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13. ABSTRACT (Maximum 200 Words)

Purpose: The intention of this study is to close the gaps in our knowledge regarding the decision-making experiences, challenges, and frustrations of women when breast cancer recurs. Therefore, the specific aims of this project are to: (1) provide a robust description of decision making processes of women faced with recurrent disease, (2) to describe preferences and values instrumental in the selection of treatment options (e.g., clinical trials, alternative therapies, adjuvant therapies, or no treatment), (3) to describe the manner in which previous treatment decision making experiences are, or are not influential, and lastly, (4) to describe the appraisals of decision processes and outcomes to identify those factors that contribute to, or impede, quality decision making. Scope: Approximately 50 women recently diagnosed with recurrent disease will be recruited to participate in a semi-structured qualitative interview to describe her decision making experiences including her values and preferences regarding treatment. Major Findings : A Post-Award Change Approval was granted to modify the performance period to 10 Sep 2003 to 9 Sep 2004 due to extenuating circumstances surrounding the events of September 11, 2001 (PI is Commander of an Aeromedical Evacuation Squadron heavily involved in OEF and OIF activities) and the process of obtaining approval of 3 IRBs.

14. SUBJECT TERMS recurrent breast cancer, decision making, psychological stress, decision outcomes	**15. NUMBER OF PAGES** 18
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Award Number: DAMD17-01-1-0565

TITLE: Defining Decision Support for Women with Recurrent Breast Cancer

PRINCIPAL INVESTIGATOR: Penny F. Pierce, Ph.D.

CONTRACTING ORGANIZATION: University of Michigan
Ann Arbor, MI 48109-1274

REPORT DATE: October 2003

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Fort Detrick, Maryland 21702-5012

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INTRODUCTION

The intention of this study is to close the gaps in our knowledge regarding the decision-making experiences, challenges, and frustrations of women when breast cancer recurs. Therefore, the specific aims of this project are to: (1) provide a robust description of decision making processes of women faced with recurrent disease to generate hypotheses for future testing, and ultimately, for the design of prescriptive decision support interventions, (2) to describe preferences and values instrumental in the selection of treatment options (e.g., clinical trials, alternative therapies, adjuvant therapies, or no treatment), (3) to describe the manner in which previous treatment decision making experiences are, or are not influential, and lastly, (4) to describe the appraisals of decision processes and outcomes to identify those factors that contribute to, or impede, quality decision making. The proposed qualitative methodology uses a theoretical sampling of approximately 50 women newly diagnosed with recurrent disease to participate in a semi-structured interview designed to capture this complex and threatening real-world decision making experience. The ultimate objective of this preliminary descriptive work is to support the design of decision support interventions to enhance quality decision making in this vulnerable population.

BODY

This project has been granted a no-cost time extension setting a new start date of September 2003, due to the circumstances outlined in the request granted recently. The new completion date is 9 September 04. Therefore, the project has just begun data collection so there are no data-based findings yet to report. As the Statement of Work prescribes, the tasks to be accomplished to initiate the project have been accomplished on schedule. Specifically, the proposal has been approved by the IRB at the Medical School at the University of Michigan and the protocol has been approved by the Protocol Review Committee of the Comprehensive Cancer Center. Coordinating the IRB requirements among the DoD, IRBMED, and the Cancer Center Protocol Review Committee contributed to the delay in beginning data collection. Data collection efforts between the Ann Arbor site and a community-based setting at St. Joseph's Mercy Hospital in Pontiac, Michigan, are staggered to allow for preparation of the second site and for the interviewers to gain experience. The additional site at St. Joseph's Mercy Hospital in Pontiac, Michigan, is included to provide a community-based sample and also to increase the attainment of an adequate sample size within the time constraints of this project. It is anticipated that we will be able to reach the goal of approximately 50 women with recurrent disease on or before August 2004.

Recruitment and hiring of a qualified team has been completed. The staff includes two experienced research assistants (RA) to recruit and interview subjects, to assist with data analysis, and to participate in dissemination of the findings through publications and presentations. An extensive interviewer training program was developed for this project and both RAs have undergone this training in preparation for approaching potentially distressed women to recruit them into the project. In addition, the training protocol provides guidance and feedback on conducting a non-threatening interview and introduces measures to insure quality data are obtained through use of the semi-structured interview instrument. Interviewers are instructed in ways to use probes, reflection, and other techniques to help subjects thoroughly cover the pertinent topics. Such training enhances the quality of interview data and minimizes the risk of psychological distress when asking questions regarding a potentially life threatening illness.

A Statement of Work that was submitted with the last annual report has been revised deleting the tasks of obtaining IRB reviews and developing data collection sites since those have been completed. The revised Statement of Work articulates the proposed tasks to be accomplished during the remainder of the project.

STATEMENT OF WORK (Revised)

	2003				2004								
	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUNE	JULY	AUG	SEP
TASK													
Build Research Team													
• *Recruit Research Interviewers*	■												
• *Provide Interviewer Training*													
Develop Recruitment Protocol													
• *Create Recruiting Brochure*	■												
• *Create Physician Information Sheet*	■												
Develop Interview Protocol	■												
Develop Protocol	■												
• *Train Interviewers on Protocol*													
• *Revise Protocol as Needed*		■											
Data Collection													
• *Interviews from Ann Arbor site*			■	■	■	■	■	■	■	■	■		
• *Interviews from St. Joseph's Mercy*				■	■	■	■	■	■	■	■	■	
• *Transcribe Interviews for Analysis*				■	■	■	■	■	■	■	■	■	
Qualitative Data Analysis													
• *Train on Coding & Analysis*													
• *Develop Coding Scheme*					■								
• *Data Analysis of Transcripts*					■	■	■	■	■	■	■	■	
Publications													
• *Theoretical Paper- Decision Making*											■		
• *Data-based Paper- Decision Making*												■	
• *Clinically-relevant Paper*												■	
Submit Final Report												■	

KEY RESEARCH ACCOMPLISHMENTS

- Recruited research interviewers
- Provided interviewer training using a standardized protocol including feedback
- Trained interviewers on protocol
- Revised the interview based on testing feedback
- Developed recruitment site at the University of Michigan Comprehensive Cancer Center
- Purchased supplies and printed all documents (consent form, recruitment brochure, etc.)
- Obtained IRB approval from IRBMED (University of Michigan) and review of the Comprehensive Cancer Center Protocol Review Committee
- Interviewers and PI have begun to attend clinic to recruit subjects
- PI has started work on the theoretical paper concerning decision making issues of women with recurrent disease

REPORTABLE OUTCOMES

None at this time.

CONCLUSIONS

None at this time.

APPENDICES (Appendix D has been added to show the relationship between the objectives and the interview questions)

APPENDIX A **Recruitment Brochure**

APPENDIX B **Survey Instrument**

APPENDIX C **Interview Schedule**

APPENDIX D **Table 1. Relationship Between the Protocol Objectives and Interview Questions**

APPENDIX A

Recruitment Brochure

Breast Care Choices...

Are sometimes difficult, frightening, overwhelming, and challenging to patients and their families.

Health care professionals do not always know the needs of women facing decisions for recurrent breast cancer treatment and care.

Expressing your needs, preferences, and values is an important part of making quality decisions.

Answers to these important questions only come from sharing decision experiences in a way that helps improve care and support.

Deciding how one lives is an important determinant of one's quality of life.

Decision Making Research Program

Penny Pierce PhD, RN
Principal Investigator

Minnie Bluhm, MPH
Project Coordinator

University of Michigan
School of Nursing
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* * *

This project is supported by a grant from the U.S. Army Breast Cancer Research Program (BC996510;DAMD17-01-1-0565)

Defining Decision Support for Women with Recurrent Breast Cancer

The University of Michigan
School of Nursing

A Program of Research Dedicated to Understanding the Breast Cancer Decision Making Experiences of Women and Their Families

Cancer Care Choices

When you have cancer, you and your loved ones are faced with many decisions about issues that are probably new and unfamiliar to you. Sometimes people find these decisions to be troublesome because they are not feeling well, they are distressed about the diagnosis, or they simply don't know how to go about making such choices.

The University of Michigan
School of Nursing

is currently conducting a project that is intended to better understand the decision making experiences of women who are facing recurrent breast cancer treatment. In this project we will be trying to learn more about this important decision making experience, including the values and preferences of women and their families regarding cancer treatment, and how their wishes are communicated to those who care for them.

Cancer Care Choices

If you are currently facing a second cancer treatment decision, we invite you to consider joining this project.

First, let us tell you what your participation would involve:

- Completion of a 16-item questionnaire and demographic information.

- One interview lasting approximately an hour where you would be asked to share your experiences with making breast cancer treatment decisions.

- The interview will be scheduled at a place and time that is most comfortable for you, including your home, should you desire.

Cancer Care Choices

The information provided by women like yourself will guide the development of future programs. Such programs will be designed to assist and support women and their families as they face the many decisions involved in breast cancer treatment and care.

* * *

If you would like more information about the project, please call The Decision Making Research Program at the University of Michigan School of Nursing and speak to the Project Coordinator, Ms. Minnie Bluhm, at (734) 763-2068, or send an E-mail message to Dr. Pierce at:

pfpierce@umich.edu

Your participation is completely confidential and private.

APPENDIX B

Survey Instrument

Defining Decision Support
For Women With Recurrent Breast Cancer

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This project is funded by a grant from the U.S. Army Breast Cancer Research Program (BC996510; DAMD17-01-1-0565)

Defining Decision Support for Women
With Recurrent Breast Cancer

DEMOGRAPHIC AND BACKGROUND INFORMATION

1. Please write down ***today's*** date .... ___ ___/___ ___/___ ___
MONTH DAY YEAR

2. What is your date of birth?.. ___ ___/___ ___/___ ___
MONTH DAY YEAR

3. What is the highest grade of school or year of college you have completed?

Circle the appropriate number

Grades of School	College/Yrs. of School
01 02 03 04 05 06 07 08 09 10 11 12	13 14 15 16 17+

4. Taking into consideration all sources of income including wages, pensions, unemployment compensation, and other sources, what was the total income of your family household before taxes last year?

Circle the appropriate number

01. $4,999 OR LESS
02. $5,000 - 9,999
03. $10,000 - 14,999
04. $15,000 - 19,999
05. $20,000 - 24,999
06. $25,000 - 29,999
07. $30,000 - 34,999
08. $35,000 - 39,999
09. $40,000 - 44,999
10. $45,000 - 49,999
11. $50,000 - 54,999
12. $55,000 - 59,999
13. $60,000 - 64,999
14. $65,000 - 69,999
15. $70,000 - 74,999
16. $75,000 - 79,999
17. $80,000 - 84,999
18. $85,000 - 89,999
19. $90,000 - 94,999
20. $95,000 - 99,999
19. $100,000 - 124,999
20. $125,000 - 149,999
21. $150,000 OR MORE

5. Which of the following possibilities best describes your **present** marital status?

Circle only one answer

1. Never Married
2. Living with a partner
3. Married
4. Geographically separated due to conflicting military assignments
5. Separated (Breakdown of marriage)
6. Divorced (Due to conflicting military commitments)
7. Divorced (Breakdown of marriage)
8. Widowed

6. Are you currently living with your husband <u>or</u> with a partner?

1. Yes 5. No

The following are questions about your ethnic or racial background:

7. How would you describe your ethnic or racial background?

Please circle <u>all</u> that apply

1. White
2. Black/African American
3. American Indian, Eskimo or Aleut
4. Asian or Pacific Islander
5. Other, specify ______________________________

8. Are you of Hispanic descent?

1. Yes 5. No

9. What is your current employment?

1. Full time
2. Part time
3. Unemployed
4. Student

The following are questions about your history of breast cancer

10. When were you first diagnosed with breast cancer?

____

11. What was the type of breast cancer that was diagnosed at that time?

____

12. What treatment did you select at that time?

____

MICHIGAN ASSESSMENT OF DECISION STYLE
(Pierce, 1995)

Following are a few statements that describe typical decision making behavior of people considering medical treatments. Thinking of the decision you are about to make, circle the number on the scale that most closely resembles the way you are thinking about the decision you are about to make.

	1 No, definitely not	2	3 Neither yes or no	4	5 Yes, definitely
1. I would make a quick decision once I was told what my options were.	1	2	3	4	5
2. I would follow the recommendations of my physician	1	2	3	4	5
3. I would agree to the option that seemed the most reasonable to me at the time.	1	2	3	4	5
4. I would develop a plan for gathering further information	1	2	3	4	5
5. I would read magazines and articles about different treatments.	1	2	3	4	5
6. I would read scientific articles about the treatments that were being offered to me.	1	2	3	4	5
7. I would spend as much time as I could gathering information.	1	2	3	4	5
8. I would prefer to seek advice from specialists.	1	2	3	4	5
9. I would ask about the risks involved with each treatment alternative.	1	2	3	4	5
10. I would carefully consider the risks of each option as I was making a choice.	1	2	3	4	5
11. I would want to know the possible outcomes of each alternative that was being offered to me.	1	2	3	4	5
12. I would ask a lot of questions concerning the treatment options.	1	2	3	4	5
13. I would want someone else to make the decision for me.	1	2	3	4	5
14. I prefer, in situations like this, that someone else tells me what to do.	1	2	3	4	5
15. I prefer not knowing the possibility that unexpected things could happen to me.	1	2	3	4	5
16. I believe that what will happen, will happen and there is little I can do to change things.	1	2	3	4	5

APPENDIX C

Interview Schedule

Defining Decision Support for Women with Recurrent Breast Cancer

INTERVIEW SCHEDULE

INTRODUCTION

Hello Ms./Mrs/Dr ______________.
My name is _______and I am from the University of Michigan School of Nursing. We are conducting a research project that is intended to help us better understand how women like yourself make decisions for breast cancer when they are faced with the diagnosis a second time. In this study, we are trying to learn more about how women's experiences of making these choices, in what ways it might be different or similar to the first diagnosis, and how their values and preferences get communicated to those who care for them. If you would be interested in participating in the study, I would be happy to review the informed consent procedure with you at this time.

If no ➔ **Thank the patient for her time**

If yes ➔ **Review the Informed Consent document, obtain a signature, and provide a copy to the subject**

Set a date and time for the interview if the current setting is not appropriate

I would like to ask you to tell me about how you made the decision regarding treatment the first time you were diagnosed with breast cancer and how you are going about making a decision regarding treatment at this time. We can take a break when you wish or end the interview whenever you want to. Just let me know, at any time, if you would like to stop. If I ask a question you prefer not to answer, that's fine. You can just say "pass," and we'll move on.

Do you have any questions for me at this time?

OK then, we can begin if you are ready.

Can you tell me about the first time you were diagnosed; when that was and how you remember making the decision.

[Interviewer: allow the subject to complete her story in her own words at her own pace. Use the following probes only if she has not addressed the issue]

Probe ➔ Do you remember the kinds of things that were important to you at the time you were making that decision?

Probe ➔ Did you find that making the decision was difficult? If so, what made it difficult for you?

Probe ➔ Who or what helped you make the decision?

As time has passed, what do you think now about the decision you made?

Probe ➔ What are you most pleased/satisfied with about that decision?

Probe ➔ Is there anything about how you went about making that decision that, on reflection, you would like to change now?

Probe ➔ What "words of wisdom" would you pass along to other women who may find themselves in the same situation?

Probe ➔ Was there anything that health professionals did to help you make your decision at that time?

Let's move forward to where we are today…

What is your reaction to facing this decision once more?

Probe ➔ In what ways was this decision different from the first time?

Probe ➔ Did you find that your experience from the first time helped or hindered you in making this decision? In what ways?

Probe ➔ What did you learn about making decisions at that time that is helpful to you now?

Probe ➔ What suggestions do you have for health professionals that might be helpful to them as they counsel and support patients in making treatment decisions such as the one you are facing?

Is there any part of your experience that we did not talk about that you would like to share at this time?

Do you have any last questions for me?

Thank you for taking the time to share your experience with me.

[Give the subject the envelope containing the gift certificate of her choice]

APPENDIX D

Table 1. Relationship Between the Protocol Objectives and Interview Questions

Objective	Interview Questions
(1) Provide a robust description of the decision making processes of women faced with recurrent disease	(a) In what ways is this decision different from the first time you were diagnosed? (b) What is your reaction to facing this decision once more?
(2) Describe preferences and values instrumental in the selection of treatment options	(a) Do you remember the kinds of things that were important to you at the time you were making that decision? (b) In what ways have those things you valued in your life then influence the decision you are now making? (c) When you think about the treatment options before you now, which option do you prefer? Why? (d) Are there both attractive and unattractive features of each option? How do you see them? (e) What kinds of things go through your mind when you think about the options you have been given? (f) How do you think you will decide upon the best option for you?
(3) Describe the manner in which previous treatment decision making experiences are, or are not influential, in the current situation	(a) Can you tell me about the first time you were diagnosed; when that was and how you remember making the decision? (b) Did you find that making the decision was difficult? If so, what made it difficult for you? (c) Did you find that your experience from the first time helped or hindered you in making this decision? In what ways? (d) What did you learn about making decisions at that time that is helpful to you now?
(4) Describe the appraisals of decision processes and outcomes to identify those factors that contribute to, or impede, quality decision making concerning treatment for recurrent disease	(a) As time has passed, what do you think about the decision you made? (b) What are you most pleased/satisfied with about that decision? (c) Is there anything about how you went about making that decision that, on reflection, you would like to change now? (d) Do you believe you have all the information you need to make your decision? (e) What would be most helpful to you now in making this decision? (g) What "words of wisdom" would you pass along to other women who may find themselves in the same situation? (h) Was there anything that health professionals did to help you make your decision at that time? (i) What suggestions do you have for health professionals that might be helpful to them as they counsel and support patients in making treatment decisions such as the one you are facing?