Engaging Your Community about Clincal Trials

A Toolkit for Organizations

Engaging Your Community about Clinical Trials

How this Guide May Help Your Organization

Are you interested in engaging your community to better understand what they think about participating in clinical trials? Maybe you're interested in developing resources about clinical trials created to fit your community's needs, or you'd like to help researchers build better clinical trials for your community. Whatever your motivation, we've created this toolkit so you can engage your community with surveys or guided discussions that you can take and make your own, based on your own knowledge and resources.

What You Might Need: Resources and Considerations

To engage your community, you may wish to host a survey or simply have discussions based on the questions we have developed (which are in the Appendix). The list of necessary resources outlined below might change depending on the approach you choose. This list isn't prescriptive – the idea is to suggest options to help you plan your approach. You may need:

- ***A person to lead the work.*** Depending on your approach, more than one person may be needed given the different tasks to be done and the skills required to do these tasks.
- ***Survey design expertise*** if you do a survey, since answers can be skewed by how the questions are asked.
- ***Knowledgeable patients or caregivers from your community*** to work with you so they can provide feedback about your planned approach and questions.
- ***Survey software.*** There are many options available for online survey software, and some offer free trials (e.g., Survey Monkey and Fluid Survey). Usually the free trials have a maximum number of free questions or number of respondents, and once these are passed, there may be charges for use. You should consider how to minimize people completing the same questions multiple times or completing the survey multiple times. Survey software can suggest different methods to help.

- ***A plan for publishing the results in a scientific journal.*** Approval from a Research Ethics Board (also called an REB for short) is recommended along with a plan to use a survey reporting guidance tool.
- ***A plan to keep all collected data confidential.*** Consider who will be able to access the data, how it will be protected, etc.
- ***A plan for how you will use the survey data.*** Knowing how you wish to use the survey results is an important part of doing the survey in the first place. Maybe you simply want to communicate the results back to your community or maybe you want to use those results to build other resources to help your community. Whatever your plan is, it's a good idea to let participants in the survey know when, how, and where they can find out the results of the survey.

There are plenty of scientific papers to help you out. These references might be helpful about behaviour change interventions developed using a theory-informed approach (1-3) and pre-testing surveys (4). We have valuable references for you in the Appendix if you're interested in these articles.

Some Starting Questions

We have already developed some survey questions for you to use (see the survey we used in the Appendix). Whether you choose to do a survey or simply focused discussions with groups (also called 'focus groups'), these questions are a great place to start.

If you do a survey, our process might be helpful to you (4), where we:

- worked with knowledgeable community members to help us pick the starting questions
- did 'think-aloud' interviews (this is where people talk through their thought process as they read and respond to the survey questions). This helps you know how clear the questions are or if changes need to be made. We also asked these individuals if they thought of any other questions that might be missing.
- had people test out the survey and we made changes based on their feedback about how questions were worded
- put the survey in the software and had a few people respond to the survey (as tests that were then deleted) to check it one final time for any errors or typos,
- and launched the survey.

Ideas to Promote the Survey

Chances are your organization has lots of ways it communicates with your community - maybe through newsletters, social media, and more. You will likely know the best way to ensure your community members see opportunities to respond to the survey (or to participate in discussion groups). If your organization is going to host a survey, it will be helpful to include information about it being voluntary to fill out and responses being anonymous. There are some scientifically-proven ways to get better responses to surveys, and we've included information about that in the Appendix.

A Bit About Us

This How-to Guide comes from a collaboration of Clinical Trials Ontario, patient organizations and health charities (the Canadian Breast Cancer Network, Huntington Society of Canada, and the Sickle Cell Awareness Group of Ontario), and the Centre for Implementation Research at the Ottawa Hospital Research Institute. The team set out to understand facilitators and barriers to clinical trials for different communities. We know not everyone has the resources to work with academic partners, so we wanted to share some ideas with you about how you might adapt our work or use it based on the resources and know-how you have access to.

We would like to thank Angèle Bénard (Huntington Society of Canada), Jamie Brehaut (Ottawa Hospital Research Institute), Carly Gregory (Canadian Breast Cancer Network), and Lanre Tunji-Ajayi (Sickle Cell Awareness Group of Ontario) for taking the time to review this document and for providing comments and insights that have been incorporated in to it.

Feel Free to Get in Touch!

We're happy to be contacted with any questions you have. You can reach us via email: info@ctontario.ca.

Appendix

Who We are and Why We Created this Toolkit

This Toolkit comes from a collaboration amongst Clinical Trials Ontario, patient organizations and health charities (to date, the Canadian Breast Cancer Network, Huntington Society of Canada, and the Sickle Cell Awareness Group of Ontario), and the Centre for Implementation Research at the Ottawa Hospital Research Institute team. The team's work to understand facilitators and barriers to clinical trials for different communities has included developing surveys and hosting focus groups. Our work is helping organizations and researchers better understand their communities' perspectives on clinical trial participation. To date, our collaborative work has resulted in three peer reviewed publications (5-7).

The Survey Questions and How they were Developed

Our survey questions were developed using the Theoretical Domains Framework (TDF). The TDF organizes over 100 constructs known to be associated with behavior and behavior change into 14 domains that describe determinants of professional and patient health behaviors (1, 8, 9). This framework identifies many factors that can determine behaviours like trial participation and suggests ways to leverage that information into better trial design. After searching the literature for barriers and drivers to trial participation relevant to each of the TDF domains, we designed separate surveys with three health charities (the Canadian Breast Cancer Network, the Huntington Society of Canada, and the Sickle Cell Awareness Group of Ontario) to show how the approach can be adapted to different settings or communities. We did think-aloud user interviews with members of each group (about 10 in total) to maximize the clarity and usability of the surveys, identify which barriers/drivers were relevant for each group, and to suggest additional barriers/drivers for the group. In think-aloud interviews, people verbalize their thought process as they do a task, which was doing the survey in this case. Interviews proceeded iteratively, with changes to the survey incorporated into subsequent interviews.

The Science to Promoting a Survey

There is an evidence-based approach to optimize responses to surveys called Dillman's Tailored Design (10). Before sharing the survey, a 'prenotification' to potential participants is shared, which is then followed by an invitation to participate in the survey a few days later. The survey invitation should include a short description of the survey, an estimate of time to complete it, contact information if people have questions, the survey link, and the participant information sheet. Information about the survey being anonymous and voluntary should be provided. There should be two follow up emails at one-week intervals. There are also other references about factors that improve survey responses (11, 12).

A Template of the Survey Questions and its Structure

The survey we hosted consisted of five sections:

1. A welcome page in English and French with an option to complete in either language which also includes a link to a participant information sheet
2. Questions about You (this section includes questions on demographics and trials experience
3. Knowledge about Clinical Trials
4. Barriers and Enablers to Participating in Clinical Trials (that spans over two screens in the survey software)
5. Thank- You/Contact Information page (6).

An example of a survey we created for the breast cancer community is shown on the next page.

Clinical Trial Participation in Breast Cancer: Your thoughts

SECTION 1: QUESTIONS ABOUT YOU

1. Have you or a family member ever been diagnosed with Breast Cancer?
   ___ Yes, me
   ___ Yes, a family member (please specify their relationship to you) _____
   ___ No

   If Yes, has it been described as:
   ___ Early stage
   ___ Late stage
   ___ Don't know

2. Approximately how long ago was the first diagnosis? (e.g. X years, X months) _____

3. Have you ever been approached to participate in any kind of research study about Breast Cancer?
   ___ Yes
   ___ No
   ___ Don't know/can't remember
   ___Other (please specify) _____

4. Have you ever actually participated in any research study about Breast Cancer?
   ___ Yes
   ___ No
   ___ Don't know/can't remember
   ___ Other (please specify) _____

   If Yes, what was involved in any of the studies you participated in? (check all that apply)
   ___ Clinical Trial (i.e., a study where a doctor tested a new medication or device to see how it improves your health)
   ___ Survey (a study that involved you completing a questionnaire)
   ___ Interview (a study that involved you being interviewed)
   ___ Database study (a study that involved you giving permission for your existing medical information to be analyzed)
   ___ Don't know
   ___ Other (please specify) _____

If Yes, about how long ago was your first participation? (e.g. X years, X months) _____

5. Have you ever actively LOOKED for a clinical trial to participate in?
   ___ Yes ___ No

   If Yes, how did you look for a clinical trial to participate in?
   - ___ Asked my health care provider
   - ___ Searched online
   - ___ Spoke to other people affected by breast cancer
   - ___ Other (please specify) _____

   Did you have help in your search?
   ___Yes ___ No
   If YES, from whom? _____

   Would you have benefited from a service or navigator to help with your search?
   ___ Yes ___ No

   Were you successful in finding one to participate in?
   ___ Yes ___ No

6. What are the first three digits of your postal code? _____

7. Your Age: ___ years ___ prefer not to answer

8. What sex were you assigned at birth, on your original birth certificate?
   - ___ Male
   - ___ Female
   - ___ Prefer not to answer

9. How do you describe yourself? (check one)
   - ___ Male
   - ___ Female
   - ___ Transgender
   - ___ Do not identify as female, male, or transgender
   - ___ Prefer not to answer

10. What is the highest level of education you have completed?

___ Did not complete high school
___ High school diploma
___ Some university or community college (College Classique, CEGEP, trade, technical school)
___ College Diploma or Bachelor's degree
___ Graduate degree (e.g. M.A., M.Sc., M.Ed.)
___ Professional degree (Law, Medicine, Dentistry)
___ Doctoral degree
___ Other: _____
___ Prefer not to answer

11. How many people live in your household (including yourself)? _____

12. What is your best estimate of your total HOUSEHOLD INCOME last year (before taxes)?

___ Less than $50,000
___ Less than $5,000
___ $5,000 or more but less than $10,000
___ $10,000 or more but less than $15,000
___ $15,000 or more but less than $20,000
___ $20,000 or more but less than $30,000
___ $30,000 or more but less than $40,000
___ $40,000 or more but less than $50,000

___ More than $50,000
___ $50,000 or more but less than $60,000
___ $60,000 or more but less than $70,000
___ $70,000 or more but less than $80,000
___$80,000 or more but less than $90,000
___ $90,000 or more but less than $100,000
___ $100,000 or more but less than $150,000
___ $150,000 and over

___ Prefer not to answer

13. Which best describes your current work or main activity? (check all that apply)

___working at a full-time job
___ working at a part-time job
___ self-employed
___ looking for work, in between jobs
___ on maternity/paternity leave
___ on long-term disability
___ homemaking/caregiving
___ volunteering
___ going to school
___ retired
___ Other: _____
___ Prefer not to answer

14. What best describes your ethnic background? (check all that apply)

___ White
___ Asian
___ South Asian
___ Black
___ Arab/West Asian
___ First Nations/Indigenous
___ Filipino
___ Latin American
___ OTHER (please specify) _____
___ Prefer not to answer

15. For how many months of last year did you reside in Canada?
    ___ less than 3 months
    ___ 3-6 months
    ___ 6-9 months
    ___ 9+ months
    ___ Prefer not to answer

16. What is the language that you first learned at home in childhood and can still understand? _____

17. How confident are you that you could explain what a clinical trial is to a friend or family member?
    ___ Not at all confident
    ___ Not very confident
    ___ Somewhat confident
    ___ Completely confident

SECTION 2: KNOWLEDGE ABOUT CLINICAL TRIALS

INSTRUCTIONS: On the next page you will find several statements about clinical trials that study breast cancer. Based on your own knowledge and experience, please tell us whether you agree or disagree with each statement by selecting a response. If you are very unsure or can't remember, please select 'unsure'. It is ok if you are unsure or disagree; we are interested in your opinions. Please read each statement carefully and respond as best you can.

1. People usually cannot participate in a clinical trial without signing a detailed consent document	Disagree	Unsure	Agree
2. The main reason scientists do clinical trials is to improve the treatment of future patients	Disagree	Unsure	Agree
3. Participants in clinical trials must be informed how long their participation is likely to last	Disagree	Unsure	Agree
4. The treatment being tested in most clinical trials has been proven to be the best treatment for the disease	Disagree	Unsure	Agree
5. In many clinical trials, participants are assigned randomly (by chance) to one of multiple different treatments	Disagree	Unsure	Agree
6. Compared with standard treatments, clinical trials usually do not carry additional risks or discomforts	Disagree	Unsure	Agree
7. There may be no direct medical benefit for participants in clinical trials	Disagree	Unsure	Agree
8. By participating in a clinical trial, participants are helping the researchers learn information that may benefit future patients	Disagree	Unsure	Agree
9. It's possible that people who are not directly involved in care could review trial participants' medical records (e.g., study funders)	Disagree	Unsure	Agree
10. Doctors will sometimes offer a clinical trial as the only available treatment.	Disagree	Unsure	Agree
11. Consent forms provide the names of the people to contact if participants have any questions or concerns about the clinical trial	Disagree	Unsure	Agree
12. If someone does not want to participate in a clinical trial, they can always decline (and not sign the consent form)	Disagree	Unsure	Agree
13. Once they have agreed to participate, participants must remain in the clinical trial even if they decide later they want to withdraw	Disagree	Unsure	Agree

Modified from QuIC instrument (Joffe et al, Quality of Informed Consent: A New Measure of Understanding Among Research Subjects, 2001)

SECTION 3: BARRIERS AND DRIVERS OF PARTICPATION

Imagine you were being asked today to participate in a clinical trial investigating how well a new treatment works for Breast Cancer. Please rate (using the checkboxes) how each issue would affect your decision about whether or not to participate in the clinical trial:

	This issue would:				
	Push me AWAY from participating			Push me TOWARDS participating	
	a LITTLE	a LOT	No effect	a LITTLE	a LOT
If I find the trial documents hard to understand					
If the consent documents describe probabilities of side effects and numbers of patients affected by them					
My belief that participation is part of my role as a good citizen					
If I think my cancer prognosis is poor					
If I think my health is good (other than my cancer)					
If I think there is a substantial time commitment					
My worry about unknown side effects					
My belief that I would receive better care if I participated					
My belief that I'd learn more about my condition if I participated					
My belief that participating would give me a sense of purpose					
My belief that participation would prevent me from my other activities					
My belief that participating would contribute to science					
My belief that participating would help others					
My belief that participating would give me a sense of control over what is happening to me					
If the investigators provided telephone reminders about study appointments					
If there was patient-friendly decision-making tools to help you make your participation decision					

	This issue would:				
	Push me AWAY from participating			Push me TOWARDS participating	
	a LITTLE	a LOT	No effect	a LITTLE	a LOT
If there were helpful people on hand to help you make your participation decision					
If the study provided transportation to/from study appointments					
If the study reimbursed expenses					
If the investigators provided regular study updates					
If my physician(s) thought I should participate					
If my family thought I should participate					
My feelings about whether the trial funders can be trusted					
My worry that participation would mean that others would find out about my condition					
My hope that participation would help find a cure					
My hope that participation will help me with my condition					
My experience with previous trials					
If I would gain access to new study drugs					
If I had to have more blood tests					
If I had to have more biopsies					
If I had to stay longer in hospital					
If my physician was paid to recruit patients into the study					
If I received the results of the study once it was complete					
My belief that participation would interfere with other goals of mine					
If I think participation would affect my social life/ family commitments					

	This issue would:				
	Push me AWAY from participating			Push me TOWARDS participating	
	a LITTLE	a LOT	No effect	a LITTLE	a LOT
If I think participation would interfere with my child care responsibilities					
My feelings about the quality of the health care system					
My feelings about the quality of my drug plan If the investigators provided regular study updates					
Are there any **OTHER ISSUES** that would affect your decision about whether to participate?					

THANK YOU!!!

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