

## Response Form for the Final Performance Review Report\*

1. Name of Grantee: Oncology Nursing Society
2. Year of Grant: 2008 Formula Grant

***A. For the overall grant, briefly describe your grant oversight process. How will you ensure that future health research grants and projects are completed and required reports (Annual Reports, Final Progress Reports, Audit Reports, etc.) are submitted to the Department in accordance with Grant Agreements? If any of the research projects contained in the grant received an “unfavorable” rating, please describe how you will ensure the Principal Investigator is more closely monitored (or not funded) when conducting future formula funded health research.***

The research grant oversight process by the Oncology Nursing Society (ONS) includes a peer-review process for all research grants submitted for funding. The ONS Foundation Major Grant Core Review Team (chair and two consistent members for three year term) remains available for consultation as the grant progresses and annual, final and performance review reports are submitted. An additional scientific advisory panel is also available for consultation if any issues or problem arise with the research grant. All ONS Foundation research policies apply to the Health Research Program grants to ONS.

The ONS director of research and the Executive Director of Professional Practice and Programs are responsible for ensuring that all future health research grants and projects are completed and required reports are submitted to the Department of Health in accordance with the Grant Agreement.

\* Please note that for grants ending on or after July 1, 2007, grantees' Final Performance Review Reports, Response Forms, and Final Progress Reports ***will be made publicly available on the CURE Program's Web site.***

**Project Number:** 0864401

**Project Title:** The SEA Preparatory Intervention for Women with  
Metastatic Breast Cancer

**Investigator:** Rosenzweig, Margaret

***B. Briefly describe your plans to address each specific weakness and recommendation in Section B of the Final Performance Summary Report using the following format.*** As you prepare your response please be aware that the Final Performance Review Summary Report, this Response Form, and the Final Progress Report will be made publicly available on the CURE Program's Web site.

Reviewer Comment on Specific Weakness and Recommendation (*Copy and paste from the report the reviewers' comments listed under Section B - Specific Weaknesses and Recommendations*):

Response (*Describe your plan to address each specific weakness and recommendation to ensure the feedback provided is utilized to improve ongoing or future research efforts*):

Reviewer 1:

1. Although the investigators did not achieve noteworthy research outcomes, investigators did gain some insight into the delivery of the intervention. However, the information gained was anecdotal at best. Given that this was a feasibility study, more emphasis on process data was warranted. It is not clear if investigators learned how better to implement support interventions of this type to this population.

Response:

This project resulted in an opportunity to learn a great deal about the way to introduce education and support to women newly diagnosed with metastatic breast cancer. The results of this study have prompted some important efforts to enhance the care of women with metastatic breast cancer. As with many "negative studies", the lessons learned may be beneficial to projects moving forward. Within the Magee-Womens Breast Cancer Program of UPMC Cancer Centers there have been initiatives that have resulted from these findings. After a great deal of thought we have committed to the idea that education regarding metastatic breast cancer care needs to be part of routine care. We feel that to ask patients if they want information about something that is difficult to accept is perhaps not the best approach. Any patient can refuse anything – that is always their right. However we feel this important information is similar to teaching about chemotherapy in the adjuvant setting. Information about chemotherapy may be information that patients are not happy to receive but as clinicians we are obligated to ensure that patients have the information that they need to fully participate in their care. Teaching about chemotherapy is done as per routine clinical care. Patients can engage at different levels but the education is provided in written, spoken and electronic versions. We felt the education re: metastatic breast cancer should be provided in that manner.

After a great deal of discussion with the physicians and other clinicians re: patient's reluctance to accept this education or to be recruited into the study, it was decided that the entire approach to women with metastatic breast cancer needed more focus.

Coincidentally, as we were struggling with how best to incorporate education and support, many of the physicians were struggling with the increased number of treatment options available to women with metastatic breast cancer and how best to match their patients with new treatments and possible clinical trials.

From these discussions, a new multidisciplinary project was developed. The outline for the *Metastatic Breast Cancer Program of Care* was developed. This program of care incorporates initial education, ongoing support and assurance that patients with metastatic breast cancer are receiving state of the art care. This assurance involves ongoing search for clinical trials for specific tumor markers. The development of the program was recently funded with me and a physician from Medical Oncology as co-PIs. The funding was through Magee Womens Research Institute and Foundation. Based on the SEA findings we opted to begin the first portion of this project by conducting focus groups of women with metastatic breast cancer who are well known to the practices and thought to be comfortable speaking about the illness. These women will be specifically invited by their doctor to a dinner focus group. We plan to query them regarding the best approach to the implementation of the individual components of the *Metastatic Breast Cancer Program of Care*. In short, I believed we knew that women with metastatic breast cancer wanted information about the illness and assumed that that would be at the time of diagnosis. What we did not know, and now need to learn is how to introduce that content.

2. Since the intervention was found not to be efficacious, more emphasis needs to be placed on intervention development. Developing specific interventions that address changeable targets is the first step. Although not clear from the documents provided, it is essential to show that a need exists and the intervention is addressing this need. Similar changes in both experimental and control group suggest that the support resources may be available elsewhere and no specific need of a program of this type is warranted.

Response:

The SEA was based on national and our own qualitative interviews of women with metastatic breast cancer who felt they did not have good information re: metastatic breast cancer.<sup>1,2</sup> Additionally we developed the SEA in an iterative fashion with women with metastatic breast cancer.<sup>3</sup> The measurements of the subjects willing to be recruited were of women who were experiencing relatively stable disease and who were past the initial shock of metastatic diagnosis. The need for this information is probably not as great as when the metastatic disease is initially diagnosed or when there is disease progression.

3. The investigators proposed a pilot study. The goal of pilot testing is to test the waters so that larger trials are more effective. When investigators realized the difficulties in recruiting study participants, this provided opportunities to modify recruitment procedures without threatening the internal validity of the study. Given the importance of recruitment to any study, more emphasis should have focused on attempting different recruitment strategies to learn the best way to recruit study participants. Identifying the best strategy would greatly benefit all future research with this patient population.

Response:

We did that throughout the study. We continually expanded the eligibility criteria for recruitment from initial diagnosis to 3 months from diagnosis and then 6 months from diagnosis. At 6 months from diagnosis we were then getting the feedback that women had figured it out and they would have benefitted from this information early on, lessening the distress from lack of information. However the “Catch 22” of this was that early in the diagnosis, women would not even talk to us about the study. That was a genuine surprise as other studies we have done in this population resulted in easy recruitment. Additionally, women said that to deal with the possibility of negative emotion or information may not be good for them as they believed that a positive attitude was very important to combating the disease.

Reviewer 2:

The project appears to have suffered from either a lack of collaboration from the clinicians involved in treating the METASTATIC BREAST CANCER patients or a limited understanding of the barriers to the coordination of study activities with clinical care. Future projects should include letters of support from the appropriate clinical faculty.

Response:

There was support and there were support letters from the clinical site. I am both the PI and a nurse practitioner clinician in this setting and have done multiple descriptive and interventional collaborative projects within this setting for many years. The barriers to the study were not because of poor collaboration or that eligible patients were not identified and recruited – everything was completed as detailed in the protocol. Clinical staff was helpful. The barrier to recruitment was that the patients said “no”. The eligible patients would not even agree to talk to the study personnel about the study.

Interestingly, the SEA components were based on a qualitative study of women with metastatic breast cancer prior to this study and virtually no one refused. Our hypothesis was that the recruitment for the qualitative study may have been more successful because women were asked to discuss living with metastatic breast cancer –they did not have to worry about what they may hear regarding the illness.

Reviewer 3:

1. Recruitment was insufficient; they recruited only 32 out of 48 proposed. Perhaps earlier interaction between researchers and referring oncologists could have improved the intervention and recruitment.

Response:

See above. Patients refused to discuss the study. After recruitment, was noted to be difficult, the eligibility criteria of time (months) since diagnosis was extended from 3 months to 6 months and then to year. This change in the eligibility criteria changed the meaningfulness of the results.

Data from time points at 1 year post diagnosis were not that helpful. The original intent of the materials and the theoretical basis for the research was somewhat lost. Additionally women who enrolled several months to 1 year after diagnosis were often enjoying a period of disease stability. Women reported that the “already knew” most of what was in the intervention because they had figured it out. They said it would have been good to have the information at the time of diagnosis.

2. The intervention was too limited. It needs improvement to help subjects manage emotions that inevitably occur with diagnosis of metastatic disease. Some elements seemed good, e.g., the DVD; but the one coping framework they employed to design the intervention would seem to have been shown to be insufficient.

Response:

A strategy has emerged as a result of patients being fearful of receiving needed information. Part of the MBC Program of Care is to have the physicians tell patients at diagnosis of metastatic breast cancer that some educational materials would be helpful and to offer the education at that time. Because education is considered to be best practice, this does allow patients to receive this focused information.

An additional component of the Metastatic Breast Cancer Program of care is to offer ongoing emotional support throughout the trajectory of illness in a concerted manner. We agree that the model of which the SEA Intervention is based is ideal for newly diagnosed women with METASTATIC BREAST CANCER, perhaps not as women progress through the disease continuum.

3. There was no indication of benefit on outcome measures. This is ok, but it further indicates a need to redesign an intervention of this type.

See Response to Reviewer 1, Question 1

4. Some publications should result probably based on the reflections of participants about what was helpful and what was not. Feedback from referring oncologist would also be helpful.

Response:

We agree that we missed an opportunity to do a qualitative analysis of why women were not accepting of this education. I am not sure that they would have agreed to be interviewed but we do not know. In the new “METASTATIC BREAST CANCER Program of Care” we have scheduled focus groups for the fall of this year. We will invite designated patients with METASTATIC BREAST CANCER and a loved one to a dinner and meeting regarding how best to implement this METASTATIC BREAST CANCER Program of Care. Questions to explore will be how best to provide education, what and when do women want to know, how best to recruit to clinical trials

5. No new funds materialized.

Response:

New funding that was obtained from the results of this study: A new multidisciplinary project was developed. The *Metastatic Breast Cancer Program of Care* was developed. This program of care incorporates initial education, ongoing support and assurance that patients with metastatic breast cancer are receiving state of the art care through ongoing investigations for clinical trials. The funding was through Magee Womens Research Institute and Foundation with Margaret Rosenzweig, PhD,RN and Shannon Puhalla, MD as co-PIs.

Co-Principal Investigator with Shannon Puhalla, MD  
Patient Centered Outcomes Research Institute – Magee Womens Hospital  
MBC Care: Optimal Care Delivery for Women with Metastatic Breast Cancer  
(2013-2014), Contributed

Publications resulting from this funding were:

- \***Rosenzweig, M.**, Whitehaven, T., Brufsky, A., & Arnold, R. (2009). Challenges of illness in metastatic breast cancer: A low income African American perspective. *Palliative and Supportive Care*, 7, 143–152.
- \***Rosenzweig, M.**, Weihagen, T., Conroy, B., Sillaman, A., & Arnold, R. (2009). Strengths and challenges of illness in metastatic breast cancer according to race and income. *Journal of Hospice and Palliative Nursing*, 11, 27-37.
- \***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>.

Presentation:

An abstract was developed by Dr. Rosenzweig and Ms. Slavish, was selected for podium presentation and presented by Ms. Slavish.

Slavish, K. (November, 2012) The SEA Intervention for women with MBC: Lessons Learned. The Pittsburgh Nursing Research Conference, Pittsburgh, PA

## **Recommendations for Oncology Nursing Society**

### Reviewer 1:

Overall, the investment in this project was reasonable, and falls within the guidelines of the CURE program. The investigators derived some secondary benefit from conducting this research, but benefits were anecdotal and have limited impact at this juncture. However, to maximize gains from research investment, ensuring that funded projects have secondary aims that contribute to the field is essential. These secondary aims should be developed sufficiently well so that more than just anecdotal qualitative findings are derived from population-based research.

### Response:

The Oncology Nursing Society (ONS) used the infrastructure for research grant consultation and follow-up developed by the ONS Foundation. The total amount of funding to Dr. Rosenzweig was \$10,000. The ONS Foundation increased the amount of funding for “small” research grants to \$25,000 in 2012 to address some of the limitations that occur in conducting a research project with \$10,000.

The ONS Foundation uses a peer review process based on the NIH research grant review process with staff follow-up at yearly intervals during the funding period and one, three and five year follow-up report requests. As the Director of Research at ONS, I have conferred with the research grant reviewers and a scientific advisory panel about issues and recommendations for changes in the process and overview. I will add this topic to the discussion of the research grant reviews in the future.

Gail Mallory, PhD, RN, NEA-BC,  
Director of Research  
Oncology Nursing Society

***C. If the research project received an “unfavorable” rating, please indicate the steps that you intend to take to address the criteria that the project failed to meet and to modify research project oversight so that future projects will not receive “unfavorable” ratings.***

Response:

***D. Additional comments in response to the Final Performance Review Report (OPTIONAL):***

Response: Thank you for your thorough review of this research project which was funded for \$10,000 as a subcontract from the Oncology Nursing Society 2008 Formula Fund Grant to Dr. Rosenzweig at the University of Pittsburgh School of Nursing.