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Mapping the integration of social and ethical issues in health technology assessment

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Background: Since its inception, the field of health technology assessment (HTA) has stressed the need for consideration of ethical and social issues. However, few concepts or analytic tools have been developed, and because of the complexity of the endeavor and a lack of integration of work already produced, such concepts remain difficult to apply in HTA.
Objectives: Through a descriptive "map" of concepts, tools, and processes, we summarize the most tangible efforts on the part of HTA producers to address social and ethical issues.
Methods: A literature review and content analysis of HTA reports in the Centre for Reviews and Dissemination database enables a synthesis of the reflections on, initiatives around, and gaps in knowledge related to the integration of social and ethical issues in HTA.
Results: We examine: (i) the aim of integrating ethical and social issues in HTA, (ii) the theoretical approaches used, (iii) the methods and processes applied, and (iv) the implications for HTA producers. We highlight two levels at which social and ethical issues can be considered: throughout the production process of HTA reports and as part of the organizational structure of HTA agencies.
Conclusions: Given the profound societal changes that occur in relation to healthcare technology development, HTA producers have a responsibility to inform and enlighten technology-related public and policy debates. Fulfilling this role, though, requires that socioethical dimensions of technology *and* HTA are made explicit.

Keywords: Health technology assessment, HTA, Ethics, Social issues, Values, Policy making

AIM: WHY SHOULD HEALTH TECHNOLOGY ASSESSMENT INTEGRATE SOCIAL AND ETHICAL ISSUES?

The initial description of the purpose of health technology assessment (HTA), proposed by the U.S. Office of Technology Assessment in the early 1970s, has been adopted internationally and remains almost unchanged. According to Banta and Perry,

> [HTA] enlarges the evaluation process to encompass not only the clinical consequences, but also the economic, ethical, and other social implications of the diffusion and use of a specific procedure or technique on medical practice. . . . [I]ts aim is to provide facts as a basis for not only clinical decision making, but also for policy making in health care as a societal endeavor (3).

Yet if there is a wide consensus about such an inclusive mission statement, in practice there has been remarkably

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limited commitment to the analysis of social and ethical issues. A 2000 study by Lehoux and Blume of the 1999 ISTAHC CD-ROM database of abstracts presented at the *Annual Meetings* (1994–98) and all abstracts of papers published in the *International Journal* (1985–99) found that "from a total of 2,906 records, 30 records contained 'social' in their title (1 percent), 5 contained 'political' (.2 percent), and 19 'ethical' (.7 percent)." (25). More recently, a content analysis of all official HTA documents ($n = 187$) published by six Canadian agencies between 1995 and 2001 found that, on average, only 17 percent of these reports addressed ethical and/or social issues (mean per agency ranged from 8 percent to 40 percent) (26). In 2003, the German HTA group DIMDI arrived at similar conclusions in their analysis of "short assessments on medical technologies" published worldwide ($n = 282$): twenty-five reports (9 percent) described ethical issues, whereas thirty-two (11 percent) referred to such issues without defining them explicitly (8).

For ten Have, the gap that currently exists between ethics and technology assessment is "remarkable, because systematic assessment of technologies has originated from normative worries over the uncontrolled introduction of new technologies into health-care practice" (38). He suggests various reasons (of which we will examine four) why this is the case, arguments that have been further developed in a recent collection of papers in *Poiesis and Praxis* (2004, issue 2) (9,12,13,33,35,37) that focused on the need to integrate ethical and social issues in HTA. (i) Technology is often conceptualized by HTA producers as being neutral and value-free. From this perspective, "values are not intrinsically connected with technology itself, but they are related to its application" (38). This view is challenged by other academics and HTA producers who stress the fact that society and technology are necessarily co-constitutive and that values are found in both (24;33;37;39). (ii) Perhaps stimulated by demand from decision makers for "objective" or quantifiable results, the "core" questions perceived as relevant are often reduced to: Does this technology work, and at what cost? Yet as demonstrated by the cochlear implant case, sociocultural and ethical issues are intimately intertwined with technological change (37). Reducing HTA to cost-effectiveness evaluations is an insufficient basis for the development of sound policy and practice (9). (iii) There is considerable complexity involved in integrating or adapting theories and analytical tools from fields such as bioethics or science and technology studies, which share few methodological affinities with HTA. Indeed, whereas philosophers may focus on normative recommendations derived from cases, general principles, or moral theory, and science and technology scholars may seek to describe the socially embedded and constructed nature of technologies, HTA producers rely on generalizable empirical evidence to support specific practical and policy recommendations. (iv) The training of HTA producers, and the resources available for them to conduct social and ethical analyses, are also cause for concern. Interviews by Lehoux et al. with chief executive officers and HTA producers of six Canadian agencies ($n = 40$) demonstrate that "access to staff specialized in ethical and legal issues when resources are limited and the demand great was problematic" (26). Even when HTA agencies are genuinely interested in integrating socioethical reflection, their ability to do so in a coordinated and coherent manner is undermined by a lack in human resources.

Although the answer to "why" HTA producers should pay attention to social and ethical issues appears almost unequivocal; it is the "how" question that has proven difficult, in part we suggest, because HTA lacks a coherent theoretical framework. The crux of the problem is HTA's conceptualization of the relationship between values, society, and technology. HTA needs to move beyond the determinism of technology generated "social impacts" that can be analytically isolated, to a "social shaping of technology" perspective that recognizes that technologies and the actors that develop and implement them are inherently value-laden (39) (see Figure 1).

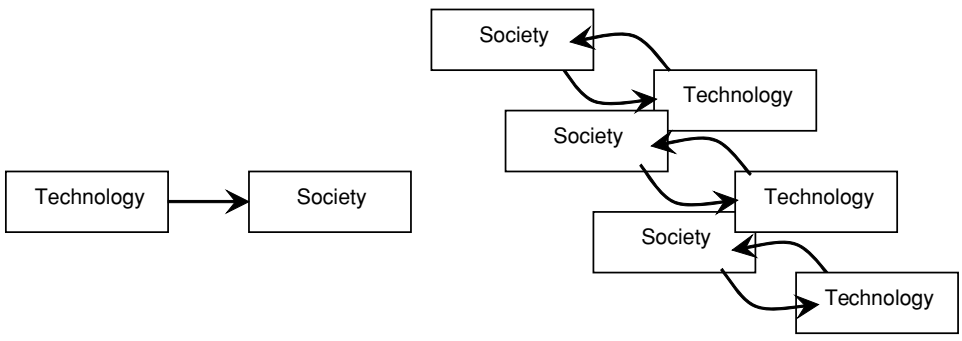

Figure 1. Two views about the relationship between society and technology.

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Knowing about the absence or presence of a disease and its evolution (e.g., screening and diagnostic tests, imaging devices)
Surveillance of health behaviors and states (e.g., monitoring systems)
Intervening in the body or in pathological processes while coping with risks and side effects (e.g., implants, surgery, therapeutic devices, drugs)
Extension of duration of life in the context of possible diminished quality of life (e.g., palliative technologies)
Risk reduction and protection (e.g., health promotion and prevention, occupational health technologies)
Autonomy and mobility (e.g., technical aids, home care)
Access and use of administrative and clinical information; efficiency, and quality assurance (e.g., information technology)

Box 1. Goals and values that health technology helps reach. Source: Lehoux (24).

THEORETICAL APPROACHES: WHAT SOCIAL AND ETHICAL ISSUES SHOULD BE CONSIDERED?

Conceptualizing technology as a "dynamic agent" enables HTA producers "to reflect on particular aspects of existing arrangements (what is envisioned through the promise of the technology itself)" (33). Technology is indeed purposefully designed to produce certain actions or provide particular information that is directly or indirectly valued by providers, patients, or healthcare managers (21;24). Box 1 indicates the "valuable" outputs that HTA producers frequently assess and often treat as value-free.

This situation is not entirely surprising. Defining such values, and by extension the underlying social and ethical dimensions, remains difficult. According to Hasman, even for philosophers "the exact relationship between preferences, principles, and values is the object of intensive discussion" (15). The tendency is for economists to examine preferences, for political scientists to consider political incentives and public opinion, and for philosophers to explore principles and values. Nevertheless, a diversity of researchers, practitioners, and policy makers commonly refer to values in their analyses.

The appeal to values is pervasive in health policy reforms. As Giacomini et al. note, "most policy analysts would agree that values influence policy goals, decisions, and conduct," and ideologies, interests, principles, and goals "figure prominently in explanatory models of the health policy making process" (10). However, in their examination of thirty-six major Canadian policy documents published between 1990 and 1999, these authors found little shared understanding of what constituted "values," nor any explicit ordering by level of importance (10). Giacomini et al. organized these values into five categories: (i) goodness (e.g., quality, effectiveness), (ii) physical entities (e.g., health system, programs), (iii) principles (e.g., efficiency, equity), (iv) specific goals (e.g., prevention, access), and (v) attitudes and feelings (e.g., compassion, respect). Lacking a coherent framework, such a diversity of values complicates and potentially limits HTA producers' ability to work effectively with experts in disciplines concerned with the analysis of social and ethical issues.

A significant point of contention, however, is the *very goal* of ethical analysis. Cooperation between bioethicists and social scientists "is traditionally based on the assumption that they are representatives of two *essentially* distinct scientific disciplines, with bioethicists representing the prescriptive sciences, and social scientists the descriptive sciences" (29). A similar divide is found in HTA, with some inclined to formulate prescriptive recommendations, whereas others prefer to limit judgments to establishing the strength of evidence for or against a particular technology.

At the heart of this divide is what philosophers call the "naturalistic fallacy"—simply because something "is" the case does not mean that it "ought" to be so. A consequence of this injunction is a historical reluctance on the part of philosophers to engage in empirical research, thus in some ways limiting their use or relevance for HTA (34). As an applied "off-shoot" of philosophy, however, bioethics is more flexible. A fundamentally interdisciplinary field of inquiry, bioethics engages scholars from disciplines such as philosophy, law, sociology, religious studies, economics, the health sciences. These scholars draw on diverse theoretical approaches and often use both qualitative and quantitative methods to conduct evidence-based analyses (6;14;17). Bioethics theories and methods are not necessarily antagonistic to HTA.

For Molewijk and colleagues (29), there are three different ways of using evidence in bioethics: (i) applying moral theory to empirical results to evaluate an action or policy (e.g., knowing the consequences to judge the appropriateness of someone's behavior); (ii) assessing the empirical validity of assumptions implicit in a moral theory or principle (e.g., examining the cognitive requirements behind informed consent); and (iii) generating insights into social practices that help improve moral theory (e.g., reappraising the notion of kinship in the context of new reproductive technologies).

For example, knowing through empirical ethics research that patient autonomy may be *more strongly* influenced by the nature of the information they receive with a decision aide than by physicians' or patients' conscious and rational argumentation, can help HTA producers better assess the efficacy and objectivity of decision-support tools. Such ethical reflection draws attention to the values that underpin the development *and* the evaluation of technology. In this regard, we draw on Heitman's list of normative assumptions underlying health technology (18;19), Hasman's insights (15), and a checklist developed by Hofmann (16) for raising HTA producers' awareness of moral issues to situate the most

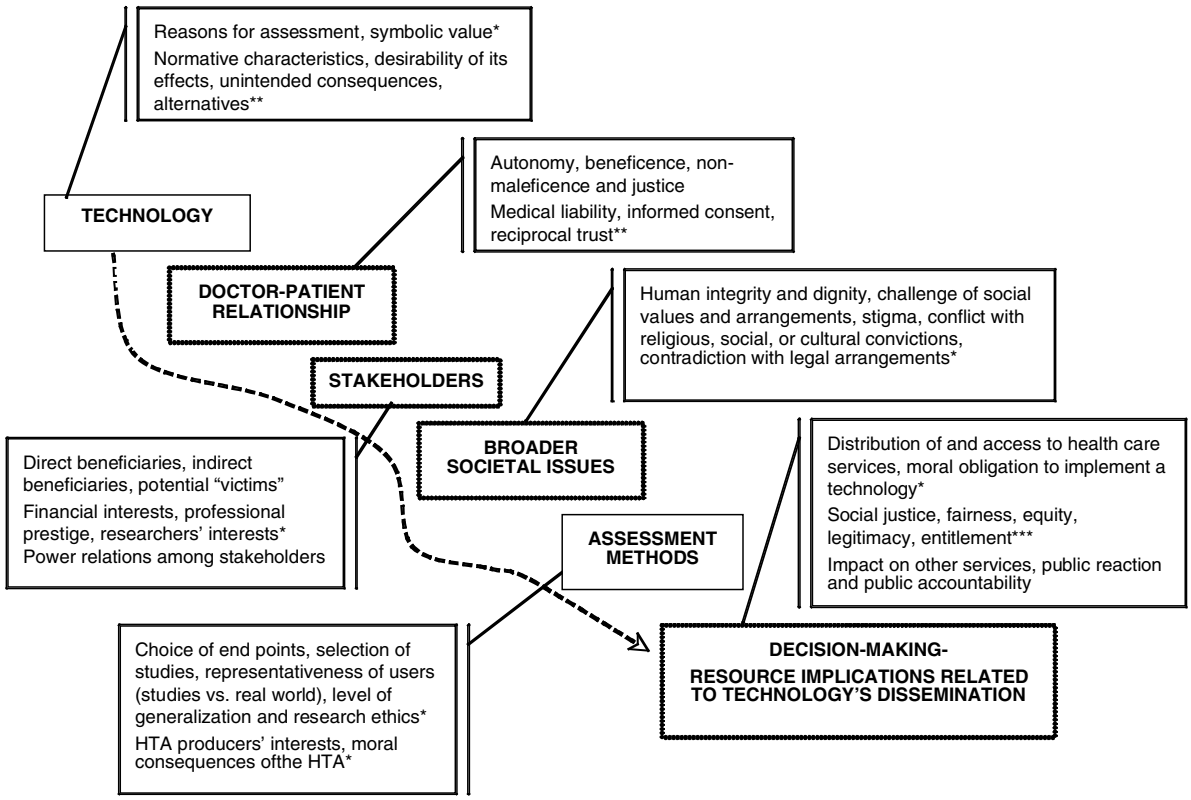

Figure 2. Social and ethical issues associated to key components of an health technology assessment (HTA). *Adapted from Hofmann (16); **adapted from Heitman (18); ***adapted from Hasman (15).

common value-laden components found in the HTA process (Figure 2).

METHODS AND PROCESSES: HOW SHOULD SOCIAL AND ETHICAL ISSUES BE CONSIDERED?

Given the diversity of theoretical approaches available for HTA producers to analyze values, ethics, and social dimensions of new technologies, defining the strengths, weaknesses, and feasibility of the various methods is a challenge. Our goal here is to highlight and clarify the rationales behind these methods, and to identify the types of issues they may capture or leave unaddressed.

In the literature, one finds three broad methodological approaches to the introduction of ethical and social issues into HTA reports: (i) seeking expert advice from bioethicists and social scientists, (ii) conducting qualitative and/or quantitative primary research, and (iii) performing secondary research that includes published literature on social and ethical issues (see Figure 3). At the HTA agency level, consultative mechanisms have also been suggested as a means of (i) informing the agency's research priorities, and (ii) helping address the perceptions and expectations of lay members or representatives of stakeholder groups (patient associations, religious groups, and so on).

Means for Integrating Ethical and Social Issues into HTA Reports

Bioethics expert advice may be sought and integrated into an HTA report, or a specific group of experts may be mandated to produce a free-standing report that "accompanies" a traditional HTA report. In both scenarios, ethics experts act as consultants. As suggested by van der Wilt (37), ethicists may apply various models of ethical reflection, some of which explicitly support a step-by-step approach to normative assessment. However, not all models will be equally appropriate in all circumstances. There has thus been some interest in the idea that HTA producers should become more familiar with ethical analyses and qualitative methods to conduct primary research to address social and ethical issues (5;19;25;30). This task would be facilitated greatly if social scientists and ethicists were recruited into agencies, and if HTA producers were to work collaboratively and more frequently with these specialists (16). Some issues or principles may be generalizable, but because context matters, analyses performed in one country or region may not be applicable in another. HTA agencies would thus benefit from using local social

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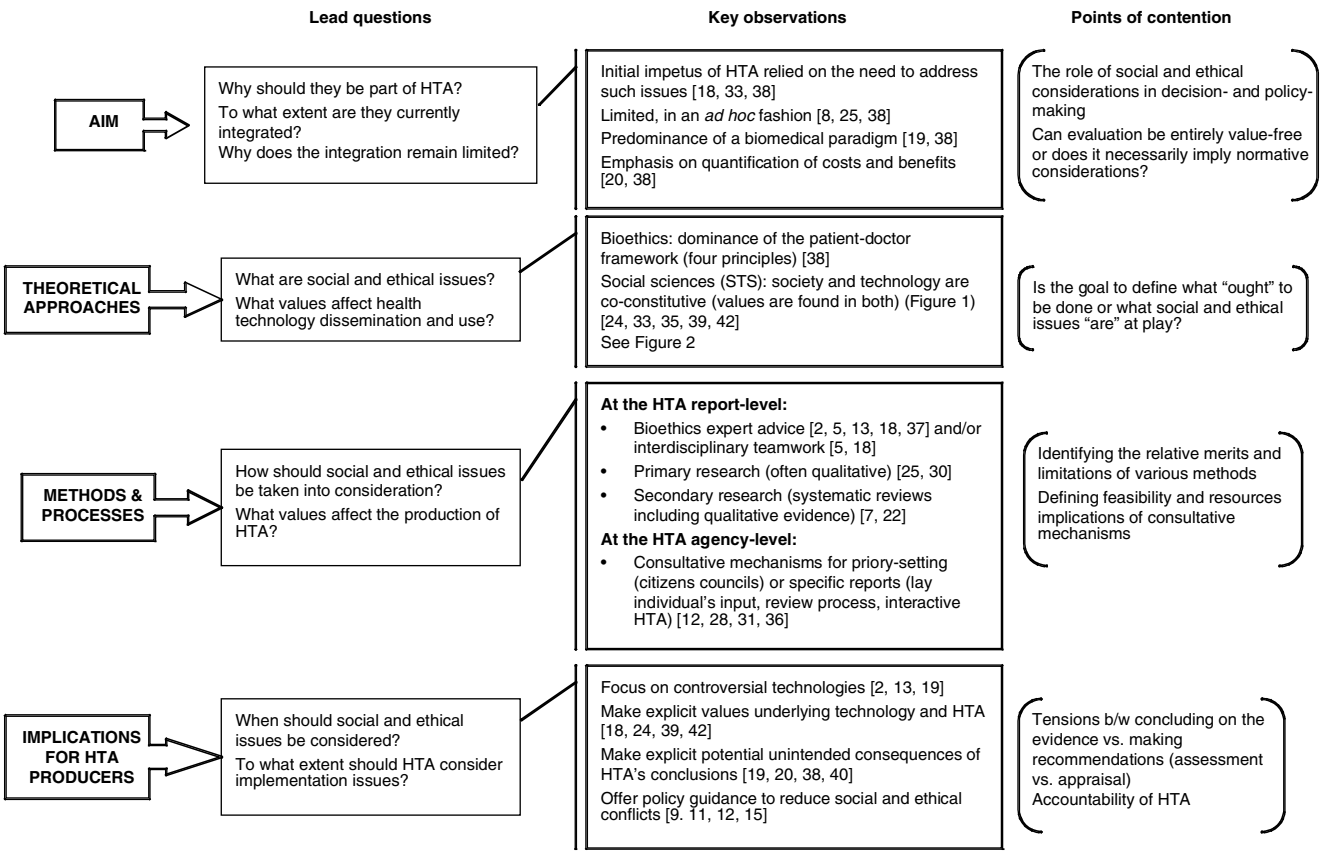

Figure 3. A "map" of the health technology assessment (HTA) community's theoretical and empirical efforts toward the integration of social and ethical issues in HTA.

scientists and ethicists who would also become familiar with HTA aims, methods, and constraints (16).

Finally, various initiatives have recently confirmed the need to broaden the scope of systematic reviews to include evidence that goes beyond quantifiable data, a suggestion that would fit well with moves to integrate socioethical analyses (7). A useful example is a report by the Alberta Heritage Foundation for Medical Research HTA unit on the social, ethical, and legal dimensions of genetic cancer risk assessment technologies (22). In the United Kingdom, the National Institute for Clinical Excellence (NICE) has also issued guidelines on how social value judgments should be incorporated into the processes used to develop its guidance (32).

Consultative Mechanisms

A variety of consultative mechanisms have been deployed in recent years to elicit or respond to public perspectives related to new health technologies. The purposes of these mechanisms vary, and only some are conducive to the integration of social and ethical issues (4;27). Such mechanisms can either inform an HTA agency's activities or transform the production of HTA reports. An example of the former is a UK Citizen's Council set up in 2002 by NICE. Its mandate is to provide information about the general public's views and the "motivations and values that underlie these opinions," to help NICE make decisions about how the National Health Service should administer treatments and therapies (31).

An example of a consultative mechanism that both informs an agency's activities and also underlies a specific assessment process is the Swiss Technology Assessment Agency. Citizens' panels, called Publiforums, have been organized to explore and debate broader social and ethical issues arising from new technologies (www.ta-swiss.ch). Inspired by other European experiences with consensus conferences, these panels promote a participatory method where public representatives are able to both obtain information and experts' views and also call into question scientific evidence. HTA is here situated as a part of wider democratic processes that explicitly engages the public in debating the normative considerations related to new technologies (1;12;8). More than simply clarifying "public perspectives" for policy makers, public participants are active members in just decision-making processes that aim to develop socially acceptable policy recommendations (4;41).

The existence (and popularity) of such participatory mechanisms may confirm the perception on the part of some governments and HTA agencies that the public should be

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engaged in HTA; but the diversity of these mechanisms and their varying effectiveness also highlight the complexity involved in public deliberative processes (1). For example, the terminology used is problematic. The "public" is supposed to represent diverse civil society, whereas "patients," "advocacy groups," "consumers," or "users" represent specific stakeholder groups. Furthermore, as Royle and Oliver (36) found in their research on the U.K. HTA program, it is difficult to identify appropriate participants, and even when enrolled, participants often require substantial support to be able to actively engage with the questions and technologies under consideration.

HTA agencies may thus be inclined to approach already organized and informed groups such as "volunteer-led organizations, major charities, campaigning groups and self-help groups" (36). But these *organized* groups are not strictly speaking "ordinary" citizens, because they come to the table with pre-existing agendas. That these individuals also need to be supported to become proficient and useful in HTA thus begs the question of the extent to which members of "the general public" can effectively express their concerns. In line with other evaluations of the role of deliberative and consultative mechanisms in public policy development (and deliberative democracy more generally), HTA agencies must reflect on if, how, and in what manner they will engage with public perspectives (1).

WHEN SHOULD SOCIAL AND ETHICAL ISSUES BE CONSIDERED AND HOW WILL THIS IMPACT HTA PRODUCTION?

Giacomini et al. argue that "new medical technologies" purposes and effects must be judged for their moral, social, or political value before technology assessment information can inform decisions in a meaningful way" (11). But does this mean that these issues should be analyzed for *all* technologies?

Health technologies that have been subject to social or ethical analysis in the past—such as in vitro fertilization, preimplantation genetic diagnosis, or cochlear implants—have been morally controversial, culturally and socially challenging, expensive, and subject to prioritization (16). Yet social and ethical issues do not occur uniformly across all technologies, or in all circumstances, or are necessarily in need of response from HTA producers (2;13). Hoffman, who identified thirty-three questions to aid HTA producers in socioethical analysis, also acknowledges that it may be difficult in practice to anticipate whether a new technology might lead to social controversy (16).

A prudent approach, then, would be to acknowledge that individual, clinical, managerial, economic, commercial, political, and social perspectives are concurrently active in the development of new medical technologies and the associated values and expectations. Instead of trying to predetermine and respond in advance to potential socioethical issues, HTA agencies would be better off ensuring that their researchers are sensitive to and can identify issues that may turn out to be ethically and socially debatable. A decision can then be made about whether these issues should be analyzed more thoroughly, for example, by hiring a specialist or conducting a comprehensive literature review. This decision will depend largely on an HTA agency's mission, because "some only commission assessments, others perform the assessments themselves. Some only provide the background information for the decisions; others develop recommendations and guidelines" (16).

Building in-house capacity to address ethical and social issues through staff training in primary research or by hiring social scientists and ethicists may make sense for large HTA agencies, but for smaller agencies, it might be sufficient to contract out their socioethical analyses to academic experts. More generally, there is room for collaboration—and not just delegation—such that ethicists and social scientists conduct research with and alongside HTA producers as part of a broader interdisciplinary research culture. This would then allow for greater reflexivity and shared learning in the conduct of HTA (5) and would enlarge the knowledge base upon which to draw for identifying what issues to address and when, and for comparing methods and processes.

POLICY IMPLICATIONS AND CONCLUSION

We have sought to take stock of the literature and initiatives developed by the HTA community to define why and how socioethical issues should be integrated into HTA. Although we believe the "why" question has been largely resolved, several important points of contention arise for each of the four themes we covered (as indicated in Figure 3).

As discussed earlier with respect to the "how" question, further reflection and experimentation with various methods will be required before drawing conclusions about their strengths and weaknesses. Moreover, multiple approaches may be appropriate, depending on the particular circumstance, issue, or technology in question (18). Nevertheless, although the "how" question is one that has been the cause of legitimate debate and even some discomfort in the HTA community, it is the much less debated "what" question that represents the biggest stumbling block.

With respect to the "what" question, there are significant variations in how the disciplines concerned by social and ethical issues define and develop their concepts and theories. As suggested in Figure 2, the focus may be on the normativity of technology, the doctor–patient relationship, the meaning of life, disease, handicap or death, the individuals or groups positively or negatively affected by a given technology, the value-laden nature of decision and policy making, or the unintended consequences and long-term social changes that follow from actions, decisions, or policies.

In light of this diversity, HTA producers cannot simply apply particular methods without first defining an appropriate conceptual framework to identify the relevant issues, organize the analytical observations, and reach a normative conclusion (or not).

From our perspective, a very promising approach to bridging HTA's pragmatic concerns with a normative sensitivity can be drawn from the science and technology studies literature (24;42). Further research on health technology should seek to make explicit the social, ethical, and political values embedded in a given innovation (and its context) and reinforced through its use. Such research might, for instance, examine the extent to which an innovation exacerbates dependence on medical expertise, supports patient autonomy, or fosters social inequalities. It could also explore how the use of certain technologies reinforces or undermines institutional values (e.g., efficiency, accountability, responsiveness).

The idea of making values explicit should be understood as seeking first and foremost to foster open deliberation about the desirability of current practices and of new healthcare delivery models. It should not entail defining and choosing a single utopian moral perspective capable of answering all the ethical dilemmas likely to arise in society. Although it remains unclear how far HTA producers should go in saying what is right or wrong, they clearly have an important responsibility to help surface the diversity of socioethical issues that may affect individuals and society, particularly with regard to equity, social justice, transparency, and impact of technologies on marginalized groups.

Because moral issues and ethical dilemmas "tend to work well in the public debate" (16) and may more easily attract media attention when also compared with, or supported by, "hard evidence" in the form of numbers and statistics, further research could explore the interface between public expectations, values, and HTA-based decision making. Rationing access to technologies that have not been clearly proven harmful or ineffective are common triggers for strong public reaction (20). The uptake of HTA's conclusions in this case largely depends upon the way policy makers position their policies around public expectations (23). Thus there is need for a much better understanding of how values support and/or contradict HTA's conclusions (40).

As the primary source of policy guidance in most jurisdictions, we argue that HTA agencies have a professional responsibility to provide policy makers with comprehensive assessments that highlight and integrate discussions of the associated social and ethical challenges. When cast at the societal level, priority-setting should emphasize "social justice, fairness, equity, legitimacy and entitlement" (15). These ethical principles stipulate that decisions regarding the allocation of scarce resources must be based on fair, transparent, and nondiscriminatory criteria that entitle individuals with a particular health need to receive appropriate healthcare services. HTA producers are acutely aware of these principles, and although they may not have decision-making authority, they can nonetheless contribute to ensuring that decisions are made in a manner that is socially, ethically, and publicly justifiable.

The results of recent HTA community efforts to integrate social and ethical issues are substantial. Further reflection and experimentation, however, are still required before methods and processes can be standardized. Such systematic exploration would be enhanced by recognizing the complexity of social and ethical issues and by actively seeking pragmatic ways forward. Given the profound societal changes associated with the integration of health technologies, HTA producers have a particular responsibility to enlighten and inform technology-related policy and public debate. Fulfilling this role, though, requires making social and ethical dimensions explicit in HTA processes and products.

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