Leadership’s View

A Brief Introduction to Ethics and HTA

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Applied Health Ethics is concerned with what is ‘right’ and ‘good’ to do, and can be helpful in providing guidance in a situation with more than one view of what might constitute the right course of action.

The disciplines of health ethics, broadly, can be divided into clinical, research and organizational ethics: where clinical ethics addresses individual and collective clinical interactions; research ethics addresses the ethical considerations inherent in research on human and animal subjects, tissues and information; and organizational health ethics deals with how policy and health system management decisions impacts the organization itself, served populations and system workers. Organizational ethics often addresses issues such as the allocation of resources, disaster management, fair policy, and issues in delivery of care and system performance. Specialized health ethics can address specific clinical areas, such as neuroethics, reproductive technology ethics or transplant ethics.

When people deliberate about ethics tensions, they utilize various normative ethics theories and frameworks to organize thinking and bring to bear values that might inform a resolution. There are a number of different frames, each with strengths and weaknesses. None of the approaches is sufficient itself to fully inform challenging decision-making, and so ethics deliberation will often pull from a number of theoretical approaches.

For instance, Principlism uses a list of principles to guide moral actions or resolve ethical tensions. Principles often encompass a list that can be distilled to fairness, providing maximal benefit, minimizing harm, and respecting autonomy, but there are other important candidates for inclusion in the list. Another approach - Virtue ethics - animates a list of commonly held virtues that form the basis of a person’s good character. According to Beauchamp and Childress, it is expression of moral character that is important in judging goodness, rather than adherence to rules or acting out of obligation. Their primary list of virtues include compassion, discernment, trustworthiness, integrity and conscientiousness. Care ethics holds that benevolent care within interpersonal relationships informs moral action. Communitarian ethics focusses on the community impacts and regulation of individual behavior in service of the broader good. Feminist ethics re-characterizes ethical thought in ways that reflect the moral experience of women, and focuses important moral direction towards advantaging those who have traditionally not had full access to the goods and opportunities of society. Narrative ethics turns to the stories of individuals and groups to shape moral action and the way we think about our world.
How does this all relate to health technology assessment? We know that scientific advances have allowed health practitioners and health systems to do amazing things in service of individuals and populations. But we always have to ask ourselves of any clinical activity, or of any funding decision, at least the following questions in order to answer the over-riding challenge, i.e. on balance, is it the right thing to do?

- Does this course of action provide the best benefit amongst options?
- What harms might be entailed?
- Can we afford it?
- What might be foregone by engaging in this? and,
- To what degree does doing this increase or lessen inequity?

Many of these questions are at the core of health technology assessment. In HTA, we also focus work on assessing whether or not there is evidence that can assist us to make ideal decisions regarding use of the technology. Of course, underlying such questions are certain values. Those values can be contested regarding their relative importance. Let’s consider some brief examples:

a) Equity is enjoying a welcome ascendancy in attention. But each society places differential value on equity as a foundational consideration.

b) The ascribing of benefits and burdens to individuals through a clinical intervention must be carefully weighed, especially with a novel technology. How might incorporation of a technology relate to our desire to advance science by ‘pushing the boundaries’, purportedly for the benefit of all future individuals? Can we ever use an individual as an instrument for others’ benefit?

c) We might ask to what degree must a promising technology be certainly safe and cost effective, when dealing with a potential threatening pandemic – that is, can we bend the usual standards of evidence or of cost-effectiveness considering the consequences of not acting, even though available information is imperfect?

d) Ought we value freedom for clinicians and patients to choose particular tests and interventions, or should we constrain those choices to what evidence currently shows to be the most cost-effective? The value our society places on individual ‘choice’, conflicts with our values in assuring that as many crucial health needs as possible are available for all within limited budgets.

Generally, it is useful to think about values and principles underlying an issue from two angles: the substantive considerations - addressing the substance or content of the issue; and the procedural ones - addressing the process of coming to a decision. Here’s an example – when assessing the introduction of novel therapies or novel combinations of therapies for a certain cancer, HTA substantive considerations might look at clinical response rate, patient burden, total cost burden, value for money, number of people potentially affected, opportunity for substitution, and person-values addressing relative desire for cure, control, prolongation of life or symptom abatement. Procedural considerations might include mechanism of evaluation, agreement on whether uniformity of decision across jurisdictions is important, who is included in any of the steps in a decision-making process (patients, advocacy groups, clinicians, economists, administrators, funders), how the decision is publicized to potentially interested parties, what our duties are in supporting public decision-makers, and what decisional appeal mechanisms exist.

Turning to allocation decisions, we want such decisions to be legitimate and fair. Daniels and Sabin have established the ‘accountability for reasonableness’ framework in support of these goals. The framework asserts the need for four conditions to be met: 1) that any process should be public by being fully transparent regarding the basis for decisions, 2) that decisions are based on reasons that stakeholders believe are relevant, 3) that new evidence and ways of thinking that emerge can lead to revisability of decisions, and 4) that all these conditions are enforceable. Overarching considerations of justice underpin these considerations. Gibson et al subsequently added a fifth consideration, that of empowerment, in order to ensure stakeholder participation is effective by minimizing power differentials, in part through appropriate education and information relay. Health Technology Assessment activities can be nicely informed by this model, especially thinking about the end-user of an HTA process. Trust in the results of an HTA is fostered when each of these conditions is explicitly met.

The incorporation of deliberate ethics thinking in an HTA activity likely requires systematic embedding within the process. We already use this concept in human research, program evaluation and QI activities, and in policy development and review. It seems to me not to be a leap to expect similar attention to an embedded ethics process for the important activity of HTA. I would justify my claim this way: Increasingly, some health systems utilize ethicists as part of teams developing or reviewing important policies. Those experts bring a unique lens to decisions, and tend to pay attention to both the substantive and procedural considerations that will lead to the development of better policy. Further, much like ethics deliberation and approval is required for research conducted on human subjects, in Alberta an ARECCI (A PReject Ethics Community Consensus Initiative) process is expected to be completed for projects such as quality improvement, knowledge translation, program evaluation and needs assessments. This rigor helps assure that ethics considerations have been identified and mitigated, if any exist. One of the important benefits of the ARECCI approach is that participants do this assessment themselves, aided by experts in use of the tool only if assistance is needed. That keeps the ethics considerations at the forefront for the participant. Alberta has training programs in the use of this tool. Developing such useable tools for anyone to work through elevates ethics knowledge and skills more broadly. It reserves consultation by specially trained ethicists to situations that require their unique expertise.

HTA programs can similarly develop and embed ethics considerations into regular work processes. Developing a useful and rapid ethics screening tool might add to the trust that decision-makers place on the HTA results. I suspect that would be due to awareness that a broad set of explicit societal values now informs aspects of the technology assessment. My presupposition is that fulsome HTA does not only describe the technical benefits or weaknesses and financial costs of a technology. Rather, it also weighs the relative merits, and considers broader values questions about whether or not this is the right technology to use at this time, in what circumstances, for the benefits of whom and at what opportunity cost regarding other courses of action.

In HTA, developing and utilizing such frameworks can assist stakeholders to feel the process and resulting decisions are legitimate and can be trusted. The stakes are of course high for patients, clinicians, health systems, researchers, innovators and entrepreneurs. Attention to ethics considerations provides HTA practitioners with one more set of tools to animate good decisions that can guide the enterprise of health care in service of our population.
Ethics in HTA: A Brief Review of Some Major Articles
(Compiled by Mahmood Zarrabi, HTAI Department)

Scope of HTA work by definition is not limited to determining economic impacts healthcare technology, rather it concerns with medical, social, and ethical aspects of the technology as well. HTA is a multi-disciplinary study and so it requires health economists, medical professions, healthcare managers and decision makers as well as bioethicists to study and evaluate impact and merits of healthcare technology. In this article, I review some techniques, guidelines, and obstacles for incorporating ethics into HTA.

In a report by INAHTA’s (International Network of Agencies for Health Technology Assessment) Working Group on Handling Ethical Issues in 2005, the authors emailed HTA agencies within INAHTA to find out how agencies address ethics in HTA by asking questions regarding procedures for handling ethical issues, what questions are relevant to be answered, how far HTA should go in, what type of methods should be used, how INAHTA can help, and what type of skills required by HTA agencies to handle ethical issues.

The report indicates (pp. 3-4):

“The most important part of ethics in HTA has to do with the actual consequences of applying the technology to be assessed. There are also ethical questions, however, related to the HTA analysis itself, including the starting point of choice of an area to be looked upon...

The starting point of an area to be looked upon – the prioritization of technologies to be assessed – has several ethical implications. Both identification and the final selection of areas for HTA are of ethical concern to stakeholders, such as patient groups, professionals, health care administrators, and politicians. To make the implicit ethical standpoint clear, the process has to be explicit, systematic, and transparent. There could be a risk of distorting priorities if all stakeholders were to be involved at the early stage of prioritization of the topics. Policy makers and politicians have their own reasons for interfering with the process. Scientists as well as patient organizations are needed, but can be in league with, and supported by, industry. Transparency, therefore, is of uttermost importance.

Important ethical questions that have to be dealt with in the prioritization process are:

- What are the reasons that this technology is selected to be assessed?
- At what stage in development of the technology is it assessed?
- Are there related technologies that have not been assessed?

Early involvement of stakeholders in the prioritization process, e.g. paying attention to their concerns for societal relevance or their interest in cost-effectiveness, necessitate a balance between these views - a balance that needs to be based on ethical enquires. Such a balance could be beneficial for dissemination and implementation of the results of the specific HTA.”

In a survey conducted by Nazila Assasi [available online], the author argues that close to 90% of total 26 HTA agencies that were surveyed indicated they assign some level of priority to inclusion of ethical considerations into HTA, however a few of them incorporate ethical analysis methods into their assessments and more than 25% of the agencies either were not aware of any existing guideline for addressing ethics in HTA or the believe the existing guidelines are not useful. In another survey conducted by Assasi et. al. [Expert Rev Pharmacoecon Outcomes Res. 2014;14:203–20], the authors found that from 223 reports published in the period 2003 to 2006 by HTA agencies in Canada, UK, Denmark and USA, ethical, social and organizational issues were only considered in 5% of them.

More recently, there have been more efforts to develop methods for analyzing ethical issues in HTA and in results there have been acceptance of those methods among HTA producers. For a brief review of most studied and adopted methods, the remaining of this article summarizes six methods described in the literature which were compiled and reviewed by Lysdhal et al. [BMC Medical Ethics (2016) 17:36] for analyzing ethics in HTA of complex health interventions:

1. The four principle approach
The most frequently used form of Principlism (i.e. to apply principles to solve moral problems) addresses the four basic ethical principles: respect for autonomy, non-maleficence, beneficence and justice. These principles have a prima facie nature, which means that the principle must be fulfilled unless it conflicts with an equal or stronger obligation. The principles constitute a basic framework and they need to be specified and balanced (i.e. the practical activity becomes that of specifying how the principles are to be used in specific situations and balancing the principles with the other competing moral principles). Principlism is a popular approach because it is simple and feasible.

2. Casuistry
With deep roots in ancient moral philosophy and modern anti-theoretical bioethics, Casuistry uses practical cases with an undisputed solution to solve the moral challenging situation or dilemma in hand. Oriented away from theory or principles and towards the particular, the procedure in Casuistry starts by identifying the structure of the case, i.e., by describing the circumstances (who, what, when, where, how, by what means) and the relevant maxims involved, e.g., “the morals of the story.” Then it compares the case with similar “paradigmatic” cases. Paradigmatic cases are those where a solution is found which is generally accepted. The comparison of cases should reveal the moral maxims at stake and the subsequent practical implications. In HTA, Casuistry can be at play informally, e.g. when referring to solved cases such as coverage decisions.

3. Wide Reflective Equilibrium
Wide Reflective Equilibrium is a coherentist model of moral argumentation. Coherentist, here, is used in contrast to foundational approaches, which assume that there are certain undisputable basic principles from which moral judgments can be
derived. Given the—allegedly—undisputable nature of these basic principles, the validity of moral judgments hinges on the validity of the deductive argument. In a coherentist approach, no such assumption is made. Instead, the validity of a moral judgment depends on the coherence (or mutual support) among general moral principle, moral judgment, and background theory.

4. Interactive, participatory HTA approaches
Interactive Health Technology Assessment (iHTA) is a specific approach to HTA, involving stakeholders throughout the entire assessment process, i.e. people who may experience the consequences of the assessment are involved in defining the research question(s) to be addressed (scoping), in designing the assessment and in the collection and interpretation of the data. The term ‘interactive’ refers to an interaction among the various stakeholders: the explicit objective of the HTA is that stakeholders learn from each other. As such, iHTA is a specific type of frame-reflective analysis: it aims to reconstruct and critically appraise the frames that stakeholders use to interpret the problem and to judge solutions. Typically, such reconstruction of interpretative frames is achieved through semi-structured interviews with stakeholders. Philosophically, iHTA is an approach to HTA which accepts fallibilism without embracing scepticism, and which puts primacy on practice. As such, iHTA can be considered to be firmly rooted in pragmatism. iHTA has been used to evaluate a wide range of technologies, both within and outside the healthcare domain.

5. The HTA Core Model 3.0
The HTA Core Model 3.0 has been developed in the course of the European network for Health Technology Assessment. It consists of nine domains, among which is the domain “ethical analysis”. The “ethical analysis” domain is divided into six topics; three of them (Beneficence/Non-maleficence; Autonomy; Justice and Equity) are directly related to the Principlist approach to bioethics. The other three topics are respect for persons, legislation, and ethical consequences of the HTA. Each topic consists of two to four questions, adding up to nineteen assessment “issues”. Authors of HTAs are encouraged to start by gathering information on ethical issues using systematic literature searches, professional guidelines, and the stakeholder views.

In a second phase, it is suggested that users choose from different methods that have been assembled by a working group of the International Network of Agencies for Health Technology Assessment (INAHTA). The choice of the method should depend on factors such as the type of technology, the role and

These comprise e.g., stakeholder within authority of the HTA organization, the time and resources available and the expertise with ethical analysis available within the organization. Beyond the ethical domain, the HTA Core Model introduces ethics as a wider principle and provides a list of ethical issues that should characterize each HTA.

These comprise e.g., stakeholder involvement, “morally relevant reasons for performing/not performing a HTA” on specific topics, or the description of the interests of the manufacturer. It acknowledges that the HTA-process itself is characterized by value judgments and that these value judgments should be made explicit. Examples for the ethical analysis guided by the HTA Core Model are an HTA on Multi-Slice Computed Tomography, an HTA on Drug Eluting Stents, and an HTA on Abdominal Aorta Aneurism Screening.

6. The Socratic approach
The Socratic approach is axiological as it studies values. The aim is to uncover and highlight the values, norms and ethical challenges that are relevant for the health intervention, the HTA process, as well as for the decision making process. The Socratic approach consists of six steps and seven basic morally relevant questions, which are further specified in thirty-three explanatory and guiding questions. The exact phrasing of steps and questions can be found in the revised version of the approach by Hofmann et al [Int J Technol Assess Health Care. 2014;30:3–92]. The Socratic approach has been applied in a range of assessments, e.g. of bariatric surgery, autologous stem cell transplantation and welfare technology.
Introducing Dr. Anderson (Andy) Chuck
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Dr. Chuck is the Senior Program Officer in Financial Planning at Alberta Health Services. He was previously the Director of Economic Evaluations and Analytics at the Institute of Health Economics in Edmonton, Alberta. He specializes in policy impact evaluation, economic evaluation, econometrics, experimental economics, Marko modeling, discrete event simulation, and budget impact analysis. He has extensive experience in leading evaluation initiatives including health technology assessments for provincial ministries, health authorities, health technology assessment agencies, and private industry to inform and guide health policy as well as to inform strategies for optimizing implementation of innovations into the health system. He has produced and collaborated on a wide range of evidence-based products in various clinical areas and across the spectrum of interventions (e.g. pharmaceuticals, medical devices, programs, services, and policy).

Dr. Chuck previously served on the PanCanadian Health Technology Assessment Collaborative for the Canadian Agency for Drugs and Technologies in Health (CADTH) and the board of the International Network of Agencies for Health Technology Assessment.

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