A Report from O’Hara Consulting

Results of a Literature Search on the Role of the Lay Representative in Research

Presented to: The Canadian Cancer Clinical Trials Network (CCCTN)
Lay Representative Working Group

Prepared by: *Dr. Rodney M. Schmaltz*

Assisted by: *Dr. Paddi O’Hara*

O’Hara Consulting
942 Kingsmere Avenue
Ottawa, Canada K2A 3K4
Telephone 613-728-2816
Email: PaddiOHara@rogers.com

November 8, 2013

Table of Contents

Acronyms

AHS	Area Health Service (Australia)
CAREB	Canadian Association of Research Ethics Boards
CCAN	Canadian Cancer Action Network
CCCTN	Canadian Cancer Clinical Trials Network
CIHR	Canadian Institutes of Health Research
CABS	Community Advisory Boards
NA	Non-affiliated
NHS	National Health Service (U.K.)
NIH	National Institutes of Health (U.S.A.)
NIHR	National Institute for Health Research (U.K.)
NS	Non-scientist
pCODR	pan-Canadian Oncology Drug Review
REB	Research Ethics Board
TCPS	*Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*

Executive Summary

The **Canadian Cancer Clinical Trials Network (CCCTN)** is a pan-Canadian initiative to improve the efficiency and quality of clinical trials in Canada. CCCTN will provide support and coordination for a network of teams at cancer treatment centres and hospitals. With regional participation, CCCTN will develop a business plan to enable sites to increase their capacity and capability to conduct academic trials. To that end, CCCTN has established a number of working groups whose deliverables during Phase I (the first six months of the project) will be the processes, systems, templates, and standards for the CCCTN portfolio.

The “Lay Representative Working Group” has been tasked by CCCTN to explore and identify means by which to develop and enhance meaningful participation of lay representatives in CCCTN activities. As a foundation for this activity, the Group requested a literature search on the topic. This report represents the results of that search.

There is a growing realization that being a research participant is not the only way for a *civilian* (i.e. someone not directly involved in the conduct of research) to be part of such investigative endeavours. There are also a growing number of research advisory boards, ethics review panels and knowledge translation groups – just to name a few examples – that are seeking the input of lay representatives. The question then becomes, how are such representatives identified, recruited, utilized and even rewarded for their contribution? While it is apparent that the idea of finding new and useful ways of incorporating the input of the public in research is still in its formative stages (as evidenced by the limited availability of data, particularly in a Canadian context) it is clear that in more and more research settings, thought is being given to how best to encourage the participation of lay representatives.

The report begins with a discussion of the multiplicity of terms used to represent the notion of a “lay representative” on a board or committee. It was ultimately decided to adhere to the term "community member."

Much of the discussion presented is based on the four general ethical goals of community consultation, that is: enhanced protection, enhanced benefits, legitimacy and shared responsibility. The roles and expectations of being a community member are discussed from the perspective of the members themselves as well as the board.

Education is a critical component in ensuring the success of community members on committees. Often community members do not have expertise in research methodology or the way in which a committee or board functions (or at least they do not feel as if they have the expertise of other board members). Various approaches to education are presented, including the possibility of mentorship as an ongoing source of support and training for these community members.

Recruiting community members is a challenge for many organizations as a community member is required to have the expertise, time and motivation to be involved with the committee in question and yet not be involved directly with the sponsoring or supporting organization, or tied to it in some way that could be considered a conflict of interest. This apparent contradiction is discussed and recommendations offered for successful recruitment techniques.

There are numerous organizations that employ the use of community members. A list of organizations and resources that could serve as examples of this service are provided.

There are recommendations provided throughout the report and, ultimately, a concise list of general suggestions are supplied:

1. There are a variety of terms that can be used to define public representation on boards. Regardless of the term used, it is critical that public members are given clear roles and expectations regarding their participation on the board.

2. Non-community board members need to be provided with information on the role of community members, the value community members provide and the expectations and roles of community members.

3. Education is a critical component of successful public representation on a board. Education programs need to be tailored such that the community member receives training in the area of focus for the board (e.g., oncology trials), as well as how the board functions and how best to contribute as a community member.

4. Ongoing support and training in the form of mentoring from administrative personnel could be extremely useful to community members, particularly those who are reluctant to approach their fellow board members with questions, or for those reticent about expressing their opinions during meetings.

5. There is need for a review of the current community member education processes in place, as well as further information on the perspectives of community members in Canada. A systematic review of best practices in all aspects of identifying, training and utilizing community members – perhaps starting with a survey of boards employing community members in Canada - could be extremely useful for the objectives of the CCCTN Lay Representative Working Group

6. Potential recruitment strategies for community members includes the press, social media, patient-focused groups and former patients and research participants. Organizations such as INVOLVE provide a successful model.

Introduction

As long as humans have been the subject of research investigations, there has been concern about how to ensure that they are treated appropriately, safely and even with dignity. The evolution of many codes of research ethics (such as the Nuremberg Code of 1948 and the Declaration of Helsinki, first conceived in 1964 and updated frequently) has demonstrated that it is essential to clarify what this means although it is obvious that a consensus is very difficult to achieve.

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS, 1998) serves as a guideline for investigators, members of Research Ethics Boards (REBs), research administrators and sponsors for much of the funded research that takes place in Canada. In the second version of the TCPS (2010) one of the significant changes in the document was to describe human volunteers as *participants* rather than *subjects*, thus acknowledging that these people are important players in the endeavour of research and not merely guinea pigs that serve as experimental fodder.

However, there is a growing realization that being a research participant is not the only way for a *civilian* (i.e. someone not directly involved in the conduct of research) to be part of such investigative endeavours. There are also a growing number of research advisory boards, ethics review panels and knowledge translation groups – just to name a few examples – that are seeking the input of lay representatives. The question then becomes, how are such representatives identified, recruited, utilized and even rewarded for their contribution?

This purpose of this report is to provide a foundation for addressing some of those questions. It provides the results of a literature search that was conducted on this topic and while it is apparent that this is still an idea in its formative stages (as evidenced by the limited availability of data) it is clear that in more and more research settings, thought is being given to how best to encourage the participation of lay representatives in new and important ways.

Terms Used to Describe Non-affiliated Committee / Organization Board Members

This report focuses on the role of community members on health-related boards and committees. Throughout the report the terms board, committee and organization are used interchangeably.

There is a wide range of terms used to describe the role of public representation on research ethics boards. The list of "public representatives" includes:

- public members
- associates
- community representative
- a non affiliated person from outside the organization but who still uses the services of the organization
- unaffiliated
- an outside consultant
- an outsider
- lay persons
- non-affiliated (NA)
- non-scientist (NS)
- patient representative

For the purpose of this paper, we will refer to public representatives on boards or committees as "community members." "Community member" is a commonly used term, especially in Canada, although there is some debate about the appropriateness of this descriptor (Klitzman, 2012). It is difficult for only a few people on a board to fully represent the "community" which may be extremely diverse in terms of ethnicity, socio-economic status, education levels and experience with the focus of the board they serve. As such, the term "community member" may be overly vague and potentially confuse the member's role on the committee. For example, does "community" refer to the local area that the committee supports, or does it refer to patients and/or research participants as a whole (MacQueen & McLellan, 2001)?

Using terms such as "non-scientist," "layperson" or "non-affiliated member" may remove the potentially confusing connotation of "community." Furthermore, a survey of nonscientist ethics board members conducted by the National Institutes of Health (NIH) indicated that "layperson" best described their role on the board (see Table 1) (Allison, Abbott, & Wichman, 2008). However, a potential difficulty with using the term “layperson” arises from the possibility that board members may be physicians, researchers, scientists or have other professional designations. In this sense being labeled a “layperson,” defined as a “person without professional or specialized knowledge in a particular subject” seems inappropriate. While there is no perfect solution in terms of terminology, it is critically important that non-affiliated members, regardless of how they are labeled, fully understand the nature of their role on the board. As well, public membership must be transparent to the public, both in terms of understanding the role of community members the opportunity to participate as a board member. It is important, therefore, to focus on how to recruit members and to ensure that the members are able to contribute to the board in a way that is meaningful to the public, the board and the community members themselves.

Table 1: Roles of Nonscientist Institutional Review Board Members (Allison, Abbott, & Wichman, 2008)

Title Used for Role	Overall (N = 25)		Affiliated (N=9)		Nonaffiliated (N = 16)		*p*
	Agree	Disagree	Agree	Disagree	Agree	Disagree	
Layperson	68%	32%	44%	56%	81%	19%	0.087
Public Representative	28%	72%	22%	78%	31%	69%	0.682
Community Representative	16%	84%	11%	89%	19%	81%	1.00
Research Subject Advocate	16%	84%	11%	89%	19%	81%	1.00

Research Sources

Databases used for research in this paper included PubMed, Medline, PsycInfo, Health Policy Reference Center, Health Sciences, Proquest Public Health the Web of Science. The majority of the articles referenced can be found on PubMed and/or Medline.

Role of Community Members

While the role of community members varies across boards and committees, Dickert et al. (2005) provide four general ethical goals of community consultation (see Table 2):

1. Enhanced protection (for the most part this refers to REBs but it can also apply to other boards);
2. Enhanced benefits;
3. Legitimacy; and
4. Shared responsibility.

Throughout this report, the framework proposed by Dickert et al is utilized as the foundation for categorizing the primary goals of involving community members on a board.

Table 2: Ethical Goals of Community Consultation (Dickert et al., 2005)

Ethical Goal	Definition
Enhanced protection	Enhance protections for subjects and communities by identifying risks or hazards that were not previously appreciated and by suggesting or identifying potential protections
Enhanced benefits	Enhance benefits to participants in the study, the population for which the research is designed, or the community in which the study is conducted

Table 2: Ethical Goals of Community Consultation (Dickert et al., 2005)

Ethical Goal	Definition
Legitimacy	Confer ethical/political legitimacy by giving those parties with an interest or stake in the proposed research the opportunity to express their views and concerns at a time when changes can be made to the research protocol
Shared responsibility	Consulted communities may bear some degree of moral responsibility for the research project and may take on some responsibilities for conducting the study

The Value of Community Membership to the Board

Public participation serves numerous benefits to boards and committees. Til Wykes of King's College London highlights the need for public participation in research by saying, "For treatments to be anywhere near feasible and useful for patients in the NHS [National Health Service, U.K.], it is essential that patients are involved in every step of the research process: from setting the research questions, guiding us on the best outcomes, helping us communicate and determine what's feasible considering the restrictions of the illness." In fact, research by Ellis and Wykes (2013) highlights how involving members from the community (in this case, specifically patients in health research,) can aid in the recruitment process for research. Ellis and Wykes (2013) propose that the reasons for an increase in recruitment through the use of patient involvement are threefold:

a. *The language used in materials such as information sheets is more appealing or easier to understand for patients because of vetting by other patients*
b. *Patients contribute insight into the realities of living with a health problem (mental health, in this case) and therefore understand which designs will be the least burdensome; and*
c. *Patients are more willing to participate in research that they know has involved other patients, as the principle of patient involvement is in itself appealing.*

While the research here focused on the recruitment process in mental health trials, the general principles apply to the overall benefit of community members across a variety of boards. Community members help ensure that the language used in materials is clear and appropriate and, in the case of patients, may offer insight into living with a health problem. The benefit of understanding a health problem is clear for boards that focus on ethics; however this understanding can also provide insight into which projects might receive funding and how participants best be recruited for research (in ways that benefit both the participant and the researcher).

Ensuring a Valuable Experience for the Board Member

Although there is an increasing call for community representation on boards and committees, the simple addition of community members does not necessarily improve board performance. Community member turnover is a major concern, and community members need to feel that they are in an environment where their voice can be heard and the roles of the community member are clearly defined.

Saver (2005) points to the following issues that potentially hinder the role of the community member on a board:

- Lack of training
- Member fatigue due to lengthy tenure
- Member time constraints
- Overly large committees which make it more difficult for members to have effective contributions.
- Perceived pressure from presence of expert members (e.g., scientists/physicians).

Saver's focus is on research ethics committees; however, his points translate well to community membership on a variety of boards.

The Canadian Institutes of Health Research (CIHR) provide a model for community membership which minimizes the impact of the points described by Saver. CIHR uses a feedback program to evaluate the community member experience (http://www.cihr-irsc.gc.ca/e/41733.html). By allowing community members to provide detailed feedback, CIHR is able to learn if community members are sufficiently trained and, if not, in what areas they are weak. As well, members are able to report issues of fatigue and discuss time constraints. By learning of a member who has issues with availability and time, an organization can either add an additional member to supplement the current member, thus reducing burden, or reframe the role of the community member such that they would be able to participate in a meaningful way.

Feedback also allows committees to learn if the member is uncomfortable during meetings and whether or not there is perceived pressure from other members of the board. If members do feel this pressure, the chair of the committee should be responsible for working with the member to help alleviate concerns (Anderson, 2006). In addition, access to staff members outside the board is a valuable asset for community members.

One of the critical issues to be addressed when considering the topic of community membership is the need for clear definitions of roles and expectations for both the community members and the boards on which they are serving. There are cases where board members report that they are not certain about the nature of their role. In addition to the lack of clarity regarding their function and responsibility, they sometimes feel that their roles are minimized or that community membership is perceived as simply an exercise in public relations (e.g., Wodak, 2013). Community members need to be aware of the scope of their role, the input they are expected to provide, the “value added” component that they bring to the table and the constituency they are there to represent, be it the perspective of the patient, the caregiver to a patient, the community at large, the non-scientist who is there to bring balance to what is usually a largely scientific environment or simply a person who is outside of the organization.

It is critical that the community members understand their role on the board and it is equally important that the board members understand the role of community member. While training for community members is relatively common (though the extent of training is varied, which will be addressed later in this report), there are few organizations that provide training to the board on the nature and role of community members. If a board member does not fully understand the function of the community member on the board, he or she may not engage the community member when it would be appropriate and potentially highly useful. One of the reasons that there is a problem retaining community member on boards is that community members report feeling that their voice is not heard. This may be due to the board members being unaware of when to refer to the community member and their lack of understanding of the value of the perspective of the community member.

It is worth noting that although the chief focus of this report is on the community member sitting on a board or committee where the majority of members are not considered lay representatives, there are also groups that are composed *entirely* of community members. In the latter case, the role of the complete committee must be clearly defined. It may be helpful, for example, to create a lay advisory group that offers advice to an REB. The REB community member(s) could then take the input of the advisory group back to the full REB. The REB would need to be informed about the benefits of having a lay advisory group as well as the role of the community member who acts as the liaison for the community perspective.

Education and Training for Community Board Members

Education is a critical component in ensuring the success of community members on committees. Often community members do not have expertise in research methodology or the way in which a committee or board functions (or at least they do not feel as if they have the expertise of other board members). For example, a patient would have expertise in areas related to their illness, the consent process, etc. but might not have a high level of expertise in terms of the way in which clinical trials are conducted, the funding process in research, the way in which research protocols are vetted or policy regarding research ethics. All boards that involve members of the community generally have some form of training, though the quality and scope of the training varies considerably.

Interview data (Anderson, 2006) collected from community members highlighted the following reoccurring themes

- Initial training was overwhelming
- There is need for follow-up training
- The training should be applied and, when possible, interactive.

Those surveyed also noted that it would be useful to collaborate with community members in other institutions. This would provide an opportunity for members to discuss their experience with other board members who share similar concerns. As well, members reported that the majority of training happened "on-the-job." It was suggested that there could be value in educational exercises that occurred outside of the real time life of the committee, such as working through specific protocols or issues related to the board with a focus on providing information to the community member about what they are expected to contribute. For example, an ethics committee could walk a new community member through a previously reviewed protocol and provide detail on the issues that the board discussed and importantly, what the community member contributed and is expected to contribute.

One of the benefits of enhancing education and training for community members is that it will provide members with the confidence to have their voices heard during committee meetings. If community members perceive a large gap between their level of knowledge and that of the other board members, who may be physicians and researchers, they may be less likely to voice their opinions in meetings. (Pinto, Spector, Rahman & Gastolomendo, 2013). An interesting approach to assist in training and to ensure that members' voices are both heard and valued can be found in Australia (Nathan, Johnston, & Braithwaite, 2010). Community representatives are made aware that "their role on committees can promote greater public confidence in health services and ensure a broader non-professional view-point." Each community member is matched with a health service staff member when joining a committee. Staff is charged with providing assistance and support for the representative. This strategy appears to be effective for at least two reasons; not only does the community member have access to additional information through the support of the staff member but the committee member also has an opportunity to ask questions which she or he may be afraid to bring up in a full-board meeting.

Research on the perspectives of community members has illustrated how they are not always sure just what aspects of the community they are to represent, the exact nature of their role on the board and the ways in which they can best contribute to a successful board or organization. Across policy, academic literature and committees, there is near uniform agreement that community members have the potential to add great value to a board; however, there is concern that the training some community members are receiving may be inappropriate. If the training is not conducted properly, community members may take the organizational perspective, thus negating the purpose of the community member which is to represent the perspective of those outside of the organization (Epstein, 1996). To ensure that the training is appropriate for community members, boards should have educational materials focused on the role of the community member. This does not preclude community members from participating in standard board training, rather, this allows community members to have insight into the nature of their role and allows them to view the standard organizational training through the unique perspective that is needed from a community member.

The training specific to the community member should be conducted by someone outside of the board. Board members may impart their own biases and place social pressure on the community member to be consistent with the trainer’s position during meetings. As well, the trainer may be held in somewhat higher regard by the community member. From the literature in psychology, we know that people are quick to form impressions of others that may not be accurate. In this case, simply being trained by a board member may make the community member view the trainer as particularly knowledgeable and thus, make it difficult to disagree with the trainer.

Recommendations:

1. Community members should participate in standard board training (e.g., several of the CITI-Canada online courses could be extremely helpful to community members) but must also be offered additional training to ensure that they understand their role on the board and given further information on the organization. Where it could be unreasonable to ask an experienced investigator[1] to undergo training in the role and function of an organization (e.g., CIHR), it could be extremely helpful to community members who may not be familiar with the "basics" of an organization and who would benefit from such fundamental training sessions.

2. Many organizations have initial training but do not have ongoing training. It is valuable for members to receive opportunities for further education. It is important not to overburden members with excessive mandatory training, while at the same time offering sufficient training to ensure that they can fulfill their role on the board.

3. Community members should have access to administrative support or a board member who could field general questions **before meetings**. Ideally, a senior administrator would best serve this purpose as interacting with a board member (e.g. a physician or researcher) could still be intimidating for someone without knowledge in these areas. Community members have reported feeling awkward when asking questions whose answers may be considered too obvious by board members. The use of an administrative person would help alleviate some of these concerns and allow the board member to gain the knowledge and

---

[1] It is beyond the scope of this report to elaborate on the nature of the training that should be recommended for “standard” committee or board members (i.e. non-community members); however, it should be remembered that simply being a physician, investigator or having another professional designation does not mean knowing about all aspects of the research process. In other words, there are probably many “standard” committee members who would benefit from some of the training – and the approaches to training – being suggested here for community members. It is analogous to taking a guided tour of one’s own city; sometimes it is amazing what one can learn by temporarily adopting a naïve perspective.

confidence to contribute more meaningfully to board meetings. In other words, the role of the administrative person would be one of supporting as well as mentoring the community member.

4. Interview data from community members indicates that a lot of the learning happens "on the job." To further help with the learning process, it would be valuable for board members or high-level administrators to meet **after board meetings** and allow community members to reflect on their experience and clarify any questions they may have. This is particularly important for new members as, once again, they may feel intimidated when speaking in a room of perceived experts. The purpose of the community member reflection is two-fold: it allows the community member to feel appreciated and it also provides the committee with valuable feedback from the community member. If the member does not feel that her/his opinion is being heard or valued, or if the member is uncomfortable speaking in front of a group of experts, the board may be able to make changes that will ensure that these difficulties are minimized. In other words, this post-meeting reflection can help community members maximize their contributions and feel comfortable in their role while also helping the committee to function in a way that is respectful to, and gets the most from, all members.

5. There is a need for community members to be able to share experiences, concerns and ideas with their counterparts from other organizations. This could be facilitated through conferences devoted exclusively to community membership on boards (perhaps through organizations such as INVOLVE – see section on Additional Resources – which encourage public involvement in research) or through organizations interested in research (e.g., CAREB: the Canadian Association of Research Ethics Boards) which may be willing to include sessions within their conferences that could be devoted to community membership.

Identification and Recruitment of Community Board Members

Recruiting community members is a challenge for many organizations (Klitzman, 2012). A community member is required to have the expertise, time and motivation to be involved with the committee in question and yet not be involved directly with the sponsoring or supporting organization, or tied to it in some way that could be considered a conflict of interest. Many public health/research ethics boards require members to read over complex documents using highly technical language; in other words, members are expected to operate in the world of scientific investigation and research. A valuable community member is one who has the necessary skills to understand the subject matter that is the focus of the board without being an active member of that world of scientific investigation and research. That community member – regardless of expertise and professional background – must also represent the views of the community.

One of the issues facing boards recruiting community members is clearly defining the role of the member deciding how the member can best represent the community. For boards that deal with a specific area, such as clinical trials in cancer, it may be reasonable to recruit a former patient. However, in boards that represent a more diverse area, this issue becomes more difficult. A non-Aboriginal cancer patient may not be an appropriate representative of the community when looking at research on genetics in an aboriginal populations (Avard et al., 2009). Guidance can be found from the Coriell Institute for Medical Research policy for the collection, storage and research use of human genetic samples. The policy offers the following questions as a starting point for identifying community representatives:

- What is the total number of individuals (approximately) who are part of the named population from which sample donors will be recruited?
- What communities exist within that population and what is the total number of individuals (approximately) who are part of those communities?
- Can a particular community or communities within the larger population be identified as an appropriate forum for the consultation?
- Is this community politically organized in any way (i.e., tribe, municipality, etc.)? If so, that political organization, or community leaders, must be consulted.
- If not, are segments of the community politically organized? If they are, will samples be collected from one or more of those organized segments? If so, each of these political units should be consulted.
- If no local political organizations exist, then what cultural or other social organizations exist at the local level? If such cultural or social organizations do exist, they should be consulted.
- If no organized groups exist at all, the collector must identify other effective ways to consult the community.

While the focus of these guidelines is on the collection of genetic material, the overarching themes apply to community representation on boards.

It is recognized that one or two people on a board cannot be fully representative of the community as whole (Martin, 2008) and, as such, it is critical for the community members to *best* be able to represent the voice of the community, at least within the confines of the interests of the board. It is common practice to recruit retired researchers and physicians, though this group arguably does not necessarily represent the "community" if one's definition focuses on the targets of the research rather than the ones who conduct the research For example, a retired oncologist on a medical REB would certainly have the expertise to contribute in a meaningful way - based on extensive experience with the ins and outs of clinical trials - but such a member would be providing a perspective quite different from that of a layperson – perhaps a patient - who was not a physician or researcher.

There is no agreed upon solution to the issue of recruiting community members (Avard et al., 2009). Generally, most organizations have some policy in place regarding conflict of interest and the need for the community member to be at arm's length from the organization. Most organizational policies stress the importance and need for community members but do not offer clear guidance in how to identify or obtain these members. In terms of research ethics boards, Article 6.4 of the TCPS 2 gives little guidance. According to the TCPS 2, community members should:

1. Not be affiliated with the institution.
2. Ideally be a former research participant.
3. Should not be engaged in research or legal work as their principle activities.

In terms of recruitment, the level of detail provided by the recommendations in the TCPS 2 are fairly standard for most boards seeking community members. While the TCPS 2 provides some guidance (which is specific to REBs) and states the importance of community members, the document does not provide many specific details as to the best approach to identify and potential members.

Green (2007) proposes that committees (in this case ethics committees) aim for community representation from members in the following areas:

1. A person with an ethics background (e.g., counselor/ethicist)
2. A person representing societal/ethnic presence
3. A person from local media or academia/education.
4. A person qualified in a different research area, such as a chemist or engineer
5. A person from a related profession, such as a lawyer

Green based these recommendations on the assumption that a working committee might comprise between four and six community members. The difficulty, as Green points out, is finding members who meet these criteria and who have "an informed interest, articulacy, evaluation capability, reasoned balance, personal commitment and committee experience." Some suggestions coming from Green, a lay member of a research ethics committee, include: using the media to promote community involvement in research and raise awareness; developing fliers for community organizations; and information sheets prepared (both print and electronic) for potential members. These information sheets could be included with consent procedures for research and/or medical procedures.

In the case of many organizations, community members tend to be recruited through recommendations from current committee members, or someone employed by the organization's institution. For example, members of the HIV Prevention Trials Community Advisory Boards (CABs) are recruited through recommendations from community leaders, volunteers past and present, people living with HIV and/or former study volunteers, recommendations from CAB members and the HIV Prevention Trials Network Staff. While recommendations by current board members can be a valuable recruitment tool, the organization must be aware of potential problems using this recruitment strategy. For example, it has been argued that recruitment of people who are known by the organization's board can lead the member to become "encumbered" by social ties and less likely to challenge the status quo (Saver, 2005).

One recommendation is that committees (in this case, specifically ethics boards) consider a corporate model in which committees composed of non-committee members (in the case of corporations, independent directors) nominate candidates for community member positions. It stands to reason that board members would nominate community members who are likely to support or mirror their views. Organization board members may not intentionally recruit a community member who would not deviate from the current perspectives on the board but it is likely that a current member would see potential community members as more effective if they held similar perspectives. This is not to say that there is a paucity of excellent and varied community board members but rather it is important to be aware that this recruiting strategy could narrow the diversity of perspectives on the board.

For community involvement in funding agencies, CIHR requires community reviewers to have experience working on a committee but they may not currently be involved in academia or health research. CIHR uses a self-nomination process. The community reviewer position is advertised "through existing committee members and community reviewers, CIHR staff, the Canadian Association of University Research Administrators, CIHR's university delegates, CIHR e-news alerts, CIHR's Institute Advisory Boards and CIHR's website." Candidates who meet the criteria are then interviewed by telephone.

In other parts of the world, the situation mirrors what is happening in Canada. There is general agreement that community members are valuable, though there is little guidance in the recruitment process. For example, in the United Kingdom, community members are solicited though community councils as well as patient and public forums, while in Australia, community representatives for the health services are recruited through newspapers and word of mouth. In the case of Australian health services community members, recruitment is usually facilitated by a connection with a health care centre or hospital. Community representatives usually have a connection with a particular hospital in their area (e.g., patient or volunteer) (Nathan, Braithwaite, & Stephenson, 2013). The selection criteria for community network members offers some guidance but, again, little in terms of recruitment strategies:

- Lives within the Area Health Service (AHS).
- Is not an employee of the AHS.
- Willing to commit time to attend scheduled meetings.
- Able to relate own experience of health care to broader.
- Able to represent and respect the views of other people who use the health system.
- Have some knowledge of the health system and experience on a committee or representing other people.

An interesting example of how the availability of community positions can be promoted is through websites such as INVOLVE in the United Kingdom. The information on the INVOLVE website stresses the importance of community representation and provides potential community members with a wealth of information with regard to available positions and the role of community members in their organizations. Patient advocacy groups may also be a valuable resource to recruit community members.

To ensure the recruitment of community members who will best represent the needs of the board, it is useful to explore the reasons why community members join boards and why they remain on the board. INVOLVE's report on public involvement in the NHS provides guidance in this area. In this report, an extensive literature review revealed that community members reported the benefits of board membership in terms of acquiring new skills and knowledge; personal development; support and friendship; enjoyment and satisfaction; and being rewarded financially. While other researchers have found that payment is not particularly important (Anderson, 2006), there is general consensus that members should at least be compensated for costs (e.g., parking, lunch, etc.). If there is compensation to board members, it is only just that the compensation should be consistent across all members. That is, community members should not be compensated more or less than any other member on the board.

Payment of board members should be considered carefully before being implemented. If payment to community members goes beyond compensation for time or costs associated with attending the meeting, the member may be less likely to disagree with board members for fear of losing his or her position (in other words, the voice of the community being represented may be adversely influenced) . On the other hand, by not offering compensation there is the possibility that members may feel that their contribution is not highly valued. This philosophical dilemma is similar to the one faced by investigators who struggle with the idea of monetary incentives for research participants at the risk of negating the voluntariness their consent (TCPS 2, 2010). In the end, however, we are faced with the reality that many committees or boards involving the public are underfunded and the question of significant compensation may be moot.

Recommendations:

1. Promote volunteer opportunities through websites, modeled after sites such as INVOLVE in the UK, which allow potential volunteers to learn more about the organization and the role that community members can play.

2. Volunteer opportunities should be posted in hospitals/research centres to inform patients and/or friends and family members of patients. As well, the organization could consider open public forums, or radio/television programs to explain the need for community members.

3. Involve organizations which may reflect the voice of the patient, such as the Canadian Cancer Society, Cancer Advocacy Coalition of Canada, Canadian Cancer Action Network and the Canadian Partnership Against Cancer, to advertise community board positions.

4. Where feasible, information about roles for lay representatives on committees could be provided to research participants in the debriefing process following their involvement in the study.

5. Recommendations from current board members are a potentially valuable resource in recruiting community members. The organization should be aware though, that recruiting through board member recommendations could limit the diversity of perspectives on the board (i.e., it is unlikely that a current board member would recommend a community member with strongly differing opinions or perspectives). As well, the organization wants to avoid the perception that the opportunity to participate as a community member is based on knowing the right person.

Additional Resources

There are numerous organizations that employ the use of community members. The following organizations and resources serve as examples that should be of use when implementing policy for community members to serve on a board:

a) ***Canadian Institutes of Health Research: Enhancing Citizen Representation on CIHR's Boards and Committees***

http://www.cihr-irsc.gc.ca/e/42209.html

This website provides a strong model for the use of community members on boards. In this report, CIHR has guidance for community members, a webpage devoted to recruiting community reviewers, the opportunity to interact with scientific experts through informal meetings at pubs, cafes and restaurants social media resources. Organizations looking to incorporate community members would be well-served to use this website as a template.

b) ***The Canadian Cancer Action Network (CCAN)***

http://www.ccanceraction.ca

This network is devoted to patient issues. There are many valuable resources for patients and community members here, as well as an opportunity to solicit community members. The CCAN report, Maximizing Patient Voices (found here: http://www.ccanceraction.ca/wp-content/uploads/2010/11/7-Maximizing-Patient-Voices-Report.pdf) provides an excellent overview of the patient representation in cancer-related government committees and decision-making organizations. Of particular importance is Appendix IV, which outlines all of the Cancer Research Funding Agencies as of 2005 the role of community members.

c) *INVOLVE*

http://www.invo.org.uk

Funded by the National Institute for Health Research (NIHR) in the UK, this national advisory group "supports public involvement in the National Health Service (NHS), public health social care research." This site provides a great deal of information regarding public participation in health-related boards. The resource centre provided by INVOLVE provides many valuable resources for public members is a template that could be used for organizations seeking community membership. INVOLVE's report on public involvement in the NHS (http://www.invo.org.uk/posttypepublication/exploring-impact-public-involvement-in-nhs-public-health-and-social-care-research/) provides an extensive literature review on issues related to community involvement.

d) *Australia Community Participation Program*

http://www.childhealthresearch.org.au/community-engagement/community-participation-program.aspx

The Community Participation Program for the Telethon Institute for Child Health Research provides resources for current and potential community members, including training and general information about the nature of community participation.

The Coriell Institute for Medical Research Policy for the Responsible Collection, Storage Research Use of Samples from Named Populations for the NIGMS Human Genetic Cell Repository

http://ccr.coriell.org/Sections/Support/NIGMS/CollPolicy.aspx?PgId=220

While focused on issues in genetic repositories, there is strong guidance here on community membership on boards, much of which generalizes to community board membership in general.

e) The pan-Canadian Oncology Drug Review (pCODR)

http://www.pcodr.ca/wcpc/portal/Home?_afrLoop=2052449893334000&_afrWindowMode=0&_adf.ctrl-state=bwarx867s_4

The pan-Canadian Oncology Drug Review (pCODR) was established by the provincial and territorial Ministries of Health (with the exception of Québec) to assess the clinical evidence and cost effectiveness of new cancer drugs and to use this information to make recommendations to the provinces and territories to guide their drug funding decisions. The pCODR process brings consistency and clarity to the cancer drug review process, ensuring individual provinces and territories can make drug funding decisions informed by evidence. In October 2013 the pCODR Guide for Patient Advocacy Groups was released (http://www.pcodr.ca/idc/groups/pcodr/documents/pcodrdocument/pcodr-patient-guide.pdf). The Guide is the first resource of its type in Canada and was created through a joint collaboration between pCODR and the Canadian Cancer Action Network (CCAN).

f) *Ontario Citizen's Council*

http://www.health.gov.on.ca/en/public/programs/drugs/councils/

Established in 2009, the Ontario Citizen's council is an advisory body to the Executive Officer of Ontario's Public Drug Programs and the Minister of Health and Long-Term Care. The council is made up of 25 Ontario citizens. The organization is interesting, as it is based on the public-engagement model from the UK, however the group appears to be facing some challenges. There has not been a meeting since 2011, and no new appointments in 2012/13. The primary problem seems to be a lack of clarity over the council's mandate.

g) CBC – White Coat Black Art: "Turning Patients into Health-Care Partners"

http://www.cbc.ca/whitecoat/episode/2013/09/20/turning-patients-into-health-care-partners/

If there is any doubt that the public is anxious to play a more directive role in the health care system, the CBC podcast of the White Coat Black Art episode which visits Kingston General Hospital is very instructive. Until recently, Kingston General had a less than stellar reputation with patients. Then it did something very unusual. It recruited a group of those unhappy patients to tell them how to do things better. Dr. Brian

Goldman tours the hospital to see how it's working. Darryl Bell, the hospital's patient and family-centred care lead shows Brian the patient-driven changes which have been implemented at the hospital. Brian also speaks with the patients and family members who give their two cents on everything from which MRI machine to buy to which nurses to hire. There is also a feature interview with Leslee Thompson, Kingston General Hospital's CEO who needs to get front line workers on board in order for this idea to stand a chance.

Conclusion

Public representation has numerous benefits for organizations, especially in the public health sector. Community members lend a voice that is unique to the organization and can enhance efficiency of the board by ensuring that the materials are clear to the public and provide assistance with participant recruitment, both in terms of participant understanding of research and helping researchers recruit to target numbers.

While the benefit of community membership is generally agreed upon in the literature, there are a number of challenges to ensure that public participation on boards maximizes the contributions of the community member for the board, the community the member represents and the member themselves. One of the keys to successful community membership on boards is having the role of the community member clearly defined. Community members should be fully aware of the contributions they are expected to make on the board and the population they are representing. To achieve these ends, education is a critical component of a successful board. Community members must be educated on the issues relevant to the board (e.g., clinical research) and also on the part the member plays on the board. As well, non-community board members must be educated on the role of the community member and have a clear understanding of how the community member can make valuable contributions.

Recruitment and retention of community members is a difficult issue for many boards. Successful recruitment strategies include raising awareness of positions through the press, social media, groups that promote patient-involvement and patients themselves following participation in research. Retention of members can be improved by clearly defining member roles and by having education opportunities in place to ensure members have the necessary tools to contribute both to the board and to understand where community member contributions are most needed.

General Recommendations

1. There are a variety of terms that can be used to define public representation on boards. Regardless of the term used, it is critical that public members are given clear roles and expectations regarding their participation on the board.

2. Non-community board members need to be provided with information on the role of community members, the value community members provide and the expectations and roles of community members.

3. Education is a critical component of successful public representation on a board. Education programs need to be tailored such that the community member receives training in the area of focus for the board (e.g., oncology trials), as well as how the board functions and how best to contribute as a community member.

4. Ongoing support and training in the form of mentoring from administrative personnel could be extremely useful to community members, particularly those who are reluctant to approach their fellow board members with questions, or for those reticent about expressing their opinions during meetings.

5. There is need for a review of the current community member education processes in place, as well as further information on the perspectives of community members in Canada. A systematic review of best practices in all aspects of identifying, training and utilizing community members – perhaps starting with a survey of boards employing community members in Canada - could be extremely useful for the objectives of the CCCTN Lay Representative Working Group.

6. Potential recruitment strategies for community members includes the press, social media, patient-focused groups and former patients and research participants. Organizations such as INVOLVE provide a successful model.

References and Relevant Literature

Abelson, J., Forest, P.-G., Eyles, J., Casebeer, A., Martin, E., & MacKean, G. (2007a). Examining the role of context in the implementation of a deliberative public participation experiment: Results from a Canadian comparative study. *Social Science & Medicine*, *64*(10), 2115–2128. doi:10.1016/j.socscimed.2007.01.013

Abelson, J., Giacomini, M., Lehoux, P., & Gauvin, F.-P. (2007b). Bringing “the public” into health technology assessment and coverage policy decisions: From principles to practice. *Health Policy*, *82*(1), 37–50. doi:10.1016/j.healthpol.2006.07.009

Allison, R. D. R., Abbott, L. J. L., & Wichman, A. A. (2008). Nonscientist IRB members at the NIH. *IRB*, *30*(5), 8–13.

American Society of Clinical Oncology Policy Statement: Oversight of Clinical Research. (2003). American Society of Clinical Oncology Policy Statement: Oversight of Clinical Research. *Journal of Clinical Oncology*, *21*(12), 2377–2386. doi:10.1200/JCO.2003.04.026

Anderson, Elizabeth, Shepherd, M., & Salisbury, C. (2006). “Taking off the suit”: engaging the community in primary health care decision-making. *Health expectations : an international journal of public participation in health care and health policy*, *9*(1), 70–80. doi:10.1111/j.1369-7625.2006.00364.x

Anderson, Emily. (2006). A Qualitative Study of Non-Affiliated, Non-Scientist Institutional Review Board Members. *Accountability in Research: Policies and Quality Assurance*, *13*(2), 135–155. doi:10.1080/08989620600654027

Avard, D., Stanton-Jean, M., Woodgate, R. L., Pullman, D., & Saginur, R. (2009). Research Ethics Boards and challenges for public participation. *Health Law Rev*, *17*, 66–73.

Canadian Institutes of Health Research, Canada, Natural Sciences and Engineering Research Council of Canada, Social Science and Humanities Research Council of Canada (2010). Tri-council Policy Statement: Ethical Conduct for Research Involving Humans.

Chung, P., Grogan, C. M., & Mosley, J. E. (2012). Social Science & Medicine. *Social Science & Medicine*, *74*(10), 1652–1659. doi:10.1016/j.socscimed.2012.01.029

Crosby, L. E., Parr, W., Smith, T., & Mitchell, M. J. (2013). The Community Leaders Institute. *Academic medicine : journal of the Association of American Medical Colleges*, *88*(3), 335–342. doi:10.1097/ACM.0b013e318280d8de

Dickert, N., & Sugarman, J. (2005). Ethical Goals of Community Consultation in Research. *American journal of public health*, *95*(7), 1123–1127. doi:10.2105/AJPH.2004.058933

Dyer, S. (2004). Rationalising public participation in the health service: the case of research ethics committees. *Health & Place*, *10*(4), 339–348. doi:10.1016/j.healthplace.2004.08.004

Dyrbye, L. N., Thomas, M. R., Mechaber, A. J., Eacker, A., Harper, W., Massie, F. S., et al. (2007). Medical education research and IRB review: an analysis and comparison of the IRB review process at six institutions. *Academic medicine : journal of the Association of American Medical Colleges*, *82*(7), 654–660. doi:10.1097/ACM.0b013e318065be1e

Enfield, K. B. K., & Truwit, J. D. J. (2008). The purpose, composition and function of an institutional review board: balancing priorities. *Respiratory Care*, *53*(10), 1330–1336.

Ennis, L. & Wykes, T. (2013). Impact of patient involvement in mental health research: longitudinal study. *British Journal of Psychiatry, 203*(3), 1-6. doi: 10.1192/bjp.bp.112.119818

Epstein, S (1996). *Impure Science: AIDS, Activism and the Politics of Knowledge*. Berkeley: University of California Press.

Gilbert, S. G. (2006). Supplementing the Traditional Institutional Review Board with an Environmental Health and Community Review Board. *Environmental Health Perspectives*, *114*(10), 1626–1629. doi:10.1289/ehp.9005

Green, F. A. (2007). Further Thoughts on the Recruitment of REC Lay Members. *Research Ethics*, *3*(1), 8–12. doi:10.1177/174701610700300104

Havens, G. (2004). Ethical implications for the professional nurse of research involving human subjects. *Journal of Vascular Nursing*.

Herman, S. S. S. (1984). The noninstitutional review board: a case history. *IRB*, *6*(1), 1–12. doi:10.2307/3564062

Houghton, D. G. (1988). Citizen Advisory Boards: Autonomy and Effectiveness. *The American Review of Public Administration*, *18*(3), 283–296. doi:10.1177/027507408801800304

Hung, Y., Ayala, A., Morales, F., & Frierman-Hunt, G. (2013). Sustaining Engagement and Partnership: A Model of Enhancing Cultural Capital among Nonaffiliated IRB Members. Journal of Empirical Research on Human Research Ethics, 8(3).

INVOLVE. (2012). Briefing notes for researchers: public involvement in NHS, public health and social care research. *INVOLVE*, 1–52.

Kim, S. Y. H., Wall, I. F., Stanczyk, A., & De Vries, R. (2009). Assessing the Public's Views in Research Ethics Controversies: Deliberative Democracy and Bioethics as Natural Allies. *Journal of Empirical Research on Human Research Ethics*, *4*(4), 3–16. doi:10.1525/jer.2009.4.4.3

Klitzman, R. (2012). Institutional Review Board Community Members. *Academic medicine : journal of the Association of American Medical Colleges*, *87*(7), 975–981. doi:10.1097/ACM.0b013e3182578b54

Koski, G. G., Aungst, J. J., Kupersmith, J. J., Getz, K. K., & Rimoin, D. D. (2005). Cooperative research ethics review boards: a win-win solution? *IRB*, *27*(3), 1–7. doi:10.2307/3564071

Lidz, C. W., Simon, L. J., Seligowski, A. V., Myers, S., Gardner, W., Candilis, P. J., et al. (2012). The Participation of Community Members on Medical Institutional Review Boards. *Journal of Empirical Research on Human Research Ethics: An International Journal*, *7*(1), 1–6. doi:10.1525/jer.2012.7.1.1

Litva, A. A., Coast, J. J., Donovan, J. J., Eyles, J. J., Shepherd, M. M., Tacchi, J. J., et al. (2002). “The public is too subjective”: public involvement at different levels of health-care decision making. *Social Science & Medicine (1967)*, *54*(12), 1825–1837. doi:10.1016/S0277-9536(01)00151-4

Martin, G. P. (2008). “Ordinary people only”: knowledge, representativeness and the publics of public participation in healthcare. *Sociology of Health & Illness*, *30*(1), 35–54. doi:10.1111/j.1467-9566.2007.01027.x

Mitton, C., Smith, N., Peacock, S., Evoy, B., & Abelson, J. (2009). Public participation in health care priority setting: A scoping review. *Health Policy*, *91*(3), 219–228. doi:10.1016/j.healthpol.2009.01.005

Nathan, S., Braithwaite, J., & Stephenson, N. (2013a). Facilitating the action of community representatives in a health service: the role of a community participation coordinator. *BMC Health Services Research*, *13*, 154–154. doi:10.1186/1472-6963-13-154

Nathan, S., Johnston, L., & Braithwaite, J. (2010). The role of community representatives on health service committees: staff expectations vs. reality. *Health Expectations*, *14*(3), 272–284. doi:10.1111/j.1369-7625.2010.00628.x

Nathan, S., Stephenson, N., & Braithwaite, J. (2013b). Sidestepping questions of legitimacy: How community representatives maneuver to effect change in a health service. *Health: An Interdisciplinary Journal for the Social Study of Health, Illness and Medicine*. doi:10.1177/1363459312473617

National Institutes of Health. (1979). National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *Te Belmont Report. Ethical Principles and Guidelines for the protection of human subjects of research*.

Pinto, R. M., Spector, A., Rahman, R., & Gastolomendo, J. D. (2013). Research advisory board members' contributions and expectations in the USA. *Health Promotion International*. doi:10.1093/heapro/dat042

Porter, J. P. J. (1986). What are the ideal characteristics of unaffiliated/nonscientist IRB members? *IRB*, *8*(3), 1–6. doi:10.2307/3564370

Porter, J. P. J. (1987). How unaffiliated/nonscientist members of institutional review boards see their roles. *IRB*, *9*(6), 1–6. doi:10.2307/3563622

PytlikZillig, L. M., & Tomkins, A. J. (2011). Public engagement for informing science and technology policy: what do we know, what do we need to know and how will we get there? *Review of policy research*, *28*(2), 197–217. doi:10.1111/j.1541

Rothstein, W. G. W., & Phuong, L. H. L. (2007). Ethical attitudes of nurse, physician and unaffiliated members of institutional review boards. *Journal of Nursing Scholarship*, *39*(1), 75–81. doi:10.1111/j.1547-5069.2007.00147.x

Rowe, G., Rawsthorne, D., Scarpello, T., & Dainty, J. R. (2010). Public engagement in research funding: a study of public capabilities and engagement methodology. *Public Understanding of Science*, *19*(2), 225–239. doi:10.1177/0963662508096780

Saver, R. S. (2005). What IRBs could learn from corporate boards. *IRB*, *27*(5), 1–6. doi:10.2307/3564528

Sengupta, S. S., & Lo, B. B. (2003). The roles and experiences of nonaffiliated and non-scientist members of institutional review boards. *Academic medicine : journal of the Association of American Medical Colleges*, *78*(2), 212–218.

Simons, L., Wren, G., & Buckland, S. (2009). Survey of Lay Members of Research Ethics Committees (RECs). *INVOLVE*, *2009*, 1–44.

Slaven, M. J. (2007). First Impressions: the experiences of a community member on a research ethics committee. *IRB*, *29*(3), 17–19.

Speers, M. A., & Rose, S. (2012). Commentary. *Academic medicine : journal of the Association of American Medical Colleges*, *87*(7), 842–844. doi:10.1097/ACM.0b013e318257f115

Staley, K. (2009). Exploring Impact: Public involvement in NHS, public health and social care research, INVOLVE, 1–116.

Staley, K., & Minogue, V. (2006). User involvement leads to more ethically sound research. *Clinical Ethics*, *1*(2), 95–100. doi:10.1258/147775006777254489

Thurston, W. E., MacKean, G., Vollman, A., Casebeer, A., Weber, M., Maloff, B. & Bader, J. (2005). Public participation in regional health policy: a theoretical framework. *Health Policy*, *73*(3), 237–252. doi:10.1016/j.healthpol.2004.11.013

Van Dyke, C. C., & Schlesinger, H. J. H. (1997). Training the trainers. *Administration and Policy in Mental Health and Mental Health Services Research*, *25*(1), 47–49.

Veatch, R. M. (1975). Human experimentation committees: professional or representative? *Hastings Center Report*.

Woodak, J. (2011). *Public engagement in choosing health priorities. CMAJ, 183*(2), 227.