



## A consumer involvement model for health technology assessment in Canada

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Received 21 August 2003; accepted 17 December 2003

### Abstract

Similar to other health policy initiatives, there is a growing movement to involve consumers in decisions affecting their treatment options. Access to treatments can be impacted by decisions made during a health technology assessment (HTA), i.e., the rigorous assessment of medical interventions such as drugs, vaccines, devices, materials, medical and surgical procedures and systems. The purpose of this paper was to empirically assess the interest and potential mechanisms for consumer involvement in HTA by identifying what health consumer organizations consider meaningful involvement, examining current practices internationally and developing a model for involvement based on identified priorities and needs. Canadian health consumer groups representing the largest disease or illness conditions reported a desire for involvement in HTA and provided feedback on mechanisms for facilitating their involvement.

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*Keywords:* Consumer involvement; Health technology assessment; Health policy; Priority setting

### 1. Introduction

Health care delivery in Canada is changing as a result of advances in medical procedures, increased knowledge about diseases and the availability of effective new drugs. For example, hospitalization rates and the average length of hospital stays are declining [1] and outpatient treatment is making health care more cost-effective [2]. The Canadian Institutes for Health Information report that, compared to 20 years

ago, older Canadians can look forward to a longer and better quality of life [3].

However, the rising cost to provincial health plans associated with the aging population and medical advances is increasing the scrutiny with which new technologies are assessed and approved for coverage. In the context of a publicly funded health care system constrained by finite resources, these advances place greater significance on health technology assessment, as decision-makers struggle to balance finite resources while trying to maintain population health [4]. Health technology assessment is defined as the rigorous assessment of any medical intervention utilized in health treatment and maintenance across a whole spectrum of medical and health practices,

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including drugs, vaccines, devices, materials, as well as medical and surgical procedures and systems [5].

Of particular interest to health consumers is the assessment and decision process involved in determining which technologies are covered under the Canada Health Act and which drugs are included on the “formulary” of drugs that the provinces provide for its most vulnerable citizens. These technologies and drugs can be extremely expensive. For example, it is estimated that the cost of a single magnetic resonance imaging (MRI) machine is CDN\$ 4.2 million (US\$ 2.5 million in capital costs, CDN\$ 0.8 million in installation costs, and CDN\$ 0.9 million in operating costs for 1 year) [6].

Directly affecting the public is the availability and cost associated with medicines. For example, the chemotherapy drug Fludara costs between CDN\$ 400 and 700 per treatment [7]. Enbrel, a life-changing drug for many individuals suffering from rheumatoid arthritis costs CDN\$ 330 per week [8]. Biotechnology treatments, while offering hope of more effective treatment with fewer side effects are also increasingly expensive. The biotech treatment, Zevalin, that treats lymphoma can cost as much at CDN\$ 28,000 for a single injection. Similarly, Rituxan, another biotech drug for the treatment of lymphoma and leukemia can cost between CDN\$ 15,000 and 27,000, depending on the number of treatment weeks. [9].

To achieve the balance between finite resources and providing the most effective treatment options, current recommendations are that health technology assessment be based on scientific and objective foundations and on the product’s level of effectiveness and efficiency [10,11]. Gathering and producing the necessary information for analysis has presented major challenges to provincial expert committees. In the past, each province has made HTA decisions with the help of its own committee of health experts. However, in September of 2002, the Federal–Provincial–Territorial Ministers of Health approved the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) as the home of the “permanent, single common drug review”. Essentially, one organization is now responsible for reviewing the applicability of new drugs submitted for coverage under participating federal, provincial, and territorial drug benefit plans.

The common drug review (CDR) process is expected to reduce duplication, maximize the use of

limited resources and expertise and enhance the consistency and quality of drug reviews [12]. While CCOHTA is known for its rigorous review of the scientific material related to health technologies, at present no opportunities exist for consumer input into this process. As of May 2003, CCOHTA was in the process of reviewing nominations for its Canadian Drug Expert Advisory Committee (CEDAC). According to its terms of reference, members of the committee must “hold qualifications as a physician, a pharmacist, an economist, or other professional designation” with expertise in a designated arena [13]. It is readily acknowledged that tough choices are required in order to make the most appropriate decisions concerning whether a province can afford to include a new drug on its formulary list. Many consumer groups feel that alongside scientists, physicians and pharmaco-economists, patients have the most intimate knowledge of the disease and its effects and have valuable expertise to contribute to assessments. Along with providing experiential knowledge, involving consumers in health decision-making is believed to promote a sense of empowerment, provide an efficient solution to the distribution of health resources and is a necessary requirement for health care reform [14].

## 2. Rationale

For the past 25 years, citizen participation in health decision-making has been considered an important feature of responsive and equitable health systems. The federal and provincial governments of Canada have made numerous efforts to increase consumer participation in health initiatives and public policy-making [15–19]. For example, consumers have been represented on hospital boards, consulted for health reform initiatives, and participated in identifying health research priorities. Many consider that patients/consumers have both a moral and ethical right to participate in health care decisions, particularly within the context of a publicly funded health system [19]. In the recent royal commissioned report, *Building on Values: The Future of Health Care in Canada*, Roy Romanow, Q.C., emphasized the need for increased consumer input through the creation of a *Health Council of Canada*. This inter-governmental council would serve “as a meeting place and focal

point for collaboration among governments, providers and citizens in establishing overall system objectives, common indicators and benchmarks, measurement criteria, health tracking and reporting to Canadians on system performance” [20].

Routes for public participation have already been established in other branches of Health Canada, such as the Public Advisory Committee associated with the Health Products and Food Branch. According to their mandate, “the committee is a key component of the Health Products and Food Branch strategy to increase public involvement in policy development through consultation processes. PAC has been established in response to Canadians’ desire for more information about health protection issues and the need for more public involvement in the development of policies and programs designed to protect their health and safety” [21].

Recent years have seen an increasing number of changes in health policy within other countries, all recognizing the need for increased consumer input. For example, over the past 10 years, the United Kingdom has implemented a number of processes for including consumers in health decisions at the national level; from giving consumers a key role in deciding how hospitals will be run [22], to including consumer representation in the development of clinical practice guidelines [23]. The Food and Drug Administration in the United States has implemented consumer representation on their Human Drug Advisory Committees. Implicit in these government-initiated processes to include consumers in policy development and service planning is the recognition that consumers have a different perspective than service providers or health planners.

Further, consumer involvement can contribute to ensuring that policies and programs are more closely attuned to their needs and imperatives [24,25]. Other reported advantages include health care that addresses the specific values, culture and attitudes of citizens. Additionally, consumer involvement provides the opportunity for greater support of resulting decisions and services, a more efficient use of scarce resources, an enhancement of community awareness of health issues, a mechanism for public feedback and increased networking, access to local resources and skills of community members, and an enhanced sense of control and empowerment within the community [26–28].

It has been postulated that consumer involvement is part of new health reforms for theoretical, practical and political reasons [29]. For example, it has been suggested that citizen involvement allows governments to share the blame and pain in rationing decisions [30]; that social justice ideologies prevail, where health services are expected to reflect the values and needs of users and that individuals have the right to participate in services that impact them [31,32]; and that the act of involvement impacts on communities by promoting healthier behaviours, increased education and support [33,34]. Regardless of the reason, consumer involvement is now present in most health care decision-making arenas [35] with the exception of HTA.

“Health experts” such as physicians, researchers, and economists largely dominate HTA decision-making. This situation is antithetical to the belief that acceptable health decision-making requires a process that is transparent, not dominated by any particular interest and reflects the values of all users [36,37]. As a result, there has been a call for greater ethical consideration in health priority setting, largely based on the influence of values impacting decision-making [38–40]. According to Frith, values are influential in how treatments are prioritised.

There may be other factors to take into account, such as the cost of the treatment or its availability. The decision will be made both on the basis of the factual information of effectiveness and the values, priorities and concerns of the decision-maker, which cannot, as the scientist position assumes, be eliminated from the process” ([40], p. 14).

Frith [41] gives an example of how value judgments influence treatment choices for breast cancer. The scientific and systematic review of the evidence indicates that mastectomy and lumpectomy followed by radiation have equal rates of local recurrence and survival rates in early stage breast cancer. As such, the definition of treatment effectiveness will be influenced by the patient’s current situation; a woman who fears a social and marital impact may be more likely to opt for the lumpectomy, whereas another woman may opt for the mastectomy to avoid the radiation and its effects. Health professionals must acknowledge that their values have an influence on HTA decisions and that those values may differ from consumers who

have experienced the effects of an illness, condition or treatment.

Kelson [42] describes the specific contributions that consumers/patients can give into their experiences of, and perspectives on assessing treatment and therapies.

Living/coping with their condition; access to services; perceived benefits and harms of treatments are care regimens; patient preferences for treatment options and care regimens; how well or badly treatment and care are delivered; accessibility, efficiency and effectiveness of care delivery across different sectors; the extent to which outcomes important to patients are achieved; patient and carer information and support needs” ([43], p. 2).

Saltman and Figueras [44] also contend that decisions related to health care priorities are essentially value judgments based on an individual’s personal values. Therefore, it is in the policy-makers’ best interests to ensure that all decision-making processes are open, transparent, and *inclusive*. Only an open, inclusive and transparent system will counterbalance claims that funding issues or the desire to maintain control influences health planners’ decisions.

In order to make HTA a more inclusive process, consideration must be given to the reported challenges associated with consumer involvement. These include: time constraints, lack of representation, difficulty reaching marginalized populations and a lack of education and training specific to consumer participation [44]. As well, a lack of resources, perceived status differentials, processes that are not fully accessible, poor communication, differing definitions of participation, conflicting vested interests, incongruence between stated purpose and practice, tokenism and role strain have impeded consumer participation efforts [45–47]. It seems logical that any plan to involve consumers should prospectively address these issues. One obvious method to address potential barriers to involvement is to ask consumers how to deal with these challenges from their perspective.

Relatedly, determining what is considered *meaningful* involvement is a question best posed to consumer organizations. Levels of participation can range from consultation to decision-making partnerships [48]. The type of involvement utilized depends on the goal of the initiative; however, caution must be exercised to ensure that the decision is not based on fear of power

imbalances, a lack of effort or poor planning of time and resources. Asking consumer organizations what type of involvement is best suited to their needs and resources can circumvent these concerns.

HTA has a profound impact on the health care services, treatment options and resources available to patients, and consumers need to have meaningful input to these processes and decisions. The challenge is to identify applicable models for consumer involvement and adapt these to the specific needs and realities in Canada.

### 3. Methodology

Identifying a model of consumer involvement for HTA involved four stages: (1) a literature and Internet review of existing models or methods; (2) identifying criteria for the assessment of working models; (3) evaluating the models; and (4) surveying Canadian health associations.

An extensive literature review was conducted using the following databases: Medline, PsychINFO, EMBASE, CDSR, ACP Journal Club, DARE, CCTR, CINAHL, and HealthSTAR. Key words used to define the search were: health technology assessment and citizen or user involvement; drug review process and patients; user participation; health policy and priority setting; and, consumer participation, health and evidence-based. As well, an Internet search was performed using the same key words to identify any current working models of consumer participation in health technology assessment. The information from these reviews was used to identify evaluation criteria specific to both consumer and health professional perspectives and associated with the current method of HTA evaluation, i.e., a decision-making committee. These criteria were then applied to existing working models of consumer involvement to identify strengths, weaknesses and gaps. A survey of Canadian health associations was then designed according to needs identified in the analysis of the working models.

Participants in the survey were selected in two stages. Initially, 81 groups were chosen from a large established database that had been compiled from the book *Associations in Canada* [49]. Only groups that were active in advocacy and information dissemination on behalf of their members were targeted for

Table 1  
Consumer health associations who responded to the survey

Group	National or provincial	# Canadians affected by condition
Allergy & Asthma Information Association	National	1000000
Allergy & Asthma Information Association (ON)	Ontario	As above
Alzheimer Society (PEI)	PEI	364000
Alzheimer Society of Canada (NF & LBR)	Newfoundland & Labrador	As above
Amyotrophic Lateral Sclerosis (ALS) Society	National	1500
Anaemia Institute	National	Currently unavailable
Arthritis Society	National	4000000
Arthritis Society (AB & NWT)	Alberta & NWT	As above
Arthritis Society (BC & Yukon)	British Columbia & Yukon	As above
Arthritis Society (PEI)	PEI	As above
Asthma Society of Canada	National	2245200
BC Lung Association	British Columbia	3000000
BC Persons with AIDS Society	British Columbia	40000
Canadian Arthritis Network	National	See arthritis
Canadian Arthritis Patient Alliance	National	See arthritis
Canadian Association for Independent Living Centres	National	1400000
Canadian Breast Cancer Network	National	See general cancer
Canadian Cancer Society	National	136900
Canadian Cancer Society—AB/NWT	Alberta/North West Territories	As above
Canadian Cancer Society—NB	New Brunswick	As above
Canadian Cancer Society—NS	Nova Scotia	As above
Canadian Cystic Fibrosis Foundation	National	3300
Canadian Diabetes Association—ON	Ontario	2000000
Canadian Diabetes Association (SK)	National	As above
Canadian Haemophilia Society	National	3000
Canadian Liver Foundation	National	2800000
Canadian Liver Foundation—BC	British Columbia	As above
Canadian Liver Foundation—NB	New Brunswick	As above
Canadian Liver Foundation—NS	Nova Scotia	As above
Canadian Mental Health Association (MB)	Manitoba	7000000
Canadian Network for Asthma Care	National	As above
Canadian Prostate Cancer Network	Saskatchewan	See general cancer statistics
Canadian Treatment Action Council (CTAC)	National	See BC persons with AIDS
CARP, Canada's Association for the 50 Plus	National	3888550
Epilepsy Ontario	Ontario	300000
Haemophilia Ontario	Ontario	As above
Haemophilia Saskatchewan	Saskatchewan	As above
Heart & Stroke Foundation	National	689400
Heart & Stroke Foundation (PQ)	Quebec	As above
Heart & Stroke Foundation (ON)	Ontario	As above
Hepatitis C United Resource Exchange (Hep Cure)	National	100000
Hepatitis C Resource Centre (MB)	Manitoba	As above
Kidney Foundation of Canada	National	190000 (Stats Can)
Lupus Canada	National	20000
Multiple Sclerosis Society of Canada	National	50000
Osteoporosis Society of Canada	National	1400000 (Stats Can)
Spina Bifida & Hydrocephalus Association	National	1 in 1000 children born in Canada are affected
Titz n Glitz Breast Cancer	Nova Scotia	See general cancer statistics

the study. In the second stage, the list was expanded in order to ensure contact with as representative a sample of health consumers as possible. Burden of Illness data from Statistics Canada was scanned to identify those diseases or conditions that affect most Canadians. Conditions identified include: cardiovascular disease, mental illness, liver, lung and kidney diseases, osteoporosis, cancer, asthma, diabetes and arthritis. The websites associated with those conditions were then examined to identify current statistics of Canadians associated with those organizations. From this population, 15 national organizations and their provincial chapters were added to the list.

Twelve national chapters responded to the initial contact. Of those organizations, three or four of their provincial chapters were contacted in order to gain a cross-Canada representation. Of the 143 organizations contacted, the final study sample comprised interview data from 25 national and 24 provincial organizations, resulting in a 34% response rate. (A total of 55 interviews were performed, however data from six interviews were discarded since their focus was either entirely regionally-based or related to fundraising for research activities, and as such, did not fit the inclusion criteria.) Table 1 describes the groups that responded to the survey, representing a large number of Canadian health consumers.

The majority of the questionnaires were administered via semi-structured telephone interviews. The selected groups were emailed an information sheet about the study and health technology assessment in Canada as well as the actual survey questions. The participants were then contacted by phone and an interview time scheduled. The semi-structured interview consisted of both open and closed ended questions, and participants were given many opportunities to add comments freely. One individual conducted the telephone interviews. Half of the interviews were randomly taped in order to ensure the accuracy of the results. Telephone interviews were chosen as the primary methodology since they: provide rich information, allow consumers the opportunity to provide feedback on related matters, offer participants a degree of anonymity, and, are more cost and time effective than face to face interviews [50]. Organizations were also provided the opportunity to fax or e-mail the questionnaire if time did not permit a telephone survey. In total, 39 organizations completed the survey via telephone in-

terviews, and 10 organizations responded by fax or e-mail.

## 4. Results

### 4.1. Defining meaningful consumer involvement in HTA

Based on the review of the literature, three decisions were made regarding meaningful health consumer involvement in HTA: (1) that focus would be placed on involvement versus consultative strategies; (2) that the most feasible type of involvement based on current practices involved consumer participation on a decision-making committee, and (3) that both health professional and consumer perspectives would be represented. These decisions led to the following sources for evaluation criteria: (1) Elements of Fairness Framework identified by Martin et al. [51] which identified eleven specific elements related to fairness to supplement the fairness and accountability for reasonableness criteria [52]; and (2) The Conceptual Framework for Citizen Involvement in Health Planning by Pivik and co-workers [53].

The Elements of Fairness Framework is based on the perspective of priority setting decision-makers and includes: external transparency, multiple perspectives, external consultation, consensus, honesty, identifying potential conflicts of interest, an appeal mechanism, leadership, internal transparency, understanding, opportunity to express views, and agenda setting opportunities.

The Conceptual Framework for Citizen Involvement in Health Planning was developed specifically for community and institutionally based consumer participation. The recommendations were derived from an extensive literature review that synthesized the wisdom and opinion of consumers, health professionals and governments who have had experience and expertise related to citizen involvement in health planning. Information describing the techniques, strategies and recommendations for facilitating citizen involvement came from journal articles, occasional papers and reports from consumer organizations, health care institutions and governments. The recommendations comprising this framework are grouped into four broad categories and include: (1) nurturing a climate

conducive for citizen participation (mobilizing the community, fostering respect and trust, developing an attitude shift for professionals and utilizing a partnership approach); (2) process issues (defining partners, developing a common vision, clarifying roles and responsibilities, defining a decision-making process and assessing participation); (3) knowledge requirements (information, education and training); and (4) support requirements (financial, organizational and political).

These sources provided the criteria used to evaluate health consumer involvement models identified in the Internet search. The evaluation focused particularly on the Elements of Fairness Framework listed above, process issues, the establishment of roles and expectations, the transparency of the decision-making process, and the ability for patients to obtain the knowledge, information and support they need to participate. The inclusion of these elements in current models was identified as a strength, their absence as a weakness.

#### 4.2. *The search for working models*

No models specific to consumer involvement in HTA were identified, a finding also noted by Wade et al. [54] in their search for best practice models for engaging consumers in the quality use of medicines. However, two models were identified which matched the criteria in all other ways: the National Institute for Clinical Excellence (NICE) Citizens' Council in the United Kingdom; and the Breast Cancer Network Australia Consumer Representative Project in Australia. There is also evidence that both these nations are considering consumer involvement in health technology assessment [55,56].

In 2001, the National Institute for Clinical Excellence in the UK launched the Patient Involvement Unit (PIU), an independent body within the College of Health of the National Health Service. The PIU facilitates interaction between NICE and patient organizations at defined points in the guidelines process and provides support to those patient representatives who are involved in guidelines development. Currently, the unit supports patient and caregiver involvement in the development of clinical guidelines, but is expecting to expand to the technology appraisal process in the near future.

Australia's experience with consumer involvement was highlighted by the 1997 launch of the Consumer

Focus Collaboration, established under the National Expert Advisory Group on Safety and Quality in Health Care, to strengthen the focus on consumers in health service planning, delivery, monitoring and evaluation. In March 2001, the CFC provided funding to Breast Cancer Network Australia to develop a model for recruiting, selecting and supporting consumer representatives affected by breast cancer.

These models were assessed using the evaluation criteria described above and are presented in Tables 2 and 3. Strengths and weaknesses of the models were identified and then used in the development of the survey of Canadian health consumer organizations. The NICE model of the United Kingdom brings the strengths of a nationally supported infrastructure framework; where consumer involvement is integrated into health policy decision-making. The Breast Cancer Network of Australia model's main strengths lie in the comprehensive processes developed for involvement from the consumers' perspective.

#### 4.3. *A Canadian perspective*

Based on both the strengths and weakness of these models, it was determined that the following factors need to be examined from a Canadian perspective in relation to HTA and consumer involvement: (1) the type of involvement preference (from consultation to decision-making); (2) needed informational resources; (3) the best methods for providing that information; (4) other resources that would facilitate involvement; (5) accessibility issues; (6) feedback mechanisms of the health organization; (7) the level of interest in a database that would list members' skills, knowledge and level of expertise; (8) importance for consumer involvement in health technology assessments as well as the common drug review process; and (9) timelines required for consumer involvement. To that end, an interview questionnaire was developed that addressed those issues.

The questionnaire focused on HTA in general, however, two questions concerned the CDR process. These included: (1) were you aware of the CDR process? And (2) how important is it that your organization is involved in the drug assessment process?

Descriptive analyses were used to evaluate the quantitative data and thematic analyses were employed for the open-ended answers using Hycner's guidelines

Table 2  
The National Institute for Clinical Excellence Citizens Council (NICE), UK<sup>a</sup>

	Strengths	Weaknesses
1	The Commission for Health Improvement is a national governmental initiative to involve patients in clinical governance processes, where patient experiences and social values judgements are defined as one of the key tests of effectiveness of management	Guideline developers (which do not include patient representatives) determine: (1) the scope of the project, (2) whether patient information is to be included as evidence, and, (3) what guidelines are developed
2	The Patient Involvement Unit (PIU) is a semi-independent supporting unit of NICE; based at the College of Health, a national charity that promotes patient interests in the National Health Service	NICE has total control of who the patient representatives will be
3	NHS policy explicitly states that services are to be based around the needs of the patients vs. the organizations; with the aim of developing fair, transparent and defensible methods of patient involvement and that patient issues and perspectives are directly addressed and presented in meaningful ways to patients	Mechanisms need to be put in place that assists in evaluating qualitative or anecdotal evidence from patients. However, the Patient Impact Assessment project is currently being evaluated which may address this issue
4	NICE has developed a formal stakeholder consultation process	Training for professionals not identified
5	PIU coordinates the identification of potential patient representatives through a database	Patient representatives are typically short term, providing feedback but not meaningfully involved in committee decision-making
6	A mechanism is in place where national organizations can register to become part of the consultation process	Developers are given 1 year to develop the guidelines but patient groups are only given 1 month to review them. This time line makes it difficult for patient groups to get feedback from their constituencies. In November 2002, the board is examining a recommendation from the Citizen's Council for extending the tenure for a minimum of 2 years
7	Patient information on guideline development process is created and distributed by PIU	
8	8 PIU expects all guideline groups to have 2 patient representatives	
8	9 Training and resources are provided to patients to facilitate their involvement	
10	PIU has an evaluation component associated with patient involvement	
11	Feedback is provided to patient groups and the public	
12	Patient representatives are paid to assist in clinical guideline appraisals	

<sup>a</sup> National Institute for Clinical Excellence (see <http://www.nice.org.uk>).

[57] for qualitative data analysis. Hycner's guidelines involve initially examining the data to determine the context of potential themes, and then delineating it into units of meanings relevant to the research purpose, where themes and meta-themes are identified.

$\chi^2$ -Analyses (categorical data) and *t*-tests (continuous data) were performed to determine if there were

significant differences in responses between the national and provincial organizations. Only two questions indicated significant differences, and thus the data were combined for the remaining questions. However, when the mean responses indicate differences at  $P < 0.05$ , both the provincial and national data are reported.



Table 3  
The Breast Cancer Network Australia's model<sup>a</sup>

	Strengths	Weaknesses
1	Extensive consumer consultations to develop the process, resources for the patient involvement model	No policy stating that each committee should have more than one patient representative
2	Selection of patient representatives is conducted by the consumer organization	No policy requiring patient representatives to be paid for their involvement, in fact, they are typically volunteers
3	National database of potential patient representatives that includes Diagnosis Treatment Skills Expertise Interests	Evaluation process discussed but not implemented to date
4	Request for patient representatives broadly disseminated	
5	All patient request submissions reviewed	
6	Selection of patient representative by consumer-based selection committee through consensus	
7	Guidelines regarding role and responsibilities are provided to patient representative prior to their acceptance	
8	Informational kit provided to patient representatives that includes Guidelines for working on committees Research glossary Information about the topic (cancer) A list of additional resource material/sources	
9	Informational kit for organization/professionals	
10	Training is available to all patient representatives and includes Understanding the health system Communication and networking skills Advocacy skills training Scientific aspects (biology, risk, epidemiology, screening) Information about diagnosis, treatment, multidisciplinary care Making sense of scientific research: clinical trials, reading and appraising research articles, issues associated with evidence-based medicine Information on libraries, medical literature, Internet	
11	Replacement process in place if patient representative becomes ill or unable to attend	
12	On-going support provided to patient representatives via consumer organization	
13	Information dissemination strategies using Internet, e-mail, newsletter	
14	Patient representatives involved in committee decision-making	
15	Entire process has external and internal transparency	

<sup>a</sup> A model for selecting and supporting consumer representatives: Breast Cancer Network Australia's process (see [www.bcna.org.au](http://www.bcna.org.au)).

The 49 health consumer groups who completed the survey interview represent a large number of Canadian health consumers. Along with representing the greatest number of patients in Canada, they also represent all provinces and territories except Nunavut. The groups were active in advocacy and information dissemination on behalf of their health consumer members. Of the 49 organizations that responded to the survey, 67.3% are currently involved in decision-making activities related to health, or in helping their constituents choose between similar treatments or therapies. Of this group, only two organizations were involved in decision-making activity related to drug selection while the other 47 organizations focused on providing education, counseling, and support to their members in order to help them make their own decisions related to health. Ninety-six percent of the organizations' mandate involves advocacy for their constituents. In general, these organizations advocate on behalf of their constituents for anything related to their condition, including access to treatment. The organizations' chief executive officer completed the majority of the surveys.

#### 4.4. Is consumer involvement in HTA a priority?

When respondents were asked to rate how important it is for their organization be involved in the treatment or therapy assessment process on a scale of 1–10 (where 1 is not at all important and 10 is extremely important), the majority of responses (89%) reported the level of importance for being involved at 7 or greater, with 46% of respondents reporting their participation as a 10 or "extremely important".

Virtually all respondents (98%) felt that consumers had important information to add to the CDR process and that consumer input was essential to legitimate CDR assessments. In the words of one respondent: "Consumers must have effective meaningful involvement in the CDR decision-making process, which must be transparent and include an appeal mechanism." National and provincial health consumer organizations in Canada associated with the major disease states or conditions are therefore very interested in having a role in priority setting for both HTA and the CDR process, and consider their involvement to be very to extremely important in these decision-making processes.

#### 4.5. How would consumer groups be involved?

Groups were asked what type of involvement they wanted, and were able to select as many of the mechanisms that their organization would be interested in participating in with regard to the assessment of treatments or therapies. All respondents (100%) wanted updated information and over 70% expressed willingness to participate in other ways: 82% would fill out surveys, 80% would participate in focus group discussions, 74% would take part in key informant interviews, 71% would be willing to participate in community forums, and 71% would be willing to send representatives to take part in a decision-making committee.

When asked to choose a primary involvement type for their organization, half the provincial groups (50%) and a quarter of the national groups selected updated information, while half the national groups (52%) and 38% of the provincial groups selected assigning a representative to decision-making body. An examination of the comments indicated that choosing updated information as a primary involvement choice was not necessarily the "best case scenario" but the "most realistic based on past experiences".

#### 4.6. What resources would they need to participate?

##### 4.6.1. Information

Respondents were asked to indicate what type of information they considered necessary for meaningful involvement for a member of their organization to make decisions about health technology assessment. They were allowed to select as many of the options as they considered useful. Almost all (92%) felt they would need information on the specific treatment being reviewed; 89% wanted information on health issues, health policies and programs; 78% wanted information that would help them understand the scientific research process, including information about how clinical trials are conducted, how to read and appraise research articles, as well as information on issues associated with evidence-based practice. Information on effective communication and networking skills was important to 78% of the national organizations but only 42% of provincial organizations, a difference that was statistically significant ( $\chi(1, 48) = 4.1, P < 0.05$ ).

Regarding the best methods for imparting the above information, 76% thought workshops would be effective, 60% (national), 42% (provincial) wanted information presented in easy to read manuals; 92% of national groups and 50% of provincial groups ( $\chi(1, 48) = 10.5, P = 0.001$ ) believed guidelines over the Internet would assist. Organizations that used the Internet extensively were most interested in that form of dissemination (this tended to include most of the national organizations). The provincial organizations that did not use electronic information dissemination tended to prefer workshops. Regardless of mode of transmission, participants stressed the importance of “ensuring that the information is presented in lay language”.

4.6.2. Resources

Respondents were asked to indicate what resources would be necessary for members of their organization to achieve meaningful participation on a HTA committee. Fig. 1 provides a breakdown of needed resources by provincial or national organizations.

National and provincial organizations felt that educational material, reimbursement of expenses and access to experts for advice would facilitate their involvement. The low response for payment for services was unexpected.

4.6.3. Accessibility requirements

Sixty-three percent of respondents indicated that accessibility issues would need to be considered to make participation possible. The main accessibility issues were physical accommodations (mentioned by 31%) which ranged from meeting places that are wheelchair accessible, opportunities for breaks dur-

ing longer meetings, and accommodations related to one’s illness or disability such as scent-free rooms for people with asthma. One respondent emphasized the need to “always ask them what they need.” Also of concern to some were financial requirements (16%); primarily reimbursement for travel expenses, and geographical considerations such as the location of the meeting and the time required to travel.

With a view to facilitating access to specific advice or expertise, respondents were asked to indicate whether their organization would support the idea of a database that listed members’ skills, knowledge, and level of expertise. Eighty-three percent of respondents supported the idea of a database. Some responders stressed the need to ensure the consent of participants.

4.7. Willing to participate on a Decision-Making Committee?

Given the necessary resources and support, the majority of organizations considered HTA important enough that they were willing to participate in a Decision-Making Committee that involved a significant time commitment. Eighty-eight percent of the national organizations and 71% of the provincial organizations indicated that their members would be willing to participate on a Decision-Making Committee that lasted between 12–18 months (participants would meet for 1 day, once each month), 10% responded “maybe”, 4% didn’t know, and 6% said “no”.

4.8. Committee composition

Respondents were asked to indicate how many patient representatives should sit on a ten-person

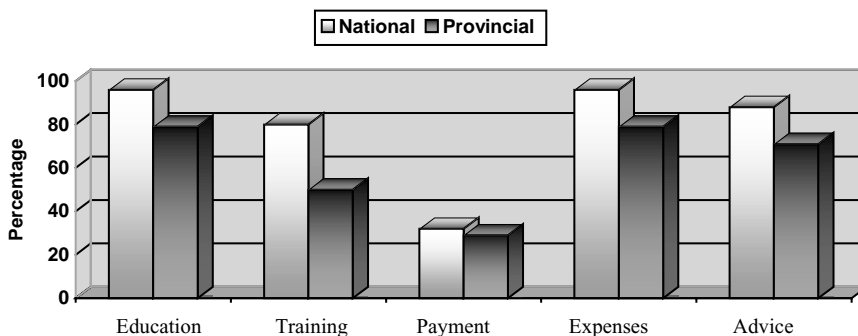


Fig. 1. Necessary resource support for consumer involvement on a Decision-Making Committee.

Decision-Making Committee. Fifty-eight percent of responders believed there should be at least two patient representatives, while 21% felt there should be at least three.

#### 4.9. Constituency feedback mechanisms

For consumer organization representatives to truly represent their constituencies on decision-making bodies, they must be able to acquire feedback to and from their organization on specific issues that arose in HTA discussions. The survey sought to determine how decisions were made within the organizations, what mech-

anisms were used for communication, and how much time would be needed for this sort of internal consultation to take place.

Typically, health consumer organizations maintained that their Board of Directors was responsible for “strategic” decision-making while management and advisory committees made day-to-day decisions. In terms of getting feedback from their constituency, 65% use electronic means, 18% hold meetings and 8% use mailings. Although many organizations stressed that important decisions are expedited, typical response time for getting feedback from their constituents was greater than 30 days for 30% of

Table 4

Consumer involvement model for health technology assessment in Canada

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A fair and transparent process of consumer involvement in health technology assessment requires an independent organization that works in tandem with but is not governed by the centralized review committee. This consumer organization should be nationally based and supported.

#### Federal Government

Funds the development and sustainability of an independent consumer-led organization focused on health technology assessment

#### Health Technology Assessment Consumer Organization (Mandate)

The development of a *health consumer network* interested in health technology assessment

The development of a *formal health consumer stakeholder involvement process* that considers

- Selection
- Feedback mechanisms
- Timelines
- Accommodation needs
- Training and educational support
- Access to expert advice

The development of a *national database* that includes health consumer knowledge, interests, skills, expertise

Coordinates *health consumer selection* for HTA committee. Provides *training and educational* support for health

- consumers in lay language on
- Health issues, health policies and programs
- Information on the therapy/treatment being reviewed
- Information on the scientific process
- Information on the research process
- Information on planning and evaluating
- Information on procedures for meetings
- Information on communication and networking skills
- Develops and maintains a *web page* for information dissemination
- Organizes and runs educational *workshops*
- Evaluates program and process effectiveness

#### Health Technology Assessment Committee

- Recognizes and supports the formal health consumer stakeholder involvement process
  - Decision-Making Committees involve a minimum of 2 health consumer representatives for the entire duration that each technology/therapy is reviewed
  - Funds made available for reimbursement of expenses and salary/honorarium if desired
  - Funds made available to ensure accommodation needs of health consumers (financial, geographical, physical)
-

the groups interviewed. Thirty-six percent stated they could get feedback from their constituencies within 10 days.

#### 4.10. A consumer involvement model for HTA in Canada

Findings from the survey were combined with the strengths of the existing international models to develop a model of consumer involvement in health technology assessment for Canada (see Table 4).

The model is essentially a guideline of pertinent issues and questions that should be considered and discussed by organizations interested in promoting meaningful consumer involvement in health technology assessment.

### 5. Discussion

More research examining evidence-based practices is needed in consumer health decision-making. Although this study provides a glimpse into strategies that would facilitate involvement from the perspective of health consumer organizations in Canada, more research is needed to determine if the model is applicable to other health systems. An effort was made to balance primarily health professionals' perspectives (the Elements of Fairness Framework and the NICE working model) with primarily consumer perspectives (The Conceptual Framework for Consumer Involvement and the Australian Breast Cancer working model). Evidence-based research looking at the effectiveness and efficiency of these different perspectives would provide further information into their usefulness under different settings, initiatives and programs.

The main focus of the survey was to broadly identify meaningful consumer involvement strategies for assessing all treatments or therapies, although a few questions specifically asked about participation on a drug assessment committee. In general, the survey addresses the questions most health organizations confront when attempting to involve consumers, i.e., what kind of participation are they interested in? What resources are needed to meaningfully involve them? How many consumers should be involved? How will they communicate with their constituency to ensure representation? Will more time and resources be needed to involve consumers? Presumably, the an-

swers to these questions would apply to other health initiatives assuming the goal is important to health consumers. However, research would confirm whether these questions are valid to other health initiatives beyond participation in an HTA Decision-Making Committee.

Three answers on the survey provided unanticipated results. The first was the question of payment for involvement. Payment has been suggested as a way to promote involvement of individuals who are typically under-represented in these committees and are not able to commit additional time without remuneration [58,59]. This is important since the individuals who are participating must be able to represent a larger collective. If, for example, most of the consumer participants are retired as noted in earlier research [60,61], there is a potential for skewed feedback. However, the majority of health consumer organizations surveyed in this study did not want payment for participation, a finding also noted by Ahern et al. [62]. Early on in the survey when it became apparent that many were saying no to payment, we began to ask why, and the answers were interesting. Although most organizations felt that reimbursement for expenses were appropriate, there was a divide between being given an honorariums as a sign of respect of their expertise and the belief that being a volunteer was synonymous with dedication to a cause (where payment would call into question that dedication). Also, most of the organizations were volunteer based and had policies against payment for services. Finally, it was mentioned that payment would negatively impact on one's applicability for disability benefits. Further research into the issue of payment for involvement, the socio-economic status of the participants, the amount of time spent volunteering and the representiveness of the participants is needed.

Another unexpected result of the survey was the organizations' response to interested involvement type. The organizations were provided with options such as: being provided with up to date information, being involved in community forums, answering surveys, participating in focus group discussions, participating in key informant interviews, and being part of a Decision-Making Committee. This question addresses not only the activities of participation but also the level of power or decision-making that the organization desires regarding health care decision-making. Some studies have suggested that consumers do

not really want or feel capable of making rationing decisions [63,64], while we suggest that consumer decision-making can be facilitated with educational support and a focus on the expertise of each participant [65]. In other words, not asking health consumers to understand the pharmacological properties of a certain drug or the technology behind a heart valve, but rather seeking their feedback on the experiential knowledge of living with a health condition and providing information and support in those areas that would promote further participation. Although 75% of the organizations were interested in most aspects of participation, when asked to pick a primary type, there was a distinct divide between the provincial and national organizations. The provincial organizations primarily chose receiving up to date information (no decision-making power) while the national organizations chose involvement in a Decision-Making Committee (high involvement type). As mentioned, the qualitative comments indicated that information provision was not necessarily the best option but the status quo for many of these organizations. It would be interesting to determine whether the preferred involvement type is a reflection of current decision-making processes, that is, is the system set up where provincial organizations rely on their national offices to make certain types of decisions? Although this may be true, it appears that the answer also has to do with support and resource issues. When asked whether their organization would participate in a Decision-Making Committee that lasted up to 18 months, provided that they were given the necessary support and resources, 88% of the national organizations and 71% of the provincial organizations agreed.

The final question that provided interesting results was that of committee composition, i.e., how many consumers should sit on a 10 person Decision-Making Committee. This question indirectly addresses the issues of power and tokenism. Seventy-nine percent of the health organizations believed there should be at least two or three consumer representatives. This suggestion is consistent with research conducted by Martin et al. [66] where committee membership is facilitated when there are more than one patient representative. Although no organization wanted a single representative, only 2% of the responders felt there should be five or more representatives. To have 20–30% consumer representation on a committee

typically dominated by health professionals speaks to a sense of confidence and assurance on the part of these health organizations.

## 6. Conclusion

Based on the results of this national survey of health organizations, health consumers believe they should have a role in determining their treatment options. By providing support and training, these organizations believe they would be capable of and are willing to devote a considerable amount of time and effort to have an influence on the assessment and evaluation of potential treatments and therapies and their availability for access.

In order to have a fair and transparent process, an independent consumer led organization dedicated to health technology assessment should be created and supported by the national government. This HTA consumer organization would be responsible for developing a network with health organizations, the development of a database of health consumers' expertise, knowledge, etc., the development of a formal health consumer stakeholder involvement process, the training and education of health consumers, information dissemination, and the evaluation of the processes and program. These activities would provide this organization the support and resources needed to nominate the most effective health consumers to participate in HTA committees.

This model also requires the support of the central organization conducting HTA reviews to respect the health consumer stakeholder involvement process and provide resources for accommodating the needs of these health consumer experts. Although this model will require systematic evaluation, it stands to reason that more informed decisions would be made when all of the experts, including those most directly affected, are involved in the process.

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