# A Canadian Partnership of Patient/Citizen Groups and Government: Engagement in National Health Initiatives and Policy Directions

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**Abstract**

Patient and citizen groups from across Canada expect to be 'engaged' in discussions and decisions regarding Canada's health care system and policy reform. Many chronic disease and non-government organisations such as the Best Medicines Coalition (alliance of patient and consumer organisations) of Canada, along with Health Canada, health professional associations, pharmaceutical companies, and other stakeholders, came together at a National Health Summit in January 2004 to discuss the development and implementation of a partnership and framework for patients, citizens, and government.

There are several outcomes from this summit, including: (1) the formation of a partnership among patient and stakeholder groups, Health Canada and other organisations; (2) the development of a patient and citizen partnership and engagement framework; (3) the implementation of patient and citizen representation on Health Canada advisory committees, and for strategic planning discussions; (4) the coordination to address 29 outstanding recommendations from the National Health Summit 2002, primarily concerning the drug review process; and (5) improvement of communications between government and stakeholder groups.

A partnership among patient and citizen groups, government and other stakeholders is a good beginning to implementing a framework for meaningful engagement of patients, consumers and stakeholders in the discussion and decision-making related to health and health care policies. In addition, a training program is being developed for patients, consumers, and citizens to be prepared as representatives on decision-making committees. Research is being conducted on the framework and training program to ensure that they are practical and will meet the needs of patients, consumers and stakeholders, as well as decision makers. The processes of engagement of citizen groups will continue to be evaluated, but more needs to happen for effective partnership outcomes and for unconditional patient/citizen engagement in national health initiatives and policy decisions.

**Keywords**

National multi-stakeholder partnership, patient and citizen involvement/engagement framework, decision-making processes

## Introduction

There is a substantial history linked with the development of a partnership between patient/consumer groups and government, and a framework for patient and stakeholder engagement in decision-making processes at the national or provincial health levels. In the 1990s, some of the first initiatives began with several national community organisations (e.g. Canadian Treatment Action Council for HIV/AIDS, and Hepatitis C Network) advocating for access to specific drugs in a timely manner. Being confronted with a situation of not being able to access medications in Canada when they are available in the US or elsewhere, patient advocates will stop at very little to become part of the decision-making processes to bring life-saving drugs into Canada and have them approved for access in an expedited manner. Now there are other groups and coalitions which advocate for patient and stakeholder involvement in the decisions concerning general and specific health care and drug reform in Canada. No longer is it adequate for the Canadian government to make decisions without the involvement of patients, consumers, health professionals, and the public.

The purpose of this paper is to present some of the background process and outcomes related to the creation of a Canadian-made partnership between government and citizen groups, and of a citizen engagement framework. Processes will specifically be described for outcomes achieved for the (1) formation of a partnership among patient and stakeholder groups, Health Canada and other organisations; (2) development and implementation of a patient and citizen partnership and engagement framework; (3) representation of patients and citizens on Health Canada's advisory committees, strategic planning discussions; and (4) coordination of responses for the 29 outstanding recommendations from National Health Summit 2002, primarily concerning the drug review process; and (5) improvement of communications between governments and all stakeholder groups.

## Significance of patient/citizen engagement

When the question is raised as to 'why' citizen engagement in decision-making processes are important, there are a number of studies and reports from the past five to ten years that confirm the public interest in the healthcare system, its reform, and the policy impact on citizens in general. First of all, studies conducted by the National Consumer Council of England (2002) make the case for citizens or consumers to be involved in decision-making processes even though their work also indicates their confusion of how or why they would be involved — other than giving individuals and communities a voice on issues, establishing a change in a law that should enhance citizen safety and care, and creating more public awareness and involvement. These reasons for people becoming involved supports the view taken by the public on heath care reform and issues. The public has stepped forward to admit that the way things currently are in the health care system is not working well. Waiting lists are increasing or at least not going down, health professional labor shortages are affecting the service delivery and access for patients and citizens, drug access is changing to the lowest cost drugs regardless of whether or not they are effective, and other issues. The concept of self-management of disease is becoming more of a reality, but citizens need to be prepared to make these changes and also receive the resources, medicines, and prevention interventions, as well

education about what the evidence supports for positive health outcomes and quality of life (Montague 2004). The quality of care and access to drugs and services is critical. But how are these measured and who is accountable? Reports do exist that include a variety of measures such as financial measures, indicators of resource use and outcomes, measures of access and waiting times, and the satisfaction of citizens (Baker et al. 2005). More research in this area is needed, particularly concerning the type of data and information needed by citizens or patients who not only need to be part of the decisions regarding cost cuts and reform, but also need to self manage their health or disease. Healthcare performance measures as well as accountability and transparency of these with the public would provide a good reason to have citizens more actively engaged in decision-making, which would in turn make citizens more responsible and accountable for their health and self-management of disease. Romonow stated:

> "…healthcare organizations are expected to show transparency in the provision of care to the public, as well as to governments and stakeholders who seek information on the quality of care and services provided. Strengthening accountability may include goals such as increasing public knowledge about whether the system is being effectively managed, money is well spent, and efforts are being made to improve in areas where performance information has raised concerns. Accountability and transparency have undoubtedly been increased simply by making performance data available to the public" (Morris and Zelmer 2005, p. v).

By having citizens involved in decision-making discussions, there would be evaluations built into various processes to examine the primary goals and outcomes of healthcare services and programs. These processes would include such things as Health Technology Assessment, which implies that new health innovations, drugs or other technologies will impact on patients or citizens and will need to be assessed for their effectiveness in making a difference for patient outcomes. Good technologies will be in high demand, which will have an impact on the health care system and costs involved. The public including patients need to be part of the health technology assessment or evaluations and also part of the policy decisions made as a result of approved health technologies (National Health Services 2005).

Citizens, therefore, have a role to play in evaluating policies and the research and evidence used to support policies (Pestieau 2003) and in contributing towards the experience and knowledge coming from living with diseases or conditions, or a health care system which may not be meeting their needs. Different evidence, types of research and methodologies provide decision makers with different perspectives and ways to tackle persistent issues and make relevant policies.

**Background and context**

In the 1990s in Canada, citizens became more critical about the health care system, particularly since the system was increasingly failing on delivering high quality and timely access to safe care in hospitals. Increased expenditures in care and prescription drugs raised the question of sustainability of the present heath care system. Canadians were asking for major reform but not a total dismantling

of the system (Abelson et. al, 2004). Canadians have and will continue to believe that health care is the ‘right’ of every Canadian citizen, but they are not necessarily in favor of a market-driven, privatised system such as in the US. Core services need to be preserved for every Canadian to access, while non-core can be approached from different options.

In theory citizen participation in health planning and policy decision is supported by international, national, and regional governments, other organisations, consumer groups, and health researchers (Pivik 2002). The perception and the reality of who is involved in policy decision-making are quite different from the theory. The perception is that depending on the venue (meeting, committee, council, forum, town hall meeting, focus group, consultation, other), there needs to be appropriate representation from all stakeholder groups who would be impacted by decisions coming out of policy or other directives. The reality is that policy is most often made by high-level politicians, board members or other persons in positions of power or authority or expertise. It is rare, in fact, to see citizens or the public involved in these processes. This latter attitude and position is what is being challenged by various citizen or health stakeholder groups.

One other shift in thinking regarding citizens and their involvement is with the meaning of involvement. There are many different forms of being involved, from receiving information, exchanging information, consultation, involvement, engagement, to partnership. There is a continuum of the different types of involvement (Figure 1), and the most common is providing information or consultation with citizens, when what is more desirable is engagement. The optimum is citizen engagement, which means that citizens are actively part of the interactive debate, discussions and results for policy and program decisions. There are active discussions between government and citizens and between/among citizens themselves. Citizens are exercising their democratic rights regarding policy decisions, and the purpose is to ensure that citizens contribute in a meaningful way to specific public policy or program decisions in a transparent and accountable manner (Phillips and Orsini 2002; Graham and Phillips 1998; Abele et al. 1998; Mendelsohn and McLean 2000).

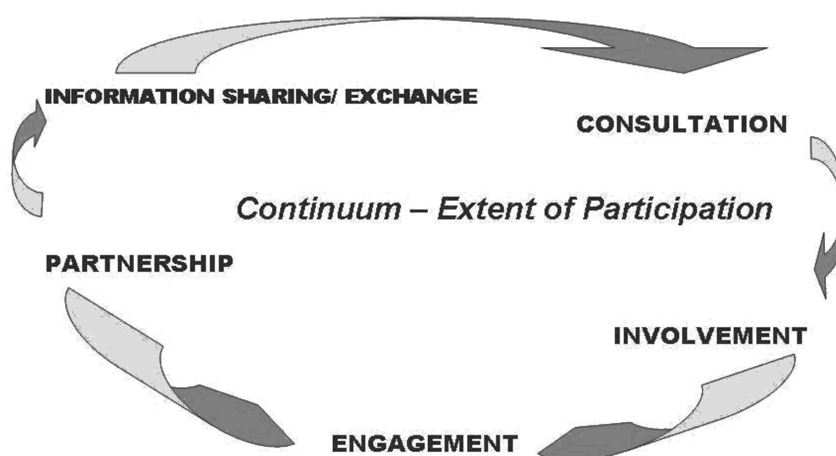


**Figure 1. Extent of public participation**

Source: Adapted from Health Canada (2005)

**1. Historical context of patient and consumer advocacy efforts**

Much of the earlier advocacy initiatives involved patients' needs to access specific drugs, such as for HIV/AIDS, which were not available in Canada but were available in Europe or the United States. Access to new effective medicines is a critical quality-of-life issue for Canadian patients and fundamental to our health-care system. But for many disease and disability groups, Canadians wait 18 months to two years longer for new medicines than citizens in other countries such as the United States, the United Kingdom, Australia and Sweden (Rawson 2002). The federal government and the Common Drug Review are responsible for reviewing new drugs and have made improvements in the timeliness of access to drugs in Canada, but there is still a long way to go before Canadian patients receive the same timely access as in other countries.

The drug review system in Canada has been the subject of many internal and external reviews over the past 15 years. The objective of these reviews has been to identify opportunities to improve the system (i.e. to recommend changes that will result in a more efficient and timely review system without compromising the quality of the decisions involved).

In the fall of 1998, a Health Canada sponsored Working Group on the drug review process or system was formed. The Working Group completed its research and delivered a series of recommendations for improvements to the system in August of 1999. Those recommendations, which focus on increasing the systems resources, efficiency, comprehensiveness, timeliness and transparency, were subsequently satisfied by a much broader spectrum of stakeholder groups — at a consultative workshop. The underlying message from the attendees was the urgency of the needed changes — and the fact that all Canadians are beneficiaries of an efficient drug review system.

The first National 'Prescription for Performance' Summit was held 8–9 May 2000 in Ottawa, as part of an initiative by grassroots consumer health and disability groups to obtain the commitment of the federal government to reform the drug review system in Canada. The Summit had as its outcomes the following goals:

- Reform of the drug review system in Canada
- Raise public awareness about the gravity of this issue.

Summit stakeholders and the panel of international speakers reached consensus that when the drug review system in Canada is benchmarked against international comparisons, Canada performs at less than optimal standards.

The Canadians for Best Medicines 2nd National Summit on Reform of Canada's Drug Review System, 2002, continued to address the need for Canadians to have safe, timely, affordable access to the best evidence-based medicines through government commitment to needed reforms. The

following is a summary of the key recommendations/action plans of the meeting, many of which are still outstanding in 2005:

1. Advocates will *lobby federal elected officials for dedicated funding* increases to TPD specifically for HR dedicated to drug reviews and to the funding of the Marketed Health Products Directorate.
2. Advocates will *lobby TPD for adopting 'best practices' from the FDA model* for the inclusion of patient advocates in all aspects of decision-making in the drug review process and clinical trials development.
3. Advocates, in partnership with sponsors and government bureaucrats will undertake to *develop transparent processes for public consultation* on issues including demystifying the 'public perception' about 'made-in-Canada' drug approvals, proprietary interest and public interest. The process will include a comprehensive public opinion survey, and a summit.
4. Advocates will support qualified researchers in the development and publication of *updated international comparison data* on approval times.
5. Advocates will recommend to RX&D, the development of an accessible, *transparent and current database to provide comprehensive and timely access to on-going clinical trials data.*
6. Advocates will develop and adopt *guidelines for ethical funding partnerships* with corporate sponsors, including pharmaceutical companies, with a mechanism for making public the agreements.
7. Advocates will develop and submit for publication, *articles relating to the benefits and models for citizen/patient participation in public health policy*, in order to educate the professional community on the benefits and opportunities for healthcare advocacy.
8. Advocates will undertake the development of a series of *public consultations at the provincial level*, regarding 'best practices' for a common review system, and other issues relating to access to medications through provincial formularies.
9. Advocates will prepare a *submission to the Romanow Commission* relating to the 2nd Summit on Reform of Canada's Drug Review System and these recommendations.
10. Advocates will undertake this work through *broadening and strengthening the Best Medicine Coalition*, representing Canadians for the best medicines.

Within these recommendations are embedded several that relate to the need to educate those in the professions and governments about the benefits and models for patient/citizen participation or involvement in public health policy, and to ensure public consultations take place at the provincial government levels as well as at the federal or national level.

**2. The creation of 'The Best Medicines Coalition': Patient and consumer groups align**

For many years, patients, consumers and citizens of Canada have expressed their concerns about not being invited or represented at the national and provincial decision-making tables/meetings where policies or directives have been developed to frame the delivery of health care services and drug or other therapies across the country. Not much has happened overall to ensure consistencies in how this is to happen, even today. But some patient groups such as HIV and hepatitis have made some

strides in getting to the table to argue for better drug access and coverage, as well as for universal policies to ensure consistencies across the country. Some things are in place for this latter group. Other groups have tried over the years but have found that their individual voices were not being heard. Coalitions began to form to unify the voices into one much stronger and louder voice. The Best Medicines[1] Coalition came into being as a result of these efforts. Starting its efforts in 2000 and officially becoming known as the BMC in 2002, it set out to ensure that patients/consumers and citizens would be at the various decision-making tables talking with and being a part of the processes and outcomes for policies and directives. The BMC had set out specific position papers in 2002 (Kovacs Burns for BMC), including ones concerning partnerships and patient engagement (Appendix 1).

Many meetings with government officials, including ministers of health, have taken place between April 2002 and the present, and one meeting between BMC and the Office of Consumer and Public Involvement (OCAPI) in Health Canada, began to frame what patient/consumer participation and engagement in processes and committees should look like. This started for one department In Health Canada, the Health Products and Food Branch (HPFB). Although this latter session resulted in having BMC and others invited to meetings and committees, it did not really influence or result in change that was officially recognised as a patient/consumer engagement framework to be utilised by all Health Canada and even other government ministries. Since these initial meetings, in the *Smart Regulation: A Regulatory Strategy for Canada* (2004), the inclusion of a transparency clause that links directly with consultation as a dialogue, citizen involvement and engagement opens the door to ensuring that citizens' expectations are heard and that the public interest is heard, respected and supported through policy decisions.

## 3. Creating an infrastructure for a patient/consumer engagement framework

### *The process*

By the end of 2003, there was still an outstanding gap in ensuring that the public interest and perceptions about health, health care and the drug review process was respected. This gap was a lack of inclusion or representation of patients/consumers/citizens at decision-making tables. Various reasons and excuses were given by decision-makers, and even patient/consumer groups themselves. This inconsistency in approach or strategy lead to the development of the 3rd National Health and Drug Review Reform Summit called Moving Words to Action, 28–30 January 2004. The purpose of this summit was to:

1. develop achievable mechanisms to educate and empower patients and patient groups to play a meaningful role in healthcare reform and other critical issues pertaining to access to best medicines for Canadians

[1] 'Best Medicines' by definition include primarily prescription drugs, and include non-prescription drugs, alternative medicines or therapies, and other medically necessary supplies, devices, or therapeutics, and general health care used in the treatment of any medical condition.

2. develop attainable mechanisms to assist patients and patient groups to respond to issues of the day that will ensure engagement at all levels of policy development that affect patient outcomes
3. develop a sustainable model of patient engagement/participation at federal/provincial/territorial levels.

The 3rd National Summit was attended by over 100 patients/consumer delegates who joined over 30 representatives from government, voluntary organisations, and industry. The results and highlights of this Summit (report) is available at <http://www.bestmedicines.ca>.

One of the initiatives coming out of this summit is an analysis of the work of the participants during their breakout sessions. There were two breakout sessions — one during which participants discussed the foundations for a patient/consumer engagement framework or model including a purpose statement to guide the framework or model's efforts, core elements and principles of the model. The second breakout session on day two of the summit focussed on the development of a patient/consumer engagement model, including describing the purpose, principles and core elements of the framework, as well as the challenges and short and long-term recommendations. Each of these areas makes mention of partnership or collaboration or meaningful participation.

***Purpose of a patient/consumer engagement framework***

Out of the 3rd Health Summit emerged the strong theme of 'moving words to actions'. Consistent with this were the following sub-themes, which consistently dominated discussions:

- Better health outcomes
- Equal partnership
- Shared decision-making
- Accountability
- Patient/consumer-focussed approach
- Collaborative at all levels
- Engagement at all stages of the decision-making process.

The one purpose statement from the summit discussions that best reflects the theme and sub-themes as well as general purpose statements is "to have meaningful involvement as an equal partner[2] at all stages of the multilevel collaborative decision-making and implementation processes, resulting in better health outcomes for all Canadians."

***Principles***

The participants unanimously stated that the key guiding principles of a framework for patient/consumer engagement are mutual respect, transparency, accountability/mutual accountability,

[2] Equal or equitable is used in this report as being representative of patients'/consumers' rights to be at the table, and not to represent shared responsibility and accountability. Partner includes patients, consumers, government, health professionals, academics, industry and others with shared collaborative commitment and investment.

and trust. Other principles mentioned include inclusiveness/wide representation, shared responsibility (e.g. for change), partnership, integrity, openness, no demarcations promoting ‘us’ and ‘them’, consumer-driven, comprehensive, action-oriented, recognising human dignity, meaningful participation/collaboration, listening, physical infrastructure and promoting education/understanding.

***Core elements of the engagement framework***

Along with the purpose, themes, and guiding principles, core elements or components around which the framework is to be developed or structured are identified as follows:

- Principles of participation (including collaborative process, conflict resolution, and respectful culture)
- Human/financial resources (including training)
- Communication (including outreach/education)
- Service delivery (including implementation, focus groups)
- Measurement/evaluation.

Others elements identified include political will/government commitment, a sustainable structure (including legislated mandate), planning/goal setting, infrastructure, set expectations/mandate, coalition development, organisational integrity, a consumer selection process, capacity building and consideration of the process’ continuum and type of involvement.

***Vision for the framework***

The structure of the framework is dependent on three key entities: the Office of Consumer and Public Involvement (OCAPI) or something similar for Health Canada or the national/federal government; a ‘network’ of Canadian patient alliance (organisations and individuals) along with other stakeholders (includes consumers, health professionals); and a decision-making portal or opportunity for meaningful engagement of patients, consumers and others within the network as well as official mandate through the OCAPI/government. All three entities linked by partnership or processes are guided by the engagement framework. The participants at the summit did not have adequate time to develop a vision or visual presentation of what a potential engagement framework might look like. The author’s vision of a conceptual engagement framework, based on information coming out of the summit, is depicted in Figure 2.

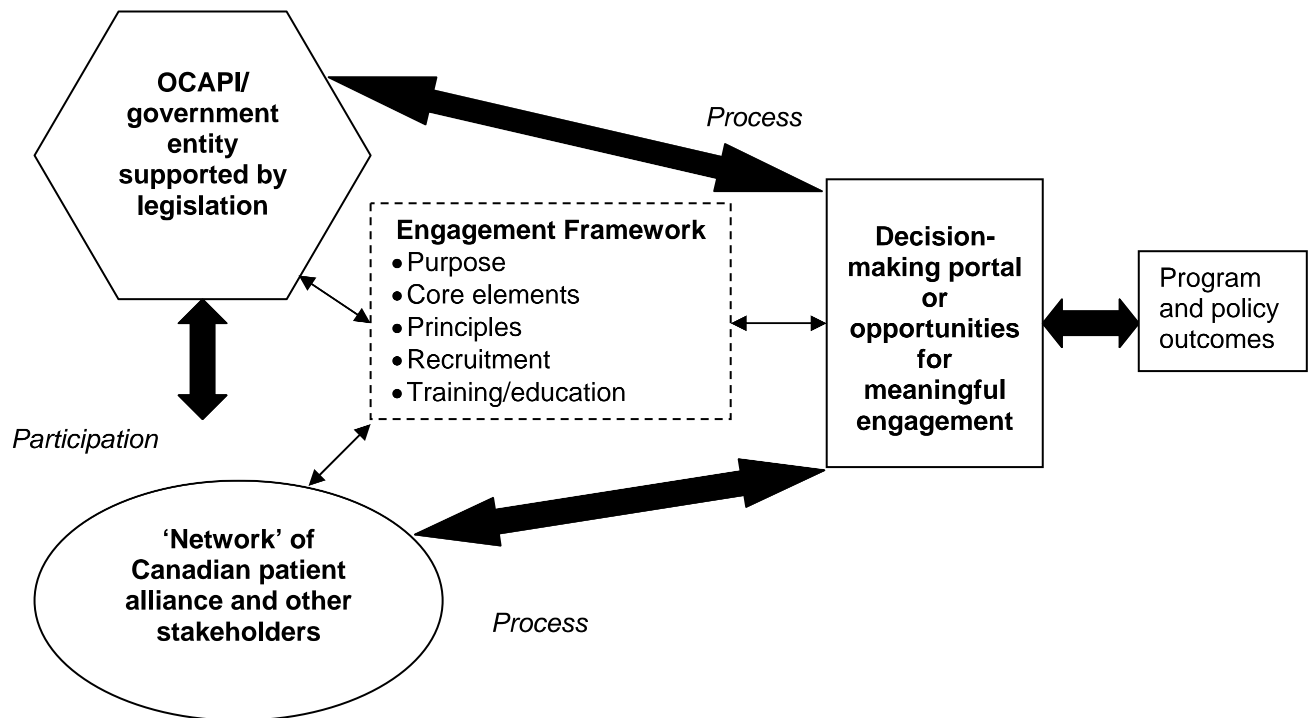


**Figure 2. A conceptual patient and stakeholder engagement framework**

Source: Kovacs Burns (2005)

The direction provided by the vision needs to incorporate the following:

- 'One-stop shopping' to leverage optimal engagement of patients and stakeholders in decision-making opportunities, as mandated and supported through OCAPI or other government entities
- OCAPI represents the link between government portals or opportunities for engaging patients and stakeholders and the Network of patient, consumer, public groups, organisations and individuals
- Patient/consumer engagement needs to be mandated or legislated to ensure its implementation and consistency in being a part of decision-making processes across government departments
- There should be more representation of patient, consumer and public groups at decision-making tables — some discussions have suggested a 50/50 split
- The Network exists to effect social and inclusion changes, and to play a leadership role on behalf of patients, consumers and public for representation and meaningful engagement in health care and drug review and reform decision- making processes
- The partnership between OCAPI and the Network provides the incentive to seek out opportunities to implement the engagement framework
- Outcomes such as policies, programs/services, drug reviews, and others, all impact on funding decisions, and will need to be tracked and evaluated/measured.

***Challenges and issues***

A variety of challenges and issues must be considered along with the process of developing a framework. Some of these challenges and issues include:

- patient/consumer recruitment which includes such things as how this is done, who makes the selection, how broad is the recruitment, what mechanism is used (criteria needed) and finding champions for all issues and in all areas being discussed
- training/education of representatives/participants as well as organisations, which includes defining and clarifying the roles of participants involved in any committee, and who will do the training or education (i.e. should it be OCAPI or government to takes this lead?)
- communications internally and by outreach to all interested or involved participants or public concerns the issue of how best to reach all relevant audiences and organisations to advise them about opportunities for engagement (local, regional, provincial/territorial, and national)
- rationale for engagement which means a clarification of the issue or need for patient engagement in decision-making processes and for a terms of reference or focus of engagement effort
- evaluation of all aspects is needed to assess what works or does not work
- resources are needed such as human expertise and money
- the bureaucracy and governmental inertia needs to be examined, particularly with the lack of political will and government commitment to ensuring stakeholder engagement in decisions that concern policies or programs. This also includes looking at provincial commitment and involvement as much as it does the federal or national commitment and involvement.
- leadership is needed — who takes the lead on this type of initiative at national or provincial levels? Who bears the cost?
- reassurance that there will be patients, consumers and others engaged in decision-making processes is needed. This needs to be mandated to be enforceable.
- stakeholder buy-in towards common agendas is important to outcomes. This includes government.
- consultation fatigue is always an issue for all groups concerned with some of the same issues
- egos must be put aside to ensure solidarity and strong group dynamics
- implementing this type of structure is complex and must consider many variables and possible outcomes
- timeframes for all these activities must be considered, particularly around how feasible some of the deadlines are for various tasks.

Each of these challenges must be anticipated and managed in accordance with the partnership and process aspects that are part of the engagement framework.

***Recommendations and actions for framework design***

There are several recommendations to be considered for the development of the framework:

- A steering committee or working group should be created to design and assist in the implementation of the framework. This committee would help to establish some leadership of the initiative.
- A strategy or business plan is needed so that activities proceed as scheduled.
- A database of potential stakeholder groups must be identified as 'network' contacts. This should include patient, consumer, health professional, government and industry groups.
- Champions for issues, who are informed and have experiences or expertise, should be established for various opportunities or committees (may need to use criteria for selection including resumés, interviews, references, and other selection information).
- Resources must be guaranteed and secured from various sources including government.

**Developing the patient/consumer engagement framework: From initial consultation to partnership**

Some of the first meetings concerning what a patient or consumer engagement framework might look like, began with consultations on this topic in 2002. The consultation was hosted by the Office of Consumer and Public Involvement of the Health Products and Food Branch of Health Canada in Ottawa on 13 December 2002. This first session included the discussion concerning health issues (broad and specific), for which the patient community or organisations should be consulted, other issues, challenges and obstacles to effective consultation, and identifying how groups should be consulted which is really assessing the type of involvement. At this time, OCAPI had identified two goals of effective and meaningful public involvement: (1) to improve the quality of policy and decision making; and (2) to enable Health Canada to fulfill its mandate and build public trust. As part of the discussion, the Public Involvement Continuum (Health Canada 2005) was described with level one being the lowest level of public involvement and influence, which is to 'inform or educate' someone. Communication is one-way from the person providing the information to the recipients of this information. Level two is gathering information, which means that although communication is both ways between provider and recipient, there is still the element that the provider of the information is really just listening and recording information from recipients, and whether the information that is gathered is used or not remains an unknown in this type of involvement. Level three involves discussion between the provider and recipients of information. A consultation is taking place with exchange of information and questions. Level four is engaging people/participants or recipients in a more meaningful way. There is shared agenda setting, opportunity for deliberation on issues and on shaping policies and decisions. The ultimate level in this continuum is level five which is partnering. This level is beyond consultation as we know it since it involves having citizens and public groups develop solutions for themselves. This also means that citizens are empowered to manage the involvement process and some of the outcomes, and to enable the process of creating a meaningful partnership where the parties involved benefit in a mutual way from the outcomes. OCAPI also outlined five patient involvement options at the time, which included a consultative committee for

patients, conferences on patient involvement issues, patient roundtables, regional citizen forums and patient representation on advisory committees. The pros and cons to each of these were also discussed.

This session was followed up with two other activities in 2003. The first one was the joint effort of OCAPI and BMC to present a paper at the International Alliance on Public Participation (IAP2) 2003 Conference on Information to Empowerment: A Global Perspective. The presentation was on the 'Collaboration between the Office of Consumer and Public Involvement in Health Canada and the Best Medicines Coalition in developing a Patient Involvement Strategy'. Another initiative shortly after the conference was the development of an issues analysis paper on the patient involvement strategy within the Health Products and Food Branch (2003). The paper highlights the branch's statement on "informed consultation, citizen engagement and openness in Branch decision-making" (p. 11), and also identifies two key issues that the branch must address: (1) how to strengthen patient involvement in branch decision-making; and (2) the fact that there had not been a branch-level patient involvement strategy in the past. Seven objectives were identified for the branch to discuss options and make recommendations. These objectives were to:

- increase the understanding and awareness within the HPFB of the commitment to seek patients' input regarding their interests and concerns about health and food
- identify and address opportunities and challenges for enabling patient involvement in activities being planned and implemented at the directorate and branch levels
- engender a commitment to patient engagement in all consultation/public involvement activities as early as possible and throughout the consultation process.
- establish collaborative working relationships with patient groups on issues of mutual concern.
- integrate patients' perspective into policy and regulatory decisions and activities
- develop horizontal linkages across the department as required in order to facilitate patient participation
- draw from lessons learned to build best practices for how to engage and learn from the patient community (Health Products and Food Branch 2003, pp. 1, 2).

In 2004, the focus for patient/consumer involvement was on the issue of representation and representativeness of the patient/consumer representatives. From this consultation process came some key deliverables:

1. Voluntary Disclosure of Information (VDI), which has to do with developing and implementing a policy and procedures guide on voluntary disclosure of information for all stakeholder groups for HPFB public involvement activities
2. Stakeholder Selection Criteria Toolkit, which defines a standard tool (of set criteria and measurements) and which HPFB can use with staff to guide the selection of stakeholder representatives for public involvement activities
3. Selection Process, which includes practices on how to recruit, nominate and select stakeholder representatives for public involvement activities

4. Resources include financial support to voluntary groups such as patients and consumers, so that they are able to attend branch and other activities, and provide orientation and training to stakeholders tailored to specific needs.

Also in 2004, a performance evaluation was conducted on all the branch initiatives that had patient/consumer or stakeholder engagement activities identified in the business plans. From this plan it was determined what initiatives had been successfully dealt with or still needed to be addressed. The actual Public Involvement Framework, developed by OCAPI in consultation with patient, consumer, and other stakeholder groups, was published in 2005. Its focus is on using the framework as a guide to public involvement in all of the HPFB responsibilities. The Framework has many of the same elements/components for frameworks, principles, and vision statements, as was identified in the Health Summit 2004. Along with the Public Involvement Framework, OCAPI has developed training modules to prepare patients and consumers to participate in the Health Products and Food Branch meetings, advisory committees, and expert advisory panels.

Presently, OCAPI and other groups are piloting the 2005 framework as drafted. This framework will be compared with the frameworks developed in other countries such as Australia, the UK, Finland/Denmark and Hungary.

**Discussion**

Although the discussion and debate about patient, consumer and stakeholder participation in government has been going on for at least a decade, the work of the Romanow Commission with the cross-country consultation on Health Care Reform set a gold standard (Romanow 2002). The door had been opened to the public to voice their concerns about the health care system in addressing the needs of the diversity of Canadians. Today, several years later, we see some shift in attitude and actions to ensure the public's interest is incorporated into policy discussions and decisions, as with the Smart Regulation Strategy (2004). With a good first attempt at developing the Public Involvement Framework, OCAPI took some significant steps to involve patients, consumers and other stakeholders in developing a public engagement framework and some training modules for the health sector. These initiatives are progressive — it remains to be seen how extensively this framework and training modules will be implemented in other directorates and branches outside of the HPFB.

Over 2005 and 2006 the author, as researcher, along with The Arthritis Society and other non-profit health organisations — some affiliated with BMC — received funding to conduct a research project with the framework and training modules. OCAPI's framework or an adapted version will be compared with other frameworks from Canada, such as the VOICE project policy involvement framework (Office of Voluntary Sector 2004) and others from around the world (Australia, the UK, Finland, Denmark, and Hungary). The project involves more engagement workshops with patients, consumers, other stakeholders and the public to come up with an adapted/revised framework and training program that

reflects the expectations of the public as well as OCAPI and government departments who will be implementing them.

In 2006 and 2007, the intention is to implement and evaluate the effectiveness of the adapted framework and training program within Health Canada and the Public Health Agency.

**Concluding remarks**

> "Over the last decade it has become clear that there is a growing risk of "disconnection" between government and citizens. Research tells us that citizens are increasingly concerned that their democratic institutions are out of sync with their values and interests. Moreover, citizens strongly believe that there is a growing gap between their actual and desired level of influence in government decision making. As one citizen stated, "I don't think unless you work trying to get your government to be democratic and to work with you … that you discover the kind of pain you feel when you find out you're invisible" "(Wyman et al. 2004).

It goes without saying that every person is concerned about health, being healthy, remaining healthy (through whatever means including some type of health care provision) and having some say about what happens to improve or affect his/her health outcome. By analysing the different aspects of health and its related areas including the politics of health, we begin to understand why health is such a complex entity. It has a traditional base or start that frames our thinking, values and beliefs, but the politics associated with health presents other challenges for the average person, and even more so for those who are disadvantaged or vulnerable in any way (e.g. low income, chronic condition or illness, language or cultural diversity, others).

In the 1990s in Canada, there has been a movement for health care reform, both from the government and the public perspectives, but for different reasons. Canadians do not want to dismantle what is currently working, and part of this is the security of ensuring that in Canada, health care is a 'right' of every Canadian citizen. Canadians want a say in preserving these rights, and also to be heard about what is not working effectively to meet the needs of people. With a new attitude towards health care reform as in pursuing the principles of primary health care and patient-focussed/centered health care, there is more chance for the public to become directly involved in making informed choices/decisions regarding access and approach of health care and expert. People expect their involvement to be meaningful, not tokenism.

The partnership and public engagement framework are good first starts in ensuring that patients, consumers and others are actively and meaningfully engaged in health care and policy decisions that will have a long-term impact on Canadians, particularly those who are vulnerable or marginalised in anyway. Although the processes of engaging citizens has begun in some sectors of government and society, more needs to happen in the way of policies which ensure that all the work and effort of OCAPI, BMC and others will not go in vain. Canadians, like others globally, want and need to know

that the health care system will be sustainable in the long term, and that they are part of the solution in making the system more efficient, effective, and better in terms of health service delivery and health outcomes.

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## Appendix 1. Position papers on partnership and patient/citizen engagement

### Position area: Require public participation/engagement in health care and drug/medicines reform process to explore effective outcomes

Canadians see themselves as owners of the healthcare system and are therefore inclined to activate their rights to voice their opinions and concerns about the system or the lack of services within the system. To actively become engaged in activities, individuals must be directly involved in the discussions and decision-making processes. Their names or their identity must be recognised in the reports and documents that result in changes to the system or process, and implementation of any recommendations must have consumers and patients at the table and part of committees where decisions are made. The Best Medicines Coalition is one group of advocates for patients and consumers, representing a number of organisations and speaking on behalf of millions of Canadians.

**1. The rights of individuals to Best Medicines and health care**

*Position statement*

BMC advocates that Patients and Consumers have the right to access the best medicines/drugs and health care, as health care services which are recognized under the Canada Health Act.

*Background and rationale*

"Patients have rights to new drugs that often provide benefits not afforded by previously available products.[3]

The question that the National Forum on Health (2002) posed was: "Are drugs market commodities, or health care services?" And if we consider drugs to be health care services, then under the Canada Health Act, individuals have the right to access them as part of the criteria of] the Canada Health Act (i.e. accessible, universal, comprehensive, portable, and publicly administered).

**2. Patient/consumer engagement in the drug reform process**

*Position statement*

The Best Medicines Coalition believes there should be public participation in reforming the drug review process, thus ensuring government accountability

Health Canada needs to explore and implement models for increased patient and consumer involvement in clinical trials, drug reviews and approvals, and post-market surveillance processes. The whole system must become more transparent and accountable.

Provincial Governments must provide for patient/consumer involvement on drug approval committees which make decisions about formulary listings.

*Background and rationale*

The Canadians for Best Medicines Summit brought knowledge levels of different consumer and advocate organisations to the same level, ensuring that Canadian consumers can participate in the decision-making process in a meaningful way.

The Best Medicines Coalition possesses the knowledge and political will to work towards a common goal — reform of the drug review system and implementation of an efficient post-approval drug surveillance program in Canada.

[3] Denis Gagnon, Laval University Vice-Rector of Research for the Minister of National Health and Welfare (Begin et al., 14 November 2002, p. 34).

Presently, there are many more questions than answers about what system would best meet the current need, and it is therefore important to have patient and consumer involvement in discussions.

The Romanow Commission's inquiry into the Future of Health Care in Canada was successful because it relied on true citizen engagement. Canadians, through Commissioner Romanow, have sent a clear message to the federal and provincial/territorial governments that they want Canada¹s publicly funded health care system preserved and enhanced.

Pivik (2002) identifies some points in support of citizen involvement in health planning:

> "Citizen participation in health planning is widely supported by international, national, and regional governments, non-governmental organizations, consumer organizations and health researchers.
>
> Reported advantages to citizen participation have included: a health care system that reflects the specific needs, values, culture and attitudes of the community; a more efficient use of resources; increased support for resulting programs and services; greater access to local skills and resources; increased community awareness of health issues; and an enhanced sense of control and empowerment.
>
> Challenges to citizen participation have been reported to include resource limitations, lack of representativeness, conflicting vested interests, time constraints and a lack of knowledge and training for both citizens and health planners. Recommendations for federal, provincial, regional and community-based organizations are designed to address these challenges."[4]

**3. Partnerships a key in supporting public participation in drug and health reform processes**

*Position statement*

The Best Medicines Coalition represents millions of Canadians living with serious and debilitating illness whose common goal is to accelerate the pace of reform through partnerships and consumer involvement. This is a people-driven process, and patients and consumers want to be part of the consultation and decision-making process with other stakeholders and partners.

The government must have the appropriate stakeholders or partners involved in each step of the drug reform process including drug review, approval, and post-market surveillance. The process must be transparent and credible.

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[4] Pivik J R 2002, *Practical Strategies for Facilitating Meaningful Citizen Involvement in Health Planning*, p. iv.

*Background and rationale*

Developing a transparent and equitable process would necessitate partnerships between lobby groups (e.g. patients, physicians, pharmacists), governments, industry, and academia. Allowing these groups to seek common interests would be conducive to ensuring that the drug reform process would be comprehensive and equitable (Levy and Gagnon 2002).

> "Canada should embark on a path of greater cooperation between all stakeholders within the health care system. This inter-sectoral cooperation must include such partners as public policy makers, health service providers, academics, private insurers, employers and manufacturers of pharmaceuticals. One of the best ways to promote such a cooperative effort would be to pursue heath management programs. Such programs have improved the management of the priority diseases that inflict undue personal burden on the affected population and an excessive financial burden on society at large" (Rx& D, January 2002, p. 9).

**4. Establishing ethical guidelines for partnering and engaging**

*Position statement*

Patients and Consumers engaging in the drug reform process must be respected for sharing their experiences as part of the fact and information gathering components, and must not be jeopardized in any way.

Ethical guidelines and principles must apply in partnerships and in having patients engaged in the drug reform process. These guidelines should be developed at the outset of committee work as part of the Terms of Reference.

*Background and rationale*

Patients and consumers who are consulted or who actively engage in discussions and activities are placing themselves in some risky situations. However, there must not be any repercussions for these patients or consumers as a result of their participation. If patients and consumers consent to be part of a committee or group which explores some sensitive issues around the drug reform system, they are then considered to be part of the public domain. They will run the risk of being interviewed for media, or of being involved in heated debates.