Study Title: Building Engagement using Financial Incentives Trial – Colorectal cancer screening (BENEFIT-C)

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1. Study aim, background, and design

Meta-analytic evidence suggests that ***patient navigation*** (which involves connecting patients with trained non-provider professionals who can guide them through the complexities of the healthcare system and provide tailored resources for overcoming barriers to accessing care) and ***mailed stool-based screening kits*** can improve the timely utilization of colorectal cancer screening,[1-5] especially for populations experiencing health disparities.[4,5] *Despite the strong evidence in support of these strategies for increasing patient engagement with preventive healthcare, low intrinsic motivation* among patients in real-world primary care settings may undermine the effectiveness of these evidence-based interventions. In light of low intrinsic motivation, extrinsic motivation in the form of ***financial incentives*** has been proposed to increase patient engagement with health behaviors.[6] LA-CEAL will test the value of financial incentive-based interventions to increase engagement with preventive healthcare via the following objective:

> **OBJECTIVE:** To determine if proven incentive-based interventions targeting SDOH as barriers to uptake of preventive healthcare and chronic disease management increase flu and COVID-19 booster vaccination, colorectal cancer screening (CRS), and hypertension-related health behaviors (self-monitoring of medication adherence, blood pressure, and sleep) in underrepresented minorities and rural communities.

Using a 2-arm randomized controlled trial design, we will test the effectiveness of patient financial incentives for enhancing routine outreach for preventive health services, namely colorectal cancer screening, flu vaccines, and COVID-19 vaccines. FQHC patients who are aged 45-75 years old and due for a colorectal cancer screening (up to n=100) will be identified through the electronic health records of our FQHC partners. Participants who meet eligibility criteria and enroll in the study will be randomized to one of two arms: the control arm will receive outreach by FQHC staff to encourage completion of a stool-based colorectal cancer screening provided by the FQHC as well as flu and COVID-19 vaccination. They will receive $50 financial incentives/service for completion of flu and COVID-19 vaccines. The intervention arm will receive the same patient outreach and flu/COVID-19 incentives and will also be offered $50 financial incentives for completion of colorectal cancer screening.

2. Subject Population

Using the following criteria, we will enroll up to 100 patients at partner FQHCs:

Inclusion criteria: Age 45 to 75; receive care at a participating FQHC; due for a colorectal cancer screening; ability to understand and speak English

Exclusion criteria: currently participating in another clinical trial or research study on colorectal cancer screening; unable or unwilling to give informed consent

3. Procedure

After obtaining verbal consent, FQHC outreach staff will verify eligibility and consent participants. The FQHC staff will then read either the intervention or control script depending on the random group assignment of each participant. The script for the control group will follow standard clinical practice for scheduling colorectal cancer screening (a stool-based test), flu and COVID-19 vaccination. The script will offer financial incentives ($50 per service) for completing flu and COVID shots. The script for the intervention group will be adapted from the control script to include the offer of financial incentives (and additional $50) for completion of colorectal cancer screening. Study staff will verify completion of each preventive service via weekly limited EHR data downloads for participating patients. After a 2-month follow-up period, a final EHR download will be obtained. The primary outcome is the difference in proportion of participants completing colorectal cancer screening between the two groups. All electronic data will be stored on secure cloud-based servers and accessed on HIPAA-compliant, encrypted, password-protected computers that are only accessible to the FQHC and study staff.

4. Risks

The risk of physical, psychological, social, or legal harm associated with participation in all components of this study is minimal:

- Participants may find it inconvenient to take time to participate in the study. All study activities will be arranged at a time that is convenient for participants. The option to complete study activities via telephone or Zoom will also ease the burden of participation for participants.
- There is a small risk of unauthorized disclosure of participants' responses, which will be prevented by following a strict protocol for data handling and rigorous training of study staff:
    - No identifying data (e.g., name, address) will be recorded on study forms. Identifying data used for participant recruitment will be kept separate from study data and no linkage will exist.
    - All electronic study records will be stored with password-protection. All paper study records will be locked in a secure study office. Data will be accessible only by study staff with approval from the PI.
    - The data will be retained without identifiers in a secure location for possible use in a future project, which will be consistent with the original research purpose.
    - Data may be shared with the NIH or other researchers upon request. Any data shared with the NIH or other researchers will not contain identifying information.

5. Benefits

If the BENEFIT-C financial incentives are found to be effective at increasing engagement with preventive health services, individuals randomized to the intervention could benefit from those services. In addition, the knowledge gained from the study may benefit society in general by providing evidence for a strategy to increase patient engagement with preventive healthcare, with ensuing benefits for reducing morbidity and mortality.

6. Remuneration

While participants will not receive remuneration for participating in the study (as participation does not entail any activities beyond normal clinical practice), they will receive $50 gift cards for completing each of the following services: flu shot, COVID-19 shot. In addition, those who are randomly assigned to the intervention group will receive a $50 gift card for completing colorectal cancer screening within two months of the call. These financial incentives comprise the intervention being tested in this study.

7. Costs

There will be no costs to the participant for participating in this research study.

8. Consent process and documentation

FQHC partners will query their EHR systems and provide a list of eligible patients and their contact information to their outreach staff, who will call patients, verify eligibility, and read a consent script over the phone. All participants will provide verbal consent over the phone. We are requesting a waiver of documentation of consent and a waiver of HIPAA authorization due to practical concerns of obtaining written consent over the phone and the minimal-risk nature of the study.

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