NCI Community Oncology Research Program

EAQ222CD/COSTCOM

For Patients with Any Newly Diagnosed Solid Cancer

Please Enroll Your Eligible Patients!

EAQ222CD Available Through ECOG-ACRIN Cancer Research Group

Effectiveness of Out-of-Pocket Cost COMmunication and Financial Navigation (COSTCOM) in Cancer Patients

Patient Population

See Section 4 for complete eligibility criteria

Non-Patient Participants: Subset of study coordinators, oncology providers, and practice financial counselors/social workers/financial navigators/pharmacists (n=~40) from a minimum of 15 participating NCORP sub-affiliates

- Must speak English; must be employed at NCORP site for at least 6 months
- Must have provided care/been in contact (in the last 3 months) to a patient on the CostCOM arm and who completed the ≥ 6 month study follow-up

Patient Eligibility– Step 0 (Screening Registration):

- Age ≥ 18 years; able to answer surveys/interact with the study team in English **or** Spanish; ECOG PS ≥ 3 (or must not be deemed medically unable to participate)
- Must be within 120 days of a new diagnosis of any solid cancer of any stage at the time of Step 0 (see protocol for details); must have had their first oncology visit at the time of Step 0
- Must have initiated oral or IV cancer systemic therapy either any time before Step 0 registration or have received a prescription order with stated intent to initiate within 30 days following Step 0 registration
- Must not be undergoing curative surgery alone or radiation therapy alone (must be receiving systemic therapy)
- Must not be enrolled in 1) treatment clinical trials where cancer systemic therapy is provided at no cost; 2) EAQ221CD/S1912CD; 3) trials where OOPC communication/financial navigation is offered

Patient Eligibility– Step 1 (Randomization):

- Must have completed Baseline Survey within 30 days of OPEN registration (Step 0)
- Must have initiated cancer treatment (note: Step 1 registration mut be within 45 days of Step 0 registration)

Methodology Plan

See Section 6 for complete methodology details

- Site leadership will complete an electronic survey via REDCap with information on the number of new solid cancer patients visited annually, their payer mix, zipcode mix, etc. (this will be updated annually)
- Participating NCORP affiliates/sub-affiliates will work with TailorMed to launch the estimator and navigation platform (training to be completed after study activation prior to first patient enrollment)
- 15 months after first patient enrollment, site leadership will distribute a survey to eligible candidates (distributed every 3 months). The goal is to identify **non-patient participants** who are interested in participating in the qualitative interviews (20-30 minutes long)

Patient Participant:

- Enhanced Usual Care (Arm A): UCI study coordinator will send the patient an introductory package of Patient Advocate Foundation (PAF) financial navigation services
- CostCOM (Arm B): NCORP CRA will use TailorMed price estimator and financial navigation platform and schedule patients for a 1-hour one-on-one session with a remote financial counselor at TailorMed (4 sessions– 30 days after randomization, and 3, 6, and 12 months)
  - ◊ UCI study coordinator will mail patients a study overview/contact info for TailorMed
  - ◊ Each session covers OOPC communication, a review of insurance benefits, and financial navigation/assistance/counseling. After each session TailorMed will generate a report with information discussed
  - ◊ Patients will complete a 5-minute post-intervention survey after each session
- For both arms: follow-up EASEE-PRO surveys at 3, 6, and 12 months
- *Note: gift cards are distributed per protocol*

Study Chair:
Gelareh Sadigh, MD

Patient Enrollment (Oncology Patient Enrollment Network [OPEN])

https://open.ctsu.org/open 1-888-823-5923

Protocol Information (ECOG-ACRIN Operations – Boston)

http://ecog-acrin.org (Member Login) 1-857-504-2900

Patient Schema

A. Identify Site Population (i.e., potentially eligible patients),
B. Screen/Approach Patients (site staff to enter a monthly summary into UCI REDCap survey)
C. Consent Patients and OPEN Screening Registration (Step 0)

D. Baseline Procedures

Site Staff:

- Have the participant complete the Patient Contact sheet and fax it to the Brown OEAU (Tel: 855-404-3278 Fax: 401-863-9635)
- Submit a REDCap form with consented patient contact information, choice of compensation, and preferred method of its receipt and CRA contact
- Encourage the patient to complete the baseline survey as soon as possible either by activating their EASEE-PRO account by logging into the pride portal at https://pride.stat.brown.edu/Participant-Login or by administering the baseline survey on paper in clinic and uploading responses in the PRIDE portal.[1]

Refer to the protocol for the Non-Patient Participant's Intervention Schema

E. OPEN 1:1 Randomization within stage strata[2] (Step 1)

Site Staff:

- Return to OPEN within 45 days of Step 0 registration to randomize patient upon completion of the baseline survey (site staff will get a notification when baseline survey completed), and verify eligibility based on baseline survey completion date and initiation of systemic therapy.
- Baseline survey should be completed within 30 days of the date of OPEN screening registration (see Section 4.2.2.3)
- Patients must have initiated their cancer treatment (see Section 4.2.2.4)

UCI staff: Mail patients' incentives

Arm A: Enhanced Usual Care

Site Staff: Submit a redcap form with information on internal financial counseling and assistance patients received in the practice.

UCI Staff: distribute a copy of Patient Advocate Foundation brochure

Arm B: CostCOM

Site Staff:

- Submit a REDCap form with information on internal financial counseling and assistance patients received in the practice, as well as patient treatment diagnoses and insurance information.
- Schedule patients for financial counseling with TailorMed.

TailorMed: Deliver CostCOM (out-of-pocket cost communication, financial navigation and counseling), generate reports on intervention

EASEE-PRO/OEAU: Send patient email notifications and reminders that post-intervention survey is available to complete or mail paper survey. Provide patient outreach to recover delinquent surveys. Send UCI notification when survey has been completed.

UCI Staff: Document and send appropriate incentives to patient for timepoint completion. Send TailorMed report to patients and site CRA

F. Follow-Up (3, 6, and 12 months)

EASEE-PRO/OEAU: Send patient email notifications and reminders that follow-up survey is available to complete or mail paper survey. Provide patient outreach to recover delinquent surveys. Send UCI notification when survey has been completed.

Site Staff:

- Review medical records
- Update redcap on patient's receipt of internal financial counseling for both arms. Update redcap on changes in patients' medication or insurance for Arm B.
- Schedule patient for follow-up financial counseling with TailorMed for Arm B.

TailorMed: Deliver CostCOM, generate reports on intervention

UCI Staff: Document and send appropriate incentives to patient for timepoint completion. Send TailorMed report to patients and site CRA

G. Qualitative Interview (12-18 months)

Emory/UCI:

Select and interview 40 patients from the CostCOM arm

ECOG-ACRIN cancer research group

Footnote: Please note the study sample size is recruitment of 720 patients to Step 1.

1. It is encouraged for completion of consent, baseline survey, and randomization to occur on the same day.
2. Stage stratification is based on early vs. metastatic stage.