness and disease are mostly hidden and perhaps, therefore, more frightening. The fact that very many people, who choose to continue to smoke, are prepared to accept, with enthusiasm, medication for high blood pressure or raised cholesterol reveals that their understanding of the gambles within medicine is less sure. How are people to be properly informed?

THE DIFFERENCE BETWEEN EFFICACY AND APPROPRIATENESS

HTA operates against a background of ever-increasing public expectations of perfect health and consistent longevity. Indeed, to an extent, HTA and its exploitation by both journalists and politicians fuel these expectations. The aim of health care and the endpoint against which it is evaluated has become, to a very great extent, the simple prolongation of life. We talk all the time about preventable deaths—as if death could ever be prevented rather than merely postponed (1). We indulge in activities and restraints that we suppose will make us live longer, and the timeliness of many deaths seems never to be discussed. A rational evidence-based intervention of proven efficacy can turn out to be inappropriate, wasteful, and futile. Some years ago, an elderly patient on my list was admitted to hospital when the warden in her sheltered accommodation called an ambulance after she collapsed. She was in her late eighties, a widow, and very frail. The furor over ageism in medicine was at its height and, perhaps as a result, she was admitted to a coronary care unit and received the highest possible standard of care, including fibrinolytic treatment delivered according to the latest evidence-based guidelines. She made a good recovery and was discharged home, apparently well, a week later. I went to see her and found her to be very grateful for the care that she had been given but profoundly shocked by a course of treatment that she perceived to be completely inappropriate. She explained to me that not only her husband but almost all her generation of friends and acquaintances were already dead, that her physical frailty prevented her doing almost all the things that she had previously enjoyed and that she had no desire

to live much longer. No-one had asked her about any of this or attempted to discover whether the effective and, therefore, recommended treatment for her condition was appropriate in her particular case (8). She died 3 weeks later while asleep in bed. The considerable costs of her earlier treatment had been futile, distressing, and wasteful.

WHOSE DECISION?

Attempts to disseminate the results of HTAs are almost always predicated on the notion that health-care decisions are taken by clinical professionals. This runs completely counter to all the work that has gone into recasting the clinical encounter as "a meeting of experts"—the doctor being the expert in medical science and the patient the expert in their own values, biography, and social context. Some people are desperate for the latest expensive treatment; others are simply not interested. By no means does everyone want every effective treatment that is available to them, and this is substantiated by the vast amounts of hoarded and discarded medication. Yet there have been only very limited attempts to put across to patients the true odds of the gamble involved in the treatment decision they are being asked to share with their doctor. The very limited amount of research into decision analysis shows that patients will make a range of decisions on the basis of attaching different utilities to the various possible outcomes of a treatment decision. Genuinely involving patients in decisions about their care has the potential to save the costs of a currently unknown amount of unwanted treatment.

EXPECTATIONS OF PERFECT HEALTH AND MULTINATIONAL COMMERCIAL PRESSURE

All the studies mention the pressures exerted by pharmaceutical companies on the HTA process, with biased information used to further commercial interest. Less attention is drawn to the pressure that large multinational companies are able to bring to bear on politicians and the influence that this has on political decisions and policy making (2). In this context and from my perspective, I find it surprising that none of the studies draws a distinction between preventive and treatment technologies. The former are responsible for a substantial proportion of the exponential increases in health-care costs and can also be seen as diverting health-care expenditure away from the old, poor, and sick toward the young, rich and well. Preventive technologies demand a health-care system driven by paper and computers, which gradually displaces care and treatment mediated by touch. Only a minority of most populations is acutely ill at any one time, whereas the majority is healthy and susceptible to persuasion that they need to take action to remain so by undergoing screening or by taking a preventive medication. Clearly, from the point of view of the pharmaceutical industry, there is more money to be made out of selling health-care interventions for the healthy majority than for the sick minority. From the very different perspective of the tax-payer funding a national health-care system, preventive technologies are much more likely to prove futile and to be overtaken by other disasters or pathologies. When a patient on my list died within three months after the presentation of an aggressive thyroid cancer, all the years of treatment for her raised blood pressure and all her regular cervical smears were ultimately wasted. The study from England and Wales warns against extrapolating into the future beyond the time-frame of the primary research and using formulae that value speculative future benefits over current need. Both practices, common in HTA, act in the interests of pharmaceutical companies selling preventive technologies. Western society, encouraged by advances in medical science, consistently underestimates the power of chance and misfortune in people's lives, and begins to see every failure of health as a failure of health care deserving of blame and censure.

COMPLEXITY AND HEALTH CARE

Increasingly, complexity science is demonstrating the dangers of assuming linear and measurable relationships between inputs and outputs in health care, and between research evidence and either policy or practice. Every system, whether an individual human body or a health-care organization, is inherently evolutionary and subject to changes over time which are not reversible. Thus, all systems are essentially historical. This begins to explain why it is so difficult to achieve the politicians' Holy Grail of "rolling out good practice" from one organization to another, and why the same evidence-based treatment delivered to the same standard to two individuals with the same diagnosis can have completely different outcomes. Complexity science predicts that the reductive and blanket implementation of the findings of an HTA exercise can be expected to have perverse and unexpected effects.

INEVITABILITY OF POLITICAL JUDGMENT

All the studies mention the usefulness of HTA as a basis for the equitable allocation of resources. However, this potential has foundered because of the apparent unwillingness to make decisions in line with the outcomes of HTA. With the continuing avoidance of the necessary tough decisions it has become very clear that compelling evidence of cost-effectiveness, or the lack of it, is only one small component of a successful political decision. From my perspective, it is sad to see that, having made this uncomfortable discovery, politicians and policy makers have sought to pervert the outputs of HTA to exert control over professional behavior (11). In so doing, they have yet to concede that clinical decisions are no less complex than political decisions and that evidence is inevitably only one component of both.

There is an inevitable conflict between sensitivity to individual need and fairness. Increasingly, in the laudable

pursuit of equity, a utilitarian public health agenda is being actively imposed on the fragile good of the clinical encounter. Population-based public health objectives with centralized control and a strong emphasis on cost-effectiveness and equity (where both doctors and patients become replaceable parts in a larger system) damage and detract from the individual focus of patient-centered care. Patients' needs extend far beyond the biomedical and are easily marginalized if the agenda of the consultation is dictated by forces outside it. If the patient believes that their concerns are unheard and their predicament not understood, concordance with treatment plans is proportionately less likely. Much of the political history of the past century demonstrates how easily utilitarianism at a policy level can degenerate into the coercion of individuals. The forced sterilization of those with mental health problems or learning disabilities provides just one of many examples.

It is possible to see HTA with its aspiration to rational scientific impartiality holding the balance between the unavoidable imperatives of political and clinical judgment. Politicians must always put the needs of the population above those of the individual; the clinician must necessarily do the reverse.

HEALTH INEQUALITIES

By promoting the universal application of effective treatments and informing the equitable allocation of resources, the application of HTA is expected to reduce health inequalities. However, this expectation is likely to be confounded by the disproportionate prevalence of multiple morbidity within deprived populations. There is a socio-economic gradient in the incidence and prevalence of almost all major disease categories, meaning that individuals and families who are socio-economically disadvantaged are at risk of a compounding multiplicity of health and social problems (12). Poorer patients are less likely to be helped by conventional healthcare guidelines because they are proportionally much more likely to have other overriding clinical or social priorities, or an excessive burden of medications, or a mental health problem that undermines concordance. Health care that is both driven and evaluated by HTA-based protocols, derived from studies of single disease conditions, seems likely to disadvantage systematically those with complex and overlapping health problems.

FLAWS WITHIN COST-UTILITY

The deliberations of HTA often use the notion of the quality-adjusted life year (QALY) which, as the study from England and Wales points out, is the crucial unit for cost-utility analysis. The structure of HTA is partly built on the supposed validity of the QALY, which, from the perspective of clinical practice, seems a very uncertain foundation. The limitations of the QALY, which have been extensively discussed elsewhere (9), are hardly mentioned in the studies. The QALY is an astonishingly reductive device, which assumes that the values assigned to a limited number of health states often by a small group of people represent the values the general population will assign to all possible outcomes of different disease states. As a currency of comparison, the QALY has failed to convince patients, clinicians, journalists, or even politicians. The suffering of different individuals in the face of the varied consequences of different diseases is simply not measurable or recordable on a single numerical scale. The QALY pretends that such an exercise is possible. Sonia Hunt has described how in the development of the Nottingham Health Profile, "unnoticed and unremarked, this attempt to objectify the subjective had led to the elimination of items which did not 'perform well,' regardless of their relevance to some patients. The restriction of response categories forced respondents to make false accounting of themselves in the interests of statistical neatness" (5). QALY maximization is predicated on the validity of health maximization as the overriding goal of health policy, but the public values other goals, including, for example, heroic life-saving treatments for children and young people even if the money involved could yield a higher return if spent on chiropody (6).

COST-UTILITY OF HTA ITSELF

The scope of HTA is vast but the costs begin to outweigh the potential benefits. The studies demonstrate that all four countries have made an enormous investment of both money and professional time in the pursuit of HTA. There must inevitably be huge opportunity costs and there must be some doubt about the overall cost-utility of the whole exercise. Each country seems slowly to be coming to terms with the impossibility of the proposed task and is making increasing efforts to set realistic priorities for HTA. It is ironic that a methodology that was supposed to help inform rationing decisions has itself become subject to rationing. There are simply too many technologies to be assessed, too many guidelines to be updated—or even read. The studies suggest that there has been enormous duplication of effort internationally. Clearly, decisions, both political and clinical, must always be sensitive to the local context, but the core of HTA, which strives to maximize scientific rationality, must be capable of being shared internationally. The 800 pages of Sweden's SBU report on back pain illustrates the way in which HTA has become more and more exhaustive and, in parallel, more and more expensive. Investment in HTA begins perhaps to threaten the funding of primary research and, in so doing, the development and growth of clinical science itself. HTA may even threaten the funding of clinical services. From my perspective in clinical practice, there is an urgent need to establish more international cooperation and to concentrate HTA effort where it is likely to offer the greatest benefit in relation to cost. This means focussing on interventions that are either very expensive or which concern noncurative treatments for common

chronic conditions. Even in these circumstances, as the study from England and Wales emphasizes, HTA is only needed if there is significant controversy over the interpretation or significance of the evidence available from primary research.

COST-UTILITY DATA AT THE LEVEL OF THE INDIVIDUAL CLINICIAN

As a practicing clinician, the only data on the costs of my work, which is made available to me, concerns my prescribing of pharmaceutical products. I receive a detailed quarterly breakdown of the costs of my prescribing from the Prescription Pricing Authority. However, no attempt is made to present these data in terms of cost-effectiveness or cost-utility. Furthermore, I receive no information whatsoever about the costs of the laboratory investigations that I initiate or the costs of the referrals that I make. I have little doubt that, just as the information that I do receive helps me to reflect on and adjust my prescribing practice, information about the costs of the other modalities of care could be similarly useful and has the potential to increase the cost-utility of clinical work.

A WAY FORWARD?

In its current incarnation, the processes of HTA suggest those of the sorcerer's apprentice, becoming ever more exhaustive and unwieldy, while failing to meet the varied needs of the different stakeholders. However, the potential of HTA to inform decisions by both clinicians and politicians survives. From my perspective in ordinary general practice, I would like to see much more attention paid to the interface between the technical rationality of HTA and the decision making that it seeks to inform.

There has always been, and will always be, a conflict between the legitimate needs of individuals and the demands of utilitarian fairness (10). With a more explicit acknowledgment of the differing priorities and values of clinicians and politicians, illustrated in my rudimentary figure, HTA could have a significant role in facilitating communication between these two arms of health-care decision making. Both science and decision making are complex; guidance, protocols, and guidelines are necessarily simplistic. It would help if the implications of this could be understood and acknowledged by everybody involved. Information derived from HTA that is provided to patients, clinicians, and politicians should always include calculations of numbers needed to treat and numbers needed to harm, and be completely transparent about the absence of absolutes and the consequent need for judgment. Money currently being spent fueling the avalanche of guidance might be better spent on technology to support decision analysis so patients can genuinely make their own decisions about the direction of their health care. Certainly any guidance for clinicians should be made available as decision support software instantly available on practice computers during the consultation. All information and guidance should be scrutinized by a peer group of its prospective users to ensure that it has practical relevance and usefulness.

Chekhov, who was, of course, a general practitioner, argued that the task of the writer is to formulate questions properly, not to answer them. Rudolf Klein has drawn a distinction between two ways of conceiving decision making:

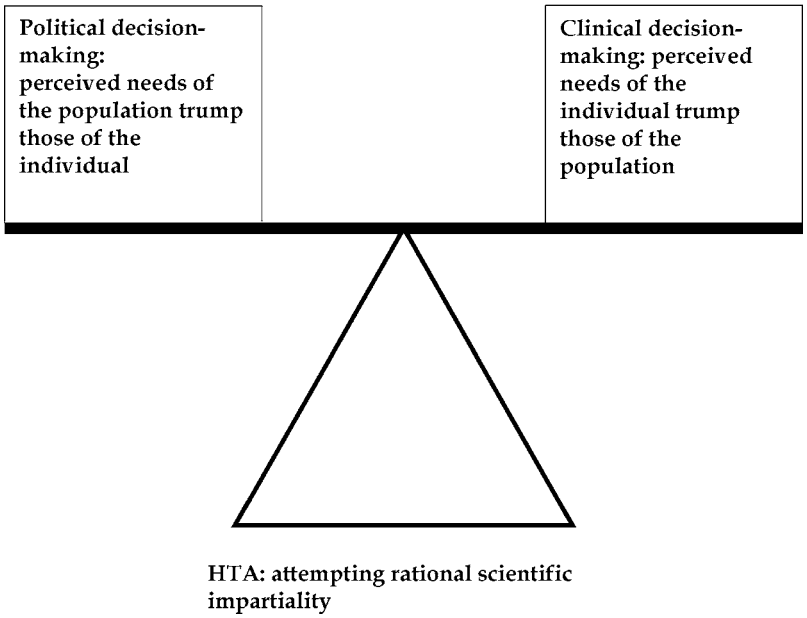

Figure 1. The role of health technology assessment (HTA) is balancing the differing priorities and values of clinicians and politicians.

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Plato's and Aristotle's. The first sees decision making as a search for an ideal solution while the other sees it as deliberation and dialogue, as an exercise in making judgments based not only on science but on practical wisdom (7). Politicians have a weakness for ideal solutions, but perhaps, as the French study suggests, what is needed is inclusive debate at all levels of the health-care system from consultation to policy making at local, national, and international levels. HTA must inform and even orchestrate that debate but should not seek to dictate it.

NOTE

[1] "Swampy lowlands" is a phrase taken from Schön DA. *The reflective practitioner: how professionals think in action.* New York: Basic Books; 1984.

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