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Talking Numbers: How Women and Providers Use Risk Scores During and After Risk Counseling - - NRG Oncology/NSABP DMP-1

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Original Research

Talking Numbers: How Women and Providers Use Risk Scores During and After Risk Counseling - - NRG Oncology/NSABP DMP-1

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Abstract: Objectives: Little research exists on how risk scores are used in counseling. We examined (I) how breast cancer risk assessment (BCRAT) scores are presented during counseling and (II) how women react and (III) discuss them afterwards.

Design: Consultations were video-recorded and participants were interviewed after the consultation as part of the NRG Oncology/National Surgical Adjuvant Breast and Bowel Project Decision-Making Project 1 (NSABP DMP-1).

Setting: Two NSABP DMP-1 breast cancer care centers in the United States: one large comprehensive cancer center serving a high-risk population and an academic safety-net medical center in an urban setting.

Participants: Women diagnosed with breast cancer risk and their counseling providers**.**

Results: Risk scores were individualized and given meaning by providers through: (A) presenting thresholds, (B) making comparisons, and (C) emphasizing or devaluing the calculated risk. The risk score information elicited little reaction from participants during consultations, though some added to, agreed with, or qualified the provider's information. Results: During interviews, participants reacted to the numbers in four primary ways: (1) engaging easily with numbers; (2) expressing greater anxiety after discussing the risk score; (3) accepting the risk score; and (4) not talking about the risk score.

Conclusions: Our study highlights the necessity that patients' experiences must be understood and put into relation to risk assessment information to become a meaningful treatment decision-making tool, for instance by categorizing patients' information engagement into types.

Running title: Patients use risk scores from risk assessments in four ways

Keywords: Individual risk assessments, risk score, risk counseling, primary prevention, breast cancer risk, qualitative research, BCRAT

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Strengths and limitations of this study

- Videos recorded individual consultations conveyed interactions between a provider and patient in primary cancer prevention settings.
- Interviews including a review of the own video consultation with participants enabled scrutiny of risk score meaning by participants.
- Risk assessments that were routinely conducted as part of breast cancer risk counseling in our sample and may not be applicable where a cancer prevention risk assessment is not routinely used or discussed.
- Need for future patient type validation with a wider range of cancer prevention counselors in non-urban settings.

1. Introduction

Counseling on prevention and interventional strategies to reduce disease risk is considered an important aspect of clinical care from primary to specialty practice [1-4]. Treatment guidelines about prevention encourage the use of risk scores to identify individuals at risk and counsel them on the likelihood of developing a particular disease within a given time period [5-8]. As the first point of cancer prevention care, primary care providers and specialists, including family physicians, obstetricians/gynecologists, and internists, as well as nurse practitioners, are tasked with counseling on risk for disease across a whole spectrum of preventive medicine [9-13].

In risk counseling, the benefits of lowering the risk of developing breast cancer should be weighed against the intervention options, from lifestyle changes (such as lowering alcohol intake, maintaining a healthy body weight, limiting hormone exposure), to surgery (prophylactic mastectomy and oophorectomy), and taking an oral selective estrogen receptor modulator (SERM) [7 14 15]. Standardized risk assessment instruments such as the Breast Cancer Risk Assessment Tool (BCRAT) [14] and others [16-21] provide a base value of risk for individuals, which is presented in a percentage of risk over time; both five years and over a lifetime (up to the age of 90 years). This individually calculated risk can be used to initiate a discussion between providers and patients about risk option preferences. The BCRAT is particularly relevant for epidemiological and clinical risk factors outside of family history and is used to determine eligibility for SERM. SERM presents an option for individuals with a calculated BCRAT over 1.66% for five years or 20% for a lifetime [22-24].

The National Surgical Adjuvant Breast and Bowel Project Decision-Making Project 1 (NSABP DMP-1) investigated social, cultural, and psychological factors driving decision-making regarding SERM use in women counseled on breast cancer prevention options [25]. Physician recommendation was found to be the most important factor for SERM uptake [25], but only if it aligned with the social and experiential factors of the counseled women [25-28]. Objective risk assessment was not found to be a decisive factor. Detailed investigation of decision-making processes showed the importance of perceived control in relation to perceived risk as a factor determining decision-making, as well as an understanding of the reversibility of the decision, the perception of medications, and how close the possibility of cancer felt to oneself [26 28].

Provider risk counseling is often the most important entry point for identifying women at high risk of developing breast cancer and providers are increasingly recognizing the importance of (genetic) risk factors and counseling [11-13], yet how frequently risk assessments are used depends on specialty and training [9 29-31]. When risk assessments are conducted with patients, little is known about the communication strategies in practice. In this article, we aim to identify and describe how risk information and risk scores used in counseling is provided and worked with in the communication between provider and participant. We specifically explored: (I) how BCRAT scores are introduced during counseling; (II) the reactions of women during counseling sessions; and (III) discussions of these scores afterward, as they pertain to an individual's own breast cancer risk.

2. Materials and Methods

NRG Oncology/NSABP DMP-1

This study used the data available from the qualitative arm of the NSABP DMP-1 to investigate the communication strategies and role of risk information in breast cancer risk counseling. The DMP-1 was a mixed-method study to investigate the social, environmental, and psychological factors involved in decision-making about risk reduction strategies in women counseled on SERM use for breast cancer risk. It consisted of a survey arm and a qualitative, observational arm [25]. The qualitative arm recorded 30 consultation sessions from two DMP-1 study sites: a large comprehensive cancer center serving a high-risk population and academic safety-net medical center in an urban setting. In addition, in-depth interviews with participants from the recorded consultation sessions were conducted within six weeks of the consultation [25 26].

The Institutional Review Board gave ethical approval for both sites. All providers and participants gave written informed consent.

Data collection

Between April 2012 and August 2013, participants were contacted and recruited purposively before breast cancer risk counseling sessions appointments and gave written consent prior to being video-recorded during their session. In order to capture regular care counseling, providers were not given counseling content outside of the eligibility criteria that SERM was to be discussed [26]. Subsequently, a qualitative interview was conducted with participants on-site by experienced and trained interviewers. Both interviewers were women, a health researcher (CG) and clinical psychologist (PP) who contacted participants for setting up interviews and explaining research background and goals before securing informed consent. Using a previously pilot-tested, semi-structured guideline that was tailored to the content of the viewed, individual consultation session. Overall, the interviews addressed: the experience of the consultation and treatment options discussed; the experience of breast cancer risk and views of treatment options; and feedback and input after viewing their own consultation. As participants watched their own consultation video, they were encouraged to comment on the recorded consultation session content and to answer questions from the research team (health researcher JK, social scientist doctoral candidate SB, CG, and PP). A follow-up telephone interview on the decision made by each participant finalized the data collection for the primary study.

Analysis

We used all 30 available NSABP DMP-1 data protected[26] qualitative consultations and interview transcripts. Consultation videos were summarized jointly as a team according to Schubert [32]. Next, the joint summaries were coded thematically (JK, SB). Joint summary themes that discussed risk calculation and/or assessments were compiled and corresponding video segments reviewed for participant reactions. Each reaction was described in further analytical memos. The video data was then coded inductively according to presentation and interaction types that evolved from the analysis.

In addition, the interview material was searched for text segments that contained themes related to risk assessment. Subgroup analysis according to demographic variables such as age and Gail score were conducted, investigating reactions to risk scores and contrasting and comparing them with the pertinent video analysis data. From this, four descriptive categories of reactions to risk scores emerged. The descriptive categories were clearly defined after 19 interviews; all 30 interviews fit principally into one of the four descriptive categories.

Analysis was done by the first author (SB), in regular consultation with the last author, senior principle investigator (CH, PhD medical ethnographer and epidemiologist). Regular meetings and presentation of findings were discussed with a qualitative methods working group at the Institute for Public Health, Charité-Universitätsmedizin Berlin. Analysis was assisted and organized throughout in MAXQDA v18 [33], reported using the COnsolidated criteria for REporting Qualitative research[34]

3. Results

Key demographics for the sample are summarized in **Table 1**, and reported in extensive detail in previous publications [26-28].

Five providers conducted the 30 counseling sessions. All but one provider had extensive experience counseling on risk; one was new to risk counseling. The 5 medical providers included the following specialties: general internists with specialty training in breast health, nurse practitioner, and oncologist. The total consultation length ranged from 11-37 minutes. Further characteristics can be found in a previous publication [26]. For 16 participants (53%), this was their first visit with this provider. There were 21 participants (70%) for whom SERM was recommended. Providers presented the risk score to all but one participant either as a printed handout or on the computer screen; the discussion of the risk score took place at the beginning of the consultation in nearly all consultations. The amount of time that providers and participants discussed the risk score ranged from 13 seconds to 6 minutes, corresponding to 2-24% of the consultation time. In two cases, no risk score was discussed. Almost all consultations closely followed the discussion topics about breast cancer risk as listed in existing breast cancer risk guidelines, from lifestyle changes for prevention, to screening and surgery, in addition to SERM [7 14]. However, how systematically breast cancer risk factors were discussed varied according to the provider's style and experience.

During Counseling: Providers' Personalized Risk Score Numbers

During counseling, providers gave meaning to the risk score by: (A) presenting thresholds, (B) making comparisons, and (C) emphasizing or devaluing risk and risk reduction.

Presenting Thresholds

Risk levels, which are set as the minimum levels at which tamoxifen may be prescribed as a risk reduction therapy (5-yr=1.66%; lifetime=20%), were introduced as a threshold at which a provider should discuss breast cancer prevention options. One provider referred to such thresholds as “magic numbers” (**Table 2**).

Framing Risk Scores and Risk Reduction

The strength of the provider's recommendation for SERM use for a participant influenced the way the risk score was explained during counseling. Most risk scores were clarified by an emphasis on the likelihood of developing breast cancer. For example, a provider who strongly recommended that a participant consider SERM as a result of atypical cell biopsy findings regularly cited a relative risk reduction of 86% based on findings from prevention clinical trials. When a provider clearly recommended against SERM use, risk scores were framed to illustrate how unlikely the person was to develop breast cancer. The residual risk, or remaining likelihood of developing breast cancer after SERM treatment, was discussed only with people demonstrating statistical proficiency during the office visit and showed eagerness to grasp risk statistics (**Table 2**).

Making Comparisons

Another important strategy that was used to make the risk score meaningful was to compare the patient’s risk score to that of the “average” women (**Table 2**). For example, providers highlighted how the participant’s risk score was double or three-times the average. The risk score of the participant as compared to that of the average woman was presented in a format using absolute numbers.

Devaluing: Undermining and Qualifying Risk Scores

In some consultations, providers undermined or devalued the risk score (**Table 2**). This happened particularly when the explanation of the provider highlighted that they felt the risk score did not adequately reflect the risk factors of a given participant. For those with complicating medical factors, such as a simultaneous family history of breast cancer and stroke, or for those who were young, providers emphasized that for such a combination of factors, the available risk score might not provide an appropriate risk estimate. Those women who had atypical cell findings (e.g., through lobular carcinoma in situ (LCIS)) and were thus ineligible for the use of the BCRAT tool were presented with a percentage range. In such instances, providers expressed ambiguity, were careful not to give a precise risk estimate or did not use an risk score to underscore the recommendation.

During Counseling: Participants' Reactions

Overall, most consultations did not illicit reactions to the risk score information during the counseling session. Most participants simply listened or gave signs of affirmation while the providers presented the risk score information. Engaged discussions about risk scores were characterized by a high level of comfort with risk numbers on the part of the participant or their need for clarity about the presented information (**Table 3**). A subset of the participants was prompted to engage in discussions about their risk when the way provider communicated or framed risk scores resulted in less clarity or when participants added their own information to what the provider presented.

Discussion in Counseling: Prompted by Participant Comfort and Provider Ambiguity

Participants who engaged in discussion were those who expressed the most comfort with or certainty about the risk score presented. Those who had been previously counseled and had discussed their risk score in the past, or who worked with statistics, appeared most comfortable in discussing risk numbers. When providers communicated uncertainty about the risk score, undermined the score, or presented risk levels surprising to the participant, discussion was also prompted (**Table 3**).

Adding Information to Risk Scores

Some participants tried to understand the risk values presented to them during counseling by providing additional information, which they thought might change their risk level (e.g., see **Table 3**).

After Counseling: Four Primary Reactions to Risk Score Information

In contrast to the counseling sessions, in the interview participants had lively discussions on risk scores and risk levels. Participants engaged primarily with their risk score in four ways during the interviews: (1) being at ease with the risk score; (2) being anxious about the risk score; (3) accepting the risk score; or (4) being non-conversant about the risk scores (**Table 4**). These responses were not mutually exclusive and overlapped in the ways participants engaged with the risk score. Patterns of engagement were viewed according to participants' risk and health background, the actual risk score, and the way the providers had delivered the information.

Being at Ease with the Risk Score

Some participants discussed the statistical calculations of their risk score easily during the interviews. These participants described their prior expertise in statistics and familiarity with their breast cancer risk score from previous counseling discussions or through their own work. Irrespective of their risk score, they asked further questions about values or candidly discussed in the interview the way in which they understood a statistical presentation They felt comfortable discussing numbers. In these cases, providers and participants familiar with risk scores shared a common language for describing them (**Table 4**).

Anxious about risk score

A number of participants expressed feeling confused and/or anxious regarding what the risk score meant for them personally (**Table 4**). Unease after discussing the risk score was expressed in one of two principal ways: either through confusion or through anxiety about the information. Most often, when the information was new to them, participants discussed how it was difficult to understand and how they struggled to grapple with the meaning of the risk score for them as an individual. Other participants had a more anxious reaction to their risk score, especially when ambiguity around the risk score was introduced. Both groups were interested in engaging with the numbers and statistics, but had difficulty doing so for lack of experience or because risk factors (such as age or an LCIS diagnosis) rendered the statistical information uncertain and unclear.

Accepting of risk score

During the counseling and thereafter, the majority of participants indicated acceptance of the risk score they received, although this manifested in different ways (**Table 4**). Some participants now felt at risk of getting breast cancer. Others accepted their risk score, but it did not change their feeling of being at risk. Acceptance of the risk score was marked by an expression of trust in the provider.

Non-conversant about risk score

A few participants, e.g., some who were older or who had competing health risks, did not discuss their risk score in interviews at all. Some highlighted how other health experiences were of greater importance, which appeared to help them define their understanding and perception of their own risk (**Table 4**).

4. Discussion

During clinical counseling sessions, risk score values were presented and tailored by providers in ways that gave meaning to the individual patient. As with the use of comparative risk [35 36], presentation can affect the way that risk assessment information is absorbed. We found that providers either emphasized greater risk reduction benefits or the likelihood of developing disease, bolstered their recommendations with persuasive statistics, and augmented uncertain statistical values with clinical experience. Because challenges exist in determining patient comprehension [27], patient-preferred formats suggested by risk communication research [28] are most cohesive when patients and providers share a common sense of risk numeracy and trust. In the counseling sessions observed for this study, exchanges between most study participants and providers were provider-led, unless risk numeracy and trust was already established. Without the context of the interview, little meaning could be taken from watching many of the consultations, where there was little reaction to the risk score outside of small affirmations of listening. When counseling introduced uncertainty, however, the active discussion signaled how participants tried to reach an understanding of their risk score and risk factors.

A particular strength of our study is that after the consultation, we were able to parse out in the interviews whether and by what means participants scrutinized their risk score. Most participants integrated risk score understanding into their overall sense of risk and accepted or even embraced the risk score. However, some were unable to reconcile the numbers with what they knew about themselves, which caused anxiety. When risk scores were unimportant to individuals' risk narratives, other health factors took precedence.

These findings add to previous findings about counseling in the larger study group of the NSABP DMP-1 [25 26]. The category types that describe how the women in the study engaged with the risk score presented to them disentangle how risk assessment and risk information are conveyed in primary cancer prevention settings, including the interactions between provider and participant. For instance, formats that provide numerical outcomes using simple percentages and frequencies, describe changes over time, tailor estimates, and convey uncertainty [35 37-39] are helpful but still lacking when risk scores uncertainty cause anxiety. Our study underscores the idea that for risk assessment information to become a meaningful tool for making treatment decisions, patients' illness and risk experiences must be considered [27 28].

The sparse existing research into how risk assessments and risk scores are used in other health contexts points to gaps and limitations in applying assessment tools in counseling sessions with patients about their risk, and echoes our findings about how providers pragmatically tailor risk score information by adding their own knowledge and experience [10 16 40 41]. Provider knowledge of prevention intervention has been closely

associated with attitudes toward such interventions [9] a finding that is exemplified in our study by showing how risk assessments are concretely conducted.

Our work has some important limitations. Risk assessments in our sample were routinely conducted as part of breast cancer risk counseling and may not be applicable to other cancer prevention counseling where a risk assessment is not routinely used or such extensive discussions of risk scores might not take place. The number of providers in our sample was small and all but one had extensive experience in counseling. This has an important effect on how risk scores are discussed. Future research would benefit from a validation of these patient types with a wider range of cancer prevention counselors in non-urban settings.

5. Conclusions

As risk assessments become a more frequently-used tool in primary cancer prevention counseling, there is an increasing need to understand how providers present these scores and how patients use this information for decisions about their health. For instance, the ways in which socio-demographic factors such as racial/ethnic, educational, and income disparities affect how patients are counseled on risk assessment remain unexplored. Providers work to build relationships that ideally lead to candid discussion and shared decision-making about health, however the exchanges we observed in our sample were provider driven and prompted few exchanges on what these values meant. If risk score information is to move beyond a simple transactional information exchange, understanding the ways that this information is processed during and after counseling is crucial. Having awareness of how risk scores are presented is important because this may influence how information on primary cancer risk is understood and interpreted. Knowing how to make this information meaningful will augment its capacity as decision-making tool for providers and patients.

Supplementary Materials: Prior to this publication, the material has been presented as follows:

Brandner S, Adam Y, Blakeslee S, et al. Qualitative cancer research - - Taking stock, stepping further. Category: Conference Reports, Med Anthropol Theory. 24 March 2015; http://www.medanthrotheory.org/read/4798/qualitative-cancer

Blakeslee SB, McCaskill-Stevens W, Parker PA, et al. Deciding on breast cancer risk reduction: The role of counseling in individual decision-making - A qualitative study. Patient Educ Couns. 2017; 100(12):2346-2354.

Holmberg C, Bandos H, Fagerlin A, et al. NRG Oncology/National Surgical Adjuvant Breast and Bowel Project Decision-Making Project-1 Results: Decision Making in Breast Cancer Risk Reduction. Cancer Prev Res (Phila). 2017; 10(11):625-634.

Gunn CM, Bokhour B, Parker VA, et al. Exploring Explanatory Models of Risk in Breast Cancer Risk Counseling Discussions: NSABP/NRG Oncology Decision-Making Project 1. Cancer Nursing. 2019; 42(1):3-11.

Gunn CM, Bokhour BG, Parker VA, et al. Understanding Decision Making about Breast Cancer Prevention in Action: The Intersection of Perceived Risk, Perceived Control, and Social Context: NRG Oncology/NSABP DMP-1. Med Decis Making. 2019:272989x19827258.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board (or Ethics Committee) of the study was approved by each site's institutional review board in accordance with assurances filed with and approved by the US Department of Health and Human Services**.**

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data for this study are not publicly available for reasons of ensuring anonymity to participants.

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Conflicts of Interest: The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

[1] https://www.clinicaltrials.gov/ct2/show/NCT01399359?term=DMP-1&rank=1

Table 1: Key Participant Demographics

Participant Characteristics	N (%)[1]
Age range	37-73 years
BCRAT score range	
5 years	1-20 %
Lifetime	10-41 %
Previous atypical cell biopsy findings	
Yes	22 (73 %)
No	8 (27 %)
Biopsy with lobular carcinoma in situ (LCIS)	5 (17%)
Race/Ethnicity	
White	21 (70 %)
Black/African American	6 (20 %)
Latino/Hispanic/Multiracial/ Unknown	3 (10 %)

[1] Total n= 30.

Table 2: Video Analysis Codes

Code system: Video Analysis - Risk Memo Analysis	Nr. Coded Segments
Reactions to risk numbers	
Participant risk score not given	3
Confused reaction to risk score	5
No reaction to risk score	4
Accepting positively-framed numbers	4
Accepting negatively-framed numbers	8
Rejection of risk assessment level	6
Negative reactions	11
Positive reaction to risk score information	10
Risk presentations	
No numerical values discussed	3
Tailoring risk information	5
Risk number ambiguities / grey areas of risk numbers	5
Percentages	22
Relative risk reduction	19
Negative framing	15
Emphasis on negative	5
Frequencies	9
Combined positive/negative framing	11
Positive framing	10
Numerical benefits	1
Material presentations	5
Presentation of absolute numbers	0

Table 3: During Counseling - Providers' Personalized Risk Score Numbers and Participants' Reactions

Providers' Personalized Risk Score Numbers	
Theme	**Quote**
Giving thresholds	*Provider BA: "The chemoprevention drugs are the next thing I want to talk about. That's where this magic number comes in. So 1.66% makes you eligible to consider chemoprevention drugs." (Participant L)*
Framing risk scores and risk reduction	*Provider BC: "If we say your lifetime risk is 36%, that means 36 women out of 100 will develop breast cancer. 1 in 3. That's kind of high. If all 100 women take tamoxifen or raloxifene, that risk is reduced by 86%. Or there's a residual 5% risk of getting breast cancer. So instead of 36 women out of that 100 getting breast cancer, only 5 out of 100 get breast cancer. Thirty-one out of that 100 don't get told in their lifetime they have breast cancer. That's big." (Participant Z)*
Making comparisons	*Provider BE: "We use the [BCRAT] to help assess your risk - - and I have the [BCRAT risk score], it's all in that packet at the bottom. The [BCRAT] uses a variety of interchronologic history: your age, and whether you had atypical hyperplasia. The atypical hyperplasia lesion is the one that … is driving your risk the most. The [BCRAT] gives you a 5-year risk of breast cancer and a lifetime risk of breast cancer. As you see, your 5-year risk is estimated to be 1.8%, that's compared with an average risk of 0.7%. Alternatively, the lifetime risk is 15.3% as compared to 7.5%. Basically, that says you're at approximately a double risk of developing breast cancer in your life." (Participant M)*
Devaluing: Undermining and qualifying risk scores	*Provider BA: "So I would say you're a good candidate for it were your risk high enough based on these numbers. I don't know what your risk is really. I know you're negative for the gene and you're not 1.6 or higher on this scale. So based on the data I have available you don't really fall into the category where it's appropriate. However, I also know that you're in a little bit of a grey zone." (Participant A)* *Provider BB: "I will quote you exact numbers - - let me get you the exact numbers. I think it was about 1.4, so it was a very low risk." (Participant N)*

Table 3 Continued: During Counseling - Providers' Personalized Risk Score Numbers and Participants' Reactions

Participants' Counseling: Reactions to Risk Score	
Theme	**Quote**
Discussion in counseling: Prompted by participant comfort and provider ambiguity	*Participant U: "So those who got there [into the study] … with atypical [biopsy findings], most likely had a - -"* *Provider BC: "86% risk reduction."* *Participant U: "Over the 5-year? Or lifetime?"* *Provider BC: "Both, both. So that means we would reduce this [by] 86%, the lifetime risk of 30% down to …"* *Participant U: "By 86%?"* *Provider BC: "Well, down to 4-5%."* *Participant U AND Provider BC in unison: "Which is lower than an average person."* *Participant V: "We both understood [the previous provider] to say 40 to 50% [lifetime risk range]."* *Participant companion: "40 to 60%! Has that changed in the last year or two?"* *Provider BC: "No, that hasn't changed."* *Participant V: "So this is new information, … you're saying on the high side 30%?* *Provider BC: "Sure."* *Participant V: "This is new information to me. I just felt like a 50% chance [told to me by the previous provider]. - - I'm kind of like a ticking bomb!"*
Adding information to risk scores	*Participant A: "Does this number obviously go up as I age?"* *Provider BA: "As well, as well."* *Participant A: "So as this number goes up to one [percent 5-yr risk], this [lifetime risk] number goes up higher?"* *Provider BA: "So you're [at] one percent [5-yr risk], 20.6 [percent lifetime risk]. So I'm a little bit on the fence about this."* *Participant A: "I'm wondering if this is the right time to start it, or next year if we revisit it, is that the best time to say, 'As you're approaching forty, you can come back and start [taking tamoxifen]'?"*

Table 4: After Counseling - Four Primary Reactions to Risk Score Information

After Counseling: Four Reactions to Risk Score Information	
Category Type Important Variables	**Quote**
Being at ease with risk score Counseling visitation (1+)	*Participant U: "Well, it took me a few times, like I said, initially to understand that 5-year risk for myself… versus 5-year average risk for someone that is not… I deal with probability all the time, but I was looking at it from a different perspective."*
Anxious about risk score Counseling visitation (1) Finding lobular carcinoma in situ	*Participant W: "It was scary. Who wants to hear that they're, you know, at double the risk for breast cancer? Nobody wants to hear that. Plus, I'm still confused..."* *Participant V: "I feel confused about these statics as I revisit this… I understand she's doing her best to get a model for me… but it's hard to combine the two. That's what I remember thinking too after we left there, that that was going through my mind."*
Accepting of risk score Signaled trust in provider Age range (65 yrs. +)	*Participant X: "Twenty-six is not a small- I mean, I guess that's a high number… I would probably say I wouldn't think so, but now that I have had [an atypical biopsy finding] there's always a possibility that I could develop breast cancer – that I know is there."* *Participant R: "She reiterated some things to me: 'You'll be at four percent if you take it, your risk factor is like 4% rather than maybe like 20%.' Just her numbers and everything make me feel comfortable taking it[medication]."* *Participant N:"I mean, I think I was not more worried. I knew I was at a higher risk, but I didn't think the ratio was that much more substantial…"*
Non-conversant about risk score Co-morbidity (1+)	*Participant J: "Basically [what the provider shared with me was how based on] my age, my family history, the probability or possibility within my age group of getting cancer within the next five years and thereafter. And the percentages are mostly what she explained… It's a big concern for me, the possibility of having a stroke and certainly the possibility of having cancer because - - and that's another problem and situation, you know. The only thing is, you know, it's weighing one I guess against the other."*

References

1. Hood L, Friend SH. Predictive, personalized, preventive, participatory (P4) cancer medicine. *Nature reviews Clinical oncology* 2011;8(3):184-7. doi: 10.1038/nrclinonc.2010.227 [published Online First: 2011/03/03]
2. US Preventive Services Task Force. Guide to clinical preventive services: report of the US Preventive Services Task Force: DIANE publishing 2014.
3. Health, United States, Annual Perspective, 2020-2021. In: National Center for Health S, ed. Hyattsville, MD: https://dx.doi.org/10.15620/cdc:122044, 2023.
4. Holmberg C, Sarganas G, Mittring N, et al. Primary prevention in general practice - views of German general practitioners: a mixed-methods study. *BMC family practice* 2014;15:103. doi: 10.1186/1471-2296-15-103 [published Online First: 2014/06/03]
5. Amir E, Freedman OC, Seruga B, et al. Assessing Women at High Risk of Breast Cancer: A Review of Risk Assessment Models. *JNCI: Journal of the National Cancer Institute* 2010;102(10):680-91. doi: 10.1093/jnci/djq088
6. Ladabaum U, Patel A, Mannalithara A, et al. Predicting advanced neoplasia at colonoscopy in a diverse population with the National Cancer Institute colorectal cancer risk-assessment tool. *Cancer* 2016;122(17):2663-70. doi: 10.1002/cncr.30096 [published Online First: 20160524]
7. Moyer VA. Risk assessment, genetic counseling, and genetic testing for BRCA-related cancer in women: U.S. Preventive Services Task Force recommendation statement. *Annals of internal medicine* 2014;160(4):271-81. doi: 10.7326/m13-2747
8. Wang W, Niendorf KB, Patel D, et al. Estimating CDKN2A carrier probability and personalizing cancer risk assessments in hereditary melanoma using MelaPRO. *Cancer Res* 2010;70(2):552-9. doi: 10.1158/0008-5472.Can-09-2653 [published Online First: 20100112]
9. Samimi G, Heckman-Stoddard BM, Holmberg C, et al. Cancer Prevention in Primary Care: Perception of Importance, Recognition of Risk Factors and Prescribing Behaviors. *Am J Med* 2020;133(6):723-32. doi: 10.1016/j.amjmed.2019.11.017 [published Online First: 2019/12/22]
10. Samimi G, Heckman-Stoddard BM, Holmberg C, et al. Assessment of and Interventions for Women at High Risk for Breast or Ovarian Cancer: A Survey of Primary Care Physicians. *Cancer Prevention Research* 2021;14(2):205. doi: 10.1158/1940-6207.CAPR-20-0407
11. Guerra CE, Sherman M, Armstrong K. Diffusion of breast cancer risk assessment in primary care. *Journal of the American Board of Family Medicine : JABFM* 2009;22(3):272-9. doi: 10.3122/jabfm.2009.03.080153 [published Online First: 2009/05/12]
12. Crew KD, Albain KS, Hershman DL, et al. How do we increase uptake of tamoxifen and other anti-estrogens for breast cancer prevention? *NPJ Breast Cancer* 2017;3:20. doi: 10.1038/s41523-017-0021-y [published Online First: 20170519]
13. Armstrong K. Calling on Primary Care to Prevent BRCA-Related Cancers. *J Gen Intern Med* 2020;35(3):903-05. doi: 10.1007/s11606-019-05469-7 [published Online First: 20191021]
14. Breast Cancer Risk Reduction Clinical Practice Guidelines in Oncology. *Journal of the National Comprehensive Cancer Network : JNCCN* 2003;1(2):280-96. doi: 10.6004/jnccn.2003.0026
15. Bevers TB, Helvie M, Bonaccio E, et al. Breast Cancer Screening and Diagnosis, Version 3.2018, NCCN Clinical Practice Guidelines in Oncology. *Journal of the National Comprehensive Cancer Network : JNCCN* 2018;16(11):1362-89. doi: 10.6004/jnccn.2018.0083
16. Akanuwe JNA, Black S, Owen S, et al. Communicating cancer risk in the primary care consultation when using a cancer risk assessment tool: Qualitative study with service users and practitioners. *Health expectations : an international journal of*

public participation in health care and health policy 2020;23(2):509-18. doi: 10.1111/hex.13016 [published Online First: 20200122]

17. Claus EB, Risch N, Thompson WD. The calculation of breast cancer risk for women with a first degree family history of ovarian cancer. *Breast cancer research and treatment* 1993;28(2):115-20. doi: 10.1007/bf00666424
18. Berliner JL, Fay AM. Risk assessment and genetic counseling for hereditary breast and ovarian cancer: recommendations of the National Society of Genetic Counselors. *Journal of genetic counseling* 2007;16(3):241-60. doi: 10.1007/s10897-007-9090-7 [published Online First: 20070517]
19. Murff HJ, Byrne D, Syngal S. Cancer Risk Assessment: Quality and Impact of the Family History Interview. *American Journal of Preventive Medicine* 2004;27(3):239-45. doi: http://dx.doi.org/10.1016/j.amepre.2004.05.003
20. Trepanier A, Ahrens M, McKinnon W, et al. Genetic Cancer Risk Assessment and Counseling: RECommendations of the National Society of Genetic Counselors. *J Genet Counsel* 2004;13(2):83-114.
21. Evans DG, Howell A. Breast cancer risk-assessment models. *Breast cancer research : BCR* 2007;9(5):213. doi: 10.1186/bcr1750
22. Committee on Practice Bulletins–Gynecology CoG, Society of Gynecologic Oncology;. Practice Bulletin Number 179: Breast Cancer Risk Assessment and Screening in Average-Risk Women. *Obstetrics & Gynecology* 2017;130(1)
23. Bevers TB, Ward JH, Arun BK, et al. Breast Cancer Risk Reduction, Version 2.2015. *Journal of the National Comprehensive Cancer Network : JNCCN* 2015;13(7):880-915. doi: 10.6004/jnccn.2015.0105
24. Owens DK, Davidson KW, Krist AH, et al. Medication Use to Reduce Risk of Breast Cancer: US Preventive Services Task Force Recommendation Statement. *Jama* 2019;322(9):857-67. doi: 10.1001/jama.2019.11885 [published Online First: 2019/09/04]
25. Holmberg C, Bandos H, Fagerlin A, et al. NRG Oncology/National Surgical Adjuvant Breast and Bowel Project Decision-Making Project-1 Results: Decision Making in Breast Cancer Risk Reduction. *Cancer prevention research (Philadelphia, Pa)* 2017 doi: 10.1158/1940-6207.capr-17-0076 [published Online First: 2017/10/06]
26. Blakeslee SB, McCaskill-Stevens W, Parker PA, et al. Deciding on breast cancer risk reduction: The role of counseling in individual decision-making - A qualitative study. *Patient Educ Couns* 2017;100(12):2346-54. doi: 10.1016/j.pec.2017.06.033 [published Online First: 2017/07/25]
27. Gunn CM, Bokhour B, Parker VA, et al. Exploring Explanatory Models of Risk in Breast Cancer Risk Counseling Discussions: NSABP/NRG Oncology Decision-Making Project 1. *Cancer nursing* 2019;42(1):3-11. doi: 10.1097/ncc.0000000000000517 [published Online First: 2017/07/01]
28. Gunn CM, Bokhour BG, Parker VA, et al. Understanding Decision Making about Breast Cancer Prevention in Action: The Intersection of Perceived Risk, Perceived Control, and Social Context: NRG Oncology/NSABP DMP-1. *Medical decision making : an international journal of the Society for Medical Decision Making* 2019;39(3):217-27. doi: 10.1177/0272989x19827258 [published Online First: 2019/02/26]
29. Hamilton JG, Abdiwahab E, Edwards HM, et al. Primary care providers' cancer genetic testing-related knowledge, attitudes, and communication behaviors: A systematic review and research agenda. *J Gen Intern Med* 2017;32(3):315-24. doi: 10.1007/s11606-016-3943-4 [published Online First: 20161219]
30. Corbelli J, Borrero S, Bonnema R, et al. Use of the Gail model and breast cancer preventive therapy among three primary care specialties. *Journal of women's health (2002)* 2014;23(9):746-52. doi: 10.1089/jwh.2014.4742 [published Online First: 2014/08/15]
31. Bellhouse S, Hawkes RE, Howell SJ, et al. Breast Cancer Risk Assessment and Primary Prevention Advice in Primary Care: A Systematic Review of Provider Attitudes and Routine Behaviours. *Cancers (Basel)* 2021;13(16) doi: 10.3390/cancers13164150 [published Online First: 20210818]

32. Schubert C. Video analysis of practice and the practice of video analysis. Selecting field and focus in videography. In: Knoblauch H, Schnettler B, Raab J, et al., eds. Video analysis: methodology and methods. 3rd Edition ed. Frankfurt am Main: Peter Lang 2012:115-26.

33. Software for qualitative data analysis [program]. Version 18 version. Berlin, Germany: VERBI Software – Consult – Sozialforschung GmbH, 1995-2017.

34. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care* 2007;19(6):349-57. doi: 10.1093/intqhc/mzm042

35. Fagerlin A, Zikmund-Fisher BJ, Ubel PA. Helping patients decide: ten steps to better risk communication. *Journal of the National Cancer Institute* 2011;103(19):1436-43. doi: 10.1093/jnci/djr318 [published Online First: 2011/09/21]

36. Fagerlin A, Zikmund-Fisher BJ, Ubel PA. "If I'm better than average, then I'm ok?": Comparative information influences beliefs about risk and benefits. *Patient Educ Couns* 2007;69(1-3):140-4. doi: 10.1016/j.pec.2007.08.008 [published Online First: 20071017]

37. Lipkus IM. Numeric, verbal, and visual formats of conveying health risks: suggested best practices and future recommendations. *Medical decision making : an international journal of the Society for Medical Decision Making* 2007;27(5):696-713. doi: 10.1177/0272989x07307271 [published Online First: 20070914]

38. Trevena LJ, Zikmund-Fisher BJ, Edwards A, et al. Presenting quantitative information about decision outcomes: a risk communication primer for patient decision aid developers. *BMC medical informatics and decision making* 2013;13 Suppl 2:S7. doi: 10.1186/1472-6947-13-s2-s7 [published Online First: 2013/01/01]

39. Zikmund-Fisher BJ, Fagerlin A, Roberts TR, et al. Alternate methods of framing information about medication side effects: incremental risk versus total risk of occurrence. *Journal of health communication* 2008;13(2):107-24. doi: 790919454 [pii],10.1080/10810730701854011 [published Online First: 2008/02/27]

40. Liew SM, Blacklock C, Hislop J, et al. Cardiovascular risk scores: qualitative study of how primary care practitioners understand and use them. *Br J Gen Pract* 2013;63(611):e401-7. doi: 10.3399/bjgp13X668195

41. Oriol-Zerbe C, Abholz HH. Primary prevention of cardiovascular diseases by lipid-lowering treatment in German general practice: results from GPs ignoring guidelines and risk calculators. *Eur J Gen Pract* 2007;13(1):27-34. doi: 10.1080/13814780601050541

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Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	
Duration	21	What was the duration of the inter views or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
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Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

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Talking Numbers: How Women and Providers Use Risk Scores During and After Risk Counseling - A qualitative investigation from the NRG Oncology/NSABP DMP-1 study

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Original Research

Talking Numbers: How Women and Providers Use Risk Scores During and After Risk Counseling - A qualitative investigation from the NRG Oncology/NSABP DMP-1 study

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Abstract: Objectives: Little research exists on how risk scores are used in counseling. We examined (I) how breast cancer risk assessment (BCRAT) scores are presented during counseling and (II) how women react and (III) discuss them afterwards.

Design: Consultations were video-recorded and participants were interviewed after the consultation as part of the NRG Oncology/National Surgical Adjuvant Breast and Bowel Project Decision-Making Project 1 (NSABP DMP-1).

Setting: Two NSABP DMP-1 breast cancer care centers in the United States: one large comprehensive cancer center serving a high-risk population and an academic safety-net medical center in an urban setting.

Participants: Thirty women evaluated for with breast cancer risk and their counseling providers were included**.**

Results: Risk scores were individualized and given meaning by providers through: (A) presenting thresholds, (B) making comparisons, and (C) emphasizing or minimizing the calculated risk. The risk score information elicited little reaction from participants during consultations, though some added to, agreed with, or qualified the provider's information. Results: During interviews, participants reacted to the numbers in four primary ways: (1) engaging easily with numbers; (2) expressing greater anxiety after discussing the risk score; (3) accepting the risk score; and (4) not talking about the risk score.

Conclusions: Our study highlights the necessity that patients' experiences must be understood and put into relation to risk assessment information to become a meaningful treatment decision-making tool, for instance by categorizing patients' information engagement into types.

Running title: Patients use risk scores from risk assessments in four ways

Keywords: Individual risk assessments, risk score, risk counseling, primary prevention, breast cancer risk, qualitative research, BCRAT

Word count: 3673 Number of Figures: 0 Number of Tables: 4

Strengths and limitations of this study

- Videos recorded individual consultations conveyed interactions between a provider and patient in primary cancer prevention settings.
- Interviews including a review of the own video consultation with participants enabled scrutiny of risk score meaning by participants.
- Risk assessments that were routinely conducted as part of breast cancer risk counseling in our sample and may not be applicable where a cancer prevention risk assessment is not routinely used or discussed.
- Need for future patient type validation with a wider range of cancer prevention counselors in non-urban settings.

1. Introduction

Counseling on prevention and interventional strategies to reduce disease risk is considered an important aspect of clinical care from primary to specialty practice [1-4]. Treatment guidelines about prevention encourage the use of risk scores to identify individuals at risk and counsel them on the likelihood of developing a particular disease within a given time period [5-8]. As the first point of cancer prevention care, primary care providers and specialists, including family physicians, obstetricians/gynecologists, and internists, as well as nurse practitioners, are tasked with counseling on risk for disease across a whole spectrum of preventive medicine [9-13].

In risk counseling, the benefits of lowering the risk of developing breast cancer should be weighed against the intervention options, from lifestyle changes (such as lowering alcohol intake, maintaining a healthy body weight, limiting hormone exposure), to surgery (prophylactic mastectomy and oophorectomy), and taking an oral selective estrogen receptor modulator (SERM) [7, 14, 15]. Standardized risk assessment instruments such as the Breast Cancer Risk Assessment Tool (BCRAT) [14] and others [16-21] provide a base value of risk for individuals, which is presented in a percentage of risk over time; both five years and over a lifetime (up to the age of 90 years). This individually calculated risk can be used to initiate a discussion between providers and patients about risk option preferences. The BCRAT is particularly relevant for epidemiological and clinical risk factors outside of family history and is used to determine eligibility for SERM. SERM presents an option for individuals with a calculated BCRAT over 1.66% for five years or 20% for a lifetime [22-24].

The National Surgical Adjuvant Breast and Bowel Project Decision-Making Project 1 (NSABP DMP-1) investigated social, cultural, and psychological factors driving decision-making regarding SERM use in women counseled on breast cancer prevention options [25]. Physician recommendation was found to be the most important factor for SERM uptake [25], but only if it aligned with the social and experiential factors of the counseled women [25-28]. Objective risk assessment was not found to be a decisive factor. Detailed

investigation of decision-making processes showed the importance of perceived control in relation to perceived risk as a factor determining decision-making, as well as an understanding of the reversibility of the decision, the perception of medications, and how close the possibility of cancer felt to oneself [26, 28].

Provider risk counseling is often the most important entry point for identifying women at high risk of developing breast cancer and providers are increasingly recognizing the importance of (genetic) risk factors and counseling [11-13], yet how frequently risk assessments are used depends on specialty and training [9, 29-31]. When risk assessments are conducted with patients, little is known about the communication strategies in practice. In this article, we aim to identify and describe how risk information and risk scores used in counseling is provided and worked with in the communication between provider and participant. We specifically explored: (I) how BCRAT scores are introduced during counseling; (II) the reactions of women during counseling sessions; and (III) discussions of these scores afterward, as they pertain to an individual's own breast cancer risk.

2. Materials and Methods

NRG Oncology/NSABP DMP-1

This study used the data available from the qualitative arm of the NSABP DMP-1 to investigate the communication strategies and role of risk information in breast cancer risk counseling. The DMP-1 was a mixed-method study to investigate the social, environmental, and psychological factors involved in decision-making about risk reduction strategies in women counseled on SERM use for breast cancer risk. It consisted of a survey arm and a qualitative, observational arm [25]. The qualitative arm recorded 30 breast consultation sessions of women who were identified prior to counseling as at risk for breast cancer by their provider from two DMP-1 study sites: a large comprehensive cancer center serving a high-risk population and academic safety-net medical center in an urban setting serving a large population of racial and ethnic minorities. In addition, in-depth interviews with participants from the recorded consultation sessions were conducted within six weeks of the consultation [25, 26].

The Institutional Review Board gave ethical approval for both sites (The Boston University Medical Campus FWA00000301 / IRB00008404 / study application number H-31403; The University of Texas MD Anderson Cancer Center FWA00000363 / IRB4 - IRB00005015 / protocol name NSABP DMP-1). All providers and participants gave written informed consent.

Data collection

Between April 2012 and August 2013, participants scheduled for appointments to discuss their breast health who were identified as at risk for breast cancer after a regularly scheduled mammogram or check up, due to a family risk of breast cancer or to discuss biopsy results were contacted and recruited purposively before breast cancer risk counseling sessions appointments. Written consent was given prior to being video-recorded during their session. In order to capture regular care counseling, providers were not given counseling content outside of the eligibility criteria that they intended to discuss SERM use[26]. Subsequently, a qualitative interview was conducted with participants on-site by experienced and trained interviewers. Both interviewers were women, a health researcher (CG) and clinical psychologist (PP) who contacted participants for setting up interviews and explaining research background and goals before securing informed consent. Using a previously pilot-tested, semi-structured guideline that was tailored to the content of the individual consultation session, prior to the interview, after being viewed by members of the qualitative team (health researcher JK, social scientist doctoral candidate SB, PhD medical ethnographer

and epidemiologist CH, CG and PP). Overall, the interviews addressed: the experience of the consultation and treatment options discussed; the experience of breast cancer risk and views of treatment options; and feedback and input after viewing their own consultation. As participants watched their own consultation video, they were encouraged to comment on the recorded consultation session content and to answer questions from the research team (JK, SB, CH, CG, and PP). A follow-up telephone interview on the decision made by each participant finalized the data collection for the primary study.

Analysis

We used all 30 available NSABP DMP-1 data protected [26] consultations and interview transcripts. Consultation videos were summarized jointly and inductively as a team according to Schubert [32]. Next, the joint summaries were coded thematically (JK, SB). Joint summary themes that discussed risk calculation and/or assessments were compiled deductively according to these themes and corresponding video segments reviewed for participant reactions. Each reaction was described in further analytical memos. The video data was then coded inductively according to presentation and interaction types that evolved from the analysis.

In addition, the interview material was searched deductively for text segments that contained the inductively-derived themes related to risk assessment. Subgroup analysis according to demographic variables such as age and Gail score were conducted, investigating reactions to risk scores and contrasting and comparing them with the pertinent video analysis data. From this, four descriptive categories of reactions to risk scores emerged. The descriptive categories were clearly defined after 19 interviews; all 30 interviews fit principally into one of the four descriptive categories.

Analysis was done by the first author (SB), in regular consultation with the last author, senior principle investigator (CH). Regular meetings and presentation of findings were discussed with a qualitative methods working group at the Institute for Public Health, Charité-Universitätsmedizin Berlin. Analysis was assisted and organized throughout in MAXQDA v18 [33], reported using the COnsolidated criteria for REporting Qualitative research[34]

Patient and Public Involvement

No patients were directly involved in the design or recruitment of this study. However, our previous studies about patients' priorities, experience, and preferences regarding breast cancer risk informed this current study, design and recruitment [26-28, 35]. Results of the study will be made available to study participants at the participating centers.

3. Results

Key demographics for the sample are summarized in **Table 1**, and reported in extensive detail in previous publications [26-28].

Five providers conducted the 30 counseling sessions. All but one provider had extensive experience counseling on risk; one was new to risk counseling. The 5 medical providers included the following specialties: general internists with specialty training in breast health, nurse practitioner, and oncologist. The total consultation length for each participant ranged from 11-37 minutes. Further characteristics can be found in a previous publication [26]. For 16 participants (53%), this was their first visit with this provider.

There were 21 participants (70%) for whom SERM was recommended. Providers presented the risk score to all but one participant either as a printed handout or on the computer screen; the discussion of the risk score took place at the beginning of the consultation in nearly all consultations. The amount of time that providers and participants specifically discussed the risk score itself within the consultation session ranged from 13 seconds to 6 minutes, corresponding to 2-24% of the consultation time. In two cases, no risk score was discussed. Almost all consultations closely followed the discussion topics about breast cancer risk as listed in existing breast cancer risk guidelines, from lifestyle changes for prevention, to screening and surgery, in addition to SERM [7, 14]. However, how systematically breast cancer risk factors were discussed varied according to the provider's style and experience.

During Counseling: Providers' Personalized Risk Score Numbers

During counseling, providers gave meaning to the risk score by: (A) presenting thresholds, (B) making comparisons, and (C) emphasizing or minimizing risk and risk reduction.

Presenting Thresholds

Risk levels, which are set as the minimum levels at which tamoxifen may be prescribed as a risk reduction therapy (5-yr=1.66%; lifetime=20%), were introduced as a threshold at which a provider should discuss breast cancer prevention options. One provider referred to such thresholds as "magic numbers" (**Table 2**). In three cases, providers discussed the risk and SERM, but never cited a risk score to the patient during counseling (**Table 2**).

Framing Risk Scores and Risk Reduction

The strength of the provider's recommendation for SERM use for a participant influenced the way the risk score was explained during counseling. Most risk scores were clarified by an emphasis on the likelihood of developing breast cancer. For example, a provider who strongly recommended that a participant consider SERM as a result of atypical cell biopsy findings regularly cited a relative risk reduction of 86% based on findings from prevention clinical trials. When a provider clearly recommended against SERM use, risk scores were framed to illustrate how unlikely the person was to develop breast cancer. The residual risk, or remaining likelihood of developing breast cancer after SERM treatment, was discussed only with people demonstrating statistical proficiency during the office visit and showed eagerness to grasp risk statistics (**Table 2**).

Making Comparisons

Another important strategy that was used to make the risk score meaningful was to compare the patient's risk score to that of the "average" women (**Table 2**). For example, providers highlighted how the participant's risk score was double or three-times the average. The risk score of the participant as compared to that of the average woman was presented in a format using absolute numbers.

Minimizing a risk score: Recognition of risk assessment tool limitations

In some consultations, providers recognized the limitations and ambiguity of risk assessment tools. In these cases, the provider verbally minimized the meaning of the individual's calculated risk score in order to incorporate other factors that would modify the meaning of a counselee's individual risk (**Table 2**). This happened particularly when the explanation of the provider highlighted that they felt the risk score did not adequately reflect the risk factors of a given participant. For those with complicating medical factors, such

as a simultaneous family history of breast cancer and stroke, or for those who were young, providers emphasized that for such a combination of factors, the available risk score might not provide an appropriate risk estimate. Women who had a specific finding of atypical cells called lobular carcinoma in situ (LCIS) were presented with a percentage range because the BCRAT tool is unable to calculate an individual risk score. In such instances, providers expressed ambiguity, were careful not to give a precise risk estimate or did not use an risk score to underscore the recommendation.

During Counseling: Participants' Reactions

Overall, most consultations did not illicit reactions to the risk score information during the counseling session. Most participants simply listened or gave signs of affirmation while the providers presented the risk score information. Engaged discussions about risk scores were characterized by a high level of comfort with risk numbers on the part of the participant or their need for clarity about the presented information (**Table 3**). A subset of the participants were prompted to engage in discussions about their risk when the way provider communicated or framed risk scores resulted in less clarity or when participants added their own information to what the provider presented.

Discussion in Counseling: Prompted by Participant Comfort and Provider Ambiguity

Participants who engaged in discussion were those who expressed the most comfort with or certainty about the risk score presented. Those who had been previously counseled and had discussed their risk score in the past, or who mentioned in the consultation or interview that they worked with statistics, appeared most comfortable in discussing risk numbers during the consultation. When providers communicated uncertainty about the risk score, undermined the score, or presented risk levels surprising to the participant, discussion was also prompted (**Table 3**).

Adding Information to Risk Scores

Some participants tried to understand the risk values presented to them during counseling by providing additional information, which they thought might change their risk level (e.g., see **Table 3**).

After Counseling: Four Primary Reactions to Risk Score Information

In contrast to the counseling sessions, in the interview participants had lively discussions on risk scores and risk levels. Participants engaged primarily with their risk score in four ways during the interviews: (1) being at ease with the risk score; (2) being anxious about the risk score; (3) accepting the risk score; or (4) being non-conversant about the risk scores (**Table 4**). These responses were not mutually exclusive and overlapped in the ways participants engaged with the risk score. Patterns of engagement were viewed according to participants' risk and health background, the actual risk score, and the way the providers had delivered the information.

Being at Ease with the Risk Score

Some participants discussed the statistical calculations of their risk score easily during the interviews. These participants described their own prior expertise in statistics and familiarity with their breast cancer risk score from previous counseling discussions or through their own work. Irrespective of their risk score, they asked further questions about values or candidly discussed in the interview the way in which they understood a statistical presentation. They strongly signaled that they felt comfortable discussing numbers. In these cases,

providers and participants familiar with risk scores shared a common language for describing them during their consultation session (**Table 4**).

Anxious about risk score

A number of participants expressed feeling confused and/or anxious regarding what the risk score meant for them personally (**Table 4**). Unease after discussing the risk score was expressed in one of two principal ways: either through confusion or through anxiety about the information. Most often, when the information was new to them, participants discussed how it was difficult to understand and how they struggled to grapple with the meaning of the risk score for them as an individual. Other participants had a more anxious reaction to their risk score, especially when ambiguity around the risk score was introduced. Although participants from both groups mentioned they were interested in engaging with the numbers and statistics, they also signaled that they had difficulty doing so for lack of experience or because risk factors (such as age or an LCIS diagnosis) rendered the statistical information uncertain and unclear.

Accepting of risk score

During the counseling and thereafter, the majority of participants indicated acceptance of the risk score they received, although this manifested in different ways (**Table 4**). Some participants now felt at risk of getting breast cancer. Others accepted their risk score, but it did not change their feeling of being at risk. Acceptance of the risk score was marked by an expression of trust in the provider.

Non-conversant about risk score

A few participants, e.g., some who were older or who had competing health risks, did not discuss their risk score in interviews at all. Some highlighted how other health experiences were of greater importance, which appeared to help them define their understanding and perception of their own risk (**Table 4**).

4. Discussion

During clinical counseling sessions, risk score values were presented and tailored by providers in ways that gave meaning to the individual patient. As with the use of comparative risk [36, 37], presentation can affect the way that risk assessment information is absorbed. We found that providers emphasized greater risk reduction benefits or the likelihood of developing disease, they bolstered their recommendations with persuasive statistics, and augmented uncertain statistical values with clinical experience. Because challenges exist in determining how each patient comprehends information [27], risk communication research suggest patient-preferred formats, such as visual representations, absolute risk values or comparisons may facilitate communication between the patient and provider [28]. However, communication tools in our study appeared to be most useful when patients and providers share a common sense of risk numeracy and trust. In the counseling sessions observed for this study, exchanges between most study participants and providers were provider-led, unless risk numeracy and trust was already established. Without the context of the interview, little meaning could be taken from watching many of the consultations, where there was little reaction to the risk score outside of small affirmations of listening. When counseling introduced uncertainty, however, the active discussion signaled how participants tried to reach an understanding of their risk score and risk factors.

A particular strength of our study is that after the consultation, we were able to parse out in the interviews whether and by what means participants scrutinized their risk score. Most participants integrated risk score

understanding into their overall sense of risk and accepted or even embraced the risk score. However, some were unable to reconcile the numbers with what they knew about themselves, which caused anxiety. When risk scores were unimportant to individuals' risk narratives, other health factors took precedence.

These findings add to previous findings about counseling in the larger study group of the NSABP DMP-1 [25, 26]. The category types that describe how the women in the study engaged with the risk score presented to them disentangle how risk assessment and risk information are conveyed in primary cancer prevention settings, including the interactions between provider and participant. For instance, formats that provide numerical outcomes using simple percentages and frequencies, describe changes over time, tailor estimates, and convey uncertainty [36, 38-40] are helpful. Despite a tailored presentation, risk scores that cannot be presented in absolute numbers or contain some ambiguity, may still cause anxiety for some individuals. Our study underscores the idea that for risk assessment information to become a meaningful tool for making treatment decisions, patients' illness and risk experiences must be considered [27, 28].

The sparse existing research into how risk assessments and risk scores are used in other health contexts points to gaps and limitations in applying assessment tools in counseling sessions with patients about their risk, and echoes our findings about how providers pragmatically tailor risk score information by adding their own knowledge and experience [10, 16, 41, 42]. Providers have been found to be more positively inclined toward prescribing prevention interventions when they are more knowledgeable about an intervention [9], a finding that is exemplified in our findings from the NSABP DMP-1 study whereby the most experienced counseling providers recommended SERM most frequently [26]. This study of how risk assessments are counseled on highlights how conducted risk scores are used to give meaning to recommendations.

Our work has some important limitations. Risk assessments in our sample were routinely conducted as part of breast cancer risk counseling and may not be applicable to other cancer prevention counseling where a risk assessment is not routinely used or such extensive discussions of risk scores might not take place. The number of providers in our sample was small and all but one had extensive experience in counseling. This has an important effect on how risk scores are discussed. Future research would benefit from a validation of these patient types with a wider range of cancer prevention counselors in non-urban settings.

The findings from this analysis has implications for risk counseling practice using risk assessment tools. Taking a comprehensive view, our analysis of this sample previously suggested that posing patient-centered questions during breast cancer risk counseling will help women assess their own priorities [27] and this engagement will enhance the trust in a patient-provider relationship [28]. At the same time, the recognition that patient beliefs and understandings are vital to the decision making process [26] advances a strong argument for providers to ask specifically about a patient's comfort-level with numeracy. Risk counseling could be adapted in various ways, for instance by using absolute risk values or visual aids for individuals who are less numerically comfortable or anxious about this information.

5. Conclusions

As risk assessments become a more frequently-used tool in primary cancer prevention counseling, there is an increasing need to understand how providers present these scores and how patients use this information for decisions about their health. For instance, the ways in which socio-demographic factors such as racial/ethnic, educational, and income disparities affect how patients are counseled on risk assessment remain unexplored. Providers work to build relationships that ideally lead to candid discussion and shared decision-making about health, however the exchanges we observed in our sample were provider driven and prompted few exchanges on what these values meant. If risk score information is to move beyond a simple transactional information exchange, understanding the ways that this information is processed during and after counseling is crucial. Having awareness of how risk scores are presented is important because this may

influence how information on primary cancer risk is understood and interpreted. Knowing how to make this information meaningful will augment its capacity as decision-making tool for providers and patients.

Supplementary Materials: Prior to this publication, the material has been presented as follows:

Brandner S, Adam Y, Blakeslee S, et al. Qualitative cancer research - - Taking stock, stepping further. Category: Conference Reports, Med Anthropol Theory. 24 March 2015; http://www.medanthrotheory.org/read/4798/qualitative-cancer

Blakeslee SB, McCaskill-Stevens W, Parker PA, et al. Deciding on breast cancer risk reduction: The role of counseling in individual decision-making - A qualitative study. Patient Educ Couns. 2017; 100(12):2346-2354.

Holmberg C, Bandos H, Fagerlin A, et al. NRG Oncology/National Surgical Adjuvant Breast and Bowel Project Decision-Making Project-1 Results: Decision Making in Breast Cancer Risk Reduction. Cancer Prev Res (Phila). 2017; 10(11):625-634.

Gunn CM, Bokhour B, Parker VA, et al. Exploring Explanatory Models of Risk in Breast Cancer Risk Counseling Discussions: NSABP/NRG Oncology Decision-Making Project 1. Cancer Nursing. 2019; 42(1):3-11.

Gunn CM, Bokhour BG, Parker VA, et al. Understanding Decision Making about Breast Cancer Prevention in Action: The Intersection of Perceived Risk, Perceived Control, and Social Context: NRG Oncology/NSABP DMP-1. Med Decis Making. 2019:272989x19827258.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board (or Ethics Committee) of the study was approved by each site's institutional review board (The Boston University Medical Campus FWA00000301 / IRB00008404 / study application number H-31403; The University of Texas MD Anderson Cancer Center FWA00000363 / IRB4 - IRB00005015 / protocol name NSABP DMP-1) in accordance with assurances filed with and approved by the US Department of Health and Human Services.

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[1] https://www.clinicaltrials.gov/ct2/show/NCT01399359?term=DMP-1&rank=1

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Table 1: Key Participant Demographics

Participant Characteristics	
Age range	37-73 years
BCRAT score range	**N (%)**[1]
5 years	1-20 %
Lifetime	10-41 %
Previous atypical cell biopsy findings	
Yes	22 (73 %)
No	8 (27 %)
Biopsy with lobular carcinoma in situ (LCIS)	5 (17%)
Race/Ethnicity	
White	21 (70 %)
Black/African American	6 (20 %)
Latino/Hispanic/Multiracial/ Unknown	3 (10 %)

[1] Total n= 30.

Table 2: Video Analysis Codes

Code system: Video Analysis - Risk Memo Analysis	**Nr. Coded Segments**
Reactions to risk numbers	
Participant risk score not given	3
Confused reaction to risk score	5
No reaction to risk score	4
Accepting positively-framed numbers	4
Accepting negatively-framed numbers	8
Rejection of risk assessment level	6
Negative reactions	11
Positive reaction to risk score information	10
Risk presentations	
No numerical values discussed	3
Tailoring risk information	5
Risk number ambiguities / grey areas of risk numbers	5
Percentages	22
Relative risk reduction	19
Negative framing	15
Emphasis on negative	5
Frequencies	9
Combined positive/negative framing	11
Positive framing	10
Numerical benefits	1
Material presentations	5
Presentation of absolute numbers	0

Table 3: During Counseling - Providers' Personalized Risk Score Numbers and Participants' Reactions

Providers' Personalized Risk Score Numbers	
Theme	**Quote**
Giving thresholds	*Provider BA: "The chemoprevention drugs are the next thing I want to talk about. That's where this magic number comes in. So 1.66% makes you eligible to consider chemoprevention drugs." (Participant L)*
Framing risk scores and risk reduction	*Provider BC: "If we say your lifetime risk is 36%, that means 36 women out of 100 will develop breast cancer. 1 in 3. That's kind of high. If all 100 women take tamoxifen or raloxifene, that risk is reduced by 86%. Or there's a residual 5% risk of getting breast cancer. So instead of 36 women out of that 100 getting breast cancer, only 5 out of 100 get breast cancer. Thirty-one out of that 100 don't get told in their lifetime they have breast cancer. That's big." (Participant Z)*
Making comparisons	*Provider BE: "We use the [BCRAT] to help assess your risk - - and I have the [BCRAT risk score], it's all in that packet at the bottom. The [BCRAT] uses a variety of interchronologic history: your age, and whether you had atypical hyperplasia. The atypical hyperplasia lesion is the one that … is driving your risk the most. The [BCRAT] gives you a 5-year risk of breast cancer and a lifetime risk of breast cancer. As you see, your 5-year risk is estimated to be 1.8%, that's compared with an average risk of 0.7%. Alternatively, the lifetime risk is 15.3% as compared to 7.5%. Basically, that says you're at approximately a double risk of developing breast cancer in your life." (Participant M)*
Minimizing a risk score: Recognition of risk assessment tool limitations	*Provider BA: "So I would say you're a good candidate for it were your risk high enough based on these numbers. I don't know what your risk is really. I know you're negative for the gene and you're not 1.6 or higher on this scale. So based on the data I have available you don't really fall into the category where it's appropriate. However, I also know that you're in a little bit of a grey zone." (Participant A)* *Provider BB: "I will quote you exact numbers - - let me get you the exact numbers. I think it was about 1.4, so it was a very low risk." (Participant N)*

Table 3 Continued: During Counseling - Providers' Personalized Risk Score Numbers and Participants' Reactions

Participants' Counseling: Reactions to Risk Score	
Theme	**Quote**
Discussion in counseling: Prompted by participant comfort and provider ambiguity	*Participant U: "So those who got there [into the study] … with atypical [biopsy findings], most likely had a - -"* *Provider BC: "86% risk reduction."* *Participant U: "Over the 5-year? Or lifetime?"* *Provider BC: "Both, both. So that means we would reduce this [by] 86%, the lifetime risk of 30% down to …"* *Participant U: "By 86%?"* *Provider BC: "Well, down to 4-5%."* *Participant U AND Provider BC in unison: "Which is lower than an average person."* *Participant V: "We both understood [the previous provider] to say 40 to 50% [lifetime risk range]."* *Participant companion: "40 to 60%! Has that changed in the last year or two?"* *Provider BC: "No, that hasn't changed."* *Participant V: "So this is new information, … you're saying on the high side 30%?* *Provider BC: "Sure."* *Participant V: "This is new information to me. I just felt like a 50% chance [told to me by the previous provider]. - - I'm kind of like a ticking bomb!"*
Adding information to risk scores	*Participant A: "Does this number obviously go up as I age?"* *Provider BA: "As well, as well."* *Participant A: "So as this number goes up to one [percent 5-yr risk], this [lifetime risk] number goes up higher?"* *Provider BA: "So you're [at] one percent [5-yr risk], 20.6 [percent lifetime risk]. So I'm a little bit on the fence about this."* *Participant A: "I'm wondering if this is the right time to start it, or next year if we revisit it, is that the best time to say, 'As you're approaching forty, you can come back and start [taking tamoxifen]'?"*

Table 4: After Counseling - Four Primary Reactions to Risk Score Information

After Counseling: Four Reactions to Risk Score Information	
Category Type Important Variables	**Quote**
Being at ease with risk score Counseling visitation (1+)	*Participant U: "Well, it took me a few times, like I said, initially to understand that 5-year risk for myself… versus 5-year average risk for someone that is not… I deal with probability all the time, but I was looking at it from a different perspective."*
Anxious about risk score Counseling visitation (1) Finding lobular carcinoma in situ	*Participant W: "It was scary. Who wants to hear that they're, you know, at double the risk for breast cancer? Nobody wants to hear that. Plus, I'm still confused..."* *Participant V: "I feel confused about these statics as I revisit this… I understand she's doing her best to get a model for me… but it's hard to combine the two. That's what I remember thinking too after we left there, that that was going through my mind."*
Accepting of risk score Signaled trust in provider Age range (65 yrs. +)	*Participant X: "Twenty-six is not a small- I mean, I guess that's a high number… I would probably say I wouldn't think so, but now that I have had [an atypical biopsy finding] there's always a possibility that I could develop breast cancer – that I know is there."* *Participant R: "She reiterated some things to me: 'You'll be at four percent if you take it, your risk factor is like 4% rather than maybe like 20%.' Just her numbers and everything make me feel comfortable taking it[medication]."* *Participant N:"I mean, I think I was not more worried. I knew I was at a higher risk, but I didn't think the ratio was that much more substantial…"*
Non-conversant about risk score Co-morbidity (1+)	*Participant J: "Basically [what the provider shared with me was how based on] my age, my family history, the probability or possibility within my age group of getting cancer within the next five years and thereafter. And the percentages are mostly what she explained… It's a big concern for me, the possibility of having a stroke and certainly the possibility of having cancer because - - and that's another problem and situation, you know. The only thing is, you know, it's weighing one I guess against the other."*

References

1. Hood L, Friend SH. Predictive, personalized, preventive, participatory (P4) cancer medicine. *Nature reviews Clinical oncology* 2011;8(3):184-7. doi: 10.1038/nrclinonc.2010.227 [published Online First: 2011/03/03]
2. US Preventive Services Task Force. Guide to clinical preventive services: report of the US Preventive Services Task Force: DIANE publishing 2014.
3. Health, United States, Annual Perspective, 2020-2021. In: National Center for Health S, ed. Hyattsville, MD: https://dx.doi.org/10.15620/cdc:122044, 2023.
4. Holmberg C, Sarganas G, Mittring N, et al. Primary prevention in general practice - views of German general practitioners: a mixed-methods study. *BMC family practice* 2014;15:103. doi: 10.1186/1471-2296-15-103 [published Online First: 2014/06/03]
5. Amir E, Freedman OC, Seruga B, et al. Assessing Women at High Risk of Breast Cancer: A Review of Risk Assessment Models. *JNCI: Journal of the National Cancer Institute* 2010;102(10):680-91. doi: 10.1093/jnci/djq088
6. Ladabaum U, Patel A, Mannalithara A, et al. Predicting advanced neoplasia at colonoscopy in a diverse population with the National Cancer Institute colorectal cancer risk-assessment tool. *Cancer* 2016;122(17):2663-70. doi: 10.1002/cncr.30096 [published Online First: 20160524]
7. Moyer VA. Risk assessment, genetic counseling, and genetic testing for BRCA-related cancer in women: U.S. Preventive Services Task Force recommendation statement. *Annals of internal medicine* 2014;160(4):271-81. doi: 10.7326/m13-2747
8. Wang W, Niendorf KB, Patel D, et al. Estimating CDKN2A carrier probability and personalizing cancer risk assessments in hereditary melanoma using MelaPRO. *Cancer Res* 2010;70(2):552-9. doi: 10.1158/0008-5472.Can-09-2653 [published Online First: 20100112]
9. Samimi G, Heckman-Stoddard BM, Holmberg C, et al. Cancer Prevention in Primary Care: Perception of Importance, Recognition of Risk Factors and Prescribing Behaviors. *Am J Med* 2020;133(6):723-32. doi: 10.1016/j.amjmed.2019.11.017 [published Online First: 2019/12/22]
10. Samimi G, Heckman-Stoddard BM, Holmberg C, et al. Assessment of and Interventions for Women at High Risk for Breast or Ovarian Cancer: A Survey of Primary Care Physicians. *Cancer Prevention Research* 2021;14(2):205. doi: 10.1158/1940-6207.CAPR-20-0407
11. Guerra CE, Sherman M, Armstrong K. Diffusion of breast cancer risk assessment in primary care. *Journal of the American Board of Family Medicine : JABFM* 2009;22(3):272-9. doi: 10.3122/jabfm.2009.03.080153 [published Online First: 2009/05/12]
12. Crew KD, Albain KS, Hershman DL, et al. How do we increase uptake of tamoxifen and other anti-estrogens for breast cancer prevention? *NPJ Breast Cancer* 2017;3:20. doi: 10.1038/s41523-017-0021-y [published Online First: 20170519]
13. Armstrong K. Calling on Primary Care to Prevent BRCA-Related Cancers. *J Gen Intern Med* 2020;35(3):903-05. doi: 10.1007/s11606-019-05469-7 [published Online First: 20191021]
14. Breast Cancer Risk Reduction Clinical Practice Guidelines in Oncology. *J Natl Compr Canc Netw* 2003;1(2):280-96. doi: 10.6004/jnccn.2003.0026
15. Bevers TB, Helvie M, Bonaccio E, et al. Breast Cancer Screening and Diagnosis, Version 3.2018, NCCN Clinical Practice Guidelines in Oncology. *Journal of the National Comprehensive Cancer Network : JNCCN* 2018;16(11):1362-89. doi: 10.6004/jnccn.2018.0083

16. Akanuwe JNA, Black S, Owen S, et al. Communicating cancer risk in the primary care consultation when using a cancer risk assessment tool: Qualitative study with service users and practitioners. *Health expectations : an international journal of public participation in health care and health policy* 2020;23(2):509-18. doi: 10.1111/hex.13016 [published Online First: 20200122]

17. Claus EB, Risch N, Thompson WD. The calculation of breast cancer risk for women with a first degree family history of ovarian cancer. *Breast cancer research and treatment* 1993;28(2):115-20. doi: 10.1007/bf00666424

18. Berliner JL, Fay AM. Risk assessment and genetic counseling for hereditary breast and ovarian cancer: recommendations of the National Society of Genetic Counselors. *Journal of genetic counseling* 2007;16(3):241-60. doi: 10.1007/s10897-007-9090-7 [published Online First: 20070517]

19. Murff HJ, Byrne D, Syngal S. Cancer Risk Assessment: Quality and Impact of the Family History Interview. *American Journal of Preventive Medicine* 2004;27(3):239-45. doi: http://dx.doi.org/10.1016/j.amepre.2004.05.003

20. Trepanier A, Ahrens M, McKinnon W, et al. Genetic Cancer Risk Assessment and Counseling: REcommendations of the National Society of Genetic Counselors. *J Genet Counsel* 2004;13(2):83-114.

21. Evans DG, Howell A. Breast cancer risk-assessment models. *Breast cancer research : BCR* 2007;9(5):213. doi: 10.1186/bcr1750

22. Committee on Practice Bulletins–Gynecology CoG, Society of Gynecologic Oncology;. Practice Bulletin Number 179: Breast Cancer Risk Assessment and Screening in Average-Risk Women. *Obstetrics & Gynecology* 2017;130(1)

23. Bevers TB, Ward JH, Arun BK, et al. Breast Cancer Risk Reduction, Version 2.2015. *Journal of the National Comprehensive Cancer Network : JNCCN* 2015;13(7):880-915. doi: 10.6004/jnccn.2015.0105

24. Owens DK, Davidson KW, Krist AH, et al. Medication Use to Reduce Risk of Breast Cancer: US Preventive Services Task Force Recommendation Statement. *Jama* 2019;322(9):857-67. doi: 10.1001/jama.2019.11885 [published Online First: 2019/09/04]

25. Holmberg C, Bandos H, Fagerlin A, et al. NRG Oncology/National Surgical Adjuvant Breast and Bowel Project Decision-Making Project-1 Results: Decision Making in Breast Cancer Risk Reduction. *Cancer prevention research (Philadelphia, Pa)* 2017 doi: 10.1158/1940-6207.capr-17-0076 [published Online First: 2017/10/06]

26. Blakeslee SB, McCaskill-Stevens W, Parker PA, et al. Deciding on breast cancer risk reduction: The role of counseling in individual decision-making - A qualitative study. *Patient Educ Couns* 2017;100(12):2346-54. doi: 10.1016/j.pec.2017.06.033 [published Online First: 2017/07/25]

27. Gunn CM, Bokhour B, Parker VA, et al. Exploring Explanatory Models of Risk in Breast Cancer Risk Counseling Discussions: NSABP/NRG Oncology Decision-Making Project 1. *Cancer nursing* 2019;42(1):3-11. doi: 10.1097/ncc.0000000000000517 [published Online First: 2017/07/01]

28. Gunn CM, Bokhour BG, Parker VA, et al. Understanding Decision Making about Breast Cancer Prevention in Action: The Intersection of Perceived Risk, Perceived Control, and Social Context: NRG Oncology/NSABP DMP-1. *Medical decision making : an international journal of the Society for Medical Decision Making* 2019;39(3):217-27. doi: 10.1177/0272989x19827258 [published Online First: 2019/02/26]

29. Hamilton JG, Abdiwahab E, Edwards HM, et al. Primary care providers' cancer genetic testing-related knowledge, attitudes, and communication behaviors: A systematic review and research agenda. *J Gen Intern Med* 2017;32(3):315-24. doi: 10.1007/s11606-016-3943-4 [published Online First: 20161219]

30. Corbelli J, Borrero S, Bonnema R, et al. Use of the Gail model and breast cancer preventive therapy among three primary care specialties. *Journal of women's health (2002)* 2014;23(9):746-52. doi: 10.1089/jwh.2014.4742 [published Online First: 2014/08/15]

31. Bellhouse S, Hawkes RE, Howell SJ, et al. Breast Cancer Risk Assessment and Primary Prevention Advice in Primary Care: A Systematic Review of Provider Attitudes and Routine Behaviours. *Cancers (Basel)* 2021;13(16) doi: 10.3390/cancers13164150 [published Online First: 20210818]

32. Schubert C. Video analysis of practice and the practice of video analysis. Selecting field and focus in videography. In: Knoblauch H, Schnettler B, Raab J, et al., eds. Video analysis: methodology and methods. 3rd Edition ed. Frankfurt am Main: Peter Lang 2012:115-26.

33. Software for qualitative data analysis [program]. Version 18 version. Berlin, Germany: VERBI Software – Consult – Sozialforschung GmbH, 1995-2017.

34. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care* 2007;19(6):349-57. doi: 10.1093/intqhc/mzm042

35. Holmberg C, Waters EA, Whitehouse K, et al. My lived experiences are more important than your probabilities: The role of individualized risk estimates for decision making about participation in the Study of Tamoxifen and Raloxifene (STAR). *Medical decision making : an international journal of the Society for Medical Decision Making* 2015 [published Online First: In review]

36. Fagerlin A, Zikmund-Fisher BJ, Ubel PA. Helping patients decide: ten steps to better risk communication. *Journal of the National Cancer Institute* 2011;103(19):1436-43. doi: 10.1093/jnci/djr318 [published Online First: 2011/09/21]

37. Fagerlin A, Zikmund-Fisher BJ, Ubel PA. "If I'm better than average, then I'm ok?": Comparative information influences beliefs about risk and benefits. *Patient Educ Couns* 2007;69(1-3):140-4. doi: 10.1016/j.pec.2007.08.008 [published Online First: 20071017]

38. Lipkus IM. Numeric, verbal, and visual formats of conveying health risks: suggested best practices and future recommendations. *Medical decision making : an international journal of the Society for Medical Decision Making* 2007;27(5):696-713. doi: 10.1177/0272989x07307271 [published Online First: 20070914]

39. Trevena LJ, Zikmund-Fisher BJ, Edwards A, et al. Presenting quantitative information about decision outcomes: a risk communication primer for patient decision aid developers. *BMC medical informatics and decision making* 2013;13 Suppl 2:S7. doi: 10.1186/1472-6947-13-s2-s7 [published Online First: 2013/01/01]

40. Zikmund-Fisher BJ, Fagerlin A, Roberts TR, et al. Alternate methods of framing information about medication side effects: incremental risk versus total risk of occurrence. *Journal of health communication* 2008;13(2):107-24. doi: 790919454 [pii],10.1080/10810730701854011 [published Online First: 2008/02/27]

41. Liew SM, Blacklock C, Hislop J, et al. Cardiovascular risk scores: qualitative study of how primary care practitioners understand and use them. *Br J Gen Pract* 2013;63(611):e401-7. doi: 10.3399/bjgp13X668195

42. Oriol-Zerbe C, Abholz HH. Primary prevention of cardiovascular diseases by lipid-lowering treatment in German general practice: results from GPs ignoring guidelines and risk calculators. *Eur J Gen Pract* 2007;13(1):27-34. doi: 10.1080/13814780601050541

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	
Duration	21	What was the duration of the inter views or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.