



The Importance of Patient Participation in Health Policy Decision Making

***Consumer Engagement in Health Technology Assessment:
Recommendations for the Mandate and Makeup of a Citizens' Council
as Created under Ontario's Transparent Drug System for Patients Act***

A report to the Ministry of Health and Long Term Care
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EXECUTIVE SUMMARY

The use of patients and 'lay representatives' in health policy and health decision making is becoming more widespread as decision makers acknowledge the right of the public to have input into how the public purse is spent. Ontario's Bill 102, the *Transparent Drug System for Patients Act*, which mandates the creation of a Citizens' Council, is just one example of this trend. The Ministry of Health and Long Term Care (MOHLTC) should be congratulated for its forward thinking and for taking these steps to ensure that the public and patients will have input into the decisions that will affect the health of people living in Ontario.

Incorporating the views and opinions of patients and caregivers into health decision making provides a plethora of advantages including:

- More relevant and improved research studies;
- Ensures a thorough and unbiased review of research protocols and improved sensitivity to members of the targeted research population;
- Provides a human context to quantitative measurements, and improves accuracy of some economic measures;
- Provides a bridge between public and research communities;
- Allows researchers and health decision makers to learn how best to approach the public;
- Ensures the incorporation of more patient-centered care;
- Broadens the range of health information included in electronic health records, and ultimately helps improve clinical decision support;
- Improves health outcomes;
- Makes service more responsive to the needs of consumers;
- Creates a health care system that addresses the specific needs, values, culture and attitudes of the community;
- Allows for a more efficient use of scarce resources;
- Enhances community awareness of health issues;
- Enhances the sense of control and empowerment within the community

As different areas of the world seek to make use of patients and patient groups, these untapped resources will serve to better the health of their representative population. Each region must assess how to best utilize the patient population available to them, and take advantage of well established, successful programs. Additional data supporting the benefits of patient involvement continues to gather strength, further exemplifying the advantages of patients' undeniable right to actively participate in the organizations which govern their health.

There are a number of programs that now use patients and consumers for their input. A few are described in some detail in this paper:

- Technology Appraisals Committee (UK)
- Patient and Public Involvement Programme (UK)
- The FDA Patient Representative Program (US)
- Parkinson's Pipeline Project (US)
- Cancer Drug Development Patient Consultant Program (US)

In December 2006, an email notice was sent to representatives of approximately 50 health charities. The recipients were provided with a brief introduction to Bill 102, and

were invited to take part in a survey to gain their feedback and thoughts regarding the proposed Citizens' Council. Respondents to the survey provided thoughtful comments on issues related to this topic.

The following suggested recommendations are provided based on previous work on related topics published in the literature, lessons gleaned from the jurisdictional review, and responses to the survey.

Council Composition:

It is suggested that the Citizens' Council be comprised of 12-14 individuals with an equal mix of lay citizens, people living with chronic conditions, and representatives of patient groups.

Council Member Recruitment

There are a number of ways in which the MOHLTC can recruit members of the Council. The most obvious, and perhaps most straightforward is to advertise for the positions in Ontario-based and community newspapers. Applicants can be directed to a web site, or asked to call a 1-800# for further information.

Frequency & Duration of Meetings:

It is suggested that the Council meet once every 3-4 months for a period of 1-1.5 days at a time. It is further suggested that Council members be asked to commit to a term of two to three years.

Training:

It is expected that some training will be required on issues related to the Ministry, health care in Ontario, and meeting 'comportment' (presenting ideas, differing opinions, etc.) Council members should be provided with binders or manuals for reference but all training should take place on a face-to-face basis in workshops. During transition periods it is suggested that a 3 month cross-over period be instituted in order to facilitate coaching and mentoring.

Resources:

Participants will require a number of resources in order to facilitate their attendance at meetings including educational materials, access to experts, and reimbursement of expenses. Each new Council member should be asked if they have any special requirements, such as wheelchair access, scent free rooms, etc.

Payment:

It is suggested that all Citizens' Council members be paid a modest daily honorarium (i.e. \$250) for their time.

A consensus conference with representatives of patient groups, the public and decision makers will be held in mid-February to discuss and expand upon these recommendations.

This study was made possible through an unrestricted educational grant from Merck Frosst Canada Inc.

INTRODUCTION

“For the past 25 years, citizen participation in health planning has been considered an important feature of responsive and equitable health systems.”¹

The use of patients and ‘lay representatives’ in health policy and health decision making is becoming more widespread as decision makers acknowledge the right of the public to have input into how the public purse is spent. Ontario’s Bill 102, the *Transparent Drug System for Patients Act*, which mandates the creation of a Citizens’ Council, is just one example of this trend. The Ministry of Health and Long Term Care (MOHLTC) should be congratulated for its forward thinking and for taking these steps to ensure that the public and patients will have input into the decisions that will affect the health of people living in Ontario.

According to some, there are no “right” or “wrong” answers when making decisions about health care in a budget-constrained society - for every decision made, at least one person will not be happy. Therefore, it is in the decision-makers’ best interests to ensure that decision-making processes are open, transparent, and inclusive. *“There can be no right answer to questions about health care priorities. Such decisions are essentially value judgments, which will vary between (sic) individuals, groups and societies. Legitimacy, therefore, is derived from the decision-making process. This process is more likely to be seen as legitimate if it is open, if it enables different interests to contribute.”²*

The Ministry has indicated that it welcomes input for the formulation of the Citizens’ Council and this report is an attempt to provide this feedback to the Ministry with suggestions for moving forward. The report begins with a literature and jurisdictional review of patient participation in health decision making, followed by the results of key informant interviews (survey) that were completed in December of 2006 with representatives of Ontario based health charities. This report builds upon the work previously completed by Pivik *et. al.*, and concludes with recommendations for the creation of the Citizens’ Council.

PATIENTS IN HEALTH DECISION MAKING

It has been acknowledged for many years that the use of patients and consumers in health decision making is an important right, and that this practice provides innumerable benefits to the patient, the provider, and the health system as a whole. As early as 1978, the World Health Organization advocated for the patients’ rights to be active partners in their care: “Individuals have a right and duty to participate individually and collectively in the planning and implementation of their health care.”³ As a result, the use of patients and their community representatives is becoming more widespread throughout health

¹ Pivik, Jayne Renee, *Practical Strategies for Facilitating Meaningful Citizen Involvement in Health Planning*, University of Ottawa, Discussion Paper No. 23, Commission on the Future of Health Care in Canada, September 2002.

² Saltman B, Figueras J, Health Care reform. Analysis of current strategies. Copenhagen: World Health Organization, 1997, p.112

³ World Health Organization, 1978

http://www.participateinhealth.org.au/why/policy_examples.htm

care and health research. Many examples exist and a number are described in the following section.

In a recent study published in the *Journal of the American Heart Association*, Ali *et al.* sought to incorporate the opinions of stroke patients and those who care for them to produce research which is relevant and incorporates their needs and expectations.⁴ By including stroke patients and their caregivers Ali *et al.* were able to identify outcome measures not typically addressed in current stroke assessment scales which could lead to improved research on how best to provide care for this population.

The Food and Drug Administration also regularly uses patients, consumers and individuals living with chronic conditions to help inform their expert committees, and the use of patients is enshrined in US law: *The Public Health Services Act* and the *National Research Act*. This latter Act mandated the use of what are usually referred to as Institutional Review Boards (IRBs): a group designated to monitor behavioral and biomedical research involving human subjects.⁵ IRBs, as a part of the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) regulatory regimes have the ability to approve, disapprove, or require changes to research that falls under their scope of governance.

Included in this responsibility are FDA and HHS Code of Federal Regulations specifying the structure of all Institutional Review Boards. Often referred to as “The Common Rule” the Code of Federal Regulations stipulates that IRBs must be composed of both scientific and non-scientific members to ensure thorough and unbiased review of research protocols and sensitivity to the members of the targeted research population.^{6,7} As such many leading research institutions take great care to create diverse IRBs to ensure protection of all humans involved in research. Johns Hopkins University, a leading institution in research, ensures that at least one member of their IRB is of a non-scientific background.⁸ Often utilizing individuals from the community such as church leaders and members unaffiliated with the research institution, the Johns Hopkins’ IRBs ensure the best possible protection and outcomes for the patients participating in these studies.

The United Kingdom has become a leader in researching and making use of the advantages of consumer and patients in health care. The Technology Appraisals Committee (TAC) provides recommendations on the use of current and new treatments and medicines for use within the National Health Service.⁹ TAC includes patient and clinician experts with relevant experience and knowledge of the condition in their

4 Ali, K., Roffe, C., Crome, P. (2006). What Patients Want: Consumer Involvement in the Design of a Randomized Controlled Trial of Routine Oxygen Supplementation After Acute Stroke. *Stroke* 37: 865-871

⁵Institutional Review Board. (2007, January 22). In *Wikipedia, The Free Encyclopedia*. Retrieved 17:30, January 23, 2007, from

http://en.wikipedia.org/w/index.php?title=Institutional_Review_Board&oldid=102528161

³ Institutional Review Board. (2007, January 22). In *Wikipedia, The Free Encyclopedia*. Retrieved 17:29, January 23, 2007, from

http://en.wikipedia.org/w/index.php?title=Institutional_Review_Board&oldid=102528161

⁷Organization Policy List of IRB Members (Policy No. 103.4). (2007, January 22). In *Johns Hopkins Medicine* Retrieved 17:40, January 23, 2007, from http://irb.jhmi.edu/Policies/103_4.html

⁸ IRB Membership, (2007, January 22). In *Johns Hopkins Medicine* Retrieved 17:45 January 23, 2007, from http://irb.jhmi.edu/GeneralInformation/irb_membership.html

⁹ What we do, (2007, January 22). In *the National Institute for Health and Clinical Excellence*, Retrieved 17:45 January 23, 2007, from <http://www.nice.org.uk/page.aspx?o=whatwedo>

assessment of the treatment in question. They believe the benefits of incorporating patient experts in this process as: providing a human context to quantitative measures; allowing interpretation of Quality Adjusted Life Year cost analysis; and an improved ability to explore the issues of most importance to the patients.¹⁰ Patients and patient advocates improve the quality of research and health related endeavors by providing unique insight, and offering relevant perspectives on healthcare interventions which may enhance the ability to assess health related technology.¹¹ Sandra Oliver, an antenatal teacher from the National Childbirth Trust, suggests that consumer groups act as a bridge between the public and research communities. These groups can present research issues to their constituents and represent the needs and opinions of the public to the research community. This allows researchers and the health community to learn how best to approach the public on health related matters.¹²

Medicines Australia, a group representing research based pharmaceutical companies in Australia, has placed an emphasis on improving the health and quality of life for Australians. They have made recommendations to follow the UK's models of the National Institute for Health and Clinical Excellence (NICE), Citizen's Councils, and the newly established Patient & Public Involvement Programme. The Citizens Council is a diverse 30 member group composed of all sections of the population to convey a wide range of opinions. The Citizens Council provides public opinion for the guidance and development of NICE issues. The Council's deliberations provide a basis by which they and other Committees can advise NICE in the development of their recommendations.¹³

The FDA has taken a great deal of initiative by incorporating patient opinion in many of its evaluation programs. The Parkinson's Pipeline Project is an initiative to facilitate the evaluation and approval of new treatments for Parkinson's.¹⁴ Recently the FDA approved the Pipeline Projects' application to include Parkinson's patient's perspectives in the drug review regulatory process. Based on a successful Cancer Drug Development Patient Consultant Program established in 2001 and an HIV/AIDS patients' advocate program, the Pipeline Project helps to expedite the process of bringing more effective treatments to market and permits measurement of a broad range of clinical outcomes.¹⁵ Patient representatives are now included within the FDA's Advisory Committees as participants in the decision making process. The FDA believes it is the undeniable right of the patient to participate in this process; patients have been given opportunities to provide feedback to the Advisory Committee on medical products or the treatment of serious or life threatening conditions such as cancer and HIV/AIDS.¹⁶

¹⁰ Burchell M, Ruiz F, Barnett D. NICE Health Technology Appraisal Programme. *Ann R Coll Surg Engl* 2005; 87: 283-4

¹¹ Entwistle V, Renfrew M, Yearley S, Forrester J, Lamont T. Lay perspectives: advantages for health research. *BMJ*. 1998; 316: 463-466.

¹² Goodare H, Smith R. The rights of patients in research. *BMJ* 1995;310: 1277-8.

¹³ (AAPP (2005), Impact of Advances in Medical Technology on Healthcare Expenditure in Australia: Submission to the Productivity Commission, Canberra: AAPP.)

¹⁴ Pipeline. (2007, January 22). In *Parkinson's Pipeline Project Preparing for the Final Assault on PD*, Retrieved 17:49 January 23, 2007, from <http://www.parkinsonscare.org/RxDEV.html> Last accessed January 19, 2007

¹⁵ OpEd The Parkinson's Pipeline Project, (2007, January 22). In *FDA and the Voice of Patients*, Retrieved 17:50 January 23, 2007, from http://www.pdpipeline.org/yy_advocacy/fda_patientinvolvement.htm

¹⁶ The FDA Patient Representative Program, (2007, January 22). In *US Food and Drug Administration*, Retrieved 17:50 January 23, 2007, from <http://www.fda.gov/oashi/patrep/patbroc.html>

A number of recent studies have examined the impact of including patients in the formulation and design of electronic health records. Perhaps not surprisingly, the positive impact of patient participation in these projects is overwhelming: “While not all areas of the world have been as quick to incorporate patients as a resource, their beneficial impact on research and the health community is undeniable”¹⁷ and “Patient participation in EHR [Electronic Health Record] creation can significantly broaden the range of healthcare information in the record and, ultimately, improve clinical decision support...web-based access, self-service management, consent delegation and agent permissions management...”¹⁸

ADVANTAGES OF CONSUMER INVOLVEMENT IN HEALTH

The advantages of involving consumers in decision making are clear and wide ranging. According to Jayne Pivik, they include: *“a health care system that addresses the specific needs, values, culture and attitudes of the community; decision making that is more accountable by incorporating the specific concerns identified in the community; a more efficient use of scarce resources; an enhancement of community awareness of health issues; increased support for the resulting programs and services; the opportunity for increased networking between health care service providers and community members; access to local resources and skills of community members; a mechanism for public feedback; the opportunity for training and educating community members for future community development activities; an enhanced sense of control and empowerment within the community.”*¹⁹

The National Resource Centre for Consumer Participation in Health lists the benefits of consumer participation for health services as *“higher quality services and projects; higher profile for health services in the community; gives staff new insights into how people perceive aspects of their care; enables organizations to set priorities about areas of improvement that matter to consumers; provides opportunity for joint problem solving between health professionals and consumers; greater accountability for public funds; potential for decreasing expenditure; likely to lead to fewer complaints and litigation; greater credibility when lobbying government.”*²⁰

According to The Consumer Focus Collaboration, there are four main reasons for encouraging consumer participation in health care decisions:

1. Participation is an ethical and democratic right
2. Participation improves service quality and safety and helps gain health service accreditation

¹⁷ Bonnie Kaplan, PhD and Patricia Flatley Brennan, RN, PhD. Consumer Informatics Supporting Patients as Co-Producers of Quality. *J Am Med Inform Assoc.* 2001 Jul–Aug; 8(4): 309–316.

¹⁸ Thomas M Jones. Patient participation in EHR benefits. *Health Management Technology*; Oct 2003; 24, 10; Business Module

¹⁹ Pivik, Jayne Renee, *Practical Strategies for Facilitating Meaningful Citizen Involvement in Health Planning*, University of Ottawa, Discussion Paper No. 23, Commission on the Future of Health Care in Canada, September 2002.

²⁰ National Resource Centre for Consumer Participation in Health, *An Introduction to Consumer Participation* Fact Sheet No. 1, August 02.

3. Participation improves health outcomes
4. Participation makes service more responsive to the needs of consumers.

Each of the above has in common the concept that involving consumers in health care decision-making, planning, evaluation and review will lead to changes that will improve health²¹.

As different areas of the world seek to make use of patients and patient groups, these untapped resources will serve to better the health of their representative population. Each jurisdiction must assess how to best utilize the patient population available to them, and take advantage of well established, successful programs. Additional data supporting the benefits of patient involvement continues to gather strength, further exemplifying the advantages of patients' undeniable right to actively participate in the organizations which govern their health.

JURISDICTIONAL REVIEW

The following describes in more detail the organizations that are listed above, and provides some detail regarding how patients and consumers are involved in health decision making and health technology assessment.

Patient & Public Involvement Programme²² (UK)

The National Institute for Health and Clinical Excellence (NICE) is charged with providing national guidance on the promotion of good health and the prevention and treatment of ill health. As a function of this mandate, the Patient Involvement Unit (PIU) became known as the Patient and Public Involvement Programme (PPIP). PPIP provides advice and support to NICE on patient, care giver and public involvement, and works to develop opportunities for involving patients, carers and members of the public across NICE's work programmes. It does this by identifying patient and carer organizations interested in contributing to NICE's programmes. The PPIP promotes effective patient and carer input by providing training and support to patient and carer organizations, and to those patients, carers and lay people who contribute to the NICE work programme.

The PPIP works with NICE to:

- Advise the NICE guidelines team on patient and carer issues.
- Identify appropriate patient and carer organizations to register, if they wish, as stakeholders for individual guidelines.
- Seek out nominations from patients and carers to join Guideline and Guidance Development Groups (the groups that produce clinical guidelines and service guidance on behalf of the Institute).

²¹ *Improving Health Services Through Consumer Participation: A Resource Guide for Organizations*, Department of Public Health, Flinders University and the South Australian Community Health Research Unit, 2000.

<http://www.participateinhealth.org.au/why/frameworks.htm>

²² Patient and Public Involvement Program web site, Accessed January 24, 2007, <http://www.nice.org.uk/page.aspx?o=113698>

- Support the guideline developers (the National Collaborating Centres) and patient and carer members of guideline groups on involvement issues throughout the development process.
- Advise on methods for involving patients and carers in the work of the Collaborating Centres and their Guideline Development Groups.
- Provide formal training and informal support to the Collaborating Centres and to patient and carer members.
- Comment, from a patient and carer perspective, on all draft documents.
- Review, from a patient and carer perspective, the NICE guideline process.

Technology appraisals are recommendations on the use of new and existing medicines and treatments within the NHS in England and Wales. The PPIP works with NICE to:

- Develop and support effective patient and carer input to its technology appraisals programme.
- Promote the effectiveness of patient and carer input by providing information, training and support to individual patients and carers and patient and carer organizations.
- Support patient and carer organizations who wish to make written submissions of evidence to individual NICE technology appraisals.
- Support individual lay people who make verbal submissions to the Technology Appraisal Committees.

The Institute's independent advisory committees include members from the healthcare professions working in the NHS and people who are familiar with the issues affecting patients and carers. Although these committees seek the views of organizations representing healthcare professionals, patients and carers, manufacturers and government when developing guidance, their advice is independent of any vested interests.

The PPIP works with NICE to:

- Identify and recruit lay people onto its advisory committees.
- Support lay input by providing information, training and support to lay people on the committee.

Technology Appraisals Committee (UK)

The Technology Appraisal Committee (TAC), is an independent committee that provides technology appraisal recommendations for the National Institute for Health and Clinical Excellence (NICE) in the UK. TAC members are appointed for a term of three years representing the NHS, patient and care giver organizations, academia, and pharmaceutical and medical devices industries. NICE also reviews information provided to it by national groups representing patients and care givers, organizations representing health professionals, and manufacturers of the technology under review.

The FDA Patient Representative Program (US)

The US government believes that patient participation is important to medical decision making, whether the setting is a doctor's office or a government agency. The Food and Drug Administration (FDA) is committed to expanding opportunities for patients to participate in FDA's decision making. The FDA invites Patient Representatives to participate in its Advisory Committee meetings to discuss medical products for the

treatment of serious or life-threatening diseases such as cancer or AIDS. The medical product discussed may be a drug, a biologic product such as a vaccine, or a medical device. The FDA believes the right of patients to participate in this process is undeniable.

The FDA Advisory Committees provide independent expert advice, helping the FDA make sound decisions about new drugs, biologics, medical devices, and other public health issues. Committee members are scientific experts such as physician-researchers and statisticians, as well as representatives of the public, including patients. Patient Representatives usually have a history of the disease for which a new treatment will be discussed, with the ability to effectively communicate patient concerns. In some cases, a care giver or a representative of a patient group might be chosen to serve. Patients do not require a background in science, or as a researcher, but a general knowledge of the disease, scientific principles and basic statistics is important for comprehension of the scientific data presented. More importantly, their experience as a patient enables Patient Representatives to bring a unique perspective to FDA Advisory Committees.²³

Parkinson's Pipeline Project (US)

The Parkinson's Pipeline Project was established in 2001 in response to the "lengthy, rigorous process of science"²⁴, research and politics. Spurred by increases in research funding and the resulting advances of science, the project focuses on working with industry to deliver a cure. The project works to fill the gaps between scientific research and new treatments and between scientific discovery and cures for patients.

As the ultimate customer of both the regulatory agencies and industry, patient groups have a stake in the results of the evaluation process for new treatments. The pipeline project and the companion Quadpac (Quality Access and Delivery of Parkinson's Care) program are designed to take those extra steps to realize the cure.

A key component of the PPP is the effort to create a network of PD patient advocates and Research Partners, who will work on the front line in clinical research settings. Drawing on their most valuable asset, Parkinson's patients, the advocate's efforts are aimed at facilitating research. Generally, the advocates put the face of the patient, and the urgency they feel, in touch with their various constituencies.

Cancer Drug Development Patient Consultant Program (US)

The Food and Drug Administration (FDA) initiated the Cancer Drug Development Program to incorporate the perspective of patient advocates into the drug development process. This program provides cancer patient advocates an opportunity to participate in the FDA drug review regulatory process. The Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Office of Special Health Issues (OSHI) in the Office of the Commissioner (OC) are participating in this program.

²³ FDA Web Site <http://www.fda.gov/oashi/patrep/patbroc.html>

²⁴ Pipeline, (2007, January 22). In *Parkinson's Pipeline Project Preparing for the Final Assault on PD*, Retrieved 17:49 January 23, 2007, from <http://www.parkinsonscare.org/RxDEV.html> Last accessed January 19, 2007

In 2001 the FDA selected 25 cancer advocates representing 15 types of cancer to participate in the Program. The patient consultants were selected from a pool of 109 applicants representing 20 cancer types. The patient consultants participate in a two-day orientation workshop and continue learning about the FDA through monthly telephone lectures. The patient consultants have participated in over 50 sponsor/FDA meetings providing the patient perspective on topics such as clinical trial design, endpoint determination, expanded access protocol development, and clinical trial patient recruitment strategies.²⁵

CITIZEN'S COUNCIL SURVEY RESULTS

In December 2006, an email notice (please see Appendix I) was sent to representatives of approximately 50 health charities. The recipients were provided with a brief introduction to Bill 102, and were invited to take part in a survey to gain their feedback and thoughts regarding the proposed Citizens' Council. The email alerted the individuals to the issue and follow up phone calls were then made. The majority of respondents (90%) responded to the survey over the phone, the remainder emailed their responses.

Description of Organizations

Representatives from 20 organizations responded to the survey; the majority were Ontario based organizations, or if a pan-Canadian organization the respondent was Ontario-focused in their responsibilities. Sixty-five percent of the respondents indicated that their organization was involved in decision making related to health, or in helping patients choose between similar therapies (although the manner in which this service was provided to constituents differed among organizations). Ninety percent of respondents work in organizations that are involved in providing direction on policy issues to federal or provincial governments; however this is a formal arrangement in only 40% of organizations. The rest provide this service in a more ad hoc manner: lobbying for access to government officials, taking part in consultations, writing letters, and so on.

Nearly all respondents (85%) were aware of Bill 102 and the Citizens' Council prior to responding to this survey, indicating that this is a well informed group. All indicated their agreement that patient groups have important information to add to this process.

Furthermore, the great majority were willing to invest significant time and effort in order to be part of the process.

²⁵ Cancer Drug Development Patient Consultant Program, (2007, January 22). In *US Food and Drug Administration*, Retrieved 17:53 January 23, 2007, from <http://www.fda.gov/oashi/cancer/pconback.html>

Level of involvement

Respondents were provided with a list of possible ways in which they could be involved in the assessment of treatments and therapies. The list provided a wide array of options, with differing levels of involvement – from low and passive involvement (i.e. being provided with updated information and attending community forums) to high and active involvement – including participating on a Citizens’ Council, or being part of a decision making committee with respect to drugs. Respondents were allowed to respond affirmatively to as many of the options as they felt feasible. The results were overwhelmingly positive, with the great majority of groups indicating that they would be willing to participate in any manner available to them. This indicates that they have a strong desire to be active in health policy decision making in Ontario.

The following table represents the percentage of respondents who indicated that they would be willing to take part and the type of involvement:

Participation Type	% Affirmative Responses
Receiving updated information	85%
Participating in focus group discussions	85%
Participating in key informant interviews	80%
Participating on a Citizens’ Council	75%
Being part of a decision making committee	75%
Attending Community Forums	70%
Responding to Surveys	70%

It is interesting to note that while ‘receiving updated information’ and ‘participating in focus group discussions’ received the highest number of affirmative responses, when respondents were asked to chose just one form of involvement from the list above, the two options that received the most votes by far were first being part of a decision making committee, followed by participation on a Citizens’ Council.

These facts indicate that respondents are willing to be very active in health policy decisions, and are willing to do what they can to participate. However, if given a choice, they will more often than not, choose the highest level of involvement.

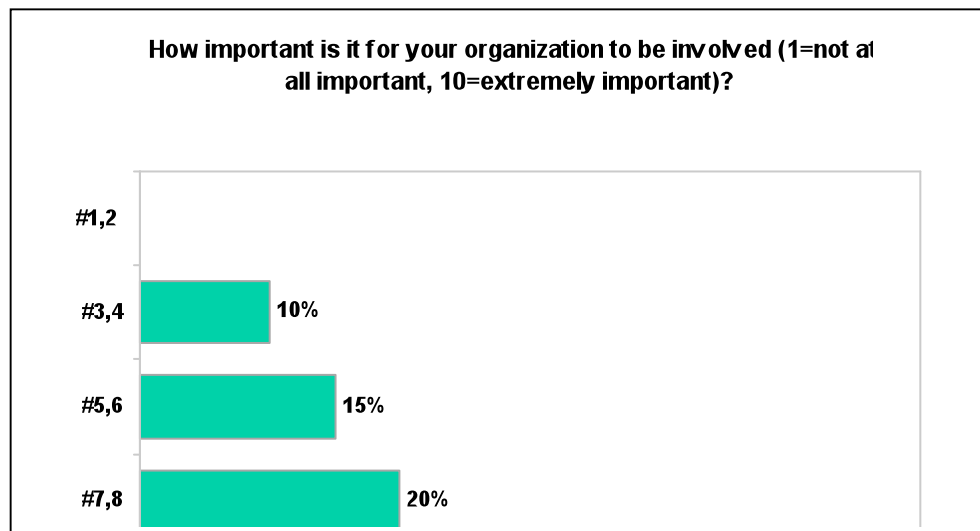
Citizen’s Council Composition

While it is in the best interests of those who intend to use Drug Evaluation committees as mechanisms for cost containment to suggest that members of patient organizations be excluded from participation on a Citizens’ Council, the jurisdictional review and the responses garnered from the survey indicate that members of patient groups should in

fact be welcomed onto the Council.²⁶ While 35% of respondents felt that they had adequate opportunities to have their concerns heard by the government, only 25% felt that their issues were well understood by the government. Fifty percent did not feel that they had adequate opportunities for interaction, and 60% felt that their issues were not well understood by government. This clearly indicates that representatives of patient groups would welcome representation on a Citizens' Council.

Question:	Yes	No	Don't Know
Do you feel that you have adequate opportunities to have your concerns heard by the provincial government?	35%	50%	15%
Do you feel your organizations' concerns and issues are well understood by the provincial government?	25%	60%	15%

When asked to rate how important it was for their organization to be involved in a Citizens' Council, 75% gave this a rating of 7 or higher (Respondents were given a ten-point scale, where "1" indicates a response of "not at all important" and "10" indicates a response of "extremely important".)



²⁶ University of Toronto Priority Setting in Health Care Research Group *Review of Citizens' Councils and recommendations for the creation of a Citizens' Council as mandated under the transparent drug system for patients act*. September 15, 2006, page 10.

When asked what composition respondents felt would be most appropriate for the make up of the Citizens' Council, the overwhelming message from respondents was that the make up of the Council should be such that it will provide a balanced perspective. The following quotes sum up many of the respondents' suggestions:

- *“Fair representation from all - there needs to be a balance, but also expert opinion”*
- *“The Citizen’s Council should include a cross section of citizens without a health condition, patients and health charities.”*
- *1. Various ages; 2. Specific disease conditions; 3. Health professionals; Special expertise in specific areas could be provided as needed to the council.*

Other suggestions include:

- Ethicists
- Experts
- Economists
- An ex-facto individual from the Ministry for consultation

The issue of including health professionals in the Citizens' Council was controversial for respondents. Some felt that the inclusion of health professionals was important, while others were adamant that health professionals must be excluded from the Council. Those in the latter group felt that health professionals already had adequate avenues for communicating with the Ministry, and that the 'professional' title may intimidate other members of the Council, and lend their voice too much weight.

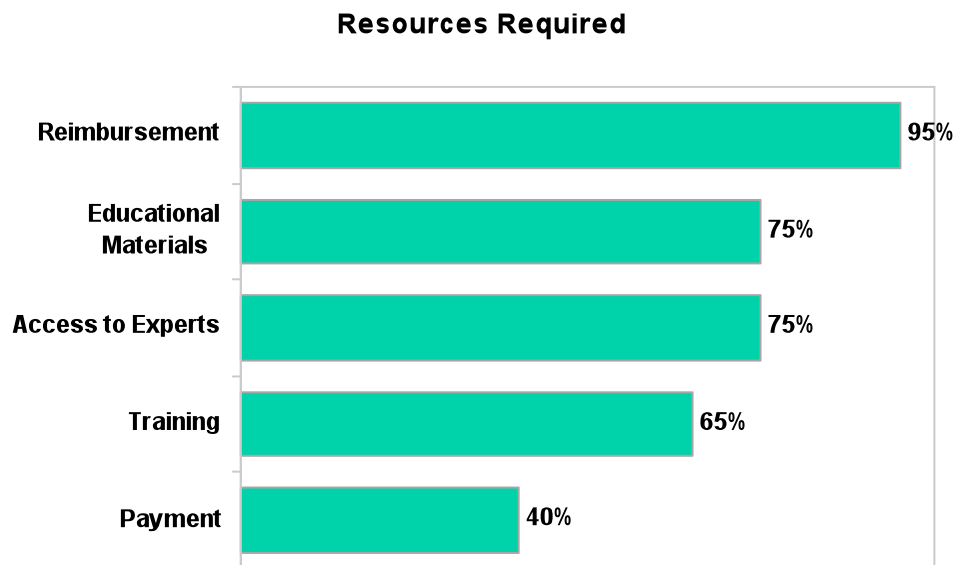
Training and Resources Required

Representatives of patient groups are also willing to put in a significant amount of time and energy in order to be part of the policy process in Ontario. When asked whether they would be willing to be part of a committee that met once a month for a full day each month, 80% responded affirmatively. This provides us with a strong indication of how committed these groups are as they are willing to offer a significant time investment.

Given the complexities of the topics that Citizens' Council members are likely to discuss, it is understood that participants will require some training; 65% of respondents felt that training would be required. Survey participants were asked what they felt would be the best method of providing this training, and were offered the choices of workshops, easy-to-read manuals, web-based guidelines or “other” (respondents could check more than one box for this question). All respondents felt that workshops would be the best choice, with 70% indicating that manuals would also be helpful. Only 50% felt that web-based guidelines would be useful. Many of the respondents indicated that face to face instruction is best for learning, and that mentorship or coaching are also important.

The participants were also clear in their direction regarding what kinds of resources they would require in order to facilitate their participation on a Citizens' Council. Nearly all respondents (95%) indicated that they would require reimbursement for the expenses incurred in attending a meeting; 75% indicated that they would also need access to educational materials and experts for advice. Only 40% indicated that payment would

be necessary. (Some did indicate that if other experts sitting on the committee were being paid for their time, then in the interests of fairness, they should also be paid.) The fact that respondents were willing to offer their time on a volunteer basis provides another indication of the level of dedication that these individuals feel for this topic.



Respondents were also asked to indicate if there were any accessibility issues that would need to be addressed. Only 45% indicated that accessibility would be a problem, with issues ranging from wheelchair access (most common issue) to including time for travel in meeting planning.

Issues to be discussed by the new Citizens' Council

All respondents were asked what issues they felt would be appropriate for the Citizen's Council to discuss, given the stated mandate of the Council. Their responses follow six main themes including:

1. Access to medicines, and speed of access;
2. Orphan drug policy;
3. Transparency & accountability of government decisions related to drug coverage;
4. Expansion of public drug programs, including income-based co-payments;
5. Funding issues for those not covered by public or private plans (affordability of drugs); and
6. The need to balance risk versus benefit. The need to balance cost versus benefit.

(For a full list of suggested topics, see Appendix II).

RECOMMENDATIONS

The creation and organization of the Citizens' Council provides an exciting opportunity for members of the public, patients and consumers to have involvement in the direction and creation of health policy in Ontario. The following suggested recommendations are provided based on previous work on related topics published in the literature, lessons gleaned from the jurisdictional review, and responses to the survey.

Council Composition:

It is suggested that the Citizens' Council be comprised of 12-14 individuals with an equal mix of lay citizens, people living with chronic conditions, and representatives of patient groups. It is felt that a number much greater than 12 will cause the Council to become too unwieldy, slow down deliberations, and decrease the number of recommendations emanating from this group. This size of body is also consistent with the guidelines for governance promulgated by the Toronto Stock Exchange. Health professionals will not be asked to participate as sitting members of the Council. Their role will be relegated to one of 'expert opinion': if there is an issue in which an expert opinion is required, the Council may request that a health professional, (or other expert as appropriate) be brought in for the duration of the discussion, or for an educational workshop.

Council Member Recruitment:

There are a number of ways in which the MOHLTC can recruit members of the Council. The most obvious, and perhaps most straightforward is to advertise for the positions in Ontario-based and community newspapers. Applicants can be directed to a web site where an initial screening would be performed (i.e. are they willing and able to commit to attending 4 meetings per year, travel to Toronto in order to do so, be actively involved in lively debate, etc.) Once the individual has agreed to the initial basic requirements, they will be invited to fill out an on-line application form. Applicants will then be screened by Ministry of Health and Long Term Care staff (or an outside consultant if the Ministry lacks the resources or for the sake of transparency) based on agreed-upon criteria, to be developed in consultation with Ministry of Health and Long Term Care staff.

Given the desire to gain a wide spectrum of voices and perspectives from across Ontario it is important to provide alternate methods for application for those who are not connected to the internet. 1-800 # should be instituted where potential applicants can ask for an application to be mailed or faxed to them.

Frequency & Duration of Meetings:

While most survey respondents indicated that they would be willing to meet for one day once per month for a period of 12-18 months, it is felt that this would become too cumbersome for many individuals, particularly if travel is required. It is therefore suggested that the Council meet once every 3-4 months for a period of 1-1.5 days at a time. This will ensure that members will only be required to commit a maximum of two days of their time four times per year, even if traveling from home. This is similar in scope to other groups of this type.

It is further suggested that Council members be asked to commit to a term of two to three years, and Council members will not be able to renew their membership more than once (i.e. sit for more than two terms in a row). This will ensure that members have the opportunity to become comfortable in their role, and to ensure that the Ministry of Health and Long Term Care receives a good return on investment for resources spent on training and education. It is also suggested that a “rolling” membership be instituted originally, with some members completing their term after three years and others after four. This will ensure that the Council does not change as a whole once the first term is completed.

Training:

Each Council member will bring their unique and varied blend of expertise and knowledge to meetings and it is expected that some training will be required on issues related to the Ministry, health care in Ontario, and meeting ‘comportment’ (presenting ideas, differing opinions, etc.) It is suggested that Council members be provided with binders or manuals for reference but that all training takes place on a face-to-face basis in workshops. During transition periods (where some members of the Council are leaving and new members are taking their place) it is suggested that a 3 month cross-over period be instituted in order to facilitate coaching and mentoring. Therefore new members will receive initial training prior to their first meeting, and then receive coaching and mentoring from peers for their first few months of active participation. If the Ministry lacks the resources to prepare this material ‘in house’ it is suggested that they hire an external consultant who specializes in health communications and training to provide this service for them.

Resources:

Participants will require a number of resources in order to facilitate their attendance at meetings. Survey respondents indicated that the most important resources include access to educational materials and experts, and reimbursement for expenses.

Educational Materials & Experts

As in the preparation of training materials, if the Ministry lacks the resources to compile information and present it to Council members in a workshop they should hire an external consultant who specializes in the topic area under discussion to prepare and deliver the materials. Outside experts may also be called in from time to time in order to provide updated information, insight, and respond to questions as needed by the Council.

Expenses

The Ministry will have to provide Council members with reimbursement for all reasonable expenses incurred while attending Council meetings.

Expenses may include:

- Transportation & Parking costs,
- Accommodation (if required),
- Payment for child care (if required),
- Meals
- Long Distance Telephone calls to home (within reason)

Accessibility Issues

Furthermore, each new member should be asked if they have any special requirements, such as wheelchair access, scent free rooms, etc.

Payment:

The majority of respondents to the survey did not wish to be paid for participating in the Citizens' Council. This is similar to the findings of Pivik²⁷ *et al* and Ahern²⁸ *et al*. Both studies concluded that payment should however be provided, in order to ensure wide representation of consumers: *"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. This is important since the individuals who are participating must be able to represent a wider community. If for example, most of the participants are retired, as noted in previous research, there is the potential for skewed feedback."*

Given that 40% of respondents did require payment, coupled with the fact that many of the others felt payment would be appropriate if other experts were also being paid, and the need to ensure a balanced perspective, it is suggested that all Citizens' Council members be paid a modest daily honorarium (i.e. \$250) for their time in addition to the reimbursement of expenses as discussed above.

CONCLUSION

The Citizens' Council is an exciting undertaking and it is hoped that the Ministry will find the recommendations included in this report to be useful. A consensus conference with representatives of patient groups, the public and decision makers will be held in mid-February to discuss and expand upon these recommendations.

²⁷ Pivik J, Rode E, Ward C. *A Consumer Engagement Model for Health Technology Assessment Health Policy*, (69) 2004, 253-268.

²⁸ Ahern K, .Donohue M, Manga P, *The Role of Consumers in Health Care Decision Making Healthcare Management Forum*, 1997 (Summer);10(2):25-32

APPENDIX I

Dear ,

On behalf of Dr. Wayne Taylor of the Health Leadership Institute at McMaster University, Ward Health Strategies is conducting a survey of patients, consumers and advocates regarding patient/consumer involvement in the Citizen's Council as described by Bill 102: *Ontario's Transparent Drug System for Patients Act*. A representative from Ward Health Strategies will be calling you in the next couple of days to conduct the survey over the phone; however the survey questions are attached for your reference.

The new law is intended to strengthen the Ontario Ministry's transparency and accountability in the drug system by giving patients a role in drug listing decisions. The bill states that "*the Minister shall establish a Citizens' Council whose duty shall be to ensure the involvement of patients in the development of pharmaceutical and health policy.*" The Council will report directly to the Executive Director, and will provide citizens with an opportunity to help to shape drug policy.

The purpose of this survey is to gain your feedback and thoughts regarding the Citizen's Council.

We greatly appreciate your input, however if you wish not to participate in this study, please let us know by responding to this email.

Best regards and thank you,

APPENDIX II

Respondents were asked to provide a list of key issues that should be addressed by the new Citizens' Council. The following list represents the topics and issues suggested by respondents, in no particular order:

- Funding issues for those not covered by programs. Many issues, such as coverage of devices, (i.e. epi pens, not covered, \$120 and life saving)
- Allocation of benefits to different populations needs policy direction.
- Issue of age is important, as is poly-pharmacy. There is a need to discuss interdisciplinary issues within the professions with an improved role for pharmacists.
- The broader task is to define 'fair'. Discuss who is in control and who decides what is going to be appropriate in terms of drug access. There has to be a balance of risk vs. benefit.
- Emergency access to drugs that are not available.
- The speed at which new drugs are approved by HC.
- Need for income support for those who are working poor.
- Less restrictions on Trillium Foundation
- Quicker mechanism to replace Section 81: The details of how a new appeal process will be established need to reflect patient and caregivers' needs.
- Decisions re drug approval will be made public: Will this information include how a decision has been reached? Will the public be able to understand the rationale as posted? Again, a patient/caregiver/public perspective on what information is posted and how it is posted would be important.
- How will the changes to the Act/processes be communicated to patients? Again, a patient/caregiver perspective would be important to have.
- Rapid Review system: Again, details re this process are not yet available. The patient viewpoint should be included to ensure this new process meets the desired goals.
- Other policy issues as they arise that will have a direct impact on patient access or affordability
- Ontarians living with a chronic disease like diabetes can pay from zero to \$10,000 a year for the medications, devices and supplies to manage their chronic condition depending on whether they are covered by ODB, a private or employer drug plan or have no coverage at all. Should the Ontario government extend drug benefit coverage to all Ontarians living with a chronic disease after the individual has paid the first X amount. So for example, should the government implement a program that ensures no Ontarians pays more than 3% of their annual adjusted family income for medications, devices and supplies? Please note that BC, MB and SK provide this type of coverage for their citizens.
- Promote equal access to all Canadians.
- Define public interest and the criteria for what serves the public best. Access to new drugs quickly.
- Guarantee that patients with rare disorders are treated equally to Canadians with more common
- Assess the lack-of or the over-kill bureaucratic processes that impact these systems and as a result, peoples' ability to access programs and in some cases manage their own health within the constructs of these public programs.
- Equal access to orphan drugs for all patients within an indication; diseases;

- Deductibles and co-payments that do not limit access for any patient regardless of income or age;
- Look at an orphan drug policy, post-market surveillance, and pharmaco-economic analysis with the intention of breaking down silo thinking. Interact with other ministries that affect the socio-political determinants of health (education, labour, environment, housing etc...)
- Universal care should be the goal. Consider making drugs available even when they are off-label. There is an example of a substitute for a very expensive clotting factor drug that could be substituted for a different drug that isn't indicated for clotting. This knowledge would save the province money.
- Coverage for drugs for children for rare diseases or expensive treatments for cancers etc. Coverage especially for families not covered by plans eg. Social insurance.
- Advice is just advice... look at ways to strengthen this council when it is implemented.
- I don't think the Council will be asked to comment on senior pay. I think the Council will address a narrower range of issues related to the specifics around reimbursement policies rather than societal values around healthcare funding. That being said, I think the broader issues are important but unless the Council were representative or there were a process for broader input or consultation, it would be dangerous to have a select body make those recommendations on behalf of all. How will the Council fairly represent Ontarians' values?
- Making the distinction between chronic disease and the regular public should be done. The Needs of a chronic disease population are different.
- An arms-length report card annually to the public on the effectiveness and soundness of processes the government is involved in – ie. Common drug review
- Costs of medications and medical devices
- Whether or not the gov't funds all CDR approved drugs
- There is a need to be clear on how to pay for the newest treatments. How are Ontarians going to have access to new therapies is a question to ask. Must make this cost effective.
- To ensure access is not further reduced
- Council should ensure timely review of new medications
- What are the decision making criteria under which new products will be reviewed? Need to ensure that cost containment is not the only criteria that will be used to determine whether products are listed on the formulary
- How will quality in the new drug program be assessed? How will savings (not just financial savings) be measured?
- Ease of transition onto programs such as Trillium Plan – this is a barrier for many who are not aware of the program and how it works.
- Find ways to include more lower income people in government plans! (ie. One province actually will issue \$1 cheques monthly to low income individuals with extraordinary health costs (hiv/aids drugs) so that they have dental, medical and other basic healthcare services)
- Who the Citizens Council is ultimately accountable to... if the Minister of Health only... then it is another bureaucratic process that will be bound by the agenda of the actual bureaucracy and their plans.



ADDENDUM

The Importance of Patient Participation in Health Policy Decision Making

*Consumer Engagement in Health Technology Assessment:
Recommendations for the Mandate and Makeup of a Citizens' Council
as Created under Ontario's Transparent Drug System for Patients Act*

**Results of a Consensus Symposium
February 12, 2007**

Prepared by:

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On February 12, 2007 representatives of patient groups met to review and discuss the report ***The Importance of Patient Participation in Health Policy Decision Making***, and provide further feedback to Ministry of Health and Long Term Care officials.

Update on Bill 102

Helen Stevenson, Executive Lead, Drug System Secretariat (DSS), provided an update of the progress on Bill 102 in general and the Citizens' Council in particular at the beginning of the meeting. Some of the highlights of her presentation are below:

Citizens' Council:

- Bill 102 came into force in October 2006, and since then the DSS has been working their way through the processes through which both the Pharmacy Council and the Citizens' Council are instituted and formalized. They have been working on much of the 'behind the scenes' processes such as recruitment processes (working with the Government's Public Appointments Secretariat).
- The DSS has been looking to other jurisdictions in order to learn from others' experiences such as NICE in the UK, and the Citizen's Assembly on Electoral reform in British Columbia.
- The DSS is just about to retain the services of an outside agency to help them with the process of selection and recruitment.
- In September, they received an unsolicited report from the Priority Setting Group at the University of Toronto. The DSS has built upon some of the recommendations from that report.
- The DSS also intend to use the results of this meeting to help map out publicly the recruitment and selection process.
- Helen Stevenson indicated that one of the most important decisions that will need to be made with respect to the Citizens' Council lies in deciding what types of questions they want to put to this Council. There is some indication that a Committee will be struck to initially take on this task.
- Members of the public can expect to see much more information on the recruitment and selection process in the next month to 6 weeks.

Patient Participation in the Committee to Evaluate Drugs (CED):

- A training process for the new representatives on the CED is currently being developed under the leadership of two representatives of patient groups.
- The CED is a government appointed council and therefore they have to follow the government process for selection and recruitment.
- They are also in the process of revising the terms of reference of the existing committee because that will change with the changing committee structure.
- In early March it is expected that documentation on the CED will be posted.

Other Bill 102 Initiatives:

- Helen Stevenson indicated that the plans laid out in Bill 102 are moving forward and that they believe the plan is working.
- They have listed 51 new drugs since October 1st 2006, of which many are brand drugs.
- They are also entering into many partnership agreements which they feel are beneficial.
- Conditional agreements appear to be working well. The DSS is now monitoring them closely and are satisfied with the results.

- Details for the Rapid Review process will also be posted on the web site. Nine drugs have gone through the process and at least one or two have received approval to be funded. As it is a new process there are some small adjustments that may be made in the coming months, but from the perspective of the DSS, the process is working well.
- Ms. Stevenson indicated that they have moved 4 of the top 5 Section 8 drugs from Section 8 to the formulary. (This means that they have eliminated 40,000 section 8 letters each year). They are actively working on moving some other drugs over as well.
- The Pharmacy Council is having its third meeting next week and the focus of that meetings have been on professional services. They are working on developing a framework and the technical details for these services. It is expected that in six weeks pharmacists will be able to be compensated for professional services. (April 1st).
- The Ministry is now producing monthly formularies which they feel is significant for stakeholders. They have also done a major 'housekeeping' of the formulary.
- Ms. Stevenson indicated that she could not comment on the Executive Officer at this time as the DSS is being kept out of the process. The Ministry is recruiting for the position, and they are in the final stages of that process.

Presentation: Study Results & Recommendations

Dr. D. Wayne Taylor then provided a review of the results and recommendations of the report *The Importance of Patient Participation in Health Policy Decision Making*. His presentation can be found in the power point presentation attached. A Q&A Session followed this presentation. Highlights of this session are described below:

Q: How will the legitimacy of Citizens' Council be assured?

This question was directed to Helen Stevenson, who responded that they were still deliberating on this topic, but that they see the Council as a body that will provide a summary of deliberations to the Executive Officer and the Committee to Evaluate Drugs. This model is similar to the NICE (National Institutes of Health and Clinical Excellence in the UK) model whose role it is to inform, rather than drive consensus.

Q: Will Recommendations of the Council be transparent and public?

Ms. Stevenson indicated that it is the intent that the recommendations and deliberations of the Council be transparent and public. For example, they could track the status of the recommendations. In response to a question about whether all Citizens' Council recommendations will result in policy changes, it was noted that some policy changes have big fiscal implications that Government would need to consider.

Q: Will the Council initiate its own issues for deliberation, or simply respond?

Ms. Stevenson believes that a smaller committee will be required to formulate questions and context for the Citizens' Council. "We believe the focus should be policy, and the council should not be dealing with specific drug listing issues."

Round Table Discussions

Participants were divided into three groups and were asked to deliberate and respond to the following three questions:

1. What are the key issues that a Citizens' Council should address?
2. What types of individuals would be best suited to provide the most valuable advice?
3. How should these individuals be recruited?

Participants then reported back to the group with their recommendations. Their suggestions and results are described below:

Question 1: What are the key issues that a Citizens' Council should address?

The three groups had very similar responses to this question and indicated that the mission, values and expectations of this group must be clarified before the Council begins its first deliberations, and further, that transparency will be extremely important. There was consensus among the groups that the Council will likely be asked to discuss "politically loaded" or value-driven issues and policies.

Key issues identified include:

- rationing decisions;
- access and safety;
- determinants of health and how this influences medication policy;
- 'who benefits and who is harmed' from drug policy decisions;

Question 2: What types of individuals would be best suited to provide the most valuable advice?

In response to this question there was agreement from all groups that a balance of perspectives was important, however the difficulty (and variation in opinions) lay in determining how this balance should be achieved. One group indicated that a mixture of individuals were required including people living with conditions (or their caregivers), representatives of patient groups, and 'lay citizens'. This group felt that the inclusion of members of patient groups was important as they have the feedback and input of their membership to draw upon, and therefore can provide the perspective of more than just one person. Another group felt that it was less restrictive and more appropriate to have 100% lay citizens, as everyone living in the province will be a patient at one point in their lives. The third group simply identified a 'balance of perspectives' as being required.

Question 3: How should these individuals be recruited?

Responses to this question garnered a range of advice, opinions, and suggestions.

These include:

- Ensure that appropriate and clear screening criteria be implemented. The process must also be as open and transparent as possible.
- Stagger term limits to avoid the 'constant refresh' of Council members every 2 or 3 years.
- Recruit geographically as well as ethnically (i.e. if you are advertising in the paper for members, make sure you advertise in more than the Globe & Mail and the Toronto Star. Initiate outreach through community and cultural media).
- Outreach through existing networks, such as through established patient organizations or health charities.

- Ensure that individuals selected be credible members of their communities.
- Implement a 'check list' of sorts in order to ensure that the final Council members "look like Ontario".
- There was a request that the 'ex officio' government Council member be from the upper levels of the bureaucracy.

Just prior to adjourning, a question arose regarding the Chair of this group – who will this person be, and how will they be chosen or elected? It was suggested that there are three methods for choosing a Chair. These include:

- Create the Council, and then "parachute" a Ministry hand-picked Chair into the role. It was felt that this would be the worst case scenario, and would be unlikely to garner much support.
- Allow the Council to define its' own process for electing a Chair. It may be necessary to appoint the first Chair for a short term (as Council members will not know each other well) and then allow Council members to choose their Chair for subsequent terms.
- Define the role of the Chair as a figurehead; this individual will sign letters for the Council, respond to questions from media and meet with Ministry officials. The 'facilitator' role will be assumed by an external consultant.

There was no consensus on which of the latter two definitions of Chair the group felt would be most appropriate.

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The Founding Director of the HLI is Dr. D. Wayne Taylor who is an internationally recognized expert in the areas of strategic planning, health services management, total quality management and business-government relations. Named "Professor of the Year" a record five times at the DeGroote School of Business, Dr. Taylor has also worked as a consultant, corporate manager and public servant. He has over thirty years' of experience working with managers in long-term care, acute care, public health and health policy planning as well as the private and not-for-profit sectors.