Guide to enable health charities to increase recruitment to clinical trials on dementia

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Abstract

Introduction: The Alzheimer Society embarked on a project to improve ways that the 60 provincial and local Societies in Canada can work with local researchers to support recruitment of volunteers to clinical trials and studies. A Guide to assist these offices was produced to design ethical recruitment of research volunteers within their client populations.

Methods: Consultations with individuals from provincial and local Societies, as well as researchers and leaders from health-related organizations, were conducted to identify in what ways these organizations are involved in study volunteer recruitment, what is and is not working, and what would be helpful to support future efforts. The Guide prototype used scenarios to illustrate study volunteer recruitment practices as they have been or could be applied in Societies. An implementable version of the Guide was produced with input from multiple internal and external reviewers including subject-matter experts and target users from Societies.

Results: Society staff reported that benefits of using the Guide were that it served as a catalyst for conversation and reflection and identified the need for a policy. Also, it enabled Society readiness to respond to requests by persons with dementia and their caregivers wishing to participate in research. A majority (94%) of participating Society staff across Canada agreed that they would increase their capacity to support research recruitment.

Discussion: Charitable organizations that raise funds for research have a role in promoting the recruitment of persons with dementia and their caregivers into clinical trials and studies. The Guide was produced to facilitate organizational change to both create a positive culture regarding research as well as practical solutions that can help organizations achieve this goal.

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1. Introduction

Improvement in access to clinical trials and other studies has included opportunities for the general public to learn about studies through public online databases [1]. But this assumes they understand the trial enrollment process and puts the onus on them to figure out how to participate. Health and disease associations can increase awareness and support recruitment of the numerous and diverse study volunteers needed as interest, and funding of research on Alzheimer’s disease and other dementias increases.

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The G8 Legacy 2013 meeting held in London was a critical turning point for achieving commitment. It declared that there is a need for increased research funding to discover therapies that could slow or stop the progression of dementia by 2025 [2]. On December 18, 2015, the United States Congress signed an agreement that legislated raising Alzheimer’s research at the National Institutes of Health to $1 billion annually. This doubled the total funding since the Alzheimer’s Association, United States, collaborated with Congress to unanimously pass the 2010 National Alzheimer’s Project Act [3]. At the end of 2016, the United Kingdom (UK) government announced 150 million British pounds to establish the UK Dementia Research Institute with plans to increase by 100 million in the subsequent years [4]. The Canadian Consortium on Neurodegeneration in Aging [5] and Brain Canada [6] are examples of newly funded research initiatives in Canada.

The challenges for the public to engage in dementia research has been outlined by Alzheimer’s Disease International [1] and elsewhere [7,8]. One challenge is the lack of awareness about studies and the research process. Physician-related challenges include not informing their patients about studies. Another challenge is the requirement that the caregiver of the person with dementia has to be involved in studies but time, constraints, for example, prevent this. Trials tend not to be designed to optimally engage persons with dementia and their caregivers. Also, cultural and linguistic differences prevent participation for some groups. Socioeconomic status and educational factors among some populations prevent access to studies. In addition, coexisting medical conditions can reduce ability to participate in studies. This report also outlines the challenges that the drug industry and other researchers face including multiple regulatory processes; variation in assessment tools and measures; and uncertain return on investment.

Overcoming challenges to participation in dementia studies are also suggested in the Alzheimer’s Disease International report [1]. The recommendations include increasing funding for dementia research; increasing public awareness of Alzheimer’s disease and other dementias; increasing awareness of dementia research; and incorporating dementia research into the care continuum. Other initiatives that will increase participation in studies include establishing national ethic or institutional review boards; harmonizing and collaborating on regulatory efforts; supporting public-private partnerships; and de-risking the drug development process; and last, but not least, improving access to clinical trials and other studies.

In addition to these issues with regards to recruitment of persons with dementia and their caregivers into studies, engagement in the research process has been argued to lead to research findings that are more pertinent to their concerns and dilemmas. A systematic review on the “science” of “patient engagement” in research found that this is feasible in many settings [9]. However, the review also concluded that this engagement comes at a cost and can become tokenistic. Research on identifying the best methods to achieve engagement is needed. In an environmental scan and stakeholder consultation process for the project [8] reported here, one consultation participant observed

“We all know that if you donate blood or an organ it’s “life-saving”; the public understands this but not in terms of research participation being ‘life-saving’ ... look at the discourse around organ donation 20 years ago and how much it’s changed. This is how far the conversation about research participation needs to go.”

Thus, the challenges to recruitment to clinical trials on dementia are numerous and span industries, partner organizations, clinicians and researchers, and the potential participants themselves [1]. As a promoter and funder of research, the Alzheimer Society of Canada’s leadership role is to collaborate with researchers and clinicians to increase participation in clinical trials and studies. We report here how a “Research recruitment: A guide to get started” [10], herein referred to as the “Guide”, was produced and its use by provincial and local Alzheimer Societies to assist them in determining how best to support research recruitment and participation within their own unique context (see Supplementary Material 1 for a copy of the Guide).

2. Methods

A mixed-method, iterative approach was undertaken to develop the Guide, organized by a research and development phase, and followed by a piloting phase. The first step of the research and development phase involved a scoping review of the literature and stakeholder consultations (see Supplementary Material 2 for a copy of the scoping review). The second step involved drafting the Guide as informed by findings from the review and stakeholder interviews, and collaborative review process to generate relevant organizational scenarios illustrating the support of research recruitment in practice. The piloting phase involved two rounds of review with a sample of Society offices across Canada. The goals of the piloting phase were to

a) assess the content, design, and usability of the Guide;

b) refine the Guide based upon user feedback; and

c) determine the opinion of Society staff regarding potential for uptake and gather any early outcomes.

2.1. Research and development phase

2.1.1. Step 1: Scoping review and stakeholder consultations

A scoping review of literature [11] was conducted by M.H. and L.L. to investigate best approaches to securing volunteer participation in studies, answering research participant questions, summarizing and presenting study results, and informing the public about the importance of volunteers in studies. In addition, potential benefits and risks to volunteers participating in studies were explored. Key words used in the search for indexed articles in the last 10 years as well as gray literature were research/study
participation, study/research recruitment, study/research participation risks/benefits, research/study recruitment methods, and research/study participation methods. In addition, over 20 websites of research funding organizations that referred to volunteer recruitment and study participation. The scoping review (Supplementary Material 2) yielded 16 articles and reports (Table 1, List 1), 11 tools and templates (Table 1, List 2), and 17 websites (Table 1, List 3), and all three informed the content of the Guide.

Next, semi-structured interviews were conducted by M.H. and L.L. with a convenience sample of Society staff (n = 6), dementia researcher physicians (n = 3), and executive leaders of health associations (n = 2), to identify research participation practices and explore organizational processes supporting research participation best practices identified in the scoping review.

Findings of the scoping review and stakeholder interviews helped the design team (M.H. and L.L.) to decide that the Guide should identify how the Societies could improve their support of research participation and enable their clients to make informed decisions about participating in research.

2.1.2. Step 2: Creation of Guide prototype

The main components of the Guide are a set of case scenarios, a fillable worksheet, and a set of tools.

A collaborative review process was facilitated with multiple internal and external reviewers including subject-matter experts and target users from Societies, to generate a set of case scenarios that illustrate how supporting study volunteer participation could be achieved in Societies across Canada. Case scenarios were chosen as the principal method to organize the main content of the Guide, as they are an effective way to facilitate learning and knowledge translation and can serve to support practice change initiatives [10]. The best practices illustrated in each case scenario are both supported by the literature related to supporting research participation and have been implemented by at least one Society office in practice. Together, the process yielded five organizational, case-based scenarios titled (1) Raising Awareness; (2) The Learning Session; (3) First Link™; (4) The Recruitment Policy; and (5) Social Media Ad.

The Guide outlines a process to review the case scenarios and respond to a set of questions outlined on a fillable worksheet embedded in the Guide. This process enables the Society to capture their ideas and reflections and determine how they will support research participant recruitment, given their unique context. In addition, a “Tool” section was created via the collaborative review process outlined previously, resulting in a clinical trials and study frequently asked questions (FAQs), a sample research recruitment support policy for a Society office, a checklist to provide researchers wishing to work with the Society, and a client/caregiver checklist for those considering participation in a clinical trial or study. Society offices are encouraged by way of the instructions in the Guide to consider adapting the tools for their use, if relevant to achieve their goals related to supporting research participation for their clients.

2.2. Pilot phase

2.2.1. Round 1

Early-adopter Societies assessed the Guide for ease of use and feasibility of the strategies in the Guide. Participation in the round 1 review required approximately 4.5 hours for staff to review and discuss the questions in the Guide (worksheet). At first, these Societies were briefed by the project team with a 30-minute teleconference where they were provided an orientation to the Guide and background related to the production process, instructions to review the Guide, expectations related to the review process, and offering of support should Society staff have any questions during the process. In addition, Society staff were invited to participate in optional peer knowledge exchange sessions with other Society staff piloting teams approximately mid-way through the review process. Following review and completion of the worksheet in the Guide, each Society was invited to participate in one 60-minute structured interview/focus group (see Table 2 for Round 1 Interview/Focus Group Questions). The results of the round 1 review were used to create a revised version of the Guide (version 2.0).

2.2.2. Round 2

Another sample of Society offices was recruited to review the Guide to assess use, perceived value, and potential for uptake and impact. Guide review participation followed the same process outlined in round 1 with an additional offer to participate in one of two webinars about the research process, hosted by L.W.C. Participant feedback was collected following review and completion of the worksheet in the Guide through an online follow-up survey (See Supplementary Material 3 for the Round 2 Evaluation Survey). Version 3.0 of the Guide was created based on findings from the second round of review and field-testing.

3. Results

A total of 28 of the 60 Societies in Canada were engaged in the review and field-testing of the Guide, capturing feedback from over 70 staff across Canada.

3.1. Round 1

The first round of review involved eight Societies. Each Society participated with a minimum of two staff for a total of 18 staff (mean = 2, range = 1–4 per Society office) reviewers. All eight Societies participated in one of the two optional online knowledge exchange sessions offered for Societies to connect with each other and discuss current clinical trial and study recruitment processes, as well as early reactions to working with the Guide to-date. Following review and completion of the worksheets in
Table 1

| Resources and references located in the scoping review |
|--------------------------------------------------------|

1. Alzheimer’s Disease International. Advancing research: a physician’s guide to clinical trials of Alzheimer’s disease. 2009 cited 2014 Apr. Available at: http://www.alzheimer.ca/~/media/Files/national/Drugs/Drug_ClinicalTrialsChecklist_2009_e.ashx

2. Alzheimer Society “Checklist for Participating in Clinical Trials: What Should I Ask” [Internet]. 2009 cited 2014 Apr. Available at: http://www.alzheimer.ca/~/media/Files/national/Drugs/Drug_ClinicalTrialsChecklist_2009_e.ashx

3. Best Medicine Coalition Issue Working Groups: Patient Involvement Working Group R&D: Saving Lives–Transforming Care

4. British Columbia Clinical Research Infrastructure Network

5. Canadian Cancer Clinical Trials Network

6. CHAP: Cardiovascular Health Awareness Program. Implementation Guide.

7. Clinical Trials Toolkit [Internet]. 2014 cited 2014 Apr. Available at: http://www.ct-toolkit.ac.uk/routemap/dissemination-of-results

8. FasterCures–The Centre for Accelerating Medical Solutions: Clinical Trials Recruitment and Retention: Best Practices and Promising Approaches

9. Micheal J Fox Foundations for Parkinson’s Research: Clinic Trials Recruitment Best Practices Manual

10. ResearchMatch: website to bring together volunteers and researchers without a specific disease focus

11. Successful Healthcare Personnel Influenza Immunization Programs: A Guide for Program Planners

2) List 2 Scoping Review Tools and Templates

1. Alzheimer Society Checklist for Participating in Clinical Trials: What Should I Ask [Internet]. 2009 cited 2014 Apr. Available at: http://www.alzheimer.ca/~/media/Files/national/Drugs/Drug_ClinicalTrialsChecklist_2009_e.ashx

2. Canadian Diabetes Association: http://www.diabetes.ca/research/trials-participate-in-a-clinical-trial and allows investigators to submit details of their study, to be posted on the website. Available at: http://www.diabetes.ca/research/trials-participate-in-a-clinical-trial

3. CAMH. Available at: http://www.camh.ca/en/research/research_areas/studies_and_recruitment/Pages/studies_and_recruitment.aspx

4. Centre Watch, Dementia Clinical Trials. Available at: http://www.centerwatch.com/clinical-trials/listings/condition/312/dementia

5. Clinical Trials Ontario. Enhancing the Recruitment and Retention of Research Participants. 2013.

6. Crohn’s and Colitis Canada: provides details on how to join the “Gem Project” and how to get involved within the study, as well as links to other clinical trials sites. Available at: http://www.ccfc.ca/site/c.ajIRK4NLLhJ0E/b.6373995/k.67C4/Research_Recruitment.htm

7. CHIR Best Practices for Protecting Privacy in Health Research [Internet]. 2005 cited 2014 Apr. Available at: http://www.chir-irc.gc.ca/e/29072.html

8. Available at: http://www.alz.org/research/clinical_trials/why_participate_in_clinical_trials.asp

9. Alzheimer Society “Checklist for Participating in Clinical Trials: What Should I Ask” [Internet]. 2009 cited 2014 Apr. Available at: http://www.alzheimer.ca/~/media/Files/national/Drugs/Drug_ClinicalTrialsChecklist_2009_e.ashx

10. Getz K, Hallinan Z, Simmons D, Brickman M, Jamadilova Z, Pauer L, Wilenzick, Morrison B. Meeting the Obligation to Communicate Clinical Trials Results to Study Volunteers. Expert Review of Clinical Pharmacology. 2012; 5:149–156.

11. Hennink-Kaminiski H, Willoughby J, McMahan D. Joining the Conquest: Developing a Campaign to Increase Participation in Clinical Research in North Carolina. Science Communications. 2013 August; 36:30–55. Available at: http://scx.sagepub.com/content/early/2013/08/21/1075547013492434.full.pdf

12. McKeeown J, Clarke A, Ingleton C, Repper J. Actively Involving People with Dementia in Qualitative Research. Journal of Clinical Nursing. 2010 June; 19:1935–1943.

13. Millum J. Canada’s new ethical guidelines for research with humans: a critique and comparison with the United States. CMAJ April 3, 2012 vol. 184 no. 6.

14. Plain Language: A promising strategy for clearly communicating health information and improving health literacy [Internet]. 2005 cited 2014 Apr. Available at: http://www.health.gov/communication/literacy/plainlanguage/PlainLanguage.htm

15. Shalowitz D, Miller F. Communicating the Results of Clinical Research to Participants: Attitudes, Practices, and Future Directions. PLoS Medicine. 2008; 5(7):1–720.

16. Warburton J, Dyer M. Older Volunteers Participating in a University Registry Regist: Helping Others My Age. Educational Gerontology, 30:367–381, 2004.

3) List 3 Scoping Review of Websites

1. ALS Society: Available at: http://www.als.ca/en/node/434/clinical-trials/current-clinical-trials

2. Canadian Diabetes Association: http://www.diabetes.ca/research/trials-participate-in-a-clinical-trial and allows investigators to submit details of their study, to be posted on the website. Available at: http://www.diabetes.ca/research/trials-participate-in-a-clinical-trial

3. CAMH. Available at: http://www.camh.ca/en/research/research_areas/studies_and_recruitment/Pages/studies_and_recruitment.aspx

4. Centre Watch, Dementia Clinical Trials. Available at: http://www.centerwatch.com/clinical-trials/listings/condition/312/dementia

5. Clinical Trials Ontario. Enhancing the Recruitment and Retention of Research Participants. 2013.

6. Crohn’s and Colitis Canada: provides details on how to join the “Gem Project” and how to get involved within the study, as well as links to other clinical trials sites. Available at: http://www.ccfc.ca/site/c.ajIRK4NLLhJ0E/b.6373995/k.67C4/Research_Recruitment.htm

7. CHIR Best Practices for Protecting Privacy in Health Research [Internet]. 2005 cited 2014 Apr. Available at: http://www.chir-irc.gc.ca/e/29072.html

8. Available at: http://www.alz.org/research/clinical_trials/why_participate_in_clinical_trials.asp

9. Alzheimer Society “Checklist for Participating in Clinical Trials: What Should I Ask” [Internet]. 2009 cited 2014 Apr. Available at: http://www.alzheimer.ca/~/media/Files/national/Drugs/Drug_ClinicalTrialsChecklist_2009_e.ashx

10. Getz K, Hallinan Z, Simmons D, Brickman M, Jamadilova Z, Pauer L, Wilenzick, Morrison B. Meeting the Obligation to Communicate Clinical Trials Results to Study Volunteers. Expert Review of Clinical Pharmacology. 2012; 5:149–156.

11. Hennink-Kaminiski H, Willoughby J, McMahan D. Joining the Conquest: Developing a Campaign to Increase Participation in Clinical Research in North Carolina. Science Communications. 2013 August; 36:30–55. Available at: http://scx.sagepub.com/content/early/2013/08/21/1075547013492434.full.pdf

12. McKeeown J, Clarke A, Ingleton C, Repper J. Actively Involving People with Dementia in Qualitative Research. Journal of Clinical Nursing. 2010 June; 19:1935–1943.

13. Millum J. Canada’s new ethical guidelines for research with humans: a critique and comparison with the United States. CMAJ April 3, 2012 vol. 184 no. 6.

14. Plain Language: A promising strategy for clearly communicating health information and improving health literacy [Internet]. 2005 cited 2014 Apr. Available at: http://www.health.gov/communication/literacy/plainlanguage/PlainLanguage.htm

15. Shalowitz D, Miller F. Communicating the Results of Clinical Research to Participants: Attitudes, Practices, and Future Directions. PLoS Medicine. 2008; 5(7):1–720.

16. Warburton J, Dyer M. Older Volunteers Participating in a University Registry Regist: Helping Others My Age. Educational Gerontology, 30:367–381, 2004.
the Guide, representative(s) from each Society participated in an online interview/focus group to share feedback on the content, design, usability, and outcomes of the Guide. Feedback related to each of these areas is described below.

### 3.2. Content

Generally, Societies were very pleased with the Guide, finding the worksheets and the scenarios the most helpful. Most of the reviewers (75%, 6 of 8) spoke about how the scenarios gave them concrete examples of components they had not yet considered, though cited disregarding examples if it did not align with their current context.

“I do sort of like the approach with the scenarios. It gives you something to think about, a framework to start from.”

As I read through them I would say “yes that works for us,” or “no that would never work for us”.

“We’d have to find another way to make these scenarios work b/c here we don’t share client information across departments. Our education coordinators don’t work directly with the clients.”

### Table 2

**Round 1 questions used to guide interviews and focus groups**

| Question | Note |
|----------|------|
| Tell us a little bit about how you used the Guide to-date? | Probe: Did you follow the steps or use it differently - there is no wrong answer here! |
| What specific features of the Guide were most helpful to you? | Probe: Think of the sections of the Guide or content within a specific section of the Guide |
| What features of the Guide were less helpful or useful to you? | Probe: Is there anything that you would like to add or remove from the Guide?何 easy or difficult was it to navigate the Guide (content)? |
| When thinking about navigating through the Guide, what, if anything, is confusing to you? | What, if anything, do you find frustrating or unappealing about the Guide? |
| Do you have any suggestions on how we could improve the Guide to make it more useful? | |
| If you could add any feature to the Guide, what would it be? | |
| If you would recommend this Guide to another Society or colleague within your Society, what would you say to convince your colleague to use the Guide? | |
| Are there other ways you would like to learn about volunteer research recruitment practices? | Probe: Is there anything else generally or about the Guide that you would like to share? |

The majority (75%, 6 of 8) spoke about how the worksheets helped advance their approach to recruitment. Half referenced the checklists as tools they plan to use to support this work in the future. Additional components that were identified as valuable include the section on why volunteer recruitment is important, the sample policy on research recruitment and the FAQs section of the Guide.

Most Societies (88%, 7 of 8) cited that the Guide was long, though also reflected the content was needed and that there were no sections they would remove. The main suggestion to consolidate the Guide was to remove the section on how the Guide was created and offer it separately, upon request.

“It would be difficult to shorten it—the information is too important and there are some statements that need to be repeated and you do that well throughout the Guide because some concepts are really important”

“It’s quite lengthy but as I said I don’t think there are any huge areas to cut out… If you try and simplify it completely it would lose a lot of the value of the content”

Some reviewers suggested adding content to cover in the Guide pertaining to what a Society should do when people have expressed an interest in research and there is not anything available; what makes research “good” research; and how could a Society work with researchers to support knowledge translation.

### 3.3. Design

Societies identified that the information design of the Guide (page layout, typeface, use of color, and call out copy) enabled it to be usable and easy to navigate.

“I did appreciate that you didn’t try to make it cute by putting in a lot of graphics; that you used your symbols (awareness etc.) when appropriate, but didn’t try to make it like a graphic novel. Research is a serious, process-oriented thing; I’m glad the document reflects this.”

“The Guide was very easy to go through, chapters are clearly indicated. The content reflected perfectly what I expected to have.”

A few reviewers recommended adding more details to the table of contents, embed the worksheets following each section in the Guide, offer a digital version with a fillable worksheet (so that answers to worksheet questions can be typed and saved as a digital file), and for the worksheets and tools
be made available both in the Guide and as a set of individual documents.

3.4. Usability

Reviewers cited that piloting the Guide helped them engage in dialog with staff and consider how they could improve their practice to enhance partnerships with research community and reprioritize their work.

“It made me think about how we could better...I’ve had requests to participate in research and now I see it’s not just the burden but also about helping researchers”

“Going through the document helped us feel like we wanted to be more proactive and not just reactive, as we have been to-date.”

“If they [another Society] were someone like us who have been very reactive, I would say that the prework, the preamble, and getting start piece was really valuable and raised some questions for us. You may think you [your team] are on the same page, but you might not be. There are very different communities across the regions and these discussions were very valuable.”

Reviewers spoke about how valuable the Guide would be as a training tool to onboard new staff, and others felt they would use parts of the Guide in the future as speaking points.

“The FAQ was helpful—it gives rapid and tidy responses that I could use with staff who might get a phone call asking them something”

Over half (5 of 8) of the reviewers cited that the Guide ignited an interest to learn more about participation in research and about dementia research more broadly. Societies expressed an interest in additional online exchange opportunities and suggested several topics, such as an overview of research processes; ethics and the intersection between client work and timing of recruitment; and how to promote your Society as a vehicle to connect researchers and study participants.

“If I had this Guide [when I embarked on my first activity with a local researcher] I would have had a clearer understanding of what I was getting into, what the expectations of the Society would be. I think there are a lot of things I would have done differently. It was a positive experience, but now I’d have some structure to follow.”

3.5. Outcomes

Before field-testing the Guide, most (88%, 7 of 8) Societies reported they have some staff in their organization with knowledge and skills to promote study opportunities, half (50%, 4 of 8) reported they use their website, newsletter, posters and/or Facebook to promote clinical trial and study opportunities, and a few (38%, 3 of 8) of the Societies reported a policy or procedure is in place to support participation in study volunteer recruitment. The majority (75%, 6 of 8) reported they provide few if any opportunities for staff to improve their knowledge of clinical trials and studies. After field-testing the Guide, half (50%, 4 of 8) of the Society offices established support for study recruitment as an expectation attributed to a person’s role at the Society; and one Society secured financial support from a research team for a Society staff member to work with them in a way that extends beyond working hours. A few (38%, 3 of 8) of the Societies established new processes or procedures to promote clinical trial and study opportunities, and all Societies (100%, 8 of 8) reported an intent to use the tools in the Tools section of the Guide to support future participation in clinical trial and study recruitment. Overall, reviewers were pleased with the Guide and its potential impact.

“I am looking forward to standards in this area”

A revised Guide (version 2.0) was produced based on the data collected in the first round of review. Primary revisions included a consolidation of copy, elimination of the Guide development process content, and embedding the worksheet in the Guide.

3.6. Round 2

Twenty-two Societies were recruited to participate in the round 2 review process. A total of 20 Societies completed the review with an average of three staff per Society (range of 1–5) participating; two Societies were lost to follow-up. Feedback on the Guide was obtained through an evaluation survey completed by 55 Society staff reviewers (see Table 3 for survey findings).

Most of reviewers agreed the study volunteer recruitment strategies in the Guide are appropriate (92%, 48 of 55), the Guide is easy to use (83%, 43 of 55), and the information is presented well visually (87%, 45 of 55). Most participants agreed the study volunteer recruitment principles (92%, 48 of 55) and scenarios were useful (91%, 47 of 55) in addition to the Clinical Trial and Study FAQ (91%, 47 of 55), the Research Recruitment Request Sample Policy (92%, 47 of 55), the Researcher Checklist (94%, 49 of 55), and the Client Checklist for Participating in Research (93%, 48 of 55).

The main perceived benefits of using the Guide cited by the reviewers were that it served as a catalyst for conversation and reflection, identified the need for a policy, and enabled readiness of the Society to respond to the requests by persons with dementia and their caregivers wishing to participate in research. Overall, 95% (52 of 55) of Societies either strongly agreed (47%, 26 of 55) or agreed (47%, 26 of 55) that Alzheimer Societies across Canada would benefit from using the Guide.

This data collection collected through the round 2 process also clarified the scope required for a Society to adequately support research recruitment. A framework was generated to include in the round 3 version of the Guide (see Table 4). The framework states that in the research recruitment process, a Society has a role with the client, the staff, and the researcher with examples of how this can be done in each instance.
The final Guide (version 3.0, see Supplementary Material 1) was created based on findings and debriefing with reviewers. Primary revisions included the addition of a framework, consolidation of the worksheets into one worksheet now organized by the framework, the creation of a digital fillable worksheet, and the addition of content about research processes as part of the introduction section of the Guide.

### 4. Discussion

Participating Society staff reported that the main perceived benefits of using the Guide were that it served as a catalyst for conversation and reflection as well as identifying the need for a Society research recruitment policy for each of its offices. Also, it enabled readiness of each Society to respond to the requests by persons with dementia and their caregivers wishing to participate in research. Nearly all participating Societies (94%, 49 of 55) reported Alzheimer Society offices across Canada would benefit from using the Guide.

Charitable organizations that raise funds for research have a role in promoting the recruitment of persons with dementia and their caregivers into clinical trials and studies. The Guide was produced to facilitate organizational change to both create a positive culture regarding research as well as practical solutions that can help organizations achieve this goal.

One key finding derived from production and implementation of the Guide in Societies across Canada was the lack of connectedness of Societies with their local researchers and with family physicians and primary care teams who might promote dementia research. Thus, two advisory groups have been established to assist the newly named...
The Alzheimer Society of Canada “Research Engagement Leadership Program”. The researcher advisory group and the family physician advisory groups are providing advice on how to create productive relationships between local Societies, their local researchers, and their local family physicians. In addition, a Research Engagement Symposium was held in July 2016 immediately before the Alzheimer Association International Conference 2016 in Toronto. The Symposium was attended by over 100 persons with dementia and their caregivers, researchers, family physicians, and policy makers. A number of recommendations were generated at the Symposium, which are informing the work of the Research Engagement Leadership Program.

The strengths of the work in developing the Guide reported here are numerous. The Guide has launched an evidence-based approach to determining best practices for Alzheimer Societies to use to promote the involvement of persons with dementia and caregivers in their research. The Guide was produced in collaboration with “early-adopter” Societies that served as role models for other Societies in terms of providing information on what works. For example, having a policy on research recruitment can improve a Society’s competence in connecting persons with dementia and their caregivers with researchers. In addition, supplementary resources were developed such as slides for webinars to facilitate implementation of the approaches in the Guide being used by Societies.

Limitations of this work include the fact that 30 of the 60 Societies have not yet implemented the Guide. It may be that the project has exhausted the list of Societies who are attracted to changing their approach to supporting research by implementing the Guide. Although 30 Societies have implemented the Guide, at this point in time no data have been collected on whether more persons with dementia and their caregivers have volunteered in these Societies. Future work of the Research Engagement Leadership Program will be to return to these 30 Societies to collect this type of data. Finally, we are unaware of any of other health associations that have focused on using similar types of Guides to promote organizational change within their organizations to improve their support of research. Such knowledge would be useful to the Research Engagement Leadership Program of the Alzheimer Society of Canada. This work has also identified the need for resources to improve the research literacy among staff, volunteers, managers, and directors of Society governance boards.

As recommended in the Strategy for Patient Oriented Research [11] patient engagement framework, the Research Engagement Leadership Program will fully use experiential (persons with dementia and their caregivers) and researcher mentors. It also will use reciprocal learning relationships. In addition, the Program will make a long-term commitment to engagement of persons with dementia and their caregivers in the Society’s infrastructure and funding to ensure inclusive recruitment, training, and mentoring. Finally, it will strive to create realistic expectations and manage relationships.

As there are 60 Societies operating across Canada, the other Societies not involved in the pilot testing of the Guide were e-mailed the final Guide (version 3.0), and the Guide was shared at CEO Council (CEOs of ASC and the Societies) meetings who were encouraged to use the Guide within their Societies. Future plans include a survey to determine the number of new policies and practices in place across Canada following introduction of the Guide in the Societies.

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Disclaimer: Views or opinions presented in this manuscript are solely those of the authors and do not necessarily represent those of their organizations.

Ethics Approval: Not relevant as this was an internal project of the Alzheimer Society.

Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.trci.2017.08.008.

RESEARCH IN CONTEXT

1. Systematic review: The literature review included reviewing research reports, tools and templates and websites of research funding organizations that referred to volunteer recruitment and study participation. The search yielded information on volunteer recruitment and study participation located best approaches to securing volunteer participation in studies, answering research participant questions, summarizing and presenting study results, and informing the public about the importance of volunteers in studies. Additionally, the review identified potential benefits and risks to volunteers participating in studies.

2. Interpretation: Reports on how to recruit clients typically ignore organizational change that must occur to improve Alzheimer Societies’ ability to support recruitment. The Guide contributes to our knowledge about how to promote this organizational change.

3. Future directions: Use of the Guide is a first step to improve Society recruitment capacity. For example, research on interventions to improve Society collaboration with local researchers and family physicians is needed. The impact of multipronged interventions could be assessed using information sources such as the Alzheimer Association’s TrialMatch to measure recruitment trends.
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