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Bringing 'the public' into health technology assessment and coverage policy decisions: From principles to practice

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Abstract

Those making health care coverage decisions rely on health technology assessment (HTA) for crucial technical information. But coverage decision-making, and the HTA that informs it, are also inherently political. They involve the values and judgments of a range of stakeholders as well as the public. Moreover, governments are politically accountable for their resource allocation decisions. Canadian policy makers are at an early stage in the design of legitimate mechanisms for the public to contribute to, and to be apprised of, HTA and coverage decisions. As they consider the options, questions arise about whom to involve (e.g., which publics), how to engage them (e.g., through what public involvement or accountability mechanisms), and for what purpose (e.g., to inform the public of decisions and their rationales, or to have the public directly affect those decisions). Often key concepts, such as the difference between public accountability and public participation, are not well articulated or distinguished in these debates. Guidance is needed regarding both rationales and methods for involving the public in HTA and technology coverage decisions. We offer a framework that clearly distinguishes specific roles for the public, and relates them to several layers of policy analysis and policy making where 'the public' may engage in different tasks. The framework offers a menu of choices for policy makers contemplating changes to public involvement, as well as a model that can be used to characterize and analyze different approaches across jurisdictions.

Keywords: Public involvement; Accountability; Health technology assessment; Decision-making

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Finding better ways to manage the use and cost of health technology is a high priority for Canadian policy makers [1] as it has been in the US [2,3], Australia [4] and various European countries [5,6]. New health technologies have been a major source of increased Canadian health care spending over the past decade [7] and "technological change" (consisting of innovation and utilization) is expected to continue to drive costs due to demographic changes, genetic sciences and consumer-directed marketing [8]. A major input to health technology policy is the production of health technology assessments (HTAs) intended to provide "unbiased information to policy-makers on a technology's clinical effectiveness, impact on providers, service improvements to patients, and economic impact" [1]. As health policy makers face increasing pressure from the public to make explicit determinations about how and which technologies will be covered within the public 'basket' of services, the profile and scrutiny of HTA activity has, consequently, also increased [9].

There is a tension between universal, unbiased assessment of the instrumental value of a technology and the local, values-laden judgment of whether it performs the right job, fulfills community needs, and poses fair costs. Traditional HTA methods have addressed the former task and are only just beginning to address the latter. Of particular concern in the Canadian HTA community is the perceived inability of current HTA approaches to "effectively address policy issues common to all federal/provincial/territorial jurisdictions" [1] and to "provide a full contextual application of research to different health systems [1]". Studies of HTA dissemination and uptake have identified deficiencies in HTA products and services that have prompted calls for new approaches to health technology policy (HTP) development and the HTA that informs it [1,10].

As the landscape of health technology assessment and health technology policy in Canada evolves, their political and ethical backdrops loom large. It is clear that evaluative evidence alone cannot determine which technologies a publicly funded health plan can justify morally, afford economically, and use to good purpose. Technology decisions resist a purely technocratic approach. There is now much interest in how governments actually make coverage decisions – through which mechanisms, with whose input – and with what outcomes [9,11,12]. Public interest in both the processes and outcomes of these decisions is clear, and a role for 'the public' is widely promoted [13,14]. In particular, governments face pressure to demonstrate the public accountability of these decisions by providing assurances that public resources are being allocated in ways that serve the public interest [15].

In Canada, both HTA and HT decisions traditionally have been invisible and inaccessible to the public, especially during their formulation [16]. Canadians normally first learn of specific assessments and decisions as *fait accompli*. This convention is expected to change. Canadian policy makers are beginning to consider how the public should contribute to and be apprised of HTA and HT coverage decisions, questions that can only partially be answered by research evidence [14]. Imminent questions will include whom to involve (e.g., which publics), how (e.g., through what public involvement or accountability mechanisms), and for what purpose (e.g., to inform or to be apprised of decisions and their rationales). While some other nations are well ahead of Canada in their public involvement efforts and provide admirable case examples [17,18], the HTA community remains in need of a general framework for mapping the activities of HTA/HTP onto opportunities for public involvement – understanding how to combine the two could affect the many goals of each.

The purpose of this paper is to offer a framework of public involvement in technology assessment and health policy. While existing frameworks have made important contributions to its component parts [26–28,30] we have not found any that apply public participation and accountability theory and concepts to the full spectrum of health technology assessment, coverage policy and decision-making activities to address the following questions: What are the different public involvement and accountability goals that might be pursued, through which models and mechanisms, and by whom? The framework is intended for health policy makers in Canada and abroad who are grappling with a new imperative to make technology assessment and policy more "public."

1. HTA and health technology policy

Health technology assessment is sandwiched between two policy arenas (Table 1): coverage *policy* making at the macro level, which defines the general

Table 1
Nine tasks that help bridge HTA and coverage policy and decision-making

Coverage *policy* making—Macro principles and policies	Technology assessment		Coverage *decision* making—Meso decisions
Coverage Policies: What should be the scope of covered health services?	TA policies: how should we assess any given health technology?	TA decisions: what is the potential impact and value of a specific health technology?	Coverage Decisions: Should a specific technology be funded?
1. Defining the scope of public funding for health care as opposed to other social welfare needs; 2. Determining eligibility criteria and standards for the coverage of any given health technology.	3. Specifying technology assessment agencies, membership, governance, terms of reference, resources; 4. Operationalizing specific eligibility criteria (e.g., effectiveness, efficiency, purpose); 5. Developing methods (e.g., surveys of public values regarding health states or technological capacities) and measures (e.g., health outcomes, utility scales); 6. Setting priorities among possible emerging and established technologies to be assessed.	7. Deliberating and characterizing evaluative evidence for a specific technology; 8. Applying eligibility criteria and standards to judge the value of a specific technology in relation to alternatives.	9. Determining whether a specific technology should be covered or delisted, given evaluative information from HTA, budget constraints, political pressures, moral obligations, etc.

scope of government obligations to cover health care services and how health technologies will be assessed, and coverage *decision* making at the meso level, which determines whether specific technologies fall within the coverage policies. For example, Canadian *coverage policy* dictates that all medically necessary services be covered and determines the eligibility criteria and standards for the coverage of specific health technologies. *Technology assessment policy*, in turn, specifies the arrangements for carrying out HTA (e.g., which agencies, governance models terms of reference, etc.). This level of activity also includes the many assumptions about that nature of public values that are made in the development of methodological tools and measures such as scales of well-being, quality, willingness to pay, and so forth. This level is also concerned with setting priorities regarding which health technologies will be assessed. Subsequently, *technology assessment decisions* are made regarding the potential impact and value of specific health technologies, which are used by *coverage decision makers* in provincial ministries, to decide whether to include the assessed services in the provincial health plan (Table 1). In theory, each of these levels of activity offer opportunities for the public to contribute.

1.1. Calls for public involvement and accountability

In Canada, three dominant rationales command a greater role for 'the public' in both HTA and HT coverage policymaking. First, concerns about the public's eroding confidence in the Canadian health system have driven governments to place principles of accountability and transparency on par with core health system principles of universality and equity [19–21]. Second, increased scrutiny of the science community and public investments in scientific research funding have prompted calls for greater accountability from all publicly funded research, including technology assessment agencies and basic researchers [22–24]. In parallel, citizens and stakeholders expect greater clarity about how this information is used to approve and fund health technologies [19,25]. Third, the recent proliferation of process-oriented decision-making frameworks to guide coverage decisions [26–28] have emphasized the importance of seeking greater public legitimacy in rationing decisions through a variety of mechanisms including participation, deliberation, publicity, and appeal. In the HTA context, this has been articulated generally as the need to "attend to the procedural

features that are also relevant in the technology assessment process" [29].

At the same time, a growing consumerist orientation to health care policy routinely draws health system "users" into consultations, evaluations and decision-making processes about health technology by health planners and managers [30,31]. The UK's Health Technology Assessment Program has, for example, established an infrastructure to support direct consumer involvement in the identification and prioritization of HTA topics and in the review of selected HTA research proposals and reports [32,33]. Similar types of activities have been documented in the Patient Involvement Unit (PIU) established by the National Institute of Clinical Excellence (NICE) in 2001 and through the establishment of Australia's Consumer Focus Collaboration under the National Expert Advisory Group on Safety and Quality in Health Care [30]. These top-down technocratic approaches to consumer or 'user' involvement are to be distinguished from consumer activity led by advocacy groups and/or their sponsors [34]. As these forces converge, the technology assessment and policy communities face a wave of concern over citizen and consumer accountability that now seems to drown out more traditional concerns with effectiveness and efficiency. The latter are still there, of course, but no longer suffice to legitimate the role of technology assessment in policy decisions. Appropriate procedures for considering and applying such criteria in real policy arenas, on behalf of real communities, have become equally important. New process models [26–28] focus on procedural principles for interaction among policy makers and the public. Yet the participants remain blurrily identified as simply "the public", "consumers", or "stakeholders". These categories overlap but are not interchangeable either philosophically or pragmatically. Operationalizing public involvement raises a host of questions about the differences between citizen values and consumer preferences [35]; the extent to which selected individuals or groups can legitimately or accurately represent the public; how to deal with the heterogeneity of stakeholders that include large, professionally run organizations as well as smaller, volunteer-led groups; and how to address the potential biases associated with groups that may be funded by industry and/or professional organizations [12].

In sum, the call for public involvement has become a popular "motherhood" gesture but this vague requirement sweeps over potentially conflicting interpretations of who the public is, how the public expresses values, what public involvement involves and how public accountability might be achieved in this particular policy context. An even larger gap within current frameworks is the discussion of *how* the broader public will be apprised of these decisions and the manner and extent to which public values contributed to them. As policy makers feel pressure to interface with the public through the HT policy decision-making and the HTA that informs it, attention must be given to clearly articulating the goals and objectives for the public vis a vis HTA and coverage policy, which models and mechanisms might operationalize these goals and which publics are to be involved at key junctures.

1.2. Specifying the goals for public involvement and public accountability

The democratic participation literature cites numerous goals for *public involvement* [36], each of which activates a different set of instruments and actors. For example, *process*-oriented goals that seek to improve the legitimacy of decision-making call for attention to the design of fair and transparent processes that will garner broad-based support for the final decisions that are taken with particular attention to communication of decisions and their rationales. In contrast, more *instrumental* goals (i.e., to inform policy decisions) emphasize finding the most meaningful ways to gather input from relevant patient groups and publics to make better quality decisions that reflect these groups' preferences and values. Still another goal may be to increase a particular constituency's *knowledge* and *capacity*, which would call for carefully designed knowledge dissemination strategies. These goals are not mutually exclusive; they may and likely will be pursued simultaneously, sequentially or in a dissociated fashion to respond to different tasks of the organization, decision-making contexts or technological attributes. The question of purpose should be posed routinely within the organization. Only when the purpose and goals for public involvement and accountability are clearly articulated can the questions of by whom, for what and how, be addressed. Consideration should also be given to how these goals match up against the expectations for public involvement of relevant stakeholders and publics.

The design of *accountability* mechanisms could be guided by a similar goal-articulation process. The public accountability literature identifies three core dimensions or goals for pursuing accountability. *Sanction* (*or correction*) is typically viewed as the most stringent form of accountability (i.e., outcome-oriented). It consists of requirements and penalties embodied in laws and regulations if agreed-upon expectations or performance standards are not met [37]. In contrast, the *answerability* dimension of accountability (generally viewed as weaker than sanction) emphasizes accountability for processes and decisions rather than their outcomes. It obliges governing bodies, provider groups, and relevant decision-making committees to answer questions (either ex ante or ex post) by providing information about and justification (i.e., rationales) for their decisions [15]. A third accountability dimension emphasizes the structural aspects of accountability that are called upon to *build relationships* between those making, and those who are affected by, public policy decisions. While generally considered the least stringent accountability tool, the properties of this dimension resonate with the growing interest in engaging citizens more meaningfully and directly in HTA and HT policy.

1.3. Choosing among models and mechanisms

To approach the more pragmatic task of developing public involvement models and public accountability mechanisms that might be used in HTA and HT policy, consideration must be given to how the relevant organizations currently function, which of these functions might be informed by the public and which public accountability mechanisms could be built into these processes (see Table 2). In Table 1, we identify nine discrete tasks that offer a potential participatory role for the public or the opportunity to establish public accountability mechanisms. For each of these nine tasks, we can ask the following questions represented by the columns in Table 2. First, what, if any, public involvement and accountability goal or function is to be met (Table 2, column 1)? Second, what model of public involvement is called for (Table 2, column 2)? Third, what is the appropriate mechanism for accountability to the public (Table 2, column 3)? Fourth, which publics are to be involved (Table 2, column 2)?

1.3.1. Public involvement models

When health policy decision makers involve the public, two substantive roles are generally considered: public *representatives* who participate *directly* in a decision-making process or public *consultants* whose perspectives are solicited to inform decisions (i.e., *indirect* participation) [36,38]. Experience with public *representative* models demonstrates that this is no guarantee for meaningful participation in health care policy where implicit power hierarchies, unequal administrative skill sets and an inadequate infrastructure for consumer involvement have been the norm [39,40]. Moreover, citizens have historically been "reluctant rationers" [41] preferring the role of consultant to decision-maker [42,43] and are only in a position to make meaningful contributions when they form a critical mass of decision makers [44].

Citizens' roles as public *consultants* have been the focus of much experimentation over the past decade and a half through efforts to incorporate public input into health care priority setting and resource allocation processes using both individual and group methods [45–47]. A recent systematic review concluded that "no single 'generic' approach has been identified as the gold standard [48]. Of the range of public involvement methods to choose from, processes that emphasize deliberation and its principles of providing information as a basis upon which to come to reasoned public judgments have become popular instruments for eliciting public values in complex, contentious and ethically controversial areas of public policy such as HTA and HT policy. They are routinely used by some European technology assessment bodies [17,49] and form the basis for the work of the Citizens Council of the National Institute for Clinical Excellence (NICE) [50]. But while these methods may be seen as *de rigueur* compared to more conventional public consultation methods, they are neither suitable nor feasible for all issues or decision processes [51,52]. Moreover, despite their popularity among citizens who routinely find these processes stimulating and informative, their influence in shaping the final decision outcomes to which they contribute, remains an empirical question [50].

Beyond the specifics of whether direct or indirect methods will be used, HTA and HT policy organizations face decisions about whether to approach public involvement in an *ad-hoc* or more *institutionalized*

Table 2
HTA/HT policy functions, public involvement and accountability mechanisms

HTA/HT policy functions	Public involvement models	Public accountability mechanisms
Priority setting tasks[a] • Defining the scope of public funding, allocating budget for health care services among competing social welfare needs • Setting priorities for assessment, among specific services • Setting priorities for public funding within a budget, among specific services	Direct representation • How will a 'public' representative be defined? • How many of them should there be? • How diverse should they be? • How will they be selected?	Answerability • Achieved through the communication and provision of information through all steps of the HTA/HT policy process • Emphasis on the publicity of recommendations, decisions and their rationales Citizen engagement
Criteria development tasks[b] • Developing, promulgating general eligibility criteria • Operationalizing specific eligibility criteria • Applying specific eligibility criteria (esp. developing cutoffs and standards)	Ad-hoc public involvement • What is to be collected from the public (e.g., values, preferences)? • What methods will be used? (e.g., surveys, focus groups, deliberative methods)?	• Used as a mechanism for achieving direct accountability to the public • Fosters information sharing; two-way exchange between experts and citizens Sanction • Used to control abuse and misuse of authority
Technology assessment tasks[c] • Commissioning, funding HTA agencies • Evaluating specific technologies • Using evaluation evidence	Institutionalized public involvement • Which tasks will the public contribute to on an on-going basis? • What structures and methods will be used?	• Operationalized through penalties, incentives, codes of conduct or negative publicity Appeals • Allows for direct challenges to policy recommendations and decisions

[a] These correspond to tasks 1, 6 and 9 listed in Table 1.
[b] These correspond to tasks 2, 4 and 8 listed in Table 1.
[c] These correspond to tasks 3, 5 and 7 listed in Table 1.

(i.e., on-going) manner. In general, public involvement methods are employed to bring citizens together to provide input on an issue deemed of policy importance. This may be done through a multi-staged approach but often participants are brought in on an 'as needed' basis. As 'one-time' events, these processes can yield useful input but they may not be suitable if the development of longer-term 'sounding board' relationships are desired.

Institutionalized approaches to public involvement may be a preferred route for organizations keen to foster more sustained relationships with the public or specific patient organizations. The Citizens Council of NICE is the highest profile example of an *institutionalized* public involvement model. Established in August 2002, the Citizens Council meets twice per year to provide non-binding input to NICE on issues identified by NICE but informed and shaped by council members (e.g., which disease and patient features should be considered in determining clinical need; what role age should play in determining how treatments should be used and what constitutes value for money). Experience to date has demonstrated that both parties (i.e., citizen council members and NICE decision makers) entered into this relationship with some hesitancy but that over time, and with incremental changes to the council's structure and process, the model's potential is starting to be realized [50].

Institutionalized public involvement models have been in place for over a decade in other jurisdictions, namely Denmark where the Danish Board of Technology (DBT) was established by the Danish Parliament in 1995 to "promote the technology debate and public enlightenment concerning the potential, and consequences of technology" [18]. Danish experience with deliberative methods of public involvement builds on the "public understanding of science" tradition with its commitment to informed public debate [17]. Pio-

neers in the development of the consensus conference and the scenario workshop, the DBT has used these deliberative methods in the assessment of controversial technologies such as infertility interventions, electronic patient records, alternative medicine and gene therapy [17].

1.3.2. Accountability mechanisms

As new approaches to designing accountability mechanisms are considered, traditional views of 'weak' and 'strong' accountability should also be revisited. *Sanction*, for example, only wields its strength when used consistently and, in practice, this is difficult to achieve. When it is held up as an available instrument of accountability, and then ignored, it fuels greater frustration among the public. Meaningful sanctions are difficult to develop and apply in the case of health technology assessment and policy. First, outcomes of coverage decisions do not typically have a clear "good/bad" valence – some people will be benefited, some will be burdened; some health problems or organizational problems may improve while others may be exacerbated. Second, easily agreed-upon outcomes – e.g., overall population health – have complex causes that are difficult to trace back to a health technology decision per se. More generally, sanctions create antagonistic rather than trusting relationships and may diminish the likelihood of engaging in open processes with the public. With these weaknesses, sanction should be an available instrument of accountability, but it should be used sparingly. In contrast, the *answerability* and *relationship* dimensions of accountability are potentially stronger forms of accountability with their emphasis on transparency, trust and active dialogue [53]. Through the formation of strong relationships built upon trust, openness and responsiveness between citizens and governing bodies, the need for sanction and its associated threats of public exposure and negative publicity are mitigated [54,55]. Trust has become a central feature of coverage policy processes and has been strengthened through efforts to increase the transparency of the US Medicare and Medicaid coverage processes, which include appeal mechanisms and opportunities for the public to comment of draft decisions [2].

Appeals mechanisms serve as another accountability mechanism that might be classified as an antagonistic form of answerability. As discussed above, the more conventional view of answerability puts the onus on government to provide (without coercion) explanations for decisions. This serves a dual function: (1) it fulfils a moral obligation for government to engage earnestly with the public; and, (2) it challenges government to rationalize decisions in acceptable ways, enhancing legitimacy. Appeals mechanisms, in contrast, put the onus on an unhappy citizen to demand explanations and challenge government decisions. This version of answerability is far less conciliatory in spirit, places government in a more powerful position, and may leave decision makers far more content to disagree with public (or at least individual citizens') values and to challenge their representativeness.

2. Which publics?

The question of who constitutes 'the public' lurks behind every element of the framework discussed so far. While explicit questions about the selection of public representatives have been confined to the first section of Table 2, column 2, the same questions apply to the identification and selection of public consultants. Answers will be found in part through the articulation of organizational goals for public involvement and accountability. But careful reflection on the following is also needed: Whose interests are likely to be acted upon (i.e., who *wants* to be involved and likely *will* be involved)? Whose interests are not being acted upon but should be (i.e., who *should* be involved)? For example, provider organizations and pharmaceutical companies have the resources to mobilize to advance their interests but patient groups, unless generously funded, do not have these opportunities and their involvement needs to be courted. Moreover, ordinary citizens, will go unheard without considerable recruitment effort.

Lack of agreed upon terminology can also be problematic. Although often used interchangeably, the terms "stakeholders" and "the public" are not the same thing. Stakeholders, as the term suggests, are parties that have a 'stake' (self-interest in terms of resources, power, etc.) in a given issue (e.g., professional, consumer advocacy groups and pharmaceutical companies). Technically, the public also holds a stake on many issues, but representing the public's interest incorporates a much broader, diffused and fragmented set of interests that are not easily mobilized [56].

If the idea of 'the public' is multi-faceted, dynamic and socially constructed [57–59], this concept will be prone to manipulation by those with strong interests. Policy makers need to be aware of competing characterizations of 'the public' as they decide who will be involved in which HTA and HT policy tasks and as they respond to various requests for 'seats at the table'. Stakeholder involvement presented as public involvement gives greater voice to professionals and industry interests than to citizens and patients. Moreover, when "public" and "stakeholders" both sit at the table, inequalities in their powers of persuasion must be overcome if the public perspective is to have any force [54].

2.1. The public and HTA/HT policy in Canada: some preliminary observations

In the remaining sections of the paper, we use the framework described above to consider how Canadian HTA and HT policy advisory bodies are currently responding to the challenges of designing public involvement and accountability processes within their organizations. We review approaches currently being taken by five Canadian HTA and HT policy advisory bodies that represent the full spectrum of activity level (i.e., national and provincial) and type (i.e., HTA, HT policy advisory committees): the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), now called the Canadian Agency for Drugs and Technology in Health (CADTH); the Canadian Expert Drug Advisory Committee (CEDAC); Agence d'évaluation des technologies et des mode d'intervention en santé (AETMIS) of the Quebec Government; the Policy Advisory Committee of Cancer Care Ontario (PAC-CCO); and the Ontario Health Technology Advisory Committee (OHTAC) (Table 3).

We posed the following questions regarding organizational activities pertaining to public involvement and accountability:

(1) Is there any public representation on committees charged with setting priorities, developing criteria, making assessments or policy recommendations?
(2) Does the agency/committee make any explicit statements regarding the incorporation of public input into HTA or HT policy decision-making processes?
(3) What vehicles are routinely used to disseminate HTA reports, HT policy recommendations, decisions and their rationales? Are these accessible by the public?

Transparency was of particular interest in this analysis; it drove the principal method of data collection. We were specifically interested in determining whether an interested member of the public could find answers to each of the questions posed above with readily available information? As such, we are answering these questions based solely on *publicly* available (i.e., published – on the web or elsewhere) descriptions concerning any or all of these elements of public involvement and accountability and how they are used in the HTA/HTP process (Table 3). To monitor any organizational practice changes that may have occurred, we accessed websites on three separate occasions: May/June 2003, April/May 2004 and May/June 2005. Through on-going monitoring of these organizations since the spring of 2005, we have documented several additional changes recently announced.

2.2. Public involvement models

2.2.1. Direct representation through committee membership

In 2003 and 2004, two of the five organization websites we reviewed advertised the inclusion of public representatives on their committees. The Quebec HTA agency, AETMIS, advertised one government appointed public member on the advisory committee that establishes the organization's assessment priorities. The PAC of CCO advertised an undefined number of "community representatives". Eligibility criteria and membership selection processes were undisclosed in both cases. By 2005, AETMIS had changed the composition of its committees and now advertises a priorities assessment advisory committee that is comprised of a broad array of stakeholders, and no lay membership.

Ontario's PAC-CCO was disbanded in the autumn of 2004 and was re-constituted in early 2005 as a joint subcommittee of the provincial health department's Drug Quality and Therapeutics Committee (DQTC) and the province's cancer agency, Cancer Care Ontario. The sub-committee provides expert advice to the DQTC, whose recommendation on whether to provide funding is made to the Minister of Health and Long-Term Care.

Table 3
Publicy available information about public involvement in Canadian HTA and HT policy advisory committees

	CCOHTA[a]	CEDAC[b]	AETMIS	OHTAC	PAC-CCO
Public representation					
In setting assessment priorities	–	–	• 1 public member (2003, 2004); "stakeholder participation" with no lay members (2005)	–	
In developing and applying assessment criteria	–	–	–	–	• community representatives (2003, 2004); undisclosed(2005)[c]
In formulating assessments	–	–	–	–	–
Public involvement					–
In setting assessment priorities	can propose topics via web	–	can propose topics in writing	–	–
In developing and applying criteria	–	–	–	–	–
In formulating assessments	–	–	–	–	–
Accountability (through answerability)					
Assessment reports	• on web; • mailout	n/a	• on web	• on web	–
Assessment methods (replicable)	• mailout	n/a	• on web	• on web	–
Recommendations for decisions	n/a	• on web	• on web	• on web	–
Rationales for recommendations	n/a	• on web	• on web	• included in individual reports which are on web	–
Accountability (through citizen engagement)					
Accountability (through sanction or appeals)		• appeal provisions for industry only			

[a] In April 2006, CCOHTA's name was changed to the Canadian Agency for Drugs and Technology in Health (CADTH). This organization is in the process of changing many of its programs and functions including the development of a formal public involvement policy. The information presented in this table reflects the organization's recent history, prior to this reorganization.

[b] In conjunction with the CCOHTA reorganization in April 2006, CADTH announced that it will appoint 2 public members to the Canadian Expert Drug Advisory Committee (CEDAC) who will deliberate as full and equal members of this committee. As these appointments were not yet made at the time of manuscript submission, the information presented in this table reflects CEDAC activities prior to April 2006.

[c] This committee was disbanded in 2004 and was reconstituted in 2005 as a joint sub-committee of the provincial health department's Drug Quality and Therapeutics Committee (DQTC) and the provincial cancer agency, Cancer Care Ontario (CCO).

This new joint advisory body is intended to streamline the cancer drug approval process and to ensure a consistent approach to drug funding decisions. It is unclear what if any public representation exists on this committee (www.health.gov.on.ca).

In April 2006, CCOHTA changed its name to the Canadian Agency for Drugs and Technologies in Health (CADTH) and announced its new approach toward increased public involvement in its programs and initiatives. Public members are to be included on its advisory committees, starting with two public members on the Canadian Expert Drug Advisory Committee (CEDAC) and the COMPUS Expert Review Committee (CERC). In their June 14, 2006 call for public members, CADTH announced that "public members for each committee will be selected to represent the broad public interest and will have some experience or demonstrated interest in issues related to health care, at the community, regional or national level and will ideally have some experience working with committees." Also emphasized in this call was a desire for these members to "serve in the capacity as a member of the general public and not as a representative of any specific interest, group, or organization." (www.cadth.ca).

2.2.2. *Incorporation of public input*

Public input may be obtained through means outside of committee membership. None of the organizations we reviewed publicly advertised efforts to incorporate public input into any of their priority setting, assessment or decision activities. Some (e.g., OHTAC and AETMIS) report the gathering of evidence from surveys of patient perspectives or preferences regarding specific technologies. This is used as a form of technology-specific evidence (as per Table 1, point 5) rather than broader, routine mechanisms for soliciting public input on matters of priorities, principles, or processes for technology assessment generally.

Although its precise links to the cancer drug approval process are unclear, the Provincial Government of Ontario recently passed the Transparent Drug System for Patients Act (2006) in an effort to improve the overall drug approval process in Ontario. Two elements of this plan relevant to this discussion include: (i) the creation of a Citizen's Council to advise the Ministry on the social aspects of drug policies and priorities; and (ii) the provision of a role for patients in drug listing recommendations (www.health.gov.on.ca).

2.3. *Accountability mechanisms*

2.3.1. *Publicity of reports, decisions and rationales (answerability)*

Several committees demonstrate explicit commitments to transparency by posting all of their HTA reports, recommendations and rationales on their websites. All CADTH and AETMIS HTA reports are posted on their websites. Key decision makers receive mail reports from CADTH and detailed reproducible descriptions of the review process are provided. The newly established CEDAC posts all its decisions and rationales on its website as does OHTAC. Prior to its reconstitution, information dissemination practices for the PAC-CCO were not publicized on their website.

2.3.2. *Citizen engagement*

None of the organizations we reviewed publicly advertised the use of any citizen engagement methods as means for developing accountability relationships between interested publics and experts. As with the public involvement efforts described above, some efforts are underway to engage more meaningfully with the public within specific evaluation projects but these are distinct from any systematic efforts within the organization as a whole. Depending on whether and how it is implemented, the Ontario government's proposal to establish a Citizens Council to advise the Ministry of Health on the social aspects of drug policies and priorities may signal a move in this direction.

2.3.3. *Appeals*

CEDAC offers an appeals mechanism to drug manufacturers through a Request for Reconsideration provision. After considering this request it will make a Recommendation on Reconsideration that will either uphold or change the original recommendation. As strictly HTA agencies CADTH and AETMIS do not provide this provision. OHTAC does not describe any appeals process.

3. Discussion and policy prospects

The functions and activities described above provide a glimpse into what public involvement and accountability mechanisms are currently in place within some of the major HTA, HT policy advisory committees in

Canada. In addition to these current practices, we also identified initiatives on the horizon including a proposal for stakeholders (including patient groups) to be brought into the new Canadian HTA strategy [1], and plans to experiment with different public involvement approaches [60]. We rely here upon website information, as websites are probably the most publicly accessible window into agency policies. It is not unreasonable to expect HTA organizations to post some description or mention of their public involvement and accountability activities. Indeed, it would be ironic for agencies with strong public involvement policies to make no mention of this on their public website.

Our findings reveal the following: (i) two of the five organizations we reviewed included public or community representatives in their committee membership through 2004 but have since moved away from this form of direct public representation; (ii) one organization has announced plans to include public membership on two of its committees; (iii) there were no discernible efforts to systematically involve citizens in assessment or policy advisory activities in any of the five organizations; and (iv) answerability appears to be the accountability mechanism of choice among these organizations through the publication of assessments, recommendations and their rationales (appeals are used sparingly and are geared towards industry only).

What do these findings tell us? The emphasis on posting HTA reports and HT policy advisory recommendations and their rationales suggests widespread interest and perhaps some pressure within these organizations to meet accountability demands, for transparency in particular. The change in committee composition within AETMIS may signal a shift in thinking about public representation and whether lay membership on its own is the most appropriate public involvement vehicle. Indeed, much of the research evidence would support a halt to the practice of what is largely considered tokenistic public representation [39–42]. However, the decision of the newly branded CADTH to appoint two public members to two of its flagship committees provides a new opportunity to assess this claim.

The reincarnation of Ontario's PAC-CCO into a newly constituted joint health ministry-cancer agency committee with initially much less public visibility is especially noteworthy given the publicity associated with the funding of promising but costly new cancer drugs [61,62]. Removing this committee from the public's purview signals an emphasis on discretion over publicity for these types of decisions, which is inconsistent with the policy rhetoric calling for greater transparency. Indeed, the recent passage of provincial "transparent drug system" legislation suggests that a reversal of this trend is planned.

The apparent absence of systematic efforts to involve the public in HTA and HTP activities could be interpreted either positively or negatively. The exclusion of the public may be deliberate, and the result of careful consideration. A more probable scenario is that these agencies are just beginning to sort through and make explicit decisions about how they will move ahead on this front. Indeed, the organizational changes that have taken place in the first half of 2006 within Canada support this scenario. We expect further responses in the future as the profile of HTA and HT policy continue to receive sustained public attention prompting more announcements to "move to more openness, more transparency, more accountability and, of course, more public input from stakeholders involved in the process" [25].

As Canadian and international policy makers refine their HTA strategies, we urge them to clearly articulate the goals of their public involvement efforts (e.g., legitimacy, instrumental, educative). They can then proceed to select and fashion public involvement methods that will fulfill these goals, as well as demonstrate how public contributions were used to shape decisions. Political and technical challenges must be faced. In the case of the former, efforts to democratize health policy making through greater public involvement have been staunchly resisted in favour of technocratic (i.e., expert-driven) approaches [24,39,63–65]. In the case of the latter, opting for careful design over the 'quick fix' requires organizational resources (e.g., dedicated and qualified personnel to design, implement and link public involvement input to decision-making) that even the most committed decision makers have difficulty justifying [50].

The framework (Tables 1 and 2) and discussion presented here will assist HTA producers and policymakers as they approach the challenging questions of how to bring 'the public' into public coverage decisions and the HTA that supports these decisions. It offers a menu of policy activities in which the public may be engaged, as well as a variety of goals and means for

engaging the public in each. Although not explicitly discussed here, the relative roles for HTA agencies and governments in assuming these responsibilities should also be part of this work. Given the broad, unpredictable and profound implications of health technologies on present and future societies, careful consideration of who is making decisions about which technologies are assessed and funded (and how), is and will remain of profound societal interest.

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