

# Patient decision aid for contralateral prophylactic mastectomy for use in the consultation: a feasibility study

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## ABSTRACT

**Background** Rates of contralateral prophylactic mastectomy (CPM) continue to rise internationally despite evidence-based guidance strongly discouraging its use in most women with unilateral breast cancer. The purpose of the present study was to develop and assess the feasibility of a knowledge translation tool [a patient decision aid (DA)] designed to enhance evidence-informed shared decision-making about CPM.

**Methods** A consultation DA was developed using the Ottawa Patient Decision Aid Development eTraining in consultation with clinicians and knowledge translation experts. The final DA was then assessed for feasibility with health care professionals and patients across Canada. The assessment involved a survey completed online (health care professionals) or by telephone (patients). Survey data were analyzed using descriptive statistics for closed-ended questions and qualitative content analysis for open-ended questions.

**Results** The 51 participants who completed the survey included 39 health care professionals and 12 patients. The DA was acceptable; 88% of participants viewed it as having the right amount of information or slightly more or less information than they would like. Almost all participants (98%) felt that the DA would prepare patients to make better decisions. The aid was perceived to be usable, with 73% of participants stating that they would be willing to use or share the DA.

**Conclusions** The CPM patient DA developed for the present study was viewed by health care professionals and patients across Canada to be acceptable and usable during the clinical consultation. It holds promise as a knowledge translation tool to be used by clinicians in consultation with women who have unilateral breast cancer to enhance evidence-informed and shared decision-making with respect to undergoing CPM.

**Key Words** Contralateral prophylactic mastectomy, unilateral breast cancer, decision aids, shared decision-making, evidence-informed care

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## BACKGROUND

### The Knowledge-to-Practice Gap

Breast cancer (BCA) is the most common cancer in Canadian women, with more than 23,000 women diagnosed annually<sup>1</sup>. Contralateral prophylactic mastectomy (CPM) refers to removal of the contralateral unaffected healthy breast in a patient with known unilateral (that is, limited to only one side) BCA. A patient's decision to undergo CPM as

part of the initial treatment for BCA is a growing challenge in the management of the disease.

Outside of individuals who are at high risk for bilateral BCA (such as those who carry a gene mutation), who constitute a small proportion of BCA patients (5%–10%)<sup>2–5</sup>, the risk of contralateral BCA in patients with known BCA is well studied and documented to be low (0.5%–0.75% per year, a risk similar to that in the non-breast-cancer population)<sup>6,7</sup>. Furthermore, undergoing CPM can result

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in harms to patients, both medical (for example, wound healing, infectious, cardiorespiratory, neurologic, thromboembolic)<sup>8,9</sup> and psychological (for example, poor cosmetic outcomes<sup>10</sup>, feelings of lessened sexuality<sup>10</sup>, depression<sup>11</sup>). Thus, evidence-based guidance “strongly discourages” the routine use of CPM in most women with unilateral bca<sup>12–15</sup>. Despite that guidance, rates of CPM among women treated for unilateral bca have continued to rise in Canada and internationally<sup>16–20</sup>. That knowledge-to-practice gap (undergoing CPM when not medically indicated) has precipitated a need for knowledge translation (KT) strategies and tools to better integrate the evidence about CPM into practice and to support patients and health care professionals in making shared decisions about whether to undergo CPM.

### Patient Decision Aids

Shared decision-making (SDM) involves the joint participation of patients and health care professionals in making health care decisions based on the best available evidence and patient preferences—a common tenet in health policy<sup>21</sup>. Patient decision aids (DAs) are an effective KT tool in supporting SDM and achieving patient-centred care<sup>22–25</sup>.

At a minimum, patient DAs make the decision explicit, provide information about options and outcomes (benefits and harms) based on scientific evidence, and guide patients to consider their own values for the outcomes of their options<sup>26</sup>. Patient DAs are intended to be used in preparation for or during consultation with health care professionals to assist in discussion and subsequently making a health decision. They have demonstrated effectiveness in enhancing patient participation in decision-making, improving decision quality, increasing knowledge, lessening decisional conflict, and reducing overuse of inappropriate treatment options<sup>27</sup>. When evidence from DAs developed for use by patients alone was compared with evidence from DAs used in clinical consultation, similar improvements in knowledge and a lessening of decisional conflict were observed<sup>27</sup>. The International Patient Decision Aid Standards (IPDAS) is an evaluation tool used to ensure that patient DAs being disseminated to the public are a reliable and valid source of health information, with minimal risk of biasing decision-making<sup>28</sup>.

There is evidence to support the use of DAs by patients with early-stage bca. Zdenkowski and colleagues<sup>29</sup> conducted a systematic review of DAs for patients making a decision with respect to multiple treatment modalities for early bca. Their synthesis of thirty-three studies revealed that DAs are helpful to bca patients by decreasing decisional conflict and increasing knowledge of options. No DAs for CPM were included in the review. Despite their advantages, DAs for several bca decisions, including CPM, are lacking<sup>30</sup>. Therefore, the purpose of the present work was to report on the development and feasibility of a patient DA for CPM as a treatment in early-stage unilateral bca.

### Theoretical Considerations

Our study was guided by two theoretical frameworks:

- the Ottawa Decision Support Framework, and
- the IPDAS.

The Ottawa Decision Support Framework is rooted in psychological theories, social support theories, decisional conflict, and expectancy value. It is used to guide patients in making health and social decisions<sup>31</sup>. The Framework explains the relationships between the 3 main elements of decision-making<sup>23,32</sup>:

- Decisional needs
- Decision quality
- Decision support

It is used to inform the development and evaluation of decision support tools, including the CPM patient DA reported here. The IPDAS is a set of standards that was developed in recognition of a need for a framework of quality criteria for patient DAs<sup>33,34</sup>. The IPDAS workgroup established a quality checklist (a valid and reliable instrument) and certification standards relevant to the creation and evaluation of patient DAs<sup>28,35–37</sup>. The Ottawa Decision Support Framework and the IPDAS are both embedded in the Ottawa Patient Decision Aid Development eTraining online tool<sup>38</sup>, which was used to develop the CPM patient DA for the present study.

## METHODS

### Intervention Development

The KT tool for this study was the CPM patient DA. Its development occurred in two steps:

- Preparation phase
- Development of the CPM patient DA prototype

#### Preparation Phase

In the preparation phase, a literature scan was conducted by 2 clinical experts (AA, AR). The literature review identified current evidence and practice recommendations with respect to CPM in early-stage unilateral bca. The consensus statement from the American Society of Breast Surgeons (ASBS)<sup>39</sup> and a similar Canadian consensus statement about CPM<sup>15</sup> were deemed to be the most up-to-date and clinically relevant evidence available in terms of CPM outcomes and risks. A secondary objective of the literature review was to search for any pre-existing patient DAs about CPM that might exist; none were located.

#### Development of the CPM Patient DA Prototype

A prototype of the CPM patient DA to be used in patient consultations was developed using the Ottawa Patient Decision Aid Development eTraining<sup>38</sup>, which is an online tool developed by DA experts from the University of Ottawa. The e-training tool outlines the systematic step-by-step development process for patient DAs according to the IPDAS Collaboration criteria and the Ottawa Decision Support Framework<sup>28</sup>. The training tool provides evidence-based resources and templates to guide and support users in each step. The development of the DA was led by 2 research team members who are clinical experts on CPM and bca treatment (AR, AA). The initial draft of the DA was developed by AR using the e-training; it was then reviewed and amended by AA, a senior clinical expert. Evidence included in the DA was extracted from the ASBS Consensus Statement<sup>39</sup>. The draft was reviewed by 2 research

team members who are content experts in κT (JES, DS) and DAS (DS). The DA underwent several iterations until consensus about a final version for feasibility testing was reached. Supplementary Appendix 1 presents the final version of the DA prototype that was evaluated in the study.

### Intervention Implementation and Evaluation

Intervention implementation and evaluation for the present study consisted of a national assessment of the CPM patient DA for feasibility with various health care professional specialties and with women (patients) having unilateral bca at low risk for contralateral bca. Ethics approval for the study was obtained from the Ottawa Health Science Research Ethics Board (protocol 20140664-01H).

### Design and Recruitment

A mixed-methods survey was used to evaluate the feasibility of the DA. The survey was designed to measure the aspects of acceptability, usability, clarity, and agreement. The target users of the DA, women with early-stage unilateral bca and health care professionals involved in the care of women with bca, were recruited to participate in the evaluation study. Multiple recruitment strategies were used. For health care professionals, master lists were compiled using publicly available information in databases including the Canadian Association of General Surgeons, the Canadian Society of Surgical Oncology, the Canadian Society of Plastic Surgeons, the Canadian Association of Radiation Oncology, and the Canadian Association of Medical Oncologists. Registered nurses working in oncology were recruited at bca centres across Canada through their nurse unit managers, who were asked to distribute a recruitment poster to their unit nurses. Patients were recruited through national bca organizations (for example, The Breast Cancer Society of Canada, Willow Breast Cancer Support Canada) using newsletters, Web sites, social media, and a recruitment poster in medical offices nationwide. Patient recruitment posters were also posted at online advertisement platforms (Kijiji, Used.ca) in Canadian cities with cancer centres.

### Data Collection

Health care professionals evaluated the DA by completing an online survey (Supplementary Appendix 2). The survey contained both closed- and open-ended questions. The first set of closed-ended survey questions were multiple-choice items that asked about the usability and acceptability of the DA. The second set of closed-ended questions asked health care professionals to rate the clarity of the information presented in various sections of the DA (for example, What are your options?) on a 4-point scale from “poor” to “very good” and to rank their agreement with statements pertaining to the DA’s preparation for decision-making (helpful to prepare patients to make a better decision) on a 5-point scale from “not at all” to “a great deal”<sup>40</sup>. The survey also posed 4 open-ended questions about the DA:

- What the respondent liked about it
- What the respondent disliked about it
- The ease or difficulty of understanding the risks and benefits section
- What alternations to the DA might be needed

Women with unilateral bca (patients) evaluated the DA by completing a survey (Supplementary Appendix 3) during a telephone interview with a research team member (KD). The structure used in the telephone evaluation was the same as that used in the health care professional online evaluation, with some slight modifications. Some of the closed-ended questions were reworded to fit the patient perspective (for example, Would the DA fit into the discussion with your clinician?). The open-ended component of the evaluation used a semi-structured interview format and consisted of 2 questions about the DA:

- What the interviewee liked about the DA
- What the interviewee disliked about the DA

The patient interviews were conducted using cognitive “think-aloud” methods<sup>41,42</sup>, in which patients were provided a copy of DA and were asked to vocalize all of the thoughts that came to their mind about the DA as they reviewed it. The telephone evaluation was digitally recorded, transcribed verbatim, and verified for accuracy by the team member who conducted the telephone evaluation.

### Data Analysis

Data from the closed-ended questions were analyzed in the IBM SPSS Statistics for Windows software application (version 24: IBM, Armonk, NY, U.S.A.). Descriptive statistics were used to calculate the frequency of the ratings provided in the survey. The transcripts of the patient interviews and the patient and health care professional responses to the open-ended questions were imported to the NVivo software application (version 10: QSR International, Melbourne, Australia). Data from the open-ended questions underwent qualitative thematic content analysis<sup>43,44</sup> independently by research team members trained in qualitative analysis (JES, MC, MG, MDV) and occurred in 3 steps: coding, theming, and calculation of frequencies. In the first step, 2 research team members independently coded the open-ended questions from the first 4 patient and health care professional surveys to establish a coding scheme (comprising codes, definitions of codes, and examples of quotes for the codes). The remaining transcripts were then coded independently by 2 team members using the established coding scheme, with consensus. In the second step, similar codes were amalgamated into themes and then categories were agreed upon by 2 team members. Lastly, the frequencies of the themes and overarching categories were tabulated based on how often they appeared across transcripts.

## RESULTS

### Participant Demographics

The 51 participants in the evaluation study included 39 health care professionals and 12 patients (Table 1). The health care professional sample had representation from 8 Canadian provinces and multiple disciplines: medical oncology ( $n = 10$ , 26%), surgical oncology ( $n = 8$ , 21%), plastic surgery ( $n = 7$ , 18%), radiation oncology ( $n = 6$ , 15%), general surgery ( $n = 5$ , 13%), nursing ( $n = 2$ , 5%), and genetics ( $n = 1$ , 3%). Similar proportions of health care professionals were male ( $n = 19$ , 49%) and female ( $n = 20$ , 51%), and most

**TABLE I** Participant demographics

| Variable                         | Value [n (%)] |
|----------------------------------|---------------|
| <i>Health care professionals</i> | 39            |
| Province of employment           |               |
| Ontario                          | 18 (46)       |
| Alberta                          | 5 (13)        |
| British Columbia                 | 5 (13)        |
| Manitoba                         | 3 (7)         |
| Prince Edward Island             | 2 (5)         |
| Nova Scotia                      | 2 (5)         |
| Quebec                           | 2 (5)         |
| Saskatchewan                     | 1 (3)         |
| Missing                          | 1 (3)         |
| Hospital type                    |               |
| Teaching                         | 35 (90)       |
| Community                        | 4 (10)        |
| Specialty                        |               |
| Medical oncology                 | 10 (25)       |
| Surgical oncology                | 8 (21)        |
| Plastic surgery                  | 7 (18)        |
| Radiation oncology               | 6 (15)        |
| General surgery                  | 5 (13)        |
| Nursing                          | 2 (5)         |
| Genetics                         | 1 (3)         |
| Age group                        |               |
| <30 Years                        | 1 (3)         |
| 30–39 Years                      | 7 (18)        |
| 40–49 Years                      | 9 (23)        |
| 50–59 Years                      | 14 (35)       |
| 60–69 Years                      | 7 (18)        |
| ≥70 Years                        | 1 (3)         |
| Sex                              |               |
| Female                           | 20 (51)       |
| Male                             | 19 (49)       |

( $n = 35, 90\%$ ) worked in teaching hospitals. With respect to the patient sample, 4 Canadian provinces were represented. The sample included women who had ( $n = 5, 42\%$ ) and had not ( $n = 7, 58\%$ ) undergone a CPM. Most patients were between 40 and 60 years of age ( $n = 8, 67\%$ ) and were within 5 years of their initial bca surgery ( $n = 11, 92\%$ ).

### Usability and Acceptability of the DA

Most health care professionals ( $n = 34, 87\%$ ) and all patients ( $n = 12, 100\%$ ) responded that the wording of the DA made sense (Table II). Most respondents (health care professionals:  $n = 33, 85\%$ ; patients:  $n = 12, 100\%$ ) felt that the DA had the right amount of information or only a little more or less than they wanted. Most respondents (health care professionals:  $n = 30, 77\%$ ; patients:  $n = 11, 92\%$ ) also felt that the font and icons used in the DA were readable.

| Variable                   | Value [n (%)] |
|----------------------------|---------------|
| <i>Patients</i>            | 12            |
| Province of residence      |               |
| Ontario                    | 5 (42)        |
| Alberta                    | 4 (33)        |
| New Brunswick              | 2 (17)        |
| Manitoba                   | 1 (8)         |
| Level of education         |               |
| High school                | 1 (8)         |
| College                    | 0 (0)         |
| Undergraduate              | 9 (75)        |
| Graduate                   | 2 (17)        |
| Time since surgery (years) |               |
| <2 Years                   | 5 (42)        |
| 2–5 Years                  | 6 (50)        |
| 6–10 Years                 | 1 (8)         |
| >10 Years                  | 0 (0)         |
| Time since CPM             |               |
| <2 Years                   | 5 (42)        |
| 2–5 Years                  | 2 (16)        |
| 6–10 Years                 | 0 (0)         |
| >10 Years                  | 0 (0)         |
| Not applicable             | 5 (42)        |
| Age group                  |               |
| <30 Years                  | 0 (0)         |
| 30–39 Years                | 1 (8)         |
| 40–49 Years                | 4 (33)        |
| 50–59 Years                | 4 (33)        |
| 60–69 Years                | 2 (16)        |
| ≥70 Years                  | 1 (8)         |
| Sex                        |               |
| Female                     | 12 (100)      |
| Male                       | 0 (0)         |

CPM = contralateral prophylactic mastectomy.

With respect to balance between undergoing or not undergoing a CPM (asked to health care professionals), most ( $n = 31, 79\%$ ) felt that the DA was balanced or only slightly unbalanced. Instead of balance, patients were asked about the length of the DA; half ( $n = 6, 50\%$ ) felt that it was about the right length; others felt that it was a little too long ( $n = 4, 33\%$ ) or too short ( $n = 2, 17\%$ ). Most health care professionals ( $n = 26, 67\%$ ) and patients ( $n = 11, 92\%$ ) indicated that they would share the DA with others.

### Agreement That the DA Helped to Prepare for Decision-Making

All patients and most health care professionals agreed with all 7 statements presented in the evaluation survey (Table III). Agreement was more frequent among patients than among health care professionals, with more than 70%

**TABLE II** Usability and acceptability of the decision aid

| Factor   | Endorsed<br>[n (%)] |
|--|---------------------|
| <i>Health care professionals</i>                   | 39                  |
| Amount of information?                             |                     |
| Much less than I wanted                            | 5 (13)              |
| Little less than I wanted                          | 9 (23)              |
| About right  | 21 (53)             |
| Little more than I wanted                          | 3 (8)               |
| Much more than I wanted                            | 1 (3)               |
| Fonts and icons readable?                          |                     |
| Yes  | 30 (77)             |
| No   | 9 (23)              |
| Enough space?                                      |                     |
| Yes  | 23 (59)             |
| No   | 16 (41)             |
| Do words make sense?                               |                     |
| Yes  | 34 (87)             |
| No   | 5 (13)              |
| Balance of decision aid?                           |                     |
| Clearly slanted to having both breasts removed     | 2 (5)               |
| Slightly slanted to having both breasts removed    | 10 (26)             |
| Completely balanced                                | 15 (39)             |
| Slightly slanted to having only one breast removed | 6 (15)              |
| Clearly slanted to having only one breast removed  | 6 (15)              |
| Information added/removed?                         |                     |
| Yes, added   | 20 (51)             |
| Yes, removed                                       | 1 (3)               |
| No   | 16 (41)             |
| Missing  | 2 (5)               |
| Fit into patient–HCP discussion?                   |                     |
| Yes, as it is                                      | 20 (51)             |
| Yes, with some alterations                         | 1 (3)               |
| No   | 16 (41)             |
| Missing  | 2 (5)               |
| Would you use/share the decision aid?              |                     |
| Yes  | 26 (67)             |
| No   | 12 (30)             |
| Missing  | 1 (3)               |

of patients agreeing quite a bit or a great deal with 5 of the 7 statements. Among the health care professionals, the same percentage agreement was seen for only 2 of the 7 statements. The statements attracting the highest agreement by health care professionals were “help patients know that decision depends on what matters to them” ( $n = 30$ , 77%, agreed “quite a bit” or “a great deal”) and “help patients think about the pros and cons of each option” ( $n = 29$ , 74%, agreed “quite a bit” or “a great deal”). The latter statement about pros and cons also attracted high agreement from patients ( $n = 12$ , 100%, agreed “quite a bit” or “a great deal”). Other statements that attracted high agreement from patients included “help patients think about which pros and cons are most important”

| Factor                                | Endorsed<br>[n (%)] |
|---------------------------------------|---------------------|
| <i>Patients</i>                       | 12                  |
| Amount of information?                |                     |
| Much less than I wanted               | 0 (0)               |
| Little less than I wanted             | 3 (25)              |
| About right                           | 6 (50)              |
| Little more than I wanted             | 3 (25)              |
| Much more than I wanted               | 0 (0)               |
| Font and icons readable?              |                     |
| Yes                                   | 11 (92)             |
| No                                    | 1 (8)               |
| Enough space?                         |                     |
| Yes                                   | 9 (75)              |
| No                                    | 3 (25)              |
| Do words make sense?                  |                     |
| Yes                                   | 12 (100)            |
| No                                    | 0 (0)               |
| Length of decision aid?               |                     |
| Much too long                         | 0 (0)               |
| Little too long                       | 4 (33)              |
| About right                           | 6 (50)              |
| A little too short                    | 2 (17)              |
| Much too short                        | 0 (0)               |
| Fit into patient–HCP discussion?      |                     |
| Yes, as it is                         | 9 (75)              |
| Yes, with alterations                 | 3 (25)              |
| No                                    | 0 (0)               |
| Any information missing?              |                     |
| Yes                                   | 8 (67)              |
| No                                    | 4 (33)              |
| Would you use/share the decision aid? |                     |
| Yes                                   | 11 (92)             |
| No                                    | 1 (8)               |

HCP = health care provider.

( $n = 11$ , 92%, agreed “quite a bit” or “a great deal”) and “help patient recognize that a decision needs to be made” ( $n = 10$ , 83%, agreed “quite a bit” or “a great deal”).

### Clarity of Information in the DA

Health care professionals rated the clarity of the information contained within the 8 sections of the DA (Table IV). Most sections (6 of 8) were rated as “good” or “very good” by more than 70% of health care professionals. Only 2 sections were rated as “good” or “very good” by less than 70% of health care professionals: “information on funding/authors” (rated “good” or “very good” by 25, 64%) and references (rated “good” or “very good” by 27, 69%).

**TABLE III** Ratings by 39 health care professionals and 12 patients of agreement with the decision aid helping prepare for decision-making

| Statement  | Rating [ <i>n</i> (%)] |          |          |             |              |         |
|--|------------------------|----------|----------|-------------|--------------|---------|
|  | Not at all             | A little | Somewhat | Quite a bit | A great deal | Missing |
| <i>Health care professionals</i>                                     |                        |          |          |             |              |         |
| Help patients recognize that a decision needs to be made             | 1 (3)                  | 3 (8)    | 9 (23)   | 18 (46)     | 8 (20)       | 0 (0)   |
| Prepare patients to make a better decision                           | 1 (3)                  | 2 (5)    | 9 (23)   | 18 (46)     | 9 (23)       | 0 (0)   |
| Help patients think about the pros and cons of each option           | 1 (3)                  | 3 (8)    | 5 (13)   | 19 (48)     | 10 (25)      | 1 (3)   |
| Help patients think about which pros and cons are most important     | 2 (5)                  | 5 (13)   | 7 (18)   | 17 (44)     | 8 (20)       | 0 (0)   |
| Help patients know that the decision depends on what matters to them | 1 (3)                  | 5 (13)   | 3 (8)    | 24 (61)     | 6 (15)       | 0 (0)   |
| Help patients organize their own thoughts about the decision         | 0 (0)                  | 6 (15)   | 6 (15)   | 17 (44)     | 8 (20)       | 2 (5)   |
| Help patients prepare questions to their doctor                      | 0 (0)                  | 6 (15)   | 8 (20)   | 20 (51)     | 5 (13)       | 0 (0)   |
| <i>Patients</i>  |                        |          |          |             |              |         |
| Help patients recognize that a decision needs to be made             | 0 (0)                  | 0 (0)    | 2 (17)   | 4 (33)      | 6 (50)       | 0 (0)   |
| Prepare patients to make a better decision                           | 0 (0)                  | 0 (0)    | 4 (33)   | 5 (42)      | 3 (25)       | 0 (0)   |
| Help patients think about the pros and cons of each option           | 0 (0)                  | 0 (0)    | 0 (0)    | 7 (58)      | 5 (42)       | 0 (0)   |
| Help patients think about which pros and cons are most important     | 0 (0)                  | 1 (8)    | 0 (0)    | 6 (50)      | 5 (42)       | 0 (0)   |
| Help patients know that the decision depends on what matters to them | 0 (0)                  | 0 (0)    | 4 (33)   | 4 (33)      | 4 (33)       | 0 (0)   |
| Help patients organize their own thoughts about the decision         | 0 (0)                  | 2 (17)   | 1 (8)    | 5 (42)      | 4 (33)       | 0 (0)   |
| Help patients prepare questions to their doctor                      | 0 (0)                  | 1 (8)    | 2 (17)   | 5 (42)      | 4 (33)       | 0 (0)   |

**TABLE IV** Ratings by 39 health care professionals and 12 patients of the clarity of information in the decision aid

| Statement   | Rating [ <i>n</i> (%)] |        |         |           |         |
|---|------------------------|--------|---------|-----------|---------|
|   | Poor                   | Fair   | Good    | Very good | Missing |
| <i>Health care professionals</i>                            |                        |        |         |           |         |
| Why we are discussing removing the other (healthy) breast?  | 2 (5)                  | 6 (15) | 19 (49) | 12 (31)   | 0 (0)   |
| What are your options?                                      | 0 (0)                  | 4 (10) | 15 (39) | 20 (51)   | 0 (0)   |
| What do you think of the benefits and risks of each option? | 2 (5)                  | 8 (21) | 20 (51) | 8 (21)    | 1 (3)   |
| Which option do you prefer?                                 | 1 (3)                  | 4 (10) | 20 (51) | 14 (36)   | 0 (0)   |
| What are your decision-making needs?                        | 3 (8)                  | 7 (18) | 19 (49) | 10 (25)   | 0 (0)   |
| Additional information                                      | 3 (8)                  | 5 (13) | 20 (51) | 10 (25)   | 1 (3)   |
| Information about funding or authors                        | 2 (5)                  | 8 (21) | 15 (39) | 10 (25)   | 4 (10)  |
| References  | 2 (5)                  | 8 (21) | 18 (46) | 9 (23)    | 2 (5)   |
| <i>Patients</i>   |                        |        |         |           |         |
| Why we are discussing removing the other (healthy) breast?  | 0 (0)                  | 2 (17) | 5 (42)  | 5 (42)    | 0 (0)   |
| What are your options?                                      | 1 (8)                  | 1 (8)  | 6 (50)  | 3 (25)    | 1 (8)   |
| What do you think of the benefits and risks of each option? | 1 (8)                  | 1 (8)  | 9 (75)  | 1 (8)     | 0 (0)   |

Patients rated 3 of the sections for clarity of information. Most patients rated all 3 sections as “good” or “very good” (>70%: “why are we discussing removing the other (healthy) breast” (*n* = 10, 83%); “what are your options” (*n* = 9, 75%); “benefits and risks of each option” (*n* = 10, 83%); Table IV].

### Open-Ended Responses

Tables V and VI summarize the themes emerging from the open-ended survey questions for health care professionals and patients respectively. Among the responses from the

health care professionals, 13 themes were identified, which were grouped based on the 4 corresponding survey questions: likes (4 themes), dislikes (4 themes), understanding of risks and benefits (3 themes), and other comments (2 themes). Responses to the question about alterations to the DA were themed under “dislikes.” Similarly, among the responses from the patients, 11 themes were identified, which were grouped based on the corresponding interview question: likes (5 themes), dislikes (3 themes), and other comments (3 themes).

**TABLE V** Open-ended responses from 39 health care professionals

| Theme                                      | Topic                              | Endorsed<br>[n (%)] | Exemplar quote  |
|--|------------------------------------|---------------------|---|
| <i>Likes</i>                               |                                    |                     |   |
|  | Formatting                         | 6 (15)              | I like that it follows the example of previously developed and clinically useful tools.   |
|  | Visual representations of data     | 5 (13)              | I like the ability for patients to rate each factor for them and the visual representation of the number of people affected.  |
|  | Readability                        | 5 (13)              | I like that it spells out statistics in readable format and gives pros and cons.  |
|  | Helpfulness                        | 3 (8)               | [Makes it] easier to explain concepts to patients.  |
| <i>Dislikes</i>                            |                                    |                     |   |
|  | Missing information                | 11 (28)             | I think an important piece of information is missing—impact on survival.  |
|  | Formatting, wording, or length     | 10 (26)             | Although there are benefits to having the decision aid on one page, right now it looks very crowded.  |
|  | Too simplistic                     | 4 (10)              | I think statistics on grouped outcomes, without much context (that is, one contralateral cancer diagnosis is not necessarily the same as another, one surgical complication is not the same as another), are somewhat over simplistic, and may tend to push people in a direction that the tool maker feels is optimal. |
|  | Too complex for patients           | 3 (8)               | Some of my patients would have trouble with it, I think.  |
| <i>Understanding of risks and benefits</i> |                                    |                     |   |
|  | Easy                               | 9 (23)              | Easy to understand.   |
|  | Moderate or requires explanation   | 9 (23)              | I am worried that it may be too complex for patients to navigate and understand on their own without physician or nursing guidance.   |
|  | Difficult                          | 6 (15)              | Too complex an issue to have a standard decision aid.   |
| <i>Other comments</i>                      |                                    |                     |   |
|  | Would not use in all circumstances | 6 (15)              | I am also unclear on how this is used in conjunction with the surgeon's recommendation. Is this strictly for the patient to understand and organize their thoughts? Do decision aids typically mention whether the procedure or treatment is recommended? ... Are patients just choosing on their own?                  |
|  | Unclear on how to use              | 5 (13)              | Would it only be used if a patient specifically asks about prophylactic contralateral mastectomy, or would it be presented to all patients?   |

### DA Likes

Specific likes about the DA were mentioned by 16 health care professionals (41%) and 10 patients (83%). Of the 16 health care professionals, 6 (15%) mentioned liking the formatting (for example, layout, wording), and 5 (13%) liked how the data were visually represented. Of the 10 patients who reported likes, 4 (33%) mentioned that they liked the statistics presented in the DA; others reported simply that they liked the DA overall ( $n = 3$ , 25%).

### DA Dislikes

Specific dislikes about the DA were mentioned by 22 health care professionals (56%) and 9 patients (75%). Health care professionals ( $n = 10$ , 26%) and patients ( $n = 6$ , 50%) both reported disliking aspects of the format (for example, too crowded with words or figures). The dislike most commonly reported by health care professionals ( $n = 11$ , 28%) was missing information (not enough emphasis on lack of survival benefit:  $n = 7$ , 18%; lack of information about psychological implications:  $n = 2$ , 5%; missing a strong statement against CPM:  $n = 2$ , 5%). The dislike most commonly reported by patients was the visual diagram with faces used to rate the benefits and risks of CPM ( $n = 7$ , 58%).

### Understanding of Risks and Benefits

Just more than half of the health care professionals ( $n = 22$ , 56%) commented on the understandability of the

risks and benefits. Of those 22 health care professionals, 6 (27%) reported that understanding the content about the risks and benefits was difficult; 9 (41%), that it was easy; and 9 (41%), that it was moderately difficult or required explanation. Patients were not directly asked the same question. However, comments made by patients addressed similar themes, with 5 patients (42%) reporting feeling that some risks and benefits were missing or not appropriately addressed. Other patients ( $n = 4$ , 33%) reported that the DA was too complex or overwhelming for patients to use, or not comprehensive enough ( $n = 3$ , 25%).

## DISCUSSION

### Summary of Findings

In the present study, a DA to facilitate shared and evidence-informed decision-making about whether to undergo CPM as a treatment choice in (low-risk) unilateral bca was developed and assessed for feasibility across Canada. Overall, our findings support the CPM DA as an acceptable and usable κT tool for clinicians and patients during the consultation process. The feedback received from participants is being incorporated into a final version of the DA which will be made publicly available through The Ottawa Hospital Research Institute's international A to Z Inventory of Decision Aids (<https://decisionaid.ohri.ca/AZinvent.php>).

**TABLE VI** Open-ended responses from 12 patients

| Category       | Topic                                   | Endorsed<br>[n (%)] | Exemplar quote  |
|----------------|---|---------------------|---|
| Likes          |   | 10 (83)             |   |
|                | Statistics                              | 4 (33)              | I like the fact that you see numbers/statistics and it is not just based on your doctor's recommendations. In other words, it substantiates the doctor's recommendation.  |
|                | Helpful                                 | 4 (33)              | [I]t's a very methodical way of helping somebody walk through a difficult time and doing a logical decision tree to help them decide where to go when they could be in a case where they could be very emotional. So, kind of, it's a very structured way to help them make their decisions.  |
|                | Overall liked                           | 3 (25)              | Well, as a whole, I mean it's a very good idea.   |
|                | Raises awareness of CPM as option       | 2 (17)              | And it would be good to get that information out there because for example, the contralateral prophylactic was never given as an option to me. I had to bring that forward to my oncologist, and he thought it was the greatest thing since sliced bread that I came up with that idea after doing some research. But it was not something that he actually proposed. |
|                | Provides honest facts                   | 2 (17)              | It opens your eyes to the lack of benefits associated with CPM.   |
| Dislikes       |   | 9 (75)              |   |
|                | Visual diagram with faces               | 7 (58)              | You know, like even just with your little smiley faces and stuff, I see what you're trying to get at there, but ... people would be confused.   |
|                | Formatting and editing                  | 6 (50)              | I think the format was confusing, could be confusing. I mean you had to kind of concentrate more than you might have expected you had to.   |
|                | Information unclear                     | 4 (33)              | I almost feel like there needs to be an appendix where the benefits and harms are sort of a little bit more [fleshed] out.  |
| Other comments |   | 9 (75)              |   |
|                | Does not address all risks/benefits     | 5 (42)              | One thing they do downplay, and ... I was actually kind of surprised, is asking for the cosmetic part. They put it down as a link. You know, just about dismissed it. And it should be; I know it doesn't sound like you know what I mean, but it is important.   |
|                | Too complicated or information overload | 4 (33)              | I think it's overly complicated. And when I first read, I mean I had to read through it like two or three times to figure out how it was sort of flowing.   |

CPM = contralateral prophylactic mastectomy.

### Relevance to Current Practice Recommendations

Choosing Wisely (<http://www.choosingwisely.org>) is a well-established U.S. campaign that promotes SDM and choosing appropriate care (evidence-based, necessary, non-duplicative, and free from harm). In 2016, Choosing Wisely released recommendations from the ASBS that included a recommendation against routine double mastectomy (that is, CPM) in patients with unilateral bca<sup>45</sup>. That recommendation comes from the consensus statement about CPM developed by experts of the ASBS based on a literature review, polling of the society's membership, an in-person consensus group meeting, and approval from the Executive Committee<sup>39</sup>. The latest guideline from the U.S. National Comprehensive Cancer Network also recommends against CPM in early-stage unilateral bca<sup>46</sup>. In response to the recommendations against CPM, a call was made for improved SDM in CPM to better reflect patient preferences and values<sup>47</sup>, thus supporting the rationale for creating patient-centred KT interventions such as a DA for CPM.

A recently released Canadian consensus statement about the indications for CPM was based on the results of a modified Delphi process conducted with a 26-member nationally representative expert panel<sup>15</sup>. In line with the pre-existing American consensus statement, the Canadian consensus statement also recommends against CPM in women with early-stage unilateral bca (92.3% agreement of the consensus panel). In addition, the Canadian con-

sensus statement advocates for adequate education of patients with respect to the benefits and drawbacks of CPM, with specific mention of a DA as a possible option ("Most importantly, patients should receive appropriate information and recommendations, possibly supplemented by decision-aids, about the benefits and drawbacks of CPM."<sup>15</sup>). That recommendation has yet to be adopted by Choosing Wisely Canada (<http://www.choosingwiselycanada.org>), the Canadian counterpart to the American Choosing Wisely campaign.

Our work to develop the CPM DA aligned with Canadian practice recommendations by providing a tool to facilitate shared and informed decision-making about CPM. Recently, other groups such as the CPM Decision Aid Advisory Group in Australia have also formulated a DA based on the IPDAs and the Ottawa Decision Support Framework<sup>48</sup>. Findings from that study demonstrated that women appreciated receiving information about CPM at diagnosis, even though it might appear to be overwhelming to them at first. The study also emphasized the importance of discussing the potential downsides of the procedure in addition to the benefits, and the acceptability of the DA for the facilitation of such discussions<sup>48</sup>. However, the Australian publication, and other studies, emphasized that DAs are an adjunctive tool in the discussion, not to be used to replace the importance of discussing personal risks and indications with the surgeon<sup>48,49</sup>.

During the development of our DA, tension was evident during team discussions about whether to create a patient DA, given the fact that current guidelines (such as that from the ASBS<sup>39</sup>) recommend against CPM in average-risk women with unilateral bca. In addition, comments from health care professionals interviewed in our previous work indicated a need to more strongly communicate within a DA that CPM is not recommended. In contrast, the patients we interviewed did not express similar concerns. It should be noted that the publication of the ASBS guideline also emphasized the importance of SDM<sup>39</sup>, a collaborative process in which doctors and patients work together to select tests, treatments, and care management or support packages based on clinical evidence and the informed preferences and values of patients. Shared decision-making explicitly acknowledges the fact that there is usually more than one way to treat a problem, including no treatment or investigation, and that patients could require help to weigh the benefits and harms of the options to determine the best choice for them. It should also be noted that another fundamental aim of campaigns such as Choosing Wisely is to use the SDM approach to reduce unnecessary tests and treatments. There is good evidence that SDM benefits patients, improving the quality and appropriateness of clinical decision-making. Patients involved in SDM report greater satisfaction with medical consultations<sup>50</sup> and are more likely to choose less-invasive surgical procedures<sup>51</sup>. The SDM process is also an effective strategy for tackling overdiagnosis and overtreatment. For example, interventions to promote SDM, including SDM skills training, have been shown to lead to reductions in inappropriate antibiotic use in acute respiratory infections<sup>52</sup> and better understanding of the risk of overdiagnosis in breast screening<sup>53</sup>. The Canadian Task Force on Preventive Health Care has published a series of articles about SDM and ways to support patient involvement in decisions informed by their clinical practice guidelines<sup>54–56</sup>. Other guideline producers are now recommending SDM as one of a guideline's statements to ensure that guideline evidence is used at the individual level alongside patient preferences<sup>57–61</sup>.

Recently, a study showed that women report feeling dissatisfied with consultations if surgeons recommend against CPM without further substantial discussion<sup>49</sup>; however, time constraints can be a barrier to such patient-clinician discussions<sup>62</sup>. Given time constraints, one way to facilitate SDM is to use a DA. In fact, many of the recommendations at the Choosing Wisely Web site and in its patient materials have links to DAS<sup>63,64</sup> that will support physicians in having the necessary conversations with their patients such that the ultimate decision is not only based on the best available evidence but is also congruent with the patient's values and preferences. There is evidence to show that patients who are better informed opt for more conservative treatment options and that patient decision support interventions such as DAS lead to system-wide cost savings<sup>65,66</sup>.

### Implementation of a DA

Although the efficacy of DAS in facilitating SDM and improving knowledge for patients has been very well established, DAS have not been widely adopted by health care professions in clinical practice<sup>24,67</sup>. Our group has published

extensively on the barriers to DA implementation<sup>67–69</sup>. The most commonly cited barriers are lack of time during the consultation, inapplicability of the DA to the patient population, physician motivation, and organizational policy barriers. The literature lacks evidence-based interventions about the best methods for implementing patient decision support into routine practice<sup>70</sup>. However, we can make suggestions that address some of the known barriers to DA implementation.

For example, the involvement of patients in the development of our DA helped to make it applicable to patients, whose insights informed the content of the DA. Supporting the recommendations of the ASBS, women want an active, informed discussion about CPM early in the decision-making process. Experienced surgeons know that most patients with unilateral bca who are undergoing a mastectomy and are at average risk will be thinking about a similar contralateral procedure. We therefore propose providing our DA to that specific patient population at their initial surgical consultation, alongside other reading materials given at diagnosis. It is preferable for the surgeon to preempt the provision of the DA with a brief comment about the lack of oncologic benefit of CPM and the guidelines that recommend against it and to use the DA as a source of more information for the patient's perusal. Depending on the clinical setting and the human resources available, a senior resident in training, a nurse practitioner, or a specialist breast nurse can be properly trained by the surgeon to communicate that information while also providing the DA. Depending on the patient, a copy of the ASBS or Canadian guideline recommending against CPM (or both) could also be provided. To address physician motivation, training of health care professionals about the value of SDM and the associated evidence demonstrating that patients who are better informed opt for more conservative treatment options<sup>51,66</sup> could be important. The importance of a "champion" to encourage DA use has been shown to be helpful<sup>24,71</sup>. Educating organizations about patient decision support interventions such as DAS and how they can lead to system-wide cost savings might also be of value.

### Strengths and Limitations

The strengths of our study include the rigorous and systematic process followed to develop the CPM DA. Clinical and KT experts were involved in the development process. The work was also informed by two theoretical frameworks, the IPDAS<sup>28</sup> and the Ottawa Decision Support Framework<sup>32</sup>, and by a comprehensive feasibility assessment undertaken with target users of the DA (health care professionals and patients).

Current best evidence in patient-centred research suggests that patients be engaged in all phases of a study from conception to completion<sup>6,72</sup>. A limitation of the present study was therefore the lack of patient involvement during development of the DA prototype. However, feedback from patients was sought in the feasibility assessment of the DA. Another limitation was that the patient DA was designed for use during consultation with the clinician, but in the interviews, patients were walked through the content of the DA with the research assistant. The walk-through might have influenced feedback about the complexity of the DA.

## Reflections About the Value of Catalyst Project Funding

Catalyst grants such as those that funded our project are very important to advancing  $\kappa\tau$  research and for moving specific research findings into practice. They provide opportunity for developing  $\kappa\tau$  tools (such as the patient DA developed for the present study) with broad and rigorous evaluation of feasibility that is otherwise not often possible. The grants also provide opportunity to conduct the preliminary work needed to apply for larger provincial and national funds to conduct larger-scale evaluations of the  $\kappa\tau$  interventions developed.

## CONCLUSIONS

Evidence-based recommendations clearly discourage the routine use of CPM in women with unilateral bca who are at low risk for contralateral bca; however, CPM rates continue to rise. The increase in CPM is likely arising from the discussions between health care professionals and women diagnosed with bca. Although health professionals have access to clinical practice guidelines, no resources are available to inform women facing this decision. During the present study, a patient DA for use in the clinician–patient consultation was developed to facilitate evidence-informed SDM specific to CPM. Overall, the DA was found to be an acceptable, usable, and clear  $\kappa\tau$  tool to support SDM at the time of consultation between clinicians and women with low-risk unilateral bca.

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## CONFLICT OF INTEREST DISCLOSURES

We have read and understood *Current Oncology's* policy on disclosing conflicts of interest, and we declare that we have none.

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