

## **Proposed Study Conduct and Methodology:**

### **Primary Goal:**

To improve the quality of information exchange between physician and patient during the initial breast cancer treatment encounter.

### *Primary Outcome:*

To determine if Balint group-based approaches are a superior method for improving information exchange in oncological interactions when compared to the current cultural competency curriculums and standard of care. We will measure this through video recordings of physician and patient encounters to document time spent in discussion of side effects, number of questions asked, and physician responsiveness to questions.

The recordings will be modified appropriately to protect the fiduciary nature of the clinical encounter and patient and physician privacy. Patient and physician surveys will be used to evaluate overall satisfaction and perception of quality of interaction.

### *Secondary Outcomes:*

To compare treatment decisions of oncologists in each of the three treatment centers as accessed by percentage of patients in each strategy receiving >80 percent of the recommended initial adjuvant chemotherapy dosage when indicated.

### *Study Methodology:*

After the study protocol is approved by the IRB, three oncology practices with similar catchment and physician age and ethnicity demographics will be recruited – one for each arm of the study. The strategy allotted to each center will be determined by random selection. Prior to randomization, all physician providers in the study will be asked to volunteer to participate and sign a consent form. This consent form will also seek the physicians' permission to record the patient-physician encounter as part of research. The encounter data will be anonymized and stored in a secure location. Access to this encounter data will only be provided to the research investigator. At the completion of the study, the patient encounter data will be permanently deleted.

Following site randomization, physicians at each center will receive site-specific training. One group will receive training in Balint groups; the second will receive the standard cultural competency training; the third will practice as they did before the start of the intervention. Although it may seem intuitive to select the same medical center to control for racial, ethnic, and socioeconomic status in the patient population and help to control for geographic location and institutional culture, this carries the risk of information-sharing. Finding three centers with similar catchment and physician demographics therefore emerges as a superior approach. To avoid disrupting physicians' careers, training will be held after work hours or on weekends.

All initial clinical encounters to discuss treatment with female patients over the age of 18 with breast cancer will be considered for inclusion in the study. All patients will be asked to sign informed consent, which explicitly informs patients that their interactions will be monitored and explains to them the safeguards in place to protect their privacy. Patients will also be asked if they are willing to complete a survey reflecting on their encounter. It will be made clear that refusing to sign consent in no way compromises quality of care and that patients can withdraw from the study at any time. Encounters will be grouped by patient ethnicity – white:African

American:other on a 1:1:1 basis with 30 subjects per group. Total study size across the sites will be 270 clinical encounters.

**GROUP A:** Physicians working in the hospital randomized to this group will continue to practice as they have been. No formal training will be implemented.

**GROUP B:** Physicians working in the hospital randomized to this group will be trained with status quo cultural competence curricula outlined above. This will be performed as part of a lecture series performed at a convenient time with a content expert. All physicians in the study will be mandated to attend these lectures.

**GROUP C:** Physicians working in the hospital randomized to this group will be trained in mindfulness techniques, specifically Balint groups. A content expert will educate the physicians on this methodology. After receiving initial training, physicians randomized to this group will meet for an hour on a weekly basis. At each session, the group will choose a leader to moderate the presentation of cases.

### **Analysis:**

Study recruitment and analysis will be conducted over an 18-month period.

We will use several metrics as analogues for quality of patient-physician information exchange. We will first examine patient and physician satisfaction surveys to gather a qualitative assessment of clinical interactions. We will also analyze recordings of clinical interactions to evaluate discussion of side effects, length of exchanges, and physician responsiveness to patient inquiries. Oncologists' initial dosing decisions will also be examined. Specifically, the number of patients receiving >80 percent of indicated initial adjuvant therapy dose will be evaluated. As we have stated earlier, initial dosing decisions represent a valuable metric because they do not reflect adjustment due to side effects of the treatment itself, but simply physicians' clinical judgment based on patient characteristics. Given the association of underdosing and perceived patient reticence, improvement can perhaps reflect improved physician and patient communication. We will also note whether or not the patient brought a companion to see whether this has an impact on the quality of information exchange.

### **Expected Results:**

The deleterious impact of physician bias on information exchange and dosing decisions in breast cancer likely represents a significant factor in disparities in treatment and outcomes. One would hypothesize that introducing and refining cultural competence and training in patient-centered approaches such as Balint groups would lead to more equitable care. As a result, we expect more equitable dosing strategies between breast cancer patients of different ethnic background, improved provider responsiveness to patient questions, and improved discussion of side effects. We would also expect improvement in satisfaction scores from both patients and physicians.

### **Limitations:**

Although the proposed study has a number of strengths, limitations do exist. One potential hurdle is a lack of willingness on the part of physicians to adapt their clinical practice despite the training. This inertia may result in a failure to prove the efficacy of both intervention arms in comparison to the control group. Another methodological challenge is our inability to control for doctor-patient racial concordance. However, given that many minority physicians exhibit similar levels of implicit bias as their majority colleagues, this may not be as significant as one would

predict. We must also consider the heterogeneity of doctors themselves. Even after accounting for institution where they practice and years of clinical experience, physicians, in light of their unique backgrounds, may approach and engage with patients differently. Despite this inherent and inescapable variation, however, the data this study can provide will be robust enough to be scientifically and ethically valuable. A final limitation is the possibility that physicians will modify their behavior knowing that they are being recorded. The recording of clinical interactions is, however, a vital component of the proposed study.

**Summary:**

In this study, we seek to evaluate the relative effectiveness of Balint groups in comparison to both current cultural competency curricula and standard of care in the context of breast cancer treatment. It is my hope to demonstrate that training physicians in Balint groups will result in improved information exchange during clinical encounters, as well as more equitable initial dosing decisions. Although these findings will be determined in the context of breast cancer, they carry potential implications for the entirety of the medical system. If we can demonstrate the greater efficacy of mindfulness approaches like Balint groups over current approaches, we could favorably modify the paradigm of physician-patient interaction.