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Health technology assessment and its influence on health-care priority setting

Adam Oliver
Elias Mossialos
Ray Robinson
London School of Economics and Political Science

In this article, we review the development of health technology assessment (HTA) in England and Wales, France, The Netherlands, and Sweden, and we summarize the reaction to these developments from a variety of different disciplinary and stakeholder perspectives (political science, sociology, economics, ethics, public health, general practice, clinical medicine, patients, and the pharmaceutical industry). We conclude that translating HTA into policy is a highly complex business and that, despite the growth of HTA over the past two decades, its influence on policy making, and its perceived relevance for people from a broad range of different perspectives, remains marginal.

Keywords: England, Wales, France, The Netherlands, Sweden, Health technology assessment, Priority setting

As all readers of this journal will know, health technology assessment (HTA) activity has grown in many countries over the past two decades. This activity was initially driven by two common concerns among health policy makers/analysts and (some) clinicians. First, it was widely believed that new, "high-tech" medical interventions ought to be assessed for their clinical effectiveness. Second, there was much concern that many existing medical practices had not been adequately assessed for their clinical effectiveness. In more recent years, health-care cost concerns, due to the often cited factors of rising medical and pharmaceutical costs, increasing public and patient expectations, and the ageing of many populations, have shifted the thrust of the HTA movement from *increasing* effectiveness toward *maximizing* effectiveness. This shift reflects a common desire beholden by most health economists to derive the maximum possible units of health "outcome" from each unit of health-care resource. The underlying ethos, therefore, has become one of assessing the value for money of health technologies with a view to using this information to aid priority setting in health-care resource allocation—"a health maximization from available resources" approach. In addition to individual HTA studies, a large amount of literature has reviewed HTA processes and priority setting in various countries (and across countries). A few select (and not necessarily indicative) publications on this general issue, written from a variety of disciplinary perspectives, are cited in the references (1–12,14,15).

Although important as a research program in many countries, the manner in which HTA is organized and undertaken and the incorporation of its results in the public policy-making process differs quite markedly across countries. Moreover, HTA both influences and is influenced by a

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wide array a disciplinary (e.g., epidemiologists, economists), sectoral (e.g., academics, policy makers), and stakeholder (e.g., patients, industry) groups.

The principal aim of this volume is not to offer a cross-country review of HTA (for this, see, for example, references 3;4;7). Nor is the intention to analyze in depth the similarities and differences in HTA and policy structures/processes across countries (although this is done to a limited extent). Such an approach would represent an interesting future political science research program. Instead, we chose to offer a multidisciplinary/stakeholder series of commentaries on contemporary HTA practices, because we believed that this would offer an original, initial attempt at collating a wide breadth of important viewpoints on HTA in a single volume. Single disciplinary approaches in describing HTA may be more coherent, but we believe that they may not offer the broad wealth of knowledge on the complexity and limitations of HTA and priority setting offered in this volume.

With these points in mind, the volume is structured as follows. First, reports that detail the current HTA "state of play" in four individual countries are presented. The criteria used to choose the countries were as follows: (i) that they would be countries with health-care systems funded through taxation or social insurance contributions (we limited ourselves to four countries because of space limitations); (ii) that HTA activity within a chosen country was known to be high; (iii) that the countries represented a variety of health-care system organizational structures. On the basis of these criteria, England and Wales (commissioned authors: Andrew Stevens and Ruairidh Milne), France (Jacques Orvain, Bertrand Xerri, and Yves Matillon), The Netherlands (Marc Berg, Tom van der Grinten, and Niek Klazinga), and Sweden (Per Carlsson) were selected.

Second, commentaries are offered on the country case studies from different disciplinary and stakeholder perspectives. No specific criteria were used in selecting the perspectives, other than to expect intuitively that the expert offering each commentary would view their professional life as (potentially) intimately affected by the growth of HTA. Again due to space limitations, the perspectives are limited to nine and are those of (i) political science (David Chinitz), (ii) sociology (Andrew Webster), (iii) economics (Frans Rutten), (iv) ethics (Henk ten Have), (v) public health medicine (Walter Holland), (vi) general practice (Iona Heath), (vii) clinical medicine (Cyril Chantler), (viii) patients (Angela Coulter), (ix) industry (Mickael Lothgren and Mark Ratcliffe).

The four country case studies are there to set the scene for the commentators to offer their perspectives, although it ought to be noted that the commentaries are not necessarily indicative of the perspective from which they are written (for example, Chantler's perspective *may* not be shared by all clinical medics). The commentaries may be influenced by the country or institutional settings in which their authors are based. A further point to note is that the country case studies were not themselves meant to offer a particular disciplinary perspective but were intended to be largely descriptive, "neutral" articles, with their authors addressing a series of specific questions. These questions were included in the terms of reference (briefly described below), although, inevitably, the country case studies were to some extent influenced by the particular disciplinary perspectives of their authors.

The presentation of the articles in this volume follow the format outlined above; that is, the four country case studies followed by the nine perspectives. The key findings are that, although interest in HTA—and the number of HTA studies undertaken—has grown enormously over the past two decades, the complexity and limitations of translating assessment into policy have not been adequately addressed.

The authors of the country case studies were asked to take as their definition of HTA that offered by the U.S. Office of Technology Assessment: "The structured analysis of a health-care technology, a set of related technologies, or a technology related issue that is performed for the purpose of providing input to a policy decision" (14). The full terms of reference for the country case studies consist mainly of a series of questions that the authors were asked to consider and are available from the guest editors on request.

In summary, the authors were asked to include in the first half of their articles some discussion relating to the policy environment that stimulated the focus on HTA in their countries, and the current organization of both official and unofficial HTA programs. They were also asked to outline the current priorities for HTA, to state how these priorities were established, and to detail the process and requirements by which evidence is collected and evaluated. Finally, they were requested to say how the results of HTA are integrated into the policy-making process (e.g., with respect to guidance/guidelines), and how influential and effective the results of HTA are at the practical decision-making level. The authors were encouraged to offer, in the second half of their articles, their own critical assessment of the development of HTA and its relationship with priority setting in their countries. They were also asked for their recommendations regarding the future development of HTA in their countries. Those who were asked to offer commentaries on the country case studies were requested to write articles that offered their views on HTA and its link with health-care priority setting from their own disciplinary/stakeholder perspective.

COUNTRY CASE STUDIES

Some key HTA trends across all four countries can be identified. These comparisons can be ordered around the origins of HTA and the current organization of HTA programs; current

priorities and HTA requirements; and the influence of HTA on policy.

Origins of HTA and the Current Organization of HTA Programs

Dating from the 1970s/early 1980s, as indicated quite explicitly in all four country case studies (and earlier in this article), two factors appear to have stimulated the development of HTA in all of the countries investigated: (i) concern about the high cost of medical interventions, particularly (originally) high-tech medical technology; (ii) concern about the nonevaluated benefits of many health-care interventions used by medical practitioners. A very brief synopsis of the development and organization of HTA out of these initial concerns offers an appropriate starting point.

In England and Wales, Stevens and Milne show that, in addition to the Medicines Control Agency, which licenses pharmaceuticals on the basis of safety, efficacy, and quality (similarly, the Medical Devices Agency assesses devices on the basis of safety, quality, and performance), there are three main types of HTA, which vary according to the customer/funder: (i) researcher curiosity reports, driven by the research interests of particular funders; (ii) reports produced under the National Health Service's Research and Development program (the NHS R&D program, established in 1993); (iii) reports produced for the National Institute for Clinical Excellence (NICE, established in 1999). Stevens and Milne note that, although the HTA movement arose out of health-care cost pressures and an overenthusiastic adoption of ineffective medical technologies by medical practitioners and was facilitated by a favorable prestigious medical press in the face of resistance from a powerful indigenous pharmaceutical industry, the 1991 internal market reforms were a crucial catalyst in the development of HTA in England and Wales. This is because the internal market created purchasers who were (and still are) responsible for their own budgets, which triggered—at the purchaser-level—a focus upon the value for money of health-care interventions. Subsequently, the Labour Government's support for "national standards" has generated a significant amount of HTA-based guidance over recent years. Possibly the most vivid illustration of this is the creation of NICE, with its original remit to provide "national" guidance informed by evidence of effectiveness and cost-effectiveness as a means to end differential access to different types of health care across different geographical areas (commonly known as "postcode prescribing").

In France, the HTA commissioning and production process is highly decentralized. Orvain et al. write that the principal HTA agencies are the Health Products Safety Agency (AFSSAPS), which possesses state powers of market approval over new pharmaceuticals on the basis of safety and efficacy, and the National Agency for Accreditation and Evaluation in Health (ANAES), which offers a purely advisory role to its customers (who are mainly the medical and allied professions) on the effectiveness and cost-effectiveness of nonpharmaceutical medical technologies. Orvain et al. point out that there are several other French HTA agencies, but like ANAES, none have regulatory powers. Moreover, some agencies, including ANAES, have a variety of customers, whilst others serve a particular clientele (e.g., the Committee for the Evaluation and Diffusion of Innovative Technologies (CEDIT), which serves public hospitals located in the Paris area).

In The Netherlands, Berg et al. argue that the active role of HTA dates from the early 1980s. It was embodied in a Health Insurance Council that suggested that all major new interventions ought to be subjected to an economic evaluation before their inclusion into any benefits package was considered. The main Dutch HTA program—the Fund for Investigative Medicine—was established in 1988 (now administered by the Dutch Health Research and Development Council but was until recently administered by the Health Insurance Council), and generates HTA evidence with the intention that it be used at both the national (i.e., with a view to limiting the total health-care package) and practice (i.e., with a view to encouraging the appropriate use of health-care interventions) levels. In 1991, the Dutch Health Council recommended the production of guidelines, informed by evidence of cost-effectiveness, for medical practice as a means of reducing the use of interventions of limited (cost-) effectiveness. The influential Dunning Report of 1992 also called for interventions to be of proven efficiency and effectiveness before being allowed entry within the social insurance system. Of these two sets of recommendations, those from the Dutch Health Council appear to have been directed more toward the practice level, and Berg et al. note that this is the direction that Dutch HTA took during the 1990s.

Carlsson writes that HTA had an early start in Sweden, stimulated in the 1970s by concerns about high costs and unassessed effectiveness of medical interventions, and influenced by the HTA movement in the United States. The Swedish Medical Products Agency assesses the safety and efficacy of new pharmaceuticals; when a product is licensed, the National Insurance Board and the interested pharmaceutical company agree on a price. There are several other HTA agencies at both the national and local levels, but the leading HTA agency is the Swedish Council on Technology Assessment in Health Care (SBU), created in 1987 with the objective of informing both the central government and the health-care providers of the effectiveness of medical technologies. The creation of the SBU was synonymous with an official recognition of the growing gap between the demand for and the supply of health care. This recognition has become more explicit over very recent years, with the new National Centre for Priority Setting in Health Care (established in January 2001), and a new agency to evaluate the effectiveness and cost-effectiveness of pharmaceuticals (in operation from October 2002) that negotiates prices and

makes reimbursement decisions concerning pharmaceutical products.

Current Priorities and HTA Requirements

From this point, it is perhaps worthwhile to keep in mind the distinction between *assessment* and *appraisal*. Assessment is the science that underlies HTA (i.e., the HTA study). Appraisal is the process by which the science is considered at the policy-making level. The processes for deciding priorities for HTA in the main agencies across three of the four countries (namely, England and Wales, The Netherlands, and Sweden) are similar, although the types of HTA evidence produced do seem to vary somewhat, even within countries. Large expected costs and/or benefits of a health-care intervention seem to be a common driver across England and Wales, The Netherlands, and Sweden (and perhaps France) for whether that intervention is prioritized for assessment, which seems logical because these two factors are likely to serve as good indicators of the total impact that an intervention will have on a health-care system. The general pattern across all four countries in terms of the types of HTA undertaken appears to be a movement from effectiveness to cost-effectiveness analysis. It is clear from the country case studies that this movement has progressed further in some countries (e.g., England and Wales) than in others (e.g., France), but a possible explanation for the general trend is that attention is moving away from merely identifying interventions of doubtful effectiveness (i.e., with a view to recommending how *better* use may be made of the health-care budget), toward identifying those interventions that generate the most health-care benefit from each unit of resource spent (i.e., with a view to recommending how *best* use may be made of the health-care budget). In other words, a wish to *maximize* effectiveness appears to be subsuming that of merely increasing effectiveness.

To consider what is happening in slightly more detail in each of the four countries vis-à-vis current priorities and HTA requirements, let us first turn to England and Wales. The researcher-curiosity reports usually focus upon effectiveness and have priorities driven by the research interests of their funders, whereas the reports arising from the NHS R&D program will, note Stevens and Milne, often contain an economic evaluation and will find their priorities determined by a panel of "NHS-interested" experts. Furthermore, NICE assessments are always required to contain evidence of value for money, with the recommended form of analysis being that of cost-utility, and interventions are prioritized for assessment on the basis of expected health benefit, budgetary impact, strategic benefit in contributing to other health policy concerns (e.g., alleviating health inequalities), and/or where the (potential) usefulness of an intervention is disputed. All types of clinical care can be chosen for assessment, but NICE does not at present call for the assessment of methods of service delivery nor (most) public health interventions.

In France, ANAES undertakes two major types of assessment: (i) evidence-based assessments of technologies that are expected to be used widely and are on the verge of being introduced; (ii) rapid assessments of emerging technologies that are expected to have a relatively short lifespan, fast-developing technologies, and public health issues. An element of economic appraisal is often included in the ANAES assessments. However, other than stating that imaging techniques form the focus of many of the ANAES assessments because professionals and patients often complain about access to these facilities, Orvain et al. report that it is not known what prompts requests for HTA in this customer-driven agency.

Berg et al. note that, in The Netherlands, HTA (i.e., the actual *assessment*, rather than its use in policy appraisal) has become synonymous with cost-effectiveness analysis. Initially, priorities were driven by the main cost-concerns; that is, high-tech, high-cost interventions, such as heart and liver transplantation procedures. However, priorities are now generated by a multitude of factors, including the degree of uncertainty concerning the efficacy, effectiveness, or efficiency or an intervention; the frequency of its use; its cost impact; its potential to reduce morbidity/mortality and improve quality of life; and the potential impact that HTA might have. However, Berg et al. are careful to point out that, although the Fund for Investigative Medicine is the largest HTA agency, there is no central direction for HTA in The Netherlands. Therefore, with several smaller agencies undertaking HTA activities, there are many different lists of priority setting criteria in existence.

Economic evaluation has, according to Carlsson, become an increasingly important aspect of the HTA activities of the SBU, and there are signs that this form of analysis is being embraced more broadly, as indicated by the recent establishment of a new agency to assess the effectiveness and cost-effectiveness of pharmaceuticals, mentioned above. Carlsson notes that the SBU prioritizes interventions for assessment on the basis of whether the intervention has significant economic consequences, ethical implications, significant implications for the structure of the health-care system, is expected to entail a considerable medical breakthrough, and/or is expected to affect a large number of patients or impact upon a common health problem.

Influence of HTA on Policy

In all countries, HTA agencies have insufficient resources to examine more than a small proportion of the many thousands of interventions available in all advanced health-care systems. For this reason, their policy influence will always be limited. However, with the possible exception of England and Wales, there are more fundamental problems with translating this type of evidence into policy. To be specific, the structure of the HTA process does not, in general, adequately incorporate the necessary mechanisms to translate evidence

into policy. The case of England and Wales, which does—unusually—internalize scientific *assessment* with policy *appraisal*, deserves attention.

The health-care system in England and Wales is very centralized, and NICE itself is a very "centrist" institution; that is, it issues guidance—by means of leaflets, monographs, databases, and Web sites—from the center to all purchasers and providers in England and Wales. Therefore, the conditions are appropriate for (relatively) easy and consistent dissemination of the HTA results. HTA is not, however, the only factor that guides NICE's decisions. As Stevens and Milne note, in addition to the costs and benefits of an intervention, the clinical needs of patients, NHS priorities, the impact on other NHS resources, a consideration of the environment required to encourage innovation, and guidance from health Ministers relating to the level of resources that are likely to be available, all impact on NICE's decisions. Nonetheless, the results of HTA—that is, the "science"—are incorporated into the policy appraisal process; given NICE's high profile position in the health policy arena, health policy makers are given the incentives necessary for them to consider the outcomes of HTA. All HTA guidance in England and Wales, with the exception of that relating to market approval for pharmaceuticals (which has regulatory power on the basis of safety and efficacy in all countries studied), had, until very recently, merely an advisory role. From 2001, however, it became mandatory for local health-care purchasers to provide the finance necessary to fund *positive* decisions from NICE (which has posed, and will continue to pose, problems relating to the local affordability of acting upon NICE guidance). NICE, therefore, appears to possess all the ingredients—that is, a centrist structure, an internalized assessment/appraisal process, and some regulatory powers—necessary for NICE HTA to have *some* (albeit limited) policy influence. However, Stevens and Milne state that there has so far been little effort expended in assessing the practical impact of NICE (much less the HTA aspect of NICE). It is, therefore, only really possible to guess that the HTA agencies in England and Wales have some limited impact on some very specific health-care priority setting decisions.

Although little can be said about the policy influence of HTA in England and Wales, even less can be said about its influence (or at least about its positive influence) in France, The Netherlands, and Sweden. In France, as mentioned earlier, Orvain et al. note that the main HTA agency, ANAES, serves in a purely advisory capacity to a variety of different customers. ANAES does not appear to monitor the influence that its guidance may have, but its influence, if any, is likely to relate to the isolated concerns of the medical, professional, and academic societies, rather than to strategic, national health policy objectives. Berg et al. argue that in The Netherlands, health policy is decided largely through negotiation and compromise between the government, local purchasers/providers, patient groups, and others, and that self-governance at arms length from central government is key. HTA-informed guidance, which Berg et al. define as a "rational" solution to complex decisions, ignores the crucial subjective process of (political and ethical) compromise, which, according to Berg et al., severely limits the power of HTA to impact upon the policy process.

A powerful obstacle to HTA having a (national) policy influence in Sweden is the heavily decentralized nature of the organization and funding of the health-care system. In his article in this special issue, Carlsson writes that the regionalized county councils and municipalities are responsible for many aspects of health and social care, and that the county councils compete with each other in the uptake of new medical technologies, which somewhat undermines the impact of HTA. Nonetheless, Carlsson notes that a lot of effort is expended in disseminating the findings of the SBU reports, and he outlines a few specific cases where the outcomes of HTA may have had an isolated impact on the use or otherwise of a health-care intervention, but he stresses that details on the use and impact of HTA in Sweden are vague.

The overall impression given by the four country case studies, therefore, is that, despite considerable human and financial investment in developing and conducting health technology *assessment* over the past two decades, the impact of these assessments on policy appraisal is vague and, at best, very marginal. For greater influence at the policy-making level, it seems plausible that assessment and appraisal will need to be incorporated within a common structure to provide necessary (although, on the basis of the commentaries summarized below, perhaps not sufficient) incentives for policy makers to consider the science and that the HTA agencies will need to be handed greater regulatory powers. The general structure (if not the specifics) of NICE in England and Wales could perhaps serve as a model on which other countries might wish to base their own HTA agencies, although substantial problems of local implementation would no doubt remain.

COMMENTARIES

The nine commentaries are summarized under three subheadings: (i) social science and ethics perspectives; (ii) public health and medical perspectives; and (iii) stakeholder (i.e., the consumers and producers of health technology) perspectives.

Social Science and Ethics Perspectives

Perspectives from three social sciences are included in this special issue: political science, sociology, and economics. From a political science perspective, Chinitz actually believes that HTA has historically been quite successful in influencing policy in all four countries. He argues that the success of HTA in this regard has arisen principally because politicians harbor a "technocratic wish" to liberate them from making difficult decisions. Consequently, HTA evolved within a depoliticized environment. However, this depoliticisation is under threat

as HTA is increasingly used in explicit priority setting at the national level. Therefore, the use of HTA will be subjected to increasing political accountability.

As noted by Stevens and Milne, it is highly likely that a main driver behind the development of HTA over recent years has been the introduction of internal market reforms, which, as Chinitz points out, were introduced in England and Wales, The Netherlands, and Sweden. He notes that these reforms placed pressure on both the purchasers and the providers of health care to demonstrate value for money, and, one could argue, decentralizes the health-care decision-making process. However, Chinitz also maintains that the centralization of decision making plays an important role in encouraging the development of HTA. This may explain why England and Wales, with its experimentation with internal market reforms running parallel to the maintenance of strong central powers, have seemingly been at the forefront of developing assessment and translating it into appraisal.

Chinitz also notes that all four countries have developed a dense institutional HTA structure, with multiple agencies across different sectors (e.g., government, universities) at both the national and local levels. This, he argues, protects HTA from a dependence on the impact and quality of a single center, and facilitates the production of a large critical mass of outputs. However, the dense institutional structure, and the increasing influence of HTA in priority setting decisions, draws attention to the internal and external politics of the HTA research endeavor. For example, Chinitz recommends that more research ought to be undertaken on the politics of the allocation of research funds to the different HTA agencies, and how different technologies are prioritized for assessment. Moreover, the higher profile, and consequent politicization, of the HTA process may require new institutions to serve as a conduit between the researchers and the policy-makers, who may find themselves increasingly subjected to stakeholder interests (and resistance) vis-à-vis the introduction (or otherwise) of new health technologies. In short, Chinitz concludes that, as the movement gains greater visibility, there will be an increasing need to combine the science of HTA with the politics of resource allocation.

Webster argues that a sociological exploration of HTA requires an attempt at unpacking the social meaning of HTA, its underlying assumptions and ways of ordering the world, and (resonating with Chinitz's political science approach) the social relationships between those who construct HTA reports and recommendations. Webster claims that the current development of HTA comes at a time when the primary social discourse running through all institutions is one of "responsibility" and "reflexivity." In the context of HTA, "responsibility" refers to a scientific, economic account of the application and implications of a new health technology, and "reflexivity" refers to the need to emphasize the provisional status of any such account and to make transparent the basis for any claims as to the "value" of the technology. Webster argues that reflexivity has serious implications for attempts to standardize HTA internationally, because the organizational, institutional, and cultural relationships that characterize the reflexive innovation system differ (and, indeed, change within countries over time).

A major way in which the organizational and institutional structure of HTA differs across the four countries concerns the level at which HTA is applied. As Webster notes, England and Wales is highly centrist, France consists of a set of discrete agencies, The Netherlands has a corporatist structure, and Swedish HTA is highly decentralized along county council lines. Although, as mentioned above, England and Wales appear to have the most developed HTA structure, possibly due at least in part to the highly centrist nature of the system, Webster does not think that localized HTA decision making (as in Sweden) is necessarily a weakness because this may offer better leverage for policy makers to adapt decisions appropriate to local circumstances. However, Carlsson notes that, in Sweden, the county councils tend to compete with each other for the latest technologies, which may, to some extent, undermine the efficiency ethos that, theoretically speaking, now underwrites the HTA movement.

Webster also sees HTA as a highly politicized process, which again parallels Chinitz's point of view. They both see it as involving multiple interest groups with different priorities and needs. Webster also thinks that there is more than one fundamental underlying rationale for introducing the results of HTA into the policy-making process. For example, some governments (or other health-care decision makers) may use HTA to simply serve a symbolic function, so as to give the impression that they are demonstrating cost-awareness. Alternatively, HTA may be given a legitimizing function, with the evidence being used principally in support of decisions that have already been made. A danger here, notes Webster, is that more powerful stakeholders are likely to benefit unfairly at the expense of those with lesser power.

From the perspective of an economist, Rutten appears to be more optimistic than Webster with respect to the international comparability of HTA. He points out that broadly similar methodological guidelines for economic evaluation exist in all four countries. This offers some hope that the results of such studies can be compared both within and across countries. However, Rutten notes that there are large variations in guidance for the practical application of HTA, which he seems to suggest could be overcome (but which Webster perceives as inevitable).

A further issue raised by Rutten, which is to some extent critical of standard thinking vis-à-vis economic evaluation, is related to equity concerns. Rutten recognizes that the broadly accepted ethos of health maximization may actually serve to disadvantage those who are in the worst states of health; that is, relating need with capacity to benefit from health care may serve to steer health-care resources away from those who do not benefit the most from health care but who have the highest levels of clinical need. Nord has also written about this potential problem and has recommended that the severity

of the health state ought to be internalized into the structure of health outcomes value elicitation exercises (13). Rutten, however, recommends an alternative solution; namely, the use of different cost-effectiveness thresholds for illnesses of differing severity, with interventions for more severe illnesses being offered a more lenient threshold.

Obviously, Rutten is himself broadly favorable toward the use of cost-effectiveness analyses, but he states that, in most countries, there is little support for developing cost-effectiveness informed practice guidelines, and that for HTA to have more impact in the future, there is a need to better integrate local practitioners and hospitals into the HTA process. The future impact of HTA, concludes Rutten, may lie in limiting its impact to within-patient subgroups, rather than in attempts to remove particular interventions entirely from the health-care system.

From an ethics perspective, ten Have argues that HTA oscillates between two conceptions. First, there is a narrow approach that focuses on the effectiveness, safety, and economic impact of technologies. Second, there is a broader conception of HTA that takes into account the social and ethical consequences of technologies. ten Have states that the narrow approach tends to dominate in discussions around—and applications of—HTA, but that the broader approach is occasionally advocated. Because new technologies potentially affect the health, life, and death of a great number of people, ten Have argues that moral justifications for the use of these technologies are required and that the articulation of as many values from as many different stakeholders as possible should influence (or at least be included within) the HTA process.

ten Have also raises a concern that is directly related to the difficulties in interpreting evidence of effectiveness from evidence of efficacy, in that harms observed to specific patients or patient groups when an intervention is practiced widely may not have been observed when the intervention was subjected to a clinical trial. Moreover, deciding what constitutes a harm, or whether a particular benefit outweighs any observed harms, requires value judgments that are far from straightforward. ten Have also notes that new technologies can in themselves generate new moral problems, and cites new resuscitation techniques, which may lead to a redefinition of the notion of death, as an example. For the above reasons, ten Have believes that moral considerations ought to be an intrinsic component of HTA.

ten Have postulates a possible reason why ethical considerations are not often intrinsic to HTA in that he argues that HTA tends to be undertaken from the perspective of the dominant medical paradigm, and includes one or a small number of measurable output parameters that are assessed in terms of efficacy. HTA does not tend to internalize the underlying preferences and values of the patients (and public) whose lives are potentially affected by the results of the technology assessment. ten Have challenges the view (suggested by, for example, Stevens and Milne) that all values can be considered within the appraisal (as opposed to the assessment) process, and argues that the contribution of ethics vis-à-vis HTA is essentially twofold. First, ethics can make an empirically driven contribution, in that the moral implications of the outcomes and results of HTA need to be assessed. Second, ethics ought to be considered at the theoretical level, in determining the appropriate parameters of the moral framework (e.g., preferences and values, as well as outcomes) in which HTA should take place.

Public Health and Medical Perspectives

Perspectives from public health, general practice, and clinical medicine are offered. Holland, from the perspective of public health, is disappointed that the HTA movement has tended to concentrate on clinical procedures, rather than assessing policy interventions that tackle some of the wider determinants of health. He argues that the major determinants of health are nutritional, environmental, and occupational hazards; lifestyles; incomes; and biological factors such as genetics. Clinical and medical services are lesser influences upon health, and yet the HTA processes in all four countries predominantly focus upon clinical procedures, pharmaceuticals, medical techniques, and equipment.

Although Holland would like public health issues to occupy a more central position in the HTA movement, he recognizes that the greater complexity and time-lapse between intervention and effect in public health compared with clinical medicine will inevitably complicate public health HTA research. Nonetheless, he believes that a willingness to embrace this complexity is crucial if HTA is to influence meaningfully population health.

In addition to the problems of formal assessment, Holland lists several other possible explanations for why there has been a dearth of public health HTA studies. These include the possibility that any particular public health intervention will involve the interaction of many different "agencies," which contributes to the complexity of the issue. Also, many public health interventions are politically charged and meet the resistance of powerful interest groups (e.g., banning smoking advertisements). Whereas it might be difficult to introduce some public health interventions, it may be equally difficult to remove others. This is because the effectiveness of some interventions is historically accepted, without an evaluation ever having been undertaken to confirm this assumption. Finally, Holland notes that there may currently be a lack of public health HTA research simply because of the higher profile and prestige awarded to assessing new pharmaceuticals and high-tech medical equipment. Holland concludes that a wider approach to HTA is needed to improve the health of the population, rather than the delivery of a limited number of clinical services.

Heath comments from her perspective as a general practitioner, and, like Holland, is also quite critical of the HTA movement, albeit for different reasons. She states that patients present to her with often ill-defined and confused problems

and symptoms, which vary widely from case to case, and she questions the extent to which HTA (which implicitly adopts a very general perspective) is able to address the complexity of the patients' experiences. Like ten Have, she argues that most HTA does not incorporate social and ethical concerns, which is a fundamental flaw from the perspective of general practitioners, who in their daily dealings with patients at the face-to-face individual level have to think about the social and ethical aspects of care. Thus, according to Heath, HTA in its current form can have only a marginal impact on general practice.

Heath also raises several other concerns. For example, she highlights the risk inherent in most medical decisions and seems to question whether a deterministic framework (i.e., an HTA-informed guideline) is appropriate for steering decisions that have such uncertain outcomes. The implication is that a nuanced, case-by-case decision-making process is more appropriate. Related to this, she also makes the point that politicians must assume the responsibility for making difficult societal decisions vis-à-vis HTA, rather than passing the responsibility on to the medical practitioner, whose perspective is inevitably focussed upon the individual. In addition to questioning the process by which HTA is used, Heath also questions the methods that underlie economic evaluation. In particular, she sees quality-adjusted life years (QALYs), the main outcome indicator of cost-utility analysis, as excessively reductionist in relation to their purporting to measure the "worth" of a human life in a single numerical index, and she argues that the QALY-maximization approach in itself may be fundamentally flawed, in that people may have preferences regarding health-care resource allocations that do not necessarily suggest "societal" health maximization. Furthermore, Heath claims that the HTA-informed guidelines that are issued by the UK government to general practitioners are too numerous to even read, let alone act upon.

Ultimately, Heath questions the value for money of undertaking HTA and argues that this money may be better directed toward clinical services. However, she ends on a conciliatory note by concluding that more HTA may prove useful in improving the utilization of pharmaceuticals and laboratory tests, providing that it is used to guide rather than to determine, that it incorporates social and ethical implications, and that patients are more involved in the decision-making process (so as to limit the amount of discarded medications).

Writing from his clinical science perspective, Chantler, like Heath, sees the need for a more active role for patients in deciding health-care priorities. More generally with regard to HTA, he emphasizes the need to pay attention to four main (and sometimes competing) issues. First, he asks how people can be encouraged to stay healthy for longer, an issue for public health but which also raises questions about how care should be organized and how those with disabilities ought to be supported. Second, he argues that the delivery of health care ought to be organized around the needs of those with chronic disabilities through, for example, better integration of hospital and community services. Third, he calls for improved teamwork, so as to attain a more effective and efficient use of health-care personnel. Fourth, he states that there is a continued need to pay attention to what does and does not work, which was, after all, a main factor in driving the initial growth of HTA.

Also in common with Heath, albeit in a more conciliatory tone, Chantler highlights the different perspectives adopted by politicians and managers, and medical practitioners. Politicians and managers are concerned with decisions that impinge upon society; medical practitioners are necessarily concerned with decisions that impinge upon the individual. Nonetheless, Chantler notes that, in the case of the United Kingdom, the increasing number of doctors in managerial positions over the past 15 years has to some extent loosened this dichotomy of perspectives, with doctors becoming increasingly aware—both through their medical school training and through their practical experiences—that prolificacy in their resource use will have negative implications for other parts of the health service.

Despite medical practitioners in the United Kingdom becoming increasingly aware of the need to set priorities across the whole of the health-care system, Chantler thinks that it is important that clinicians maintain their Hippocratic ethic and that they must have the flexibility to respond to individual needs. He does not think that clinical guidelines should be too deterministic, because they cannot appropriately address every specific action at the patient level, and he, therefore, appears to perceive HTA to be more useful when used at the broader, policy-making level. At this level, Chantler welcomes explicit priority setting, where politicians take more direct responsibility for rationing health care. This is because he has for a long time felt uncomfortable with clinicians having to take full responsibility for hiding from patients the fact that a particular treatment is not being provided because it is not being financed. Politicians, he argues, are elected to assume these types of responsibilities and to explain any corresponding necessary actions.

Chantler also argues that, from a clinician's perspective, HTA has to be accurate, relevant, timely, and accessible. Clinicians are concerned with timeliness as they sometimes find themselves in a difficult position where a new, expensive treatment has been evaluated and recommended in a country other than their own. This problem is important but potentially difficult to solve for HTA agencies—such as NICE—who face resource constraints that limit their powers to assess and appraise. If Webster is right in thinking that attempts to standardize HTA internationally will inevitably flounder, then it is plausible that different technologies will be assessed at different speeds in different countries, and thus this particular problem may be insolvable. However, due to the time constraints that physicians face, Chantler believes ease of access to information and knowledge to be the most crucial concern and argues that clinicians should share relevant information vis-à-vis the impact of care and treatment strategies and ought

to be given the facilities (i.e., online data and information services) to facilitate them in these practices. In addition to introducing explicit recognition of the opportunity costs of all health-care decisions at the broad policy level, Chantler ultimately believes that HTA ought not involve the search for infinite wisdom but should instead be used to try to minimize error at the individual clinical level.

Stakeholder Perspectives

Two commentaries are offered from the perspectives of non-medical stakeholder groups: the patient perspective and the pharmaceutical industry perspective. From the patient perspective, Coulter (as the Director of a research institute concerned with assessing the public and patients' views on health and health care), in common with some of the previous commentators, is disappointed with the direction that the HTA movement has taken. She argues that patients and, more generally, the public as a whole have had a very peripheral role in determining priorities for HTA, in evaluating the efficacy and cost-effectiveness of health-care interventions, and in using the results of these evaluations to make informed choices regarding health-care priorities. Consistent with the views expressed by ten Have, Heath, and Chantler, Coulter believes that the neglect of patient and public preferences in the HTA process is a fundamental mistake. She notes that this is because technology appraisal involves values and judgments, and in a democratic society, it is important that the public have a say in this "political" process.

For patients to become more involved, Coulter argues that they need access to information that will help them to participate in decisions that directly affect them, a view that parallels Chantler's "accessibility" requirement for medical practitioners. Coulter identifies four areas where she believes patients and the public ought to be more involved. First, patients/the public should be more involved in the process of determining HTA priorities. She argues that this would probably lead to more emphasis being placed on existing—as opposed to new—treatments, because the appropriate use of existing technologies may have greater impact on patient care (and patients' perceptions of their care) than attempts to control the use of new technologies. Second, patients/the public should be more involved in designing and conducting HTA, which she believes would lead to more emphasis being placed on quality of life and psychological indicators rather than physiological indicators. Moreover, she argues that there are many well-validated instruments to measure quality of life that are currently under-used in HTA, although her faith in the validity of these instruments in their current state of development, and—given that (for example) NICE recommends cost-utility analysis (and thus the use of QALYs)—her belief that they are currently under-used, are both open to question. Third, patients/the public ought to be more involved in receiving and using HTA findings, for example, through the use of "decision aids," many of which have been developed in the United States but are, according to Coulter, under-used in Europe. However, it again seems reasonable to question whether these aids—which have been developed in a very different health-care culture than that which exists in many European countries—are in fact "under-used," particularly if patients experience disutility in being required to participate in the medical decisions that affect them. Fourth, as ten Have also notes, patients/the public should be engaged in debates in an attempt to better understand their underlying values regarding policy priorities and rationing (for example, what do people generally believe to be a fair distribution of health-care resources or outcomes, and how might HTA accommodate this value structure?).

In an attempt to provide greater patient and public involvement in the four areas outlined above, Coulter argues that there needs to be explicit, publicly debated**,** and agreed-upon principles at the broad macro policy-level, greater transparency and public involvement at the health-care institutional level, and sufficient flexibility to avoid the "one size fits all" approach at the individual clinical decision-making level. A means by which to achieve this is to encourage the further development of patient representative groups, although Coulter explicitly acknowledges the dangers inherent in this. For example, she notes that in the United Kingdom, the larger, better funded, and more powerful patient groups tend to argue the case for only those patients who suffer from particular chronic illnesses, which may serve to bias resource allocations away from those patients who suffer from less "visible" illnesses. Moreover, the pharmaceutical industry is an important source of funds for many patient groups, which creates potential bias if these groups serve as little more than public relations bodies for the manufacturers of particular products. Despite these dangers, Coulter concludes that a systematic, "unbiased" attempt at generating more patient and public participation in the HTA process is a crucial step toward reducing the democratic deficit in health-care decision making.

Finally, from the perspective of the pharmaceutical industry, Lothgren and Ratcliffe state that they are concerned with three main issues: (i) the contribution of HTA to overall health-care efficiency, (ii) the potential for HTA to drive up industry costs, and (iii) the barriers to the implementation of HTA results.

With respect to point (i), Lothgren and Ratcliffe question why such a large proportion of HTA activity focuses on pharmaceuticals when these generally account for only 10–15 percent of health-care costs. Several responses could be made. For example, pharmaceuticals account for a much larger percentage of health-care *intervention* costs, pharmaceuticals are produced by entities that are driven by profit maximization, and pharmaceuticals are already assessed for safety, efficacy, and quality within clinical trials, which, at least at face value, offers relatively convenient circumstances for the application of other aspects of HTA. Nonetheless, Lothgren and Ratcliffe maintain that to make a more optimal

use of scarce HTA resources (and, consequently, scarce health-care resources), more thought needs to be given to deciding which interventions to prioritize for assessment, both in terms of the choice of interventions themselves (which resonates with the arguments offered by Holland from a public health perspective) and in terms of choosing between new and existing interventions (which is an issue touched upon by Coulter from the patients' perspective).

Lothgren and Ratcliffe express concern about the multiple, differing HTA requirements, both across countries and within countries, at the national, regional, and practitioner levels, in that they argue that this increases industry costs and, ultimately, the price of their products. Moreover, they note that HTA agencies often require good evidence of what is likely to happen with respect to a product's costs and outcomes in a real practical setting, and they state that this requires sample sizes and time frames that are more substantial than those that are usually used in clinical trials. To reduce the costs of HTA, and remove some of the barriers for its use, Lothgren and Ratcliffe conclude that there needs to be more agreement, collaboration, and partnership between the various government HTA agencies and authorities to clarify the realistic expectations, possibilities, and limitations of HTA.

CONCLUSION

In England and Wales, France, The Netherlands, and Sweden, there has been burgeoning HTA activity over the past two decades, but the impact that HTA has so far had on policy in each of these four countries has been marginal. Many people from many different perspectives and for many different reasons remain skeptical of the relevance of current HTA activities for practical decision-making purposes, which offers a possible explanation for why HTA has had a marginal impact. For example, many people see health-care decision making as an essentially political process, and the scientific nature of HTA as currently performed is not able to incorporate important political, social, equity, and ethical considerations (Chinitz, Webster, Rutten, ten Have, Coulter). Overcoming this separation of "scientific" and "policy" concerns is likely to require the integration of assessment and appraisal into a common HTA structure; England and Wales, through the auspices of NICE, appears to be the only country that has thus far moved in this direction.

Some see a danger in HTA being (and possibly remaining) an overly deterministic tool for the highly complex and variable decisions that have to be made at the individual clinical level (Heath, Chantler). Still others see HTA as inappropriately focussing upon clinical and pharmaceutical services, when a focus upon public health and/or service delivery mechanisms may represent a potentially more effective use of scarce HTA resources (Holland, Lothgren and Ratcliffe). Incorporating all of these concerns is perhaps important but does seem to present a monumental, perhaps impossible (or at least "cost-ineffective"), task. To paraphrase from Chantler's commentary, to use HTA as a means to search for infinite wisdom may represent the art of the impossible, and perhaps we therefore ought to restrict our ambitions, and use HTA as a means by which to attempt to minimize harm.

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