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13. ABSTRACT *(Maximum 200 Words)*

Prophylactic mastectomy (PM), the surgical removal of a healthy breast, is a risk-reduction option offered to women at increased genetic risk of breast cancer. There is limited data on psychological effects of PM on body image, self-esteem, marital and family relationships, etc. A psychological consultation offered to women making this irreversible decision would likely improve decision-making and subsequent coping. Design of this consultation is best informed by data about physical and emotional effects of surgery from women who have had this procedure. In Year 2 we conducted taped, telephone interviews with women with cancer in one breast who had both breasts removed (49 enrolled), women who had both breasts removed prophylactically (15 enrolled), and women considering PM (16 enrolled). We aim to determine 1.) emotional and interpersonal effects of PM, 2.) anticipated effect of PM among women at increased risk, and 3.) subjects' beliefs about the utility of psychological consultation. In Year 2 we also 1.) revised demographic forms and interview schedules for subjects considering PM, 2.) developed a statistical database and entered demographic data and 3.) transcribed and initially analyzed completed interviews. Preliminary findings were accepted for presentation at an international conference on psychosocial aspects of cancer genetics.

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Table of Contents

Introduction

Prophylactic mastectomy (PM), the surgical removal of a healthy breast, is a risk-reduction option offered to women at increased genetic risk of breast cancer. There is limited data on the psychological effects of PM on body image, self-esteem, marital and family relationships, etc. A psychological consultation offered to women making this irreversible decision would likely improve decision-making and subsequent coping. The design of this consultation is best informed by data about physical and emotional effects of surgery from women who have had this procedure. This project aims to gather such data through taped, telephone interviews with women who had both breasts removed prophylactically (N=25), women with cancer in one breast who had both breasts removed (N=50), and women considering PM (N=50). We aim to determine 1.) emotional and interpersonal effects of PM, 2.) what women at increased risk of breast cancer anticipate the effects of PM surgery to be, and 3.) if women in both groups believe psychological consultation about PM is useful.

Body

Year 1 of this project focused on development, piloting, and approval of the interview schedule and PM demographic form and preparation of the patient database representing eligible subjects in the 3 institutions where patients are being accrued. When the annual report for Year 1 was written, enrollment of PM subjects was being initiated.

Year 2 has been characterized by enthusiastic enrollment of PM subjects, some challenges in completing one subject group due to poor record-keeping at one institution, development of the interview and demographic form for the Genetic Counseling patient group (women who are considering PM), and initiation of interviews with those subjects. In addition, we have, with biostatistical consultation, created a database for demographic data and compiled demographic statistics on groups to date. Also, transcription of the PM interview tapes has been accomplished and transcription of the GC tapes is underway. Preliminary analysis of the thematic content of the PM interviews led to the submission of an abstract which was accepted for plenary presentation at the 7th International Meeting on Psychosocial Aspects of Genetic Testing for Hereditary Breast and/or Ovarian Cancer (HBOC) and Hereditary Non-Polyposis Colorectal Cancer (HNPCC) in Frankfurt, Germany.

The final 2 surgeons at the Brigham and Women's Hospital (BWH) responded affirmatively to our request to allow us to invite their patients to participate in our study. This brought to 100% the participation of BWH surgeons. At the Massachusetts General Hospital (MGH) 14 of 15 surgeons (93%) responded affirmatively, with one surgeon who had left the system refusing, citing prior unsatisfactory research participation with a psychologist (not affiliated with this project) as his reason for not wishing to participate. We also had permission to contact directly all patients whose surgeons were no longer in the Partners Hospital system.

The interview schedule and demographic form originally developed for the women in the PM groups were revised in Year 2 for the women in the Genetic Counseling (GC) group to reflect our interest in their decision-making, information

sources, motivations, and views on the value of psychological consultation as part of the process of considering a prophylactic mastectomy. The demographic data form was changed to add sections asking about the women's genetic counseling and/or testing history and perceived level of breast cancer risk. Letters for GC subjects had to also be revised. All amended forms were submitted to and approved by the Dana-Farber/Partners Institutional Review Board.

In determining subject eligibility, we have had to start with larger groups of women who had undergone bilateral (but not necessarily prophylactic) mastectomies. This is because procedure codes for prophylactic mastectomy are used inconsistently and are relatively new, so were not available for much of the period from 1990-2000 when our patients had their mastectomies. From the initial 171 patients whom we identified as having had bilateral mastectomies performed by participating surgeons at the BWH, surgeons informed us that 19 had not undergone prophylactic mastectomy (most had had double mastectomies for bilateral cancer). Of the remaining 152 patients, 3 additional patients were ineligible because they had had their surgery prior to 1990 (1), had died (1) or, because of lack of surgeon permission to contact the patient for unspecified reason (1). Thus, we had permission to contact 149 patients. We did not anticipate needing to contact all 149 patients in order to reach our accrual targets. Thus, from these 149 patients, 91 names were selected at random and invited by letter to participate in the study. Of these 91 potential subjects, we were unable to locate 19. Eleven potential subjects were disqualified because of death, cancer diagnosed subsequent to mastectomy, or because the subjects themselves informed us that their mastectomies had not been prophylactic. Five subjects were reached after we stopped accruing patients and they were informed of this. All five asked to be called back if we needed additional subjects in the future. A total of 13 of the remaining 56 subjects decided not to participate; eight subjects opted out of participating and 5 subjects were not responsive to efforts to contact them. The remaining 43 subjects from the BWH group agreed, enrolled, and were interviewed for a participation rate at the BWH of 77% (43/56).

At the MGH, of 114 patients who had had bilateral mastectomies, we were informed by the surgeons that 60 women were not eligible for our study. Reasons included no prophylactic mastectomy (56), bilateral cancer (3), patient had died (1). In addition to the remaining 54 eligible women from this group, we added 11 eligible women whose surgeons were no longer in the Partners Hospital system. From these 65 women, 48 were randomly selected to be invited. Of these, eleven women could not be located and 6 opted out of participation in our study, either actively by returning the opt-out card (3) or passively by not returning repeated follow-up phone calls (3). We reached our accrual goal for the BC/PM group before 3 of the patients could be enrolled (2 agreed to be on our waiting list should more BC/PM patients be needed but are not yet enrolled and one opted out.). Twenty-one subjects agreed and were enrolled in the study; their interviews have been completed. The participation rate for the MGH is thus 21/28 or 75%.

Subjects for the third group in our study, women considering PM, are being invited from a list of patients seen in the Dana-Farber Cancer Risk and Prevention Clinic

in Project GRACE, a study comparing genetic counseling methods for breast/ovarian cancer risk. We have to date sent letters to 46 women identified as considering PM after having had some genetic counseling and/or testing. Seven women were found to be ineligible due to having definitely decided against PM, having undergone PM, or having had bilateral breast cancer. We were not able to locate one subject (letter returned). Of the remaining subjects, it is too early to evaluate the response from 10 subjects. Twelve subjects opted out (11) or did not respond to our calls (1). Sixteen of the remaining subjects agreed to participate and are either scheduled for a telephone interview (5) or have completed their interview (11). Thus, the participation rate in the Genetic Counseling group is 57% (16/28) to date. We are continuing to send letters to potential subjects as they are received from the Cancer Risk and Prevention Clinic. We are being given names of potential subjects from that clinic only as the women reach the one year completion mark in Project GRACE. We are expecting soon to also receive names from that Clinic of women who have undergone genetic counseling or testing outside of Project Grace, whom we can contact in hopes of increasing our participation rate and speed of enrollment.

The one area where we have had difficulty accruing sufficient subjects to meet our goals is in the 2PM or bilateral prophylactic mastectomy group. We define this group quite narrowly to include women who have not had breast cancer, DCIS, or LCIS. Some have told us that this is possibly an overly-strict categorization; others might, for example, have only eliminated women with diagnosed breast cancer. We felt that women choosing PM in the absence of any on-going breast condition might be psychologically different than women who were getting medical advice for a current breast condition which increased her risk for breast cancer. We were interested in determining factors which led women to select PM in the absence of personal breast disease (typically because of family history or intense anxiety about breast cancer) and how their experience differed from women with a medical condition affecting their breasts. In addition to the reduced number of women meeting this criterion, we have also been hampered by incomplete record-keeping at the Massachusetts General Hospital. Problems in their data system, which are only slowly being repaired, have made it impossible to get lists of potential subjects for years 1999 on. We have been able to get names from some individual surgeons, but in at least one case of a surgeon with a large breast practice, this data was also unavailable personally because of a computer crash which erased her records. Hence, we know we are missing names of women who could be subjects in this group. To deal with this problem, we added (with a protocol amendment passed by the IRB) prophylactic mastectomies during the year 2000 to our criteria for eligibility criteria. It may also be necessary to add the year 2001 as well to accrue the final 10 patients. We are also currently adding an additional hospital within the Partners system, the Breast Center at the Faulkner Hospital, Jamaica Plain, MA. Dr. Kathleen Mayzel at the Faulkner Breast Center is willing to be the PI of our protocol, which is currently under review by the Faulkner IRB. If we are able to add bilateral prophylactic (2PM) patients from the Faulkner, we will also interview an equal number of women in the Breast Cancer/Prophylactic Mastectomy group (BC/PM) from that hospital for purposes of comparison. We believe that we will be able to add at least 3 potential 2PM subjects from the Faulkner Hospital population. We anticipate that with these accommodations to

our original criteria, we should be able to reach our goal of 25 women who had PM in the absence of any breast disease (2 PM group).

Subjects who have participated have been eager to contribute their own experience to help increase our knowledge of the psychosocial and physical impact of PM and of the dilemmas involved in decision-making about PM. No one who has been scheduled has later cancelled her participation. Interviews have averaged about an hour, but some have been 1.5 to almost 2 hours in length. Many of the women have offered to participate further if we desired or to be available to others deciding about PM. Thirty-two participants refused our honorarium and chose to have us donate the money, usually to cancer research or clinical breast cancer programs.

A statistical database for this project has been constructed using STATA with consultation from Dr. Rebecca Gelman of the DFCI Biostatistical Department. This database will be used for keeping demographic and accrual statistics as well as for providing data for comparisons of characteristics between subject groups.

The demographic characteristics of the women in the 2PM and BCPM groups have shown relatively little difference between groups, except for age. The women in the Breast Cancer/PM group are significantly older (average age 54 years) versus the women in the 2PM group who have not had breast disease (average age 45 years). In general, the participants are Caucasian (reflecting our patient population generally and especially characterizing women seeking genetic counseling at our center), and well-educated. Seventy-eight percent of the women in the BCPM group have college or graduate professional education, as do 71% of women in the 2PM group.

Transcription of the study interviews has been accomplished utilizing Technitype Transcripts, a San Francisco company specializing in the transcription of research and oral history audio tapes. Technitype Transcripts has been used by the Smithsonian Institute of Archives, The U.S. Public Health Service, Johns Hopkins University, and by NASA. They have been a reliable service providing highly readable transcripts of our interviews. Transcription is currently complete for the BCPM and 2PM groups and is underway for the Genetic Counseling group. Transcribed interviews have an average length of 35 pages. Review of a sampling of the audio tapes, and written transcripts and frequent discussion between the two psychologists conducting the interviews has assured uniformity in approach to subjects.

Thematic analysis of selected tapes has occurred as part of preparation of the coding book which will enable coding by outside coders. Several potential coders have been identified. We also used this thematic analysis to prepare material for an abstract sent to the 7th International Meeting on Psychosocial Aspects of Genetic Testing for Hereditary Breast and/or Ovarian Cancer (HBOC) and Hereditary Non-Polyposis Colorectal Cancer (HNPCC). This abstract (see Appendix) was accepted for plenary presentation at this meeting. Unfortunately, the events of September 11 led to cancellation of the PI's plans to attend this meeting on Sept. 27/28 in Frankfurt,

Germany. The PI has been asked, nonetheless, to contribute a summary of our preliminary findings to the meeting report to be published in the journal, Genetic Testing.

Some of the themes represented in the tapes of women who have undergone PM include:

1.) **Independence of decision-making**: Women stress that they themselves made this decision and that making it themselves was critical to their satisfaction with the result. Partners and spouses are informed, but there appears to be relatively little pre-surgical discussion of the impact PM will likely have on their sexual interaction and general relationship or about the related emotions. Physician views are sought and are given some weight in the decision. However, not infrequently, women go against the advice of physicians in insisting on having PM and changing physicians until they find a doctor willing to perform the surgery. This emphasis on independence has implications for the counseling model to be developed (see below).

2.) **Motivation:** Past experience with maternal breast cancer and/or death from breast cancer and the desire to avoid this experience themselves were primary motivators. A desire to stay alive to participate in raising children to adulthood and later and a desire to re-gain control in the face of high genetic risk were also frequently mentioned reasons for having undergone PM. Also, fear of additional surgery, either more biopsies in women who did not have cancer or recurrence in women who did were strong motivators.

3.) **Risks and Benefits:** While all women mentioned reduction in worry about cancer following PM, the overall satisfaction with appearance and sexual self-concept varied considerably among the women. Despite support from partners, many women felt that following PM, they felt less feminine and considerably sexually attractive. Libido was reportedly lowered for many women. Post-surgical pain was also reportedly greater than expected for many women.

4.) **Normalcy:** Most (but not all) women reported that life did return to normal within 6 months to 2 years following surgery.

5.) **Utility, Nature, Timing of Psychological Consultation**: Many of the women who had undergone PM expressed the view that they would have accepted psychological consultation prior to PM if the doctor had presented it as part of the pre-surgical work-up. They also said that they felt it would be important for many women. Most, however, stated that it would not have been necessary for them, as they were quite firm in their decision. It became apparent that many women thought the role of the psychologist might have been to talk them out of PM, which would have been abhorrent to them. On the other hand, many women thought that the easy availability of psychological consultation following PM would have been useful to them. Some had sought or returned to psychotherapy following PM for related problems. Many women thought it would have been

useful to them to speak with a woman who had undergone PM prior to their own surgery.

Key Accomplishments

- Completion of surgeon permission process bringing participation to 100% for BWH and 93 % for MGH.
- Enrollment of 49 subjects with prior cancer or breast disease who had PM (BC/PM group)
- Enrollment of 15 subjects with bilateral prophylactic mastectomy (2PM group)
- Enrollment of 16 subjects who are considering PM following genetic counseling (GCgroup) and /or testing.
- Development of interview schedule and demographic form for GC group. IRB approval received for these documents.
- Transcription of completed PM, BC/PM, and GC interviews.
- Development of statistical database and entry of demographic data.
- Preliminary thematic analysis of transcribed interviews for coding book.
- Summary of findings to date in abstract for international conference on psychosocial aspects of cancer genetics.

Reportable Outcomes

An abstract based on prelminary analysis of our 64 transcribed interviews was accepted for plenary presentation at the 7th International Meeting on Psychosocial Aspects of Genetic Testing for Hereditary Breast and/or Ovarian Cancer (HBOC) and Hereditary Non-Polyposis Colorectal Cancer (HNPCC) in Frankfurt, Germany.

Conclusions

The qualitative data we have compiled in Year 2 of this project attests to the intense emotional involvement of women undergoing this procedure in prior decision-making and in their post-surgical adjustment. Subjects have been very forthcoming with sensitive material concerning their reduced self-image and especially, their sense of sexual and feminine inadequacy following surgery. This has occurred for many women despite satisfaction with the risk-reduction aspects of prophylactic mastectomy and the availability of spousal or other social support. We are also finding that many women undergoing PM were unprepared for the levels of pain they experienced.

Many women feel sure that psychological services would have been very useful to them in the post-surgical period. There is less clarity about whether women would have made use of pre-surgical psychological consultation. Many say they would have attended a psychological session which was integrated into the pre-surgical work-up, but might have been fearful that the psychologist would try to dissuade them from their decision about PM. The implications are clear that the presentation of a psychologist consultant to

aid in decision-making about PM will have to include a clear statement that the psychologist is offered to help women consider issues of relevance to themselves in making a decision either for or against PM. Having the role of the psychologist include introduction to a woman who had previously undergone PM might help to de-stigmatize the visit to the psychologist. Pre-surgical acquaintance with a psychologist might have reduced barriers to post-surgical consultation, which, in turn, might reduce distress associated with PM. Our continuing interviews with women considering PM will inform us about their attitudes towards psychological consultation around PM and about the timing and nature of desired services.

"So What?" Section

The number of women making decisions about prophylactic mastectomy is increasing rapidly as more women undergo genetic testing and are identified as being at increased genetic risk for breast cancer. Researchers and physicians recognize that emotional factors play a major role in decision-making about PM. Understanding what women experience as sequelae of PM and what women considering PM want to know will, we believe, improve the utility of a psychological consultation offered to women prior to surgery. Understanding the barriers to the utilization of such a consultation can lead to a design which removes or minimizes these barriers. With the high level of surgeon participation and eager involvement of women in our study who have had PM (historically a small group), we believe that the 64 extensive, transcribed interviews conducted in Year 2 on a representative sample of women who have undergone PM at two major Boston centers from 1990-2000 form an invaluable resource. Interview data is particularly valuable in circumstances such as PM where participants report both positive and negative outcomes. Women who have had PM say they that while making their decision about PM, they would have highly valued knowing the views of other women who had undergone the procedure. The report we will develop over the next year based on these interviews about the thematic content and its relation to demographic characteristics of the women will be of help to women considering PM in the future as well as to mental health consultants offering services to this group. In addition, the data we are acquiring now from the on-going interviews with women considering PM will help us further in understanding the ideal nature, content, and timing of a psychological intervention to aid women in this decision. The development and testing of this model will be the focus of the work in Year 3 of this project.

Paid Participants in study DAMD17-99-1-9162:

Andrea Farkas Patenaude Ph.D., Principal Investigator

Sara Orozco Ph.D., Research Associate

Appendix:

1. Abstract accepted for the 7th International Meeting on Psychosocial Aspects of Genetic Testing for Hereditary Breast and/or Ovarian Cancer (HBOC) and Hereditary Non-Polyposis Colorectal Cancer (HNPCC) in Frankfurt, Germany.

2. Brochure for this meeting

3. Demographic form for the GC group, women considering prophylactic mastectomy (PM)

4. Interview schedule for the GC group, women considering prophylactic mastectomy (PM)

PROPHYLACTIC MASTECTOMY: WOMEN'S NARRATIVE REPORTS OF COSTS, BENEFITS, AND SUGGESTIONS FOR COUNSELING

Andrea Farkas Patenaude Ph.D. and Sara Orozco, Ph.D., Dana-Farber Cancer Institute, 44 Binney Street, Boston, MA 02115 USA

Prophylactic mastectomy (PM) is one risk-reducing option suggested for women at increased hereditary risk for breast cancer. Both high-risk women who have never had cancer and those who have cancer in one breast or precancerous conditions (DCIS, LCIS) consider PM. Decision-making often occurs under conditions of stress and fear, with little available data on medical or psychosocial outcomes to guide patients or health professionals. The utility of psychological consultation in this setting is unknown.

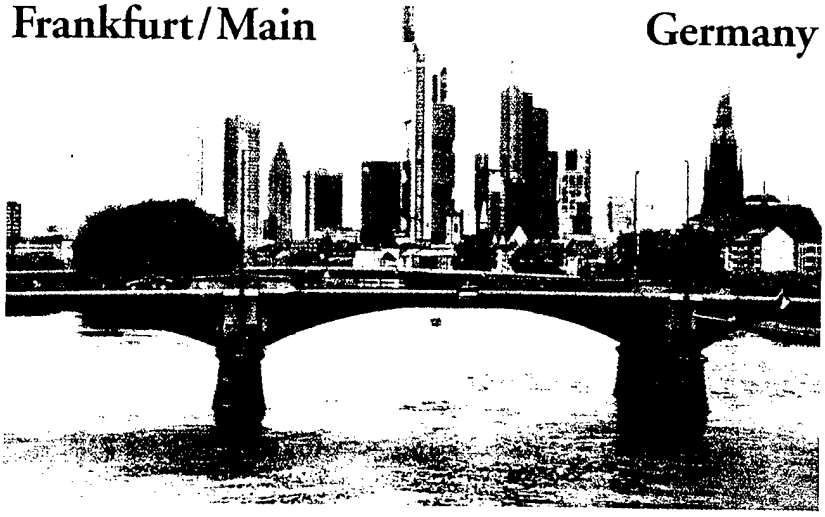
In our qualitative study, 60 women, (45 with cancer; 15 without) who underwent PM from 1990-2000 were interviewed by a psychologist via telephone about their decision-making, medical and psychosocial outcomes, family interaction, and thoughts about the value of psychological counseling for women pre- or post-PM. The women were largely Caucasian and highly educated Average age was 54 years with cancer, 46 without cancer. Narratives attest to both benefits and costs of PM. The decision for PM was made independently, not infrequently against medical advice. Motivation for PM included staying alive, finishing child-rearing responsibilities, avoiding repeated surgery, desire for symmetry, and re-gaining control. Reduction in cancer worry was universal; regrets were few. However, negative physical and emotional sequelae were reported, including loss of feeling sexually attractive (even with supportive partners), reduced sexual activity, embarrassment, and envy of women with breasts. A time frame of 6 months to 2 years was needed for return to "normalcy".

Women denied a personal need for pre-surgical counseling, fearing a therapist might have tried to dissuade them from surgery. Many wished they could have spoken to a women who had had PM pre-surgery. Therapeutic consultation was thought to be more acceptable following surgery to help with emotional, physical, and marital readjustment.

International Meeting on Psychosocial Aspects of Genetic Testing for Hereditary Breast and/or Ovarian Cancer (HBOC) and Hereditary Non-Polyposis Colorectal Cancer (HNPCC)

27th and 28th September 2001

Frankfurt/Main Germany



Johann Wolfgang Goethe-University Hospital

Department of Psychosomatic Medicine and Psychotherapy
Department of Gynaecology and Obstetrics
Department of Human Genetics
Department of Gastroenterology

Thursday

Chair: Maggie Watson and Manfred Kaufmann

9.00	Opening (Jochen Jordan)
9.30	Ethical and social implications of predictive genetic testing. Prof. Dr. J. Schmidtke, Ethical Advisory Council of the German Ministry of Health, Hannover
10.00	What affects the breast cancer risk in BRCA1/2 mutation carriers and who chooses to have predictive tests? Gareth R Evans, Manchester
10.30	State of the art: HBOC. Advices for prophylactic treatments and behaviour for women concerned. Manfred Kaufmann, Department of Gynaecology and Obstetrics, Frankfurt, Vice-Dean of the University Hospital
11.30	HNPCC: Disease mechanism and genetic testing. Sabine Tejpar, Leuven
12.00	State of the art: Diagnosis and surveillance of patients with HNPCC. Stefan Zeuzem & Jochen Rädle, Department of Gastroenterology, Frankfurt
12.30	State of the art: HBOC and HNPCC: Genetic counselling and testing. Ulrich Langenbeck, Department of Human Genetics, Frankfurt

Chair: Gerry Evers-Kiebooms and Gabriele Möslein

17.00	The German Psychooncologists present their Multicenter Study. Birgit Albacht and the German Consortium
17.30	Prophylactic mastectomy: Women's narrative reports of costs, benefits, and suggestions for counselling. Andrea Farkas Patenaude and Sara Orozco, Boston

Friday

Chair: Katl

9.00	Predictive g genetic tech Maggie Wa L. Brooks, I the Steering National St gene testing
9.30	Counselling it work? Almut Helr
10.00	Psychologic hereditary b related beh of the predi E. Claes, G Denayer, A
10.30	Informed c BRCA1/2 t Irmgard Ni

14.30–16.30

Chair: Cla

Report fro

Award of t committee

Round tab
Genetics:
Maggie Wa
Penelope H
Decruyena

ID CODE:_____

PROPHYLACTIC MASTECTOMY STUDY
DEMOGRAPHIC FORM FOR WOMEN WHO CONSIDER SURGERY

We would appreciate it if you would please answer all of the following questions as they apply to you. If none of the answers provided seems exactly right, please choose the answer that comes nearest to being right for you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential and will not be linked to you by name. If you do not want to answer a particular question, please write "Chose Not To Answer" (so we know it is not an omission) and go on to the next question.

PERSONAL INFORMATION

1.

Today's Date:_____

YOUR STREET ADDRESS:

CITY: STATE: ZIP:

2. HOME PHONE NUMBER:

AREA CODE: TELEPHONE NUMBER:

Okay to call you at this number (Please circle one)? Yes No

3. WORK PHONE NUMBER:

AREA CODE: TELEPHONE NUMBER:

Okay to call you at this number (Please circle one)? Yes No

4. THE BEST TIME AND PLACE TO REACH ME IS AT (PLEASE CHECK OFF YOUR PREFERENCE):

_____HOME PHONE TIME (S):_____

_____WORK PHONE TIME (S):_____

5. WHAT IS YOUR AGE TODAY (i.e., 44, 56, etc)?
6. WHAT IS YOUR BIRTHDATE (i.e, 3/11/58)?

7. PLEASE CHECK YOUR MARITAL STATUS:	
	SINGLE
	MARRIED
	LIVING WITH OTHER
	SEPARATED/DIVORCED
	WIDOWED
	OTHER (PLEASE SPECIFY)

8. DO YOU HAVE CHILDREN? (PLEASE CIRCLE ONE)	YES	NO
If YES, please tell:	SONS:	DAUGHTERS:
	HOW MANY SONS?	HOW MANY DAUGHTERS?
	SONS' AGES TODAY?	DAUGHTERS' AGES TODAY?

PLEASE CHECK BOX WHICH APPLIES:		
HIGHEST EDUCATIONAL GRADE ACHIEVED	9. YOU COMPLETED	10. IF LIVING IN SAME HOUSEHOLD: YOUR SPOUSE/PARTNER COMPLETED
LESS THAN SEVENTH GRADE		
JUNIOR HIGH SCHOOL (9TH GRADE)		
PARTIAL HIGH SCHOOL (10 OR 11TH GRADE)		
HIGH SCHOOL GRADUATE		
PARTIAL COLLEGE (AT LEAST ONE YEAR) OR SPECIALIZED TRAINING		
STANDARD COLLEGE OR UNIVERSITY GRADUATION		
GRADUATE PROFESSIONAL TRAINING (GRADUATE DEGREE)		

11. PLEASE PLACE A CHECK IN THE BOX NEXT TO YOUR TOTAL FAMILY INCOME			
Less than $15,000		$50,000-$74,999	
$15,000- $29,999		$75,000-$99,999	
$30,000-49,999		$100,000 or above	

OCCUPATION	
12. WHAT IS YOUR USUAL (OR LAST) OCCUPATION?	
13. IF LIVING IN SAME HOUSEHOLD, SPOUSE/PARTNER'S OCCUPATION?	

14. PLEASE PLACE A CHECK NEXT TO WHAT BEST DESCRIBES <u>YOUR</u> CURRENT WORK STATUS:			
EMPLOYED: FULL-TIME		HOMEMAKER	
PART-TIME		DISABLED	
NOT EMPLOYED		LAID OFF	
ON SICK LEAVE		UNEMPLOYED, BUT LOOKING FOR WORK	
RETIRED		OTHER:	

15. WHAT RACE/ETHNICITY DO YOU CONSIDER YOURSELF TO BE?			
AFRICAN-AMERICAN		CAUCASIAN	
ASIAN/PACIFIC		HISPANIC	
NATIVE-AMERICAN		OTHER:	

16. DO YOU HAVE A RELIGIOUS PREFERENCE?			
CATHOLIC		PROTESTANT	
JEWISH		NONE	
ISLAMIC		OTHER:	

SURGICAL HISTORY

<u>RIGHT BREAST</u>		
	NO (SKIP TO QUESTION 18)	YES (PLEASE COMPLETE QUESTIONS BELOW)
17. HAVE YOU EVER HAD SURGERY ON YOUR <u>RIGHT BREAST</u> (PLEASE CHECK ONE):		

IF YES: ON YOUR RIGHT BREAST DID YOU HAVE:		
A BIOPSY OR BIOPSIES?	NO	YES TOTAL# OF BIOPSIES ON RIGHT BREAST:_____ MOST RECENT BIOPSY (Mo/Year):_____
LUMPECTOMY?	NO	YES MONTH/YEAR DONE:_____
MASTECTOMY?	NO	YES MONTH/YEAR DONE:_____
RECONSTRUCTIVE SURGERY?	NO	YES MONTH/YEAR DONE:_____
OTHER_____ MONTH/YEAR DONE:_____		

LEFT BREAST

	NO (SKIP TO QUESTION 19)	YES (PLEASE COMPLETE QUESTIONS BELOW)
18. HAVE YOU EVER HAD SURGERY ON YOUR <u>LEFT BREAST</u> (PLEASE CHECK ONE):		

IF YES: ON YOUR LEFT BREAST DID YOU HAVE:		
A BIOPSY OR BIOPSIES?	NO	YES TOTAL# OF BIOPSIES ON LEFT BREAST:_____ MOST RECENT BIOPSY (Mo/Year):_____
LUMPECTOMY?	NO	YES MONTH/YEAR DONE:_____
MASTECTOMY?	NO	YES MONTH/YEAR DONE:_____
RECONSTRUCTIVE SURGERY?	NO	YES MONTH/YEAR DONE:_____
OTHER_____ MONTH/YEAR DONE:_____		

19. HAVE YOU HAD YOUR OVARIES REMOVED? (PLEASE CIRCLE ONE)	YES	NO

IF **YES**,

MONTH:_____ YEAR:_____

REASONS OVARIES REMOVED:
(PLEASE CHECK ONE)

	BECAUSE OF CANCER		PROPHYLACTICALLY (PREVENTATIVELY)
	OTHER (PLEASE EXPLAIN):		

MEDICAL HISTORY

20. HAVE YOU EVER BEEN DIAGNOSED WITH DUCTAL CARCINOMA IN SITU (DCIS) OR LOBULAR CARCINOMA IN SITU (LCIS)? PLEASE CIRCLE YES OR NO **IF YES, PLEASE CIRCLE EITHER DCIS OR LCIS IN THE "YES" COLUMN IF NO, PLEASE SKIP TO THE NEXT QUESTION	YES** DCIS OR LCIS	NO
DCIS/LCIS WAS IN (PLEASE CIRCLE ONE):	RIGHT BREAST?	LEFT BREAST?

IF YES: DATE(S) OF DIAGNOSIS?

MONTH:_____ YEAR:_____

MONTH:_____ YEAR:_____

HOW OLD WERE YOU? _____

21. HAVE YOU EVER BEEN DIAGNOSED WITH BREAST CANCER (PLEASE CIRCLE ONE)? (IF NO, PLEASE SKIP TO THE NEXT QUESTION)	YES	NO
CANCER WAS IN (PLEASE CIRCLE ONE):	RIGHT BREAST	LEFT BREAST
IF YES: DATE(S) OF DIAGNOSIS? MONTH:_____ YEAR:_____ MONTH:_____ YEAR:_____		
HOW OLD WERE YOU? _____		

22. HAVE YOU EVER BEEN DIAGNOSED WITH OVARIAN CANCER (PLEASE CIRCLE ONE)? (IF NO, PLEASE SKIP TO THE NEXT QUESTION)	YES	NO
IF YES: DATE(S) OF DIAGNOSIS? MONTH:_____ YEAR:_____ MONTH:_____ YEAR:_____		
HOW OLD WERE YOU? _____		

23. HAVE YOU EVER HAD ANY OTHER CANCER DIAGNOSIS (PLEASE CIRCLE ONE)? (IF NO, PLEASE SKIP TO THE NEXT QUESTION)	YES	NO
IF YES: THE TYPE OF CANCER: _____ DATE(S) OF DIAGNOSIS: MONTH:_____ YEAR:_____ MONTH:_____ YEAR:_____		
HOW OLD WERE YOU? _____		

24. PLEASE CIRCLE YOUR CURRENT CANCER STATUS?	
NEVER HAD CANCER	HAD CANCER NOT CURRENTLY IN TREATMENT
HAD CANCER CURRENTLY IN TREATMENT	OTHER:

25. IN GENERAL, WOULD YOU SAY YOUR HEALTH IS (PLEASE CIRCLE ONE):				
EXCELLENT	VERY GOOD	GOOD	FAIR	POOR

FAMILY HISTORY

These questions ask about the health of your family members, both living and deceased. Please give information about blood relatives only.

26. PLEASE INDICATE WHICH OF THE FOLLOWING RELATIVES HAVE HAD CANCER?

Breast Cancer (BEFORE age 50)	**Breast Cancer (AFTER age 50)**	Endometrial Cancer (Body of Uterus/Womb	Cervix Cancer	Ovary Cancer	Lung Cancer	Leukemia		Hodgkin's Disease or Lymphoma	Colon/Rectum Cancer	Prostate Cancer	Thyroid Cancer	Malignant Melanoma	Other Skin Cancer	None
O	O	O	O	O	O	O	Mother	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Father	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Mother's mother	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Mother's Father	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Father's Mother	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Father's Father	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Sister 1	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Sister 2	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Sister 3	O	O	O	O	O	O	O
O	O	O	O	O	O	O	All other sisters	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Brother 1	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Brother 2	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Brother 3	O	O	O	O	O	O	O
O	O	O	O	O	O	O	All other brothers	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Daughter 1	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Daughter 2	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Daughter 3	O	O	O	O	O	O	O
O	O	O	O	O	O	O	All other daughters	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Son 1	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Son 2	O	O	O	O	O	O	O
O	O	O	O	O	O	O	Son 3	O	O	O	O	O	O	O
O	O	O	O	O	O	O	All other sons	O	O	O	O	O	O	O
O	O	O	O	O	O	O	All Mother's sisters	O	O	O	O	O	O	O
O	O	O	O	O	O	O	All Mother's brothers	O	O	O	O	O	O	O
O	O	O	O	O	O	O	All Father's sisters	O	O	O	O	O	O	O
O	O	O	O	O	O	O	All Father's Brothers	O	O	O	O	O	O	O
O	O	O	O	O	O	O	All Maternal Cousins	O	O	O	O	O	O	O
O	O	O	O	O	O	O	All Paternal Cousins	O	O	O	O	O	O	O

27. HAVE ANY OF YOUR RELATIVES WITH CANCER DIED OF THEIR CANCER? (PLEASE CHECK YES OR NO)

	NO - PLEASE SKIP TO NEXT QUESTION
	YES - PLEASE COMPLETE TABLE BELOW

RELATIONSHIP TO YOU (I.E., MOTHER, AUNT, FATHER)	RELATIVE'S AGE AT DEATH	YOUR AGE WHEN THIS RELATIVE DIED

IF YOU NEED MORE SPACE, PLEASE USE THE BACK OF THIS SHEET.

28. DO YOU CONSIDER YOURSELF TO BE AT (PLEASE CHECK ONE):

	LOWER THAN AVERAGE RISK OF DEVELOPING BREAST CANCER
	AVERAGE RISK OF DEVELOPING BREAST CANCER
	HIGHER THAN AVERAGE RISK OF DEVELOPING BREAST CANCER

29. DO YOU CONSIDER YOURSELF TO BE AT (PLEASE CHECK ONE):

	LOWER THAN AVERAGE RISK OF DEVELOPING OVARIAN CANCER
	AVERAGE RISK OF DEVELOPING OVARIAN CANCER
	HIGHER THAN AVERAGE RISK OF DEVELOPING OVARIAN CANCER

30. PLEASE CHOOSE THE STATEMENT THAT BEST DESCRIBES YOUR FEELINGS ABOUT PROPHYLACTIC MASTECTOMY:	
	I WILL NOT HAVE A PROPHYLACTIC MASTECTOMY
	I AM NOT CONSIDERING PROPHYLACTIC MASTECTOMY NOW, BUT MAY IN THE FUTURE
	I AM CURRENTLY CONSIDERING HAVING A PROPHYLACTIC MASTECTOMY
	I HAVE DECIDED TO HAVE A PROPHYLACTIC MASTECTOMY
	NOT APPLICABLE-BOTH BREASTS HAVE BEEN REMOVED

31. HAVE YOU EVER HAD GENETIC COUNSELING FOR BREAST/OVARIAN CANCER? (PLEASE CHECK ONE)							
NO		YES*		PREFER NOT TO SAY		DON'T KNOW	
*IF YES, WHEN DID YOU HAVE GENETIC COUNSELING?(MONTH/YEAR):_____							

32. HAVE YOU EVER HAD GENETIC TESTING FOR BRCA1 OR BRCA2? (PLEASE CHECK ONE)							
NO		YES*		PREFER NOT TO SAY		DON'T KNOW	
*IF YES, WHEN DID YOU HAVE GENETIC TESTING?(MONTH/YEAR):_____							
*IF YES, DO YOU KNOW THE RESULTS OF YOUR TESTING? (PLEASE CHOOSE ONE)						YES	NO
*IF YES, DO YOU HAVE A BRCA1 OR BRCA2 MUTATION IN YOUR BLOOD? (PLEASE CIRCLE ONE)							
NO		YES		PREFER NOT TO SAY			

33. DO ANY BLOOD RELATIVES IN YOUR FAMILY HAVE A KNOWN MUTATION IN THEIR BRCA1/2 GENES? (PLEASE CHECK ONE)			
	NO		PREFER NOT TO SAY
	YES - (PLEASE COMPLETE THE TABLE BELOW)		DON'T KNOW

IF YES,

PLEASE INDICATE WHICH BLOOD RELATIVES IN YOUR FAMILY HAVE A KNOWN MUTATION IN THEIR BRCA1/2 GENES BY CHECKING ONE OR MORE BOXES BELOW.

SIDE OF THE FAMILY (PLEASE CHECK ONE)		RELATIONSHIP (SISTER, ETC)
MOTHER	FATHER	
		MOTHER, SISTER, DAUGHTER, FATHER, BROTHER, SON
		MOTHER, SISTER, DAUGHTER, FATHER, BROTHER, SON
		AUNT, UNCLE, GRANDMOTHER, GRANDFATHER
		AUNT, UNCLE, GRANDMOTHER, GRANDFATHER
		COUSIN, NIECE, NEPHEW
		COUSIN, NIECE, NEPHEW

INSURANCE HISTORY

	YES	NO
34. DO YOU HAVE HEALTH INSURANCE?		
35. DO YOU HAVE DISABILITY INSURANCE?		

36. DO YOU HAVE LIFE INSURANCE?		
37. *ANSWER ONLY IF YOU HAVE A FAMILY HISTORY OF CANCER HAVE YOU EVER HAD TROUBLE GETTING INSURANCE BECAUSE OF A FAMILY HISTORY OF CANCER?	YES	NO

THIS IS THE END OF THE QUESTIONNAIRE. PLEASE PUT COMPLETED QUESTIONNAIRE IN THE ENCLOSED SELF-ADDRESSED STAMPED ENVELOPE AND MAIL TO THE ADDRESS BELOW AT YOUR EARLIEST CONVENIENCE.

Mail to:
Andrea Patenaude, Ph.D., Dana 363
Dana-Farber Cancer Institute
44 Binney St.
Boston, MA 02115

We will be in touch with you within the next 2 weeks by telephone to schedule an interview time. If you have any questions, please call us:

Dr. Sara Orozco (617) 632-2504

Dr. Andrea Patenaude (617) 632-3314

THANK YOU VERY MUCH.

INTERVIEW OUTLINE
FOR WOMEN WHO HAVE NOT RULED OUT
A PROPHYLACTIC MASTECTOMY.

ID Code #_____ Time Started:_____
Interviewer:_____ Time Finished:_____
Date:_____ Total Time:_____

DECISION-MAKING **Global Question 1: Could you please describe for me what led to your thinking about PM as something to consider for yourself? When did you first learn about PM? What did you think about it then and what do you now feel about whether it would ever be a possible option for you?**

Probe (if not answered)

1a. Are you still considering PM? [Given telephone pre-screening, answer should be yes, if no, discontinue interview]

1b. How seriously?

1c. What is the time frame you use in thinking about it?

1d. What do you hope would be better about your life by undergoing this procedure? What would be your personal aims or goals?

1e. Who have you talked to? Who else might you talk to and how do you think you would you come to a decision about PM?

1f. Who, if anybody, do you think would have the most influence on your decision about PM? How might they influence you?

1g. Have your doctors made any recommendations about PM or not? How do you feel about the communication you have had with your doctors about PM?

1h. Has anyone in your family or anyone you know had a PM?

1i. Have you ever talked to anyone who had had a PM? If so, how did you find that person? Was talking to them useful? Confusing at all?

CANCER WORRY/SCREENING. Global Question #2. How much do you worry about getting cancer/(or getting cancer again)?

2a. Are you the kind of person who has mammograms and other screening tests right on time, or do you put them off a little, or tend to avoid them?

2b. Are there some aspects of your own experience with cancer in your family which you would like to avoid re-experiencing? Do those experiences play much of a role in your thinking about PM?

2c. In thinking about whether or not a PM would be right for you, what do you most want to know?

2d. Have you gotten answers to those questions? Where did you get the answers?

If not, have you tried to get answers? If no, why not? If you did try to get answers, but were unable to get the information you wanted, why was that?

2e. Was any part of the information you got confusing?

2f. Do you have the information you want or are there still some unanswered questions?
If some lingering questions, what are they?

RESIDUAL RISK Global Question #3: What do you understand about the risk of getting breast cancer after having a PM?

Either:

A. ___Acknowledges a residual risk:

How important is information about residual risk to your thoughts about whether or not to have a PM?

If you were to decide to have a PM, how do you well do you think you would cope with knowing that there was still a risk of getting breast cancer?

or

B. ___Doesn't know or thinks no residual risk:
How important is information about residual risk to your thoughts about whether or not to have a PM?

3a. Do you think you are good at making medical decisions? Would you like to change anything about the way you have been approaching this decision?

SURGICAL EXPERIENCE **Global Question 4: What would you want to know about the surgery itself?**

4a. Any thoughts about the possible timing of the surgery? If you were to have PM, is there a particular time you would think about scheduling it?

4b. Do you imagine you would have any hesitation about scheduling or keeping the appointment for surgery?

About the recovery period

4c. Do you have any idea what recovery from PM surgery is like? What would you most want to know about?

Pain:

4d. Do you worry about pain management after surgery?

Mobility:

4e. Do you have any concern about the mobility of your arms in the weeks and months following surgery?

Sports:

4f. Do you have any concern about how PM might affect your ability to play sports?

4g. Do you think you might feel uncomfortable in dressing room or locker room situations after having a PM because of your breasts?

Reconstruction

4h. Have you thought about whether you would have reconstruction if you were to have PM? What would go into your decision about having/not having reconstruction?

4i. What do/would you most want to know about reconstruction?

Have you gotten any information about reconstruction?

4j. (If not already answered): Have you spoken to a plastic surgeon? Have you seen any photos of reconstructed breasts?

General

4k. Do you worry about whether life would come back to a place that you would call normal after PM? If so, how long would you think that would take?

4l. Do you have any worries about the cost of surgery? Would you consider surgery if it were not covered by insurance?

SURGICAL SEQUELAE/RECOVERY Global Question #5: Present feelings about your body? What do you think it would be like you after surgery?

5a. How do you currently feel about your body?

5b. What have you thought about how you might feel about your body after surgery?

5c. Do you have any concern about whether having a PM would affect your sense of your own sexual attractiveness? Your interest in or enjoyment of sex?

FAMILY INVOLVEMENT- Global Question #6 Spouse/Partner (For subjects with a spouse or partner): To what extent, if at all, have you shared with your partner your thinking about PM? How did your partner react to your bringing up PM? What do you think he/she feels? (If no spouse/partner, skip to Q. 6e.)

6a. Have you been concerned that there might be a change in your sexual relationship if you had prophylactic mastectomy?

6b. How concerned do you think your spouse/partner might be about a change in your sexual relationship as a result of your having PM?

6c. Did you think having a PM would change your overall relationship, for better or worse?

6d. If haven't talked to spouse/partner, why not?

Global Question 6e. for women without current spouse/partner: Do you have any concerns related to future partners and their possible reactions?

CHILDREN and OTHER FAMILY MEMBERS: Global Question #7 (For subjects with children)(If no children, skip to Q. 8a):
Children:

How important is having children to your consideration of having a PM?

7a. Have you talked to your children at all about the possibility of having a PM?

If Yes, What did you tell your children?

7b. How did they react?

7c. How did you feel about their reaction?

If No, why not?

7d. What do you think you would tell them about it if you were planning to have a PM?

7e. How do you think they would react?

Other Family:

8a. Have any other family members expressed views to you about PM? If yes, what did they say?

8b. If you were going to have the surgery, whom do you think you would tell about it?

8c. Are there any people close to you whom you wouldn't tell about your impending surgery?

MENTAL HEALTH INVOLVMENT Global Question #9 How useful do you think it would be to have a psychological consultation built into the pre-surgical consultation for PM?

Probes:

9a. Have you ever spoken with a therapist or counselor about PM? If so, was that helpful? In what way? How much did they know about PM when you brought it up? Did you feel you had to educate them about what it is?

9b. (If didn't talk to a therapist) Did you consider talking to someone and if so, what prevented you from doing so?

9c. Would you have any concern about whether or not a therapist or counselor would try to talk you into or out of having a PM?

9d. Have you found mental health services useful at other times in your life?

9e. How do you think you would react if the surgeon you saw for a pre-surgical consultation told you that speaking with a psychologist or other counselor was a standard part of the pre-surgical work-up?

9f. Do you think it would be helpful if:
a.) the pre-surgical session included role-playing or rehearsal of your feelings following surgery,
b.) relaxation training or
c.) a couples session with you and your partner?

9e. If you were to have PM, do you think it would be helpful to be able to talk with a therapist after the surgery?

9g. Would cost be a barrier to seeing a counselor about PM?

9h. Any suggestions about the ideal nature or timing or frequency of counselor involvement for people considering PM?

SATISFACTION Global Question #10 Overall, how satisfied are you with the information you have about prophylactic mastectomy? The information you have about reconstruction ? The emotional support you have from family, friends, professionals about PM?

10a. How do you think your life will be different for you if you do chose to have a prophylactic surgery versus how it would be if you decide not to have PM?

10b. Any suggestions for women considering PM?

Time ended:_____

Thank you very much for taking time to tell us about your views and thoughts. As you know, we would like to offer you a small token of our thanks by sending you a check for $25. In order to do so, may I please have your social security number? It will take a few weeks for the check to be processed.

SOCIAL SECURITY NUMBER:_____

Interviewer Comments/Themes