CHALLENGES IN CONTEMPORARY HEALTH TECHNOLOGY ASSESSMENT: A VIEW FROM THE OUTSIDE

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The Special Interest Group on Ethics and HTA (health technology assessment) has invited two renowned philosophers, Norman Daniels from Harvard University and Henry Richardson from Georgetown University to reflect on the role of HTA in healthcare policy making. Both acknowledge its importance, but at the same time warn against a too mechanistic deployment of HTA. In their view, the relevance of HTA to healthcare policy making would considerably be enhanced if it were subsumed within a broader deliberative framework. Why should this be so? What is there to deliberate on, who should do the deliberating, where and when, and how does this relate to the more technical elements of HTA such as evidence synthesis and economic modeling?

To address these issues, let us take the example of cardiac pacing. The question whether atrial pacing reduces the risk of stroke as compared with ventricular pacing in patients with sick sinus syndrome is not something that can be settled through deliberation. Whether or not cardiac pacing has this effect is not because we *decide* or *want* this to be the case. At the end of the day, we need data, preferably from randomized clinical trials. To be sure, the available evidence may not always be straightforward. Data from trials may be inconclusive, conflicting, or susceptible to all sorts of bias. Therefore, we need to look at the data carefully and ask what conclusions may confidently be drawn from them. However, this is not the sort of deliberation that Daniels and Richardson have in mind.

Taking the example of the cardiac pacemaker again, we now know that their use may give occasion to complex moral dilemmas. Specifically, a cardiac pacemaker may prevent someone from dying, for whom there seems to be little point in continuing to live. In such situations, the question arises whether the pacemaker should be deactivated. To understand the agony that this may cause on the part of the spouse and the children, the apprehension, and the feelings of betrayal and foundering, we need reports from those who have experienced such situations (1). This type of outcome is very unlikely to emerge from con-

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trolled trials. Whether the use of cardiac pacemakers can result in such situations is, again, not dependent on whether we decide this to be the case. Here, too, we need data, but of a different kind and from a different source. Stakeholders may have this sort of knowledge, which it would be unwise to ignore.

FACTS AND VALUES

What the example shows is that HTA is not a matter of collecting the facts about a healthcare technology. It is a matter of collecting facts about a healthcare technology that are considered plausible, relevant, and amenable to inquiry. The former is a function of our understanding of the health problem: what are its major contributory causes, and what sort of interventions are likely to work? The second dimension, relevance, is a function of values: what is the nature of our moral commitments, what do we consider important in terms of how healthcare is being delivered, and in terms of outcomes and their distribution? The last dimension, amenability to inquiry, is a function of methodological and epistemological considerations: what are the sort of things that we can acquire knowledge of, and what sort of methods are likely to provide us with knowledge that we can rely on? Now, importantly, people may hold different views on the nature of a specific health problem, they may differ in their interpretation of our moral commitments, and they may differ in their views of what can be known and what sort of methods are likely to lead to reliable knowledge. Some people may think that such diversity is problematic. Following Hannah Arendt, we rather think it is an asset (2). However, if this is true, the question is how this diversity can be put to good use in the context of HTA. It is this question that is addressed in the papers by Henry Richardson and Norman Daniels.

RICHARDSON: THE VALUE OF HEALTH

Henry Richardson raises the question what it is that we should deliberate about in the context of HTA. If HTA is about finding out in what way and to what extent healthcare technologies help us to preserve and restore health, how, then, should we think about the value of health? Is health an end in itself, or is health something to be pursued because and in so far it allows us to

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pursue other goals in life? Richardson argues that it is the latter. He sees two major tensions in contemporary HTA: (i) a tight focus on costs per quality-adjusted life-year on the one hand and a broadening of its concerns to a wider range of values on the other hand, and (ii) thinking of outcomes as having merely subjective importance as opposed to being of objective significance. Drawing on the work by Amartya Sen (3) and Sridhar Venkatapuram (4), he argues that health should be considered a meta-capability, facilitating engaging in all "beings and doings that people have reason to value." He then proceeds by analyzing the implications of this for the methodology of HTA.

DANIELS: HELPING STAKEHOLDERS TO DELIBERATE ABOUT FAIR DECISIONS UNDER RESOURCE CONSTRAINTS

Norman Daniels sees an important dilemma for contemporary HTA: should it focus on the safety, efficacy, and costeffectiveness of healthcare technologies, remaining an incomplete source of advice and avoiding controversy while risking an important kind of marginalization, or should it enter the controversy with as defensible a set of tools as possible to provide as complete an assessment of a technology as possible? His advice is to choose the latter option. This means that a stand must be taken on ethical issues raised by a technology and its use. Because we lack agreement on principles fine-grained enough to establish what is morally right, he proposes to add a form of procedural justice to HTA. Key elements of a fair deliberative process involve at least four conditions: (i) publicity, (ii) relevance, (iii) revisability, and (iv) enforcement. Together, these elements ensure "accountability for reasonableness." A method that may help to achieve these conditions is the method of wide reflective equilibrium. This method is illustrated using the example of the cochlear implants for deaf children.

TECHNOLOGY ASSESSMENT AS LEARNING

Of interest, there is a common theme in the two contributions that we have invited for the Journal: revisability. Daniels writes: "Fair process also requires opportunities to challenge and revise decisions in light of the kinds of considerations all stakeholders may raise." In a similar vein, Richardson states: "...a distinctive and invaluable human trait is our ability to rethink and refashion our conception of our ends when practical difficulties call for our doing so. Cultural changes and changes in technological possibility constantly call upon us to rethink the ends for the sake of which we value health... To proceed intelligently in doing health technology assessment, it is important to stay open to reframing and refashioning the ends we take to apply to that arena." This truly seems an enormous challenge and opportunity for HTA, which could significantly enhance its relevance to democratic decision making (5).

CONFLICTS OF INTEREST

The authors report no conflicts of interest.

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