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13. ABSTRACT (Maximum 200 Words) In October 2003, we completed data collection on 123 subjects for the research project: Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast biopsy Patient Outcomes. This project evaluated the impact of visual educational aids during biopsy consent on patient understanding of the biopsy procedure, patient satisfaction with the biopsy experience, and patient anxiety. These patients are also asked a series of questions about the scheduling of their procedure (same day as work-up vs. days later) to determine women's preferences and expectations.				
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Statement of Work
Flipchart Study

Introduction

My original Statement of Work (Appendix A) is a series of pilot projects over a four year period. However, the funding I have received from DOD covers three years of the four year period. A revised statement of work was submitted with last year's annual report. (See appendix). Based on this statement of work, I am on schedule with completing the planned tasks for the first 36 months.

The projects address information needs and educational issues for women with breast disease. In addition to providing valuable experience, the projects will help generate hypotheses and data for larger studies in the future. The Statement of Work also includes opportunities to acquire skills in developing patient educational materials, both in the classroom setting and by participating in projects. There are two main objectives: 1) To obtain practical experience with patient outreach and educational program development for breast patients; and 2) To further develop public health research skills by conducting a mini- projects in the field of breast imaging.

Body

Tasks 1-3, Breast Cancer: Dealing with the Diagnosis

This project was primarily funded by the St. Louis Affiliate of the Susan G. Komen Foundation. My colleague Maria Schmidt, MD was Project Director. As co-director, I shared many of the organizational responsibilities, including text writing, editing and strategic planning. This project was an excellent opportunity to acquire practical experience in producing educational materials for the lay community. Some of the materials used for Task 5 were developed initially for Tasks 1-3. We produced 1000 copies of a handbook and video with additional pro bono assistance of Fleishman Hillard, Inc.

The 32 page manual (Appendix B1), which was written at a low literacy level for minority women provides basic, factual information to newly diagnosed breast cancer patients. Although this booklet was designed for low literacy women, women of all educational backgrounds have found the booklet helpful. The 8-minute video (Appendix B2) provides personal messages from health care providers and breast cancer survivors. It includes 6 main messages for the viewer. We began distributing the handbook and video in early March, 2001. To date, we have distributed approximately 600 manuals and 500 videos free of charge to women in the St. Louis area. The contents of the manual can also viewed on the www.bjc.org website. These materials were submitted with the 2002 annual summary.

Tasks 4 and 6: Health Promotion Program Planning and Evaluation Courses

In January, 2002, I attended a course at Saint Louis University School of Public Health on Health Promotion Program Planning (BSH-C510) taught by Marshall Kreuter, PhD. The 50 hour course covered theoretical models for health promotion programs and practical exercises. The second part of this course was not offered this year.

Task 5: Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast Biopsy Patient Outcomes: Phase I

The first phase of the project was the development of an educational intervention (flip chart) for physicians to use in the clinic setting when discussing breast biopsy or breast cancer treatment options with patients. The flipchart includes original diagrams and photographs with limited text, mounted in a portable binder. Note pages for the patient are provided. This project has been expanded to include breast cancer patients, as well as breast biopsy patients. The first phase was funded primarily by an Alvin J. Siteman Cancer Research Development Award. This task was completed in June, 2001. This flipchart was an intervention used in the trial discussed in Task 7.

Task 7: Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast Biopsy Patient Outcomes: Phase I

Patient recruitment began in February, 2003 and ended in October, 2003., with a sample size of 133 women. A summary table of the demographics of the sample is in the appendix. We are currently in the process of completing data entry, transcription and data cleaning (Task 8). Once this process is complete, we will conduct the data analysis (Task 9).

Key Research Accomplishments

- Year 1: Development of low literacy handbook for newly diagnosed breast cancer patients. To date, more than 150 handbooks distributed to Sat. Louis area patients.
- Year 1: Development of video addressing coping mechanisms for women newly diagnosed with breast cancer- targets African-American women. To date, more than 600 handbooks distributed to Sat. Louis area patients.
- Year 2: Development of breast cancer educational tool for doctors and patients in the clinic setting
- Year 3: In 2003, we completed data collection for the research project entitled Evaluating the Effect of Informed Consent and Procedure Scheduling of Breast Biopsy Patient Outcomes.

Reportable Outcomes

1. Siteman Cancer Center Research Development Award (\$50,000)
Project: Evaluating the Effect of Informed Consent and Procedure Scheduling of Breast Biopsy Patient Outcomes, June 1, 2000- May 31, 2002 (Second year of funding awarded 6/4/2001.)
2. Schmidt ME, Farria DM, Bokern JF. One Step at a Time: Dealing with Breast Cancer. (Handbook for newly diagnosed breast cancer patients)
3. Schmidt ME, Farria DM, Bokern JF. Between Friends: Dealing with Breast Cancer. (Video for newly diagnosed breast cancer patients)
4. Farria DM, Schmidt ME, Bokern JF. Breast Diagnosis and Treatment Flipchart (Breast patient educational tool for clinic setting)

Conclusions

Based on the revised statement work submitted with last year's annual summary, I have completed tasks 1-5 and 7. Because the public health course was not offered this year, I was unable to complete task 6. I am currently on schedule for months 1-36. We have just started task 8.

During the course of the DOD funding, which ended in spring, 2003, I have gained experience in developing three types of patient education materials- a handbook, a video and a flipchart for the office setting. Our educational materials (handbook and video) have been useful as an introduction for our breast cancer patients of all educational levels. These projects gave me the opportunity to learn some of the basics of developing educational materials. I hope to learn more about patient education in future projects.

I have also completed data collection on a project, Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast Biopsy Patient Outcomes, which evaluates the role of "visual aids" in preparing patients for imaging guided breast

biopsies. This data collection phase has been completed, and we are beginning the data cleaning/analysis phase. The results of our research project will be valuable in assessing the quality of care for breast biopsy patients. If our results indicate that performing a biopsy the same day as the diagnostic workup reduces patient anxiety and improves patient satisfaction, the published results may encourage more facilities to offer "one-stop" breast care at their site. If the majority of patients do well when they wait a few days for a biopsy, then the additional resources required to provide "one-stop" breast care can be directed to other areas that improve quality and are more cost-effective for breast care patients. This is important since financial and staffing resources are extremely limited nationwide in the field of breast imaging. In addition, if visual aids significantly reduce anxiety and improve patients' understanding of what to expect from a biopsy procedure, the informed consent process for these procedures may change.

References

None

Appendix

STATEMENT OF WORK(Revised 2002):

Dione Farria, MD, MPH

Statement of Work: Education and Outreach for Breast Imaging and Breast Cancer Patients

Months 1-3 Task 1: *Breast Cancer: Dealing with the Diagnosis: Part 1 (Research and Development)*

This educational project is a cooperative effort of Barnes-Jewish Breast Health Center and Fleishman-Hillard International Communications Firm. The project involves the development of a free educational handbook and video for low literacy minority St. Louis women with a new diagnosis of breast cancer. I will function as co-director of this project.

- a) Handbook research and development
 - Research existing materials
 - Develop text outline and overall format
 - Identify/ develop illustrations for use in manual
 - Write draft of text and revise with literacy consultant (approximately 20 pages at 6th to 8th grade reading level)
- b) Video research and development
 - Research existing video materials
 - Meet with breast cancer survivors to identify key messages for video
 - Develop script outline and overall format (approximately 5-7 minutes)

Months 4-6 Task 2: *Breast Cancer: Dealing with the Diagnosis: Part 2 (Production)*

- a) Handbook (Produce 1000 copies)
 - Revise and edit text and illustrations
 - Obtain feedback on draft from 5 representatives of target audience through one-on-one discussions
 - Obtain feedback on draft from advisory panel members (breast cancer survivors, surgeons, radiologists, psychologists, social workers)
 - Produce 1000 handbooks
 - Develop preliminary distribution and promotion plan
- b) Video (Produce 300 copies)
 - Select narrator and speakers for video
 - Revise and edit script
 - Film video and edit as needed
 - Obtain feedback on draft from target audience and advisory panel
 - Develop preliminary distribution and promotion plan

Months 7-8 Task 3: Breast Cancer: Dealing with the Diagnosis: Part 3 (Distribution and Assessment)

- Promotion of products
- Distribution free of charge to local women and clinics
- Assess satisfaction with products by interviewing 20-30 women (10-15 who used the video and 10-15 who used the handbook)

Months 6-8 Task 4: Health Promotion Program Planning (St. Louis University School of Public Health)

I will attend 5 class sessions (total of 40 hours) which introduce the discipline of health education, including needs assessment, program planning, implementation and evaluation.

Months 9-17 Task 5: Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast Biopsy Patient Outcomes

The first phase of this project is the development of an educational flip chart for physicians to use in the office setting when discussing breast biopsy and treatment options with patients.

- a) Focus group testing of women who have had a breast biopsy and breast cancer survivors to guide the content of the flip chart
- b) Develop outline and overall format
- c) Identify/develop illustrations and photographs for use in flip chart
- d) Obtain IRB approval for Phase 2

Months 18-20 Task 6: Health Promotion Program Evaluation (St. Louis University School of Public Health)

I will attend 5 class sessions (total of 40 hours) which cover the principles and procedures used to evaluate health promotion and disease prevention programs.

Months 21-30 Task 7: Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast Biopsy Patient Outcomes: Phase 2

The second phase is a randomized trial, which assesses the utility of the flip chart in radiologist-patient discussions about imaging-guided breast procedures. Using patient surveys of women having imaging-guided biopsies, I will assess the impact of the educational tool on the following outcomes: 1) patient anxiety; 2) fulfilled expectations of the biopsy; 3) basic understanding of the procedure; and 4) patient satisfaction with the procedure. The protocol will be revised during this task.

- a) Revise survey instruments.
- b) Re-obtain Protocol Review Monitoring Committee and IRB approval at Washington U. and DOD.

Months 31-42 Task 8: Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast Biopsy Patient Outcomes: Phase 2

- a) Data collection

b) Data entry

Months 43-48 **Task 9:** : *Evaluating the Effect of Informed Consent and Procedure Scheduling on Breast Biopsy Patient Outcomes: Phase 2*

a) Data analysis

b) Manuscript preparation

FLIPCHART STUDY
Dione Farria, MD

HSC #00-0641

APPENDIX 2

	A	B	C	D
	Date on	STUDY #	Date of Birth	Race/Ethnicity
1	Study			
2	2/4/03	101	4/29/1927	W
3	2/4/03	102	10/9/1946	W
4	2/4/03	103	9/24/1950	AA
5	2/5/03	104	1/1/1964	W
6	2/5/03	105	11/30/1947	AA
7	2/6/03	106	7/2/1951	W
8	2/11/03	107	10/29/1954	AA
9	2/11/03	108	1/29/1950	AA
10	2/11/03	109	8/31/1937	W
11	2/11/03	110	2/25/1963	W
12	2/12/03	111	6/11/1955	W
13	2/13/03	112	10/15/1936	Unknown
14	2/13/03	113	2/24/1961	AA
15	2/13/03	114	1/23/1962	W
16	2/14/03	115	9/26/1956	W
17	2/17/03	116	10/24/1962	Unknown
18	2/17/03	117	7/4/1958	W
19	2/17/03	118	10/5/1957	W
20	2/18/03	119	3/13/1938	W
21	2/19/03	120	7/10/1941	W
22	2/20/03	121	2/5/1917	W
23	2/26/03	122	2/22/1955	W
24	2/28/03	123	3/12/1955	W
25	2/28/03	124	10/14/1927	W
26	3/3/03	125	10/14/1928	W
27	3/5/03	126	1/14/1934	W
28	3/7/03	127	5/28/1938	W
29	3/11/03	128	6/12/1943	W
30	3/12/03	129	8/18/1960	W
31	3/13/03	130	1/22/1958	W
32	3/14/03	131	10/29/1942	W
33	3/14/03	132	11/10/1940	W
34	3/18/03	133	11/23/1946	AA
35	3/24/03	134	5/26/1963	AA
36	3/25/03	135	3/28/1961	W
37	3/27/03	136	6/14/1961	W
38	3/31/03	137	11/1/1929	W
39	4/1/03	138	5/21/1935	W
40	4/4/03	139	8/6/1950	W
41	4/7/03	140	11/10/1939	AA
42	4/10/03	141	4/30/1954	W
43	4/10/03	142	5/19/1944	W
44	4/11/03	143	3/31/1952	AA
45	4/15/03	144	3/9/1967	AA
46	4/17/03	145	1/3/1975	unknown
47	4/18/03	146	3/25/1951	AA
48	4/22/03	147	8/25/1937	W
49	4/25/03	148	10/24/1960	AA
50	4/28/03	149	4/7/1941	AA
51	4/29/03	150	9/6/1947	W
52	4/30/03	151	1/14/1949	W

FLIPCHART STUDY
Dione Farria, MD

HSC #00-0641

	A	B	C	D
53	5/1/03	152	3/4/1980	W
54	5/1/03	153	10/22/1950	W
55	5/6/03	154	12/11/1942	W
56	5/7/03	155	5/7/1955	AA
57	5/9/03	156	7/10/1952	AA
58	5/13/03	157	8/13/1943	W
59	5/13/03	158	5/5/1944	W
60	5/14/03	159	8/25/1959	W
61	5/16/03	160	10/22/1955	W
62	5/19/03	161	3/15/1953	W
63	5/21/03	162	8/2/1943	W
64	5/21/03	163	2/12/1939	W
65	5/23/03	164	2/2/1954	W
66	5/29/03	165	10/9/1949	W
67	6/4/03	166	11/3/1935	AA
68	6/9/03	167	1/28/1929	W
69	6/10/03	168	11/29/1941	W
70	6/13/03	169	2/12/1943	W
71	6/17/03	170	1/17/1936	AA
72	6/23/03	171	11/4/1959	AA
73	6/24/03	172	4/25/1943	AA
74	6/26/03	173	7/22/1938	W
75	6/27/03	174	12/9/1947	W
76	6/30/03	175	9/3/1957	AA
77	7/1/03	176	9/5/1952	AA
78	7/2/03	177	8/19/1934	W
79	7/2/03	178	1/5/1937	W
80	7/3/03	179	9/3/1951	W
81	7/3/03	180	8/27/1951	AA
82	7/8/03	181	11/4/1949	AA
83	7/10/03	182	8/2/1941	W
84	7/11/03	183	11/1/1951	W
85	7/11/03	184	9/14/1954	AA
86	7/15/03	185	2/13/1958	AA
87	7/30/03	186	2/24/1933	W
88	7/30/02	187	2/4/1940	W
89	7/31/03	188	9/18/1948	W
90	8/1/03	189	1/30/1948	W
91	8/7/03	190	1/15/1954	W
92	8/7/03	191	4/24/1958	W
93	8/8/03	192	6/28/1923	W
94	8/8/03	193	5/8/1948	W
95	8/11/03	194	1/5/1937	AA
96	8/12/03	195	10/31/1960	W
97	8/12/03	196	2/12/1955	W
98	8/12/03	197	4/20/1929	W
99	8/13/03	198	9/4/1940	W
100	8/14/03	199	1/8/1943	W
101	8/19/03	200	3/14/1950	AA
102	8/22/03	201	4/8/1961	W
103	8/22/03	202	6/10/1940	AA
104	8/25/03	203	7/26/1947	AA
105	8/27/03	204	9/30/1959	W

FLIPCHART STUDY
Dione Farria, MD

HSC #00-0641

	A	B	C	D
106	8/28/03	205	10/20/1939	W
107	9/3/03	206	1/25/1925	W
108	9/8/03	207	4/3/1953	W
109	9/10/03	208	4/4/1948	W
110	9/11/03	209	11/17/1948	AA
111	9/16/03	210	9/10/1955	AA
112	9/18/03	211	11/21/1953	W/Native AM
113	9/22/03	212	11/12/1936	W
114	9/24/03	213	11/2/1951	W
115	9/24/03	214	10/24/1977	W
116	9/26/03	215	1/22/1960	AA
117	9/29/03	216	7/15/1964	unknown
118	9/30/03	217	2/25/1941	W
119	9/30/03	218	5/1/1956	AA
120	10/1/03	219	3/12/1950	W
121	10/1/03	220	8/10/1963	AA
122	10/2/03	221	8/25/1964	W
123	10/2/03	222	11/21/1928	W
124	10/3/03	223	10/20/1946	W
125	10/3/03	224	8/20/1936	W
126	10/6/03	225	5/23/1953	W
127	10/6/03	226	10/7/1936	W
128	10/8/03	227	9/8/1960	W
129	10/15/03	228	4/26/1951	W
130	10/21/03	229	12/10/1960	W
131	10/24/03	230	3/23/1931	AA
132	10/24/03	231	5/8/1944	W
133	10/27/03	232	5/4/1941	AA