

Effectiveness of Out-of-Pocket Cost COMMunication and Financial Navigation (CostCOM) in Cancer Patients

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High out-of-pocket costs (OOPC) of cancer treatment and lost income result in financial hardship. There is compelling evidence that OOPC communication complemented by financial navigation and counseling will decrease financial hardship by enabling cancer patients to anticipate and accommodate treatment costs and proactively seek financial assistance. Importantly, this intervention aligns with the Centers for Medicare and Medicaid Services (CMS) price transparency mandate. We will evaluate the efficacy of an innovative personalized intervention designed to improve cost-related cancer care non-adherence by conducting a randomized controlled trial of OOP cost communication and financial navigation (CostCOM) vs. enhanced usual care (EUC) at NCI Community Oncology Research Program (NCORP) practices. Our multidisciplinary team has experience with all facets of the proposed intervention including conducting clinical trials at NCORP practices. CostCOM comprises four 1-hour counseling sessions to impart: (1) OOPC communication, individualized, *patient-specific* education of the anticipated OOPC using a price estimator tool; (2) Financial navigation, real-time professional guidance to identify financial assistance programs that will alleviate costs of care and discuss information to improve insurance coverage; and (3) Financial counseling to address the range of patients' financial concerns and enroll patients in financial assistance programs. We will recruit 720 patients with newly diagnosed solid tumors (1:1 non-metastatic vs. metastatic) who plan to receive anticancer therapy at one of the participating NCORP practices. CostCOM arm patients will participate in four phone or video sessions with a remote financial counselor at baseline, 3, 6, and 12 months, with all three components of CostCOM delivered at each session. At enrollment, EUC arm patients will receive usual care enhanced by providing an educational brochure describing services and contact information of the Patient Advocate Foundation (PAF), a national non-profit financial navigation organization. Patients will complete surveys at baseline, 3, 6, and 12 months after enrollment. Our goals are to (1) compare the effectiveness of CostCOM vs. EUC at 12 months on patient-reported cost-related cancer care nonadherence, defined as any self-reported incident of delay, forgo, stop or change in cancer care due to cost concerns, as well as (2) patient-reported material financial hardship, financial worry, and quality of life; and (3) conduct a process evaluation to examine practice providers and CostCOM arm patients' satisfaction with the intervention and their perceptions of barriers and facilitators to CostCOM delivery (for providers) or receipt (for patients). A successful CostCOM is a scalable and financially sustainable program that can be disseminated across systems, conditions, and populations and improve cancer care delivery, patients' experience, and health outcomes. In our prior pilot trial of 23 cancer patients receiving CostCOM intervention in a single NCORP practice, patients' financial worry significantly improved following CostCOM (COST score of 10.0 ± 9.6 at enrollment vs. 16.9 ± 8.1 at follow-up; $p < 0.001$), and 83.3% found financial navigation beneficial.