Improving Advanced Cancer Patient-Centered Care by Enabling Goals of Care Discussions
Statistical Analysis Plan
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Analysis: **Aim 1.** Describe patients' perspectives about GoC discussions & oncologists' perspectives about barriers & facilitators of GoC discussions. *Interview data*. We will use the qualitative method of interpretive description to elucidate patients' perspectives on the nature and timing of GoC discussions. Interpretive description employs principles for analytic frameworks, sample selection, data analysis, and rigor to conduct inquiries into human health and illness experiences.[69] We will begin by reading interview transcripts line-by-line for accuracy while listening to the corresponding audiotape. Data will be openly coded with descriptive phrases to capture key concepts. Once this process has been completed independently by three members of the research team (NB, DSG, JL) for the first three transcripts, these coders will create an initial code key. The code key will be expanded and refined through independent and then joint review of subsequent transcripts. Coders will compare and discuss codes until agreement on all codes, their meanings, and conceptual categories is achieved.[70] The final code key will be reapplied to all transcripts. We will create a data display matrix to compare responses, and will analyze and integrate codes to discover themes that describe patients' perspectives on GoC discussions. We will document our ideas and questions about the data throughout this process, and findings will be discussed among all investigators as the study progresses. This iterative approach will enable us to explore emergent themes, refine interview questions as necessary, and help us to ensure that we reach saturation in data collection.[71] The research team will use the Atlas.ti software package (version 5.0)[72] to facilitate coding and data analyses, including the formal exploration of patterns and themes within the data. We will integrate findings from interviews to compare and contrast patients' and oncologists' data, and to ascertain that our findings accurately reflect their perspectives on GoC discussions. Findings will be used to inform development of patient surveys & timing of GoC visit.

Aim 2: Train primary oncologists to conduct GoC discussions utilizing Oncotalk principles & joint Oncologist-Palliative Care visits in the outpatient setting & evaluate change in communication skills & feasibility. (*audiotape data).* Communication skill will be scored via summing 22 skills evidenced in the post-intervention audiotapes of INT and UC oncologists. For each oncologist, pre-post intervention change scores will be calculated and compared using tests for continuous variables. Good communication skill will be dichotomized at the top quartile. We will explore relationships between physician descriptor variables collected in their brief survey such as comfort with GoC discussion, prior communications training and beliefs about aggressive treatments. We will examine the fidelity of the intervention, e.g., dose response relationship between effects of the full vs. partial intervention on improvement in communication skills. Feasibility will be measured by the duration of the audiotaped visit in minutes. We will compare INT vs UC visit durations.

Aim 3: Block randomize oncologists in a municipal, 3ary referral and community hospital to the Oncotalk- joint Pall Care-Oncologist GoC visit & assess the effects on patient perceived and experienced quality of care *(pt baseline, 6mo survey data, chart abstraction)*. The primary analysis will be an intent-to-treat analysis that will include all randomized participants regardless of their compliance with the intervention or follow-up schedule. All hypothesis testing will be conducted using α =0.05, two-sided. All outcome measures will be described in a univariate analysis. For continuous variables means and standard deviations will be calculated. For discrete and dichotomous variables we will use contingency tables.

Perceived GoC quality will be calculated as the aforementioned global composite score. Logistic regression will be used for the analysis of the global statistic. A global Odds Ratio (OR) will be estimated using Generalized Estimating Equations to correct for the correlation between the two measures. This measure and its 95% confidence interval will be used as the primary tool for assessing efficacy of the study intervention. We will explore whether satisfaction with GoC communication was related to the imaging result indicating disease progression. *Experienced* quality of care will include separate models of key care processes: conduct of a GoC

discussion >2 months prior to death; enrollment in hospice >1month prior to death; admission to the ICU ≤1 month of death; chemotherapy treatment ≤1 month of death. GEE and mixed regression models will be used for the analysis of the secondary outcome depending on whether the outcome measure is categorical or continuous. Models will take into account clustering by hospital and physician. Because we are block randomizing oncologists within hospitals, there is a potential danger of contamination. We believe the chance of significant contamination changing physician behavior is low. To determine whether there are more GoC discussions over time (i.e., contamination), we will conduct a time series analysis of control group patients.

Sample Size Calculations: Power for this study was determined based on the following operating characteristics: 1)Two sided type I error fixed at 0.05; 2) 85% power; 3) Expected effect size for the global statistic: OR=2.3; 4) Response rate for GoC occurrence of 45% and 24% for patient satisfaction, respectively;[7, 73] Correlations between the two measures included in the global statistic of 0.35. The global statistic OR of 2.3 is based on the clinically important change of increasing prevalence of GoC discussions from 45% to 75% (Δ30) and satisfaction from 24% to 49% (Δ25). Under the above assumptions it is estimated that 160 participants will be required to detect an OR = 2.3 or higher. This effect size corresponds to an absolute improvement of 20% for the GoC and 18% for the patient satisfaction, respectively. Since randomization will occur by physician, the sample size is adjusted assuming that patients within the same physician will be positively correlated. We assume that the level of intra-physician or intra-cluster correlation (ICC) is fairly modest. The ICC is assumed to increase the variance associated with estimated statistics by a quantity known as the variance inflation factor: VIF = [1 + (m-1)ICC], where m denotes the average cluster size (here, equal to the average number of patients per physician who are recruited and contribute to the final analyses). Power is computed by applying the VIF to obtain the final sample size. We anticipate that the number of patients per physician will on average be equal to 18. Assuming an ICC = 0.04 the total sample size required for the study, after adjustment for clustering is 280 patients (140 in each intervention group) which gives 85% power to detect a change in GoC prevalence & improved patient satisfaction with GoC communication.