DGIM Project Summary

(1 page preferred, 2 pages maximum)

Name of Project: "Smarter Screening" for Older Adults

Investigator(s). (Include phone numbers and email address, indicate PI and primary contact)

- Principal Investigator: Judith Walsh MD, MPH judith.walsh@ucsf.edu
- Co-Investigator: Grace Lin, MD, MAS grace.lin@ucsf.edu

Research question(s):
Our objective in Aim 1 is to complete development of "Smarter Screening," a patient-centered intervention that provides decision support for individualized cancer screening decisions. The multi-component intervention includes: 1) Passport to Health, an informational patient booklet that addresses various aspects of aging, including consideration of continuing or stopping cancer screening, 2) a Clinician Report that includes the ePrognosis: Cancer Screening results, patient preferences and individual recommendations for screening; and 3) a pilot EHR integration that includes ePrognosis estimates as well as encouragement to use an existing "dot phrase" to facilitate documentation of the discussion in the encounter note. The intervention will be tested for acceptability and feasibility in Aim 2.

Our objective in Aim 2 is to evaluate acceptance of the intervention developed in Aim 1 through a pilot randomized controlled trial, to assess feasibility of incorporating the intervention into routine clinical care, and to compare the impact of the intervention to usual care in relation to breast and CRC shared decision making across diverse primary care patients aged 70 and older. The intervention will only provide education and information to support shared decision-making during the encounter and no direct intervention during the scheduled primary care appointment.

Brief Background/Significance:
Background: Promotion of evidence-based cancer screening is a national health priority. Breast and colorectal cancer screening have not been proven beneficial in adults age ≥75 and diminished life expectancy decreases the potential for screening benefit and may increase the risk of harms, including but not limited to overdiagnosis. Because of heterogeneity in comorbidity, functional status and life expectancy among older adults, decision-making is complex, and a more individualized approach to cancer screening in older adults is urgently needed, taking into account perceived risks, benefits and values. Most current discussions about cancer screening occur in patients who prefer screening, do not adequately address the harms of screening, and lack elicitation of patient preferences. This proposal will move the field forward by developing and pilot testing an intervention that provides decision support to patients and clinicians to encourage shared decision-making conversations about whether or not to continue breast and colorectal cancer screening.

Significance: Screening decisions should consider life expectancy, cancer risk, and patient values and preferences. However, there are currently few decision support interventions that help clinicians and patients address cancer screening when the benefits of screening are unclear, e.g., older adults who are beyond the recommended age for screening and those with limited life expectancy. Clinicians also lack easy access to critical information such as life expectancy at the point of care, limiting their ability to accurately assess prognosis and have an effective shared decision-making

conversation regarding cancer screening with the patient. Ours is one of the first interventions to facilitate incorporating prognosis as well as patient preferences and values into a shared decision-making process for cancer screening in older adults.

Inclusion/exclusion criteria (list)
Inclusion:

Patients:

1. age 70 and above scheduled for an upcoming appointment in UCSF General Internal Medicine or Women's Health Primary Care clinics
2. be English-speakers; and
3. have no prior history of cancer.

Providers:

1. practice in one of the designated enrollment locations;
2. have a patient scheduled for a visit that is enrolled in the pilot RCT.

Exclusion:

Patients and Providers:

1. unable to consent or complete study tasks

Patients:

1. non-English speaking
2. Are under current direct medical care of either the study PI, Dr. Judith Walsh or Co-I, Dr. Grace Lin
3. Are patients of providers who decline to be part of the study

Method of contact/recruitment (be specific)
For recruitment of the PCPs, the study team will work with staff from DGIM to identify eligible PCPs according to the inclusion and exclusion criteria. The study team will send eligible PCPs an email with information about the study, its voluntary nature, and a telephone number and an e-mail address to use if they do not want to be further contacted. PCPs who do not decline to participate in the study will receive a list of the study-eligible patients to determine suitability for inclusion. Once a PCP has a study-eligible patient that enrolls in the study, the PCP will be invited to enroll in the study via email.

For recruitment of patients for the pilot RCT we will identify eligible subjects in the following ways: 1) by submitting a DGIM Internal Research Report Request for identification of patients based on Apex Clinical Data, and 2) by a self-search in Apex by reviewing upcoming clinic schedules for the next 2-4 weeks to maximize the likelihood that the clinic appointment will not be cancelled or changed. For identification of patients via electronic search of Apex, we will include patients who are 70 and older, have an upcoming appointment within the next 3 months at DGIM or Women's Health, have not had a mammogram within the last 18 months (women), FIT within 1 year or colonoscopy within 10 years (men and women), or have a health maintenance flag for overdue breast or colorectal cancer screening. We will request monthly reports given the dynamic nature of scheduled appointments. For the self-search in Apex, the PI or study coordinator will screen schedules of the 3 DGIM sites and Women's Health for patients 70 and over who have an upcoming visit in the next 2-4 weeks, with annual physical or Medicare Wellness visit indicated in the visit notes. Appointments may be video visits or in-person visits; telephone visits will be excluded.

Subjects will be screened according to the study inclusion and exclusion criteria. The

study team will be given a list of the eligible patients and their contact information. Prior to contacting the patient, the study team will send PCPs a list of study-eligible patients to determine suitability for inclusion. Patients identified by the PCP as not suitable for the study will not be contacted. All other patients will then be sent a letter describing the study and explaining the voluntary nature of the study. Patients who choose not to participate can indicate that by calling a number or sending an email to the designated phone number/email address in the letter. If no such communication is received, within a week of probable receipt of the letter, study staff will call to follow up with the patient to see whether they are interested in participating.

Benefits/burden for participants (clearly identify potential for harm)

Benefits: Patients may gain knowledge about their health and health conditions and may feel they are contributing to knowledge in the health or social sciences field.

Burden/potential harm: Some study participants may experience personal discomfort due to some of the questions discussed in the study materials related to cancer screening. Some study subjects may also be hesitant to participate due to COVID-19 concern and desire to limit extra in-person interactions and clinic visits.

We will minimize risks/discomforts to the subjects by including in our consent process the topics that will be discussed in study materials. For study subjects concerned about in-person interactions with study staff, we will provide as many remote options to access study activities (outside of the visit with the PCP) and materials including phone, mail, e-mail, Zoom, and online applications (e.g., REDCap) as possible. All electronic data will also be maintained on secure encrypted drives, will be password protected, and paper records will be kept in a locked office to minimize risks to the patient's privacy.

Any benefits or burden to DGIM practitioners?

Enrolled providers may gain knowledge about the ePrognosis: Cancer Screening tool. Time may be added to a visit if providers choose to review and discuss the ePrognosis report with their patients and a shared decision-making conversation occurs. However, we aim to recruit patients who are coming in for visits where screening is expected to be discussed (i.e., annual physical and Medicare Wellness visits), so time burden will be in the context of conversations about cancer screening that are already occurring. The burden of time on providers after the visit to fill out surveys will be approximately 15-30 minutes total for the entire study (short 1-3 minute survey immediately after visit with patient; 10-15 minute post-study survey). Providers will also receive a gift card in appreciation of their participation.

Timeline for recruitment (projected start and stop dates)

July 15, 2021 – June 30, 2022 (Recruitment will end once 40 participants are recruited).

Funding source

Mt. Zion Health Fund

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular)

Study is led by two DGIM investigators. There might be potential for

collaboration if a DGIM resident or fellow was interested.

Do you agree to notify us when recruitment is completed?
Yes

Date form completed:
July 15, 2021