

# Oncology Nursing Society

## Annual Progress Report: 2008 Formula Grant

### Reporting Period

July 1, 2009 – June 30, 2010

### Formula Grant Overview

The Oncology Nursing Society received \$12,473 in formula funds for the grant award period January 1, 2009 through June 30, 2011. Accomplishments for the reporting period are described below.

### Research Project 1: Project Title and Purpose

*The SEA Preparatory Intervention for Women with Metastatic Breast Cancer* - The purpose of this pilot randomized controlled project is to provide information to women newly diagnosed with metastatic breast cancer (MBC) that they can use at diagnosis and across the illness continuum to maintain quality of life and reduce distress.

### Anticipated Duration of Project

1/1/2009 - 6/30/2011

### Project Overview

Aims: The aims of this project are:

- 1) To determine the feasibility (recruitment, attrition, acceptability) of the use of an anticipatory guidance intervention Support, Education and Advocacy (SEA) Intervention in women newly diagnosed with MBC
- 2) To explore the efficacy of the SEA Intervention on functional status, emotional and physical distress and quality of life in women newly diagnosed with MBC over the first six months of illness as compared to care as usual.

Results of this study will then be used for development of a larger RCT to test efficacy of the SEA Intervention.

Methods: This is a pilot study, non-blinded, repeated-measures randomized controlled trial in women (n=48) from diagnosis of MBC through the first 6 months across the illness continuum. Measures of feasibility and acceptability will be assessed at baseline and at 2 time points (1 and 6 months). Outcomes of emotional distress (Hospital Anxiety and Depression Scale) and quality of life (Functional Assessment of Cancer Therapy) will be assessed. Effect sizes for larger trial will be determined.

## **Principal Investigator**

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Principal Investigator  
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## **Other Participating Researchers**

Robert Arnold, MD, Adam M. Brufsky, MD, PhD, – employed by the University of Pittsburgh Medical Center  
Heidi Donovan, PhD, RN, Catherine Bender, PhD, RN, Kathleen Slavish, BA – employed by the University of Pittsburgh

## **Expected Research Outcomes and Benefits**

The SEA Intervention has significant potential to advance the science of oncology nursing. This intervention fills a void in essential patient preparation for a specific disease trajectory. There are many written and electronic resources for women with breast cancer. There are few resources available specifically for women with metastatic breast cancer. This SEA Intervention provides immediate concrete information to women at a time when women need specific information to better adopt coping strategies and problem solving techniques for emotional and physical distress related to metastatic breast cancer. If efficacious, the SEA Intervention can be adopted by oncology nurses and used as a standard teaching intervention at the time of the diagnosis of MBC. It will be different from many other teaching materials incorporated into the cancer clinical setting because it has been developed based on the stated patient experience, respects the similarities and differences among racial and economic backgrounds, evaluated by the patient population intended to serve<sup>1</sup> and will be empirically tested for acceptability and efficacy.

The SEA Intervention is designed to be patient driven and specifically tailored to enhance the woman's self care ability. The SEA Intervention includes:

- a. Support to promote ability to meet evolving emotional needs through identification of available resources;
- b. Education regarding 1) current treatment and side effects including physical sensations and symptoms to expect 2) temporal characteristics of the illness and symptom experience (when to expect them) 3) environmental features (what one might see and hear during an illness experience) and 4) causes of symptoms, sensations, and experiences; and
- c. Advocacy skills to enable communication regarding evolving concerns and provide resources for women to request further information and needed referrals.

## **Summary of Research Completed**

This project aims to evaluate the ability of The Sensory and Coping Intervention to

positively impact coping abilities (problem solving and communication of distress) and subsequent outcomes (quality of life and distress) from the diagnosis of MBC through the first 6 – 18 months of illness.

Aim 1: To determine the feasibility (recruitment, attrition, acceptability) of the use of an anticipatory guidance intervention Support, Education and Advocacy (SEA) Intervention in women newly diagnosed with MBC.

Progress to Date: Acceptability of the SEA Intervention has been previously evaluated. The current intervention reflects the response to patient's evaluations and concerns. Due to patient concerns with the first iteration of the SEA Intervention, our research advisory team felt it necessary to modify the intervention materials, including the written, digital and electronic resources<sup>1</sup>. The resources are available at [www.sensorvandcoping.com](http://www.sensorvandcoping.com). User Name: rosenzweig, Password: rosenzweig.

The SEA Intervention opened to recruitment in March, 2010 with sixteen patients recruited and randomized to date. Nine patients have completed follow up data at Time point 1. The recruitment rate is approximately 5 patients/month which easily allows full sample recruitment (n=48) and follow up data collection and analysis for 3 and 6 month data collection by June 30, 2011. Recruitment thus far has been very successful with 16/18 eligible patients recruited (88.8%). One patient (SEA Intervention) was lost from follow-up due to death (.6%) at Day 74. No other patients were lost to follow-up. Reasons for nonparticipation among eligible patients were "too distressed" at time of recruitment or "not wanting to be bothered".

Pre Intervention demographic information revealed that participants well represent the population of the Pittsburgh region with the majority married (73%, n=11), all high school graduates (100%, n=16), and non-white race well represented (26.7%, n=4) in the sample. Demographic variables were equal across randomization groups. (See Table 1 for Sociodemographic Characteristics)

Aim 2: To explore the efficacy of the SEA Intervention on functional status, emotional and physical distress and quality of life in women newly diagnosed with MBC over the first six months of illness as compared to care as usual.

Progress to Date: Pre intervention evaluation consisted of the Functional Assessment of Cancer Therapy (FACT), Symptom Distress Scale, and the Symptom Severity and Distress Score. (See Table 2: Functional Assessment of Cancer Therapy; Table 3: Cancer Related Distress; and Table 4: Symptom Distress). For both groups, results revealed a relatively high level of overall distress among newly diagnosed patients, a moderate mean score on the symptom assessment scale and a moderate level of specific cancer related distress.

The tables below (See Table 2: Functional Assessment of Cancer Therapy; Table 3: Cancer Related Distress; and Table 4: Symptom Distress) indicate a gap between the number of subjects in the SEA and Usual Care (UC) groups at Time point 1. To date, six UC subjects and three SEA subjects have completed Time point 1 data collection. The gap between the SEA subject count and the UC subject count at Time point 1 exists due to 1 SEA patient lost due to death, and a delay due to medical reasons after consent in providing the intervention.

We do not yet have all of the Time Point 1 data collected as of June 30, 2010 and no subjects have completed data collection at Time point 2 (6 months post intervention)

Table 1: Sociodemographic Characteristics

Sociodemographic Information		
	SEA Intervention (n=8)	Usual Care (n=8)
Age(mean)	54.9 SD=10.4 (range 38-72)	52.4 SD=7.5 (range 39 to 63)
Married, % yes	5 (62.5%)	6 (75%)
Education-High School	8 (100%)	8 (100%)
Race - African American	3 (37.5%)	1 (12.5%)

Table 2: Functional Assessment of Cancer Therapy

FACT (Higher Scores =Better QOL)		
	SEA Intervention (n=8)	Usual Care (n=8)
Baseline (n=16)	101.9 (mean) 6.8 (SD)	108.6 (mean) 3.4 (SD)
Time point 1 (n=9)	SEA Intervention (n=3) 106.7 (mean) 5.3 (SD)	Usual Care (n=6) 115.8 (mean) 2.2 (SD)
Time point 2	SEA Intervention	Usual Care

Table 3: Cancer Related Distress

Distress (Higher Score =More Distress)		
	SEA Intervention (n=8)	Usual Care (n=8)
Baseline (n=16)	3.7 (mean) 1.09 (SD)	3.1 (mean) .66 (SD)
Time point 1 (n=9)	SEA Intervention (n=3) 3.0 (mean) 1.0 (SD)	Usual Care (n=6) 3.0 (mean) 2.5 (SD)
Time point 2	SEA Intervention	Usual Care

Table 4: Symptom Distress

Symptom Distress (Higher Scores Indicate Higher Symptom Distress)		
Baseline (n=16)	SEA Intervention (n=8)	Usual Care (n=8)
	24.9 (mean)	21.1 (mean)
Time point 1 (n=9)	SEA Intervention (n=3)	Usual Care (n=6)
	23.3 (mean) 1.2 (SD)	19.7 (mean) 1.02 (SD)
Time point 2	SEA Intervention	Usual Care

References

1. Rosenzweig, M., Donovan, H., & Slavish, K. The sensory and coping intervention for women newly diagnosed with metastatic breast cancer. *Journal of Cancer Education* (Published Online February 26, 2010). <http://dx.doi.org/10.1007/s13187-010-0056-3>.