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- Title of Project. Implementing a breast reconstruction decision support tool in diverse practice settings
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1. **Structured Abstract**

Purpose and Scope: *BREASTChoice* was developed in prior work to: 1) provide breast reconstruction education; 2) estimate personalized risk for major complications from mastectomy with immediate reconstruction; 3) help patients explore reconstruction preferences; and 4) send clinicians information about patients' risk and preferences. We adapted *BREASTChoice* using semi-structured qualitative interviews (Aim 1), conducted focused usability assessments and EHR integration (Aim 2), and led a multisite randomized trial evaluating *BREASTChoice* on decision quality, surgical choice, and shared decision-making (Aim 3).

Aim 3 Methods: Eligible patients were adults, assigned female at birth, with stage 0-III breast carcinoma, considering mastectomy. Patients were randomized to *BREASTChoice* or a control website. Patients completed a survey about breast reconstruction decision quality, knowledge, decisional conflict, shared decision-making, preferred decision, and tool usability.

Aim 3 Results: 23 clinicians and 369 patients enrolled across two sites. *BREASTChoice* patient participants had higher knowledge than control participants, especially when stratified by site, age, and race and especially in analyses including only those who accessed the intervention. *BREASTChoice* did not decrease decisional conflict, improve the match between preferences and surgical choice, or increase shared decision-making. In exploratory analyses, fewer high-risk patients using *BREASTChoice* chose immediate breast reconstruction, a higher risk procedure than delayed or no reconstruction. *BREASTChoice* had high usability.

To our knowledge, *BREASTChoice* is the first breast reconstruction decision tool that incorporates personalized risk prediction, evidence-based patient education, and clinician decision support. Participants using this multilevel intervention demonstrated improved knowledge about reconstruction type, timing, and complication risks. Older adults and those from racially minoritized backgrounds especially benefitted. Future studies should overcome barriers to breast reconstruction shared decision-making and examine *BREASTChoice* on surgical choice and outcomes among high-risk patients.

Key Words: shared decision making, clinical decision support, breast reconstruction, breast cancer

2. **Purpose** (Objectives of Study).

Aim 1: Elicit stakeholder input to evaluate the implementation potential of the *BREASTChoice* tool.
Aim 2: Optimize the *BREASTChoice* tool based on stakeholder input and usability testing and prepared it for implementation into routine care. We refined BREASTChoice, focusing on changes that facilitate implementation into patient routines and clinical workflows. We embedded it into the EHR environment.
Aim 3: Evaluate the effects of the updated *BREASTChoice* tool on decision quality, decisional conflict, and treatment choice in a randomized controlled trial in diverse sites.

3. **Scope** (Background, Context, Settings, Participants, Incidence, Prevalence).

Breast reconstruction includes a series of surgical procedures to create a breast shape after patients undergo mastectomy. A clear understanding of the procedures is critical to providing comprehensive breast cancer treatment, as post-mastectomy breast reconstruction can improve patients' quality of life and psychosocial well-being after breast cancer.[1,2] It is considered a preference-sensitive decision; patients' goals and priorities are central to their choice, given the tradeoffs between benefits and possible drawbacks of reconstruction options. Patients can opt to have reconstruction or not, implant-based or autologous tissue (flap) based reconstruction, or immediate or delayed reconstruction. Unfortunately, patients often have significant knowledge gaps about reconstruction procedures and the risk of complications from reconstruction.[3] As a result, patients' decisions can be discordant with their personal preferences about risk, appearance, recovery, and the number of surgeries required to achieve an optimal result. Many women later experience regret about their reconstruction choice.[4]

Breast reconstruction can restore quality of life and body image in women of all ages and racial backgrounds.[5,6] However, there are disparities in receipt of reconstruction by age and race.[7,8] Women over age 65 often report they were not offered reconstruction.[9] Black women often have more risk factors for complications from mastectomy and reconstruction, yet report being offered reconstruction less often than White women,[10] and have lower knowledge about reconstruction and its associated risks.[11] Overall, patients considering breast reconstruction would benefit from decision support, which can improve decision quality.[12] Yet decision support is seldom used in practice,[13,14] especially in minoritized populations.[15]

The Breast Reconstruction Education and Support Tool, *BREASTChoice,* is a multilevel decision tool developed in prior work to: 1) provide education about breast reconstruction options and outcomes; 2) estimate personalized risk for major wound complications from mastectomy and immediate breast reconstruction; 3) help patients explore their preferences for reconstruction options; and 4) send information to clinicians about patients' risk and preferences.[16-18] Based on patient and community partner feedback, *BREASTChoice* was designed to be inclusive of women of all ages, races, and body types, with a photo library of reconstruction results with women of various skin tones, body shapes, and sizes. A single-site randomized trial of an earlier version of *BREASTChoice* found that patients using it had higher knowledge of reconstruction benefits and drawbacks compared to those in usual care.[16]

After extensive community partner engagement in Aim 1, the tool was refined and found to be highly usable, feasible, and acceptable by patients and clinicians.[19] To better support implementation, *BREASTChoice* was integrated into the electronic health record (EHR) and

patient portal for ease of use and access during clinical visits during Aim 2.[20] To our knowledge, *BREASTChoice* is the first breast reconstruction decision support tool that incorporates personalized risk prediction, evidence-based patient education, and clinician decision support.

This final report summarizes Aims 1 and 2, but because those data are published already, we more fully describe the multisite randomized controlled trial in Aim 3 evaluating the implementation of the *BREASTChoice* tool into usual care. We hypothesized that compared to those in a control group receiving a standard website about breast reconstruction, those randomized to *BREASTChoice* would report higher decision quality, defined as higher knowledge, lower decisional conflict, and a higher likelihood to choose an option that matched their stated preferences. We also explored whether women at higher risk for complications from immediate breast reconstruction would be more likely to delay reconstruction, and whether those in the *BREASTChoice* group would report more shared decision-making with their plastic/reconstructive surgeon.

4. **Methods** (Study Design, Data Sources/Collection, Interventions, Measures, Limitations).

We convened a stakeholder advisory group (SAG) at the start of the study and met monthly or bi-monthly throughout the duration of the study design and active recruitment period; afterwards, we met quarterly to review study results and analysis.

Aim 1: Semi-structured qualitative interviews with 35 members of end-user groups (13 patients, 13 clinicians, 9 informatics experts) were completed. Audio recordings were transcribed and coded with a codebook that was based on our conceptual framework and iteratively refined by the team following interviews.

Aim 2: Usability Testing: We completed usability interviews with clinicians and patients at Washington University (WU) and The Ohio State University (OSU). Audio recordings from each think-aloud interview were transcribed. A codebook was created with themes and subthemes about usability. NVivo software was used to organize and code transcripts. We organized results based on the sociotechnical framework.

Aim 2: EHR-Integrated Decision Support Tool: We continued to maintain a detailed tracking sheet of usability issues and how they were addressed. *BREASTChoice* was unique in its personalized risk prediction using clinical data from the EHR, clinician- and patient-facing components, and interactive education and values clarification. Integrating a decision aid with patient- and clinician-facing components plus interactive sections presented unique deployment issues that we summarized into key recommendations for others to learn from this process.

Aim 3: We convened a data safety monitoring board (DSMB) to meet monthly throughout the Aim 3 trial to advise on study procedures. We recruited patients at two sites (WU and OSU). Both were academic medical centers with urban, suburban, and rural residing patients in a large catchment area. We had plans to include a community health center (Ohio Health). However, programming and data integration process for *BREASTChoice* occurred just after the COVID-19 pandemic began in March 2020. The pandemic led to staffing shortages, and the existing informatics teams needed to prioritize pandemic-related activities. Even with extensions to programming time frames for the risk prediction and EHR integration aspects of *BREASTChoice*, the community site respectfully declined further study engagement.

Enrollment into the trial occurred between January 2021 and July 2022. Eligible patients were adults (aged 18 or older) who were assigned female sex at birth, presented with a diagnosis of incident or recurrent stage 0-III breast carcinoma, and were considering a mastectomy as primary surgery for breast cancer.

Patients were ineligible if they had metastatic disease, histology type other than ductal or lobular carcinoma, or if they had already undergone mastectomy. Patients who did not have a malignancy, were planning to have breast-conserving surgery, were unable to read or speak English, or had severe active psychiatric or cognitive impairment that would limit the ability to complete consent and study procedures were also ineligible.

Eligible clinicians were plastic and reconstructive surgeons at the two sites who performed breast reconstruction after mastectomy. Physician assistants were also included at OSU because they sometimes conduct the first consultation about breast reconstruction when a plastic/reconstructive surgeon is unavailable.

Enrollment and Randomization:

Clinicians who consented to participate in the study received a brief training on *BREASTChoice* and its features at the start of the study (virtual or in person based on site and clinician preference). The training included instructions to locate the patient summary in the EHR for patients randomized to the *BREASTChoice* group. Clinicians were sent pre- and post-trial surveys to assess their attitudes toward shared decision-making and their intention to use shared decision-making and *BREASTChoice* in routine care in the future. Clinician participants received a one-time $50 gift card as reimbursement for their participation.

The study team at each site screened for eligible patients through clinicians' schedules in the EHR. The research team could approach eligible patients in person in clinic, by phone, or via secure message in the patient portal to obtain consent. Surgical oncologists engaged in the study by handing out study flyers to patients diagnosed with breast cancer who were considering a mastectomy. Eligible patients were contacted and eligibility confirmed with a screening questionnaire. Study staff were available through phone, videoconference, or email to answer potential participants' questions.

After consenting to join the study, patients were randomized using computer random assignment in blocks of 2 and 4 to the *BREASTChoice* tool or to an attention control (a control website about breast reconstruction developed by the National Cancer Institute[21]). Participants were sent links to view their assigned condition by secure email or secure patient portal message. We sought to enroll patients prior to their appointment with their plastic/reconstructive surgeon. However, because some patients see a plastic and reconstructive surgeon within a few hours of meeting with the surgical oncologist, we were not always able to enroll patients before the reconstructive surgery appointment. We included such patients if they had not yet made a decision about breast reconstruction.

Measures

Primary Outcomes

a. Knowledge

Nine questions were used and adapted from the validated Decision Quality Index (DQI) to assess participants' understanding of the options and outcomes related to having mastectomy with reconstruction versus having mastectomy without reconstruction.[22] A value of 1 is given for each correct answer and a value of 0 is given for each incorrect answer.

b. Preference concordance

Preferences for surgery: After each *BREASTChoice* module (whether to have reconstruction, what type to have, and when to have it), or in a survey for those randomized to the control website, participants selected which surgical option they were leaning towards (reconstruction vs. no reconstruction, implant vs. flap-based reconstruction, immediate vs. delayed). For the *BREASTChoice* group, if the preference changed as they used the tool, we used their last stated preference. In addition, for the *BREASTChoice* group, we explored the percentage of people whose preferences changed as they used the tool.

Reconstruction versus no reconstruction: We reviewed patients' EHR for breast cancer-related surgery and reconstructive surgery through February 2023. If no initial breast cancer surgery (i.e. mastectomy or breast-conserving surgery) was performed during this period, then the patient was excluded from all analyses about reconstruction. If during this period, a patient had breast cancer surgery but no post-mastectomy reconstruction procedure documented in the medical record, we considered this patient to have had no post-mastectomy reconstruction by the time of chart review.

Type of reconstruction: Placement of a permanent breast implant or tissue expander followed by a permanent implant was classified as implant-based reconstruction. Any procedure that involved a flap (including placement of a tissue expander followed by a flap) was considered flap-based reconstruction. If a tissue expander or implant was placed under a flap, this was also classified as flap-based reconstruction. There are several complex factors in determining final surgical procedures (e.g., if a tissue expander is placed but removed); we created a detail matrix of procedures and reviewed with our clinical team and clinical advisors to determine final surgical procedures.

Timing of reconstruction: Patients who underwent mastectomy and a reconstructive procedure on the same day were classified as having immediate reconstruction. Patients who had a mastectomy with no reconstructive procedure on the same day, followed by a reconstructive procedure on another day in the study period, were classified as having delayed reconstruction.

Preference Concordance: We assessed preference concordance for those who had documented preferences and known surgical procedures. Preference concordance was defined as agreement between preferred and actual treatment in the following ways: reconstruction vs. no reconstruction, type of reconstruction (implant vs. flap), and timing of reconstruction (immediate vs. delayed) reconstruction.

c. Decisional conflict

The 4-item SURE Decisional Conflict Scale was used to assess participants' certainty about their choice. Higher scores indicated less decisional conflict, or more certainty.[23] Outcomes were dichotomized as a score of 4 (no decisional conflict) vs. ≤3 (decisional conflict) per scoring guidelines.

Secondary and Exploratory Outcomes

d. BREASTChoice-specific knowledge

After each *BREASTChoice* module (whether to have reconstruction, what type to have, and when to have it), or in a survey for those randomized to the control website, participants answered eleven true/false/unsure questions. These questions covered more knowledge domains than the DQI, including type of reconstruction and timing of reconstruction. They were designed to be part of the tool's educational process and were developed in past work assessing *BREASTChoice*.[16] If the participant answered correctly, their response was considered correct. If a participant skipped an item or indicated that she was unsure, their response was coded as incorrect. Knowledge was scored as a percentage correct out of the total items answered, if more than 50% of the items were answered.

e. Number of high-risk people who choose immediate breast reconstruction

Using the risk prediction model, we considered "high risk" to be two times the average risk. At site A, the *a priori* average risk for mastectomy plus immediate breast reconstruction was about 16%, so 32% was determined to be the risk threshold for considering a patient "high-risk."

f. Clinicians' intentions to engage in shared decision-making

We adapted a measure that assesses how interventions can impact clinicians' intentions to change clinical behavior.[24] Clinicians enrolled in the study were asked to complete these questions at the study's start and conclusion to assess the change in mean response; some clinicians only completed one of these surveys. We used mixed effects models to incorporate all available data. A higher change in mean score indicated greater behavior change.

g. Usability

Usability of *BREASTChoice* was measured in the intervention group using the 10-item validated system usability scale. Scores above 68 were considered above average and below 68 were considered below average.[25]

h. Shared decision-making

Shared decision-making was evaluated using the 3-item validated CollaboRATE measure, which measures the extent of patient and surgeon shared decision-making during the appointment. The top score method was used indicating whether "every effort was made" or "less than every effort was made" to engage patients in decision-making.[26]

Data Analyses:
For the primary outcome of knowledge as assessed by the DQI, an overall score was calculated for each patient by dividing the number of correct responses (range 0-9) by 9 to be re-scaled to a score from 0-100. If more than half of the items were unanswered, then the knowledge items were not scored and were treated as missing. The Wilcoxon rank-sum test compared DQI knowledge between the intervention and control groups due to skewness in the scores. The Hodges-Lehmann estimator was used to identify the location shift of the median score as well as a 95% confidence interval (CI). Two-sample proportion tests compared differences in binary outcomes (preference concordance, SURE: Decisional Conflict Scale, and proportion of high-risk patients choosing reconstruction) between the study groups along with 95% CIs for the difference in proportions. Adjusted models additionally assessed the robustness of our results accounting for our *a priori* selection of age (<65 vs. ≥65 years), race (White, Black/African American, or another race(s)), and site due to the potential for site-specific variation in clinical

practices.[27,28] Separate stratified Wilcoxon tests provided adjusted analyses of DQI knowledge, while logistic regression models including age, race, and site provided adjusted analyses of primary binary outcomes. The Student's t-test estimated differences between study groups in knowledge as assessed in *BREASTChoice*; if more than half of the items were unanswered for tool knowledge, the items were not scored and were treated as missing. Mixed effects models including a random effect for clinician (with adjusted analysis including age, race, and site) estimated differences in shared decision-making measured using CollaboRATE between study groups. For these outcomes, we present intent-to-treat (ITT) analyses as well as per-protocol (PP) analyses that excluded patients randomized to *BREASTChoice* who never accessed the tool. All analyses described above were conducted using SAS Statistical Software 9.4 (SAS Institute Inc., Cary, NC).

5. **Results** (Findings, Outcomes, Discussion, Conclusions, Significance, Implications).

Aim 1: We received extensive feedback from participants and additional feedback from our advisory group. For example, they suggested ways to soften the risk language, and suggested re-ordering the tool so the risk information comes later in the tool rather than upfront. We modified the tool in response to our informatics expertise, to facilitate MyChart and Epic integration. We submitted the tool for security review and had monthly meetings with informatics teams to discuss integration and ongoing maintenance. These data were published in *MDM Policy & Practice* (2021).

Aim 2: BREASTChoice was perceived as highly usable by patients and clinicians and has the potential for sustainability. These data were published in *BMC Medical Informatics and Decision Making* (2023).

We outlined 5 key implementation recommendations for EHR integration of decision support: 1) engage all relevant stakeholders, including patients, clinicians, and informatics experts; 2)explicitly and continually map all persons and processes; 3) actively seek out pertinent institutional policies and procedures; 4) plan for integration to take longer than development of a stand-alone decision aid or one with static components; and 5) transfer knowledge about the software programming from one institution to another but expect local and context-specific changes. Integration of patient decision aids into the EHR is feasible and scalable but requires preparation for specific challenges and a flexible mindset focused on implementation. We published this process and our recommendations with key examples from *BREASTChoice* in *MDM Policy & Practice* (2022).

Aim 3: A total of 23 clinicians (15 plastic/reconstructive surgeons and 8 physician assistants) were approached, and 22 enrolled. Clinicians were mostly female (n=12; 55%), White (n=19; 86%), and non-Hispanic (100%). Between January 2021 and July 2022, 1,426 patients were screened for eligibility (745 at Site A and 681 at Site B). Of these, 689 did not meet inclusion criteria (i.e., did not have a breast malignancy, already had mastectomy, sought care elsewhere, cancelled reconstructive surgery appointment, could not read/speak English, had histology type besides ductal/lobular, had metastatic disease, or could not complete informed consent). Some eligible patients declined participation (232, 16%) or could not be reached (132, 9%). Of the 761 who met eligibility criteria and were approached, 369 were enrolled and randomized (48%). Of those 369, 48 did not complete a survey and were not included in most analyses. The average age of the 369 randomized participants was about 51 years; 15% were over age 65. Most were White, non-Hispanic, had a college degree, and had adequate health literacy (Table 1).

Table 2 summarizes the primary and secondary outcomes using intention-to-treat (ITT) analyses, including adjustment for site, race, age, and clinician as appropriate. We also display our *a priori* planned adjusted analyses by site, age, and race.

Table 3 summarizes our per-protocol (PP) analyses. For this analysis, we excluded *BREASTChoice* participants who never accessed the tool, but responded to surveys sent outside of the tool.

Table 1: Patient Participant Characteristics by Randomized Group, Including All Randomized and Enrolled (N=369)

		BREASTChoice (n=184)	Control (n=185)
Age (years)	Mean (SD, Range)	51.0 (10.8, 31-75)	51.2 (11.2, 25-75)
	<65 years	156 (84.8%)	158 (85.4%)
	65+ years	28 (15.2%)	27 (14.6%)
Race	White	167 (90.8%)	156 (84.3%)
	Black/African-American	11 (6.0%)	21 (11.4%)
	Asian-American	2 (1.1%)	3 (1.6%)
	More than one race	4 (2.2%)	3 (1.6%)
	Another race or Unknown	0 (0.0%)	2 (1.1%)
Ethnicity	Non-Hispanic	182 (98.9%)	180 (97.3%)
	Hispanic	2 (1.1%)	5 (2.7%)
Health Literacy (SILS)		**n=142**	**n=158**
	Limited	5 (3.5%)	11 (7.0%)
	Adequate	137 (96.5%)	147 (93.0%)
Annual household income [1]		**n=152**	**n=158**
	<$30,000	12 (7.9%)	17 (10.8%)
	$30,000 to $74,999	33 (21.7%)	28 (17.7%)
	$75,000 or more	91 (59.9%)	96 (60.8%)
	Prefer not to answer	16 (10.5%)	17 (10.8%)
Educational attainment [1]		**n=142**	**n=158**
	High school or less	15 (10.6%)	16 (10.1%)
	Technical training/Some college	31 (21.8%)	27 (17.1%)
	College degree	47 (33.1%)	58 (36.7%)
	Graduate/professional degree	49 (34.5%)	57 (36.1%)
When was *BREASTCHOICE* accessed?	Prior to appointment	102 (55.4%)	
	After appointment	50 (27.2%)	----
	Never accessed	32 (17.4%)	
Estimated Risk of Complication (%)[2]	Mean (SD, Range)	17.8 (19.5, 7-90)	16.4 (16.3, 7-90)
	Median (IQR)	12 (9-17)	12 (9-17)
	N (%) at high risk (score 32+)	16 (8.7%)	13 (7.0%)
Breast cancer Stage	Stage 0	41 (22.3%)	32 (17.3%)
	Stage I	75 (40.8%)	77 (41.6%)
	Stage II	45 (24.5%)	54 (29.2%)
	Stage III	22 (12.0%)	19 (10.3%)
	Stage IV[3]	1 (0.5%)	3 (1.6%)
Breast Cancer Surgery		**n=184**	**n=185**
	Had Mastectomy	156 (84.8%)	149 (80.5%)
	Had Breast-Conserving Surgery	23 (12.5%)	29 (15.7%)
	Not yet had breast cancer surgery by medical record review	5 (2.8%)	7 (3.8%)
Reconstructive Surgery (of those who had Mastectomy)		**n=156**	**n=149**
	Had reconstruction	117 (75.0%)	118 (79.2%)
	Had no Reconstruction at time of chart review	39 (25.0%)	31 (20.8%)
Timing of Reconstruction (of those who had Reconstruction)		**n=117**	**n=118**
	Immediate Reconstruction	112 (95.7%)	114 (96.6%)
	Delayed Reconstruction	5 (4.3%)	4 (3.4%)
Type of Reconstruction (of those who had Reconstruction)		**n=117**	**n=118**
	Implant-Based	55 (47.0%)	59 (50.0%)
	Flap-Based	32 (27.4%)	36 (30.5%)
	Unsure (final reconstruction procedure not completed at time of chart review)	30 (25.7%)	23 (19.5%)

[1] Clinical variables were obtained from EHRs; age, race, ethnicity, health literacy, income, education were participant-reported

[2]Risk was manually calculated for Site B controls (n=78) & Site B *BREASTChoice* participants who did not access the tool (n=13)

[3]Stage IV was a criterion for exclusion, but some participants were eligible at the time of enrollment and upstaged later

Table 2: Primary and Secondary Patient-Level Outcomes by Group, ITT analysis

	BREASTChoice (n=156)	Control (n=165)	Unadjusted Analysis	Stratified Analysis	
Primary Outcomes (continuous)					
DQI Knowledge			Location shift =		By age: p=0.04
Mean (SD)	70.6 (13.2)	67.4 (14.7)	5.5 (0.0, 11.1)	By site: p=0.04	By race: p=0.04
Median (IQR)	66.7 (66.7-77.8)	66.7 (55.6-77.8)	p=0.08		
Primary Outcomes (categorical)	**BREASTChoice (n=156)**	**Control (n=165)**	**Difference in proportion or means (95% CI)**	**Adjusted (for site)**	**Adjusted (for site, age, race)**
Reconstructive surgery [1]					
Yes	103 (76.3%)	109 (79.6%)			
No	32 (23.7%)	28 (20.4%)	-	-	-
Preference Concordance					
Reconstruction vs. No reconstruction [2]	**n=156**	**n=165**	-6.2%		
Treatment matches preference	83 (86.5%)	113 (92.6%)	(-14.3, 1.9%)		
Treatment doesn't match preference	13 (13.5%)	9 (7.4%)	p=0.14	p=0.04	p=0.04
Immediate vs. Delayed Reconstruction [3]	**n=103**	**n=109**	4.5%		
Treatment matches preference	48 (81.3%)	73 (76.8%)	(-9.0%, 18.0%)		
Treatment doesn't match preference	11 (18.6%)	22 (23.2%)	p=0.51	p=0.38	p=0.35
Flap vs. Implant Reconstruction [4]	**n=103**	**n=109**	5.7%		
Treatment matches preference	33 (84.6%)	60 (78.9%)	(-9.8%, 21.1%)		
Treatment doesn't match preference	6 (15.4%)	16 (21.1%)	p=0.45	p=0.39	p=0.40
SURE: Decisional Conflict [5]	**n=142**	**n=157**	-6.2%		
Decisional conflict	31 (21.8%)	44 (28.0%)	(-16.1%, 3.7%)		
No decisional conflict	111 (78.2%)	113 (72.0%)	p=0.22	p=0.24	p=0.22
Secondary Outcomes					
Proportion of high-risk patients choosing reconstruction [6]	**n=16**	**n=13**	-28.6%		
Chose reconstruction	10 (71.4%)	11 (100.0%)	(-57.9%, 0.8%)		
Chose no reconstruction	4 (28.6%)	0 (0.0%)	p=0.056	-	-
Knowledge as assessed in *BREASTChoice* (Range 27.3-100%)	**n=147**	**n=154**	18.2% (14.8, 21.6)		
Mean (SD)	84.7 (13.8)	66.5 (15.8)	p<0.001	p<0.001	p<0.001
Exploratory Outcome					
CollaboRATE Top Score Method [7]	**n=141**	**n=156**	3.7%		
Less than every effort was made	78 (55.3%)	92 (59.0%)	(-7.6%, 14.9%)		
Every effort was made	63 (44.7%)	64 (41.0%)	p=0.53	p=0.26	p=0.37

[1] Excluded: no mastectomy yet (BC n=4, Control n=4); breast-conserving surgery (BC n=17, Control n=24)

[2] Excluded: no mastectomy yet (BC n=4, Control n=4); "unsure" preference about having reconstruction reported (BC n=3, Control n=7); no preference about having reconstruction reported (BC n=43, Control n=13); breast-conserving surgery (BC n=10, Control n=19)

[3] Of those who had Reconstruction. Additional excluded participants: "unsure" timing preference reported (BC n=9, Control n=6); no timing preference reported (BC n=35, Control n=8)

[4] Of those who had Reconstruction. Additional excluded participants: final reconstruction type not available yet (BC n=23, Control n=21); "unsure" type preference reported (BC n=8, Control n=6); no type preference reported (BC n=33, Control n=6)

[5] Excluded: missing SURE questions (BC n=14, Control n=8)

[6] Includes all randomized participants, not just those with survey data. P-value and estimated differences are provided for the proportion who chose reconstruction versus no reconstruction. Additional excluded participants: had breast-conserving surgery (BC n=2, Control n=1); did not yet have mastectomy (Control n=1)

[7] Adjusted models for CollaboRATE also included a random effect for surgeon. 20 patients at Site B saw a PA to discuss reconstruction and did not have a reconstructive surgeon listed in the EHR, so were excluded from the CollaboRATE adjusted analysis

Table 3: Per-protocol analysis considering those in the *BREASTChoice* group who accessed the tool compared to control participants, for selected outcomes

	BREASTChoice (n=150)	Control (n=165)	Unadjusted Analysis	Stratified Analysis	
Primary Outcome (continuous)					
DQI Knowledge			Location shift =		By age: p=0.02
Mean (SD)	71.4 (12.8)	67.4 (14.7)	5.5 (0.0, 11.1)	By site: p=0.01	By race: p=0.01
Median (IQR)	66.7 (66.7-77.8)	66.7 (55.6-77.8)	p=0.03		
Primary Outcomes (categorical)	**BREASTChoice (n=150)**	**Control (n=165)**	**Difference in proportions or means (95% CI)**	**Adjusted (for site)**	**Adjusted (for site, age, race)**
Reconstructive surgery [1]					
Yes	100 (76.9%)	109 (79.6%)			
No	30 (23.1%)	28 (20.4%)	-	-	-
Preference Concordance					
Reconstruction vs. No reconstruction [2]	**n=150**	**n=165**	-6.2%		
Treatment matches preference	83 (86.5%)	113 (92.6%)	(-14.4, 1.9%)		
Treatment does not match preference	13 (13.5%)	9 (7.4%)	p=0.14	p=0.04	p=0.04
Immediate vs. Delayed [3]	**n=100**	**n=109**	4.5%		
Treatment matches preference	48 (81.4%)	73 (76.8%)	(-9.0%, 18.0%)		
Treatment doesn't match preference	11 (18.6%)	22 (23.2%)	p=0.51	p=0.38	p=0.35
Flap vs. Implant [4]	**n=100**	**n=109**	5.7%		
Treatment matches preference	33 (84.6%)	60 (78.9%)	(-9.8%, 21.1%)		
Treatment doesn't match preference	6 (15.4%)	16 (21.1%)	p=0.47	p=0.40	p=0.40
SURE: Decisional Conflict [5]	**n=136**	**n=157**	-5.2%		
Decisional conflict	31 (22.8%)	44 (28.0%)	(-15.3, 4.0%)		
No decisional conflict	105 (77.2%)	113 (72.0%)	p=0.31	p=0.32	p=0.30
Secondary Outcomes					
Proportion of high-risk patients choosing reconstruction [6]	**n=13**	**n=13**			
Chose reconstruction	8 (66.7%)	11 (100.0%)	-33.3%	-	-
Chose no reconstruction	4 (33.3%)	0 (0.0%)	(-64.3%, 2.4%)		
			p=0.04		
Knowledge as assessed in *BREASTChoice*			18.2%		
(Range 27.3-100%)	**n=147**	**n=154**	(14.8, 21.6)		
Mean (SD)	84.7 (13.8)	66.5 (15.8)	p<0.001	p<0.001	p<0.001
Exploratory Outcome					
CollaboRATE Top Score Method [7]	**n=135**	**n=156**			
Less than every effort was made	73 (54.1%)	92 (59.0%)	4.9%		
Every effort was made	62 (45.0%)	64 (41.0%)	(-6.5%, 16.3%)	p=0.19	p=0.27
			p=0.40		

[1] Excluded: no mastectomy yet (BC n=4, Control n=4); breast-conserving surgery (BC n=16, Control n=24)

[2] Excluded: no mastectomy yet (BC n=4, Control n=4); "unsure" preference about having reconstruction reported (BC n=3, Control n=7); no preference about having reconstruction reported (BC n=37, Control n=13); breast-conserving surgery (BC n=10, Control n=19)

[3] Of those who had Reconstruction. Additional Excluded participants: "unsure" timing preference reported (BC n=9, Control n=6); no timing preference reported (BC n=32, Control n=8)

[4] Of those who had Reconstruction. Additional excluded participants: final reconstruction type not available yet (BC n=22, Control n=21); "unsure" type preference reported (BC n=8, Control n=6); no type preference reported (BC n=31, Control n=6)

[5] Excluded: missing SURE questions (BC n=14, Control n=8)

[6] Includes all randomized participants, not just those with survey data. P-value and estimated differences are provided for the proportion who chose reconstruction versus no reconstruction. Additional excluded participants: had breast-conserving surgery (BC n=1, Control n=1); did not yet have mastectomy (Control n=1)

[7] Adjusted models for CollaboRATE also included a random effect for surgeon. 20 patients at Site B saw a PA to discuss reconstruction and did not have a reconstructive surgeon listed in the EHR, so were excluded from the CollaboRATE adjusted analysis

Primary Outcomes

a. Knowledge (DQI)

BREASTChoice participants had higher average knowledge score (mean 70.6) compared to control participants (mean 67.4); however, this difference was not statistically significant (p= 0.08) in our ITT analyses (Table 2). ITT analyses stratified by site, age, and race were all statistically significant (p=0.04). In our PP analyses, *BREASTChoice* participants had significantly higher knowledge (mean score 71.4) compared to control participants (mean 67.4; p=0.03; Table 3). PP analyses stratified by site (p=0.01), age (p=0.02), and race (p=0.01) were also significant (Table 3).

b. Decisional conflict

Participants randomized to *BREASTChoice* reported about the same level of decisional conflict (22%) compared to those randomized to the control group (28%) in ITT (Table 2) and PP (Table 3) analyses.

c. Preferences

96/156 (61.5%) people in the *BREASTChoice* group compared to 121/165 (73.3%) people in the control group preferred to have reconstruction. 60/103 (58.2%) people in the BREASTChoice group compared to 80/109 (73.4%) people in the control group who wanted reconstruction preferred to have immediate reconstruction, and 38/103 (36.9%) people in the *BREASTChoice* group compared to 56/109 (51.4%) people in the control group who wanted reconstruction preferred to have an implant-based reconstruction. Tables 2 and 3 display the percentage of people in each group whose treatment choice matched their stated preferences. Most people in both groups chose a treatment that matched their preferences; interestingly, a slightly higher percentage of people in the control group received a treatment that matched their preference for whether or not to have reconstruction (p<0.04), although many participants in the *BREASTChoice* group were unsure of their preferences at the time of the survey (38.5% skipped a preference question when completing the tool, whereas 13.3% skipped a preference question when completing the control group survey). In addition, 96/156 (61.5%) of people randomized to the *BREASTChoice* group had stable preferences while using the tool across all three questions about surgery choice, 43 (27.6%) were unsure of their reconstruction preferences, and 17 (10.9%) changed their preferences as they went through the tool. In the control group, 148/165 (89.7%) had stable preferences from the first to last question in the survey, and only 13 (7.9%) were unsure of their preferences while four (2.4%) changed their preference as they went through the survey.

Secondary and Exploratory Outcomes

c. BREASTChoice-specific knowledge

In ITT analyses focusing on knowledge using a measure created and piloted in past work[16] and reviewed with end users and community partners, participants randomized to *BREASTChoice* had higher knowledge (mean 84.7) compared to control participants (mean 66.5; p<0.001). Those randomized to *BREASTChoice* who accessed the tool also had higher knowledge (mean = 85.3) compared to control participants (mean = 66.5; p<0.001).

d. **Number of high-risk people who choose breast reconstruction**

There was no difference in the proportion of high-risk patients in the *BREASTChoice* group who opted for reconstruction compared to the control group, in ITT analyses (71.4% in the *BREASTChoice* vs. 100% in the control group; p=0.11; Table 2). In PP analyses, this difference approached statistical significance (66.7% in the *BREASTChoice* group vs. 100% in the control group; p=0.056; Table 3).

e. Clinicians' intentions to engage in shared decision-making

Clinicians' intention to engage in shared decision-making increased slightly from pre- to post-trial. At pre-trial the average score was 6.4, whereas at the end of trial, the average score was 6.6. On subscales of this measure, providers reported slightly higher social influence (5.8 vs. 5.2), beliefs about their capabilities (6.2 vs. 6.0), moral norms (6.7 vs. 6.4), and beliefs about consequences (6.5 vs. 6.3) pertaining to shared decision-making post-trial compared to pre-trial. Despite slight improvements, these differences were not statistically significant (all p's >0.05).

f. Usability

Among participants in the intervention arm, *BREASTChoice* was found to have strong usability with a mean score of 84.6 (SD=14.3).

g. Shared decision-making:

Participants allocated to the intervention reported about the same levels of shared decision-making (44%) compared to the control group (41%); this was not significantly different in intent-to-treat (Table 2) or per-protocol (Table 3) analyses.

Discussion

To our knowledge, *BREASTChoice* is the first breast reconstruction decision support tool that incorporates personalized risk prediction, evidence-based patient education, and clinician decision support. Participants randomized to this multilevel intervention demonstrated improved knowledge about reconstruction, and reconstruction type, timing, and complication risks. In addition, in PP analyses including only those in the *BREASTChoice* randomized group who accessed the intervention, fewer high-risk patients chose to have immediate breast reconstruction, which is a higher risk procedure than delayed or no reconstruction. *BREASTChoice* did not decrease decisional conflict, improve the match between preferences and surgical choice, or increase shared decision-making in this study.

Our findings are consistent with past work about decision aids improving knowledge,[12] including an earlier version of *BREASTChoice*. Specific knowledge about type and timing of reconstruction demonstrated the strongest improvement between the intervention and control groups. Specific information about implants, flaps, and risks of complications from immediate breast reconstruction are essential to informed choices; it is a unique strength of *BREASTChoice* that patients learned information that clinicians and patients in past work deemed important.[27] The impact of *BREASTChoice* on patients' knowledge was even more pronounced when stratified by age, race, and site. Older adults and those from racially minoritized backgrounds could benefit more from evidence-based, accessible information in this context. Future research could specifically design or adapt decision aids for these groups.

Although *BREASTChoice* did not improve perceptions of shared decision-making in this study, future research should explore methods to encourage the implementation of decision tools in routine care. In our study, some clinicians did not access the *BREASTChoice* summary

page to use at the point of care. Others used it some of the time, but not during every encounter. At one site, technology challenges prevented some clinicians from receiving the *BREASTChoice* summary. In addition, baseline intentions to engage in shared decision-making were high. Future studies should work to overcome implementation barriers to encourage and support shared decision-making between patients and clinicians, especially clinicians who might not already support this approach. In addition, conducting the study at a time without additional COVID-19 pandemic-related stressors could influence clinicians' intentions to engage in shared decision-making.

It was surprising to note that *BREASTChoice* did not improve the match between stated preferences and choice. Measuring preferences is challenging and time-sensitive; many *BREASTChoice* participants left the preference sections blank or changed their preferences as they proceeded through the tool. It is possible that *BREASTChoice* facilitated deliberation[26] among options and that preferences could have matched by the time a surgery choice was made. Future work should study preferences and preference shift over time.

This study should be interpreted within the context of some study limitations. First, the study began during 2020 at the peak of the COVID-19 pandemic. The pandemic led to staffing shortages, and the existing informatics teams needed to prioritize pandemic-related activities. Even with extensions to programming time frames for the risk prediction and EHR integration aspects of *BREASTChoice*, one community site declined study engagement, and the two included sites took slightly longer to launch the study than planned. The final sample might not have been representative of patients at both academic and community locations. In addition, programming bugs took longer to reconcile given these staffing and resource challenges. For example, at one site, clinicians were unable to see the patient data at one point in the study, and later the slider scale data indicating the strength of patients' preferences was missing at the site. Control group participants were also fairly activated in clinical encounters, as evidenced by asking questions and engaging with their care team; in fact, in both sites, control participants commented that they wished the usual care materials provided had photos or information to help facilitate choice. It is possible that control group participants searched on their own for this information which could have affected study results. Finally, this implementation study started during the peak of the COVID-19 pandemic when clinicians and patients had additional stressors on top of the stressors of usual care practice (e.g., virtual visits, staffing shortages, anxiety about contracting COVID-19, clinician burnout). Future work could revisit some key study questions over time.

Future Directions

Across all Aims, we identified key facilitators and barriers to EHR integration of decision tools. We plan to maintain *BREASTChoice* in the EHR while also working to make it available outside the EHR to share with family or friends in future work. Our informatics teams noted that it is easier to maintain in the EHR due to security features and added protection; however, our patient participants told us that it is easier to access outside the EHR so they do not need to be connected to the patient portal to access the tool. They can also share it with family or friends if not linked to the EHR. Future work can explore these opportunities. In addition, we hope to explore clinicians' preferences for receiving information (e.g., as a Best Practice Advisory (BPA) pop-up or as part of the patients' history forms) to facilitate implementation. Finally, Dr. Lee has funding pending (with Dr. Politi as a consultant) to translate *BREASTChoice* into Spanish and adapt it for patients for whom Spanish is their primary language. She also has funding pending

with Dr. Politi as a co-I to better understand how to use social media to disseminate breast reconstruction decision support.

Summary of Significance and Impact

To our knowledge, *BREASTChoice* is the first breast reconstruction decision support tool that incorporates personalized risk prediction, evidence-based patient education, and clinician decision support.

In Aim 1, *BREASTChoice* was adapted to be responsive to extensive input from end users, including patients, clinicians, informatics experts, and community partners.

In Aim 2, it was found to be highly usable and was programmed to be integrated directly into the EHR and patient portal. It pulled risk factors from the EHR (allowing patients to enter any missing data into the risk prediction model that was not available or inaccurate from the EHR). It was also made available for use outside of the patient portal for those not enrolled in the portal. Using the sociotechnical framework, we documented the integration process and usability.

In Aim 3, participants randomized to this multilevel intervention demonstrated improved knowledge about reconstruction, and improved knowledge about reconstruction type, timing, and complication risks. In addition, in analyses including only those in the *BREASTChoice* randomized group who accessed the intervention, fewer high-risk patients chose to have immediate breast reconstruction, which is a higher risk procedure than delayed or no reconstruction.

Results of Aim 3 suggest a potential for significant improvement in decision quality and the match between surgery and patients' clinical risk and preferences.

Although we were not able to include our community site, we did receive supplemental funding from the Healthy State Alliance to create a brochure and a video from *BREASTChoice* for use in community clinics. Preliminary feedback from the clinicians suggest that it has been helping their clinic flow by giving patients something to review (either in a brochure or video, but mostly through video) while they are waiting in an exam room. Feedback also suggests that it is helping clinicians learn who might want a referral to plastic/reconstructive surgery, when not all patients are able to see a plastic/reconstructive surgeon.

6. List of Publications and Products

Publications From the Study

Chetta MD, Schoenbrunner AR, Lee CN. Postmastectomy Breast Reconstruction in the Time of the Novel Coronavirus Disease 2019 (COVID-19) Pandemic. *Plast Reconstr Surg Glob Open*. 2020 Jun 9;8(6):e2967. doi: 10.1097/GOX.0000000000002967. PMID: 32766087; PMCID: PMC7339321

Boateng J, Lee CN, Foraker RE, Myckatyn TM, Spilo K, Goodwin C, Politi MC. Implementing an Electronic Clinical Decision Support Tool Into Routine Care: A Qualitative Study of Stakeholders' Perceptions of a Post-Mastectomy Breast Reconstruction Tool. *MDM Policy Pract*. 2021 Sep 17;6(2):23814683211042010. doi: 10.1177/23814683211042010.

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