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A Scoping Review of Personalized, Interactive, Web-Based Clinical Decision Tools Available for Breast Cancer Prevention and Screening in the United States

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Abstract

Introduction. Personalized web-based clinical decision tools for breast cancer prevention and screening could address knowledge gaps, enhance patient autonomy in shared decision-making, and promote equitable care. The purpose of this review was to present evidence on the availability, usability, feasibility, acceptability, quality, and uptake of breast cancer prevention and screening tools to support their integration into clinical care. **Methods.** We used the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews Checklist to conduct this review. We searched 6 databases to identify literature on the development, validation, usability, feasibility, acceptability testing, and uptake of the tools into practice settings. Quality assessment for each tool was conducted using the International Patient Decision Aid Standard instrument, with quality scores ranging from 0 to 63 (lowest-highest). **Results.** We identified 10 tools for breast cancer prevention and 9 tools for screening. The tools included individual (e.g., age), clinical (e.g., genomic risk factors), and health behavior (e.g., alcohol use) characteristics. Fourteen tools included race/ethnicity, but no tool incorporated contextual factors (e.g., insurance, access) associated with breast cancer. All tools were internally or externally validated. Six tools had undergone usability testing in samples including White (median, 71%; range, 9%–96%), insured (99%; 97%–100%) women, with college education or higher (60%; 27%–100%). All of the tools were developed and tested in academic settings. Seven (37%) tools showed potential evidence of uptake in clinical practice. The tools had an average quality assessment score of 21 (range, 9–39). **Conclusions.** There is limited evidence on testing and uptake of breast cancer prevention and screening tools in diverse clinical settings. The development, testing, and integration of tools in academic and nonacademic settings could potentially improve uptake and equitable access to these tools.

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Highlights

- There were 19 personalized, interactive, Web-based decision tools for breast cancer prevention and screening.
- Breast cancer outcomes were personalized based on individual clinical characteristics (e.g., age, medical history), genomic risk factors (e.g., BRCA1/2), race and ethnicity, and health behaviors (e.g., smoking). The tools did not include contextual factors (e.g., insurance status, access to screening facilities) that could potentially contribute to breast cancer outcomes.
- Validation, usability, acceptability, and feasibility testing were conducted mostly among White and/or insured patients with some college education (or higher) in academic settings. There was limited evidence on testing and uptake of the tools in nonacademic clinical settings.

Keywords
Web-based decision tools, breast cancer, screening, prevention

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Breast cancer remains a serious public health concern despite the medical advancements made in breast cancer prevention and screening research in the past 50 y.[1] Currently, breast cancer is the most prevalent cause of cancer-related deaths in women.[2] The American Cancer Society estimates that in 2022, approximately 287,850 women were diagnosed with invasive breast cancer, and more than 43,000 women have died due to breast cancer in the United States.[3] Recently, the United States Preventative Services Task Force recommended decreasing the biennial mammography screening start age for women to 40 y (from the previous start age of 50 y), highlighting that 19% more lives could be saved by starting screening at age 40 y for all women.[4,5] The implementation of these recommendations will need to involve women in their personal prevention and screening decision-making processes in practice settings.[6]

Breast cancer prevention involves breast cancer risk assessment to identify modifiable (e.g., smoking, physical activity) and nonmodifiable risk factors (e.g., family history, genetic mutations) and then taking action to reduce the risk of developing breast cancer during the person's lifetime.[7] Breast cancer screening involves early detection and aims to reduce the risk of breast cancer morbidity and mortality.[8,9] Personalized information on prevention and screening can help women better understand their individual risk and adopt optimal risk management strategies considering their individual (e.g., age), clinical (e.g., comorbidities), behavioral (e.g., past screening), and contextual characteristics (e.g., access to screening facilities), as well as their needs (e.g., newly discovered family history), preferences, and values.[10–12]

Over the past few decades, several approaches have emerged to facilitate personalized breast cancer

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prevention and screening decisions in primary care settings.[13–15] One such approach includes Web-based, interactive, personalized clinical decision tools. These tools have the potential to revolutionize decisions regarding primary prevention and screening for breast cancer in the United States.[16] For example, the Breast Cancer Surveillance Consortium (BCSC) 5-y invasive breast cancer risk calculator is a widely used, validated, Web-based tool used to assess a woman's 5- and 10-y breast cancer risk based on her age, race/ethnicity, family history of breast cancer, history of breast biopsy, and breast density.[17,18] The tool can be used by health care providers to guide decisions on screening.[19]

Overall, the use of Web-based clinical decision tools have been shown to support patient-provider communication, reduce patient anxiety, increase patient knowledge, and promote patient autonomy and involvement in the decision-making process.[16,20–23] Contextual characteristics incorporated into tools, such as insurance status, access to screening facilities, or environmental pollutants that increase the risk of cancer, could potentially help address the underlying causes of cancer disparities.[24–26] For example, clinical decision tools for bladder cancer include contextual factors such as occupational exposures and drinking well-water to identify high-risk individuals.[27]

Recently, the US Food and Drug Administration issued a regulation classifying clinical decision tools as medical devices to help increase the quality of the tools used in clinical settings.[28] However, there are several barriers to integrating clinical decision tools in current clinical care.[29] These barriers include limited time and lack of knowledge among health care providers and patients about the validity, usability, feasibility, acceptability, quality, and uptake of these tools in real-world clinical settings.[24,26,30] We aimed to fill this gap in clinical care by reviewing the current English-language, Web-based, interactive tools available to support breast cancer prevention and screening decisions in the United States. The overarching goal of our review was to present evidence on the availability, validity, usability, feasibility, acceptability, quality, and uptake of existing breast cancer prevention and screening clinical decision tools to support the integration of these tools into clinical care by patients and their health care providers.

Methods

Data Sources and Search Strategy

This scoping review was conducted using the Arksey and O'Malley framework[31] and the Joanna Briggs Institute guidelines for scoping reviews.[32] The framework consists of 6 stages to guide scoping review processes, including specifying the research question; identifying relevant literature; selecting studies; data mapping; summarizing, synthesizing, and reporting the results; and expert consultation. We used the Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR) checklist (Supplementary Table S1).[33] The review was registered in Open Science Framework.[34] Institutional review board exemption or approval was not required since study-level data were used in this review.

A literature search was executed within 6 databases including PubMed, Embase, PsycInfo, Scopus, Web of Science Core Collection, and Cochrane Central. A trained librarian (G.B.) at the National Institutes of Health conducted 2 rounds of preliminary searches and refined the search strategy based on the initial search results. We incorporated relevant keywords, synonyms, MeSH and Emtree terms related to concepts on interactive and personalized clinical tools, online/Web-based calculators/risk prediction models, and breast cancer. We pilot tested 50 papers to ensure that the inclusion/exclusion criteria were suitable for the review. The final search strategy can be found in Supplementary Table S2. We conducted a separate search for additional papers on validation, usability, feasibility, and acceptability testing of the tools. In clinical decision tool development, usability testing assesses the functionality and ease of use of the tool,[35] while feasibility testing evaluates its likelihood of use. Acceptability testing captures the end-user's engagement and satisfaction with the tool,[36] and validation determines the tools' ability to replicate the estimated outcomes in independent data sets.[37] Finally, we conducted an additional search to find studies indicating integration and sustained uptake of these tools to support clinical practice by searching for trials and observational studies that evaluated the efficacy, effectiveness, dissemination, implementation, and integration of the tools into clinical practice including electronic health record systems (e.g., Epic).

Study Selection

We included 1) peer-reviewed articles; 2) articles and tools written in English; 3) articles that described the original development of online Web-based interactive personalized clinical decision tools; 4) tools that were accessible through a Web page or screenshots; 5) articles on tool validation in independent data sets and usability, feasibility, and acceptability testing of the tools; 6) articles on the integration and uptake of the tools in clinical settings; and 7) articles involving human participants,

samples, and/or data sets. Detailed inclusion/exclusion criteria are provided in Supplementary Table S3.

Search results were imported into the citation software Endnote 20,[38] and duplicates were removed. The studies were screened in Covidence,[39] and relevant data from the studies were extracted using Microsoft Excel. Four authors (D.K., K.W., J.Z., L.S.) manually and independently screened the 3,044 titles and abstracts for eligibility. Full-text screening was performed independently by 4 authors (D.K., K.W., J.Z., L.S.) to identify relevant articles using the eligibility criteria, and discrepancies were resolved through discussion.

Data Extraction

Data charting was conducted using a previously developed data extraction template to ensure reviewer consistency and reliability across all articles.[23] This template was specifically developed to extract information on clinical decision tools. For this study, we updated the template to include new variables guided by the National Institute on Minority Health and Health Disparities research framework.[40] The new variables included physical/built/sociocultural environment and health care systems factors that could potentially influence individual health outcomes[41] and therefore could potentially be considered for personalized risk assessment and tool development.[40] The data extraction template was pilot tested by J.J., D.K., and K.W. (Supplementary Table S4).

We extracted information on the name of the tool, purpose, target population used to develop the tool, data sources, the environment of tool development, methods, individual and clinical characteristics, genomic characteristics, health behavior factors, contextual factors, race/ethnicity, preferential factors, outcomes, target user/s, date of the tool's last update, validation, usability, acceptability, and feasibility testing and evidence on the tool's uptake and integration into clinical care. We obtained information on each tool by either viewing the available website using synthetic data inputs or by analyzing screenshots provided within the publication to retrieve the parameters of interest. Authors categorized articles into either prevention or screening decision tools based on the purpose of the tool. For usability, feasibility, and acceptability testing, we extracted information on the name of the tool, purpose, survey and study design, study population, testing environment, outcomes, and results. In addition, we collected information on race/ethnicity, education, marital status, insurance status, and income level of the sample of individuals included in the validation, usability, feasibility, and acceptability testing of the tools. For evidence on uptake, we extracted information on the name of the tool, reference(s), and a summary on evidence of uptake in clinical settings.

Quality Assessment

We conducted a quality assessment of each interactive tool using the International Patient Decision Aid Standard instrument (IPDASi) checklist (Supplementary Table S5).[42] IPDASi scores range from 0 to 63, with 63 being the highest-quality tool.

Results

Search Results

We found 5,237 references through PubMed, Embase, Cochrane, Web of Science, Scopus, and PsycInfo, and after removing duplicates, there were 3,044 articles. After the application of the inclusion criteria, we included 34 articles associated with 19 unique decision tools (Figure 1), with 10 tools for prevention and 9 tools for screening (Tables 1 and 2).

Personalized Tools for Breast Cancer Prevention

These tools were developed for women or men[43,46,75,79] with no history of breast cancer or benign breast disease,[43,46,49,52,54,56,59,62,75,79] individuals who engaged in less than 150 min/wk of aerobic physical activity,[59] and healthy postmenopausal women.[56] Four tools were developed for use by only health care providers,[43,46,49,54] 4 tools for only women/adults,[59,62,75,79] and 2 tools for both providers and women.[52,56] Eight tools were developed in academic medical centers,[43,46,52,56,59,62,75,79] 1 in a nonprofit hospital system,[49] and 1 in a government agency (Table 1).[54] Five tools were developed in the Northeast (i.e., New England, Middle Atlantic)[43,46,62,75,79] 2 in the Midwest (i.e., West North Central),[49,59] 2 in the West (i.e., Pacific),[52,56] and 1 in the South Atlantic regions of the United States (Table 1).[54]

All interactive tools provided breast cancer risk estimates[43,46,49,52,54,56,59,62,75,79] for 5, 10, 15, 20, 25 y or lifetime.[46,49,52,54,56,59,62,75,79] Breast cancer risk was predicted using a wide range of inputs such as age, medical history, menopausal status,[46,52,59,62,79] height and weight,[52,56,59,79] prior breast biopsy,[46,49,52,54,56,62] family medical history/history of cancer,[46,49,52,54,56,59,62,75,79] age at menarche,[46,52,54,56,79] childbirth/pregnancy resulting in live birth history,[46,49,56,59,79] and breastfeeding

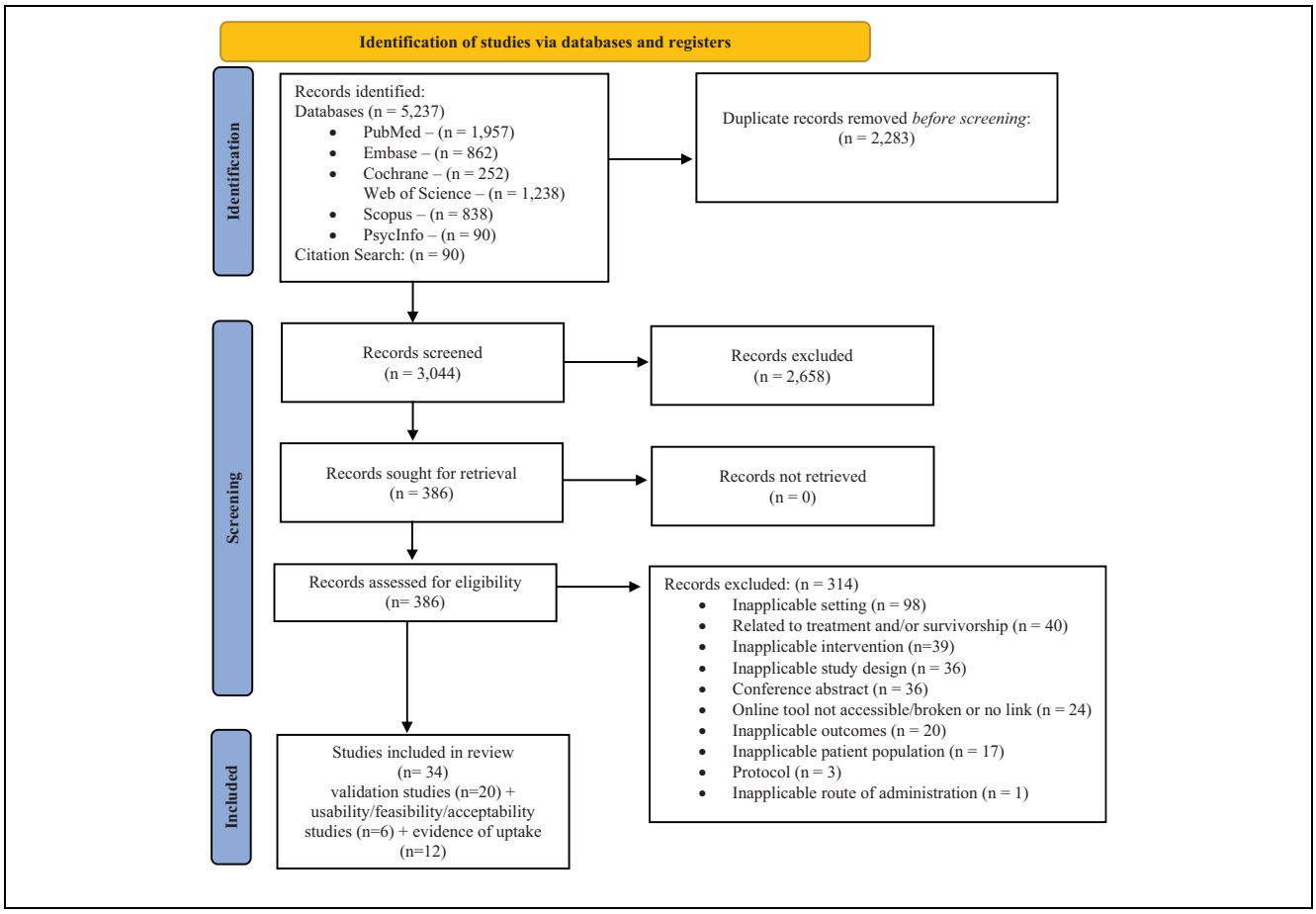

Figure 1 PRISMA flow diagram for record identification.
From: Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. 2021;372:n71. DOI: 10.1136/bmj.n71

history.[46,56] Four tools considered genomic factors such as BRCA1/2 gene mutation status and other genes associated with breast cancer (e.g., ATM, PALB2).[43,52,54,79] Health behavior inputs included smoking status,[56,59,79] exercise status,[52,56,59,79] alcohol intake,[52,56,79] aspirin use,[56,59] daily multivitamin intake,[59] and servings of food types (e.g., fruits, fish).[56,59] Tools also considered use of oral contraceptives[46] and hormonal therapy.[46,52,59,79] Seven tools included race/ethnicity, such as Ashkenazi Jewish, Asian or Pacific Islander, Black, White, Hispanic, and Native American or Alaskan Native as breast cancer risk factors.[52,54,59,62] However, no tool considered contextual factors. The RealRisks tool aimed to address the patient's values and concerns by asking the patient about risk uncertainty, distrust of the health care system, and perceptions about health care rationing based on risk assessment results.[62]

All interactive tools were internally[49,52,56] and/or externally validated.[43,46,49,54,59,62,75,79] The validation samples included mostly unmarried (median: 58%; range, 55%–61%), insured (97%), White women (62%; 35%–100%) with a college-level education or higher (41%; 33%–69%) and an annual income of $25,000 to $50,000 (42%) (Supplementary Table S6).[43,46,49,54,59,62]

Usability, Feasibility, and Acceptability Testing for Breast Cancer Prevention Tools

Studies suggest that 3 (out of 10) breast cancer prevention tools had undergone usability, feasibility, or acceptability testing (Table 3).[52,59,62] All of the tools were tested in academic settings. Usability testing was conducted for RealRisks[62] and Imagine Health.[59] Specifically, RealRisks was first evaluated by a focus group of

Table 1 Summary of the Web-Based Clinical Decision Tools Used to Guide Breast Cancer Prevention Decisions

Tool Name	Purpose	Target Population	Data Source	Environment of Tool Development	Methods	Input Factors						Outcome(s)	Target User(s)	Validation	Usability/Feasibility/ Acceptability Testing
						Individual and Clinical	Genomic	Health Behaviors	Contextual	Race and Ethnicity	Other				
Ask2Me[43,44a]	To develop a tool that provides patient-specific risk predictions for all cancer susceptibility genes	Patients at risk of cancer based on 65 gene-cancer associations	SEER, PubMed, and Embase	Academic medical center, Northeast (New England)	Ask2meKnowledgeBase package in R combined reported relative ratios with the baseline risk for noncarriers for each cancer	Age, gender, prior cancer history, prior surgery (e.g., hysterectomy or bilateral mastectomy)	ATM, BRCA1/2, CDH1, CHECK2/ 1100del, NBN/ 657del. PALB2, PTEN, STK11, TP53	—	—	—	—	Probability that an individual will develop breast cancer by a specific age	Health care providers	External[45]	—
BWHS Breast Cancer risk calculator[46,47]	To develop a breast cancer risk calculator to predict breast cancer risk in US Black women	US Black women aged 30–70 y at risk for breast cancer	CARE, CBCS, and WCHS	Academic medical center, Northeast (New England)	Logistic regression models	Age, age of first menstrual period, bilateral oophorectomy (yes/no), breast biopsy (yes/no), breastfeeding for 1 mo (yes/no), childbirth history, family history of cancer (breast, prostate), height, menopausal status, weight at age 18 y	—	—	—	Black	Use of oral contraceptives	5- and 10-y absolute risk of invasive breast cancer	Health care providers	External[46,48]	—
Breast Cancer Risk Assessment tool for Women with BBD[49,50]	To develop a breast cancer risk assessment tool to predict breast cancer in women with BBD	Women with BBD at risk of breast cancer	The Mayo BBD cohort	Nonprofit hospital system, Midwest (West North Central)	Logistic regression models	Age, age at live birth, degree of lobular involution, family history of breast cancer, number of pregnancies resulting in a live birth, overall histologic impression from benign biopsy, presence of sclerosing adenosis or columnar alternation, radial scar	—	—	—	—	—	5-, 10-, 15-, 20-, 25-, and 30-y risk of breast cancer	Health care providers	Internal and external[49] External[51]	—
BreastCare[52,53]	To develop a personalized breast cancer risk assessment and educational tool for women at risk of developing breast cancer	Women aged 40–74 y with no previous history of breast cancer	San Francisco Bay Area general medicine practices (one academic medical center and another in an academic safety net)	Academic medical center, West (Pacific)	Gail model,[54] BCSC model[17]	Age, age at menarche, age at menopause, breast biopsy history, family history of ovarian and breast cancer, breast density, height, weight	BRCA1/2	Alcohol intake, exercise frequency and duration	—	Ashkenazi Jewish ancestry, Asian or Pacific Islander, Native American or Alaska Native Black, Hispanic, White, other or multiracial	Receipt of genetic counseling, hormone therapy use, tamoxifen or raloxifene use	5-y, 10-y, and lifetime risk of invasive breast cancer	Health care providers and patients	Internal[52]	Acceptab-ility[55] Feasibilit-y[52]
Health risk prediction tool for postmenopausal women[56,57]	To develop a calculator that predicts breast cancer risk and all-cause mortality compared to other diseases	Healthy postmenopausal women aged 50–79 y	Postmenopausal women who participated in the Women's Health Initiative aged 50–79 y who were recruited from 4 geographic regions between 1993 and 1998	Academic medical center, West (Pacific)	Proportional sub distribution hazards regression model[58]	Age, age at menarche, atrial fibrillation, blood pressure, broken bones, current or prior pregnancy, diabetes, ever breastfed, family history of bone, fracture/ myocardial infarction/ cancer, height, hypertension, medical history, migraine headaches, presence or absence of ovaries, prior breast biopsy, pulse, thyroid problems, waist circumference, weight	—	Alcohol intake, aspirin use, exercise amount and frequency, lactose-free diet (yes/no), cigarette smoking total amount, overall health perception rating	—	White, Black, other; Hispanic, non-Hispanic	Parental living status	5-, 10-, and 15-y risk of breast cancer and all-cause mortality	Health care providers and women	Internal[56]	—
Imagine Health (limited availability; accessible through screenshots on Open Science Framework)[59,60a]	To develop a tool that effectively communicates a patient's breast cancer risk based on physical activity	Individuals aged 30–64 y who exercise for less than 150 min weekly	Individual who engages in less than 150 min of weekly physical activity randomly selected from St. Louis Metropolitan area	Academic medical center, Midwest (West North Central)	Risk ladder, simple table, or bulleted list describing the impact of physical activity on disease risk	Age, children over the age of 35 y and number of children, colonoscopy in the last 10 y, height, menopausal status, personal and family medical history, sex, weight	—	Cigarette smoking status, amount, frequency, exercise amount and frequency, aspirin and multivitamin use and frequency, alcohol intake and frequency, servings of specific food categories	—	American Indian/ Alaskan Native, Asian/Pacific Islander, Black/African American, White/ Caucasian, Multiracial/ other	Postmenopausal hormones or hormone therapy and for how long	10-y risk of breast cancer	Adults	External[59]	Usability[61b]

(continued)

Table 1 (continued)

Tool Name	Purpose	Target Population	Data Source	Environment of Tool Development	Methods	Input Factors						Outcome(s)	Target User(s)	Validation	Usability/Feasibility/ Acceptability Testing
						Individual and Clinical	Genomic	Health Behaviors	Contextual	Race and Ethnicity	Other				
RealRisks (limited availability: Currently only accessible through PI)[62,63a]	To develop an application that incorporates an experience-based dynamic interface including tailored modules on breast cancer risk, genetic testing, and chemoprevention to reduce inaccurate risk perceptions	Women aged 35–75 y who are at a high 5-y risk of invasive breast cancer	High-risk women (35–74 y) eligible for a mammogram	Academic medical center, Northeast (Middle Atlantic)	Gail model[54] and a tailored action plan based on clinical and individual characteristics, family history and values and concerns regarding chemoprevention	Age, breast density, family history, history of breast cancer/implants/ mastectomy/ hysterectomy/blood clot/ stroke, medical history of menopause, results of prior benign breast biopsy	—	—	—	White, Black, Asian, Native American, Native Hawaiian, other/multiple races, unknown; Ethnicity: Hispanic or Latino, not Hispanic or Latinx, unknown	Values and concerns regarding chemoprevention	5- and 10-y and lifetime risk of breast cancer	Women	External[64,65]	Usability[62,66] Acceptab-ility[67]
BCRAT[54,68a]	To develop a risk calculator to predict a women's 5-y and up to lifetime risk of developing invasive breast cancer	Women with no history of breast cancer	BCDDP, CARE, AABC, SFBCS, California Registry, and (SEER)	Government agency, South (South Atlantic)	Unconditional logistic regression models and age-specific breast cancer hazard rates	Age, age at menarche, age at first live birth, number of previous biopsies, number of first-degree relatives with breast cancer, presence of atypical hyperplasia in a biopsy	BRCA1/2		—	White, African American, Hispanic/Latina, Asian American, American Indian or Alaskan Native, unknown	—	5-y and lifetime risk of breast cancer	Health care providers	External[69–74]	—
The Claus model[75]	To develop a tool that predicts familial risk of breast cancer in adult women	White women aged 20–54 ywith breast cancer and matching controls with no previous history of breast cancer	CASH	Academic medical center, Northeast (New England)	Segregation analysis[76] and Cox proportional hazards	The number and ages of onset of family breast cancer history (first degree and second-degree relatives)	—	—	—	—	—	Cumulative 10-y and lifetime risk of breast cancer	Women	External[77,78]	—
Your Disease Risk calculator [27,79a]	To develop a personalized risk assessment tool for individuals at risk of developing breast cancer	Adults with no history of breast cancer	SEER	Academic medical center, Northeast (New England)	Multivariate logistic regression model	Age, age at menarche, age of first childbirth, body type at 7 y, family breast/ ovarian cancer history, having dense breasts, height, history of benign breast disease, menopausal status, number of childbirths, previous cancer history, sex, total length of breastfeeding, weight, weight at 18 y	BRCA1/2	Alcohol intake, diet, smoking status, physical activity status	—	Jewish	Menopausal hormone therapy, taking tamoxifen/ raloxifene	Average risk and cumulative 10-y risk of breast cancer	Adults	External[79,80]	—

—, no information available; AABC, Asian American Breast Cancer Study; BBD, benign breast disease; BCDDP, The Breast Cancer Detection Demonstration Project study; BCRAT, Breast Cancer Risk Assessment Tool; BCSC, Breast Cancer Surveillance Consortium; BRCA, breast cancer gene; BWHS, Black Women's Health Study; CARE, Women's Contraceptive and Reproductive Experience study; CASH, Cancer and Steroid Hormone Study; CBCS, the Carolina Breast Cancer Study; PI, principal investigator; SEER, Surveillance Epidemiology, and End Results database; SFBCS, San Francisco Bay Area Breast Cancer Study; WCHS, the Women's Circle of Health Study.

[a]Ask2Me was updated in 2017; Imagine Health was updated in May 2017; RealRisks was updated in May 2023; the Breast Cancer Risk Assessment Calculator was updated in December 2017; Your Disease Risk Calculator was updated in 2020.

[b]Usability testing included determining the most effective risk communication strategy for the application.

Table 2 Summary of the Web-Based Clinical Decision Tools Used to Guide Breast Cancer Screening Decisions

Tool Name	Purpose	Target Population	Data Source	Environment of Tool Development	Methods	Input Factors						Outcome(s)	Target User(s)	Validation	Usability/ Feasibility/ Acceptability Testing
						Individual and Clinical	Genomic	Health Behavior-s	Contextual	Race and Ethnicity	Other				
B-RST™ 2.0[81–83]	To develop an interactive Web-based referral screening tool that identifies women at hereditary risk for breast/ ovarian cancer	Women at risk of developing breast cancer who are undergoing screening mammography	Women receiving a screening mammography at 1 of 3 clinics in Madison, WI	Government agency, South Atlantic	Detailed 4- generation cancer pedigree and risk classification based on previously published risk criteria[84]	Family history of breast and ovarian cancer, history of men with colon cancer before age 50 y, history of men with prostate cancer before age 50 y, number of family members with breast or ovarian cancer	BRCA1/2	—	—	African American/ Black, American Indian/ Alaskan native, Asian, Caucasian, White, Hispanic/Latinx, Native Hawaiian/ Pacif Islander, other	—	Positive screen (high risk for HBOC), negative-moderate screen (low risk-some increased risk for HBOC), negative-average screen (low risk–average risk for HBOC)	Health care providers and women	Internal[82]	—
B-RST™ 3.0[85,86a]	To improve upon B-RST™ tool and maximize sensitivities to BRCA1/2 mutations	Women with no history of breast cancer and who had undergone BRCA1/2 testing	Winship Cancer Institute for family history of breast cancer clinic database	Government agency, South Atlantic	Full 3-generation cancer pedigree and risk based on B-RST™ 2.0[81,82]	Family history of breast or ovarian cancer	BRCA1/2	—	—	Ashkenazi Jewish	—	Positive screen (high risk), negative screen (low risk)	Health care providers and women	External[85,87]	—
BCSC Invasive Breast Cancer Risk Calculator[17–19b]	To develop an interactive tool to provide a woman with her 5-y risk of developing invasive breast cancer	Women with no history of breast cancer, breast augmentation, or DCIS who had undergone at least 1 mammography	BCSC, SEER	Academic medical center, West (Pacific)	Gail[54] and proportional hazard models	Age, family history of breast cancer or DCIS, breast augmentation/ mastectomy, first-degree relatives with breast cancer, breast biopsy history, breast density	—	—	—	White, Black, Asian, Native American, Hispanic, other/ multiple races, unknown	-	5- and 10-y risk of developing invasive breast cancer	Health care providers	External[88,89]	—
BCSC Advanced Breast Cancer risk calculator[90,91a]	To develop an interactive Web-based tool to predict 6-y risk of developing breast cancer in women who have undergone annual or biannual screening	Women aged 40–74 y with no breast cancer history and a prior mammogram	BCSC, SEER	Academic medical center, West (Pacific)	Logistic regression models	Age, BMI, breast density, family history of breast cancer, history of breast biopsy, menopausal status	—	Screening interval (or 2 y)	—	Asian or Pacific Islander, Black, Hispanic, White, other/ multiracial	—	6-y cumulative advanced (prognostic stage II or higher)[92] breast cancer risk	Health care providers	Internal[90] External[93]	—
Cancer in the Family[94] (limited availability; accessible through screenshots in paper)	To develop a clinical decision tool to provide a woman with HBOC her calculated risk of breast cancer and genetic referral options	Women aged 21–60 y with no history of breast cancer	Three US primary care clinics: 2 clinics in Dallas, TX and 1 clinic in Fairfax, VA	Nonprofit research institute, South Atlantic	AI algorithm based on BRCAPRO[95] to calculate BRCA mutation risk and HBOC risk	Family history of breast and ovarian cancer	BRCA1/2	—	—	—	—	1. HBOC risk (risk scores >0.01 indicates "increased risk" for having a BRCA mutation 2. Screening recommendations based on personalized risk	Health care providers and women	Internal[94]	—
Family HealthLink[96,97a]	To improve upon a previous tool (JamesLink)[98] to provide an individual their predicted risk status for developing hereditary breast cancer and genetic consultation recommendations	Individuals who have a familial risk of breast cancer who could be at high risk of breast or cervical cancer	OSUWNC Stephanie Spielman Comprehensive Breast Center	Academic medical center, Midwest (East North Central)	Software algorithms based on published criteria[84,99,100]	Comorbidities, family history of breast cancer, history of colon polyps	—	—	—	American Indian or Alaskan native, Asian, Black/ African American, Hispanic or Latino, native Hawaiian or Other Pacific Islander, White, Ashkenazi Jewish decent	—	Breast cancer risk stratification (high, moderate, average risk)[84,99,100]	Health care providers and women	External[96,101,102]	Usability[103]
MammoScreen[104,105]	To improve upon previous tool (Mammopad)[106] developed and help women understand their personal breast cancer risk and screening options	Women at risk of developing breast cancer undergoing screening mammography	Women receiving a screening mammography at 1 of 3 clinics in Madison, WI	Academic medical center, West (Pacific)	B-RST 2.0[81,82]	Breast or ovarian cancer, current symptoms, family breast cancer history, prior breast biopsy, radiation	BRAC1/2	—	—	Ashkenazi Jewish	—	Positive screen (high risk), negative screen (low risk)	Health care providers and women	Internal, External[107]	Usability[104]
Stanford Decision tool[108,109a]	To develop a decision tool that guides cancer risk–reducing options for women with BRCA mutations	Women aged 25–69 y with BRCA mutations	Multiple data sources (observational data, clinical data trial, meta-analyses)	Academic medical center, West (Pacific)	CISNET breast model S	Age, future age of prophylactic mastectomy, future age of prophylactic oophorectomy, type of screening done	BRCA1/2	—	—	—	—	1. Breast cancer incidence: (cumulative cancer incidence to age 70 y, 10-y incidence of secondary primary breast tumor) 2. Overall survival to age 70 y 3. Cause-specific mortality	Health care providers and women	Internal[110]	Feasibility[111] Usability[111]
WISDOM (limited availability; accessible through screenshots in paper)[112]	To improve upon a previous tool (Breast HealthDecisions .org)[113] and provide a woman her predicted risk of breast cancer	High-risk women aged 40–74 ywith no history of breast cancer	BCDDP, BCSC, SEER	Academic medical center, West (Pacific)	Tailored risk assessment based on Gail,[54] BRCAPRO,[95] Claus,[75] BCSC[17]	Age, BMI, breast biopsy history, breast density, family history, menopausal status	ATM, BRCA1/2, CDH1, CHEK2, PALB2, PTEN, STK11, TP53	Alcohol intake	—	White, Black/ African American, Asian, Hispanic/ Latino/ Spanish origin, other	-	5- and 10-y and lifetime breast cancer risk	Health care providers and women	External[112]	Usability[112]

—, no information available; ACOG, American College of Obstetricians and Gynecologists; ACS, American Cancer Society; AHRQ, Agency for Healthcare Research; AI, artificial intelligence; BCDDP, Breast Cancer Detection Demonstration Project study; BCSC, Breast Cancer Surveillance Consortium; BRCA, breast cancer gene; B-RST, The Breast Cancer Genetics Referral Screening Tool; CISNET, Cancer Intervention and Surveillance Network; DCIS, ductal carcinoma in situ; HBOC, hereditary breast and ovarian cancer syndrome; NCI, National Cancer Institute; OSUWNC, Ohio State University Wexner medical center; SEERS, Surveillance, Epidemiology, and End Results; USPSTF, United States Preventative Services Task Force; WISDOM, Women Informed to Screen Depending on Measures of Risk.

[a]B-RST™ 3.0 was updated in 2023; BCSC 5-y Invasive Breast Cancer Risk Calculator was updated on July 17, 2015; Mammoscreen was updated in 2023; the Stanford Decision Tool was updated in December 2011.

[b]BCSC invasive was updated in November 2023 to include body mass index (BMI), second-degree of family breast cancer, and age at first live birth.

English-speaking women to better understand potential barriers to adopting risk-appropriate prevention strategies for breast cancer and the acceptance of these strategies. These discussions informed the iterative design of RealRisks. In addition, RealRisks was tested for usability among multiethnic English-speaking (14% non-Hispanic White, 71% non-Hispanic Black, 14% other) and Spanish-speaking patients to ensure the interface was accessible to users with various health literacy and backgrounds.[66] Patients were asked to complete the System Usability Scale (SUS) questionnaire,[114] a 10-item questionnaire that measures general usability on a total scale from 0 to 100. The tool received a "good" score (average 80; range, 55–95) among the English-speaking users and an "OK" score (average 67%; range, 55%–75%) among Spanish-speaking users. Overall, usability testing included White (31% range: 9%–71%) individuals with a college education or higher (41%; 27%–54%) (Supplementary Table S6).[49,61,66]

BreastCare[52,53] and RealRisks[62,63] explored the acceptability of these interventions. The acceptability of the BreastCare tool was assessed among high-risk women aged 40 to 74 y with no history of breast cancer.[55] Accordingly, 84% (n = 470) of women using the tool found the tool "very easy" to use, 82% (n = 459) found the tool questions "very easy" to understand, and most women (61%, n = 321) liked the breast cancer report "a lot." Physicians believed that the reports generated by the tool helped inform patients about their breast cancer risk (86%, n = 68) and encouraged them to discuss breast cancer risk with their patients (84%, n = 66).[55] BreastCare[52,53] included messages in English, Spanish, or Chinese and written in plain language to accommodate for individuals with varying demographic backgrounds. The acceptability for RealRisks[62,63] was assessed through semi-structured interviews consisting of a sample of mostly non-Hispanic (91%) White (71%) women, in which all women reported that the tool was acceptable.[67] BreastCare[52] was also assessed for feasibility.

Evidence of Uptake of Personalized Tools for Breast Cancer Prevention

We found 3 tools (out of 10), the Breast Cancer Risk Assessment Tool (BCRAT), Claus, and RealRisks that assessed the uptake of these tools in clinical practice settings.[62,64,122–130] Studies suggest that BCRAT and RealRisks tools have been directly embedded within electronic health record (EHR) systems in primary care clinics, academic medical centers, and outpatient clinics to prompt patient-provider discussions during a clinic visit.[64,122,123,127,129,130] A survey conducted by Park et al.[125] to assess the utilization of breast cancer risk assessment tools found that 86% (n = 215) of genetic counsellors with clinical practices in the United States had used the BCRAT tool to evaluate chemoprevention eligibility in women with a personal or family history of breast cancer.[125] Other reasons for use included surveillance (51%), magnetic resonance imaging eligibility (38%), insurance coverage of genetic testing (9%), and genetic testing eligibility (7%).[125]

By contrast, a survey conducted by Yadav et al[122] reported that the BCRAT tool was used by internal medicine residents only in 3.8% (n = 7/183) of their patients. Similarly, studies have found that only 25% of the primary care physicians routinely used the BCRAT tool to evaluate individual risk among women seen in their clinical practice.[124] The reasons for low usage were lack of familiarity with the tool, lack of confidence in their knowledge, and uncertainty about tool's ability to accurately assess risk.[124,131,132] Similar findings were evident among nurse practitioners. For example, a survey conducted by Edwards et al.[126] reported that only 6.5% (n = 4/62) of nurse practitioners had used the BCRAT or Claus tools to assess a women's risk of breast cancer in a clinical setting. In addition, more than 95% (n = 147/155) of the nurse practitioners were unable to identify the use of the Claus model to assess a women's breast cancer risk, and 71% of nurse practitioners reported low comfort levels when administering breast cancer risk assessment tools to patients.[126]

Several studies explored the uptake of the RealRisks tool in clinical settings.[64,128,130] Kukafka et al.[64] found that the use of the RealRisks tool increased the accuracy of breast cancer risk perceptions and chemoprevention knowledge in high-risk women after a clinical encounter with a primary care physician. However, the primary care physicians referred less than half of the women for further high-risk consultations despite the women expressing interest in taking chemoprevention after using the RealRisks tool.[64,129] An attempt to increase the uptake of the RealRisks tool in clinical settings is also potentially evident in a study conducted by McGuinness et al.[128] This study explored the impact of missing information in EHR data on automated risk calculations provided by the RealRisks decision tool. The researchers found that EHR data often did not provide sufficient information on family history of cancer, gynecologic history, or history of genetic counseling testing, which were needed to calculate risk using the RealRisks tool. As a result, a new update of the RealRisks tool is considering the use of

Table 3 Summary of the Usability, Feasibility, and Acceptability Testing of Prevention and Screening Tools

Tool Name	Purpose	Surveys and Study Design	Study Population	Environment of Tool Testing	Outcome(s)	Results
Prevention						
BreastCare[52] (Feasibility)	To evaluate the efficacy of BreastCare in primary care settings among physicians and patients	Pre- and postintervention survey[a]	1. Patients aged 40 to 74 y who spoke English, Spanish, or Chinese with no individual history of breast cancer 2. Primary care physicians	Two general medicine primary care practices in the San Francisco Bay area	Patient-provider discussion of patient breast cancer risk, family cancer history, high-risk clinics, genetic counseling/ testing	Increase in patient-provider discussions about family history (OR, 4.15; 95% CI, 3.02–5.70), referrals to high-risk clinics (OR, 3.84; 95% CI, 2.13–6.95), and genetic counseling/testing (OR, 2.22; 95% CI, 1.34–3.68)
BreastCare[52] (Acceptability)	1. To evaluate the acceptability of the BreastCare tool among patients and physicians 2. To examine if there is a difference in satisfaction among patients and physicians based on race/ ethnicity and physician type	Pre- and postsurvey[a] assessed using a 4-point Likert scale	1. Patients aged 40 to 74 y who spoke English, Spanish, or Chinese with no individual history of breast cancer 2. Primary care physicians	Two general medicine primary care practices in the San Francisco Bay area	Satisfaction, preferences, acceptability of implementation into routine care	1. 84% (n = 470) found the tool "very easy" to use, 82% (n = 459) reported that the questions were "very easy" to understand, and 61%, (n = 321) liked the breast cancer report "a lot" 2. 86% of physicians felt that the reports helped inform patients about their breast cancer risk (n = 68), and 84% were encouraged to discuss breast cancer risk with their patients (n = 66) 3. Hispanic women were more likely than non-Hispanic White women to report liking the tool "a lot" (OR = 2.04, 95% CI: 1.05–3.96) 4. Residents were more likely than physicians/ NPs to find the tool helpful in communicating breast cancer risks to patients (n = 38, 97% v. n = 25, 69%, P = 0.004)

(continued)

Table 3 (continued)

Tool Name	Purpose	Surveys and Study Design	Study Population	Environment of Tool Testing	Outcome(s)	Results
Imagine Health[61] (Usability)	To explore the effectiveness of unique combinations of 3 risk communication strategies (i.e., risk reduction information, numerical format, and social comparison information) in calculating the risk of 4 diseases (colon cancer, stroke, diabetes, and heart disease) associated with physical inactivity	Pre- and postintervention questionnaire[a] assessed using 4-point unipolar scales	1. English-speaking adults aged 30–65 y who meet current aerobic activity guidelines 2. ≥50% of sample had no more than 50% vocational-technical training 3. ≥50% of sample was racial/ethnic minority	GFK KnowledgePanel	1. Physical activity behavior 2. Message comprehension,[115] message acceptance,[116] absolute and comparative cognitive perceived risk,[117] absolute and comparative feelings of risk,[118] response-efficacy, worry,[117] anticipated regret,[119] and intentions	1. Individuals who received risk reduction information had higher acceptance scores ($\bar{x}$ = 3.04, SE = 0.04) than those who did not ($\bar{x}$ = 2.92, SE = 0.04) (n = 185) 2. Individuals who did not receive social comparison information ($\bar{x}$ = 3.03, SE = 0.04) had higher acceptance than those who were told they were at higher-than-average risk ($\bar{x}$ = 2.92, SE = 0.03) (n = 185)
RealRisks[62] (Usability)	To evaluate the tool among a focus group of English-speaking women to better understand potential barriers to adopting risk-appropriate prevention strategies for breast cancer and acceptance of those strategies	1. Pre- and postintervention self-administered questionnaire[a] assessed using a 7-point Likert scale 2. Mixed methods to assess accuracy	English-speaking women aged 18 + y residing in Northern Manhattan, NY	Community Engagement Core Resource of the Irving Institute for Clinical and Translational Research database	Demographics, numeracy,[120] Internet access, sources of information, and breast cancer risk at baseline	1. Out of 34 participants, 41% demonstrated low numeracy 2. Accuracy of perceived risk (ranged from 0%–100%) improved from pre- to postintervention (52% to 70%; P = 0.10) 3. Qualitative responses documented for 3 themes identified regarding barriers to adopting risk prevention strategies: uncertainty about breast cancer risk and risk models, distrust toward the health care system, rationing access to care perceptions about risk assessments

(continued)

Table 3 (continued)

Tool Name	Purpose	Surveys and Study Design	Study Population	Environment of Tool Testing	Outcome(s)	Results
RealRisks[66] (Usability)	To understand how individuals understand and engage with the information presented in RealRisks tool	SUS[114]	7 English-speaking and 4 Spanish-speaking women	Database of women who had undergone routine screening mammography	Content, ease of use, and navigability	The tool received a "good" score (median 80.00; range, 55.00–95.00) among the English-speaking users (n = 7) and an "OK" score (66.30; range, 55.00–75.00) among Spanish-speaking users (n = 4); overall satisfaction was moderate to high among users (n = 11)
RealRisks[67] (Acceptability)	To understand user perceptions of the tool	Qualitative study consisting of semi-structured interviews	Women at high risk for breast cancer	Randomized controlled trial of 300 high-risk women	1. Acceptability of the intervention 2. Elements of decision aid 3. Recommendations for improvement 4. Degree to which tool meets information needs	1. Women enrolled in the study (n = 21) reported the tool to be helpful and acceptable (100%), easy to navigate (62%), and increased their knowledge on breast cancer risk and chemoprevention options (43%) 2. Nine women (43%) felt that the tool could improve in its design, and terminology
Screening						
Family HealthLink[103] (Usability)	To assess the impact of the tool's design and message content on user perceptions	Interviews with qualitative themes and specific research aims	1. Female breast cancer patients 2. Male and female patient support persons	Midwestern comprehensive breast center	1. Design: user interface, visual aspects, tool name 2. Content: terminology, risk terms, risk assessment, sharing	1. Qualitative experiences among users (n = 34) revealed overall positive experience regarding ease of use, with some suggestions for improvement in color, functionality, clarity of medical terminology, and data entry of the tool

(continued)

Table 3 (continued)

Tool Name	Purpose	Surveys and Study Design	Study Population	Environment of Tool Testing	Outcome(s)	Results
MammoScreen[104] (Usability)	To measure the uptake, completion, ease of use, navigability, and completion of MammoScreen	Semi-structured telephone interviews with patients and clinical team to identify qualitative themes	1. English-proficient women aged 40–74 y with no previous diagnosis of breast or ovarian cancer enrolled in Epic MyChart patient portal 2. Clinical team members including internal medicine physicians and a medical assistant	General internal medicine clinic at an academic medical center	1. Uptake and completion rates 2. Patient and physician experience	1. Out of 448 participants, 75.7% (n = 339) read MyChart invitations, and 36.9% (n = 125) of those who read their invitations enrolled 2. 94.4% (n = 118) of participants completed MammoScreen 3. All patients (n = 8) and health care providers (n = 3) randomly selected for a telephone interview believed MammoScreen to be "highly intuitive and easy to navigate" and beneficial to patients
Stanford Decision Tool[111] (Usability and Feasibility)	To observe the ease of use, general satisfaction, clinical relevance, and ability to promote patient-doctor encounters of the tool among patients and clinicians	1. SUS[114] 2. CHCEPSQ[121]	1. Women with BRCA1/2 mutation carriers 2. Clinicians involved in the care of women with BRCA1/2 mutations	1. Stanford Hospital and community practices within the area 2. Stanford Breast Oncology Program or Clinical Cancer Genetics Program 3. FORCE	Ease of use, content, interface, visual aspects, influence on decision making	1. Both patients (n = 40) and clinicians (n = 16) found the tool to be easy to use (82.5–85 on a scale of 1–100) and were generally satisfied (mean score 4.28 and 4.38 for on a scale of 1–5), respectively 2. Most patients (77.5%; n = 31) reported comfort using the tool at home 3. Both patients and clinicians noted that the tool could improve patient-provider encounters (mean scores 4.50 and 4.69, on a 1–5 scale), respectively

(continued)

Table 3 (continued)

Tool Name	Purpose	Surveys and Study Design	Study Population	Environment of Tool Testing	Outcome(s)	Results
WISDOM[112] (Usability)	To collect feedback from participants to examine if the tool improved their understanding of their personalized breast cancer risk, motivation to reduce their risk, and consideration for lifestyle interventions	Pilot test using a post-WISDOM Study Breast Health Questionnaire[112]	17 women aged 40 and 74 y with elevated risk without breast cancer mutation	WISDOM study participants	1. Quantitative measures about helpfulness, understanding, risk reduction steps, and motivation 2. Qualitative written feedback	1. Out of 17 participants, 14 were surveyed and all reported a better understanding of their breast cancer risk after using the tool 2. Out of 14 participants, 10 felt that they were "extremely motivated" or "very motivated" to reduce their breast cancer risk after using the tool

CHCEPSQ, Center for Healthcare Evaluation Provider Satisfaction Questionnaire; CI, confidence interval; FORCE, Facing Our Risk of Cancer Empowerment; *n*, number of participants; NP, nurse practitioner; OR, odds ratio; SE, standard error; SUS, Systems Usability Scale; WISDOM, Women Informed to Screen Depending On Measures of risk; $\bar{x}$, mean.

[a]Name of survey/scale not available.

both self-reported and populated data from the EHR system to inform automated risk calculations.[128]

Personalized Tools for Breast Cancer Screening

These tools were developed for average or high-risk women[17,81,85,90,94,96,104,108,112] or men[96] with no history of breast cancer.[17,81,85,90,94,96,104,108,112] Two tools were developed for use by only health care providers,[17,90] and 7 tools were developed for both providers and patients.[81,85,94,96,104,108,112] Six tools were developed in academic medical centers,[17,90,96,104,108,112] 1 in a nonprofit research institute,[94] and 2 in government agencies.[81,85] One tool was developed in the Midwest,[96] 5 in the West,[17,90,104,108,112] and 3 in the South Atlantic regions of the United States.[81,85,94]

The tools provided breast cancer risk estimates for 5, 6, and 10 y[17,90,112] and lifetime.[112] The Stanford Decision Tool[108,109] was the only tool that provided lifetime breast cancer outcomes associated with breast cancer screening and prevention strategies (e.g., mammogram ± magnetic resonance imaging, prophylactic oophorectomy/mastectomy) for women with BRCA1/2 mutations.

The tools included family medical history of cancer,[17,81,85,90,94,96,104,112] age,[17,90,108,112] body mass index,[90,112] history of breast biopsy,[17,90,104,112] breast density,[17,90,112] menopausal status,[90,112] family history,[17,81,85,90,94,96,104,112] comorbidities,[96] current breast symptoms,[104] history of radiation,[104] and breast augmentation or mastectomy[17,108] as predictors of breast cancer risk. Six tools also included genomic characteristics.[81,85,94,104,108,112] Health behaviors considered in the tools were screening interval (1 or 2 y)[90] and alcohol intake.[112] The tools also included race and ethnicity categories such as African American/Black, American Indian/Alaskan Native, Asian, Caucasian/White, Hispanic/Latinx, Native Hawaiian/Pacific Islander, other or multiracial, and Ashkenazi Jewish.[17,81,85,90,96,104,112] However, no tool considered contextual inputs.

Five tools were internally validated,[81,90,94,104,108] and 6 tools were externally validated.[17,85,90,96,104] Mammoscreen[104,105] and BCSC advanced risk calculator[90,91] were both internally and externally validated. The tools were validated mostly among married (median 73%; range, 64%–79%), insured (89%; 60%–90%), White women (90%; 5%–99%), with a college education or higher (54%; 16%–100%) and an income of >$75,000 (37%; 2%–84%) (Supplementary Table 6).[17,81,85,90,94,96,104,112]

Usability, Feasibility, and Acceptability Testing for Breast Cancer Screening Tools

Four tools for breast cancer screening had undergone usability, feasibility, and acceptability testing with patients, clinical subject matter experts, and health care professionals (Table 3).[96,104,112] All tools were tested in academic settings. The usability of the Family HealthLink tool was assessed through a semi-structured interview administered to breast cancer patients (n = 16) and support persons (n = 18) at an academic breast cancer center.[103] Overall, the tool users (n = 34) reported a positive experience regarding the ease of use and design of the tool. The suggestions for tool improvements included color choice, functionality, and clarity of medical terminology.[103] The Stanford Decision Tool[108] reported usability and feasibility testing using the SUS and the Center for Healthcare Evaluation Provider Satisfaction Questionnaire.[121] Patients and clinicians reported ease of use of the tool with high SUS scores of 83 to 85. General satisfaction was 4 for patients and clinicians on a scale of 1 to 5 (1 = *least satisfied*, 5 = *most satisfied*). The patients included in the usability and feasibility testing consisted of mostly White women (median: 94%; range: 88%–96%), with a college education or higher (80%; 60%–100%) who were insured (100%) (Supplementary Table 6). No tool reported acceptability testing.

Evidence of Uptake of Personalized Tools for Breast Cancer Screening

A cross-sectional study conducted by Eden et al.[104] reported a high percentage (94%; 314/339) of use of the MammoScreen clinical decision tool among women aged 40 to 74 y, without a history of breast or ovarian cancer, seen at an academic medical center. Moreover, studies suggest that the B-RST 2.0 tool received a state issuance of an education and surveillance policy by the State of Georgia, which aimed to incorporate the screening tool into clinical practice within 9 public health districts across the state.[133,134] Accordingly, Brannon Traxler et al.[134] developed an intervention to educate clinical staff and high-risk women about the B-RST 2.0 tool. Following the intervention, the tool was used in 2,159 individuals, and 130 (6.0%) women with a positive B-RST screen were identified for additional screening and genetic testing.[134]

Studies also indicate that the BCSC invasive,[135] Family HealthLink,[96] and MammoScreen[104] tools have been integrated into EHR systems at academic clinical centers. However, there is limited knowledge on the dissemination, integration, and sustained uptake of these tools at safety net hospitals and federally qualified health centers (FQHCs). Studies also report barriers to uptake such as incomplete or missing EHR patient data needed for breast cancer risk assessment. A study conducted by Jiang et al.[135] found that race, ethnicity, first-degree family history, and previous breast biopsies were often missing in EHR data and that the inclusion of self-reported data collection in the EHR could improve overall tool performance.[135]

Quality Assessment

According to the IPDASi[42] checklist, the average score for the prevention and screening interactive decision tools was 21 (range 9–39; Table 4). The Women Informed to Screen Depending on Measures of Risk (WISDOM)[112] and the RealRisks[62] tools received a score of 39 and 38 out of 63, respectively. The WISDOM tool provided a detailed description of study characteristics based on clinical data and insights from a multidisciplinary team of experts in the development and presentation of tailored risk portfolios and screening options for patients.[112] The RealRisks tool used stories to guide patients in the decision-making process.[62] Only 5 tools presented risk estimates in a variety of different formats such as numbers, categories, or visual or pictorial depictions.[17,59,96,104,112]

Key Strengths and Weaknesses of Interactive, Personalized, Web-Based Clinical Decision Tools

The Web-based decision tools were validated (internally, externally, or both) and provided sufficient information on the purpose, target audience, and clinical and individual characteristics used to predict breast cancer incidence (Table 5). Key weaknesses included lack of contextual factors and limited information on the validation, usability, acceptability, feasibility testing, integration, and uptake of the tools in diverse populations in nonacademic settings including safety net hospitals or FQHCs.

Discussion

Previous reviews have evaluated personalized and interactive Web-based clinical decision tools in breast cancer treatment,[23,129] screening,[14,129] and prevention[128,129]; however, these studies have provided limited information on usability, feasibility, acceptability testing, integration,

Table 4 Results from the Quality Assessment of the Interactive, Web-Based Clinical Decision Tools for Personalized Breast Cancer Treatment Using the International Patient Decision Aids Standards instrument (IPDASi) Checklist[42]

Tool	Information about Options (0–13)	Outcome Probabilities (0–9)	Clarifying Values (0–3)	Decision Guidance (0–3)	Presenting Information (0–2)	Development Process (0–7)	Using Evidence (0–6)	Disclosure and Transparency (0–2)	Plain Language (0–3)	Internet Based (0–5)	Story Usage (0–3)	Decision Processes (0–6)	Decision Quality (0–1)	Total (0–63)
Prevention														
Ask2Me[43]	5	5	0	0	0	4	3	0	1	2	0	0	2	22
BCRAT[54]	2	6	0	0	0	4	4	0	1	4	0	0	0	21
BBD[49]	2	5	0	2	0	2	3	0	2	3	0	1	0	20
BreastCARE[52]	4	1	0	2	0	2	1	0	1	4	0	0	0	15
BWHS[46]	1	6	0	0	0	2	3	0	2	3	0	0	0	17
Health-risk prediction tool for postmenopausal women[56]	0	5	0	0	0	0	0	0	1	2	0	1	0	9
Imagine Health[59]	5	6	0	1	1	3	0	0	3	2	0	2	0	23
The Claus Model[75]	3	3	0	0	0	4	0	0	1	2	0	0	0	13
RealRisks[62]	7	6	1	2	0	4	3	1	3	5	1	4	1	38
Your Disease Risk[79]	5	3	0	0	0	3	0	0	1	4	0	0	0	16
Screening														
B-RST 2.0[81]	4	0	0	0	0	3	2	1	1	4	0	0	0	15
B-RST 3.0[85]	5	4	0	1	0	3	4	1	2	4	0	3	0	27
BCSC Invasive Breast Cancer Risk Calculator[17]	6	4	0	0	1	2	5	1	2	4	0	0	0	25
BCSC Advanced Breast Cancer Risk Calculator[90]	5	6	0	1	0	3	4	0	2	5	0	2	0	28
Cancer in the Family[94]	3	2	0	3	0	2	0	0	0	5	0	0	0	15
Family Health*Link*[96]	5	0	0	2	2	3	1	0	1	4	0	0	0	18
MammoScreen[104]	6	4	0	1	1	4	2	1	2	4	0	2	0	27
Stanford Decision Tool[108]	4	7	0	0	0	1	3	1	1	2	0	0	0	19
WISDOM[112]	6	6	1	2	1	6	5	0	2	5	0	5	0	39

BCRAT, Breast Cancer Risk Assessment Tool; BCSC, Breast Cancer Surveillance Consortium; BBD, benign breast disease; B-RST, The Breast Cancer Genetics Referral Screening Tool; BWHS, Black Women's Health Study; WISDOM, Women Informed to Screen Depending on Measures of risk.

Note. The meaning behind the items from the IPDASi checklist.[42]

Information about options: The tool describes the health condition, lists the options, lists the option of doing nothing, describes the natural course without options, describes procedures, describes positive/negative features, includes the chances of positive/negative outcomes, describes what the test is designed to measure, includes the changes of true-positive/true-negative/false-positive/false-negative test results, describes possible next steps based on test results, includes chances the disease is found with/without screening, and describes detection/treatment that would never have caused problems if one were not screened.

Outcome probabilities: The tool uses event rates specifying the population and time period, compares outcome probabilities using the same denominator, describes uncertainty around probabilities, uses visual diagrams, uses multiple methods to view probabilities, allows users to select the way of viewing probabilities, allows users to view probabilities based on their own situation, places probabilities in context of other events, uses positive and negative frames.

Clarifying values: The tool describes procedures and outcomes to help patients imagine what it is like to experience their physical, emotional, and social effects; asks patients to consider which positive and negative features matter most; and suggests ways for patients to share what matters most with others.

Decision guidance: The tool provides steps to decide, suggests ways to talk about the decision with a health professional, and includes tools to discuss options with others.

Presenting information: The tool can compare positive/negative features of options and shows negative/positive features with equal detail.

Development process: The tool includes developers' credentials/qualifications, finds out what users need to discuss options, has peer review by patient/professional experts not involved in development and field testing, is field tested with users, is acceptable, is balanced for undecided patients, and is understood by those with limited reading skills.

Using evidence: The tool provides references to evidence used; reports steps to find, appraise, and summarize evidence; reports date of last update; reports how often the patient decision aid is updated; describes the quality of scientific evidence; and uses evidence from studies of patients similar to those of target audience.

Disclosure and transparency: The tool reports sources of funding to develop and distribute the patient decision aid and reports whether authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aid.

Plain language: The tool is written at a level that can be understood by most patients in the target group, is written at a grade 8 equivalent level or less according to the readability score, and provides ways to help patients understand information other than reading.

Internet based: The tool provides a step-by-step way to move through the Web pages, allows patients to search for keywords, provides feedback on personal health information that is entered into the patient decision aid, provides security for personal health information entered into the decision aid, makes it easy for patients to return to the decision aid after linking to other Web pages, and permits printing as a single document.

Story usage: The tool uses stories that represent a range of positive and negative experiences, reports if there was a financial or other reason why patients decided to share their story, and states in an accessible document that the patient gave informed consent to use their stories.

Decision processes: The tool helps patients to recognize that a decision needs to be made, know options and their features, understand that values affect decisions, be clear about option features that matter most, discuss values with their practitioner, and become involved in preferred ways.

Decision quality: The tool improves the match between the chosen option and the features that matter most to the informed patient.

Table 5 Key Strengths and Weaknesses of Current Web-Based Clinical Decision Tools

Strengths	Weaknesses
• All tools were externally or internally validated • All tools clearly described the purpose • Stated target audience—whether the tool was designed for patients or providers or both • Included a wide variety of clinical and individual characters to predict breast cancer incidence • Used plain language/easily understood by target user	• Tools did not include contextual factors (e.g., insurance, education) • Lack of validation and testing of the tools in non-White, uninsured, or populations with less than high school education • Limited usability, acceptability, feasibility testing, and evaluations of uptake among diverse populations and non-academic clinical settings • Limited information on how to incorporate patient values and preferences for breast cancer prevention and screening

and uptake of these tools in real-world settings.[16,136,137] A recent review by Enard et al.[137] evaluated the inclusion of health literacy and insurance status in the development of cancer-related patient decision aids in socially disadvantaged populations. In contrast, we focused on a broader range of characteristics including individual, clinical, behavioral, and contextual factors that could potentially guide breast cancer prevention and screening decisions in clinical practice. Moreover, we evaluated the inclusion of diverse populations and settings in clinical tool validation and testing. To our knowledge, this is the first study to provide a detailed evaluation of the Web-based decision tools available for breast cancer prevention and screening considering contextual factors, characteristics of tool testing, and uptake of these tools.

We found 19 Web-based clinical decision tools that could inform personalized breast cancer screening and prevention decisions in primary care settings. Most tools incorporated age (13/19), race and ethnicity (14/19), family history of breast and/or ovarian cancer (16/19), and patient medical history (10/19) as input characteristics to predict breast cancer incidence. However, few considered health behaviors (6/19), and none considered contextual factors associated with breast cancer risk (e.g., access). Contextual factors such as insurance, income, and economic stability are associated with disparities in breast cancer care and outcomes.[138–142] For example, individuals with low economic stability (e.g., low income, unemployment) are less likely to pursue frequent care if they are unable to afford a leave of absence from work or screening services.[139] Studies have shown that a delay in or inability to access care are associated with late-stage diagnoses and worse survival.[138–142] There is a need for novel clinical decision tools that could facilitate clinical discussions considering contextual factors that also contribute to individual health outcomes. In addition to economic stability, other contextual factors may also include limited health care insurance, access to fresh fruits and vegetables, travel distance to the nearest health care facility, and access to green spaces for exercise and physical activity.[41] Clinical tools could address these factors by including additional resources on referrals for neighborhood health programs (e.g., exercise programs, food delivery services), contact details of patient navigators and care coordinators, neighborhood transportation services, and insurance navigation programs. These features could potentially help health care providers offer greater support to their patients by engaging in conversations to address patient needs, refer them to services, and facilitate access to these services within their neighborhoods. Moreover, the inclusion of contextual factors into a provider-facing clinical decision tool could also potentially help increase awareness, research, and advocacy among health care providers to address broader contextual factors (e.g., income, education, housing) contributing to health disparities.[41,143] The consideration of numeracy and health literacy in the development of clinical decision tools could potentially help increase tool accessibility among patients from diverse backgrounds. Recent tools developed to address contextual factors[27,144] include a tool consisting of low-income resources in the region that health care providers could share with their eligible patients.[145] However, there is insufficient evidence on the use of contextual factors as inputs for risk prediction in clinical decision tools.

While all tools included in our analysis were validated, the validation samples were mostly White, educated, and/or insured. Tool validation provides critical information on a tool's ability to accurately estimate various outcomes of interest in diverse patient cohorts.[146] Studies have shown that tool performance may vary based on the distributions of individual, clinical, and contextual

characteristics in diverse cohorts.[147] Therefore, limited representation in validation samples could limit the applicability and effectiveness of these tools in real-world settings.[148] Importantly, using tools that are unable to generate accurate estimates for certain subgroups of the population could perpetuate disparities in cancer care and outcomes.

Overall, there was limited evidence on the usability, feasibility, and acceptability testing of these tools. We found that fewer tools underwent usability (6/19), acceptability (2/19), or feasibility (2/19) testing. The tools included in our study were primarily developed and tested in academic settings. Usability testing could help identify and fix problems with website/mobile applications of the tools.[149] During usability testing, tool developers could assess the tools' ease of use and the presentation of information considering health literacy and numeracy.[150,151] In our analysis, the individuals included in usability testing of the tools were mostly White and insured with some college education or higher. Educational attainment has been shown to be associated with health literacy,[24] and studies have shown that tools that do not consider health literacy are difficult to use and are often neglected by patients despite its utility.[152] Therefore, in future studies, including individuals with different levels of education and health literacy in usability testing could potentially enhance the uptake of these tools.[149–151]

There was limited evidence on the uptake of these tools in real-world clinical settings. Health care providers' lack of knowledge about these tools,[122,123,129,153] patients' limited knowledge of their personal risk,[154–157] low health literacy and numeracy, language barriers,[62,129,158] time constraints,[127,129] and health care distrust[159] may have contributed to the limited uptake. Moreover, the tools included in our study were mostly developed and tested in academic settings. There were limited data on the development, testing, and sustained uptake of these tools in nonacademic clinical settings including safety net hospitals, and FQHCs.

Limitations

Four tools were visible only through screenshots, thus limiting our ability to fully assess the quality of the tools. In addition, we were unable to identify the date of the last update for most of the tools, which was necessary to understand the relevance of the decision tool within the current literature. Finally, there were no standards or criteria available to assess the use of the tools in diverse settings. Therefore, we individually assessed race, ethnicity, education, insurance, and income distributions of the samples included in tool testing.

Conclusion

There are several Web-based clinical decision tools to support breast cancer prevention and screening decisions in clinical practice. These tools could facilitate shared decision making between patients and physicians, reduce patient anxiety, and help clarify patients' personal preferences and values. The development, validation, and testing of clinical tools in diverse populations and settings may improve usability, uptake, and equitable access to these tools.

Author Contributions

Conception or design: JJ, DK, LS, KW, JZ
Screening: DK, LS, KW, JZ
Data extraction: DK, LS, KW, JZ
Acquisition, analysis, and interpretation of data: All
Drafting the work or revising it critically for important intellectual content: All
Final approval of the version to be published: All
Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: All

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