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research

The moral economy of health technology assessment: an empirical qualitative study

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Using data from interviews with Health Technology Assessment (HTA) professionals in Canada, this paper shows their views of the appropriate role of, and evidence required for, HTA are associated with values and norms. Recognizing HTA as a moral economy helps to explain when and why HTA professionals' views of what HTA should and can do are mutable, and may specifically help to explain why there is resistance among some HTA professionals to the inclusion of ethical issues and patients or the public in technology assessment. The moral economy framework furthermore sheds light on the nature of objectivity in contemporary HTA.

key words healthcare technology policy • evidence in healthcare • moral economy • values and ethics

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> … over time you create, if you keep doing this, you begin to create a culture of evidence. (HTA28)

Introduction

Health technology assessment (HTA) has become a central component of efforts to increase the use of clinical and scientific evidence in medicine and healthcare. When it emerged in the 1970s, the aims of HTA were broad, including the assessment of social, legal, ethical and political consequences of technologies, but as a practice it has come to focus almost exclusively on issues of effectiveness, safety and costs (Lehoux and Blume, 2000). Likely this is due in no small part to the way HTA dovetailed with the movement for evidence-based medicine (EBM), which positions randomised

controlled trials (RCTs) and the systematic review or meta-analyses of such trials at the top of a hierarchy of evidence. Dominant methods in health technology assessment are predicated upon the existence of research that takes the form of trials, or at least provides measures and results that can be compared and aggregated, usually using statistical techniques.

EBM and HTA have been regarded as ways to reduce medical fallibility, practice variations, and cost growth, but perhaps because such issues persist, there have been ongoing calls for HTA to broaden its scope and thereby its impact. These include renewed calls for HTA to assess ethical implications of technologies, which are often still included in definitions of HTA but not usually in assessments themselves (DeJean et al, 2009; Hofmann, 2008; Lehoux and Williams-Jones 2007), and related calls for including the views of the public, consumers, patients, or citizens in assessments (in Canada, Abelson et al, 2007; Bridges and Jones, 2007; Pivik et al, 2004). Frameworks have been developed to incorporate ethics into HTA (for example, Hofmann, 2005) and there has been informed speculation about why HTA does not often include analysis of ethical issues (ten Have, 2004). Other interview-based studies with HTA producers have examined the experience of HTA producers, how they view their roles, and their successes and challenges (Lavis et al, 2008; Lehoux et al, 2005; 2008; McDaid, 2003). One study examined why HTA agencies struggle with the idea of public involvement (Gauvin et al, 2010), but otherwise existing interview studies predate or do not focus on particular calls to expand or reform HTA. The analysis here is also distinct in so far as we situate the interview data in a framework that considers HTA not as an instrumentally-oriented set of practices and organisations, but as a culture that brings together ways of knowing, practices and techniques, actions and behaviours, and emotions and values.

In particular, many social scientists studying science and medicine now view ways of knowing as socially-situated and bound up with values and normative assumptions (in relation to HTA, see Lehoux et al, 2009). According to Daston (1995), specific constellations of emotions and values are 'constitutive of' science itself – ways of knowing and generating facts. Calling these constellations 'moral economies', Daston analysed how specific historical forms of quantification, empiricism and objectivity are products of distinct norms and values. Mechanical objectivity and aperspectival objectivity were, for example, variants of objectivity both rooted in the nineteenth century but driven by different values. The former 'strives to eliminate all forms of human intervention in the observation of nature', for instance through the use of machines, and is rooted in a notion of data as given by grace, with which fallen humans must be prevented from meddling. Aperspectival objectivity, on the other hand, attempts to eliminate the idiosyncracies of particular observers through the use of techniques of standardisation, based upon an image of the inevitability of individual error and the consequent necessity of scientific cooperation and collaboration (Daston, 1995, 19, 21–2). The interviews reported here were undertaken as part of a programme of research examining a range of professionals' roles and responsibilities in the adoption of new surgical devices (Ross et al, 2010), which provided the opportunity to explore the values and ways of knowing among HTA professionals, and for empirically-grounded speculation about how values may be constitutive of HTA and the nature of objectivity in contemporary HTA.

Background and methods

HTA is tasked with acting as a 'bridge between science and policy' (Gabbay and Walley, 2006, 65), providing both usable and credible assessments (Lehoux et al, 2008), and has been applied to diverse healthcare-related treatments and interventions, including drugs, devices, diagnostic and screening tests, and imaging technologies. In Canada, HTA activities are carried out at multiple levels, for example the Canadian Agency for Drugs and Technologies in Health (CADTH), provincial bodies such as the Ontario Health Technology Advisory Committee (OHTAC), university-based HTA providers, and hospital-based HTA committees (see Battista et al, 2009). We interviewed fifteen HTA professionals as part of a larger study of ethical and economic considerations in the development and adoption of devices in pelvic floor surgery (Ross et al, 2010). In the larger study, a range of healthcare system stakeholders (N=54) (administrators, clinicians, HTA producers, regulators, and device manufacturers) were interviewed about when and how they decide which devices to produce, adopt, fund, or approve (as relevant). We also asked respondents about the kinds of evidence they used to make these decisions, and found that respondents' discussions of ethical and economic considerations were intertwined with their ideas of good evidence and the nature of evidence available to them. HTA professionals were asked about the criteria and evidence they use to assess devices, their processes for technology assessment, and their role and that of their agency in getting devices and interventions into the healthcare. We found that respondents regularly referred to their values and responsibilities to explain and legitimise their practices and decisions, and that various stakeholder groups' ways of incorporating ethics, economics, and evidence into their decisions and practice could be seen as forming distinct worldviews. This paper is an analysis of these values and worldviews among the HTA professionals interviewed.

Data collection

For the larger study, we were aware that institutional and organisational environments particular to provinces would affect when and how medical devices are adopted. In order to gain a better understanding of those environments, and given practical constraints, sampling was limited to two Canadian provinces, allowing for the inclusion of a wider range of stakeholders in each. The HTA professionals were purposively sampled to capture perspectives from a spectrum of HTA entities. The sample is large enough, given the in-depth nature of the interviews, to capture meaningful similarities and differences within this group, and to allow for empirically-driven if tentative conclusions, but not representative. The interviews reached saturation on a number of themes, particularly around common frustrations and obstacles HTA professionals face in generating high-quality assessments and ensuring their impact on policy and practice, which were also moments when respondents frequently referred to the worth and responsibility of HTA.

Potential participants and their contact details were identified from publicly available sources, such as websites. Each was mailed a copy of the information and consent form and an invitation to join the study and provided with up to two reminders. Each participant provided written consent to join the study. At the time of the interviews, eleven respondents were involved in directly producing HTAs and four were involved in applying HTA to policy or practice. In terms of primary affiliations,

four respondents were working at the hospital level, four were working in provincial health system units or government agencies, five had university positions in HTA units, and two worked for hybrid HTA agencies funded from a mix of private and public sources. Respondents often held multiple affiliations or roles within HTA and health care. Ten respondents were men, five were women. The research was approved by the University of Calgary Conjoint Health Research Ethics Board. The interviews were in-depth, semi-structured (see appendix for interview guide), undertaken face-to-face in the office of the interviewee by one or both of two interviewers (SR, CT), and averaged 54 minutes in duration. The interviews were audio recorded.

Analysis and coding

All interviews were transcribed and loaded into qualitative data analysis software (NVivo 10). TP was the primary coder for the HTA interviews, using inductive techniques. The codes were often homologous to those the research team (AD, SR, CT) previously developed using inductive techniques for other stakeholder groups, but some were specific to the HTA group. Multiple coding was employed at several points for the HTA interviews (as with other interviews), to check for consistency and validity in our use and understanding of the codes, refine the coding scheme, and generate initial interpretations (Barbour, 2001). When all interviews were coded, TP used thematic analysis to construct three-column analytic memos. The first column contained specific codes, the second column contained TP's initial impressions of material included in each code as a mechanism of reflexivity and basis for collaborative discussion, and the third column identified common themes or issues within each code. A second memo was created to represent second-level themes occurring across all codes and respondents, including verbatim passages that illustrated the second-level themes. All memos were discussed among the paper co-authors, after which TP prepared a preliminary synthesis of a major second-level theme: how notions of values and responsibilities emerged in the interviews. AD subsequently refined the synthesis and put the evidence into a narrative structure by working back from the analytic memos to the full interviews to check for validity and by working out to the research literature to identify the particular contribution of the findings. The concept of moral economy as described by Daston (1995) was introduced into the analysis at this later stage because it illuminated an element of the respondents' discussions of ethics and evidence that had not been analysed in previous research. Multiple drafts of the synthesis and nascent paper were circulated and discussed among co-authors. The team approach to all elements of data collection and analysis enables increased rigour of the analysis and arguments (Barry et al, 1999).

Findings

Independence and good evidence as conditions of HTA

The HTA respondents saw their work as part of the effort to produce and assemble good evidence as understood in the EBM paradigm. Health technology assessments typically consist of reviews or analyses of existing epidemiological, scientific or clinical research, and research is preferred in the form of RCTs. One university-based HTA respondent explained:

> A lot of health technology assessments we do… they're a high level systematic review with a meta-analysis if there are data. If there's, for example, multiple RCTs we'll do a meta-analysis and we'll do an economic evaluation. But most of the data are from existing, either published studies, or clinical trials that have been done by in-house investigators. (HTA30)

Respondents recognised that the best evidence is not always available:

> Like some surgical stuff, we just did something on a rotator cuff, I don't think there was one randomised trial, it was a bunch of case series that was synthesised.Then you do something in cardiology and there were these mega randomised trials conducted to the highest standards. So this would be the range of quality of evidence we find. (HTA25)

> We would include cohort studies, we, I mean we do not want case studies, but beyond that we get the best we can and you report it, that this is the best there is. (HTA35)

Aggregate, population-level data was preferred, with studies using control groups and randomisation preferred over cohort studies, and particularistic data such as case studies avoided if possible.

Respondents also argued that the condition of assembling and analysing the best possible evidence was that HTA be autonomous from those perceived to have a stake in the assessments: pharmaceutical companies or technology producers ('industry'), policy makers, healthcare providers, and patients. Makers of drugs and devices were treated with special vigilance:

> Often industry will have information during the product development phase that might not otherwise be found in the peer review literature. They're usually keen to talk to us; I am not usually keen to talk to them… I want the facts and nothing but the facts. If they have got the facts, I will probably consult with them. If they don't have the facts, I try not to meet with them at all… I think we have to realise they have something to sell and therefore their view may not always be entirely objective… I need to keep a firewall really very clearly between us if for no other reason the concern about influence on the actual scientific work… I would rather not have to manage the relationship and keep it as unbiased as possible by not having that relationship unless it's required. (HTA23)

HTA39 also expressed concerns about device-makers' willingness to financially underwrite technology assessment:

> … so far we have been very careful because we have had a lot of industry say,"we will give you money to do the analysis", but of course it is perfectly transparent what they are trying to do is saying, "it's effective, here's the support we will help you do it". So we say,"don't want it, can't touch that". (HTA39)

HTA28, an academic involved in HTA and in generating evidence through research, recalled a 'painful learning experience' of involvement in an industry-funded clinical trial, in which industry 'insisted on having access to the randomisation sequence' and there were 'various sorts of other things they just wanted to control', ultimately leading to the research group's decision to pull out of the project altogether. In these accounts, industry is seen as biased and not objective, whereas HTA is a process of gathering and assessing the 'facts and nothing but the facts' and carrying out the 'actual scientific work'.

Similar views were held about the involvement of patients or patient groups in the HTA process, for instance through the organisation of citizens' juries or panels. One respondent spoke positively of an experience with a citizens' panel, saying 'public consultation brought a unique component' to the assessment. Others saw healthcare consumers as probably uninformed or irrational. HTA27, based at a regional health authority, discussed the early days of drug-eluting stents, in which 'the evidence wasn't there' to determine when to choose drug-eluting over standard stents, saying 'consumers' in such situations are apt to want the technology with more 'bells and whistles'. HTA43, working in an HTA organisation, said there is a pain condition for which evidence shows patients should undertake physiotherapy prior to referral for an MRI or CT scan, but patients are refusing to go to physiotherapy until they have imaging test results, thereby 'actually harming themselves' because they 'do not understand'. HTA26 also discussed how 'things just sort of gather momentum', and patient groups might push for a particular technology by using the idea of 'the imperative of use: so, "'if it's been researched and it's there, it ought to be made available to us"'. HTA26 also said the incorporation of 'citizen juries' into HTA could be a process of 'trying to legitimise the assessments of technologies', and would fail to capture 'deeper principles that people may be holding that they can't even explain, or explicate often'. HTA25 commented from a 'cynical side', that involving patients could be seen as 'a kind of political shtick, I don't see meaningful things driving this stuff'. One respondent put the matter in terms of the 'world view' of EBM and its definition of evidence:

> There are certain intellectual tools, concepts, methods that are associated with that whole world view [of EBM]… how you look at a problem. So for example patients' preferences are not so much a part of the review that says, does it work? Is it safe, is it effective? And a lot of discussion, effort, and thought go into those questions. Where are some narratives of a patient's experience? Well that's very nice that Suzie feels this way, but I mean it's not evidence. (HTA28)

The position that HTA should be autonomous from policy makers or the policy-making process was also the subject of some agreement among these respondents. HTA24 worked for a provincial health authority but said the authority wanted to be sure the HTA was conducted independently from the policy process so that policy concerns did not 'colour the HTA that you do'. Or, as HTA23, a university-based HTA provider said,

> We don't make recommendations… we do the assessments, they [provincial government] actually don't like recommendations. They like us to tell them what the facts are in terms of safety, efficacy and so on. (HTA23)

HTA55 said his hospital HTA group does make recommendations, but does not make decisions:

> So our projects are designed to identify and allow for evidence-based decision making, but we are not a policy-setting group; we make recommendations based on the information we gather, take those recommendations to a policy-setting / decision-making group – and what that allows us to do is to become completely independent of the actual decision or political landscape… someone else actually makes the decision, which we think is a nice way to try and separate those decision processes. It can be much more transparent. (HTA55)

HTA29 similarly differentiated between HTA and policy, describing how their agency's finished health technology assessments go to 'tables' of stakeholders, who use the HTA as one part of developing recommendations for government.

> We are saying to the tables here's the evidence… You draw your own conclusions from the evidence; we've drawn these recommendations based on the evidentiary platform. You have the evidentiary platform, you have the recommendation, what would you like to do with it? This is a very philosophical approach… (HTA29)

Later, HTA29 emphasised,

> what goes forward as a recommendation to the ministry is not the raw evidence but it is evidence that has now been filtered through the lens of the stakeholder table.

To a significant degree, then, these respondents presented similar views about the best ways to know about new technologies – the kinds of evidence and data that are considered an adequate basis for decisions. They also often saw independence as a condition of being able to gather and evaluate such evidence, thinking about independence as a kind of objectivity, while other stakeholders were construed as being unable to adopt an objective, unbiased approach. The view presented in these moments is that health technology assessments reveal what the facts are, they provide information and raw evidence, they are the 'actual scientific work', they define the 'evidentiary platform' which policy makers can 'filter' or use as the basis for decisions. These descriptions are perhaps not surprising, however the moral tenor of such descriptions is not often discussed and is necessary to understand the finding that these descriptions – the meaning of the terms or the practices entailed by them – appeared to be sometimes mutable.

Independence and good evidence as values

The respondents' definition of good evidence and good HTA – scientific, autonomous, based upon facts, unbiased – were often given a moral valence. When HTA55 said separation between the production of evidence and policy making makes the decision process 'much more transparent', the role of HTA is cast in a moral light, as something serving a shared value of transparency. HTA22 reinforced this when describing the implementation of a standard process for assessing health technologies in a hospital:

> Physicians love the idea of having a systematic, consistent, fair process, because they have seen, of course, many times in the past how, you know, physician number one, John, could bring whatever he wanted because he was a good buddy to the department head or his division head… And another fellow may have really good scientific background knowledge, but he is not so politically inclined and may have difficulty to bring something that potentially could be good. (HTA22)

Here HTA is protection against 'politics'; evidence-based decisions create transparency and fairness in the processes of technology adoption.

These moral forms of talk were most apparent when the respondents discussed whether and how their assessments became the basis of decisions. HTA30 said,

> you know, often health policy… health strategy… are made in the absence of evidence, in the absence of a dialogue with researchers.

HTA30 and HTA35 (both university-based) did not know whether their findings were used:

> So, my understanding was that they would use our systematic review in their guidelines, their surgical practice guidelines, in terms of making recommendations. I actually don't know exactly what happened after that. (HTA30)

> It's like we are just rushing to stand still. We just buzz through this stuff and then [the recommendation] sits and it goes to consultation and it sits and it's a bit of a black hole… (HTA35)

HTA29, a representative of a provincial HTA body, reported, '85% of our current evaluations have been turned into policy', yet another respondent commented on the same body, saying:

> We have [a provincial HTA body], but it's an advisory body, they can change government policy and they, we can introduce reimbursement for a specific technology, that's a lever that we have, but if somebody wants to buy a laparoscopic robotic surgery device in [major city], there is nothing we can do to prevent that. (HTA28)

HTA is not an obligatory passage point; much gets into the healthcare system without HTA vetting. Several respondents discussed how big-ticket, high-prestige items such as surgical robots might be purchased as gifts by philanthropic organisations or 'donated' by the manufacturers themselves, while the healthcare system then permanently picks up the associated operating costs.

Others referred to the problem of 'technology creep' – when technologies approved for one purpose or group of patients begin to be used for other purposes and patients, for which there is less or no evidence.

> I think the dangers may be… a creep effect, where they start to apply to situations that maybe there wasn't tight enough inclusion criteria, so you then start to have, oh why are we doing it for this kid? Was there really hope or was this an unethical thing to do? So you're starting to push the ethical boundaries… like you're using this and now a kid who would have died lives, but what is their quality of life? And is this really the situation which you should use it? And then it's around the anecdotes, you know the kid who survives… and returns to normal function and that gets to be cited as a success case and drives the whole process, right? (HTA25)

Illustrating technology creep through discussion of a technology that might save the life of one child but more typically cause children to suffer ('what is their quality of life?') is a dramatic way of casting the 'unproven' use of technology in a moral light. Similar moral inflections were evident when respondents expressed concern that patients might harm themselves if they obtain access to medical innovations for which there is inadequate evidence of safety or effectiveness. As HTA30 said, 'introducing new technologies in the absence of evidence is an ethical issue'. HTA25 also described the adoption of technologies that may not be harmful, but have unclear benefits because they have not been subjected to 'rigorous evaluation':

> … in the absence of rigorous evaluation systems – be they randomised trials or other things – I think you often adopt something… with unclear benefits but then it gets institutionalised. So that's the big risk, and might actually draw resources away from being invested more effectively elsewhere in the health system. And I think that's a tragedy. (HTA25)

For these respondents, the adherence by HTA organisations and professionals to widely-held notions of what good science and knowledge is – that which is rigorous and unbiased, based upon 'the facts and nothing but the facts' and requiring autonomy and independence – was not only an epistemology, but a value. Such ways of knowing and doing HTA were presented as having the potential to avert several kinds of bad outcomes – harm to patients, wasted or inefficient use of resources, arbitrary decision making or non-transparent decision making perceived as arbitrary. The image is of HTA as a remedy for that which is wrong in healthcare: that which is improper, opaque, political, anecdotal, and wasteful.

The mutability of independence and good evidence

Daston (1995) argued that values are constitutive of science itself, what is considered fact or truth, an argument based upon historical analysis showing ideas of truth and fact are mutable. It was noteworthy then, when respondents showed flexibility or inconsistency with regard to conceptualisations or practices around independence or good evidence. For instance, some respondents seemed willing to compromise their autonomy or independence, understood by many respondents as a condition for producing objective, unbiased assessments, by becoming involved in policy making or healthcare practice. HTA23 expressed frustration that the provincial government hired people to create policy recommendations 'who are not familiar with the literature' and 'in essence, cut and paste the knowledge from that into their own views on policy'. Like HTA55 (discussed above), HTA23 favoured providing policy options as a step beyond the provision of information or the evidentiary platform.

HTA22 reported involvement in training clinicians:

> … we train our physicians, and nurses and managers to think about what is the evidence that really supports the adoption of this technology in practice and, not only what is the evidence, but how do we do it so that we need to create the evidence or support the training protocol to ensure that we provide high quality services? So we're a lot more focused on trying to support evidence- based medicine and the proper application of technology into practice…. (HTA22)

Similarly, HTA43 discussed becoming involved in the creation of clinical guidelines, and described HTA as a 'service to ensure – or, to allow, decision makers to use the evidence. HTA43 corrected herself, but her comment suggests the powerful pull of moral responsibility on the practice of HTA: allowing decision makers to use evidence shades into ensuring they use evidence. Some of these differences in perspective could be related to the different kinds of organisations the respondents worked for (hospitals, health authorities, universities, or HTA agencies; see discussion in Lavis et al, 2008), though we did not find a systematic relation in this data. Likewise HTA22's group may not tell health practitioners which technologies to use and when. Yet there is a range of practices that HTA professionals engage in, some of which bring them closer to involvement in making policy decisions and determining health practices and which, we suggest, should be understood in relation to their values – the respondents' sense of responsibility.

This dynamic was especially apparent in the respondents' discussion of cost assessment. The question of whether health technology assessments should include costs was controversial among respondents. Certainly a dominant concern appeared to be that measuring costs might threaten the independence and credibility of HTA. HTA22 said, "the goal of our programme is not so much like the government… we don't want to save money… it's not cost containment". HTA29 said, "we recommend based on evidence and some of those recommendations save the ministry money, some of those recommendations cost the ministry money". Here, 'evidence' was once again set apart from political considerations of how to allocate resources.

The economic concept 'quality of life years' (QALYs), which measures the cost or resource requirements of a technology per unit of improvement, emerged in particular as a charged issue.

> … this concept arose that 50,000 dollars per quality life year was the [highest] price the government should pay for anything, based on what it cost to provide dialysis for a year for someone, when they first introduced dialysis. And governments are not keen to talk about any of that as you can imagine. How do you have a public debate about that? Or is that something you want to have a public debate about? I mean who's going to take that on really? (HTA36)

HTA26 identified a further complication – in a system of limited resources, trade-offs must be made:

> It may turn out that what you should be doing is looking at the opportunity costs… for that same amount we could buy this technology and another technology, and improve the lives of more people, for less…

For these respondents, assessment of costs quickly and problematically would embroil HTA in obvious ethical and political matters.

HTA24, however, took a different view while describing the need for a *post hoc* review of a provincial decision to expand newborn metabolic screening:

> I think we need to look at, so how many children have we identified and at what cost? I mean you can't put a value on these things because for some of them, picking them up, prevents them from being either very disabled or even dying, and you can't put a cost on that. But it's important to identify those because, what costs did you defer by doing this? Or maybe, what were the costs to the system because of drugs or significant amount of care that the child has?… (HTA24)

While saying, "you can't put a cost" on preventing a child from being "very disabled or even dying," HTA24 nevertheless argues costs can and should be measured. A moral position is staked out—that it is better to know, in the interests of the 'system'.

HTA39 too said that measuring costs and cost effectiveness is in itself a moral, responsible act:

> The reality is we do not have unlimited dollars for healthcare and so we have to be thinking about cost effectiveness.

HTA39, also a surgeon, said their process was to put physicians requesting new devices onto the HTA committee, where they would learn about the costs of their requested device and that "the guy over there wants to spend all of your money on something completely different". Still, because the measurement of costs may conflict with independence of HTA, it requires justification. The justification is a moral one, that of the good of the system. HTA39 teaches physicians to be responsible stewards of

healthcare resources. HTA22 similarly described the results of formalising decisions about technology adoption:

> Because usually physicians are not aware of the impact a technology can have on the system, whether it's for the cost, or the training of the nurses that goes along with it, how does it fit with the infrastructure, the other technologies. So, as they see the entire process they become a lot more aware of thinking in terms of their patient, but also being aware of what is the impact this technology can have on the system. So… I think they're learning a lot about, oh, I should think about the system too, not only my patient. (HTA22)

Although measuring costs was recognised as immediately drawing HTA into value-laden and political discussions, some respondents felt this potential risk to the independence and unbiased nature of HTA's role in healthcare was justified by a greater good – that of the healthcare system. In these instances, a sense of moral responsibility arguably directs the practice of HTA, exerting influence over what is considered acceptable to measure and assess.

According to Daston (1995), values constitute ways of knowing in particular, raising the question of how flexibility with regard to independence might impact ways of knowing in HTA, that is, preferred methods of measurement and assessment, and whether there is flexibility with regard to ways of knowing as such. Respondents' discussions of the possibility of incorporating ethics into their assessments shed some light on this question. Many respondents were aware of, and voiced support for, recent calls for HTA to broaden its scope to include social and ethical issues, though few respondents engaged in concrete discussion of the relationship between ethics and HTA. HTA26 had done research on the issue and found ethics "just becomes a sort of add on and a throw away at the end of the day". HTA23's comment seemed to exemplify how ethics might become a "sort of add on":

> I mean you wouldn't go and look up any of our reports and go down to the table of contents and find the ethics section, but from time to time ethical, legal, social issues that overlay the use of technologies will come up in due course. (HTA23)

HTA23 was discussing the case of *in vitro* fertilisation (IVF) just prior to making this comment, lending support to DeJean and coauthors' analysis of HTA reports, which found there is 'a common attitude that ethical analyses are only necessary for controversial technologies' (2009, 467). HTA25 said ethical issues will arise as "spontaneous, heat of the moment, in all the chaotic ways in which it happens" – suggesting chaos is to be expected when examining ethics.

The main concern for respondents, however, appeared to be whether it would be possible to develop acceptable methodologies to measure ethics (see Assasi et al, 2014), which would make their assessment consistent with dominant definitions of good evidence and how costs, safety and effectiveness are already assessed. HTA28 pointed out,

> There are really no resources dedicated to answering this [ethical] question in a routine way… in general there is no kind of ethical-reasoning systematic review of the literature; there is no kind of formal process for evaluating the ethical implications of new technology. (HTA28)

HTA28 imagined a routine methodology consistent with preferred notions of evidence: an "ethical-reasoning systematic review of the literature". HTA26 argued it should be possible to develop methods for assessing ethical issues similar to those for assessing economics and effectiveness, which HTA26 said were also once thought to be impossible. Such a methodology would require an existing body of research that operationalises ethics as variables and measures that can be aggregated and compared. HTA25, on the other hand, suggested ethical issues are not amenable to HTA simply because they are not know-able in advance, describing a particular technology for which ethical issues arose only once technology creep took place. HTA35 said the agency's "research people" would talk to clinicians or "go into patient blogs" to identify social, ethical, or system-level concerns a new technology might raise, but added, "there is no real time to stretch any kind of a big ethical discussion, so it is whatever is available in the literature frankly." These types of comments suggest the underlying epistemology of HTA, apparently closely related to that of EBM, is stable, and regarded as a defining feature of HTA and what it can contribute to healthcare systems.

On the other hand, if independence and autonomy are necessary to the production of good evidence, than some respondents' willingness to compromise their independence for the good of the 'system' could entail compromise to, or change in, their notions of good evidence. HTA39 said that having a physician who requests a specific device involved in the assessment of that device, and thereby compromising the independence of the assessment:

> … in some ways is a little bit of a bias because now the person who is working on that protocol is trying to see a particular outcome, but I think that we have enough objectivity that I think we can help them realise that in fact it [the device] is not gonna work – if that's the case. (HTA39)

Here HTA39 accepts the possibility of a bias, but a "little bit". The process, he argues, retains "enough objectivity" to produce a fact about whether the device "works". This could be read either as an indication of the stability of the notion of objectivity or its mutability. It is possible that values might be driving epistemology, rather than the other way around. Thinking about the role of values and beliefs for HTA practitioners, as Daston's framework requires, at the very least isolates an aspect of HTA as a culture that those who wish to change the scope or methods of HTA will have to consider.

Discussion

Recognizing the moral aspects of the ways HTA producers think about their work has practical and theoretical implications. At the practical level, it draws attention to aspects of these interviews that have not been the focus of other analyses of HTA practice, allows us to make sense of some of the less straightforward aspects of these

respondents' accounts, and adds a necessary dimension to the discussion of whether and how HTA practice might be reformed.

As with previous research, we found 'HTA producers regarded themselves as (and deployed efforts to be perceived as) *scientifically* autonomous and providers of rigorous, unbiased information' (Lehoux et al, 2008, 307; see also Lehoux 2006, ch 4). 'Rigorous, unbiased information' seems to consist typically of existing research that can be incorporated into a synthetic, usually quantitative, analysis of the literature, for which studies of costs, effectiveness and safety are often available, but are rarely available for ethical issues. If this view of rigorous information is understood as also a moral view, than we see that in so far as ethical issues cannot be assessed using methods HTA professionals regard as ethical, there is a *prima facie* conflict for them. Seeing definitions of good evidence as moral also helps to explain why some within HTA regard patients in a similar light as industry or policy makers or healthcare providers – as having necessarily biased views which potentially distort HTA. If the incorporation of patients and citizens into healthcare policy, research, and decisions entails transformations in dominant epistemologies and methodologies (Boote et al, 2002; Bridges and Jones, 2007; McKevitt, 2013; Popay and Williams, 1996), then it will also threaten the values and sense of worth of at least some who do HTA. Koivisto and coauthors (2010), for instance, proposed a relational model for the evaluation of patient aspects of healthcare technology, which supposes that technologies are inseparable from their social, organisational, or ethical aspects – they are co-produced. Lehoux and Blume (2000) recommended that HTA consider the experiences of less powerful actors in particular, and also plural forms of evidence, such as qualitative studies. Giacomini and coauthors (2013) have advocated for transforming HTA into health technology policy analysis (HTPA), which 'requires an expanded understanding of evidence – beyond clinical epidemiology and economic research – to encompass a wider range of 'intelligence' sources'' (2013, 74). This study suggests that HTA practitioners' views of good evidence are also moral commitments, so that the nature of the relationship between definitions of evidence and values needs to be further examined and disentangled if reforms are to be successful.

Conceptualising HTA as a movement could allow for a similar analytic focus. Movements require an 'enduring sense of purpose, group will or morale', which in the case of EBM became apparent in the 'growing sense of self-belief and rectitude' among its early clinician advocates (Pope, 2003, 271). Arguments for EBM have at times taken on an evangelical quality (Traynor, 2000) and reshaped notions of what it means to be a responsible healthcare professional (Lambert, 2006). The moral economy framework, however, attends to the links between values (about purpose and responsibility) and knowledge (what is considered fact), such as whether and how current definitions of good evidence and objectivity in HTA are *constituted by* values.

In addition, the moral economy framework points to the theoretical question of the nature of objectivity in contemporary HTA. Some have argued that standards of objectivity and good evidence may work to manage a contentious set of stakeholders or establish the credibility of HTA, which they could do regardless of their relation to truth. Berkwits (1998) noted that although standards of objectivity do not necessarily resolve disputes, they are 'essential to managing an opinionated and often contentious scientific community' (1998, 1542). The preferred form of evidence in HTA – quantified, 'aggregate, generalizable data about large population experience' (Belkin, 1997, 511) – may be held dear for its ability to generate acceptance of, or even trust

in, healthcare policy decisions in specific context of liberal governance. Aggregate, population-level data may be well suited to policy decisions that are, or need to be perceived as, fair. Hence HTA respondents' frustration when policy makers themselves seemed not to be equally invested in such evidence and decisions.

Others have noted that an emphasis on objectivity as quantification is a strategy among those who lack, but seek, authority (Belkin, 1997; Porter, 1995). Similarly, the narrowing of HTA to certain kinds of concerns and evidence perhaps 'reflected practitioners' sense of the configuration of power and influence within which they operated' (Blume, 2009, 277). HTA 'incorporates… the understanding of third-party payers, hospital administrators and health care professionals', whose purviews are largely limited to epidemiological, clinical and economic dimensions of technology, and to whom HTA must appear credible and useful (Lehoux and Blume, 2000, 1100). These institutional contexts and struggles may partially explain how those in HTA define good evidence, but we argue it is important to recognise that these definitions of good evidence are inseparable from values – HTA professionals' sense of worth and responsibility. In addition, it is important to consider that objectivity and quantification can take different forms that are influenced by values.

This study provides tentative support for the idea that the kind of objectivity prominent in HTA is organised around values of transparency and legitimacy in a specific political and economic context. HTA26 commented that in making a decision about the adoption of a new technology or treatment, ethical issues have to be weighed against the "technical assessments… with the assessment of clinical effectiveness and with the economic evaluation". The types of considerations HTA26 regards as "technical" are arguably inherently value-laden, as has been persuasively shown in analyses of definitions of costs and quality of life (Ashmore et al, 1989, ch 5; Harris, 1987), RCT studies of effectiveness (Richards, 1988), and EBM tools such as decision-support software and clinical guidelines (Berg et al, 2001; Giacomini et al, 2000; Molewijk et al, 2003). Though the measurement of costs remains controversial among these respondents, the concern seemed not to be about the inherently value-laden nature of measuring costs, but about how measuring costs might embroil HTA professionals in political decisions and questions of equity. Therefore, despite some of their ways of talking, the criteria HTA professionals' use to determine appropriate methods and measures may not be whether they are more or less truthful, or free from values and bias (which we would argue do not exist in any case), but whether they can facilitate unassailable decision-making processes for the allocation of scarce resources, resources that can determine who lives and who dies. HTA professionals may be committed to objectivity in the first instance as perceived neutrality and transparency transparency (Williams et al, 2003; resonant with what Cambrosio et al (2006) call 'regulatory objectivity'), a commitment that shapes when and how notions of good evidence and independence are mutable.

Conclusion

This study does not fully document or tease apart the different practices and visions that may coexist under the rubric HTA (see Lehoux et al, 2005). Additional research is also necessary to map whether and how HTA overlaps with EBM, neither of which may entirely cohere (on EBM, see Charles et al, 2011). The number of stakeholders interviewed was small in relation to the number of people doing HTA internationally,

potentially limiting the relevance of these findings. Nevertheless, the HTA respondents represented a variety of backgrounds and institutional positions, making it likely these findings are relevant to other settings.

This research also does not make it possible to assess how the respondents' views intersect with their practices. Perhaps any threats to HTA raised by the inclusion of ethics or lay perspectives exist only at the level of discourse. It would be valuable to know how the ideals of evidence described here relate to the day-to-day negotiation of doing HTA and making it usable. While important empirical research has been undertaken to examine how EBM is enacted (for example, Berg, 1997; Mykhalovskiy, 2003; Timmermans and Berg, 2003), we know of few similar studies of HTA in practice. May (2006) observed decision-making meetings where the value and utility of HTA evidence is considered. Others have shown just how messy the process of healthcare priority setting is (Berg et al, 2004; Giacomini, 1999). Nevertheless, even if practices are not always consistent with beliefs about the best types of evidence, 'values honed erratically are nonetheless genuine values', which

> dignify some objects of study at the expense of a great many others, trust some kinds of evidence and reject other sorts, and cultivate certain mental habits, methods of investigation, and even characters of a distinctive stamp. (Daston, 1995, 23)

If HTA is part of a 'long-term secular trend in changing patterns of knowledge production' toward formalisation and quantification (May, 2006, 518), then this analysis illuminates emotional and moral dimensions of this long-term trend in specific political and institutional contexts. More extensive research should examine the extent of agreement about the goals of HTA and meaning of good evidence; when and why different types of evidence are accepted in principle or in practice; whether and how values might alter the definitions of evidence; and the specifics of when and why HTA professionals deploy moral arguments.

The significance of thinking about HTA as a moral economy is the recognition that notions of evidence, or conventions around how to measure and judge healthcare technologies, are, as Daston (1995) wrote, 'cultural forms', making them both historically contingent and mutable, but also powerful, naturalised standards for how to think, feel, and behave. These interviews suggest that views of good evidence in HTA are inseparable from what it means to be a good actor, to prevent the potentially tragic misallocation of resources in a publicly-funded healthcare system. As HTA25 commented with apparent disapproval, "it seemed like for a while in [province], you could almost get anything you wanted. Any gizmo you want, no problem, here it is next week". Proposals for HTA to expand its notions of evidence may threaten what makes HTA distinct and valuable in the eyes of many we interviewed. Calls for HTA to incorporate lay perspectives, or the social, political and ethical aspects of technologies, challenge morally-charged boundaries around the role and worth of HTA. Any attempt to change or reform HTA must reckon with notions of evidence that are not just epistemologies, or practices ingrained through training and experience, or tactics related to institutional context, but are also genuine feelings about worth and responsibility.

Appendix: Interview Guide for Health Technology Assessment Professionals

Would you tell us about your organization as well as your personal position and roles in the HTA process?

What is the process your organization goes through in assessing a medical device? [whenever helpful, ask about cases of specific devices; whenever possible, ask about specific uro-gyne devices]

- How do you decide which devices to assess? [who hires organization and pays for assessment; who determines which devices should be assessed]
    - Has your organization been involved in evaluation of any of the following (if yes, uses the devices as cases or examples in rest of interview):
        - Suture capturing device (class II)
        - Mesh devices for pelvic organ prolapse repair (class III)
        - Implantable sacral nerve stimulator for overactive bladder? (class IV)
- What criteria do you use to assess a device?
    - Probe for criteria related to ethics and economics
- How and from where do you gather information or evidence on the device?
    - Probe for relationship between information that is available and the criteria used
- Do you seek or use the input of specific stakeholders as part of the process? [stakeholders could be patient groups; industry representatives; clinicians, etc…]
- To what degree does your role in assessing new surgical devices differ according to the class of surgical device (if needed, explain)?
- Is there information/evidence you do not have that you think would help in the assessment process?
- What happens to the assessments you prepare? To whom are you accountable?

What is your organization's role in determining which health technologies will be used in Canada?

- Does your organization make policy recommendations?
- How does your organization influence policy decisions, including whether to approve and fund technologies and devices?
    - Is it necessary for a device to go through the HTA process prior to being publicly funded?

- What role do you think ethics and economics play in whether a device is put into practice in Canada?
- How is your organization integrated with other HTA bodies at regional and national levels?

How is the health technology assessment process related to the licensing process carried out by Health Canada?

- Does HTA and the licensing process rely upon the same (or same sources of) evidence?
- Does HTA influence what is licensed?
- What is your understanding of the process for licensing surgical devices in Canada?
- What is your understanding of the process for licensing adaptations to existing surgical devices, in Canada?

What do you think about the current way medical devices are currently licensed and assessed in Canada?

- What are some of the strengths and weaknesses of this system?
- What aspects of this process that you believe are managed particularly well?
- What aspects of this process cause you concern?
- What suggestions do you have for improving this process?

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