Cancer Research Consortium of West Michigan
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FAST FACTS

EAQ222CD: Effectiveness of Out-of-Pocket Cost COMmunication and Financial Navigation (CostCOM) in Cancer Patients

Selection of Participants

4.1 Non-Patients Participants

To achieve Aim 3, we will enroll a subset of providers (n=approximately 40) from a minimum of 15 participating NCORP sub-affiliates. These providers will include:

1. study coordinators with a role involving use of CostCOM intervention price transparency and financial navigation platform (n=approximately 15),
2. oncology provider with patients, assigned to the CostCOM arm, that completed at least 6 months follow-up study (n=approximately 15), and
3. practice financial counselors, social workers, financial navigators, or pharmacist with a role in helping with co-pay assistance in at least one patient assigned to CostCOM arm (n=approximately 10).

4.1.1 Non-patient participants Eligibility Criteria for Step 0 (Screening)

1. Participant must immediately be enrolled to Step 1 (Registration)

4.1.2 Non-patient participants Eligibility Criteria for Step 1 (Registration)

1. Participant must speak English.
2. Participant must be employed at NCORP site for at least six months.
3. Participant must be able to provide informed consent to participate in this study.
4. Participant must be one of the following:
    - a study coordinator with a role involving use of CostCOM intervention price transparency and financial navigation platform,
    - a practice oncology provider (i.e., physician or mid-level), or
    - a practice financial counselor, social workers, financial navigators, or pharmacist who have provided care or been in contact (in the last 3 months) to a patient who was assigned to the CostCOM arm, and who completed at least 6 month study follow-up.

4.2.1 Patient Eligibility Criteria for Step 0 (OPEN Screening Registration)

1. Patient must be ≥ 18 years of age.
2. Patient must be able to answer surveys and interact with the study team in English
   OR
   Patient must be able to answer surveys and interact with the study team in Spanish
3. Patient must be within 120 days of a new diagnosis of any solid cancer of any stage at the time of Step 0.

NOTE: Patients with a new diagnosis of stage 0 or in-situ cancer are eligible only if systemic therapy has been initiated or planned.

NOTE: Patients with a new recurrence of a primary cancer are not eligible as this is not considered a new diagnosis of cancer.

NOTE: Patients with a history of prior cancer diagnosis and/or treatment in the previous 24 months are not eligible. Exceptions are as follows:

- Patients with a history of prior non-melanoma skin cancer are eligible even if they were diagnosed and/or treated in the last 24 months.
- Patients with a history of prior in-situ cancer are eligible even if they were diagnosed and/or treated in the last 24 months.
- Patients with a history of prior breast cancer only receiving adjuvant hormonal therapy in the last 24 months are eligible if they were diagnosed more than 24 months ago.

NOTE: Patients with a history of prior cancer diagnosis and/or treatment more than 24 months ago are eligible.

4. Patient must have had their first oncology visit at the time of Step 0.
   NOTE: The oncology visit refers to the visit where the cancer systemic therapy is prescribed.
5. Patient 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.
6. Patients must not be receiving palliative or hospice care alone.
7. Patient must not be undergoing curative surgery alone or radiation therapy alone. (Must be receiving systemic therapy).
   NOTE: This only applies to the new index cancer diagnosis.
8. Patient must confirm that they intend to receive their care or monitoring at one of the participating NCORP practices.
9. Patient must have the ability to understand and the willingness to sign a written informed consent document.
   NOTE: Patients with impaired decision-making capacity (IDMC) who have a legally authorized representative (LAR) or caregiver and/or family member available are not eligible.
10. Patient must not have an ECOG Performance Status ≥ 3.

OR

Patient must not be deemed medically unable to participate in the study by the study investigators or an oncology clinician (i.e., referral to hospice).

11. Patient must not be enrolled in treatment clinical trials where cancer systemic therapy is provided at no cost to the patient.
12. Patient must not be enrolled in EAQ221CD or S1912CD given financial navigation is offered as part of these two trials.
    NOTE: If S1912CD is activated in a participating practice, S1912CD should be offered first to patients with metastatic cancer meeting eligibility criteria

for S1912CD. Only if a patient is not eligible or not interested in participating in S1912CD, the EAQ222CD can be offered. For early stage cancer, EAQ222CD can be offered first given S1912CD does not enroll patients with early stage cancer.

13. Patient must not be enrolled in other clinical trials where OOPC communication or financial navigation (i.e., professional guidance to identify financial assistance programs to alleviate cost of care) is being offered as part of the trial.
    NOTE: If a trial is offering financial counseling alone without financial navigation patients are allowed to co-enroll.
    NOTE: Gift cards for survey completion, or parking passes are not considered financial navigation.

4.2.2 Patient Eligibility Criteria for Step 1 (OPEN Randomization)

1. Patient must meet all the eligibility criteria for Step 0 outlined in Section 4.2.1.
2. Patient must have signed a written informed consent form.
3. Patient must have a completed Baseline Survey within 30 days of the date of OPEN screening Registration (Step 0).
4. Patients must have initiated their cancer treatment (i.e., IV or Oral systemic therapy).
5. Step 1 registration must be within 45 days of Step 0 registration.