Poster # PCR19

Patient-Centric Assessment of Treatment Experience in Breast Cancer: Development and Validation of a Patient Questionnaire

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CONCLUSIONS

- Final questionnaire consists of 18 questions, refined based on input from patients and experts.
- Based on expert review, this questionnaire can capture breast cancer patient experiences and preferences on medications to help better match patients with treatments.
- Additional validation testing is planned to establish the properties of the questionnaire and identify norms.

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BACKGROUND

Breast cancer is the most common malignancy among Canadian women (excluding non-melanoma skin cancers) and treatments can substantially affect health-related quality of life.[1]

Patient experiences are highly variable and there is an increasing focus on quality of life and in offering high-value care for patients with breast cancer. Understanding the impact of interventions on Canadian patients' quality of life is crucial in promoting patient-centered care.

OBJECTIVES

Our objective was to develop and validate content of a questionnaire that captures Canadian patient experiences and preferences regarding breast cancer medication(s).

METHODS

- After conducting a literature review and consulting with subject matter experts, a set of questions focusing on the impact of treatment-related side effects was developed.
- Content validity was evaluated through a two-phase process, including a modified Delphi panel and individual interviews.
- The modified Delphi panel consisted of two rounds aimed at gathering feedback and reaching consensus among panelists, defined *a priori* as agreement by at least 70% of the panel. Consensus regarding question relevance and wording was determined by the proportion of respondents answering 'yes' or 'no' to specific statements, with a threshold of 70% considered indicative of agreement.
- Following the refinement of preliminary questionnaires, participants willing to engage in a 60-minute recorded interview, provided feedback during concept confirmation and debriefing interviews. These interviews were recorded, and transcripts were anonymized for analysis.

Figure 1. Overview of study methods

Review of literature

Development of initial questionnaire based on concepts from literature reviews

Two-rounds of a modified Delphi panel

Data analysis and revision of questionnaires

Interviews assessing content validity

Finalization of questionnaire

RESULTS

Literature searches were performed to evaluate existing resources, revealing a lack of tools for recording treatment experiences in Canadian patients with early-stage breast cancer, particularly for current research objectives.

Delphi Panel

- Three patients and four Canadian experts (one health-service researcher, one radiation oncologist, and two medical oncologists) participated in the two-round Delphi panel
- Panelists' comments on wording and relevance of question items were incorporated in the revised questionnaire
- Their response rate was 85.7% (6/7) in the first round, and 71.4% (5/7) in the second round of Delphi panel
- 4 panelists were from Quebec, 1 from Alberta and 2 from Ontario
- There was consensus among panelists on proposed revisions of 8/13 questions in the first round of the Delphi
- Additionally, panelists provided feedback to further improve 11/13 questions
- The initial list of 13 draft questions were adapted for relevance and wording and split into 18 revised questions

Figure 2. Percentage of 'Yes' or 'No' responses to statements used in round one and two

☐ This question is relevant to patients
☐ I am comfortable with the wording and understand this question
☐ I am not comfortable with the wording
☐ I do not understand this question
☐ The list of options to choose from is appropriate
☐ The wording of the question is not appropriate
☐ The wording of the question is not clear

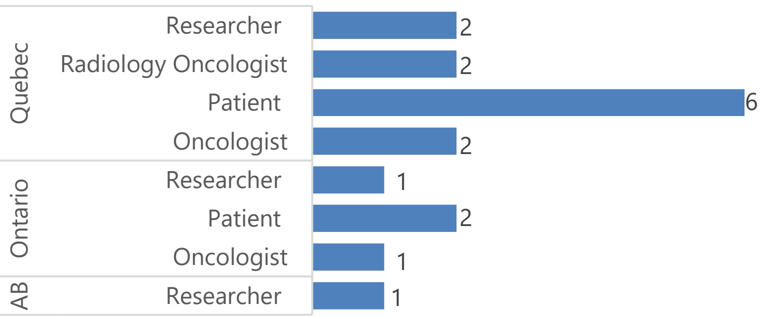
Figure 3. Five-point Likert scale used in round two

1	2	3	4	5
Extremely agree	Agree	Neither agree nor disagree	Disagree	Extremely disagree
Agree------------------------- Level of agreement -----------------------Disagree				

Content Validity Interviews

- Eight patients and seven experts provided additional feedback on revised questionnaire from Delphi.
- Plain language editing, order of questions, and response options were adjusted based on participants' comments. Final questionnaire consists of 18 questions, refined based on input from patients and experts.

Figure 4. Respondent profiles (Experts / Patients)



Examples of comments from experts

Treatment discontinuation
Do we need a response option there that "the doctor advised that I stopped taking the drugs"? A patient might stop taking medication without doctor's approval, I would hope that the patient was advised by their doctor.

Side effects
Why only one option?
For symptoms, you can probably do a "pick three or two top reasons".
Sometimes people can feel same things with both items and now must choose something.

Medication selection
Consider adding N/A or did not discuss cancer treatment.

Table 1. Sample items from the questionnaire

Concept definition	Final item	Final response option	
Treatment discontinuation	Did you stop taking a breast cancer medicine before you were recommended to stop?	○ Yes ○ No ○ I am not sure	
	If you stopped taking a breast cancer medicine early, what was the reason to stop?	☐ Side effects from the breast cancer medicine ☐ I was pregnant ☐ I was trying to get pregnant ☐ The treatment was no longer working ☐ I did not think the medication was helping me	☐ My doctor advised me to stop taking a medication ☐ I did not stop taking a medication early ☐ Not applicable – I did not need breast cancer medication as part of my treatment
Side Effects	Which side effects caused you to stop taking a breast cancer medicine early? Select all that apply.	☐ Fatigue (feeling tired or lack of energy to do activities) ☐ Hard to sleep ☐ Diarrhea (loose poo) ☐ Constipation (hard and lumpy poo/difficulty pooing) ☐ Nausea (feeling sick to the stomach) ☐ Vomiting (throwing up) ☐ Hot flashes (sudden feeling of warmth followed by sweating) ☐ Hair loss	☐ Mouth sores (round white or yellow painful sore inside the mouth) ☐ Weight changes (gaining or losing weight) ☐ Muscle aches ☐ Joint or bone pain ☐ Mood changes (feeling anxious or depressed) ☐ Changes to sexual health (having a lower sex drive) ☐ I am not sure ☐ Not applicable ☐ Other medication side effect(s) (please list the side effects in the next question)
Side Effects: time	In the last month, how did side effects from breast cancer medicine affect your daily tasks?	○ I did not have any side effects ○ The side effects did not prevent me from doing daily tasks ○ The side effects prevented me from doing some daily tasks	○ The side effects prevented me from doing most daily tasks ○ I am not sure
Side Effects: hospitalization	In the last year, how many times did you need to stay overnight at the hospital due to breast cancer medicine side effects?	○ 1 to 2 times ○ 3 to 5 times ○ More than 5 times	○ None, I did not need to stay overnight at the hospital ○ I did stay overnight at the hospital but for other reasons ○ I am not sure
Absenteeism	In the last 6 months, if you were working while receiving breast cancer medicine, did you miss work because of medicine side effects?	○ Yes, I missed work ○ No, but I reduced my workload, changed to part-time hours, or switched to remote work ○ No, I did not miss work ○ I did not work in the last 6 months	
	If you were working in the last 6 months and experienced side effects, how many days of work did you miss due to these side effects?	○ 1 to 3 days ○ 4 to 6 days ○ 1 to 3 weeks ○ One month ○ More than a month	○ I took a short term/long term leave or a disability leave from work ○ Not applicable – I did not miss work ○ Not applicable – I am not working
Quality of life	How do you rate your wellbeing overall?	○ 1 My overall wellbeing is poor ○ 2 My overall wellbeing is fair ○ 3 My overall wellbeing is good	○ 4 My overall wellbeing is very good ○ 5 My overall wellbeing is excellent
Medication selection	Does your doctor answer your questions about breast cancer medicine options?	○ 1 Always ○ 2 Often ○ 3 Sometimes	○ 4 Rarely ○ 5 Never ○ I do not discuss breast cancer medicine options with my doctor
	What was the most important factor when making decisions about your breast cancer medication with your doctor?	☐ Increasing my chances of being cured ☐ Preventing the cancer from coming back ☐ Cost ☐ Side effects ☐ Time required to be off work	☐ Time required to be in hospital for visits ☐ Other ☐ None ☐ Not applicable, I did not discuss my breast cancer medicine options with my doctor

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