

# **A Community Health Worker Intervention for Patients with Unmet Screenings**

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## **Introduction**

Preventive health interventions have a strong evidence base yet are underutilized in the United States. Even among those with health insurance this is true, with only 52% of adults in 2002 receiving age- and gender-indicated preventive services.<sup>1</sup> The underutilization of this care leads to premature deaths, preventable morbidity, and excess medical expenses.<sup>2</sup>

There are likely numerous causes of underutilized preventive interventions, however various financial, cultural, location, and time barriers to care face both patients and healthcare providers. Hospital- and outpatient-based medicine can have several problems, such as inconvenient waits and travel. Further, studies from these settings of care only offer populations that arrive to them in the first place, where as preventive interventions are often targeted at the general population. This can result in issues of unknown levels underutilization when denominators are unknown. Physician-delivered care can also provide barriers to utilization. Physician time is expensive and limited, often creating an impulse to focus on more acute issues. Physicians also are typically not from concordant racial, ethnic, socioeconomic, or language backgrounds as their patients.

Community health workers (CHWs) have been utilized to lead interventions facing similar barriers. CHWs typically are lay health workers, work at the community-level, and are of similar background to the patients that they serve. A Cochrane systematic review in 2009 assessed CHWs providing simple education, diagnostic, and curative services for infectious diseases and maternal child health issues in both developed and developing countries. This review showed that CHWs were significantly able improve health behaviors and utilization of care.<sup>3</sup> In the United States in particular, CHWs have also been used to assist with chronic care management for diabetes<sup>4</sup>, hypertension<sup>5</sup>, and asthma<sup>6</sup> by promoting health behaviors and appropriate use of care. While some medical conditions are acute requiring appropriate levels of care, and some tasks are complex requiring professional providers, the evidence suggests that CHWs can be effective at providing care, particularly to patients with economic, language, or cultural barriers.

Because these patients typically are the ones most likely to underutilize preventive screenings, more recently there has been some attention in the United States to have lay health worker-led referral interventions to improve utilization of proven preventive screenings. These have shown significant increases in breast cancer, cervical cancer, and HIV screenings.<sup>7-10</sup> However, unlike CHW programs, many of these lay health worker studies took place in medical settings. Further, they often assessed utilization rates affected by an intervention given to the entire population, not specifically to those with unmet screenings, thereby likely diluting the effect size. Lastly, these interventions have been attempted with individual screenings for specific populations, not with CHWs capable of referring to multiple screenings.

This study seeks to enroll patients in a predominantly Dominican low socioeconomic status community who have unmet screenings and to provide them with a CHW-led intervention aimed at increasing their utilization of selected Grade A USPSTF-recommended preventive screenings. We will seek to determine if a home-based background-concordant lay health worker intervention can activate patients to have significant increases in adherence to proven screenings compared to typical utilization.

### **Study Design**

This will be a prospective, randomized, controlled study to determine the efficacy of a CHW intervention in increasing utilization of preventive screenings for a population with unmet screenings. The control will be standard healthcare utilization. The primary outcome of this study will be patients with 'newly completely met screenings.'

Each participant's initially unmet screenings will be assessed for whether they were met or not; if all previously unmet interventions are met at the end of the 2 month study protocol, the patient will have achieved this endpoint.

Individual screenings will be defined as newly met if the patient or patient's physician reports that the screening was completed during the study or if the patient's physician indicates that it has been ordered or the patient has been referred. The analysis for the primary outcome will be run twice: once including patients who are told by their physician that they in fact already had the screening need met (intention to activate patient analysis) and also with these patients retroactively excluded.

### **Statistical Analysis and Sample Size**

Categorical data will be analyzed using the chi-square test for proportions. Multivariate analysis will be used to determine variables that significantly correlate with newly met screenings, such as age, gender, race, ethnicity,

primary language, other screenings met at baseline, and the CHW's as well as CHW age, gender, race, and ethnicity.

The determination of sample size is based on prior studies in breast cancer screening demonstrating 10-20% effect size. Assuming an effect size of 20%, and in order to achieve 80% power with a 5% Type I error rate, a sample size of 116 participants (58 in each arm) was calculated using the chi-square test.

## **Study Procedure**

As part of study enrollment, candidate participants will be asked when they last received age- and gender-appropriate screenings. For each of the following, any non-adherence to screening guidelines will be determined to be an unmet screening: hypertension screening (age 18 or older, every 2 years), cervical cancer screening (women age 21-65 every 3 years or age 30-65 every 5 years with pap smear and HPV testing, or told no longer need pap by MD), chlamydia screening (women 24 or younger, yearly), cholesterol screening (men 35 years or older, every 5 years), colorectal cancer screening (age 50-75, colonoscopy in last 10 years, sigmoidoscopy in last 5 years with FOBT in last 3, or yearly FOBT).

All eligible and willing participants will be randomized to intervention or control arms. The control arm will receive a battery of other health questions on topics separate from the aforementioned screenings. These questions may be relevant to future programming, but would serve also to dilute the effect of the screening adherence assessment in causing an effect in the control group. The intervention group will be assessed for insurance status (if not insured, will receive social work referral), primary care physician status (if does not have physician, will be referred to one), and will receive patient education and for the indicated screening(s). CHWs will also be trained in patient activation and empowerment techniques, and will offer patients a document to bring to their physicians to address these unmet screenings. CHWs will encourage and help, if needed, the participant to establish a next appointment with their doctor. The document will contain a list of this patient's indicated screenings and the patient will be told to have it signed by doctor at the visit; there the doctor can indicate whether the screening was ordered, was completed, was done in past but patient did not know, or if it is not actually indicated.

The CHW will follow up with the patient for the above as needed (for insurance or primary care referral/appointments) and at least 2, 5, and 8 weeks after the initial enrollment, unless the participant demonstrates completely met screenings before that time.

The control group will receive the intervention at the end of the 2 month study period.

## **Subject Selection**

Patients will be recruited by CHWs in the Washington Heights community. CHWs will be given a geographic scope in Washington Heights and will go door-to-door recruiting participants. Informed consent will be attained at the time of study selection screening and enrollment.

Inclusion criteria:

Age greater or equal to 18 years

One or more unmet indicated screening at baseline

Exclusion criteria:

Pregnant

### **Study drugs**

N/A

### **Medical devices**

N/A

### **Study questionnaires**

See above study procedure

### **Confidentiality of study data**

CHWs will use password protected iPads for data entry. These will be kept at the study location during non-work hours. Central data storage will occur on a password protected database in the study center. Data will be de-identified.

### **Location of study**

Washington Heights

### **Risks and benefits**

Minimal risks to intervention or control from referral. Referred screenings have Grade A recommendations from USPSTF indicating high benefit; both groups ultimately will be referred to screenings.

### **Alternative therapies**

None.

### **Compensation and costs to subjects**

No compensation, the only cost is subject time.

### **Minors and research subjects**

There are no minors in this study.

### **Radiation or radioactive substances**

N/A.

### **References**

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