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Health technology assessment: a sociological commentary on reflexive innovation

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This study provides a sociological commentary on the current debates within health technology assessment (HTA), specifically in response to the approaches taken in France, The Netherlands, Sweden, and the United Kingdom. It argues that HTA is part of a wider reflexive innovation system that seeks to order current and prospective technologies. The study discusses the socio-political process of HTA priority setting, the rhetorical role of HTA, the localised and contingent use of HTA, and the policy gap between guidelines and practice. It argues for the development of new types of methodologies for assessment and for a stronger social embedding of HTA practice.

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Precisely because health technologies are undergoing continual innovation, their "scientific basis" and utility for health services is increasingly scrutinized. The interactions between commercial technology innovation and service delivery/organization are crucial to health policy development, as are the social, economic, and organizational aspects of the "redesign" of healthcare. "Early warning" about technologies seen to have economic, social, and clinical significance has been identified as a major priority, raising both technical (19) and social questions (3).

A sociological exploration of the ideas and practices of health technology assessment (HTA) is distinctive in attempting to unpack the social meaning of HTA, its assumptions and ways of ordering the world, and the social relationships between those involved in constructing its reports and recommendations. As Zygmunt Bauman (18) recently argued, sociology is concerned with "decoding the meaning of human actions in reference to social conditions." As have many other theorists (10;14) exploring modernity and its risk-generative culture, Bauman also argues that our social condition is one of "ambivalence." It is, in part, our response to this wider social condition that has spurred the arrival of multiple techniques for surveillance, audit, and control, including the raft of models for measuring and evaluating the costs, benefits, and the effectiveness of the products of modernity—such as health technologies.

In this regard, we might construe HTA as one of several "political machines" (1) that regulate both technology and its socio-political positioning at the same time. Barry (1) describes the ways in which government and its agencies construct what he calls "technological zones" that reflect very specific regulatory and technological regimes. Standardized measures of technologies are a key dimension not only of a technical but also a political ordering and control; however, new technical developments simultaneously work to undermine these same standards. As he says:

> "standardisation is both expected to reduce blockages and restrictions in the circulation of technology . . . [while at the same time] the development of technology continually destabilises existing standards . . . [and may create] political conflict." (p. 63).

Barry's account of the standardizing process reflects many features of HTA used to regulate the introduction of new health technologies: the attempt to order and facilitate the dissemination of technology that meets a specific set of standards, coupled with the ever-present need to manage this

dissemination in a politically legitimate and economically efficient way.

In historical terms, we can also see how HTA comes at a time when the primary social discourse that runs through all institutional structures is not only about surveillance (16) but is also one of responsibility and reflexivity. Responsibility here refers to the sense of having to make an account (both scientific and economic) to others not only of the application but also the *implication* a new technology has (17); and reflexivity in the sense of acknowledging the inherent provisionality to such accounts and the need to make explicit or "transparent" (4) the basis on which claims are made. Strydom (21) has argued that there have been three great discourses of modernity that have shaped the historical ordering of science and technology from the enlightenment period through to today: these are a discourse of "rights" (in the 16th-18th centuries), of "justice" (in the 19th to mid-20th), and of "responsibility" (today). In each case the problem for society—and the "social conditions" that need to be addressed—is different. The most relevant for the discussion here, the responsibility discourse, appears in response to the "ambivalence" and uncertainties created by our engagement with and deconstruction of "nature", principally through the new biosciences and genetics. The innovation we find today breaks down conventional boundaries between species, humans and machines (the cyborg), humans and animals (the xenotransplant), and humans and humans (e.g. in vitro fertilization, embryonic stem cells, etc.).

Contemporary health technologies are increasingly caught up in these new forms of innovation. The shift from the confident, technocratic innovation system of the 1950s and 1960s to the current possibilities and ambivalences of the knowledge-based society (20) create the conditions for *reflexive* innovation systems. This is because the technologies we are developing in health—such as cloning or the "e-patient"—as elsewhere, disrupt traditional social orders and the terms on which people engage with and understand the meaning of, here, their health, their body, and medicine (23). As we grapple with the promise and disturbances of new technologies, the more we control, as Beck (2) notes, the "less we have control." As a result, while knowledge itself must be subject to increasing codification, surveillance, and measurement to try to harness ambivalence, the greater capacity for innovation and learning this allows simply means that there is greater momentum given to the development of new and perhaps less controllable forms of knowledge.

HTA can also be seen to be a good example of the way social actors in a more reflexive innovation system develop new tools and agencies that enable reflection and evaluation (HTA has itself a socio-technology agency, of course). Such reflexivity has, paradoxically, been routinized through the move toward what Lynch (15) has called a "systemic reflexivity," whereby in late-modern society "reflexive monitoring takes the predominant form of cost-benefit and risk-benefit analysis" (p. 31). In science and technology policy, we see this expressed through the increasing weight given to systematic review procedures, "evidence-based" policy and practice, and other forms of assessment. This is clearly rooted in a conception of evidence, facts, and judgment that is very much more in line with a Kuhnian "normal" (13)—rather than "postnormal"—science. In acknowledging, even requiring, that science is applied and meets its users' needs, we are led to a reconfirmation of its most "externalist" credentials and claims. It is seen in virtually every policy arena, but especially in health research and development (8) expressed most clearly in evidence-based meta-analyses and systematic reviews of medical technology sometimes accompanied by randomized controlled trials.

In addition, HTA not only seeks to take (systematic) stock of the current situation but can also act as a *prospective*, future-oriented technique by mobilizing claims about emerging technologies that recruit and secure institutional and economic resources from public and private sectors. HTA is in part about mapping out *expectations* about future social conditions as expressed through calculation of the cost/benefit, cost-impact, and cost-effectiveness of an emerging technology. Of course, such expectations only make sense where they are attentive to wider socio-economic changes, such as the demographic impact of an ageing population. Moreover, as one moves from one country to another, the organizational, institutional, and cultural relationships that characterize the reflexive innovation system change. Crucially, this means that no technology has the same (technocratically determined) path to follow but varies according to the national socio-technical configuration in which it is mobilized and evaluated (5). This can be very worrying for some driven by—as I noted earlier—the logic of standardization and harmonization: witness current attempts to develop information technology protocols (based on "component based software architecture") that are intended to iron out contingency and national variation.

HTA COUNTRY STUDIES

The four studies published in this special issue are interesting in that, taken together, they mark a move toward much greater reflexivity in the theory and practice of HTA itself. Some themes—such as the acknowledgment of the implicit value assumptions in the determination of the contribution a new technology makes—are apparent in all of the studies. However, there is still an unevenly developed discourse about the HTA process that reflects differences, I would suggest, in national intellectual and policy cultures within which the HTA perspective has emerged.

There are several key themes that are raised by all the authors that are especially amenable to sociological comment, or as Bauman (18) would say, "decoding." These can

be summarized as debates about four core issues that are inherently "social":

Socio-Political Process of HTA Priority Setting and the Assumptions on Which It Is Based

All the studies point to the way in which HTA priority setting is a highly politicized process, involving multiple constituencies of interest with distinct social priorities, reflecting different social interests and needs. Orvain et al. provide a very detailed matrix that identifies the range of HTA providers and consumers from the pharmaceutical industry, through various Ministries, insurance agencies, health professionals, and medical unions. Each seeks different HTA advice relating to drug evaluation, clinical practice guidelines, assessment of medical devices, and so on.

Yet at the same time, HTA priority setting is not driven simply by the discrete economic and political interests of its customers. As Carlsson observes, HTA agencies must in practice, simply to do their job—choose a technology for evaluation. The choice of technology to evaluate must in some way reflect agreed health priorities: "choosing which topics to assess is important but very difficult," involving a complex and lengthy process through which possible assessments are piloted to determine whether they will be able to meet the demands of the review process itself.

As Stevens and Milne observe, topics tend to be restricted to technical innovation rather than the wider context of use in service delivery and public health. Moreover, they note that organizational, ethical, and legal considerations are typically ignored, at least in the UK setting. And it is clear that they are well aware of the uneven political influence that different groups have on the priority setting process, especially their contrast between the pharmaceutical industry and the NHS.

Symbolic, Rhetorical Role of HTA Allied to Other Roles It Plays in the Policy Arena

Orvain et al. offer an interesting question about HTA: "is it an element of scientific debate, a means of changing practices, a decision aid in the public health arena, or even a step toward exerting market control"?

It is, presumably, all of these as different priority buttons are pushed, but more generally, and as far as Berg et al. are concerned, HTA plays a "symbolic function" that emphasizes the "importance of cost-awareness" more than being a tool that has a "direct, explicit function in policy decision making." Indeed, it seems that, in The Netherlands at least, HTA often performs a legitimating function that "underwrites the position [that stakeholders] had beforehand."

It is not evident that such a strategy will provide the basis for managing the ambivalences that seep into decision making and disturb existing stakeholder interests. Cost-effectiveness can, of course, always be defined in such a way that certain criteria or parameters take precedence over others and that thereby *some* stakeholders' positions are privileged over others. Presumably, we need to see that the *symbolic* role of raising the need for cost-awareness among resource-hungry groups does not translate into an inequitable distribution of scarce health "goods" among all stakeholders.

Tension Between the Formal, Decontextualized, Criteria of Evidence-Based HTA and the "Real," Contingent, World of Technology Evaluation

This theme points to the social dimensions that shape the actual determination and deployment of technology assessment among its diverse end-users. It can also be expressed as a *tension between the abstract, cosmopolitan level* on the one hand, and the *concrete, local level* on the other, as well as the multiplicity of social groups who shape the evaluation process. Berg et al. stress this as one of the most important arguments in their study, declaring that a rationalist approach to HTA "will always remain an illusion."

This argument also, in turn, reveals the *unstable identity and multidimensional status of the particular technologies* being evaluated. Indeed, they are not singular objects that all stakeholders regard in the same way, as having a stable identity and purpose; rather, they are *multiply* defined innovations. As Orvain et al. observe:

> ". . . it is clear that viewing any object (e.g., a medical device) from more than one angle (confrontation of expert opinions) often best reveals the multidimensional structure of the object."

Even if we agree with Carlsson that the very nature of technology today creates new problems—suggesting that there is an intrinsically problematic character to contemporary innovative health technologies—we can still say that the meaning of this character can be "multidimensional" with regard to the "*affordances*" a technology has for its different users. The notion of "affordances" can be usefully deployed here to suggest that all technologies have different meanings and utility values according to the ways in which they are harnessed.

Thus, as Orvain et al. observe, "heads of medical departments will want the benefits of a new technique to be recognized, whereas administrative staff will seek advice on a new investment at hospital or institutional level." The sort of decision making that may accompany this—a decentralized process—is regarded, at least in Sweden, as problematic: as Carlsson says, "[D]ecentralization of decision making in the Swedish system. . . . makes it difficult to control the introduction of new technology as every county council is free to take any decision irrespective of costs or exclusiveness."

Is this a weakness? No, because this emphasizes the need for socially robust science, as Nowotny et al. (17) argues—a position that Berg et al. would share. For them, localization is key. But what it does reveal is the *translation process at*

work in ensuring assessments make sense at the local level. As Carlsson says, "the results are not always clear from a policy perspective . . . results . . . need to be transferred into guidelines before they can be implemented in health care practice." "Transfer" means translation here. He goes on to say that "maybe it is impossible to communicate with . . . politicians, administrators, clinicians, nurses with one product. Therefore, the product must become much more adapted to the target group." Here again, we are reminded of Orvain et al.'s "multidimensional structure of the object." Stevens and Milne usefully suggests that, in the United Kingdom, national decisions made by NICE "ought to be consistent with the informal or formal rules used elsewhere in the system." Given the argument here about the need to adapt, however, "consistency" need not mean *uniformity* at the point of application.

Gap Between Agreed HTA Guidelines and How Decisions Relating to the Acquisition of New Technologies Are Taken

Networks come in here: a key objective is to enroll—to ensure "strong collaboration" between different social agencies/customers engaging with HTA. Berg et al. stress the social network among the key actors—which in The Netherlands is expressed as a system of "interdependencies" between government, providers, insurers, and patient groups. Carlsson also notes that it is difficult to give a "comprehensive answer" to the actual use of HTA studies by policy makers.

Can these gaps (also noted by Stevens and Milne) be resolved through improving the *methodology* or *process* of HTA? There are various perspectives on this: Orvain et al.'s rationalist model—a very French tradition perhaps—advocates giving health professionals tools to evaluate quality such that they will become more accepting of HTA itself, presumably by means of a process of professional transference. Expertise and consensus go hand in hand . . . but how many hands are there? And how does this position tie-in with the translation process acknowledged earlier? Berg et al., on the other hand, want to see formalized HTA drawing on—rather than distancing itself from—"the experience, imagination and intuition" of those engaged in the delivery of health care.

This problem of how to manage the "gap" between national HTA and local practice is echoed at an international level: that is, national cultural variation in HTA produces some different types of gap reflecting broad differences in political cultures. At the same time, wider social conditions—such as an ageing population—mean that the value of new technologies (already sensitive to demographic factors) can only be effectively understood if we develop more sensitive measures of a nonhomogenous variety: the ageing population will in fact be quite heterogeneous in its health demands and needs.

CONCLUSIONS

The four studies raise several themes that relate directly to the question of social coordination of HTA. First, they report different degrees of centralization in decision making, the networks and agencies that are involved in this, and how closely they are integrated in the process of HTA and priority setting, with the United Kingdom being highly centrist, the Dutch corporatist, the French system comprising a set of discrete agencies, and the Swedish system being highly decentralized with considerable autonomy for county and municipal councils. From a sociological perspective, we need to understand how these varying institutional configurations are more, or less, likely to facilitate the mobilization and diffusion of HTA guidelines. As Berg et al. observe, the Dutch system in practice is made up of a series of mutual interdependencies "between government, the private (not-for-profit) service organizations and insurers and independent professionals." They complain, however, that formal HTA-informed guidance appears not only to ignore the opportunities these dependencies offer, but actively to displace them in favor of "explicit knowledge laid down in rules, procedures, protocols and manuals."

Second, the studies refer with differing degrees of emphasis to the way in which HTA is only "part of the picture"—Orvain et al. note that "HTA cannot be dissociated from the settings in which the technology is or will be used." Stevens and Milne argue similarly, while Berg et al. note that guidelines are evidence-based and do not indicate whether intervention is appropriate according to some wider *values*. Carlsson argues that, in addition, the sort of "picture" that HTA actors produce might be coloured to reflect particular interests: as he observes "we cannot expect that the scientific literature or the producers of pharmaceuticals and other biomedical technologies will provide decision makers with all [the] unbiased information they need."

Third, the studies suggest the need for *early* engagement with new technologies so as to track potential opportunities, costs, and risks posed by them. How "early" an "early warning system" can operate depends of course on what one is trying to monitor, what techniques are available, and who is deemed worthy of participation. There are many different models for this from the more technocratic to the highly inclusionary Constructive Technology Assessment found (outside of HTA) particularly in The Netherlands and Denmark.

Drawing on research undertaken in the sociology of science and technology, there are some closing remarks that can be made that raise issues that those working in HTA should be considering:

First, are new health technologies significantly different from the past, especially in their tendency toward greater technical interdependency: can HTA address, in other words, the *interlinkage* of new technologies more systematically rather than focus on discrete new developments? Developments across the health-care system relating to "infomedicine" (9)

and biomedicine might call for more complex forms of assessment than those currently used (24).

Second, when HTA is undertaken, what are the "success" criteria being used: are they identical/universal across fields? This is an issue relating to the validation of the instruments and criteria found in HTA. HTA is a technology *itself* that needs assessment. Do more complex interventions need new methodologies that are more cognizant of context of use? For example, Heaton (11) has examined the domestication (in the home) of life-sustaining technologies that were originally developed for use in a hospital setting. The meaning, combination, use, and effectiveness and efficacy of the home-based devices and systems (such as assisted ventilation and intravenous feeding) is quite different in this setting, where complex care regimens have to be managed in the home by their families in conjunction with statutory and voluntary services.

Finally, at a regulatory and institutional level, how is it possible to mobilize assessment across different political and clinical networks that have differing priorities? This is true in any priority-setting domain, as is evident, for example, in recent work on the diffusion of Foresight (22). Carlsson comments that considerable resources have had to be put into the dissemination process in Sweden, indicating that "the evidence-base" does not "speak for itself", but needs a persuasive advocate. Berg et al. point out that HTA has had less impact in The Netherlands with regard to government using it to make "tough policy decisions." At the same time, they note that, because HTA only produces "guidelines" even with strong steering from government, enforcement would be equally problematic. The medical profession often welcomes this inasmuch as it reinforces medical discretion, yet at the same time, as Berg et al. note, this not only places the burden of decision making on the physician, it also reduces the transparency and accountability of such decisions.

One response to this is for HTA to become more open to alternative sources of information and "expertise," to demonopolize (12) its position in advice giving. Rather than seeing this as a recipe for a weakening of the science base we can argue that where evidence survives such an interrogation it is more socially robust. As de Jong argues: "Institutional structures where information provision for policy making has been demonopolised put scientific concepts to tougher tests than structures where one dominant view or perspective is embraced by only a few influential actors" (p. 198). Indeed, such de-monopolization is happening anyway, not least because of the massive growth of information sourcing by means of the Internet (6); this creates a different form of *lay*-driven HTA that conventional HTA should address. This suggests the need for new types of methodologies for assessment that incorporate these perspectives (and not just those relating to expert clinicians). Models for this exist with regard to research and assessment being not merely funded by, but actually undertaken among patient and lay groups—what Callon (7) calls "research in the wild." The four studies do appear to endorse this view in their concluding remarks, best captured by Carlsson's comment relating to the growth of "patient and public involvement in decision making." While the cynic in the United Kingdom might regard NICE's recent establishing of a "Citizens Council" as something through which it can legitimate its more contentious decisions, it might actually create greater involvement by the lay public in decision making.

This embedding of HTA practice in wider society should actually strengthen not only policy making but the science and methodology of assessment itself, because the greater the number of hoops HTA has to jump through, the more reliable and socially resilient its knowledge claims will become. This is, we might say, to survive a *social* rather than simply *methodological* falsificationism. The gaps in HTA noted above, are not filled through more and more evidence-based technical expertise, but by acknowledging that they can only be bridged through embracing the logic of a *reflexive* innovation system.

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