Aus dem Institut für Public Health

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DISSERTATION

Knowing the Unknown: Experience and Decision Making of American Women At Risk of Breast Cancer (A Qualitative Study)

zur Erlangung des akademischen Grades

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von

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Dedication

For Sasank.

And to all who continue the struggle with the unknown.

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Abstract (English)

Objective

This dissertation aims to understand the counseling experience of women at risk for breast cancer and their subsequent decisions about taking risk-reducing treatment. A qualitative study examines such experiences of women in the United States (1). The information gathered is used to create an explanatory model describing the women's personal origins of risk (2). Then their breast cancer risk perception is analyzed through their loci of control and how these affected the women's decision processes (3).

Methods

The qualitative sample of a larger mixed methods study was used. A cross-case synthesis inductively investigated how individuals were counseled and decided on risk treatment (1). Through a secondary analysis an *explanatory model of risk* was developed, using an inductively-grounded thematic approach (2). An additional analysis deductively applied domains of this model to categorize at-risk women into levels of perceived risk (high/low) and control (high/low), then used constant comparison for a differentiated understanding of treatment decisions (3).

Results

Thirty video-recorded breast care consultations and subsequent in-depth interviews with participants; expert interviews with the counseling providers and a structured telephone interview about their final decision with 29 of the 30 women participants resulted. In counseling, providers tailored risk information to recommendations and most women reached a treatment decision during counseling. Important contributing factors were: the ability to change the decision; how medication was viewed before counseling; how benefits and risks were weighed; and the proximity of cancer experiences of others with cancer and risk (1). The e*xplanatory model of risk* domains based on this research found similarities to those of illness, except for pathophysiology, where symptoms of risk were missing. Instead, a new domain for *social comparisons* highlighted how the women's own risk compared to the cancer and risk experience of others (2). Depending on their own level of perceived risk and control, s*ocial evidence* available to at-risk women was used differently to justify the decisions made (3).

Discussion & Conclusion

Clarity about patient-provider interactions and decision making patterns emerged through the unique and comprehensive qualitative dataset. Breast cancer risk counseling should consider a woman's own knowledge and experiences in addition to providing the necessary medical information. Asking specific types of questions during counseling could help reveal a woman's own priorities and how she thinks about her risk. Better tools are needed in counseling to account for individual experiences and counseling should be seen as an ongoing process of care.

Zusammenfassung (deutsch)

Zielsetzung

Ziel der vorliegenden Dissertation ist es, die Auswirkungen von Beratungsgesprächen für Frauen mit Brustkrebsrisiko und deren Einfluss auf die Entscheidungen der Frauen in Bezug auf eine risikoreduzierende Behandlung zu verstehen. In einer qualitativen Studie wurden Beratungserfahrungen von Frauen in den Vereinigten Staaten untersucht (1). Hierauf basierend wurde ein Erklärungsmodell entwickelt, um die persönliche Risikowahrnehmung der Frauen zu beschreiben (2). Anschließend wurde analysiert inwieweit die Wahrnehmung des Brustkrebsrisikos und seiner Kontrollierbarkeit die Entscheidungsprozesse beeinflusste (3).

Methoden

Verwendet wurde die qualitative Stichprobe einer größer angelegten Mixed-Method-Studie. Mithilfe primärer Cross-Case-Synthese wurde induktiv untersucht, wie Individuen beraten wurden und sich für eine Risikobehandlung entschieden (1). Mit Hilfe einer Sekundäranalyse und eines induktiv-fundierten thematischen Ansatzes, wurde ein Erklärungsmodell des Risikos entwickelt (2). Eine weitere Sekundäranalyse wandte die Domänen dieses Modells deduktiv an, um Betroffene in Niveaus des wahrgenommenen Risikos und der Kontrollierbarkeit (hoch/niedrig) zu kategorisieren. Der Vergleich wurde für ein differenziertes Verständnis von Behandlungsentscheidungen verwendet (3).

Ergebnisse

Das Material umfasste 30 videoaufgezeichnete Brustrisikokonsultationen und anschließende Tiefeninterviews, fünf Experteninterviews mit Beratungsanbietern und 29 strukturierte Telefoninterviews bezüglich der endgültigen Entscheidung für oder gegen eine hormontherapeutische Behandlung. Es wurde deutlich, dass beratende Ärzte die Risikoinformationen im Sinne ihrer medizinischen Empfehlungen hin anpassten. Der überwiegende Teil der Frauen traf innerhalb ihrer Beratung eine Behandlungsentscheidung. Wichtige Faktoren hierfür waren die Möglichkeit, die Entscheidung zu ändern, die Haltung zu Behandlung vor der Beratung, die Nutzen-Risiko-Abwägung und die Krebs(risiko)erfahrungen anderer nahestehender Personen (1). Das entwickelte Erklärungsmodell ähnelt dem Referenzmodell für Krankheiten, mit Ausnahme der Pathophysiologie, wofür Risikosymptome fehlen. Stattdessen wurde in einer neuen Domäne für *soziale Vergleiche* hervorgehoben, wie das eigene Risiko im Vergleich zu den Krebs- und Risikoerfahrungen anderer wahrgenommen wurde (2). Je nach wahrgenommener Höhe des eigenen Risikos und der Kontrollierbarkeit, wurde die *soziale Evidenz*, die den Frauen zur Verfügung stand, auf unterschiedliche Weise genutzt, um die getroffenen Entscheidungen zu rechtfertigen (3).

Diskussion & Schlussfolgerung

Patient-Arzt-Interaktionen und Entscheidungsfindungsmuster konnten dank des einzigartigen, umfassenden qualitativen Datensatzes mit Videos, Tiefen- und strukturierten Interviews umfänglich analysiert werden. Hieraus lässt sich schlussfolgern, dass Beratungen neben der Bereitstellung der notwendigen medizinischen Informationen auch die Vorkenntnisse und Erfahrungen der Frauen berücksichtigen sollten. Risikowahrnehmung- und Verständnis sowie Prioritäten der Betroffenen können mit Hilfe bestimmter, gezielter Fragen während der Beratung identifiziert und somit berücksichtigt werden. Hierfür sind bessere Instrumente in der Beratung erforderlich,

um den individuellen Erfahrungen der Beratenen Rechnung zu tragen. Zu diesem Zweck sollte die Beratung als ein kontinuierlicher Prozess der Betreuung angesehen werden.

Abbreviations

Abbreviations	Full Term Meaning
BRCA1/BRCA2	BReast CAncer genes
BCRAT	Breast Cancer Risk Assessment Tool (also known as the Gail score risk assessment) calculates risk factors for breast cancer
COREQ	COnsolidated criteria for REporting Qualitative research - Standards for reporting qualitative data
DMP-1	Decision-Making Project-1 - Abbreviation of the NSABP Project as the first study on decision making
FDA	Food and Drug Administration in the US approves drug use
LCIS	Lobular Carcinoma In Situ - a breast lesion that increases risk of breast cancer 9-10 greater than the general population [WEN 2019]. Little treatment consensus exists and it is not included in the most frequently used risk model BCRAT
MAXQDA	Computer-assisted qualitative data analysis software Max relates to the German sociologist Max Weber and ends with the abbreviation QDA – which stands for Qualitative Data Analysis
NCI	National Cancer Institute
NIH	National Institutes of Health
NSABP	National Surgical Adjuvant Breast and Bowel Project, NCI clinical trial cooperative 1958-2014
NSABP DMP-1	The NRG Oncology/National Surgical Adjuvant Breast and Bowel Project (NSABP) Decision-Making Project-1 - Entire mixed methods project
DMP-1 survey	Decision-Making Project-1 Survey with 1023 women Quantitative portion of NSABP DMP-1
DMP-1 substudy	Decision-Making Project-1 qualitative substudy - 30 video participant consultations and interviews, five provider interviews. Qualitative portion of NSABP DMP-1
FDA	Food and Drug Administration
NRG Oncology	NCI clinical trial cooperative since 2014
SERM	Selective Estrogen Receptor Modulators
SNPs	Single Nucleotide Polymorphisms
US	United States
USPSTF	US Preventive Services Task Force

[1]

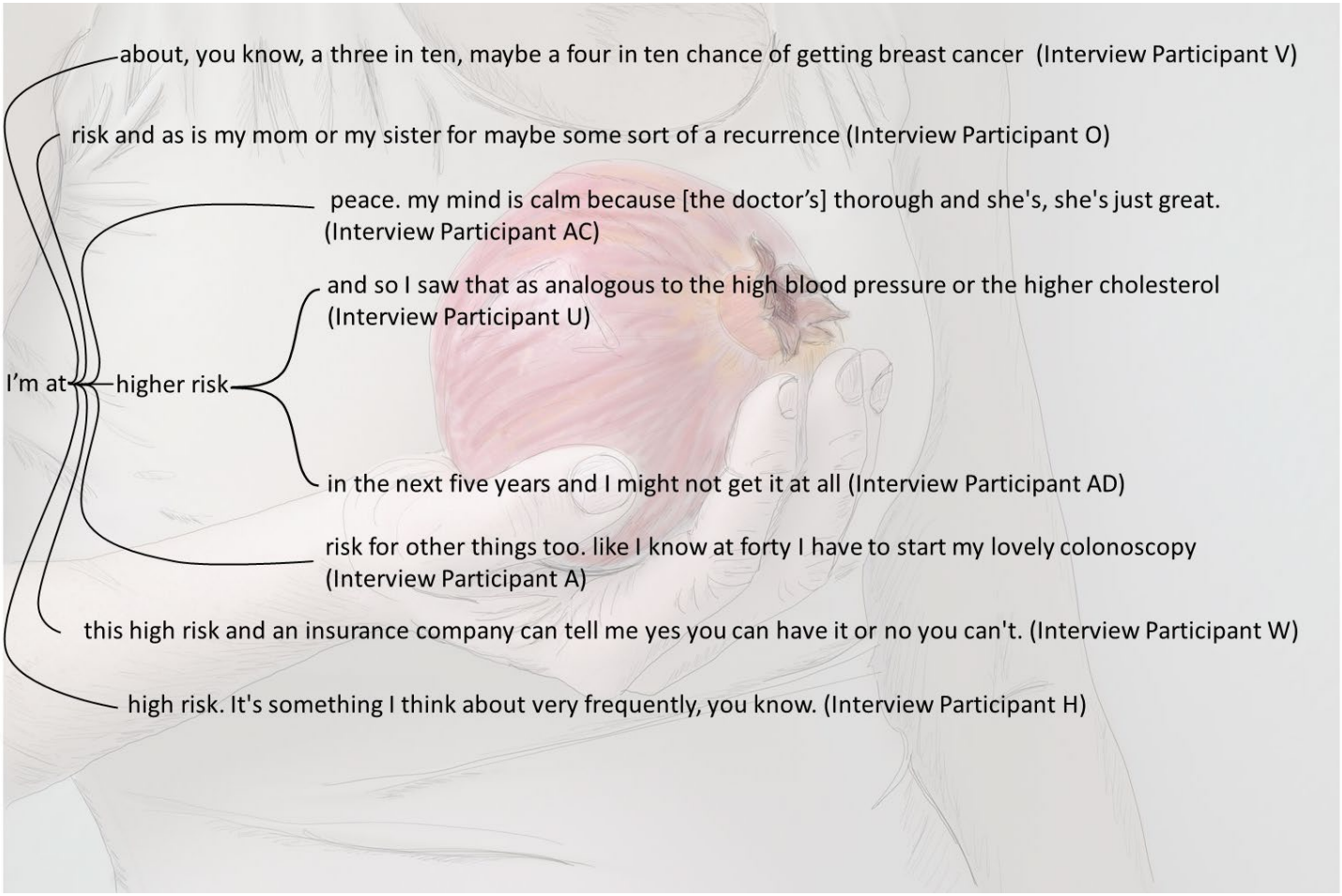

Figure 1: Participant Quote Risk Word Tree "I'm at…"

[1] Artwork: *Risk Unknown* by Sarah Blakeslee 2015/2020. Digital photography, fine liner, acrylic.

1. Introduction

This dissertation, titled “Knowing the Unknown: Experience and Decision Making of American Women At Risk of Breast Cancer (A Qualitative Study)” explores the risk experience and decision making factors between patients and providers during and after breast cancer risk counseling.

From a public health standpoint, cancer prevention has become a global health priority and in countries of the Global North, programmatic efforts have led to various screening and prevention activities [2]. For breast cancer prevention, the US has been very proactive in advocating for chemoprevention, leading to two US Federal Drug Administration (FDA) approved medications to reduce breast cancer risk, raloxifene and tamoxifen. Both are given as oral chemoprevention over five years, and are classified as selective estrogen receptor modulators (SERM). Providers counsel women on prevention of breast cancer measures, including taking a SERM, based on either genetic or non-genetic risk. The two known genetic components BRCA1 and BRCA2, account for only 15-20% of the familial-based cancers [3], although genetic alleles and foci are an increasing focus for breast cancer risk research [4]. Those with a family risk or individuals with benign breast lesions (also called atypia or atypical hyperplasia) established via biopsy histopathology and screening [5], or dense breast tissue [6], will likely be counseled on prevention options. US breast cancer risk guidelines [7-11], focus prevention efforts around genetic testing, counseling about risk options, risk reduction medication, limiting hormone exposure [12], and modifying lifestyle associated with risk (such as alcohol intake [13], smoking [14], and maintaining a healthy body weight [15]) as well as surgery via prophylactic mastectomy and oophorectomy [16]. While some prevention interventions have little associated risk and promote general good health, others such as surgery and medication, may have important health implications that must be carefully considered for each individual before making a treatment decision.

SERMs inhibit estrogen growth and reduce breast cancer risk overall by 38-50% [17-20] and are prescribed for individuals in the US if they have a calculated 5-year risk above 1.66% or a lifetime risk above 20% [19, 21-23]. In a recent statement, the US Preventive Services Task Force (USPSTF) updated their 5-year risk treatment recommendation from 1,66% to equal or above 3% [24, 25]. Meta-analysis of SERM randomized control trials as well as aromatase inhibitors, the two types of medication

that have been proven effective to significantly reduce breast cancer risk, showed an absolute risk reduction of 7-9 fewer invasive breast cancers for every 1,000 women treated with SERM over those who were not treated [25]. Though at-risk individuals may be able to cut their breast cancer risk significantly with SERM use, prevalence of risk reduction therapy uptake in US women who could benefit from SERM is low and hovers around 1% [26].

However, both SERMS are associated with serious adverse events. Increased thromboembolic events, such as stroke or blood clots, and adverse side effects, such as vasomotor or musculoskeletal symptoms are associated with both raloxifene and tamoxifen [17, 19, 20, 23, 25].

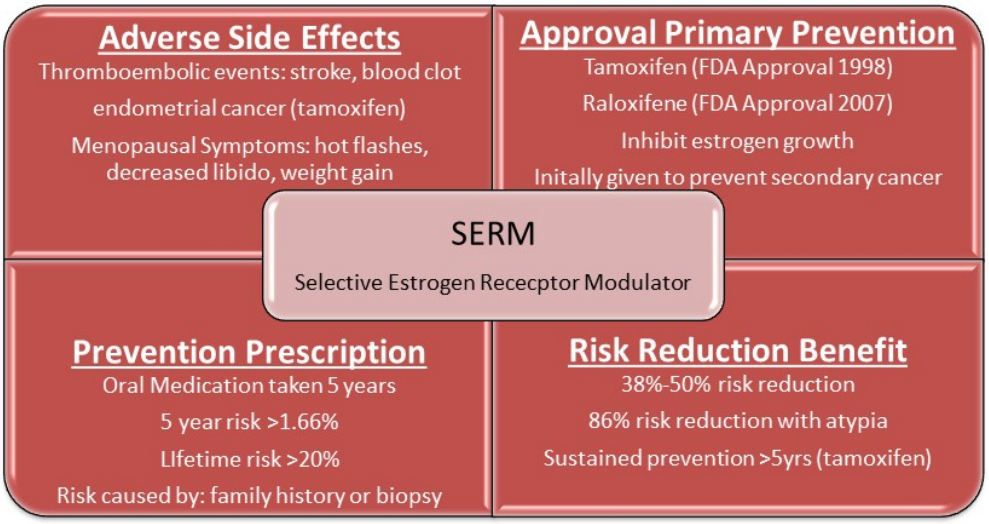

Figure 2: SERM Description & Use for Prevention in the United States

Tamoxifen in particular is associated with cataracts and endometrial cancer, especially with increasing age [25]. Therefore, the potential benefit of reducing breast cancer risk with SERM must be weighed against the risk of taking the medication itself, making this a preference sensitive decision. In order to assess preferences, the breast cancer risk management guidelines rely on risk assessment and risk counseling for breast cancer prevention [7-11]. Despite the best evidence about known risk factors, US prevention strategies are multifactorial and choice depends heavily on individual preferences [27-31] and provider knowledge [32-34].

Extensive research has explored decision making and understanding of women at risk for breast cancer in the US context [28, 35-43], but little research has sought to understand how the actual counseling experience directly impacts women's decision

making when considering taking risk-reducing medicines for breast cancer. Most studies on risk counseling focus on the presentation of risk for improved comprehension [44-47] or ways to ensure a positive patient provider relationship through shared decision making [48, 49]. Worry about breast cancer has long been a known motivational factor for women to act on risk [31, 50], as has physician recommendation [31]. The influence of social factors and the actual counseling experience on the decision making process has not been explored fully in the literature.

This dissertation contributes to this gap in knowledge. First, risk counseling practices and the decisions that result are fully explored (Publication 1) [1, 51]. Second, an explanatory illness model is expanded to help understand how women perceive the origins of their risk, resulting in the development of an adapted model for risk (Publication 2) [52]. Finally, by applying the newly developed explanatory risk model, the nexus of women's perceptions of breast cancer risk and their loci of control are analyzed to further elucidate decision processes (Publication 3) [53]. These findings are fundamental in giving context to the way that women who are counseled experience and think about their breast cancer risk and subsequently make risk reduction treatment decisions.

The NRG Oncology/National Surgical Adjuvant Breast and Bowel Project Decision-Making Project-1 (NSABP DMP-1) is an exploratory mixed methods study that sought to assess social and psychological factors involved in making decisions about breast cancer risk reduction. The mixed method study design of NSABP DMP-1 comprised the Decision-Making Project-1 survey (DMP-1 survey) and the Decision-Making Project-1 qualitative substudy (DMP-1 substudy). This dissertation is based on data from the DMP-1 substudy. Descriptive demographic data about DMP-1 substudy participants came from the DMP-1 survey.

1.1. Deciding on breast cancer risk reduction: The role of counseling [1] (Publication 1)

This publication analyzed the primary qualitative DMP-1 substudy data. In a top journal for public health (impact factor for public health: 2017- 25%, 2018 - 20%) we investigated how individuals who were counseled as part of regular medical breast care reached a decision about taking SERM. We explored how provider

recommendations were given and how patient provider interactions influenced individual decision making about reducing breast cancer risk through SERM.

The low uptake of SERMs by women treated in medical centers [54] indicates the complexity of reaching decisions on these drugs. There are complicated tradeoffs between taking medication to reduce the risk of getting breast cancer and the potentially life-threatening or intolerable side effects that may result from the taking medication [28, 37]. During consultations, new information about risk is presented by providers. This information is important for the decision [30], as are social and experiential factors [31, 42, 43]. This publication explored and described decision making about reducing breast cancer risk in the context of counseling.

1.2. Explanatory model of breast cancer risk [52] (Publication 2)

This publication is a secondary analysis of the qualitative DMP-1 substudy data, using the Kleinman framework of the *explanatory model of illness* to elucidate and develop an *explanatory model of risk* for women identified as at risk for breast cancer.

The *explanatory model of illness* is a patient-centered model developed by Kleinman et. al. to better understand individual beliefs and behaviors about health [55, 56]. This model aims to explicate treatment choices that are made by viewing health holistically. In Kleinman's model, *Illness* as a concept encompasses the belief system of an individual whereas *disease* focuses on biological processes and cure [55, 56]. Based on the model, Kleinman developed questions for providers to use during consultations in order to understand their patients' understanding of the disease.

The concept of "risk", on the other hand has distinct meanings to different individuals [57] and may require defining and delimiting it from illness. Screening, imaging and biopsies increasingly diagnose a panoply of breast tumors with atypia as well as findings such as Lobular Carcinoma In Situ (LCIS) [58-61]. At the same time, genetic testing for BRCA1/BRCA2 as well as single nucleotide polymorphisms (SNPs) have widened the field of genetic analysis [4]. A risk diagnosis implies that action is needed, yet taking action to treat risk may elicit a different choice than the decision to simply treat illnesses. This publication analyzed what being at risk for breast cancer means to women using the DMP-1 substudy data. Results aimed to develop an explanatory

model of risk that adapted etiology, symptoms, course of illness, treatment and pathophysiology illness domains to risk.

1.3. Understanding decision making about breast cancer prevention in action [53] (Publication 3)

This publication is a further secondary analysis of the DMP-1 substudy data that aimed to understand women's decision making processes based on how they perceived their risk and their control. This builds on the developed *explanatory model of risk* by using the adapted risk domains to examine how concepts of risk and control were represented in women's explanatory models. (Publication 2).

Participants from the DMP-1 substudy were categorized into a nexus of two established factors affecting decisions, high or low perceived risk and control. The risk domains described in the individual risk model made it possible to group women's sense of risk (high/low) and control (high/low). The four resulting groups were analyzed for commonalities in their decision making processes, leading to an expanded understanding of how risk reduction decisions were made and justified.

2. Dissertation Objective

The objective of this body of work was to investigate the experience of women who have been counseled about breast cancer risk in order to explicate influencing factors in the process of making decisions about risk reduction treatment. To reach this overall objective, data from the DMP-1 substudy were used for the following research goals:

(1) A primary cross-case synthesis to investigate how individuals who have discussed SERM use and other strategies for breast cancer risk reduction with a health care provider decided for or against treatment uptake (Publication 1) [1].

(2) A secondary analysis to develop an *explanatory model of risk* for women at increased risk for developing breast cancer, using the domains of Kleinman's [56] *explanatory model of illness* (Publication 2) [52].

(3) A further secondary analysis using the *explanatory model of risk* domains categorized at-risk women into levels of perceived risk (high/low) and control (high/low), for a differentiated understanding and justification of risk reduction treatment decisions (Publication 3) [53].

3. Material and Methods

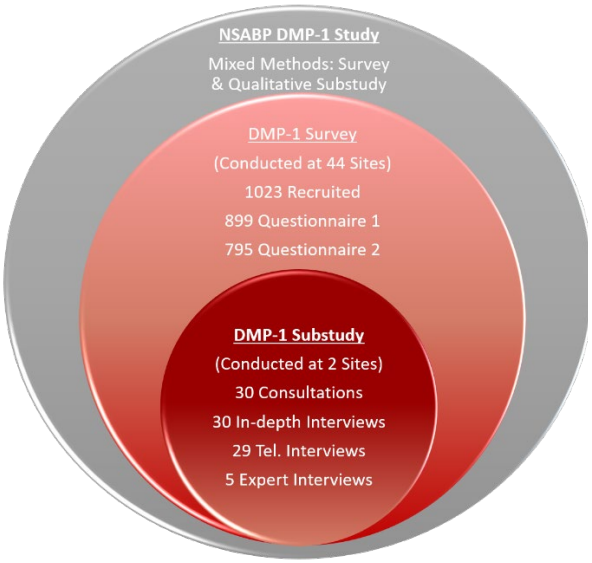

Figure 4: NSABP DMP-1 Study Design

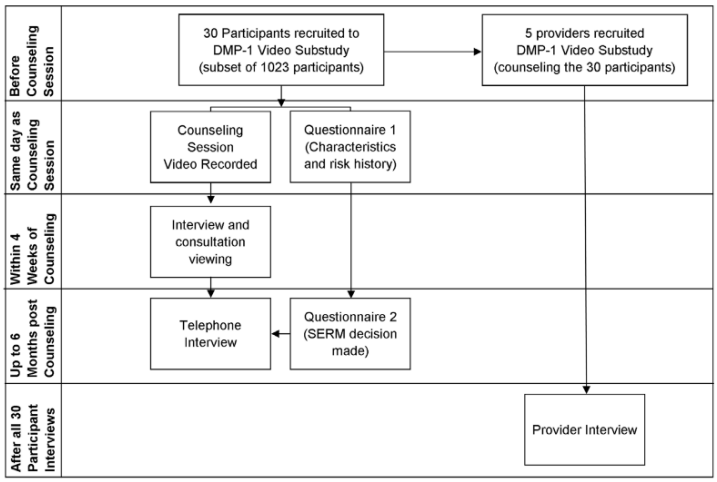

Figure 3: NSABP DMP-1 Substudy Design [1]

The NSABP DMP-1 study was an exploratory mixed methods study to assess the social and psychological factors involved in making decisions about breast cancer risk prevention. The NSABP DMP-1 Study was based in the United States, was funded by the National Institutes of Health (NIH) and was implemented by the clinical trial cooperative NSABP/NRG Oncology of the National Cancer Institute (NCI). 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. The Ethics Commission of the Charité – Universitätsmedizin Berlin were informed about the study, accepted the US reviews and gave consent that their approval was not needed. The mixed method study design of NSABP DMP-1 comprised the Decision-Making Project-1 survey (DMP-1 survey) and the Decision-Making Project-1 qualitative substudy (DMP-1 substudy). This dissertation is based on data from the DMP-1 substudy and includes demographic data from the DMP-1 survey on DMP-1 substudy participants. Other DMP-1 survey data was not used for this dissertation (Fig. 1).

The qualitative DMP-1 substudy recruited 30 at-risk women and their providers from two NSABP DMP-1 sites in separate geographical regions for participation. One community-based university hospital and one specialized cancer research center were chosen as locations. Eligibility for inclusion was limited to women determined to be at-risk by a provider, who would discuss SERM use for the prevention of breast cancer,

who spoke English, were over 35 years and were willing to be video-recorded. Women who had invasive or noninvasive breast cancer, or had prior SERM use or treatment for LCIS were ineligible. Inclusion of providers was limited to those who counseled women at risk and discussed SERM and were willing to be video-recorded. Both women and their providers gave written consent to have their counseling session recorded prior to the consultation appointment.

Data was collected and processed for the DMP-1 substudy as follows (Fig. 2):

- **30 risk consultation sessions** between providers and at-risk women were video recorded, then documented in written summaries according to Schubert 2006 to capture interactions [62]. Providers were not given guidance on how to provide risk consultations but were required to discuss SERM. The risk consultation sessions took place at both study sites. The video content was reviewed by researcher staff and specific questions about the risk consultation sessions were formulated for inclusion in the in-depth expert interviews with providers [62].
- Up to 6 weeks after the risk consultation session, a semi-structured in-depth **participant interview** was conducted with each of the 30 women, using a pilot-tested interview guideline. All interviews were in-person and all but one were conducted at the study site by onsite research staff trained to conduct the interviews. During the first part of the interview, the woman's understanding of breast cancer risk, decision making about SERMs, and the counseling experience were explored openly. Then, participants watched a video of their own counseling session, commented on it and answered tailored questions developed in a prior analysis of the video. The semi structured in-depth interviews with the at-risk women were audio-recorded, then transcribed verbatim to explore the breast cancer risk experience and decision making processes.
- After all the women had been interviewed, in-depth **expert interviews** were conducted with the five health care providers that had conducted the risk consultation sessions. Interviews with providers explored counseling strategies and included the viewing of a video recording of one of the consultation sessions they themselves had conducted. The semi structured in-depth expert interviews with providers were audio-recorded, then transcribed verbatim, to explore counseling strategies.
- To determine which final decision about SERM use had been reached by the women, a short, 5-question, structured follow up **telephone interview** was conducted with the

participating women once they were sure of with their choice. The telephone interview responses were documented in a guideline by research staff.

During data collection, all interviews were anonymized and personal data eliminated from videos. Data was stored on a password protected project server space at the Charité – Universitätsmedzin Berlin, as well as 2 external hard drives stored in a locked cabinet. Bi-weekly team meetings took place during the data collection period and regular telephone conferences took place between US and Berlin project teams. To increase rigor of analysis, findings and analysis were regularly presented in an inter-institute qualitative methods working group and a doctoral working group at the Institute of Public Health, both took place at Charité – Universitätsmedizin Berlin. Management of the data and the initial open grounded coding tree [63] for the DMP-1 substudy was done using the data management software MAXQDA [64] and a base project data was created. Publishing adhered to the COnsolidated criteria for REporting Qualitative (COREQ) [65] standards for qualitative data.

3.1. Deciding on breast cancer risk reduction: The role of counseling (Publication 1)

The primary analysis of the qualitative DMP-1 substudy data was based on a cross-case synthesis approach [66, 67], whereby cases were created using video data of the risk consultation sessions, the participant interview, and the post counseling telephone interview for each woman participant. The cases were analyzed beginning with the treatment decision stated in the telephone interview. Important themes regarding decision making were identified for each case using the video and the participant interview materials. To ensure coding consistency, regular team meetings discussed data with project team members. After themes had been identified for each case, themes were compared across cases in order to reach a synthesis and to develop categories that could explain how decisions had been made. When all themes had been grouped into categories, analysis was considered complete. Themes and categories for each participant's case were validated by comparing and contrasting the counseling strategies. Counseling strategies that were discussed in the corresponding provider's interview from the video-recorded counseling interactions was coded in the initial coding for the project.

Analysis for the primary data analysis used the qualitative software MAXQDA (Verbi; v.10) [64] to assist with analysis.

3.2. Explanatory model of breast cancer risk (Publication 2)

The secondary analysis used the base project data that had been managed and prepared by the fifth author (Blakeslee). For this publication, a grounded thematic approach to analyze participant interviews was used, applying analytic strategies derived from grounded theory [63, 68]. The first seven interviews were coded openly and jointly by the first and the second authors to capture all meaningful phrases about risk represented in the interviews. This grounded approach ensured inclusivity in comprehensively identifying constructs salient to women in the explanatory model analysis. The remaining interviews thereafter were open-coded by one investigator and reviewed by the second author, a senior qualitative researcher. When new codes were identified in subsequent interviews they were reviewed jointly before being added to the codebook. In a second phase of analysis, open codes were grouped into a priori categories that represented the domains of explanatory models as developed by Kleinman [56]: etiology, pathophysiology, onset of symptoms, course of illness, and treatment. Relevant codes were grouped into these categories, iterative amendments were made to original definitions through reflection and joint discussion with the senior researcher to understand participants' explanatory models as related to breast cancer risk. Through this process, codes that did not fit with the explanatory model framework were identified during joint analysis sessions and discussed with the entire research group. These additional codes were analyzed and used to expand the explanatory model framework to render it applicable to risk. On the basis of the explanatory model categories, a framework for a model of breast cancer risk was developed by reflecting on areas of conceptual linkage and divergence with existing explanatory models of illness. Theoretical saturation was reached after the analysis of 20 interviews; the remaining 10 interviews were also analyzed and contributed to a wider perspective and context.

This secondary analysis used the qualitative software MAXQDA (Verbi; v.11) [69] to assist with analysis.

3.3. Understanding decision making about breast cancer prevention in action (Publication 3)

The data previously coded for the explanatory model of risk paper was analyzed using the base project data that had been managed and prepared by the second to last author (Blakeslee). The coding process to develop the explanatory model of risk had sorted coded segments into explanatory domains and were used to identify salient perceived risk and control sections of interviews. The domains established in the *explanatory model of risk*: *Course to Illness*, *Symptoms*, *Etiology*, *Treatment*, and *Social Comparisons* were examined as to how the participant 1) expressed high or low concern about the risk of developing breast cancer and 2) expressed high or low levels of control over the stated level of risk. Transcripts were coded by the first and second authors independently, characterizing perceived risk and perceived control as high/low for each participant and then coming together to assess coding concordance. Twelve transcripts were categorized based on the interview sections on the perceived risk dimension and nine fit easily into the high/low dichotomy. Ten transcripts achieved coding concordance on the perceived control dimension. Salient examples supporting categorizations were discussed and reviewed with the last author to attain consensus. The remaining 18 transcripts were categorized following the same process. After each transcript had been characterized based on deductive codes related to perceived risk and control, the transcripts were then coded inductively to identify themes related to participants' decision making processes and to allow for a grounded examination of the study question to take place [63, 70]. Coding was then done line-by-line by the first and second authors to make sure that all instances in which participants were describing how they made a decision were collected. These newly generated codes were grouped into themes and reviewed by the team. Similarities and differences within and across groupings of perceived risk and control were identified using the constant comparison method [63], which enabled us to make connections between the deductive codes for perceived risk and perceived locus of control, and the influence of the explanatory model domains within and across participants.

All analytical materials used MAXQDA qualitative coding software (Verbi; v.11) [69] in preparation for analysis.

4. Results

The DMP-1 substudy recruited 30 study participants with breast cancer risk and five health care providers over a period from April 2012 until August 2013. All but one of the women at risk (n=29) were assessed to have reached a decision about SERM use through telephone interview.

The DMP-1 substudy sample participants were an average of 51 years old (range 37–73). Of the sample participants, 20% identified as African-American and 63% as white. All but one participant had health insurance, and over half (53%) had college or higher education degrees. Sixteen (53%) had a 1st degree relative (mother, sister, daughter) with breast cancer, 20 (67%) reported having a 1st or 2nd degree relative with breast cancer. No one in the sample reported themselves or a family member having a *BRCA1* or *BRCA2* mutation.

Of the 30 women participants, all but one were given a Gail score[2] risk assessment [71, 72] to calculate their level of risk in the consultation: four (13%) had a less than a 1.66% 5-year risk estimate. Twelve (40%) had 5-year risk estimates of 1.7% to 3%, eight (27%) had 5-year risk estimates between 3% - 5%, and 6 (20%) had 5-year risk estimates of greater than 5%. For the lifetime risk, 19 (63%) had a risk estimate of ≥20%.

Atypia and biopsies were common in our sample: only four (13%) had never had a biopsy, and 22 (73%) had been diagnosed with atypia after a biopsy, 7 women also reported that they had a history of untreated LCIS, indicating higher probability of developing future invasive cancer.

The five providers (four women, one man) who counseled the women about their risk had medical specialties ranging from nurse practitioner to general practitioner to breast cancer specialist.

[2] Gail score risk assessment (also known as the Breast Cancer Risk Assessment Tool or BCRAT) calculates the following risk factors into a 5-year and lifetime (until 90 years) risk of breast cancer: age, age of menarche (≥14, 12-13, <12), nr. Biopsies, nr. 1st degree relatives with breast cancer, age of 1st birth

4.1. Deciding on breast cancer risk reduction: The role of counseling (Publication 1)

Description of Counseling

Results from our first publication showed that in counseling sessions, providers gave detailed information about strategies to reduce breast cancer risk and discussed risks and benefits of the following measures: lifestyle factors, increased screenings, and SERMs. Most counseling began with a discussion of the Gail score risk assessment. Providers framed risk numbers in different ways and tailored them according to their assessment of the patient and used them to support their recommendations.

In the interviews, providers described an ideal candidate for SERM use, one without comorbidities, one young enough to experience few serious side effects from SERM use, and one with a high level of breast cancer risk above the prescribing threshold and with atypical cells. Two providers counseled 25 participants, the other three providers counseled one to three women each. One provider uniquely highlighted the temporality of the decision to use SERM by stating that this decision could be made at a later point, or pointing out that the medication could be discontinued at any time if unpleasant symptoms developed. Providers recommended SERM uptake to 21 of the 30 participants.

Participants' Decision Making

Of the 30 participants, 21 were given a recommendation to take SERM and 11 decided to take a SERM. All 11 decided to take tamoxifen as was recommended by the provider. The following characteristics were shared by all women who decided to take SERM: they were all insured and had atypia and were under 65 years of age (5 of the 11 were <45 yrs). Most were white non-Hispanic (7 of 11). Only four had a 1st or 2nd degree family member with breast cancer.

Twenty-three participants (76%)[3] , including the 11 who decided to take SERM, reached a decision about SERM during the consultation. The remaining 6 who decided later, only one participant who was unable to reach a decision. In general, concise

[3]These numbers did not appear in the publication, however they were reported in the DMP-1 substudy end of project report: Blakeslee, S. & Holmberg, C. (2014) *NSABP Protocol DMP-1 End Summary Report* (Unpublished).

determinations seemed easiest for women when their own assessment of their risk aligned with the provider's recommendation.

Temporality of the Decision

Interviews with the women demonstrated that the risk information presented by providers was only important to a participant's decision making if she was positively disposed to taking a medication prior to counseling. However, the ability to change her mind at any time played a crucial role for all women. Decisions were not considered final by many participants, including both SERM takers and decliners. Especially the younger SERM decliners expressed that they might change their decision if their risk level increased. Those that chose to start SERM treatment said they would stop the drug if side effects were intolerable. The need for a sense of control was highlighted in these narratives.

Perceptions about Medication Use

Perceptions about medication use and side effects affected a woman's willingness to take SERM. Those who decided to take SERM cited the following reasons: SERM would greatly reduce their risk, they had a very high risk for developing breast cancer, other known people had an unproblematic experience with SERM, and tamoxifen would continue to reduce their risk reduction after treatment stopped. For some, the fact that the side effect profile of the drug was similar to other preventive medications, such as the birth control pill, was a convincing argument for SERM uptake.

Overall, SERM decliners were concerned about the duration of taking the medication, how potential side effects such as hot flashes and symptoms of menopause might negatively impact their daily life and lingering doubts about taking medication to treat a potential disease as opposed to a manifest illness. Some participants had close colleagues, friends, or family who had had blood clots or cataracts, some of the serious potential side effects of SERMs.

Participants also stressed that breast cancer need not be a death sentence and that living with the possibility of breast cancer was preferable to experiencing SERM side effects. These participants said that they felt more comfortable with close monitoring or modifying lifestyle factors such as a change in diet, exercising, losing weight, and/or lowering alcohol intake rather than taking medication to reduce risk.

Personal Risk-Benefit Analysis

When participants declined SERM despite a provider recommendation to take it, they stressed how SERM side effects such as stroke could be immediate, sudden, and fatal. These side-effects felt more threatening than their fear of cancer. All of those who chose to take a SERM had atypia. Participants with atypia who declined SERM despite a provider recommendation to do so, were either surprised by a new diagnosis for being at risk of breast cancer or they worried about other health conditions that could be worsened by SERM, such as cardiovascular disease. Despite the fact that surgery was discussed at most consultations, only one participant declined the provider recommendation to take a SERM and instead opted to have a prophylactic bilateral mastectomy.

The Proximity of Breast Cancer

The close experiences of others with breast cancer impacted how participants assessed their own risk. Some participants voiced how the experiences of friends or family with breast cancer compelled them to act on their risk and start SERM treatment. For some, this was a relative to whom they felt particularly close, especially if they highlighted similarities between themselves and the cancer-affected person in terms of age, behaviors, life circumstances, or even a similarity in appearance. Conversely, those who declined SERM-use stressed how they differed from the friend or relative with cancer. The differences mentioned helped to diminish their sense of vulnerability to developing breast cancer and influenced decision making.

4.2. Explanatory model of breast cancer risk (Publication 2)

Overall Adaptation of the Explanatory Model Framework

In order to better understand how an individual's perception of their own health conditions could contribute to explaining choices made about breast cancer risk treatments, Kleinman's *explanatory model of illness* was applied to our participants by adapting the five domains established by Kleinman from *illness* and applying them to *risk*: etiology, treatment, symptoms, course to illness, and pathophysiology. Overall, four of the domains were found applicable to risk, though pathophysiology was not. One new domain was developed to better capture the risk experience (Table 1). The definition of the domains were amended to reflect risk: Etiology and Treatment were

similar. For etiology of risk, the narratives described how the risk derived from family, followed by age, lifestyle, environment, biology, stress and fate being up to god. This broadened the origins of risk cited by the provider who focused exclusively on biologically determined risk factors. Treatment narratives of risk focused on assuring an absence of disease, or maintaining a healthy lifestyle, and highlighted steep potential tradeoffs between benefits and harms of each approach. Treatment activities such as monitoring, preventive health behaviors and medical interventions were mentioned.

Symptoms and course of illness were adapted to better reflect risk categories. Descriptions of symptoms and illness were absent in risk narratives, but were substituted by signs. Signs were described as a proxy for feeling, about such things as screening results or Gail risk assessment scores. Key departures from the original concept of course of illness center around the uncertainty of risk and replace the original idea of illness trajectory. Risk narratives highlighted uncertainty and what was unknown as a main theme.

For pathophysiology, no accounts in the interviews with women at risk were found because no bodily functions of risk were determined in the accounts and would necessitate further study. Instead, social comparison was added as this element captures how risk is often compared with the others' experience. Narratives of risk used social comparisons of those in their social world to evaluate and understand their own risk, this was a central finding and informed all the other categories.

Individual Categories of the Explanatory Model Framework

Table 1:Adaptations from Kleinman's Explanatory Model of Illness to Risk [56]

Kleinman Domain	Illness Question	Domain Definiton	Risk Question adaptation	Explanatory model of risk finding
Etiology	Why am I ill?	Cause of disease	Why am I likely to get that?	women themselves attributed other factors to their likelihood
Treatment	What can I take or do to resolve my illness? How acceptable are my options?	Options for treatment	What can I take or do to lower my chances of becoming ill? Am I able to control my level of risk?	treatment for risk worked as a way to assure absence of disease, or as a way to generally stay healthy, and highlighted steep potential tradeoffs between benefits and harms.

Kleinman Domain	Illness Question	Domain Definiton	Risk Question adaptation	Explanatory model of risk finding
Symptoms	What am I feeling?	Symptoms of illness	Are there "signs" of my risk?	results related to screening or Gail risk assessment scores
Pathophysiology	What is happening in my body?	what illness does to the body and how it is experienced	No adaptation made	Not found in risk context
Social Comparisons	Not in Kleinman's model of illness	No original definition	What is it about people that causes them to be at risk? How am I like or unlike people who get this?	Behaviors and risk attributes of other known people in own social networks to compare, evaluate and personalize own risk.

4.3. Understanding decision making about breast cancer prevention in action (Publication 3)

Results from our third publication showed how decision making processes varied across groups when the sample was categorized according to perceived risk and perceived control. The domains found experience of risk in all of the 30 previously coded transcripts, adapted from Kleinman's e*xplanatory model of illness* to the developed *explanatory model of risk* model (Publication 2): *Course to Illness*, *Symptoms*, *Etiology*, *Treatment*, and *Social Comparisons*.

Social evidence used to justify decisions

Among all groups, a main common inductive theme emerged among all groups that we termed *social evidence*. *Social evidence* is defined as the information gathered from family, friends, and providers that accounted for treatment decisions in different ways, depending on the level of perceived risk and control (Table 2).

The data analysis of these domains resulted in all participants fitting into one of four categories listed below when grouped for risk (high or low) and control (high or low) and how they used social evidence to justify treatment decisions.

Table 2: Perceived Risk/Control Groupings and Social Evidence Used [53]

Perceived:	Risk High	Risk Low
Control High	n=8, SERM uptake 4 *social evidence*: to replicate behaviors that they had seen or not seen others adopt. This group felt they must act on their risk and described through the domain of social comparison how the actions of others had led to their own actions and sense of control. Unique to this group, some cited experiences in their social world to explain their own motivation.	n=9, SERM uptake 2 *social evidence*: The narratives for this group were ambivalent about risk treatment and SERM uptake but viewed their decision as an inevitable outcome. Some of these women in their narratives uniquely differentiated a lack of motivation to take action for risk from a more motivational rationale of acting on illness.
Control Low	n=7, SERM uptake 3 *social evidence*: This group was not as focused on embedding their actions into social evidence and instead focused on maintaining the status quo in order to avoid future potential increased risk. In this regard, this group was uniquely motivated to maintain current health.	n=6, SERM uptake 2 *social evidence*: They used social evidence to normalize their own experience in comparison to what others experienced or cues from providers. A unique finding in this group was that they both relativized their risk through social evidence and acted on their risk, but did not have a strong belief that these actions would have an impact on their risk.

5. Discussion

Strengths & Limitations:

The DMP-1 substudy had a novel research design. The rich qualitative dataset included video material, subsequent in-depth interviews and structured interviews about decision making, and could be used to explore in-depth risk counseling and decision making in breast cancer risk in the US context. An additional strength of the DMP-substudy was the ability to capture the real world setting of decision making about breast cancer risk in a clinic environment. The specific country context of the US is unique, in that breast cancer risk medication is approved and offered during specialized risk counseling sessions for cancer. The mixed-method design of the NSABP DMP-1 study was able to validate and support the overall findings DMP-1 sruvey and the DMP-1 substudy [31].

The DMP-1 substudy provided important context to *how* and *why* decisions about breast cancer risk are made based on available options in the US context. In particular, the in-depth exploration of counseling sessions was a strength of the DMP-1 substudy and the video material provided the ability to explore decision making

processes comprehensively. Links between the consultation session observations, exploration of the experiences of the consultation from both patients' and providers' perspectives, breast cancer risk decisions, and final verification of the decisions gave a rare and unique overview of how breast cancer risk counseling and decision making was undertaken at the two DMP-1 substudy sites.

The publications of this dissertation provided new observations and reflections of risk consultations not previously investigated. They are a profound exploration of decision making motivations, beliefs and explanations surrounding breast cancer risk experience. Data collected through the qualitative study was further analyzed with each consecutive publication, giving a comprehensive and full picture of breast cancer risk experience. The primary research of the DMP-1 substudy described risk counseling and how it impacted women's decisions to take risk reducing medications for breast cancer (Publication 1). Using the primary data gathered in the qualitative study, an explanatory model of the risk experience was developed through a secondary analysis. (Publication 2). Further categorization using domains of the explanatory model of risk gave more explicit context to how perceived risk and control factors into decision making (Publication 3). The comprehensive picture of counseling; the risk and control experience; and breast cancer risk-reduction decision making, provides a strong foundation for improving clinical practice and future research directions.

This dissertation work does have some limitations. The study design relied on the cooperation of clinical staff based in the US. For data protection reasons we were not able to contact or get verification or feedback from participants about the findings of the study. Qualitative analysis relies on an iterative analytical process using applied theories for a grounded interpretation. Because this is based on what is said and can be observed, it could be that participants might have a different interpretation of how findings applied to them.

Interviews with providers gave important insights into their counseling strategies and were valuable for analysis of the women's counseling sessions. This was a small sample of providers and two providers counseled most of the study participants. These two providers were very experienced at counseling women, which may have an effect on how applicable the counseling findings are in other US contexts. Although we were able to recruit a diverse population for participation in the study, both of the sites were

located in large clinics in urban settings. Patients living in a rural setting may have different access to risk counseling and providers' counseling may have other strategies for delivering risk information. Small community clinics would likely have less routinized structures for counseling on risk, and/or risk counseling for breast cancer may be folded into other health care topics.

In addition, from a European and global public health standpoint, the findings described are not necessarily applicable to how breast cancer risk is approached in other contexts where chemoprevention is not routinely offered or prescribed thereby limiting a broad generalizability.

Decisions about Risk

Importance of decision: place and time

Our primary analysis in the DMP-1 substudy underscored the importance of the time and place of the decision whether or not to take SERM (Publication 1). The larger DMP-1 survey found that the median time for women to reach a decision about taking a SERM was 6 days post counseling [31]. The DMP-1 substudy found that those women who reached their decision during the consultation expressed the most confidence in their decision, and yet stressed that being able to change their mind was important (Publication 1). Narratives about choices made after counseling were fraught with more uncertainty and even distress. This was seen particularly in women who had high perceived risk and low level of control (Publication 3). Affective forecasting theory, which accounts for the emotional side of decision making, was suggested by Hoerger and colleagues to account for a low SERM uptake [73] and the authors found less willingness to take a SERM over a 3 month period. Current guidelines recommend individual counseling on risk [7-11], but this body of work has shown the importance of viewing breast cancer risk counseling as a continuing and ongoing process of care. Counseling providers must account for decision making factors that are derived from both within the counseling session and from the women's lived lives.

Importance of proximity to cancer, social comparison and social evidence

The publications of this dissertation have demonstrated the importance of family, friends, and providers as influential sources of information and experience. In our primary findings, feeling akin to a person who had had breast cancer or the *proximity to cancer,* affected the decision maker's own sense of how likely they were to develop

breast cancer (Publication 1). In the development of the explanatory model of risk, narratives about others' breast cancer experiences also factored into a woman's explanation of where she felt her risk originated. Without personal signs or symptoms that could be felt herself, *social comparisons* were used. (Publication 2). And through *social evidence,* information given by others was used to justify and explain potential decision outcome, albeit in different ways depending on the level of perceived risk and control. A strong argument can be made that if sources of information and experience are conflicting, this could lead to confusion and complicate decision making. Other studies have argued that patient concepts of family risk differ from the biomedical meanings that are attributed to them [28, 74]. Social and experiential influences have been found to affect patients actions on risk [75]. The DMP-1 survey found that the decision for taking or not taking SERM was associated with the knowledge women in the study had of the good or bad experiences of others [31]. Highlighting the social and experiential factors of decision-making and risk experience is one of the strongest findings in this dissertation work and demonstrates the need to do so systematically in breast cancer risk counseling.

Implications for Counseling

Importance of the counseling recommendation

This dissertation provides the first in-depth study to observe how counseling and the recommendation of counseling providers influences views on risk and decisions. The importance of a provider's recommendation to SERM uptake has been shown in numerous studies [31, 51, 54]. In the DMP-1 survey, a recommendation to take medication was found to be predictive of SERM uptake if participants had a positive attitude toward taking medications, if a benign breast finding was discussed, or participants knew someone with a good experience with SERM [31]. In the primary analysis, findings showed that providers illustrated risk information in ways to make it more meaningful and bolster their recommendations and potentially tip the scales to take a SERM, but only if the woman herself was open to taking medication (Publication 1). Those with high perceived risk and high perceived control embedded their reasoning processes within the biomedical paradigm and in doing so, actively utilized the risk information that was given to them (Publication 3). In a forthcoming analysis of this dataset, the risk information used in counseling has been described and the extent to which provided risk calculations were integrated into individual's own

breast cancer risk were found to depend on individual interactions with the risk scores [76]. Similarly, the low perceived risk and high perceived control group were not motivated by the *social evidence* of counseling information because they do not see the risk as a threat. These findings could be applicable to recommendations made in other cancer prevention counseling and European screening contexts, for instance in German guidelines for HPV vaccine counseling, hereditary ovarian cancer screening or skin cancer prevention [77-79].

Better assessing needs in counseling

The findings of this dissertation work demonstrate that the patient perspective of risk encompasses social and experiential concepts that are important to the decision and include a wider range of topics than are currently included in counseling. Providers did tailor information to the individuals during risk counseling (Publication 1), but this work has shown a clear need to investigate patients' experiences to provide counseling that reaches shared goals and targets. The concept of shared decision making is well established in medical best practice and combines information from the provider with the values of the patient in order to come to a mutual decision. This is imperative when decisions are preference-sensitive, meaning that the benefit-harm ratio depends on the patient's values [80].

Shared decisions about chemoprevention is the existing recommended practice [81] and the tools used to assist in reaching this goal are decision aids. Decision aids have been shown to increase patient-provider communication and decision satisfaction, reduce uncertainty and anxiety about understanding breast cancer risk, but have not increased the desire to take a SERM [46, 82-84]. In addition to eliciting values, it may be important to investigate women's experiences with breast cancer. Questions may support counseling, such as: Have you had a breast cancer experience with someone you were close with? What are your perceptions of taking medications? How much of a threat do you think your risk is? How important do you think it is to act on your risk?

Even though this study is based on the specific context of breast cancer risk counseling in a US, our study has shown the need for better tools in counseling more broadly. Risk counseling in other contexts would also benefit from the findings of this work. Findings, such as how risk is processed through the social realm and appreciating timing as a crucial part of the counseling process, apply to many primary prevention patient-provider interactions.

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Statutory declaration - Affidavit

Statutory Declaration

“I, Sarah Blakeslee, by personally signing this document in lieu of an oath, hereby affirm that I prepared the submitted dissertation on the topic Knowing the Unknown: Experience and Decision Making of American Women At Risk of Breast Cancer (A Qualitative Study), independently and without the support of third parties, and that I used no other sources and aids than those stated.

All parts which are based on the publications or presentations of other authors, either in letter or in spirit, are specified as such in accordance with the citing guidelines. The sections on methodology (in particular regarding practical work, laboratory regulations, statistical processing) and results (in particular regarding figures, charts and tables) are exclusively my responsibility.

Furthermore, I declare that I have correctly marked all of the data, the analyses, and the conclusions generated from data obtained in collaboration with other persons, and that I have correctly marked my own contribution and the contributions of other persons (cf. declaration of contribution). I have correctly marked all texts or parts of texts that were generated in collaboration with other persons.

My contributions to any publications to this dissertation correspond to those stated in the below joint declaration made together with the supervisor. All publications created within the scope of the dissertation comply with the guidelines of the ICMJE (International Committee of Medical Journal Editors; www.icmje.org) on authorship. In addition, I declare that I shall comply with the regulations of Charité – Universitätsmedizin Berlin on ensuring good scientific practice.

I declare that I have not yet submitted this dissertation in identical or similar form to another Faculty.

The significance of this statutory declaration and the consequences of a false statutory declaration under criminal law (Sections 156, 161 of the German Criminal Code) are known to me.”

Date Signature

Declaration of own contribution

Sarah B. Blakeslee contributed the following to the below listed publications:

Blakeslee SB, McCaskill-Stevens W, Parker PA, Gunn CM, Bandos H, Bevers TB, Battaglia TA, Fagerlin A, Müller-Nordhorn J, Holmberg C. 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.

Contribution Details: writing of entire manuscript, editing of manuscript, undertaking the cross case synthesis (section 3. p.2349-52), literature review of current research for the Introduction (section 1. p.2346-7) and Discussion & Conclusion (section 4. p.2352-3), study design and sample trouble-shooting and data collection management as reported (sections 2.1, 2.2, and 2.3 on p. 2347-2348); development of Interview guideline with PP, CG, & CH described (section 2.3 p.2348); development of video joint summaries with CH (section 2.4 p.2348); coding (collaborating with PP & CG) and analysis with cross-case comparison with CH as described (section 2.4 p.2348-9); variable management for qualitative analysis and table analysis in collaboration with HB (Tables 4-6 p.2350); quote selection & anonymization, themes/categories analysis & presentation(Table 7 p.2351).

Gunn CM, Bokhour B, Parker VA, Parker PA, **Blakeslee S**, Bandos H, Holmberg C. Exploring Explanatory Models of Risk in Breast Cancer Risk Counseling Discussions: NSABP/NRG Oncology Decision-Making Project 1.

Contribution Details: editing of entire manuscript; collaborative development of the interview guideline and participated in group telephone conferences for interview consistency PP, CG, CH (Data Collection, p.5); transcription and audio file processing and management in MAXQDA (Data Collection, p.5); data preparation for the secondary analysis of the qualitative interview data (Analysis p.5); joint analysis session with the team to analyze secondary analysis codes (Analysis p.5); variable management in MAXQDA (Table 1, p.6) processing of transcripts for quotes and participant anonymizing system for quotes (p.7-9).

Gunn CM, Bokhour BG, Parker VA, Battaglia TA, Parker PA, Fagerlin A, McCaskill-Stevens W, Bandos H, **Blakeslee SB**, Holmberg C. Understanding Decision Making about Breast Cancer Prevention in Action: The Intersection of Perceived Risk, Perceived Control, and Social Context: NRG Oncology/NSABP DMP-1.

Contribution Details: editing of manuscript; management of 30 semi-structured interview data described (Study Design p.218); collaborative work developing interview guideline (Data Collection p.219); transcription management and preparation of analytical materials (Data Collection p.219; Table 2 p.221); preparation of transcripts Quotes in Results(p.220-3); anonymizing system for quotes (Results p.220-3) review of codes and themes (Data Analysis p. 219); processing and uploading variables in MAXQDA for demographic reporting (Results, p.219, Table 1 p.220); variable entry and analysis for provider recommendation & decision (Table 3 p.222).

Printed Publication 1: Deciding on breast cancer risk reduction…

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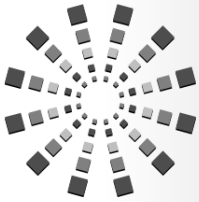

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Exploring Explanatory Models of Risk in Breast Cancer Risk Counseling Discussions

NSABP/NRG Oncology Decision-Making Project 1

KEY WORDS
Breast cancer
Explanatory model framework
Meaning of risk
Prevention
Risk perception

Background: Explanatory models represent patient understanding of etiology, pathophysiology, illness, symptoms, and treatments, but little attention has been paid to how they are used by patients "at risk" for future disease. **Objective:** The aims of this study were to elucidate what constitutes an explanatory model of risk and to describe explanatory models of risk related to developing breast cancer. **Methods:** Thirty qualitative interviews with women identified as at an increased risk for breast cancer were conducted. Interviews were coded to identify domains of explanatory models of risk using a priori codes derived from the explanatory model of illness framework. Within each domain, a grounded thematic analysis described participants' explanatory models related to breast cancer risk. **Results:** The domains of treatment and etiology remained similar in a risk context compared with illness, whereas course of illness, symptoms, and pathophysiology differed. We identified a new, integrative concept relative to other domains within explanatory models of risk: social comparisons, which was dominant in risk perhaps due to the lack of physical experiences associated with being "at risk." **Conclusions:** Developing inclusive understandings of risk and its treatment is key to developing a framework for the care of high-risk patients that is both evidence based and sensitive to patient preferences. **Implications for Practice:** The concept of "social comparisons" can assist healthcare providers in understanding women's decision making under conditions of risk. Ensuring that

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healthcare providers understand patient perceptions of risk is important because it relates to patient decision making, particularly due to an increasing focus on risk assessment in cancer.

Medical practice is increasingly engaging in individual risk assessment to identify populations that may be susceptible to developing future disease. Although there may be benefits to targeting early prevention among some high-risk groups, conceptually, risk is applied to populations, and making deterministic statements about an individual's risk based on population estimates is far from certain.[1] When statistical estimates of risk are provided to individuals, it implies that their own personal risk is objective and easily measured[2] and that individuals should act on this objective risk measure.[3] However, risk, when understood from a sociological perspective, represents a complex interplay between individual behaviors, structural and social contexts, and embodied risk, that is, risk residing within the body in the absence of manifest illness (eg, abnormal biopsies that may increase clinical estimates of risk).[4] Still, risk estimation is frequently given at the individual level as impetus for adopting preventive behaviors.

With an increasing number of conditions identified at the point of risk (vs manifest disease) and for which such individualized risk estimates are communicated, it becomes increasingly important to further tease out what happens during one-on-one risk communication. Others have shown that risk estimates differ from individual's risk understanding and may therefore not be used for individual decision making.[5–8] However, they have not investigated how different aspects of perceptions, social influences, and ideas about illness come together to inform decision making.

Theories of risk perception and health behaviors span several disciplines, adopting a range of perspectives and explanations for how individuals form risk perceptions and how perceptions are related to health behaviors. Psychologically focused theories tend to represent the process by which perceptions are formed as a 2-dimensional process.[9] One dimension represents the analytical, logical, and probabilistic processing that produces perceptions; the other is experiential—that is, it is intuitive, unconscious, and automatic.[10] Medical anthropology and sociology adopt a "meaning-centered" approach to studying risk by characterizing health beliefs to explain why groups of individuals construct health and illness in particular ways. Broader social science literature expands these understandings of risk further into the social and moral world, examining the various influences on ideas of risk.[1] The application of theory to understanding risk perceptions can help explain individual behaviors that deviate from expectations, yet more research is needed to identify appropriate theory for particular contexts. Arthur Kleinman and colleagues[11] have developed a patient-centered approach to understanding an individual's beliefs and behaviors with regard to disease, which he termed an *explanatory model*.[12] Kleinman et al[11] argued that a patient's understandings of his/her illness need to be taken into consideration in patient-doctor interactions to ensure appropriate healthcare delivery, including treatment. He posited that an individual's understanding of illness is represented in the following categories: etiology, pathophysiology, course of illness, symptoms, and treatments for a given condition. Explanatory models recognize that illness is experienced through perceptions rooted in our explanations of sickness, social positions, and systems of meaning,[11] facilitating a multidimensional understanding of perceptions. To date, explanatory models have been examined among patients who have experienced manifest disease.[12–14] However, the focus on meaning of illness from an individual's perspective that characterizes explanatory models may be a helpful framework in understanding how risk perceptions influence health behaviors. Thus, this study applies the explanatory model framework to the context of discussions about breast cancer risk in women who are counseled about treatment options for breast cancer risk. This analysis allows for an understanding of how women attribute meaning to being at risk.

Breast cancer risk counseling with the aim of prevention is common, and we chose this context to explore the social dimension of risk perceptions using explanatory models given that more logically based theories do not accurately describe women's behaviors. The most common reasons physicians discuss breast cancer risk and treatment options with women are a family history of breast cancer and/or clinical findings that indicate risk, such as biopsy results indicating atypical lobular hyperplasia, atypical ductal hyperplasia, or lobular carcinoma in situ (LCIS). Often in such situations, more formal assessments of risk including genetic testing for *BRCA1*/*BRCA2* mutations and the use of risk prediction algorithms[15–18] are used to quantify a woman's risk and help guide treatment decision making for both women and physicians. After identifying women at high risk, physicians may provide recommendations for enhanced screening, behavior changes, or medical treatments (eg, chemoprevention medications, surgery) with the goal of risk reduction.

Interestingly, although women often overestimate their risk for breast cancer relative to communicated (objective) risk levels,[19–21] the use of preventive interventions such as chemoprevention medications are seldom adopted by patients for whom these interventions would provide risk-reduction benefits.[22,23]

Again, this suggests a more complex relationship between risk perception and health behavior. We therefore investigated whether the explanatory model framework can be applied to risk conditions, such as breast cancer risk. Understanding women's meaning-making about a risk diagnosis could impact the development of more patient-centered approaches to managing risk. For example, eliciting and addressing patient understandings of the etiology of risk and cancer, or women's expectations about the trajectory of risk, may assist clinicians in counseling about personal risk, risk-reducing behaviors, and preventive treatments. Therefore, this analysis sought to (1) elucidate what constitutes an explanatory model of risk and (2) describe the explanatory models of risk held by women identified to be at an increased risk for developing breast cancer.

Materials and Methods

Thirty qualitative interviews were conducted among a subset of women participating in a large, mixed-methods NSABP/NRG Oncology Decision Making Project-1 (DMP-1) Study of the social, cultural, and psychological factors involved in making decisions about breast cancer risk reduction strategies.[24] Institutional review board approval was received from the 2 sites where interviews were conducted, and informed written consent was obtained before participation.

Participants

Women were recruited for interviews from 2 large US medical centers: a safety-net academic medical center and a larger comprehensive cancer center. The sites were purposely selected because they serve very different patient populations. One predominantly serves patients from racial and ethnic minorities and medically underserved groups, whereas the other is a renowned cancer center including a predominant cancer prevention department. Participants were at least 35 years old and English speaking and were identified as being at an increased risk for breast cancer by the healthcare provider. Women who previously had invasive breast cancer; previous ductal carcinoma in situ; previous LCIS if treated with mastectomy, radiation therapy, or endocrine therapy; or any previous or current use of tamoxifen, raloxifene, or other selective estrogen receptor modulator therapy for any reason were excluded. Women were also excluded if participating in any other cancer or osteoporosis prevention studies involving pharmacologic interventions.

Women who met the criteria listed previously were approached before their clinic visit to inform them about the study. The first 30 who agreed to participate in the video recording/interviews comprised the final sample. This sample was expected to generate enough data to reach theoretical saturation, defined as no new themes arising from the interview data. Other qualitative investigations have reached saturation in fewer than 30 interviews when conducting thematic analyses using similar techniques.[25,26]

Data Collection

Data were collected from April 2012 through August 2013. Women provided informed consent before their counseling session. The visits in which women were counseled by healthcare providers regarding their individual risk of developing breast cancer and options for prevention were video recorded. Counseling about risk was completed by the woman's physician as per their usual practice; that is, the session content, format, or recommendations were not standardized. All sessions included some discussion of the use of chemoprevention agents, but it was not recommended for all women. A range of topics including, but not limited to, using risk assessment tools, previous biopsy results, lifestyle risk factors, and the benefits/risks of medical interventions were discussed, depending on the woman's individual situation. Within 1 month after the counseling session, the participants returned for a qualitative in-depth interview with a researcher trained in the social sciences. One interviewer at each site was trained by the principal investigator during an initial site visit, with ongoing feedback provided throughout the course of the study. Group telephone conferences with the study team further ensured consistency in the interviewing process.

The interview guide was developed collaboratively by the research team at the Charité-Universitätsmedizin Berlin, and the interviewers at the 2 local sites sought to explore breast cancer risk perceptions and approaches to decision making. It was based on the study's overall aim and existing literature in the field. The semistructured interview guides were used flexibly, allowing a conversational flow to the interview, while ensuring all relevant topics to the research questions were covered. The interviewers asked the participants about issues discussed during the counseling session, the participant's experience of being at risk for breast cancer, influences on risk perception, social support, and personal approaches to decision making, both in general and specific to the risk reduction therapies discussed. Written informed consent included permission to audio-record the interview.

Each interview was transcribed verbatim by the principal investigator's staff and cross-checked for accuracy by another member of the research team. Transcripts and audio files were entered into MaxQDA for data management and analysis. All participant identifiers were removed from the transcripts for distribution to the site researchers conducting analyses.

Analysis

This is a secondary analysis of the qualitative interview data[27] focusing specifically on the portion of the interview related to perceptions and beliefs about risk. We used a grounded thematic approach, applying analytic strategies derived from grounded theory.[28,29] The first 7 interviews were jointly coded by 2 authors, who focused closely on identifying emergent (open) codes, seeking to capture all meaningful phrases represented in the interviews. This grounded approach ensured inclusivity in comprehensively identifying constructs salient to women in the explanatory model analysis. After the first 7 interviews, the remaining were open-coded by 1 investigator and reviewed by the second author, a senior qualitative researcher. New codes identified in subsequent interviews were reviewed jointly before being added to the codebook. In a second phase of analysis, open codes were grouped into a priori categories that represented the domains of explanatory models as developed by Kleinman and colleagues[11]: etiology, pathophysiology, onset of symptoms, course of illness, and treatment. After relevant codes were grouped into these categories, iterative amendments were made to original definitions through reflection and joint discussion of participant data to understand participants' explanatory models related to breast cancer risk. Through this process, codes that did not fit with the explanatory model framework were identified during joint analysis sessions and in consultation with the entire research group. These additional codes were analyzed and used to expand the explanatory

model framework to render it applicable to risk. On the basis of the explanatory model categories, a framework for explanatory models of breast cancer risk was developed with reflections on areas of conceptual linkage and divergence from explanatory models of illness.

Thematic saturation was reached after 20 interviews, after which no new categories were identified, although the additional 10 interviews contributed new perspectives and added variation within categories. To ensure the anonymity of our participants, quotes were edited, including deleting unrelated medical diagnoses or changing characteristics of others mentioned if it was not relevant for the analysis. Quotes are tagged with a letter in the text below, with 1 letter assigned to each participant along with a range of 5-year breast cancer risk calculated using the Gail score.

Results

Participants

The purposeful site selection was successful in recruiting a sample of 30 women with a range of ethnicities, experiences, and ages. Table 1 displays the demographics and risk characteristics of participants. A range of Gail Model clinical risk estimates was observed in the sample. Of the 30 women sampled, 4 (13%) had a less than 1.66% 5-year risk estimate. Twelve (40%) had estimates of 1.7% to 3%, 8 (27%) had estimates of greater than 3% to 5%, and 6 (20%) had 5-year risk estimates of greater than 5%. Seven of the women also reported that they had a history of untreated LCIS found on biopsy, rendering the Gail model inappropriate but indicating higher probability of developing future invasive cancer.

Table 1 • Study Participant Characteristics: NSABP DMP-1

	n (%)
Total N	30 (100)
Race/ethnicity	
Non-Hispanic white	19 (63)
Hispanic white	2 (7)
Hispanic unknown	2 (7)
African American	6 (20)
Mixed race	1 (3)
Marital status	
Married/living as married	19 (63)
Widowed	2 (7)
Divorced	4 (13)
Never married	5 (17)
Insurance	
Medicare	3 (10)
Medicaid	1 (3)
Private	24 (80)
Self-pay/uninsured	2 (7)
Highest grade of schooling completed	
High school/GED	6 (20)
Vocational/technical/associate degree	3 (10)
Some college	5 (17)
College	9 (30)
Graduate/professional degree	7 (23)
Income	
<$30 000	4 (13)
$30 000–$50 000	4 (13)
$50 000–$80 000	3 (10)
>$80 000	16 (53)
Missing	3 (10)
5-y Gail model risk	
<1.66%	4 (13)
1.7%–3%	12 (40)
3%–5%	8 (27)
>5%	6 (20)
Age, mean (SD), y	50.9 (9.3)

Abbreviation: NSABP, National Surgical Adjuvant Breast and Bowel Project.

Overall Adaptation of the Explanatory Model Framework

We found evidence that many of Kleinman et al's categories related to explanatory models were relevant to the context of breast cancer risk: overall, 4 of the 5 original categories were represented in women's explanatory models of risk for breast cancer: etiology, symptoms, course of illness, and treatment. The fidelity of the etiology and treatment domains to the original definitions was maintained. For other domains, for example, symptoms and course of illness, some of the concepts required revision to reflect risk, described in Table 2. There was a lack of evidence in the data that pathophysiology played a role in developing explanatory models of risk. Risk was not described as changing bodily function or something that was necessarily sensed. In addition, a category had to be added to the model that was not accounted for by Kleinman et al's concepts: social comparisons. The social comparison element captures the phenomenon that risk is consistently evaluated in comparison with others' experience in the social world.

Specific findings related to each category are discussed hereinafter.

Individual Categories of the Explanatory Model Framework

ETIOLOGY

The original definition of etiology encompasses what participants perceive to be the causes of risk or illness. The concept of etiology of risk was very closely aligned with etiology as represented in explanatory models of illness. Women described a broad range of causes of breast cancer risk, with most describing a multimodal etiology. One participant describes this multifactorial exposure perspective:

> I just feel like it's just—it's not all genetics. Who knows? It could be a little cocktail of environmental exposure, a little bit of genetic mixed up…it's just something that just—it happens and you only have so much control. I call it gravity. You just have so much control over that gravity. (participant N, Gail risk of 2.01%–3%)

Table 2 • Brief Descriptions of Explanatory Model Domains: NSABP DMP-1

	Original Definition	Amended Definition
Etiology	Why am I ill?Why do I have this?	Why am I likely to get that?
Onset of symptoms	What am I feeling?	Are there "signs" of my risk?
Pathophysiology	What is happening in my body?	Not described in risk context[a]
Course of illness	What will happen to me?	How will my risk turn into a disease?
	How serious is this illness?	What are my chances of actually becoming ill?
	Is it acute or chronic, or will I be impaired?	Am I able to control my level of risk?
		This was relabeled as "Course to Illness"
Treatment	What can I take or do to resolve my illness?	What can I take or do to lower my chances of becoming ill?
	How acceptable are my options?	How acceptable are these different options?
Social comparisons	Not described in illness context[b]	What is it about people that causes them to be at risk?
		How am I like or unlike people who get this?

Abbreviation: NSABP, National Surgical Adjuvant Breast and Bowel Project.
[a]No amended definition.
[b]No original (a priori) definition.

Although many women described the idea that causes of breast cancer risk are multifactorial, they also described individual causes of risk. The most commonly described cause of being at a high risk was family. This presented itself in 2 ways: first, women described genetics or hereditary components of risk. For example:

> I know enough that this is a genetic disease and hereditary and there's definitely links so I just assumed that I probably was at a greater risk now. (participant O, Gail risk < 2%)

Others described risk as a more general familial trait that is not traced scientifically to genetics:

> My mom's a breast cancer survivor. She has one breast…cancer runs in my family so I get more worried or paranoid than anything else because I know what I come from. (participant L, Gail risk < 2%)

Other common explanations for why women felt they were at risk included age, lifestyle, environment, biology, stress, or that being at risk was "up to God." These explanations of the causes of breast cancer risk were used by women to make sense of the information that was provided to them in consultations. Although some of these causes were explicitly addressed by providers (age, biology), others were more reflective of the participants' experience outside the medical setting (stress, environment, spiritual).

TREATMENT

Treatment encompassed the types of interventions that patients believed can be received to manage risk. Treatment, like etiology, displayed more commonality than divergence with explanatory models of illness. In both illness and risk, individuals formulated and described actions that could ameliorate or reduce illness or risk. Among these participants, 3 broad categories of "treatments" for risk were inductively identified and described: monitoring, preventive health behaviors, and medical interventions.

Monitoring

Monitoring risk encompassed 2 distinct phenomena: self-monitoring and screening strategies. Self-monitoring involved many women describing being "at risk" as generating a personal responsibility to be aware of bodily changes:

> I think that's one of the better preventative methods… being cognizant and aware of your own body. If you don't identify certain changes or aren't aware of things, you might be missed and it can be easily missed in a physical if you don't bring something to the attention of your physician. (participant A, Gail risk < 2%)

Second, women described the use of screening strategies such as mammography, ultrasound, clinical breast examinations, or other means of tracking and monitoring risk. The idea of monitoring was the most widely recognized and accepted method of reducing risk. Routine screening brought about a cycle of reassurance that risk was not increasing and cancer had not yet developed. As 1 woman stated, she will be "less worried for another year" (participant G, Gail risk of 2.01%–3%).

Preventive Health Behaviors

Preventive health behaviors included interventions such as diet changes, stress reduction, exercise, weight loss, limiting alcohol intake, and quitting smoking as means to reduce risk. Preventive health behaviors were not always recognized as a method to reduce breast cancer risk but were regarded as important for staying generally healthy. For example, 1 woman spoke about the elevated importance of lifestyle because of her high-risk status, "I mean as far as just conventional wisdom I think I knew the healthy lifestyle and exercising and moderation of alcohol and caffeine and things like that, which more or less we try to follow. But now it seems to be more important given the situation" (participant U, Gail risk of 2.01%–3%). At the same time, there were mixed reactions to the acceptability and effectiveness of behavior change in reducing breast cancer risk:

> It's in my face. You know, I'm looking at this going, he quit smoking [a long time ago], he ended up getting lung cancer. In reality, what are my chances of not getting cancer just because I stop smoking? Obviously they're not any better than if I'm smoking as such. (participant W, Gail risk < 2%)

This range of responses to preventive lifestyle behaviors represents the joint influences of medical communications about lifestyle risk factors and cultural beliefs about their impact on disease development.

Medical Intervention

Taking medications or undergoing prophylactic surgeries were the 2 treatments mentioned in relation to breast cancer risk reduction by both participants and providers. Descriptions of treatments for risk seem to present tradeoffs: the severity of risk and chances of getting cancer versus the risks of the treatments themselves. An exemplar of these tradeoffs is presented by 1 woman considered to be at a relatively high risk of developing breast cancer:

> So that was a little bit alarming of the possibility of the side effects of the drugs, you know, especially at my age and also with me having a [medical condition] that could possibly lead to a stroke, you know. I don't know which I would prefer—cancer or the stroke. I think probably cancer because a stroke, I mean that just renders you, you know, not able to function pretty much in a lot of cases. (participant J, Gail risk > 5%)

In contrast to behavioral "treatments" that posed few risks, descriptions of the risks of medical treatments highlighted the importance of what women understand and interpret about benefits and risks of treatments in conjunction with knowledge and beliefs originating outside the medical encounter.

SYMPTOMS

In explanatory models of illness, the definition of "onset of symptoms" relates to why patients think illness started when it did and the experience of bodily symptoms. In risk, there is generally a lack of experienced bodily symptoms. We thus defined symptoms as the "signs" women interpreted as representing their level of risk. These signs often were the result of screening activities. Signs of risk that women discussed included mammogram findings, breast pain, atypical cells identified by biopsy, benign breast lumps, and Gail risk estimates. These were the factors that women worried about as increasing their own risk of developing cancer that often were addressed in discussions with their providers during risk counseling.

COURSE TO ILLNESS

The course of illness in explanatory model research has focused on several interrelated concepts: the trajectory, seriousness, and severity of illness. Trajectory encompasses the expected path that an illness will take, as well as its chronicity. Seriousness and severity represent perceptions of the threat of illness to daily life. In examining explanatory models of breast cancer risk, we identified some key departures from these definitions, in particular, related to the uncertainty of risk in relation to the illness experience. On the basis of our findings, "Course of Illness" was reconceptualized as "Course to Illness."

Course to illness was framed around assessing the chances of actually becoming ill as a result of a risk diagnosis. It was described through reflections on how and when risk will turn into disease and whether women felt control over their level of risk. There was also some element of assessing the severity of being at risk: it was minimized by some and elevated to disease status by others.

One of the themes expressed throughout the "course to illness" concepts was the inherent uncertainty about the potential path to illness. Women often articulated this uncertainty, which was unique to discussions of risk versus the experience of breast cancer itself. As 1 woman stated: "You don't know, it's a roll of the dice" (participant AB, Gail risk of 3.01%-5%). Potential courses were described as a combination of 3 dichotomies: inevitability versus control, uncertain versus expected trajectory, and risk as an immediate and constant versus distant threat. Women constructed narratives about their expected courses to illness, describing these themes as the basis of their assessment. For example, 1 common narrative was that, although breast cancer was inevitable because risk would always rise with age, it was nothing to worry about until later in life. One woman expresses this particular path:

> I think right now for me personally, given my age, I'm real comfortable kind of where we're at now. I think each year we'll talk about this and I'll, you know, have to look at it through a different lens 'cause (…) and my risk factor's going to continue to increase as it does with age…. When talking about, you know, potential options in the future to take medication that may reduce my risk, you know, that to me is a bit off in the distance. (…) I don't know how I'll feel in five years or ten years. (participant O, Gail risk < 2%)

Another common course to illness included risk as an immediate threat with an expected path to breast cancer that required action to change the course:

> I can see that this is going to happen and I am doing the right things to minimize the risk…. I will do everything that I have to do, improving my eating habits, doing exercise, eating healthy or taking the medicine, everything to minimize that risk. (participant I, Gail risk > 5%)

Alternatively, risk was described as uncertain and distant, with no expected trajectory, but able to be controlled with actions taken in the present:

> I'm thankful if anything else that…I got kind of a heads up or a flag that says hey this might be down the road and then also thankful that I have the possibility of doing something. (participant U, Gail risk of 2.01%–3%)

PATHOPHYSIOLOGY

Pathophysiology was defined by Kleinman and colleagues as what illness does to the body and how it operates to make one

experience illness. This concept had no identified corollary in the setting of risk in this sample. We identified a few descriptions of pathophysiology, but these were solely related to cancer itself, rather than to cancer risk. For example, 1 woman described breast cancer as follows:

> It seems like it really progresses and you can see how it just eats away at the tissue in your breast and just how ugly it really gets inside. (participant J, Gail risk > 5%)

The nature of risk may not be conducive to thinking about bodily changes in the absence of an illness experience. Alternatively, our questions may not have allowed for this concept to be identified within the context of this interview because we did not specifically probe for ideas of pathophysiology. Further work is required to understand the role of pathophysiology in explanatory models of risk.

SOCIAL COMPARISONS

In addition to the domains previously identified as relevant to individuals' explanatory models of illness, we identified a critical theme that ran through women's narratives about risk. When discussing breast cancer risk, women frequently relied on comparing their behaviors and risk with those of others in their social networks as a means of formulating perceptions. Thus, we identified the category of "social comparisons": the process by which individuals produce and describe their explanatory models of risk. Women consider attributes of other people they know in the social world who develop cancer to evaluate and personalize their own risk. Social comparisons involved an evaluation or understanding of how personal risk estimates related to others' risk, the experience of being at risk, or having cancer. This was indeed a critical element of how women conceptualize risk, which informs all the other domains of the explanatory model of risk. It is clear that perceptions were not based solely on what women learned from medical providers or others but rather were negotiated in relation to the social world where knowledge and belief systems are formulated. This process involved an explicit evaluation of the self in relation to others in the social world that has not previously been described using data related to illness models. Hereinafter are examples of how this concept was manifested in this sample of women:

> I understand the whole cell dividing but I have a very different lifestyle than my mother did…where I'm just trying to be very healthy and we're [of a] different make up…but I feel like I'm mirroring my father. (participant N, Gail risk of 2.01%–3%)
>
> I know that, it [cancer] could happen. It is so scary that I might do the same thing [my grandmother] did because I had a knot in my breast [long time ago]…you have something and everybody thinks it's cancer, it's cancer, it's cancer. I stayed in denial for [awhile] without even going to the doctor so I'm thinking, "will I be reliving her life now that I'm just sittin' up here?" (participant Q, Gail risk of 2.01%–3%)

These quotes demonstrate how women incorporate their knowledge of the social world and contextual experience to compare themselves with others as a means of ascertaining their own risk.

■ Discussion

Understanding patient perceptions of risk and engagement with a risk diagnosis is critical in a time when we increasingly screen for undetected disease and propose preventive treatments. Healthcare activities frequently emphasize risk assessment and preventive activities to minimize risk for conditions such as cardiovascular disease, diabetes, and cancer, with the expectation that discussing these risks will promote patient engagement in preventive behaviors. Patients' understandings of risk are vital in designing prevention activities; yet thus far, patient perceptions of risk and the acknowledgement that there is a legitimate gap between epidemiologically calculated risk, a medical perspective on risk, and individuals' perceptions of risk have not factored into the design of prevention strategies.

Explanatory models have been a useful framework for understanding patient perceptions of illness.[12] We have been able to develop the concept of an explanatory model of risk, which helps one to understand how women attribute meaning to a risk diagnosis. Some categories that are important in creating meaning in illness contexts such as treatment and etiology are also of importance in a risk context. However, other categories such as course of illness, symptoms, and pathophysiology differed. Most importantly, we identified a new category that is important to attribute meaning to a risk diagnosis: social comparisons, which perhaps becomes more dominant in a risk context due to the lack of physical experiences associated with being "at risk." Before individuals engage in prevention behaviors, they first evaluate whether, for them, disease is a real possibility. The category of social comparison seems to be one of the deciding categories in this evaluation.

By using breast cancer risk assessment as an exemplar to examine explanatory models of risk, we identified several examples of divergence between lay and biomedical conceptions of risk. One example of this was related to familial risk in the category of etiology of risk: most breast cancers are sporadic in nature, with only 5% to 10% associated with specific, known genetic mutations. However, many women described holding a perception that, once any family member is given a diagnosis of breast cancer, their own chances of developing breast cancer increase significantly because of either genetics or more general family associations. This broad view of familial associations related to risk is incongruent with the more narrowly focused, Mendelian genetics view of medical risk. This divergence has been similarly noted by others.[30–32]

One of the key aspects of explanatory models of risk that we identified in this study was the addition of social comparisons. Social comparisons are a means by which the women in our study integrate and navigate different ways of thinking and are part of broader cultural models. Explanatory models are always formed and negotiated within a social context, but the experience of being "at risk" without manifest disease elevated the importance of others' experiences. The inherent uncertainty and lack of identifiable illness meant that women looked for

outside cues and social evidence to think about their risk status and to make it meaningful for themselves rather than focusing on internal bodily indicators. This is a departure from current illness explanatory model frameworks. It is also an example of the divergence between lay and biomedical assessments of risk. For example, for biomedical conceptions, others are only of relevance with regard to their genetic relationship in a risk assessment. In contrast, in our sample, women talked about family broadly and made social comparisons in assessing their own susceptibility to breast cancer. Another analysis of this data which focused on the decision-making process on SERM use and how the counseling of a health care provider influences this decision developed a similar concept: "proximity to cancer." Proximity to cancer reflected the idea that for women comparisons with regards to similarity to a person who had experienced breast cancer was more important than a genetic relationship for SERM decision-making.[33] Similarly, Pfeffer[34] has described a concept that she coined "candidacy" for breast cancer to explain why women do or do not participate in breast cancer screening programs. Candidacy represents the personal characteristics and lifestyles that make some people more/less likely to develop a disease. Pfeffer found that, in breast cancer screening, women placed a lot of emphasis on comparing moral and biographical details of candidates' reproductive histories. The concept of social comparisons is similar, although establishing "candidacy" is more limited in scope. Social comparison includes candidacy, social evidence, and evaluations of positioning of risk that are integrated with the social context and other pieces of explanatory models to produce a risk identity.

This study assessed women with whom clinical providers knew before the appointment that they would discuss treatment options for breast cancer risk reduction based on the reason of the clinic visit. This limits the sample to women who either have a family history of breast cancer or needed to discuss a breast biopsy result. The limited sampling frame restricts inferences that can be made about the broader population undergoing screening. To fully explicate what explanatory models of risk look like and their influence on decision making, expanding this work to women at all levels of risk and into other health risks is necessary. The women in the sample had different ethnic, social, and regional backgrounds. Interestingly, these differences played no role for the categories of meaning-making of the explanatory model. Thus, we did not add this information to the quotes to ensure anonymity. Further analysis is required to examine whether and how different backgrounds (race, ethnicity, culture, socioeconomic status) influence how decision making within these categories may be influenced differently. Furthermore, these women were primed to discuss their risk after a medical encounter that specifically involved personalized risk counseling. Others who do not undergo these specialized services may provide different perspectives that are not accounted for in these data.

■ Implications for Practice

The range of conditions that are known to increase the probability of developing manifest disease are on the rise, particularly with new diagnostic tools becoming available. However, what such risk conditions mean for an individual is not well understood. It is evident that risk perception and health behavior are complex and preventive behaviors do not (and perhaps should not) rest on the results of a medical risk assessment alone. Understanding how patients attribute meaning to a diagnosis that tells them that they have a risk for a disease is a necessary prerequisite to understanding how they may deal with this risk. Healthcare that aims to guide such decision making needs to know about the meaning-making processes. Kleinman et al developed the explanatory model framework particularly for use in clinical settings to help healthcare providers make sense of their patients' behaviors. To do so, they developed a range of questions based on the categories of the explanatory model to ensure such patient-centered care questions are paramount. Based on the findings of the presented analysis, we suggest that risk counseling for breast cancer should include an assessment of the social comparison category. For example, one may ask, "how do you compare yourself to family members who have had a diagnosis of breast cancer?" and "In what ways is breast cancer risk worrisome for you?". To ensure a patient-centered care approach, using these updated questions in situations related to risk (vs illness) may guide elicitation of the meaning a woman attributes to her risk diagnosis.

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Printed Publication 3: Understanding Decision Making…

Gunn CM, Bokhour BG, Parker VA, Battaglia TA, Parker PA, Fagerlin A, McCaskill-Stevens W, Bandos H, **Blakeslee SB**, Holmberg C. 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):217-227.

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Curriculum Vitae

My curriculum vitae does not appear in the electronic version of my paper for reasons of data protection

Complete publications list

Talking Numbers: How Women and Providers Use Risk Scores During and After Risk Counseling - - NRG Oncology/NSABP DMP-1, **Blakeslee SB**, Gunn CM, Parker PA, Fagerlin A, Battaglia TA, Bevers TB, Bandos H, McCaskill-Stevens W, Kennedy J, Holmberg C, (*manuscript in submission*)

Understanding Decision Making about Breast Cancer Prevention in Action: The Intersection of Perceived Risk, Perceived Control, and Social Context: NRG Oncology/NSABP DMP-1 Gunn CM, Bokhour BG, Parker VA, Battaglia TA, Parker PA, Fagerlin A, McCaskill-Stevens W, Bandos H, **Blakeslee SB**, Holmberg, C, Medical Decision Making. 2019. 39(3), 217-227.

Impact factor: 2.335 *(ISI Web of Knowledge 2017 – Medical Informatics: 5 of 25 TOP 20%; ISI Web of Knowledge 2018 – Medical Informatics: 10 of 26 TOP 38%)*

Exploring Explanatory Models of Risk in Breast Cancer Risk Counseling Discussions: NSABP/NRG Oncology Decision-Making Project 1, by Gunn CM, Bokhour B, Parker VA, Parker PA, **Blakeslee S**, Bandos H, Holmberg C, Cancer Nursing, 2019. 42(1).

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