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Health technology assessment in four countries: response from political science

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Four studies, each on health technology assessment (HTA) in a different country, are presented in this volume. Conveying differing levels of sensitivity to political aspects of HTA, their storylines are similar in terms of the importance of the institutional structures that produce HTA and mediate its influence on health policy decision making. Regarding the internal politics of HTA, the latter appears to have developed in a relatively depoliticized environment, supported by a dense and varied web of institutional sites for funding, production, and consumption of HTA, buffered from the capricious impacts of electoral politics. Regarding external politics, HTA in all the countries began with relatively politically innocuous studies of technologies recognized to be of major import to national health systems or researcher-initiated studies. However, with increased focus in health systems on explicit determination of health benefits baskets, the role of HTA has become more high profile. This means that political accountability for the entire HTA process will increase. The implication is that future management of HTA programs will require self-conscious attention to the building of institutions capable of handling the delicate process of integrating science and politics in health policy.

Keywords: Accountability, Health technology assessment, Political science

These four fascinating studies call to mind, at least for this reader, the four sons described in the liturgy for the Jewish festival of Passover. The details of this perhaps farfetched allusion are left to an end note.[1] In general, each of the four sons expresses a different kind of ambivalence about the relationship between slavery and freedom. By analogy, each of the four studies conveys a somewhat different approach regarding the relative roles of politics and research in policy making. In addition to analyzing this mix, it is important to remember that research itself is a political activity. This response addresses, based on my reading of the four studies, the research politics of health technology assessment (HTA) as well as the politics of the role of HTA in health policy.

The first-section links this response to wider theoretical perspectives on the role of science in policy making. This is followed by observations on the internal politics of HTA as a public sector activity and, in turn, by an analysis of HTA's role in health policy making. The concluding section suggests lessons learned from the four studies and avenues for further research.

ASSESSING HTA: REVISITING THE TECHNOCRACY/POLITICS DIVIDE

The four country studies included in this volume recall but do not indulge in the temptation to view HTA as being disconnected from politics or depoliticized. While it has long been realized that science and politics are intertwined, the grounding of health and medicine in scientific evidence still encourages, in some quarters, the notion that health policy can be converted from value-laden decisions to be taken by appropriately designed institutions, to decisions subject mainly to the disposition of science (8). The emphasis, witnessed over the past decade in national health systems, on outcomes research in health policy is linked to this perception. Recent signs of disillusionment with outcomes research are, perhaps, not surprising in view of the unrealistic expectation

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that it would neutralize the political difficulties of medical and health policy decision making (13).

It is, therefore, reassuring that the four studies presented here do not comply with a bottom line approach focusing on some unduly narrow measure of the influence of HTA on policy. That this was not perceived to be the mandate of the authors is demonstrated by the ample attention given in all the studies to the origins of HTA and the emphasis on the importance of institutional frameworks of HTA in their respective countries. Like any public policy realm, HTA can scarcely be understood by appeal to models assuming a dichotomous relationship between science and politics, and the institutional frameworks for production and utilization of HTA require analytical attention.

Institutions compose the rules by which various stakeholders to transactions interact (22). HTA, like most "arenas of action," is not carried out by a single rational decision maker, nor can the processes by which it is produced and used be understood solely on the basis of models of rational decision making (16). The four studies presented in this volume conform to an institutional approach by presenting the stakeholders and organizational structures involved in HTA. The latter is a policy arena in which researchers, health providers, technology producers, health insurers, consumers, citizens, and politicians, all with their own interests, compete for resources, agendas, and over policy outcomes. As can be seen from the studies, these constituents and the rules by which they interact influence the substance and impact of HTA as much as the scientific method and content of HTA.

It should be noted that, when dealing with cross-country comparisons, while the institutional parameters to be considered may be the same, they will appear in different combinations and a not always signify the same phenomena (7). For example, the policy networks, composed of alliances among stakeholder groups focused on particular conceptions of policy and the policy agenda, will differ across cultural settings (3). The tradition of respect for and admission of science into policy making will differ across countries, as will the nature of the institutions involved. In some countries, HTA may be dominated by university centers and in others the major impetus may come from in-house government research activities. Success in linking, for example, guideline development with HTA, as pointed out in the study on The Netherlands, will depend on the administrative culture in each country and its ability to "get agencies to work together" (2). National government may be the major locus of most HTA research in some countries, while in others, the key action may take place at the regional or local level.

Putting HTA, with its rich institutional structure as described in the studies and addressed below, into this type of theoretical context offers important lessons to other areas of social policy. These lessons concern the successful blending of technocratic and political inputs into policy processes. As enlarged upon below, HTA, as presented in the four studies, appears to have been relatively successful in terms of raising the overall awareness of policy makers regarding cost-effectiveness and in some cases, influencing specific resource allocation decisions, even if not usually as the determining factor. This last outcome appears to derive from the fairly strong and varied institutional HTA infrastructure in each of the countries, as well as a degree of insulation from the political accountability for health resource allocation decisions. However, as noted below, the role of HTA in health policy may be reaching a critical point of proximity to political accountability. If this is the case, more self-conscious attention to the institutional framing of both the production of HTA and the integration of HTA in political decision making is called for.

RESEARCH POLITICS OF HTA

Unlike the Passover holiday mentioned above, HTA did not originate in the context of revolutions and miracles. As is the case in many areas of social policy, in all of the countries described, HTA began quietly and "innocently" enough in the 1970s or early 1980s (1). This was an era in which expectations were high that applied social science could produce objective, scientific answers to tough social problems. In many areas, such as education and incomes policy, large-scale investments in social research, experiments, operations research, and evaluation led to "the era of disillusionment" (14). Observing that, in many cases, research results were either ignored or manipulated by politicians, the policy analysis community shifted its expectations. Research and analysis could "enlighten" the policy-making process but not provide technical solutions that would supplant politics (11;21).

Notwithstanding similar justifiable doubts expressed in some of the studies, for example by Berg et al. (5) regarding "technical solutions," HTA seems, at least in the four countries described, to have been a relative success in influencing policy making when seen in this historical perspective. Indeed, rather than seeking to control and manipulate, politicians appear to harbor the "technocratic wish" that HTA will liberate them from having to make tough decisions. An example of this tendency is the creation by the Swedish parliament of a new agency for negotiating prices and decisions on the reimbursement of drugs, which will base decisions not only on efficacy and safety but also on cost-effectiveness (6).

Perhaps this explains why there is no mention of the impact of political parties or elections on HTA in any of the studies, as might be expected given the experience of the Office of Technology Assessment and HTA in the United States (17). Carlsson (6), in providing important background, mentions a spat between the Social Democratic Swedish Government and the Conservative–Liberal coalition in Stockholm over privatization but not regarding HTA. If, as it appears, HTA is

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basically depoliticized, two questions are posed: why is this the case and how long will it remain so? Tentative responses are proposed in what follows.

Another factor common to all the countries and which appears to enhance the position of HTA is the fairly dense institutional web devoted to this activity. All of the studies describe multiple sites, in different sectors (e.g., university and government), at different levels (e.g., local, national, and international as in the case of the Cochrane Collaboration), as well as multiple sources of funding for HTA. From the point of view of the politics of policy research discussed above, such an environment protects HTA from being dependent on the outstanding quality and impact of one center or one high-profile project. The institutionalization of HTA-related research and activities permits a stream of outputs and achievement of a critical mass (as suggested by Steven and Milne [20]) that can impact on policy making and, as pointed out by Orvain et al. (15), leads to productive interfacing among HTA activities sponsored by different agencies, which "reveals the multidimensional structure of the object". However, this dense institutional context draws attention to both the internal and external politics of the HTA research endeavor.

Internally, the ostensible "peaceful coexistence" of the multifarious institutional frameworks for HTA begs for more discussion of the politics of allocation of research funds among the different types. For example, in the UK case, Stevens and Milne (20) describe incipient competition between reports motivated by researcher curiosity and the more directed National Health Service's Research and Development program (the NHS R&D program). Furthermore, the selection of seven specialist review centers linked to the National Institute for Clinical Excellence (NICE) was no doubt a process not devoid of political input.

Perhaps more importantly, HTA's external relations with its clients, and in particular, the political decision making structure, recalls the issue, mentioned above, of "evidence versus institution," that is, whether health resource allocation is a rational, scientific-minded project, or one of institution building (10). That HTA activity is spread among a wide variety of types of institutions at different levels of national health systems proves the point that science and institution building are inseparable. The internal politics of HTA is matched by the competition and coordination among different institutional users of its products. As NICE is pressed to make its procedures more transparent, the relationship between researcher-initiated HTA and R&D program-defined research will shift, influencing the content and direction of the research itself. As the Dutch system shifts back and forth between national priority setting and reliance on local guidelines, more attention will be drawn to the mechanisms by which subjects are selected for HTA. The new Swedish agency for negotiating drug prices will create an institutional context in which bureaucrats and drug companies confront each other with HTA products supporting their respective negotiating positions. In the French case, strong institutional centralization, notwithstanding the case made by Orvain et al. (15) for "centrifugal" forces, creates a situation in which *AFSSAPS* calls the tune regarding HTA of new medical devices, while the Directorate of Health can then overrule *AFSSAPS* on financial grounds. All of these examples suggest that self-conscious attention to the internal institutional aspects of HTA, is as important as the evidence produced by HTA.

POLITICS OF HTA IN HEALTH POLICY

While all four studies convey a message of qualified optimism regarding the research politics of HTA, the "timing and trajectory of the HTA response" (to borrow a phrase from Stevens and Milne [20]) to health policy varies with differences in the blend of evidence and institution that are socially embedded in the political context of different countries (18). Some key political parameters reflected, albeit not equally, in all the studies concern the structure and organization of the health system, in particular the perceived role of the state; the dynamics of health system reforms; and accountability, especially political accountability. These are addressed seriatim.

Three of the four studies stress the roles of different levels of government in the health system as crucial for the role of HTA. The United Kingdom is called "centrist," the Dutch state is described as "responsible" but "bounded," and Sweden as "decentralized" (primarily from central government to the county councils). As alluded to above, while the authors of the French study evince a desire to counter the country's reputation for strong centralized control, such control appears to enhance the role of HTA in policy making, compared, say, with the "indirect steering" described in the Dutch study. The decentralized nature of the Swedish system is said to reduce the impact of HTA, as officials at the county level are free to allocate resources as they see fit, and the councils are often in competition with each other. In the United Kingdom, on the other hand, central government is under pains to provide the decisional basis for reducing "postcode prescribing," suggesting the need for centralization of HTA and increased enforcement of "national clinical policy."

While some of the studies briefly allude to recent health reforms, it is noteworthy that none goes into great detail about the impact of the last decade's wave of health reforms, in particular introduction of various forms of market mechanisms, on the role of HTA. Ostensibly, the logic of these reforms has a great deal to do with HTA, and especially with the degree to which it remains comfortably part of the "implicit" rationing mechanism or ventures into the realm of the explicit. In France, which has experienced relatively little market style reform, HTA has continued to be concerned

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Table 1. Processes and Hierarchies Related to Health Technology Assessment (HTA)

Stages in the process of HTA	Modes of Contracting for HTA	Subject of HTA or appraisal	Types of decision which HTA is intended to support	Locus of decision making	
Selecting technologies to study	Researcher initiated	Efficacy, safety	Approval for use of a technology	Individual clinician	INCREASING POLITICAL VISIBILITY
Surveying existing assessment literature	Industry initiated	Cost-effectiveness	Pricing of new technologies Development of clinical guidelines	Lower meso-level: sickness funds, primary care groups	
Primary HTA research	Sponsor defined, general areas of interest	Cost-utility	Prioritizing treatments	Upper meso-level: associations of sickness funds, County Councils, Strategic Health Authorities	
Dissemination of HTA	Sponsor defined, specific technologies	Assessment of the social value of a technology	Prioritizing health problems or groups of patients	Macro-level: Public committees or institutes	
	Sole source contracting for specific assessments		Coverage decisions	National Ministries	
Policy determination and enforcement				National political level: National parliaments, Ministers	

mainly with evidence-based guidelines and serving as a basis for controlling the diffusion of expensive technologies. In the other three systems, some form of internal market, whether based on some type of regulated competition or purchaser-provider split, was implemented. These types of reforms tend to sharpen the demand for a "defined basket of services," or to encourage ongoing interest in priority setting as in the Swedish and Dutch cases. Once this issue is on the table, it is difficult to remove it. For example, in the United Kingdom, despite "doing away" with the internal market, the current government has retained the emphasis on purchasing, or "commissioning" for health gain. Various constituents in the system increasingly await, as described by Stevens and Milne (20), direction from NICE. But, as the authors point out, the activities of NICE are likely to lead to the need for more explicit prioritization of all health services (4).[2] Berg et al. (5) echo this by arguing that, even if the local level becomes the locus of evidence-based health-care technology decision making, the role of national level bodies in making explicit, value-laden decisions cannot be avoided. HTA at that level is an important, but not the only or the determining, input into policy making.

This brings us to the questions posed above: it appears that the relatively "de-politicized" status of HTA (even if limited to assessment and not appraisal, to use the distinction of Stevens and Milne [20]) is under threat as priority setting in general becomes more visible. In other words, HTA will be subject to increasing political accountability. Table 1 is proposed as an aid in understanding this proposition. Each of the columns represents a process or hierarchy related to HTA mentioned in all the studies.

There is no meaning to the rows in this table, except that as a country moves down each of the four columns, the "political visibility" increases, as the interests of various stakeholders become more clearly identified. All four countries seem to have moved down the columns, although at different rates by country and by column. There are also attempts to go back up some of the columns; for example, as described by Berg et al. (5) in the renewed Dutch emphasis on clinical guidelines at the individual treatment level. However, having gone down a column, "retreating" upward no longer reduces the political visibility. Stakeholders' interests have been aroused, along with their sensitivity to earlier stages of the HTA processes. The media may also take a greater interest in HTA, especially regarding highly visible issues such as accessibility to new drugs. Accountability for the financing and professional quality of HTA increasingly will be accompanied by political accountability for the conduct of HTA and its impact on decision making.[3] An example is the concern, mentioned above, expressed by Stevens and Milne (20) regarding a possible divergence between HTA and evidence-based medicine in the future, as HTA becomes increasingly accountable to "customer-driven" demands.

Finally, the staffing of various committees that set priorities for HTA, make HTA research funding decisions, and translate assessments into appraisals will come in for more intense scrutiny. While the study on the United Kingdom does, indeed, mention that the protocols of the NICE Appraisal Committee are publicly transparent, it is noteworthy that none of the studies goes deeply into the politics of the makeup of such committees or the degree to which members are subject to various political pressures.

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CONCLUSIONS

By way of summary, the four studies lead to two major thrusts in terms of propositions and directions for further research. First, in terms of the politics of research, HTA has evolved in a relatively depoliticized environment, supported by a strong institutional infrastructure. This has enabled HTA to achieve a critical mass that can influence policy. However, politicians view HTA as a technocratic solution to difficult political decisions, which may pose a threat to HTA at some point. The relative depoliticization of HTA is under threat as it becomes increasingly implicated in explicit priority setting at the national level. Stakeholders in the health system, such as producers and consumers of medical technology, will increasingly scrutinize the way in which HTA is initiated, contracted for, financed, targeted, and used in decision making.

A second realm for further inquiry concerns the relationship between the overall institutional structure of the health system and the role of HTA. The studies in this volume suggest that the more a health system is centralized with power in the hands of national government, the greater will be the impact of HTA. However, recent market-oriented reforms, such as purchaser provider splits, lead away from strong central control, or produce what the study on France nicely refers to as "centrifugal" forces. These restructurings of health systems, based on various forms of contracting, appear to bring into sharp relief the matter of explicit determinations of what services will be covered by publicly financed health systems. HTA, in turn, is called upon to support this trend toward explicit priority setting in health care, bringing it beyond the realm of "neutral science" and into the realm of values and politics.

In addition to suggesting these directions for future analyses, the four studies provide a wonderful pastiche conveying the dense and intricate relationships between HTA and health resource allocation decision mechanisms. A political scientist would be tempted to rest with the case that what is described is a relatively successful example of "the intelligence of democracy" finding a way to combine rational and institutional aspects of policy making (9). The only caveat would be that HTA has reached a point in its evolution where its link to explicit priority setting is likely to increase political visibility to a level that is uncomfortable for HTA practitioners and funding agencies. Self-conscious nurturing by political and professional decision makers of institutions capable of housing the delicate integration of HTA with the politics of resource allocation is the order of the day.

NOTES

[1] The Passover liturgy speaks of a wise son, a cynical son, a simple son, and a shy son. At the risk of making a caricature of the countries presented, the wise UK son would be the one who wants to know everything there is to know, empirically and theoretically, about the relationship between politics and HTA. He might be told that technocratic mechanisms will never squeeze politics out of health-care policy. The cynical son, The Netherlands, sees politics everywhere as a "messy and difficult" business (see Berg et al. [5]) and might be told that "but for HTA, politics would not be the art of the possible in health care." The simple Swedish son asks "where's the politics in HTA?," and he might be told that local guidelines, national priority setting, and drug price negotiation are all inherently political activities. And the shy French son, who does not know how to ask, might be told that, "HTA underpins the political mechanisms that allocate increasing resources to health care."

[2] An alternative, or complement, to prioritizing, and perhaps eliminating, some existing technologies is to provide a budgetary increment for adding new ones. HTA and priority setting activities are sometimes used as "objective justification" for adding resources (see Martin [12]; Chinitz et al. [9]; Shani et al. [19]).

[3] This has been the experience in the Israeli case, where priority setting at the national level has been very explicit and very much based on HTA (see Shani et al. [19]). The visibility of decisions to include or not include certain services in Israel's basic basket of health services (priority setting at the macro-level), draws the attention of key stakeholders and the media to the question of what items were selected for assessment in the first place. Notwithstanding Steven and Milne's (20) valid distinction between assessment and appraisal, from a political point of view the two are connected.

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