BMC Medical Informatics and Decision Making

RESEARCH

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Use of web-based decision support to improve informed choice for chemoprevention: a qualitative analysis of pre-implementation interviews (SWOG S1904)

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Abstract

Background Women with high-risk breast lesions, such as atypical hyperplasia (AH) or lobular carcinoma in situ (LCIS), have a 4- to tenfold increased risk of breast cancer compared to women with non-proliferative breast disease. Despite high-quality data supporting chemoprevention, uptake remains low. Interventions are needed to break down barriers.

Methods The parent trial, MiCHOICE, is a cluster randomized controlled trial evaluating the effectiveness and implementation of patient and provider decision support tools to improve informed choice about chemoprevention among women with AH or LCIS. For this pre-implementation analysis, 25 providers participated in semi-structured interviews prior to accessing decision support tools. Interviews sought to understand attitudes/beliefs and barriers/facilitators to chemoprevention.

Results Interviews with 25 providers (18 physicians and 7 advanced practice providers) were included. Providers were predominantly female (84%), white (72%), and non-Hispanic (88%). Nearly all providers (96%) had prescribed chemoprevention for eligible patients. Three themes emerged in qualitative analysis. The first theme describes providers' confidence in chemoprevention and the utility of decision support tools. The second theme elucidates barriers to chemoprevention, including time constraints, risk communication and perceptions of patients' fear of side effects and anxiety. The third theme is the need for early implementation of decision support tools.

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Conclusions This qualitative study suggests that providers were interested in the early inclusion of decision aids (DA) in their chemoprevention discussion workflow. The DAs may help overcome certain barriers which were elucidated in these interviews, including patient level concerns about side effects, clinic time constraints and difficulty communicating risk. A multi-faceted intervention with a DA as one active component may be needed.

Trial registration This trial was registered with the NIH clinical trial registry, clinicaltrials.gov, NCT04496739.

Background

Breast cancer is the most common malignancy among women in the United States [1]. Women with high-risk benign breast lesions, such as atypical hyperplasia (AH) and lobular carcinoma in situ (LCIS), have up to a 4- to tenfold increased risk of breast cancer compared to women with non-proliferative breast disease [2]. Chemoprevention with selective estrogen receptor modulators (SERMs) (*i.e.,* tamoxifen and raloxifene) and aromatase inhibitors (AIs) (*i.e.,*anastrozole and exemestane) is effective. Large-scale randomized controlled trials (RCTs) have shown breast cancer incidence is reduced by up to 50–65% among high-risk women, with relative risk reduction of 70–80% among women with AH or LCIS [3–7]. Low-dose tamoxifen has been shown to similarly reduce risk while improving tolerance [8]. Yet, uptake of breast cancer chemoprevention remains low, with rates ranging from less than 1 to 24% [9–13].

Significant barriers to uptake of chemoprevention include inadequate time for counseling, insufficient clinician and patient knowledge about breast cancer chemoprevention, and side effects [11, 14, 15]. In our prior qualitative work, patients described a desire for tailored and holistic approaches to reducing breast cancer risk [16]. Padamsee et al.found that amongst a population of high risk women, only 45% were aware of chemoprevention options, with those who were aware expressing significant reluctance related to potential side effects, perceived extremeness and hesitancy of taking medications in general [17]. Additionally, in a questionnaire-based survey of women diagnosed with AH, LCIS or ductal carcinoma in situ (DCIS), Trivedi et al.found that there was a strong interest in learning more about chemoprevention with 78.6% of participants indicating that they would like to learn more about chemoprevention drugs in the future [18]. Importantly, while barriers exist, several studies have shown that physician recommendation and effective communication influence uptake of chemoprevention [12, 19, 20], therefore, emphasizing the need to consider provider-level barriers in addition to patient-level barriers to address low uptake of chemoprevention.

We developed web-based decision support tools, *RealRisks* for high-risk women and *BNAV* (Breast cancer risk NAVigation tool) for providers (Supplementary Fig. 1) [21–24]. The patient-facing web-based *RealRisks* decision aid (DA) provides general education in graphic novel format and slide presentations and is organized into modules: 1) Breast cancer risk; 2) Family History and Genetic Testing; 3) Chemoprevention; 4) Lifestyle Behaviors. Within *RealRisks,*information is collected on breast cancer risk factors, including family history, in order to calculate 5-year and 10-year absolute invasive breast cancer risk according to the Breast Cancer Surveillance Consortium (BCSC) risk calculator, version 2 [25]. Upon completion of *RealRisks,* an action plan is generated summarizing the patient's personalized breast cancer risk profile and preference elicitation for chemoprevention. On the provider end, the *BNAV* tool includes educational modules on breast cancer risk, genetic testing, screening, chemoprevention, and patient-centered care, and a patient dashboard with a summary of their patient's breast cancer risk profile based upon her interactions with *RealRisks* [24, 26]. We implemented these tools among high-risk women identified during screening mammography and in primary care [27]. After using these tools, we demonstrated an improvement in accurate breast cancer risk perceptions, chemoprevention knowledge, and informed choice; however, exposure to the tools did not significantly increase chemoprevention uptake [27, 28]. Given that targeting high-risk women or primary care providers (PCPs) alone may not increase chemoprevention delivery, our objective in this trial is to expand the use of this multilevel intervention to high risk women with AH or LCIS, who may benefit most from intervention [29].

In this ongoing trial entitled MiCHOICE (Making Informed Choices Incorporating Chemoprevention into carE), we are leveraging the clinical trials infrastructure of the National Cancer Institute (NCI) Community Oncology Research Program (NCORP). The pre-implementation phase has the potential to refine implementation strategies and contextualize implementation outcomes using a basic convergent design within an intervention mixed-methods framework [30]. Within this pre-implementation study, mixed methods are used to assess characteristics related to the organizational environment, perceived barriers/facilitators, potential adaptions, pros/cons of each intervention aspect, organizational support for and comfort with aspects of patient

engagement, and the "primed patient" (exposure to *RealRisks*). The overarching goal of MiCHOICE is to address important barriers to chemoprevention uptake. The current study aimed to assess provider-perceived barriers to chemoprevention uptake and, specifically, how decision support tools may address these barriers.

Methods

Study Procedures

The MiCHOICE trial is a cluster randomized trial targeting women with high-risk benign breast lesions and clinicians, including PCPs and specialists (breast surgeons, medical oncologists, gynecologists). The trial was designed to enroll 415 patients and 200 healthcare providers and was activated in September 2020. As of June 14, 2024, 210 healthcare providers have been enrolled, and 412 patients out of the total target accrual of 415 have been enrolled [24]. The Site Principal Investigator (PI) obtained the permission of providers interested in enrolling to the study to share their contact information. The NCI Central Institutional Review Board (CIRB) approved the trial. Following the identification of eligible providers, research staff at Columbia University Irving Medical Center (CUIMC) obtained informed consent and administered an online questionnaire that collected information on demographics, professional and practice characteristics, use of breast cancer risk assessment tools, and chemoprevention prescribing patterns. The questionnaire also assessed provider confidence in medical statistics and risk communication [31].

For this qualitative study, a subset of providers randomized to the intervention group were invited via email to participate in pre-implementation semi-structured interviews. Twenty-five providers were interviewed based on the literature which suggests data saturation to occur after 12–20 interviews [32–34]. Interviews assessed implementation processes, including identifying barriers and facilitators in the discussion and implementation of chemoprevention. The role-based interview guide was informed by the Consolidated Framework for Implementation Research (CFIR) [35], a meta-framework that provides a menu of constructs associated with effective implementation, and developed for this study. The interview questions probe: 1) the intervention, 2) inner setting, 3) outer settings, 4) individuals involved and 5) the process for sustaining the chemoprevention intervention following study completion.

The CFIR-guided interviews (Supplementary Table 1) were conducted using Zoom videoconferencing. Audio recording of the interviews enabled subsequent coding of primary themes. Clinicians completed one-on-one 45-to 60-min CFIR guided video interviews (Supplementary Table 1) with a team member (JA). Interviews were audio-recorded with permission and transcribed. Consolidated Criteria for Reporting Qualitative Research (COREQ) were used to guide the methodologic approach [36].

Data Analysis

Descriptive statistics were generated to compare baseline characteristics of the total study population of healthcare providers enrolled in the parent MiCHOICE trial and the subset of providers enrolled in the pre-implementation interview study. Two-sample t-tests and chi-squared tests were used to compare continuous and categorical variables, respectively.

Transcribed and deidentified data were analyzed using ATLAS.ti software. Data analyses were performed using inductive thematic analysis, whereby the researchers immersed themselves in the interview transcripts to identify themes that emerged from the participant responses [37]. Two coders (HY and JA) met weekly to review the transcripts and to develop the codebook, with researchers generating the codes inductively [37–40]. Notably, HY (MPA) was a doctoral candidate in health education and a certified ATLAS.ti consultant with several years of experience in qualitative research, and JA had a Masters of Public Health degree with training in qualitative data analysis and also served as project manager. Initially, the coders (HY and JA) coded the 2 transcripts independently using line-by-line coding [37] and discussed potential codes with the rest of the team (HY, JA, RK) to develop consensus. As part of the coding process, the analysis team met regularly to discuss memos and compare constructs as they emerged from interview transcripts as part of the constant comparative method, an analytical process used in grounded theory for coding [38]. Modifications to the codebook were made as needed, going back to previously coded interviews to re-code as needed. Discrepancies regarding codes were discussed between the two coders. The coding of each transcript was compared consecutively. After defining the final codes, the two coders independently coded the remaining transcripts. Inter-rater reliability was calculated with a Scott's Pi measure of 0.69 (scale 0–1), or 69% agreement between the coders, indicating substantial agreement. As a final step, themes were reviewed and further defined as a group (HY, JA, AV, RK, AM). We involved an additional study team member (AM) in the analysis and write-up phases of this qualitative analysis which provided alternative perspectives and enhanced the interrogation of assumptions. All co-authors approved the final exemplar quotations included in the results section. To ensure trustworthiness, direct quotations were provided to connect the results to the raw data.

Results

Table 1 summarizes the characteristics of the providers who participated in the semi-structured interviews compared to the total study population enrolled in the trial. Providers ($N=25$) were predominantly female (84%), white (72%), and non-Hispanic (88%) (Supplementary Table 2). Eighteen (72%) were physicians, 6 (24%) nurse practitioners (NPs) and 1 (4%) physician assistant (PA). Specialties included Family Medicine (8%), Internal Medicine (8%), Oncology (40%), Surgery (32%), and other (12%). Nearly all providers (96%) reported they had previously prescribed anti-estrogens for chemoprevention. Providers reported high confidence levels (range 1–6, with 1 being not at all confident and 6 being extremely confident) in their knowledge of medical statistics (mean 4.64, SD 0.76), communication of medical statistics (mean 4.88, SD 0.73), and risk communication (mean 5.08, SD 0.57). The interview population was representative of the overall provider population taking part in the study.

Qualitative results

From the qualitative analysis of semi-structured interviews with participating providers, ten codes were generated with 873 coded quotations (Fig. 1). Three themes (each with subthemes) relating to providers' experiences

Table 1 Baseline demographic characteristics of healthcare providers enrolled in the MiCHOICE trial and the interview sub-study

Characteristic	All participants ($N=210$)	Interview Completed ($N=25$)	*P*-value
Age, years (median [IQR])	46 [38, 53]	46 [43, 55]	0.40
Female, N (%)	163 (77.6)	21 (84.0)	0.64
Non-Hispanic, N (%)	196 (93.3)	22 (88%)	0.81
Race, N (%)			0.47
Asian	39 (19.2)	4 (16.0)	
Black/African American	13 (6.4)	1 (4.0)	
Multiracial	5 (2.5)	2 (8.0)	
White	146 (71.9)	18 (72.0)	
Provider Type, N (%)			0.77
APP	50 (23.9)	7 (28.0)	
Physician	156 (74.6)	18 (72.0)	
RN	3 (1.4)	0 (0.0)	
Specialty, N (%)			0.44
Family Practice	4 (1.9)	2 (8.0)	
Internal Medicine	14 (6.8)	2 (8.0)	
Obstetrics/Gynecology	3 (1.4)	0 (0.0)	
Oncology	110 (53.1)	10 (40.0)	
Other	17 (8.2)	3 (12.0)	
Surgery	59 (28.5)	8 (32.0)	
Years since completing training, N (%)			0.64
< 5	45 (21.4)	3 (12.0)	
5–10	51 (24.3)	5 (20.0)	
11–15	28 (13.3)	6 (24.0)	
16–20	33 (15.7)	4 (16.0)	
> 20	50 (23.8)	7 (28.0)	
Have not yet completed training	3 (1.4)	0 (0.0)	
Prior use of BC risk assessment tool, N (%)	195 (92.9)	25 (100.0)	0.34
Prescribed CP, N (%)	174 (82.9)	24 (96.0)	0.16
Prescribed low-dose tamoxifen for CP, N (%)	85 (71.4)	4 (16.0)	0.38
Willingness to try new technology, mean (SD)	82.14 (17.49)	81.32 (16.86)	0.82
Confidence in knowledge of medical statistics, mean (SD)	4.43 (0.95)	4.64 (0.76)	0.28
Confidence communicating medical statistics, mean (SD)	4.64 (0.93)	4.88 (0.73)	0.21
Ability to help patient understand risk, mean (SD)	4.73 (0.89)	5.08 (0.57)	0.05

APP Advanced practicing provider, *RN* Registered nurse, *BC* Breast cancer, *CP* Chemoprevention

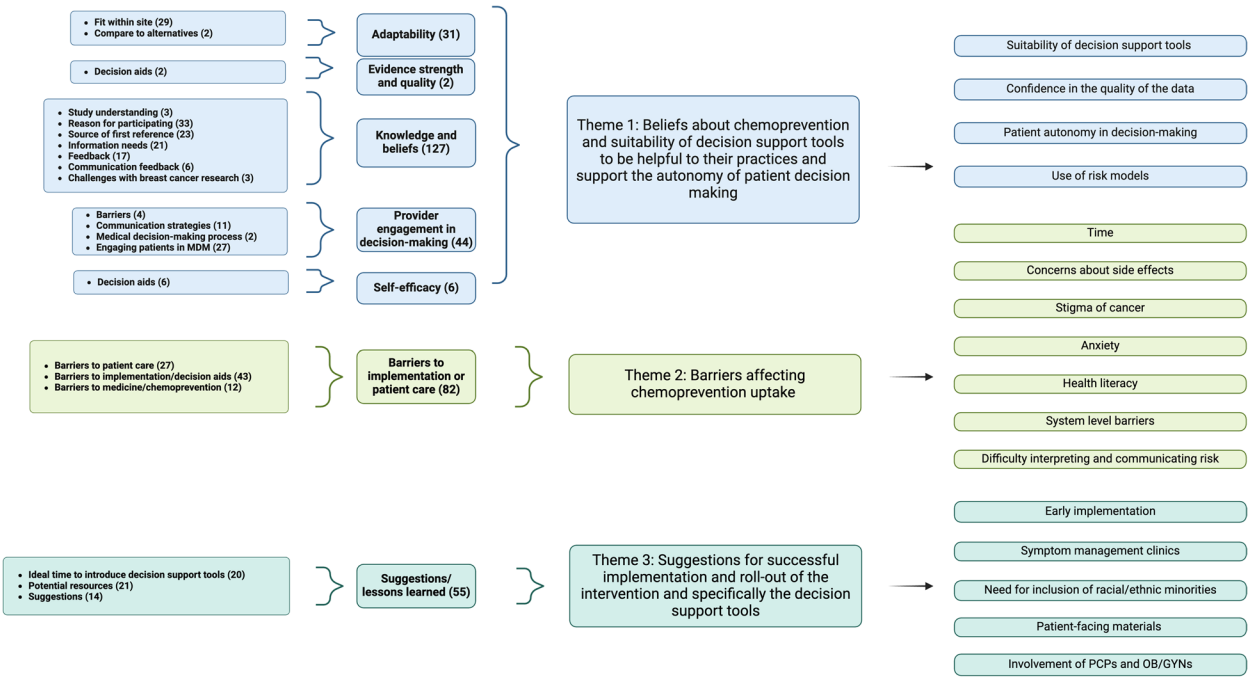

Fig. 1 Representation of the coding tree, with from left to right, sub-codes, codes, themes and sub-themes. In parenthesis, the number of quotations included in each category. Notably, three codes (role in facility, structural characteristics and engaging) were excluded from this coding tree given data was captured quantitatively and included in Table 1

with chemoprevention use in high-risk women emerged from qualitative analysis: (1) beliefs about chemoprevention and suitability of decision support to facilitate decision-making and support patient autonomy; (2) barriers affecting chemoprevention uptake; and (3) suggestions for successful implementation and roll-out of the decision support tools. Exemplar quotations for each theme are included in Table 2.

Theme 1: Beliefs about chemoprevention and suitability of decision support tools to be helpful to their practices and support the autonomy of patient decision-making

Subtheme: Confidence in the Quality of the Data

Providers ($N=14/25$, 56%) explicitly expressed confidence in the quality of data surrounding supporting recommendations for using chemoprevention. Specifically, 20% ($N=5/25$) cited the existence of robust data from large RCTs as a key factor in support of chemoprevention. As one oncologist (ID #2, with 11–15 years of experience) stated, "I think the quality of evidence for chemoprevention definitely exists. We have several large randomized trials showing that it works."

Subtheme: Suitability of Decision Support Tools

Providers ($N=22/25$, 88%) generally felt the patient decision aid (DA), *RealRisks,* would be adaptable and well-suited to their workflow. Several providers ($N=6/25$, 24%) believed it could save time in busy clinical practices, given the time required to explain chemoprevention. One oncologist (ID #6, < 5 years of experience) emphasized, "It didn't seem that an hour was enough to kind of go over all of those things and sometimes… it could take more time [compared] with someone who has invasive cancer."

Subthemes: Patient Autonomy in Decision-Making and Use of Risk Models

While expressing their support for using chemoprevention for risk reduction, providers ($N=12/25$, 48%) also emphasized their commitment to respecting patient autonomy in the decision-making process. Providers emphasized the importance of conducting risk versus benefit analyses with patients; but ultimately one stated, "I always let them know that it's their choice in the end" (ID #5, Oncology NP, 16–20 years of experience). To allow for patient autonomy, providers shared the general discussions of the risks and benefits that occur in the clinic regarding chemoprevention. Sixteen (64%) mentioned using risk assessment tools, such as the Gail [25] and Tyrer-Cuzick [41] models, as well as visual aids such as drawings and journal articles with charts to communicate risk effectively. Given the complexity of the issues, providers recognized the need for improved patient understanding and emphasized the decision does not have to be made at the first visit.

Table 2 Themes identified from semi-structured interviews of providers and selected quotes

Theme	Sub-theme	Interview Quote
Theme 1: Beliefs about chemoprevention and suitability of decision support tools to be helpful to their practices and support the autonomy of patient decision making	Suitability of decision support tools	"I thought it would be great to have some additional resources above and beyond what we have, because it didn't seem, for some patients, that an hour was enough to kind of go over all of those things and sometimes they have additional questions and like I said, it could take more time than someone who has invasive cancer." (ID #6)
		"I think the educational tools that will come with this program will be helpful in reinforcing what we're telling our patients." (ID #1)
	Confidence in the quality of the data	"The quality of evidence I think is good and definitely it works, but you know I agree that not everyone wants to be on chemoprevention, so we can help our patients actually to choose to receive chemoprevention and to take medication to reduce their risk, that would be very helpful. I don't have any doubt about the quality of evidence." (ID #4)
		"I think there's good, randomized data that shows chemoprevention beneficial in high-risk breast lesions, so I'm comfortable with the data." (ID #3)
	Patient autonomy in decision-making	"I do tell them, you know you don't have to make the decision today, and for the first few visits when you're fresh high risk, I'll keep suggesting it to you, and then every now and then after that I'll ask you if you changed your mind, and you can change your mind at any time." (ID #24)
		"So, I think giving them data that they feel confident in will help them feel confident in their decision, if that makes sense." (ID #3)
	Use of risk models	"I use the Gail Model quite a bit, just to assess their risk of breast cancer and then I go over it with them. I typically go through the different options and different levels, meaning like a dietary prevention strategy, lifestyle prevention and then chemoprevention as kind of a second tier in terms of decreasing their cancer risk and then very rarely are patients eligible for surgical prophylaxis unless they have some kind of genetic mutation." (ID #19)
		"I tend to use the Gail model for the initial visits, but later I use the Tyrer-Cuzick." (ID #24)
Theme 2: Barriers affecting chemoprevention uptake	Time	"I would make sure I mention time as a barrier…I think on the provider end, providers are pinched to like do a gazillion things now." (ID #2)
	Concerns about side effects	"Well, there's always the concern about risk and side effects, because these medications do have side effects and you know for a woman who may have hot flashes or dyspareunia or vaginal discharge, the side effects from tamoxifen and the idea that while I'm reducing my risk, it's sort of a far away goal." (ID #1)
		"So, potential side effects to the medications are a barrier or what they've read is a potential barrier or friends or family who have taken these medicines for breast cancer certainly have lots of opinions." (ID #2)

Table 2 (continued)

Theme	Sub-theme	Interview Quote
		"There are some patients that they are afraid of side effects and they don't want to be on any medication, and they choose just you know to be monitored by breast imaging and they don't want to go on any medications." (ID #4)
		"There are the drug side effects as a huge barrier and that's why when I counsel them, the majority of my patients, when they take the drug, based on my experience, they value that, that the side effects you're reading about on the internet are not as prominent as what most women describe, and when I describe it that way, women are really relieved." (ID #15)
	Stigma of cancer	"Cancer has its own stigma still and it's scary because it's unpredictable and feels less predictable." (ID #2)
		"I think another barrier is these medicines have side effects, you know, and the side effects affect some parts of women's bodies and so talking about some of the side effects that could be [stigmatized]…" (ID #2)
		"… I think sometimes not having a diagnosis of cancer, but a risk of cancer, is sort of a hard thing for them to grasp, especially when you're talking about an intervention that, to them, even though we know it's endocrine therapy, really any intervention oftentimes to a cancer patient is perceived as chemotherapy or, even if not, chemo, it's kind of perceived as the potential of a lot of untoward side effects and so I think any, whether it's web-based, whether it's in person, any additional information and resources we can give patients to help familiarize them with this and increase the uptake of chemoprevention in these patients and others would be greatly desired." (ID #3)
		"But I think it would be really hard to probably get a Pacific Island patient to take chemoprevention. I don't even know, quite honestly, if I have any Pacific Island patients that have high risk lesions. We're just trying to get them to get screening mammos… I think it's not in their paradigm, right? Like it's hard enough to get them to take treatment for breast cancer. We have such a, it's such a, I feel, a first world problem. It's like well take this pill that might prevent cancer, but we've already just cut out their pre-cancer. It's hard enough for me to have them take the pill when they have an invasive cancer, when the risk is higher, right?" (ID #5)
	Health literacy	"Certainly, for decision making, certainly health literacy. You know, how much do they understand these concepts… talking about cancer is a little different." (ID #2)
		"I think it's much harder in patients with lower health literacy to have this discussion. I always feel, honestly, a little bit uncomfortable in that scenario because I think, in particular for these prevention medicines, it really has to be shared decision-making and some patients with lower health literacy are just like, 'Well, if you think I should take it, I will." (ID #25)
	Anxiety	"This is their first kind of experience with the healthcare system in a way that makes them really nervous and anxious." (ID #6)

Table 2 (continued)

Theme	Sub-theme	Interview Quote
		"One thing that might be a barrier is their anxiety, but I'm hoping that the education tool itself helps with that." (ID #12)
		"Sometimes anxiety is a lot of the patients, especially the newer patients, are very anxious, you know, they're talking to lots of different people. They're not quite sure what to do." (ID #10)
		"Sometimes their anxiety is a little bit misguided or they're not well informed." (ID #12)
		"I think that's part of the limitations they might encounter, the amount of information for an hour and then having an oncologist in front of them, sometimes anxiety might not allow them to grasp all the information and understand all the concepts" (ID #12)
	System level barriers	"Language barrier is going to be an issue and we won't be able to have patients, we have a lot of different languages here. I know it's available in Spanish and that's pertinent to you know the majority of the continental US, for a second language that you'd want to address, but not here in Hawaii." (ID #5)
		"Some patients, depending on their insurance, it's cost prohibitive to take some of these medications." (ID #17)
		"For some of our patients that don't have any kind of prescription drug insurance at all, it's a pretty deep out of pocket, so that can become a barrier." (ID #1)
	Difficulty interpreting and communicating risk	"The idea of risk and you're going to try to reduce risk, is a hard concept. I'm going to take this pill that makes me sick with the hope that maybe I won't get cancer, but I might get cancer anyway; that's kind of how people may digest the information based on how they view this." (ID #1)
		"I still think it's a hard thing for them to wrap their mind around really how much risk there really is; how much do they really believe that data and how much do they really need to do something to reduce their risk. I think it's a tough discussion still." (ID #3)
Theme 3: Suggestions for successful implementation and roll-out of decision support tools	Early implementation	"I think they need to see one of us first, because if we send that to them without a doctor already explaining it, I have a feeling they're going to feel overwhelmed, so I almost think some early education with a face-to-face is always better than just throwing it at them, however I'm open to considering, with all this new digital technology, that could it have maybe made my visit better if they had been seen earlier." (ID #15)
		"If they had seen the Real Risk content earlier, I do think that might help some patients." (ID #15)
		"I tend to do it early on once the diagnosis is made. This gives them more time to think about things." (ID #23)

Table 2 (continued)

Theme	Sub-theme	Interview Quote
		"I would think that they'd be better served doing the intervention after their first visit in the high-risk clinic… I feel like high-risk interventions are more of a process rather than an emergency." (ID #22)
	Need for inclusion of racial/ethnic minorities	"I would say that going through some of the risk models, it might falsely have a lower risk or elevated risk depending on background, so that gets a little challenging." (ID #6)
		"We don't have the majority population here; we have multiple racial ethnic minorities here and we do know there are breast density differences between them and we do know the outcomes are different between different races and ethnic groups and so that's always something in the back of my mind when I'm talking to patients about chemoprevention, especially from different backgrounds. That I think is really important, especially since we're tailoring personal risks of breast cancer. So, I think that there is a little bit of lacking of resources for them in that way, but we do our best with the tools we have." (ID #6)
	Symptom management clinics	"They do acupuncture, so a lot of patients, that's a resource that we also have for vasomotor symptom management, or depression, anxiety, stress management, psychiatry and psychology sometimes can also be very helpful for these patients." (ID #16)
	Patient-facing materials	"I think we don't have good patient-facing materials…I don't really think anything like that exists, and I haven't seen patient facing-materials that include low-dose tamoxifen… so it would be great if I had a place to refer them to read more and think about it on their own time, and that doesn't really exist. (ID #25)
	Involvement of PCPs and OB/GYNs	"If we're really going to make an impact on breast cancer incidence and mortality, we really need to have primary care providers and OB/GYN's tuned in to evaluating patients' risk for breast cancer on a routine basis with all their patients and either getting comfortable prescribing chemoprevention to patients or referring patients but there's not enough breast surgeons or high-risk clinics to handle all of the patients who probably would benefit from chemoprevention." (ID #21)

Theme 2: Barriers to chemoprevention uptake

Despite the availability of high-quality data and the belief that decision support tools could be beneficial to discussing chemoprevention use, various barriers were identified at different levels of healthcare delivery.

Subtheme: Time

The most common barrier cited by providers ($N=6/25$, 24%) was limited time with patients due to clinic time constraints.

At the patient level, providers perceived numerous barriers to chemoprevention uptake.

Subtheme: Concerns about Side Effects

Fifteen providers (60%) highlighted patients' medication beliefs and their preference for avoiding medications. One oncologist emphasized that despite evidence for chemoprevention, "Some patients are afraid of side effects and they don't want to be on any medication, and they choose to be monitored by breast imaging" (ID #4, 11–15 years of experience). Concerning side effects, providers ($N=4/25$,16%) felt patients often lack information about risk factors and prevention, which in turn leads them to turn to the internet for information on the side effects.

Subtheme: Stigma of cancer

Regarding patients' reasoning for avoiding chemoprevention, three providers (12%) discussed the perception or "stigma" amongst high-risk women about chemoprevention medications, given their traditional association with cancer treatment. For example, the same oncologist (ID #4, 11–15 years of experience) who discussed patients' concern for side effects, elaborated on patients' fear of side effects and described grappling with patients' perceptions that chemoprevention is like chemotherapy. She emphasized the confusion surrounding the practice of prescribing the same medications to both women diagnosed with breast cancer and those at high-risk for breast cancer saying, "Sometimes patients question if they don't have any breast cancer, why do they need to take medications we actually prescribe to breast cancer patients?".

Subtheme: Anxiety

Four providers (16%) described patient anxiety as a perceived barrier to chemoprevention discussions. They described the high-risk population as a highly anxious group given their previous lack of experience with the health care system and the various decisions they are faced with at the initial visit. One provider (ID #10, Surgery NP, 16–20 years of experience) posited, "The newer patients, are very anxious, you know, they're talking to lots of different people. They're not quite sure what to do." Another provider (ID #12, Surgery NP, > 20 years of experience) felt that the anxiety may be "a little bit misguided" and suggested that the education tool may help with that.

Subtheme: Health Literacy

Additional provider-perceived barriers related to patient characteristic mentioned education level, health literacy, and cultural and socioeconomic issues. One oncologist (ID #25, 5–10 years of experience) identified low health literacy as a barrier in talking about chemoprevention and they discussed feeling "a little bit uncomfortable" given the implications of lower health literacy for shared-decision making.

Subtheme: Difficulty interpreting and communicating risk

Another challenge providers ($N=5/25$, 20%) discussed included interpreting and communicating the risk of high-risk breast lesions to their patients. They suggested risk can be difficult for patients to grasp. One oncologist (ID #1, > 20 years of experience) explained, "The idea of risk and you're going to try to reduce risk, is a hard concept. I'm going to take this pill that makes me sick with the hope maybe I won't get cancer, but I might get cancer anyway." Risk was further explained as difficult to grasp given chemoprevention's delayed benefit over the course of a lifetime. Furthermore, providers acknowledged their own difficulty in communicating risk, saying, "Risk is really tough" (ID #2, Oncologist, 11–15 years of experience) and adding that their own difficulty with risk is complicated by the varying perceptions amongst patients of what constitutes an elevated risk.

Theme 3: Suggestions for successful implementation and roll-out of decision support tools

Regarding suggestions for successful trial implementation, seventeen providers (68%) suggested introducing the patient DA early, at the time of diagnosis of AH or LCIS within the first clinic visit to maximize impact. Providers supported multiple visits for reinforcing information regarding chemoprevention given their impression that patients often feel overwhelmed due to the volume of information provided at the initial visit. Additional suggestions to help with increasing chemoprevention uptake included the need for symptom management resources, given the likelihood of side effects. One surgeon suggested greater involvement of PCPs and gynecologists saying, "There's not enough breast surgeons or high-risk clinics to handle all of the patients who probably would benefit from chemoprevention" (ID #21, > 20 years of

experience). The DA was seen as a valuable tool to educate women, particularly given the time constraints in clinical settings and a lack of other resources for high-risk women. Providers also noted the absence of tools or risk calculators tailored to racial/ethnic minorities. There was some acknowledgment that the *RealRisks* tool addresses the needs of Hispanic patients, but not other groups such as Pacific Islanders.

Discussion

In this pre-implementation study of the MiCHOICE parent trial, we found providers generally felt their practices supported decision support tools focusing on chemoprevention. Providers acknowledged the existence of sufficient, high-quality data to support the use of chemoprevention in high-risk women. Providers identified barriers to the informing of patients, including time constraints, patients' concerns about side effects, stigma of cancer, patient anxiety, and various patient-level factors such as education level, health literacy, cultural and socioeconomic issues.

Prior intervention trials of clinical decision support tools designed to increase uptake of breast cancer chemoprevention have been met with limited success. A web-based, personally tailored DA, targeting high-risk postmenopausal women, called *Guide to Decide*, demonstrated lower decisional conflict [42], but low chemoprevention uptake rates of 0.5% with raloxifene and no tamoxifen uptake [43]. Within the primary care setting, a tablet-based intervention called *BreastCARE*, consisting of an individualized risk report, led to more high-risk women being referred for specialized risk counseling within the intervention arm (18.8% vs 4.1%); yet discussions surrounding chemoprevention remained limited (1% vs 0%) [44]. In a program designed to increase risk screening, without targeted decision support, the *Ready, Set, GO GAIL!*program used the Gail model to screen more than 5700 women in a primary care setting [45]. While 15.2% of women were deemed high risk, only 14.7% were referred for risk counseling and only 2% started chemoprevention, with PCPs expressing concerns about the accuracy of the Gail model and the additional time needed to administer it [45]. Comparatively, our decision support tools are both personally tailored and contain individualized risk reports which are shared between patients and providers. In a prior RCT of decision support for 300 high-risk women and 50 providers, we found that our web-based DA, *RealRisks,*compared to standard educational materials did not significantly increase chemoprevention uptake but improved: 1) accurate breast cancer risk perceptions (56% vs 39%, $p=0.017$); 2) adequate chemoprevention knowledge (49% vs. 27%, $p<0.001$); 3) informed choice (41% vs. 23%, $p=0.003$); and 4) decreased mean decision conflict (34.0 vs. 47.0, $p<0.001$) [46]. In the MiCHOICE trial, we have targeted a population of high-risk women with AH or LCIS, who derive a greater benefit from chemoprevention, and their providers, predominantly surgeons and medical oncologists. Importantly, compared to prior research, our tools have been validated in ethnically diverse high-risk women with various educational backgrounds and health literacy [21, 46, 47] and our trial seeks to understand how the combined effect of targeting patients and their providers would impact chemoprevention informed choice.

In this qualitative study, we sought to understand how providers envisioned chemoprevention DAs would fit into their practices. Importantly, all providers reported having used breast cancer risk assessment tools. Nearly all providers (96%) surveyed had previously prescribed chemoprevention. Amongst these providers, they were generally willing and eager to incorporate our DA into their practices. Consistent with prior research, which has attributed inadequate time and competing demands to low chemoprevention uptake [48, 49], providers in our interviews cited time constraints as a challenge and discussed how offering resources such as our *RealRisks* DA could facilitate risk communication and chemoprevention decisions in a timely, in-depth manner. While Bychkovsky et al.found that the median time from first visit to chemoprevention was 54 days, with 31% of participants starting chemoprevention > 6 months after their initial visit [9], interviews suggested there may be a valuable role for our DA either prior to or after the initial visit to aid in decision making.

Prior qualitative and quantitative studies have identified patients' medication beliefs and concerns about side effects as playing a major role in the low uptake of chemoprevention [17, 18]. Among women with AH, LCIS or ductal carcinoma in situ, 71.6% previously reported they were very or extremely worried about the side effects and 56.9% reported they thought the side effects were very or extremely serious [18]. Within our interviews, providers similarly asserted patients were concerned with potential side effects of chemoprevention, often turning to the internet to better understand the risks. While side effects were repeatedly discussed, several physicians also discussed the perception of patient stigma regarding chemoprevention's traditional association with cancer treatment and "chemo" in general, suggesting that more clarification around terminology via DAs could help to clarify this further for patients.

Prior literature has implicated anxiety in the complexity of decision-making surrounding chemoprevention and even suggested anxiety may motivate interest in tamoxifen [50]; however, in our interviews, four (16%)

providers specifically reported the perception of patient anxiety as a barrier to chemoprevention uptake. Several reasons for anxiety were suggested, including a lack of prior experience with the health care system, as well as the stigma associated with concerns about taking a drug used to treat cancer when they don't have breast cancer and hesitancy to discuss side effects affecting woman's bodies.

Based upon our survey results, providers felt confident in their ability to communicate statistics regarding risk to patients. However, in the interviews, five providers (20%) cited difficulty in explaining risk as a barrier to chemoprevention uptake and suggested additional supportive tools would be beneficial. This finding is consistent with our group's prior finding amongst PCPs that a key barrier is limited risk communication about breast cancer risk [49].

In relation to the provider-related barriers we have identified in these pre-implementation interviews, our tools may be uniquely suited to address these concerns. To address providers' difficulty communicating risk, *BNAV* includes educational modules on risk as well as direct information regarding a patient's risk score and preferences regarding chemoprevention. On the patient end, *RealRisks*includes information on risk factors and calculates a personalized breast cancer risk score according to the BCSC model. Together these tools may facilitate a more robust conversation regarding chemoprevention. Given that our prior work demonstrates that our tools improve the accuracy of breast cancer risk perceptions without increasing breast cancer worry [28], our DA may address anxiety and concerns about side effects, through the personalized absolute risk calculations that are provided for risk of common side effects (*i.e.* hot flashes) and rare side effects (*i.e.* thromboembolic events, endometrial cancer) with and without chemoprevention. The direct inputting of this risk information into the provider decision support will potentially facilitate more robust and targeted conversations amongst patients and their providers. Additionally, while several providers discussed health literacy, language barriers and diverse patient populations, prior usability studies of *RealRisks*have demonstrated similar efficacy across racially and ethnically diverse populations [21, 27, 46].

Strengths of our study include the collection of quantitative data from surveys with additional qualitative data via semi-structured interviews. Limitations include the relative lack of racial/ethnic and gender diversity amongst the providers who participated in semi-structured interviews with predominantly female (84%), white (72%), and non-Hispanic (88%) providers. While our findings are about the target population of providers caring for women with high-risk breast lesions, which comprises the patient population that is most likely to benefit from chemoprevention, this specialized population of providers, including only 2 PCPs and 2 family medicine physicians, limits the generalizability of our results in this pre-implementation study. Another limitation is that we did not include the patient perspective in this analysis. We are currently conducting mid-implementation interviews of patients enrolled in the intervention arm of the parent trial to gain the patient perspective on the use of *RealRisks*, which will be reported in a subsequent publication. Other future directions will include the applicability of our decision support tools to additional populations, including lower-risk women, who may benefit from improved risk perception and understanding of universal preventative measures, including healthy lifestyles and alcohol reduction.

We acknowledge many barriers are posited to affect chemoprevention uptake. While our web-based DA has improved the accuracy of perceived breast cancer risk and decreased breast cancer worry amongst women meeting family history criteria for *BRCA1/2* testing [27], some barriers (*i.e.,* lack of time, medication beliefs, and fear of side effects) may be amenable to the role of the DA. While DAs may increase knowledge, self-efficacy and intent, Reuland et al.found that adding a patient navigator to a patient DA increased the screening rate for colorectal cancer compared to usual care alone amongst a diverse and vulnerable patient population [51]. Given the complexity of decision making surrounding chemoprevention, we similarly may need to address the topic as a multi-faceted intervention, such as by including trained patient navigators to assist patients as they interact with the DA [52].

Overall, our current study illustrates that providers recognize the potential benefits of decision support tools, which provide personalized information on breast cancer risk and the harms and benefits of chemoprevention, while also highlighting significant barriers such as time constraints and patient-related concerns that these tools may help mitigate, demonstrating their potential to enhance both provider-patient communication and informed decision-making in clinical practice. We plan to conduct additional mid-implementation interviews of providers and patients to further understand how the decision support tools were implemented into clinical care and their effectiveness. Our overarching goal is to compare the frequency of chemoprevention informed choice at 6 months after enrolling women with AH or LCIS while assessing patients' perceived breast cancer risk and worry, chemoprevention knowledge, chemoprevention intention/

decision, decision conflict and decision regret. Simultaneously, using implementation science and mixed methods research, we can contextualize quantitative findings to better understand barriers and facilitators to implement a chemoprevention DA intervention into clinical workflow.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12911-024-02691-0.

Supplementary Material 1.

Supplementary Material 2.

Supplementary Material 3.

Supplementary Material 4.

Acknowledgements
This work was supported by the National Institutes of Health, National Cancer Institute UG1CA189974, R01CA226060; The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Authors' contributions
AM: Formal analysis, Writing– original draft, review & editing. HY: Formal analysis, Writing- original draft, review & editing. JA: Project administration, investigation, review & editing. NC: Project administration; review & editing, investigation. AV: Writing- original draft. SU: Formal analysis, Writing- original draft, review & editing. GA: Writing – review & editing, Methodology, Formal analysis. KA: Writing – review & editing, Project administration, Methodology, Investigation, Formal analysis, Data curation. CL: Writing – review & editing, Project administration, Investigation. SP: Writing – review & editing, Project administration. ASL: Writing – review & editing, Project administration. RS: Writing – review & editing, Project administration. MGP: Writing – review & editing, Project administration. SC: Writing – review & editing, Project administration. SK: Writing – review & editing, Project administration. TK: Writing – review & editing, Project administration. LY: Writing – review & editing, Project administration. TB: Writing – review & editing, Project administration. CBI: Writing – review & editing, Project administration. DM: Writing – review & editing, Project administration. KW: Writing – review & editing, Project administration. CD: Writing – review & editing, Project administration. MR: Writing – review & editing, Project administration. JF: Writing – review & editing, Project administration. AK: Writing – review & editing, Project administration. LV: Writing – review & editing, Project administration. TS: Writing – review & editing, Project administration. CZ: Writing – review & editing, Project administration. SL: Writing – review & editing, Project administration. CG: Writing – review & editing, Project administration. AC: Writing – review & editing, Project administration. KY: Writing – review & editing, Project administration. DA: Writing – review & editing, Project administration. CJ: Writing – review & editing, Methodology. DH: Writing – review & editing, Project administration, Methodology, Investigation, Funding acquisition. MN: Writing – review & editing, Methodology, Investigation. BA: Writing – review & editing, Supervision, Methodology, Investigation. KC: Writing – review & editing, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization. RK: Writing – review & editing, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization.

Authors' information
Not applicable.

Funding
This work was supported by the National Institutes of Health, National Cancer Institute UG1CA189974, R01CA226060; The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Availability of data and materials
The data analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations

Ethics Approval and Consent to Participate
The trial was approved by the National Cancer Institute Central Institutional Review Board (CIRB). Informed consent to participate was obtained from all of the participants in the study.

Consent for Publication
Not applicable.

Competing interests
The authors declare no competing interests.

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Received: 28 February 2024 Accepted: 18 September 2024
Published online: 27 September 2024

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