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Feasibility evaluation of an online tool to guide decisions for *BRCA1/2* mutation carriers

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Abstract

Women with *BRCA1* or *BRCA2* (*BRCA1/2*) mutations face difficult decisions about managing their high risks of breast and ovarian cancer. We developed an online tool to guide decisions about cancer risk reduction (available at: <http://brcatool.stanford.edu>), and recruited patients and clinicians to test its feasibility. We developed questionnaires for women with *BRCA1/2* mutations and clinicians involved in their care, incorporating the System Usability Scale (SUS) and the Center for Healthcare Evaluation Provider Satisfaction Questionnaire (CHCE-PSQ). We enrolled *BRCA1/2* mutation carriers who were seen by local physicians or participating in a national advocacy organization, and we enrolled clinicians practicing at Stanford University and in the surrounding community. Forty *BRCA1/2* mutation carriers and 16 clinicians participated. Both groups found the tool easy to use, with SUS scores of 82.5–85 on a scale of 1–100; we did not observe differences according to patient age or gene mutation. General satisfaction was high, with a mean score of 4.28 (standard deviation (SD) 0.96) for patients, and 4.38 (SD 0.89) for clinicians, on a scale of 1–5. Most patients (77.5 %) were comfortable using the tool at home. Both patients and clinicians agreed that the decision tool could improve patient–doctor encounters (mean scores 4.50 and 4.69, on a 1–5 scale). Patients and health care providers rated the decision tool highly on

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measures of usability and clinical relevance. These results will guide a larger study of the tool's impact on clinical decisions.

Keywords

BRCA1; *BRCA2*; Breast cancer; Ovarian cancer; Decision support tool

Introduction

Women who inherit a mutation in the *BRCA1* or *BRCA2* (*BRCA1/2*) genes have greatly elevated probabilities of developing breast or ovarian cancer [1, 2]. These high-risk women can address their cancer predisposition with strategies including prophylactic mastectomy (PM) [3–5], prophylactic bilateral salpingo-oophorectomy (PO) [5–9], and intensive breast screening with annual mammography and magnetic resonance imaging (MRI) [10–15]. To date, no randomized trial has compared these strategies, nor does empiric evidence specify the optimal timing or combination of interventions. Evidence-based practice guidelines recommend that clinicians and patients engage in informed discussion about the selection and schedule of these risk-reducing options [16].

To guide choices about managing cancer risk, we developed an online decision support tool, using published data on the efficacy of risk-reducing interventions for *BRCA1/2* mutation carriers [1, 2, 4, 5, 7, 8, 12, 13, 17–21]. We previously described the development and characteristics of the underlying computer simulation model and the resulting online decision tool [22–28]. As an initial assessment of the tool's utility for its target audience, and to guide larger studies of its impact on clinical decision-making, we conducted a feasibility study among women with *BRCA1/2* mutations and clinicians who care for this patient population.

Methods

Computer simulation model

In collaboration with the National Cancer Institute's Cancer Intervention and Surveillance Modeling Network (CISNET), we developed and validated a computer model that simulates the natural history of breast cancer patients, reporting their outcomes on a population level [23, 27]. We adapted this model to reflect the breast and ovarian cancer incidence and outcomes specific to women with *BRCA1/2* mutations, incorporating the effects of cancer screening with annual mammography and breast MRI and of preventive surgeries including PM and PO at various ages. Model inputs were derived from the Surveillance, Epidemiology and End Results (SEER) program and from studies of cancer incidence, outcomes and interventions among *BRCA1/2* mutation carriers. We previously used this model to estimate cost-effectiveness of screening breast MRI, and outcomes, including cancer incidence, treatment recommendations and survival, of *BRCA1/2* mutation carriers selecting various options to manage their risks [24–26]; we have reported full details of our methods elsewhere [22, 24–27].

Decision tool

We collaborated with software developers at Cornerstone Systems Northwest, Inc. to develop an interactive user interface that provides results from 2,130 age-, mutation-, and intervention-specific runs of the model. We used stacked bar graphs to represent the probabilities of the following outcomes by age 70: survival with no history of breast or ovarian cancer, survival after breast cancer, survival with ovarian cancer, survival with both breast and ovarian cancer, death from breast cancer, death from ovarian cancer, or death from other causes (Fig. 1a). We included a user-directed expansion display (Fig. 1b), offering more detail about stage, hormone receptor expression, and guideline-recommended treatments for the breast cancer cases. Users can construct up to four different strategies, and compare outcomes to those of an age- and mutation-matched woman who undertakes no risk-reducing intervention, and to those of an age-matched woman without a *BRCA1/2* mutation. An introduction screen explains the data sources and recommended use conditions, a glossary screen provides explanations of terms used, and additional screens offer contact information and relevant publications [25, 26]. Throughout the feasibility testing on which we report, the decision tool was password-protected and accessible only for research purposes.

Questionnaire

We developed separate but overlapping questionnaires for two target user groups: women with *BRCA1/2* mutations and the clinicians involved in their care. The questionnaire included two validated instruments for software evaluation: the System Usability Scale (SUS) and the Center for Healthcare Evaluation Provider Satisfaction Questionnaire (CHCE-PSQ). The 10-item SUS uses a 5-point Likert scale to measure general usability, from 1 (strongly disagree) to 5 (strongly agree), with a total score of 0–100 [29]; the 8-item CHCE-PSQ uses a 5-point scale to assess contribution to clinical care and overall satisfaction [30, 31]. For the patient version, we modified the CHCE-PSQ to include questions about the usefulness of specific tool components, and re-worded questions about saving time and improving practice to render them appropriate for patients. We collected patient data on age, race/ethnicity, education, profession, parity, personal history of cancer and risk-reducing interventions, and family cancer history. We asked women with *BRCA1/2* mutations five additional questions, regarding (1) how the information in the tool could be better displayed and/or communicated; (2) the influence of the tool's results on their future plans; (3) whether the results of the decision tool were surprising; (4) their preferred setting for using the decision tool, and (5) whether they would feel comfortable using the tool at home. Questionnaires are included as Supplementary Data.

Participant accrual and tool evaluation

We obtained human subjects approval from the Stanford University Institutional Review Board (IRB) to recruit participants. We recruited clinicians from Stanford Hospital and surrounding community practices, selecting specialties most likely to care for *BRCA1/2* mutation carriers: surgical and medical oncologists, medical geneticists and genetic counselors, gynecologists, primary care physicians, and women's health nurse practitioners. We sent invitations by electronic mail, which contained a link to the decision tool, an

informed consent document, and the questionnaire. Clinicians were asked to review and sign the informed consent document, view the tool, and complete the study questionnaire. All clinician responses were de-identified prior to analysis.

Women with *BRCA1/2* mutations were eligible if they had not undergone PM, since a major focus of the tool is comparing strategies to manage breast cancer risk; those with prior PO were eligible. We obtained IRB approval to offer participation to patients seen in the Stanford Breast Oncology Program or Clinical Cancer Genetics Program, and to members of a national hereditary cancer advocacy organization, Facing Our Risk of Cancer Empowered (FORCE, <http://www.facingourrisk.org>). After signing an informed consent document, patients were offered a laptop computer with access to the tool and invited to review all screens. We subsequently administered the patient study questionnaire by interview. Interviews of Stanford patients were conducted in the Stanford Cancer Institute or patients' homes between February and July 2011; interviews of FORCE members were conducted at the Sixth Annual Joining Forces Conference on Hereditary Breast and Ovarian Cancer in Orlando, Florida from June 24–26, 2011. All patient responses were de-identified prior to analysis.

Data analysis

Characteristics of survey respondents, including demographic and clinical features, were tabulated. We calculated means and standard deviations (SD) for each item of the SUS and the CHCE-PSQ. Final scores for the SUS, from 0 (least usable) to 100 (most usable) were calculated. Responses to additional tool-specific questions were tabulated, and 95 % confidence intervals were calculated. Study data were collected and managed using REDCap electronic data capture tools hosted at Stanford University [32]. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources.

Results

Participant characteristics

Twenty-nine patients of the Stanford Cancer Institute were invited to participate, and 23 agreed, for a response rate of 79 %. Invitations to participate were distributed as a component of registration materials to all attendees (approximately 500 in total) of the Sixth Annual Joining Forces Conference on Hereditary Breast and Ovarian Cancer in June 2011, but no information was available on how many conference attendees met study eligibility criteria; 17 conference attendees participated in the study, resulting in a total of 40 *BRCA1/2* mutation carriers who reviewed the decision tool and responded to the questionnaire (Table 1). The median age was 43 years, with a range from 21 to 67. The majority (87.5 %) were Non-Hispanic White, with 7.5 % Black, 2.5 % Hispanic, and 2.5 % Asian. Twenty (50 %) carried a *BRCA1* mutation, and 20 (50 %) carried a *BRCA2* mutation. Twenty-one (52.5 %) had undergone PO. Patients were highly educated, with 19 (47.5 %) reporting graduate

school as their highest level of education. Twenty-three clinicians were invited to participate, and 16 reviewed the tool and responded to the study questionnaire, for a response rate of 70 %. Specialties included medical oncology, cancer genetics, obstetrics and gynecology, breast surgery, genetic counseling, and women's health nurse practitioner.

Patient and clinician responses to SUS and CHCE-PSQ

Responses to the SUS on a 5-point Likert scale are presented in Table 2. Both patients and clinicians reported feeling confident using the tool (patient mean: 4.18, SD 1.01; clinician mean: 4.29, SD 0.83), and considered the functions of the tool well integrated (patient mean: 4.15, SD 0.86; clinician mean: 4.27, SD 0.90). Neither patients nor clinicians found the tool to be unnecessarily complex, inconsistent, cumbersome, or requiring technical support or extensive background knowledge (mean scores: 1.23–1.68). Clinicians were more likely than patients to state that they would use the tool frequently (clinician mean: 4.46, SD 0.78; patient mean: 3.55, SD 1.04); patients exceeded clinicians in stating that the tool was easy to use (patient mean: 4.28, SD 1.06; clinician mean: 3.83, SD 1.03) and that most patients would quickly learn how to use it (patient mean: 4.10, SD 1.06; clinician mean: 3.85, SD 0.99). Patient responses were similar across age categories (< 35 years and ≥ 36 years). The mean overall SUS score was 82.5 (SD 17.0) for patients (N = 40) and 85.0 (SD 14.8) for clinicians who completed all questions (N = 11).

Responses to the CHCE-PSQ on a 5-point scale are presented in Table 3. Both clinicians and patients found the tool useful (clinician mean: 4.73, SD 0.46; patient mean: 4.20, SD 0.97) and had high general satisfaction (clinician mean: 4.38, SD 0.89; patient mean: 4.28, SD 0.96); both found the graphic displays useful, and patients rated the glossary and introduction screens highly (mean scores: 4.18–4.30). Both groups thought the tool could improve patient–physician encounters (clinician mean: 4.69, SD 0.70; patient mean: 4.50, SD 0.72), and clinicians recommended that patients use the decision tool (mean: 4.50, SD 1.10).

Patient responses to decision tool-specific questions

Patients' responses to the decision-tool specific questions are presented in Table 4. Twenty-five of 40 (62.5 %, 95 % confidence interval (CI) 44.6–73.7 %) patients stated that tool results would influence their decisions; eight (20 %, CI 10.2–35.0 %) stated that the results would not influence their plans, but were useful; three (7.5 %, CI 1.9–20.6 %) stated that they had already made plans for cancer risk reduction, one (2.5 %, CI 0–14 %) stated that the tool would not influence her decision, and three (7.5 %, CI 1.9–20.6 %) did not respond. Thirteen patients (32.5 %, CI 20–48 %) expressed no surprise at the results, but 19 (47.5 %, CI 32.9–62.5 %) expressed surprise, about the probabilities of specific cancer-related outcomes and the magnitude of benefit from PM and PO. When asked about the best time and place to use the tool, patients stated as follows: 17 (42.5 %, CI 28.5–57.8 %) during a clinician visit, 11 (27.5 %, CI 16–43 %) prior to a clinician visit, six (15 %, CI 6.7–29.5 %) anytime, one (2.5 %, CI 0–14 %) prior to *BRCA1/2* mutation testing, and five (12.5 %, CI 12.5–26.6 %) did not respond. Thirty-one (77.5 %, CI 62.3–87.9 %) patients felt comfortable using the tool at home.

Patient and clinician responses to request for additional comments

Many patients requested more information; one topic of interest was the impact of exogenous hormonal therapies, including oral contraceptive pills, menopausal hormone therapy, or prophylactic tamoxifen or raloxifene, on the estimated outcomes. Another common request was for modification of age categories, either as user-selected inputs or as model outputs. Patients also expressed interest in the impact of a prior cancer on the estimated outcomes. Some patients commented that it was uncomfortable to view estimates of cancer incidence and mortality, but these patients also emphasized the tool's relevance and value. No patient expressed distress due to viewing the tool, or regret for having done so.

Several clinicians stated that the tool would be very useful to providers, but that it seemed too difficult for patients. Additional clinician comments included requests for changes in the results screen format, for more detailed information about intervention side effects, and for presentation of outcomes at ages other than 70.

Discussion

We evaluated the feasibility of a decision tool for women with *BRCA1/2* mutations among a representative group of patients and clinicians. Most patients and clinicians rated the decision tool highly on a validated usability scale (82.5–85 out of a possible 100 points), stated that the tool could improve patient–physician encounters, and expressed high overall satisfaction (4.28–4.38, on a scale of 1–5). Although some clinicians considered the decision tool too difficult for patients to navigate, patients endorsed high levels of confidence and ease in using the tool, with little variation between women under and over 35 years of age. Most patients reported that using the tool would influence their choices about managing their cancer risks.

The goals of a decision aid include providing information, reducing uncertainty, and facilitating effective decision-making [33]. Prior studies have produced decision aids for *BRCA1/2* mutation carriers, some in the context of the choice to undergo genetic testing, and others focused on post-testing interventions [9, 34–38]. These decision aids vary in format and medium, including paper, video and CD-ROM: other key differences lie in the approach to characterizing users' knowledge, state of mind, and preferences. Some decision aids evaluate baseline understanding, and elicit health state preferences (for example, life with breast screening vs. life after mastectomy) which then drive the decision aid's recommendations for action [9, 34, 36, 37]. We have previously observed wide variation in preferences about risk-reducing strategies among *BRCA1/2* mutation carriers, both between patients and within an individual patient over time; this observation was confirmed in the present study, when two patients reached opposite conclusions about the value of PM while viewing the same estimate of its effect. Our experience of this broad range in opinion drove our non-directive approach in the tool's design, in that we present estimated health outcomes without asking patients to pre-specify their values. Similarly, our current evaluation focused on feasibility, in order to guide future studies of the tool's impact on clinical decision-making.

We received many comments, suggestions, and requests from patients and clinicians who evaluated the decision tool. Consistent with prior research on the life trajectories of *BRCA1/2* mutation carriers [39], patients' reactions varied by age. Several young women asked for smaller age increments than provided by the tool's 5-year bins; one user commented that for a woman postponing prophylactic surgery to pursue childbearing, "every year counts". A 25-year old woman stated that she planned to compare the tool's estimated outcomes at 30, 35, and 40 years of age, in order to decide when she should begin serious consideration of PM and PO. By contrast, women in their 40s and 50s asked frequently about the impact of endocrine treatments sequenced with prophylactic surgeries, including menopausal hormone therapy and the selective estrogen response modulators tamoxifen and raloxifene; this suggests a different life stage, with acceptance of risk-reducing interventions in the immediate future. We also observed differences by family history, with women who had witnessed the death of a relative from a *BRCA1/2*-associated cancer more inclined toward surgical prevention. Our finding that clinicians rated the decision tool highly, yet some questioned its suitability for patient use, warrants careful consideration. Most patients were very satisfied with the tool, with few expressing any confusion or concern, and most (77.5 %) felt comfortable using the tool alone at home. However, among a list of possible settings for the best use of the tool, "during a clinical visit" received the highest rating from patients. These findings coincide with our stated intention, on the tool's introduction screen and in our article presenting the tool [24], that the tool be used to guide shared decision-making between patients and their care providers, whether patients initially explore the tool at home to prompt questions for their doctor, or whether the tool is viewed jointly in the physician's office.

This study has several limitations. The sample size is small, consisting of 40 patients and 16 clinicians. Despite their size, these samples represent the target user population; by enrolling participants at the Joining Forces Annual Meeting in June 2011, we extended the study's scope from the local to the national level. Undoubtedly, however, the patient respondents were a highly educated and motivated group, who may not fully reflect the broader United States population of *BRCA1/2* mutation carriers. We did not evaluate users' baseline or post-use knowledge about *BRCA1/2* mutations or existing risk-reducing interventions, which limits our ability to draw conclusions about the contribution of the tool to informing decisions. Although the decision tool is freely available to any internet user, we anticipate that it will not appeal to everyone, but primarily to those who are information-seeking and computer-literate, a subset that is similar to those we surveyed. A further limitation is this evaluation's narrow focus, on short-term measures of feasibility. We did not test users' preferences or mood states before and after viewing the decision tool; we did not study the tool's long-term impact on choices about cancer risk reduction strategies, satisfaction and quality of life, or decisional conflict. Our future work will address these limitations, and evaluate the tool's impact on patients' choices.

We present a user evaluation of an online decision support tool for *BRCA1/2* mutation carriers. Both patients and health care providers rated the tool highly, and after revisions based on user comments, it is now publicly available online [24]; since January 2012, the decision tool has received an average of 1,443 visits per month, with approximately 85 % of the visits from users in the United States and the remaining 15 % of visits from other

countries. Our results demonstrate the feasibility of an online tool for women with *BRCA1/2* mutations.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Fig. 1.
a Initial view of the *BRCA1/2* decision tool results screen and **b** expanded “show details” view, providing more information about breast cancer characteristics and recommended therapies; the decision tool is available online at <http://brcatool.stanford.edu>

Table 1

Characteristics of female *BRCA1/2* mutation carriers (N = 40) who evaluated the online decision tool

Characteristic	Number (% or range)
Age in years	
Median (range)	43 (21–67)
Race/ethnicity	
Non-Hispanic White	35 (87.5 %)
Hispanic	1 (2.5 %)
Asian	1 (2.5 %)
Black	3 (7.5 %)
<i>BRCA</i> gene mutation	
<i>BRCA1</i> mutation	20 (50 %)
<i>BRCA2</i> mutation	20 (50 %)
History of bilateral salpingo-oophorectomy (BSO)	
No personal history of BSO	19 (47.5 %)
Personal history of BSO	21 (52.5 %)
Highest education level	
High school	5 (12.5 %)
College	5 (12.5 %)
Graduate school	19 (47.5 %)
No response	11 (27.5 %)

Table 2

Responses to the System Usability Scale (SUS) by patients (N = 40) and clinicians (N = 16): mean scores and standard deviations (SD) on a scale from 1 (strongly disagree) to 5 (strongly agree)

Question	Patients, age 35, mean (SD)	Patients, age 36, mean (SD)	All patients, mean (SD)	Clinicians, mean (SD)
I think that I would like to use this tool frequently	3.75 (0.87)	3.46 (1.10)	3.55 (1.04)	4.46 (0.78)
I found the tool unnecessarily complex	1.42 (0.67)	1.68 (1.06)	1.60 (0.96)	1.64 (0.92)
I thought the tool was easy to use	4.58 (0.51)	4.14 (0.51)	4.28 (1.06)	3.83 (1.03)
I think that I would need the support of a technical person to be able to use this tool	1.42 (0.90)	1.79 (1.34)	1.68 (1.23)	1.55 (1.21)
I found the various functions in this tool were well integrated	4.33 (0.78)	4.07 (0.90)	4.15 (0.86)	4.27 (0.90)
I thought there was too much inconsistency in this tool	1.08 (0.29)	1.3 (0.67)	1.23 (0.58)	1.23 (0.44)
I would imagine that most people would learn to use this tool very quickly	4.25 (0.87)	4.04 (1.14)	4.10 (1.06)	3.85 (0.99)
I found the tool very cumbersome to use	1.67 (0.98)	1.14 (0.36)	1.30 (0.65)	1.67 (0.78)
I felt very confident using the tool	4.25 (0.90)	4.14 (1.08)	4.18 (1.01)	4.29 (0.83)
I needed to learn a lot of things before I could get going with this tool	1.42 (0.65)	1.5 (0.92)	1.48 (0.91)	1.43 (0.94)
Overall score	85.4 (12.4)	81.3 (18.7)	82.5 (17.0)	85.0 (14.8)

Table 3

Responses to the Center for Healthcare Evaluation Provider Satisfaction Questionnaire (CHCE-PSQ, adapted) by patients (N = 40) and clinicians (N = 16), presenting mean scores and standard deviations (SD) on a scale from 1 to 5 (with 1 representing “poor” and 5 representing “excellent”, or 1 representing “strongly disagree” and 5 representing “strongly agree”)

Questions	Patients, age 35, mean (SD)	Patients, age 36, mean (SD)	All patients, mean (SD)
How useful was the information provided?	4.33 (0.65)	4.14 (1.08)	4.20 (0.97)
Did you find the information easy to understand?	4.33 (0.78)	4.11 (1.23)	4.18 (1.11)
How useful were the graphic displays?	4.58 (0.67)	4.18 (1.12)	4.30 (1.02)
How useful was the introduction screen?	4.75 (0.45)	3.92 (1.13)	4.18 (1.04)
How useful was the glossary screen?	4.55 (0.93)	4.06 (1.26)	4.24 (1.15)
Could this tool improve patient–doctor encounters?	4.50 (0.67)	4.50 (0.75)	4.50 (0.72)
What is the chance you would use this tool again?	4.50 (0.67)	4.37 (1.15)	4.41 (1.02)
What is your general satisfaction with this tool?	4.33 (0.65)	4.25 (1.08)	4.28 (0.96)
Questions	Clinicians, mean (SD)		
How useful was the information provided?	4.73 (0.46)		
Did you find the information easy to understand?	4.00 (0.82)		
How effective are the graphics?	4.20 (1.08)		
What is your general satisfaction with this tool?	4.38 (0.89)		
This tool could improve patient–doctor encounters	4.69 (0.70)		
This tool could save me time	4.25 (0.93)		
I would use it regularly in practice	4.50 (0.89)		
I would recommend that patients use this tool	4.50 (1.10)		

Table 4

Patient responses (N = 40) to specific questions about the online *BRCA1/2* decision tool

Questions	Number (%; 95 % CI)				
Did the tool influence your plans for managing cancer risk?	Yes	No, but still useful	No, plans made	No	No response
	25 (62.5, 44.6–73.7)	8 (20, 10.2–35.0)	3 (7.5, 1.9–20.6)	1 (2.5, 0–14)	3 (7.5, 1.9–20.6)
Did the results surprise you?	Yes	No			No response
	19 (47.5, 32.9–62.5)	13 (32.5, 20–48)			8 (20, 10.2–35)
Would you feel comfortable using the tool at home?	Yes	No			No response
	31 (77.5, 62.3–87.9)	1 (2.5, 0–14)			8 (20, 10.2–35)
What do you think is the best setting for using the tool?	Before testing	Before clinician visit	During visit	Anytime	No response
	1 (2.5, 0–14.0)	11 (27.5, 16.0–43.0)	17 (42.5, 28.5–57.8)	6 (15, 6.7–29.5)	5 (12.5, 5–26.6)