PARTNERS HUMAN RESEARCH COMMITTEE
PROTOCOL SUMMARY

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR

Karen Sepucha, PhD

PROTOCOL TITLE

Promoting Informed Decisions about Cancer Screening in Older Adults (PRIMED Study)

FUNDING

Patient-Centered Outcomes Research Institute

VERSION DATE

March 29, 2021

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

As people age, medical decisions become more complex, including conversations about cancer screening. For patients aged 76-85, the United States Preventive Services Task Force (USPSTF) advises clinicians that decisions about colorectal cancer (CRC) screening should be individualized based on overall health and prior screening history (C recommendation).[i] However, studies find that many older adults are not well-informed about, nor meaningfully engaged in, decisions about whether to continue CRC screening. Shared decision making (SDM) has been shown to improve the quality of decisions about initiating cancer screening but little is known about its effectiveness for decisions about stopping interventions. This proposal addresses an important gap in our understanding of how to support clinicians and older patients in making good decisions about whether to continue CRC screening or not.

We will conduct a comparative effectiveness trial that will randomly assign clinicians at participating academic and community practices to one of two different decision support strategies. The first strategy (Registry arm) takes a population health management (PHM) approach and uses a patient registry to identify and track use of CRC screening among older adults for each clinician. The second strategy will enhance the registry by adding an established, multi-faceted SDM training program for clinicians (SDM Skills arm). We will enroll patients of participating primary care providers (PCPs), aged 76-85, who are due or overdue for CRC screening, and survey them shortly after an office visit to determine the impact of the two strategies on outcomes of importance to patients. We plan to randomly assign about 60 participating PCPs to the SDM skills or Registry arms, and enroll about 500 of their eligible patients. We will compare reports of shared decision making, patients' knowledge, and rates of patients who get their preferred option for CRC screening across study arms. We will also compare CRC screening rates across arms and to concurrent and historical controls. Through this project, we will accomplish the following specific aims:

Aim 1: Determine the impact of the approaches on patients' involvement in decision making and knowledge about the risks and benefits of continued CRC screening.

Hypothesis 1.1 (Primary outcome): Patients seen by clinicians in the SDM Skills arm will report more SDM discussions about cancer screening compared to the Registry arm.

Hypothesis 2.1 (Secondary outcome): Patients seen by clinicians in the SDM Skills arm will have higher knowledge of the benefits and harms of CRC screening and treatment compared to Registry arm.

Aim 2: Examine the effects of the interventions on patients' preferences for screening, the extent to which patients receive their preferred approach to screening, and on CRC screening rates.

Hypothesis 2.1 (Secondary outcome): A higher percentage of patients will receive their preferred approach to screening in SDM Skills arm compared to the Registry arm.

Hypothesis 2.2: (Secondary outcome) Both interventions will reduce CRC screening rates compared to concurrent controls (rates of clinicians who are not involved in study).

Aim 3: Examine the impact of the interventions on physicians' confidence with and skills for SDM in this setting.

Hypothesis 3.1: Clinicians in the SDM Skills arm will have higher confidence in their SDM skills.

Hypothesis 3.2: Clinicians in the SDM Skills arm will demonstrate more SDM skills in simulated patient interactions than the Registry arm.

The study will advance our understanding of how to best communicate evidence of cancer screening benefits and harms to older adults. Better decisions about whether or when to stop screening may reduce unnecessary tests and treatments and allow patients to avoid potential harms of screening.

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

Colorectal cancer (CRC) is a common, lethal disease that affects both men and women. In 2016, an estimated 135,000 people were diagnosed with CRC and 49,000 people died of it. The incidence of CRC increases with age, and the average age of diagnosis is 68 for men and 72 for women. CRC screening is widespread, and data indicate that 65% of adults over 65 were up-to-date with CRC screening tests; however, almost one quarter of adults 75 and older have never been screened for CRC. The screening is performed using a variety of methods, including stool-based testing requiring patients to collect stool specimens at home, and direct visualization testing such as colonoscopy. If stool-based testing is positive, then additional testing with a colonoscopy is recommended. There is evidence from observational and randomized trials that all methods for CRC screening are effective at reducing mortality attributed to colorectal cancer, provided the tests are conducted at recommended intervals with follow-up as needed.

Although CRC screening is recommended for adults aged 50-75, the USPSTF advises clinicians to make an individual decision for adults aged 76-85. Older adults often have a small potential benefit from screening and are at higher risk for complications, particularly complications of colonoscopy. The choice of whether to continue or stop screening depends significantly on patients' individual risk of colorectal cancer, their overall health, as well as their preferences for testing. Those who are able to undergo treatment if cancer is found and those who are otherwise healthy with long life expectancy may be more inclined to continue. Further, the USPSTF notes that adults aged 76-85 who have never been screened are more likely to benefit from CRC screening than those with prior testing.

There is a growing need to address appropriate use of cancer screening tests in older adults. Screening for asymptomatic disease comes with costs and potential harms. Shared decision making (SDM) is an established approach to engaging and informing patients in medical decisions. Currently, there is a lack of evidence on effective interventions to support clinicians in communicating with patients 76-85 about the benefits and harms of cancer screening and

tailoring decisions to what matters most to patients. This study will compare two established interventions to advance our understanding of how to support clinicians in conducting SDM conversations with older adults who may be considering stopping cancer screening.

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

The main study is a cluster randomized trial enrolling about 60 primary care clinicians across all sites. We estimate including about 30-35 clinicians from primary care practices affiliated with Massachusetts General Hospital (MGH) and Brigham and Women's Hospital (BWH), 10-15 from Maine Medical Center (MMC), and 10-15 from community practices affiliated with Newton Wellesley Hospital (NWH) and North Shore Medical Center (NSMC). The participating clinicians at each site will be placed into two groups stratified by gender and years of experience. Then, each group will be randomly assigned to one of two arms: Registry arm or Registry plus SDM Skills training arm (SDM arm). Clinicians in Registry arm will be notified about their patients aged 76-85 who are due for colorectal cancer screening with an upcoming visit. Clinician participants in the SDM arm will also receive the Registry notification and in addition, they will participate in a SDM skills course that includes online training and telephone-based simulated patient interactions.

After the training, study staff will track and enroll eligible patients who have upcoming visits with participating clinicians in both arms. We plan to enroll about 10 patients per clinician for a total of 500 patients. The clinicians will complete a short survey after each eligible patient visit. The patients will be invited to participate in the survey study and will be asked to complete a survey after their visit and another short survey one year later. Patients will be asked whether a spouse, friend or caregiver was involved in the decision-making process and if so, whether they would be willing to invite them to participate in the study. Study staff will follow up to enroll caregivers that patient participants identify and administer a short survey. We expect that about half of the patients will identify a caregiver, so about 250 caregivers will be surveyed.

Staff will track colorectal cancer screening for 12 months after the recorded date of visit for participating patients, for participating clinicians and for non-participating clinicians across these sites to examine trends in screening over time. Historical controls will also be collected to calculate rates of screening across the sites for the 2 years prior to the study (approximately calendar years 2017 and 2018).

The eligibility criteria for the clinician and patient participants are in Tables 1 and 2.

Table 1: Eligibility for clinician participants

Eligible	Ineligible
• Primary Care Physician (MD or NP) • Have ≥20 potentially eligible patients in their panel • Use of Epic electronic health record	• Residents, medical students

Table 2: Eligibility for patient participants

Eligible	Ineligible
• Adults, age 76-85 at the time of a scheduled visit • Scheduled for non-urgent office visit with a participating clinician during the study period • Due or overdue for colorectal cancer screening (e.g. never been screened, <1 year to follow-up interval indicated on last test).	• Prior diagnosis of colon or rectal cancer, inflammatory bowel disease or genetic disorder that raises CRC risk (hereditary non-polyposis CRC and familial adenomatous polyposis) • Unable to consent for themselves (moderate to severe dementia or other major cognitive limitations) • Unable to read or write in English or Spanish

Briefly describe study procedures. Include any local site restrictions, for example, "Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study." Describe study endpoints.

Clinicians will be recruited from primary care practices, both internal medicine and family medicine, affiliated with MGH, BWH, MMC, NWH and NSMC. The investigators will work with Steve Atlas who has an IRB approved protocol (2004P002796) to help identify the number of eligible patients by clinician and will then target those clinicians with high number of eligible patients for recruitment on the trial. IRB protocol 2004P002796 remains an active study and continues to operate per an IRB approved protocol and amendments. The study uses data from patients followed in MGH affiliated primary care practices for research and quality improvement purposes. The IRB protocol specifically pertains to research aspects that go beyond data used for administrative purposes as part of usual hospital operations. The study involves implementing a previously validated and published methodology to identify and link patients seen in MGH primary care practices to specific providers. Information is also collected on patient characteristics and outcomes of care. The data for this study is updated on a yearly basis. The information collected as part of this study can be made available to other IRB approved studies such as the current PRIMED submission if permitted in the IRB submission. Data collected as part of IRB protocol 2004P002796 will be used to identify MGH primary care providers with patients who meet eligibility criteria for the PRIMED submission. Though IRB protocol 2004P002796 will help the current submission with identifying potential primary care providers and patients, all aspects of contacting these providers and patients are covered in the current submission. Study staff will use similar methodology to identify the number of eligible patients by clinician for recruitment from the other Partners hospitals (BWH, NWH, NSMC) using RPDR and from MMC.

The participating clinicians at each site will be placed into two groups stratified by gender, years in practice, and number of clinic sessions per week. Then, each group will be randomly assigned to one of two arms: Registry arm or Registry plus SDM Skills training arm (SDM arm).

- Clinicians in Registry arm will complete a baseline telephone-based simulated patient interaction to evaluate their SDM skills. Once patient enrollment begins study staff will send periodic notification of their patients aged 76-85 who are due for colorectal cancer screening with an upcoming visit.
- Clinician participants in the SDM arm will complete an online SDM skills course, two telephone-based simulated patient interactions, and monthly facilitated case-based discussions. Once patient enrollment begins, study staff will send periodic notification of their patients aged 76-85 who are due for colorectal cancer screening with an upcoming visit.

Study staff will use existing functionality in the electronic medical record (EMR) via RPDR and Epic Reports to generate a list of patients 75 and older with CRC screening status, prior CRC screening results, and upcoming visit dates for each participating clinician. Staff will also work within the EMR at each site to develop an automated report of these items as available.

Our target is to enroll approximately 10 patients per clinician for a total of 500 patients. The clinicians will complete a short survey after each eligible patient visit. The patients will be invited to participate in the survey study and will be asked to complete a survey after their visit and another short survey one year later. Patients will be asked whether a spouse, friend or caregiver was involved in the decision-making process and if so, whether they would be willing to invite them to participate in the study. Study staff will follow up to enroll caregivers that patient participants identify and administer a short survey. We expect that about half of the patients will identify a caregiver, so about 250 caregivers will be surveyed.

The research coordinator will track the number of study participation invitations sent to each clinician as well as the number of clinicians indicating interest. We will track any reason given for refusal to join the study as well as any reason for dropping out of the study after randomization for reporting in CONSORT flow diagram. Staff will track completion of each activity (baseline survey, simulated patient interaction, training course, etc) for each clinician participant.

Staff will also track all patient participants screened, reason for ineligibility, the number sent invitation or post-visit survey packet by mail, the number who opted out or otherwise declined participation, those lost to follow-up for any reason, and any reasons given for the refusal to participate for reporting in CONSORT flow diagram. There are no formal written consent procedures in this study. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required. Consent for the study will be implied by completion of the one survey for patient participants and email consent for clinician participants.

The primary outcome for this study is whether patients report more SDM in the visit with participating clinicians about CRC screening in the SDM arm compared to the Registry arm. Key secondary outcomes will be whether patients are knowledgeable about CRC screening benefits and harms, and whether clinicians understand patients' preferences and tailor screening decisions appropriately.

Patient reported measures: patients will complete a survey shortly after the visit.

- **Shared Decision Making Process (SDMP) Survey:** Four items assess the amount of shared decision making that occurs during a visit. These items are summed to generate a total score (0-4), with higher scores indicating greater patient involvement in decision making. The survey has been validated through its use in many studies, including two national studies of shared decision making for cancer screening and has strong evidence of acceptability, feasibility, reliability and validity.**Error! Bookmark not defined.**[ii,iii] The survey has also been endorsed by National Quality Forum as a SDM performance measure (#2962).
- **Knowledge:** Five multiple choice knowledge items will assess patients' understanding of colorectal cancer screening adapted from the Colorectal Cancer Screening Decision Quality Instrument.[iv,v] A total knowledge score (0-5) will be calculated from the number of correct answers.
- **Risk perceptions:** One item will assess affective risk perception, or cancer worry. This item will be adapted from the National Cancer Institute's Health Information National Trends Survey (HINTS).[vi]

- **Patient's preferred approach to screening:** One item will assess patients' preferred approach to screening (with responses of colonoscopy, stool card test, no screening, not sure).
- **Overall health:** SF-1 will be used to assess patient's perception of overall health (poor to excellent)[vii]
- **Screening Recommendation and Time Spent:** One item will assess the patient's perception about their clinician's recommendation about CRC screening and one item will assess how much time was spent discussing CRC screening in the visit.
- **Single Item Literacy Screener**: One item that measures comfort with reading materials from health care providers. It has high specificity according to other, more detailed health literacy screening tools, and is able to be self administered.[viii,ix]
- **Demographics and CRC risk factors**: items will assess factors such as education, employment, marital status, family history of CRC, and alcohol use.
- **Barriers and facilitators to screening**: a subset of patients (those who did not receive their preferred approach to screening) will be surveyed again by phone about one year later to discuss any barriers or reasons why the preferred decision was not completed. For patients who had screening despite indicating desire to stop we will explore reasons for this change.

Study staff will supplement patient reported data with data collected via chart review. First, staff will review chart to confirm eligibility (e.g. age, dates and types of prior CRC screening tests as well as follow up test timing recommendation, CRC cancer history, dementia or cognitive impairment that would prevent participation, upcoming visit dates with participating clinician). Second, staff will access chart of participating patients to document CRC risk factors (e.g. family history, BMI, inflammatory bowel disease, diabetes, smoking status), abstract screening discussion in the visit note, subsequent CRC tests or procedures, complications related to CRC testing for participants, and findings of tests. Missing patient demographic information may also be supplemented via chart review.

Clinician, Practice and Network level CRC screening rates: We will use established, validated algorithms for calculating cancer screening rates using a combination of administrative, billing and clinical data. Dr. Atlas (co-I) led the algorithm development efforts at MGH and Partners, and he will work with the MMC team to ensure CRC screening rates are comparable across sites. Data is aggregated at the physician, practice and network (e.g. MGH, MMC, PCPO) level to identify the percentage of eligible patients up to date for screening during the historical control period, and concurrent observation period for study and non-study clinicians. Limited data on patient characteristics (e.g. age, gender, education, insurance status, etc) will be collected along with screening rates.

Clinician reported measures: clinicians will complete a baseline survey and a telephone-based simulated patient interaction (SPI) before staff start enrolling their patients onto the trial. They will complete a short survey after each eligible patient visit. After patient enrollment is complete, all clinicians will participate in a debrief interview.

- **Baseline clinician survey** will include the same CRC knowledge items as the patients and 3 items to assess clinicians' confidence in their ability to present benefits and harms, to discuss probabilities of benefits and harms and to elicit patients' goals and concerns during an office visit, each based on a five-point scale (not at all, a little, somewhat, very, and extremely confident).
- **Post visit survey:** 4 items SDMP survey will be adapted for use by clinicians, time spent discussing CRC screening in visit, recommendation, patient's preferred approach, and satisfaction with visit.

- **Baseline SDM skills assessment:** The telephone-based SPI will be transcribed and coded by two trained coders according to the well-validated Braddock's Informed Decision Making framework. The Braddock framework covers the core areas of SDM skills. [x,xi] A total score 0-9 will be calculated with higher scores indicating more SDM skills.
- **Debrief interview and survey**: After patient recruitment is complete, study staff will conduct a brief interview with all participating clinicians and will follow a structured interview guide to assess clinicians' attitudes toward SDM, their perceptions of the study and satisfaction with the intervention, and ideas for improvement. The clinicians will also be asked to complete a short, online survey to re-assess their confidence in their ability to present benefits and harms, to discuss probabilities of benefits and harms and to elicit patients' goals and concerns during an office visit.

Caregiver measures: a short survey post visit will contain SDMP survey, their perception of physician recommendation, their preferred approach to screening and their perception of the patient's preference for screening.

Adherence to intervention(s): The online training platform will track completion of modules and time spent on the webinar. Staff will track completion rates and time for the SPIs, delivery of the registry reports, participation in monthly case discussion sessions, and documentation in notes of CRC screening discussions in order to examine whether outcomes are affected by adherence to the protocol.
Patients will self-report time spent discussing CRC screening in the visit. Finally, staff will conduct a short follow-up survey with a subset of patients at 12 months to confirm screening choice and reasons for any discrepancy between preferred and implemented approach (e.g. transportation, insurance, clinician recommendation, spouse/caregiver preference, other new or worsening illness).

All study staff are Collaborative Institutional Training Initiative (CITI) certified and will receive training from the PI and program manager in the study protocol. We will hold regular meetings to review screening, enrollment and completion data, to discuss protocol and standard operating procedures, and to identify and mitigate any issues that arise.

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

The standard of care is that physicians may discuss appropriate screening options, including their benefits and risks with each patient and individualize a decision based on the patients' risk, overall health and preferences. In this project, we will proactively remind clinicians to have these conversations with eligible patients about continuing colorectal cancer screening. Whether the physician and patient have this conversation remains at their discretion during a clinic visit. No tests or treatments will be administered as part of this study.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

There are minimal risks to participating individuals associated with or attributable to this study. The main risks are associated with loss of privacy of their health information. To minimize risks, all electronic data files that include clinician, caregiver and patient identifiers will be kept in a

Partners protected server and only members of the research team will have access to the files. Files with PHI will only be accessed from Partners computers or encrypted laptops that are protected with SafeBoot. All patient information on eligibility screeners, chart reviews, and surveys collected at MMC will be sent securely using a secure file transfer to the Partners network. To ensure confidentiality, all paper surveys will be identified by study code number only and kept in a locked file cabinet and the scanned surveys and electronic files will be on password protected Partners server. Study papers (screeners, notes, surveys) that have been scanned or entered into a database will be disposed of in the confidential shredder. To address issues of psychological discomfort, research assistants will inform patients that they may refuse to answer any question and may withdraw from the study at any time. To address privacy and confidentiality issues, analytic database with outcomes data will not contain any identifying information and will be coded by unique study ID number only.

Patients will be invited to complete survey questionnaires. The time required for patient participants to complete each survey is about 15 minutes. Participants may opt out of the survey study, may refuse to answer any question (or set of questions) and may discontinue their participation at any time. It will also be emphasized that whether or not subjects participate will not impact the medical care that they receive. The caregiver's survey should take less than 10 minutes to complete.

The clinicians in the Registry arm will spend about 1.5 hours on study related surveys and activities and clinicians in the SDM arm will spend about 3.5 hours on study related activities over the course of 12-18 months. This includes the baseline questionnaire (10 minutes), the simulated patient interaction (20 minutes), and the training course for those assigned to SDM arm (about 2 hours). Clinicians will also complete about 10 surveys after patient visits that should take 1-2 minutes to complete. The exit interview will be about 20 minutes.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

Although there are no written informed consent forms, Drs. Simmons and Sepucha are responsible for assuring that clinician and patient participants are adequately informed prior to engaging in any research procedures, that all subjects meet eligibility criteria, and that the study is conducted according to the IRB-approved research plan. The patient population in this study is older, and may have significant co-morbidities which may limit life expectancy. Staff will confirm status of patients, particularly before contacting patient participants for the follow-up survey.

There are no formal stopping rules for this minimal risk study.

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

There are minimal risks to individuals participating in this project. The main risks are the time and effort involved in participating and the potential loss of privacy. All electronic data files that include clinician, caregiver and patient identifiers will be kept in a Partners protected servers and only members of the research team will have access to the files. Files with PHI will only be accessed from Partners computers or encrypted laptops that are protected with SafeBoot. All patient information on eligibility screeners, chart reviews, and surveys collected at MMC will be sent securely using a secure file transfer to the Partners network. To ensure confidentiality, all paper surveys will be identified by study code number only and kept in a locked file cabinet and the scanned surveys and electronic files will be on password protected Partners server. Study papers (screeners, notes, surveys) that have been scanned or entered into a database will be disposed of in the confidential shredder. To address issues of psychological discomfort, research assistants will inform patients that they may refuse to answer any question and may withdraw from the study at any time. To address privacy and confidentiality issues, analytic database with outcomes data will not contain any identifying information and will be coded by unique study ID number only.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

All participating physicians will be notified of upcoming visits with eligible patients. SDM in the clinic visit has been shown to increase patient knowledge, reduce decisional conflict and improve the match between patients' preferences and their treatment choices. Those clinicians randomized to the SDM Skills arm may further benefit as prior work has shown the training results in increased confidence and competence in conducting SDM conversations with patients. Clinicians in both arms may benefit from the registry report as that may prompt them to discuss cancer screening with their older population of patients.

There are no direct benefits to patients from completing the surveys. The potential benefit to society is that the study will help determine the most effective approach to engaging and informing older patients about cancer screening.

As efforts to integrate SDM into routine care expand, understanding the effectiveness of interventions to achieve SDM is critical. This study will provide important new information on comparative effectiveness of different decision support strategies promoting SDM.

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

The patient recruitment is limited to older men and women 76 to 85 years of age as the clinical guidelines on colorectal cancer screening highlight this age group as requiring an individual decision and thus are appropriate to engage in shared decision making. Children, younger adults, and pregnant women are not eligible for this decision. We will be targeting clinicians across the sites who care for a diverse patient population in order to increase enrollment of minority patients on the trial.

The clinician recruitment is focused on primary care clinicians (MD and NPs) who spend a significant portion of time seeing patients. Residents and other health care professional (e.g. RNs, social workers) are not eligible as they rarely consult patients regarding this decision.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

Patient survey materials will be available in English, Spanish. We will try to include other languages based on the need of the population. Most patients seen at these sites speak either English or Spanish (>97%). Patients with other primary languages not translated for this study will be excluded from the survey portion of the study.

For guidance, refer to the following Partners policy:
Obtaining and Documenting Informed Consent of Subjects who do not Speak English
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Non-English_Speaking_Subjects.1.10.pdf

RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

Clinicians will be recruited from primary care, internal medicine, and family medicine practices affiliated with MGH, BWH, MMC, NWH and NSMC. At MGH, there are about 190 adult primary care clinicians across 19 affiliated primary care practices, including 12 community-based practices and 3 hospital-based practices serving a diverse patient population in Eastern Massachusetts. Four of the practices are community health centers located in low-income urban communities around Boston and we plan to target clinicians at these centers to increase patient diversity. At MMC, there are 108 primary care providers at 10 affiliated primary care practices that will be screened for eligibility. Newton Wellesley Hospital and North Shore Medical Center have about 128 clinicians across 16 community practices. Current CRC screening rates for patients 76-85 range from 52%-65% at these sites. All participating sites use the Epic EMR with similar cancer screening registry functionality.

<u>Clinician recruitment:</u>

Investigators at each site will identify clinicians with a high volume of patients aged 76-85 and those who see patients at community health centers or centers with higher patient diversity. The recruitment and study procedure for clinicians is as follows:

1. The PIs and co-investigators will inform clinicians about the study and invite their participation in multiple ways: through presentations at clinical leadership meetings, practice meetings, through HDSC newsletter, through Partners Center for Population Health Newsletter, and through calls, meetings and emails to individual clinicians. Reminder emails will be conducted for non-responders within 2 weeks of the initial outreach.
2. Clinicians will indicate interest in participating in the study by contacting the PIs or study staff (either via email, phone or in person).
3. Study staff will contact interested clinicians to collect information to confirm eligibility and to support randomization using the screener questionnaire and will send an information sheet to clinicians that details the requirements of the study.
4. Clinicians will indicate their consent to participate by sending an email with their intention to join the study.
5. Study staff will then run an RPDR report to identify the clinicians' eligible patients due for colorectal cancer screening in the study year.
6. Eligible Clinicians will be randomly assigned to an arm by study statistician.
7. Clinicians assigned to the registry arm will have 4 weeks to complete:
    a. Baseline survey via RedCap or phone
    b. A telephone-based SPI conducted with standardized patients that will be audiotaped
    c. Short meeting with staff to review protocol and preferences for receiving the registry information about potentially eligible patients (e.g. 24h in advance of visit, weekly report, at morning huddle through medical asst)
    d. Review of their eligible patient list to indicate any patient that should not be approached for the study and a reason for exclusion.
    e. Study staff will send up to six reminder emails for each activity and make two reminder calls to encourage completion of each activity.
8. Clinicians assigned to the SDM training arm will have 4 weeks to complete:
    a. Baseline survey via RedCap or phone
    b. The online training course
    c. A telephone-based interaction conducted with a standardized patient. Study staff will email feedback 1 week after completion.
    d. Short meeting with staff to review protocol and preferences for receiving the information about potentially eligible patients (e.g. 24h in advance of visit, weekly report, at morning huddle through medical asst)
    e. Review of their eligible patient list to indicate any patient that should not be approached for the study and a reason for exclusion.
    f. Study staff will send up to six reminder emails for each activity and make two reminder calls to encourage completion of each activity.
9. Clinicians in the SDM Training arm will complete a second SPI about 8-12 weeks after the first and will have the opportunity to participate in monthly 'office hours' sessions—conference calls open to all participants in this arm that will be facilitated by SDM experts, primary care physicians and/or a gastroenterologist, to discuss cases and field questions and challenges that come up as they put the skills into practice.
10. After each eligible patient visit, staff will email a short questionnaire to participating clinicians. Staff will follow up with two reminder emails at 24 and 48 hours to complete the questions.
11. After patient enrollment is complete, staff will schedule an exit interview with clinicians. For participants who are not able to attend in person, the interview will be conducted by phone.

Patient and caregiver recruitment:

1. Study staff will review clinic schedules and medical records to identify eligible patients for participating clinicians prior to their scheduled visit. An Epic Report will be created to assist with this screening and eligibility review.
2. About two weeks before the visit, the research coordinator will send a cover letter signed by the participating clinician and an information sheet describing the study to all eligible patients. The cover letter will have information for participants who wish to opt out of the survey. Eligible patients at Maine Medical Center will also receive a post-card they may send back to opt-out of the study.
3. 1-3 days before the visit, staff will call all eligible patients who did not opt out to discuss the study and answer any questions. Staff will inquire about subject's preference to receive survey via email or mail. If email is preferred, staff will discuss privacy and obtain permission to send the survey via email without send secure (and confirm address). Study staff will read the following statement to patients, "The Partners HealthCare standard is to send email securely. This requires you to initially set up and activate an account with a password. You can then use the password to access secure emails sent to you from Partners HealthCare. If you prefer, we can send you "unencrypted" email that is not secure and could result in the unauthorized use or disclosure of your information. If you want to receive communications by unencrypted email despite these risks, Partners HealthCare will not be held responsible. Your preference to receive unencrypted email will apply to emails sent from this research study only. If you wish to communicate with other research staff at Partners regarding additional studies, your preference will have to be documented with each research group." After reading the required warning language, study staff will ask for the patient's verbal agreement. The agreement and agreement date will be noted in the research records. Finally, staff will determine whether a caregiver will be involved at the visit and if so, staff will obtain contact information for the caregiver.
4. After the visit, staff will send the patient a survey packet. The mailed survey packets will include a $5 incentive. Patients completing the survey via RedCap will receive an email with the direct link to the survey.
5. Patient consent for the study will be implied by return of the completed survey.
6. Staff will also send a survey packet to the caregiver if the patient identified one. Staff will make up to three reminder phone calls in an attempt to get a response and may complete the survey via the phone. Reminder packets will not be sent to caregivers.
7. Staff will make up to three reminder phone calls (or emails for patients who preferred email). For those who don't respond to the initial survey and reminders, study staff will send all patients one reminder paper survey packet. For patients who initially received the email link, the paper packet will include their $5 incentive to complete the survey. Study staff will then make up to 3 additional reminder calls to non-responders. Patients will be given the option to complete the survey by phone.
8. Approximately one year after initial visit with PCP, a research coordinator will confirm status of each patient and will document any colorectal cancer screening tests and procedures completed since the visit from the medical record.
9. Staff will identify patients who did not receive their preferred approach to colon cancer screening and will mail a letter notifying patients about the second survey. The mailed letter notifying patients about the survey ~~packet~~ will contain the $5 incentive.
10. Study staff will follow a similar protocol as with the initial survey by making up to three phone call attempts to reach the patient and administer the survey by phone.
11. All participants who complete a survey will receive a thank you note.

Patient and caregiver recruitment during COVID-19:

Given the COVID-19 pandemic, we have to make modifications to our patient recruitment process. Physician schedules have been in flux; with most patient appointments being converted to a telehealth visit and confirmed about a week before the visit. Given this new scheduling process, we can no longer screen patients weeks in advance of the visit, nor send an invitation letter to the patient about the study. Instead, we will screen visits about a week before the visit and send the patients the invitation cover letter, information sheet and survey after their visit occurs. The process is outlined below:

1. About a week before scheduled visits, study staff will review clinic schedules and medical records to identify eligible patients for participating clinicians. An Epic Report will be created to assist with this screening and eligibility review.
2. After confirming the visit occurred, staff will send the patient a survey packet including an invitation cover letter signed by the participating clinician, an information sheet describing the study, the survey, and a $5 incentive. The cover letter will have information for participants who wish to opt out of the survey. The cover letter will also have the REDCap online link for patients who wish to complete the survey online.
3. Patient consent for the study will be implied by return of the completed survey.
4. For patients who didn't opt out, staff will make up to three reminder phone calls for the initial survey packet.
5. For those who don't respond to the initial survey and reminders, study staff will send all patients one reminder paper survey packet. Study staff will then make up to 3 additional reminder calls to non-responders. Patients will be given the option to complete the survey by phone.
6. Staff will also send a survey packet to the caregiver if the patient identifies one. Reminder phone calls will not be conducted and reminder packets will not be sent to caregivers.
7. Approximately one year after initial visit with PCP, a research coordinator will confirm status of each patient and will document any colorectal cancer screening tests and procedures completed since the visit from the medical record.
8. Staff will send a letter about the second survey to all patients who are still alive and who did not receive their preferred approach to screening. The mailed packet will contain the $5 incentive.
9. Study staff will make up to three phone calls to administer the survey by phone for all non responders. All participants who complete a survey will receive a thank you note.

All study staff are CITI certified and will receive training from the PI and program manager in the study protocol. We will hold regular meetings to review screening, enrollment and completion data.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

- At MGH, BWH, NWH, NSMC and MMC:
    - All clinician participants will receive a total of $100.
    - Clinicians in the SDM skills arm will receive 2-3 hours of risk management CME credit, as well as MOC Part II credit.
    - Clinicians' name will be entered into a quarterly lottery for a $50 amazon gift card each time they complete a survey on one of their patient participants.

- Clinicians' name will be entered into a lottery for a $50 amazon gift card upon completion of the exit survey.
- Clinicians' name will be entered into a lottery for a $50 amazon gift card upon completion of the exit interview.

- Patients and caregivers will receive a $5 incentive with each survey.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Recruitment_Of_Research_Subjects.pdf

Guidelines for Advertisements for Recruiting Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Guidelines_For_Advertisements.1.11.pdf

Remuneration for Research Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Remuneration_for_Research_Subjects.pdf

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

There are no formal written consent procedures in this project for either patients, clinicians, or the non-intervention group. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required. Clinician consent will be implied by email indicating interest and patient and caregiver consent for the study will be implied by completion of the first questionnaire.

Clinicians will be provided a written information sheet that describes the requirements of the study and will be instructed to send an email to the PIs or study staff indicating their interest in participating. By agreeing to be on the study, clinicians will give consent to study staff to identify and contact their eligible patients.

Eligible patient participants will be given an information sheet that describes the risks and benefits of the study and a cover letter inviting them to participate in the survey. The invitation will include information about how to opt out of the survey portion of study. Eligible patient participants at Maine Medical Center will also receive a post-card that may send back to opt-out of the study. Eligible patients sent a survey packet during the COVID-19 pandemic will also see information about how to opt out of the survey portion of the study in the invitation cover letter. Patient subjects will be given 7 days to review the material and opt out by calling or emailing the study staff. Participants who do not opt out will be contacted by phone by research staff and can indicate their decision to accept or decline participation when contacted. Consent will be implied by the return of the completed survey.

The principal investigators' names and contact information will be available on the information sheet if participants have any questions or concerns about the study. The study staff will be

available by phone or email to discuss the study and answer any questions. Each site has at least one primary care physician co-investigator who will be available by pager and study staff/PI will be available by phone to answer any questions.

Patients and caregivers will give verbal consent if they wish to receive surveys via unencrypted emails. The IRB information regarding send-secure vs. unencrypted emails will be included on the invitation and research staff will discuss this with the patients when they join the study. Patients and caregivers may also be read the IRB policy and ask for verbal consent to receive unencrypted emails over the phone. Participants can choose to receive the surveys via a send-secure email or on paper in the mail if they do not wish to receive unencrypted emails. Participants during the COVID-19 pandemic will all receive a paper survey and may choose to complete the survey online via the REDCap link provided in the cover letter.

Study materials will emphasize that whether or not patients participate will have no effect on the health care they receive.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:
https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb

For guidance, refer to the following Partners policy:
Informed Consent of Research Subjects:
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Informed_Consent_of_Research_Subjects.pdf

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

The data sources will be clinician surveys, transcripts of simulated patient interactions, patient surveys, caregiver surveys and, electronic health record information.

There are no foreseeable safety risks to participants for participating in a simulated patient interaction or completing a survey. Study staff will protect the privacy of research study participants as described in the Privacy and Confidentiality section. It is possible that participants may be upset by a question in the interview or survey, although our experience with similar questionnaires in other topics (including breast cancer decision making and decision

making for joint replacement surgery) have found that it is rare for participants to be upset. Nevertheless, study staff will screen for adverse events and address them as described in the next section.

Study data will be accessible at all times for the Co-PIs to review. The project manager and co-PIs will examine study conduct including enrollment, accrual, drop-outs, and protocol deviations on a weekly or every other week basis with the staff at each site. Study staff will review study related data including comments from the SPIs, reminder phone calls to participants, participant surveys and will notify the PI about any serious or moderate potential adverse events (AEs) immediately and any minor or potential ones at regular meetings. The Co-PIs will review AEs individually real-time and in aggregate on a regular basis at team meetings. No SAEs are expected based on the minimal risk trial. However, the Co-PIs and co-investigators will review potentially serious adverse events (SAEs), as soon as they are discovered. The Co-PIs will ensure all protocol deviations, AEs, and SAEs are reported to the IRB within required time frame based on severity, and will file an HRC AE Form within 10 working days as needed.

There are no formal stopping rules for this minimal risk study.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

No serious adverse events are expected. The name and contact information for the principal investigator will be included on study information sheet as well as contact for study staff and MGH IRB in case participants have a problem. We will have a clinical co-investigator for each topic who will be able to consult on any clinical issues that arise during the course of the interviews or surveys. However, if a serious adverse event occurs relating to the study, then the principal investigator will report the event to the IRB within 24 hours and will file an HRC Adverse Event Form within 10 working days. If a mild or moderate adverse event occurs, the principal investigator will summarize the event in the progress report at continuing review.

Study staff will be instructed to review surveys within 48 hours of receipt and to notify the PI about any potentially serious events immediately and all other events at regularly scheduled meetings. Study staff will keep records of any feedback, questions, concerns and/or complaints that are received and we will address them with the co-investigators and staff as needed.

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

The study staff and the principal investigator at each site will have routine meetings during the study period to ensure the project proceeds as intended per the protocol. All participant screening and enrollment will be tracked on password protected servers using an Access or RedCap database. The information is stored behind a firewall and only study staff will have access to it as needed. We will track recruitment rates and response rates weekly and identify issues as they come up. The study staff will complete all required documents for the study binder and this will be reviewed quarterly by the project manager and one of the principal investigators.

Limited data will be kept on clinician non-responders for those who received an individual invitation (site, age, gender, patient volume and years in practice) as well as patient non-responders including age, gender, physician, and all elements in the eligibility screener. This information will be used to examine non-response bias.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/DSMP_in_Human_Subjects_Research.pdf

Reporting Unanticipated Problems (including Adverse Events)
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Reporting_Unanticipated_Problems_including_Adverse_Events.pdf

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

Special efforts will be made to protect the privacy of subjects. We will review the subject's medial record to confirm eligibility to participate in the study. We will have names and addresses of eligible participants and this information will be kept separate from the study data (e.g. surveys and/or interview notes). All participants--patients, clinicians and caregivers--will receive a code number and the surveys and other data will only be identified by code number. A

separate password-protected electronic file will contain the codes linked to identifying information. Only the MGH study staff and investigators will have access to this file. These will be kept as long as required by the research project. After the study has been completed the personal contact information of all eligible participants will be destroyed.

All files (e.g. eligibility screeners) that contain PHI will be kept in a locked file cabinet or in a secure offsite file storage location or on a password protected Partners shared drive.

Patient confidentiality will be maintained as is routine for all patient care privacy guidelines. All research staff are CITI certified and will be trained on the importance of data confidentiality.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

To promote research replicability, transparency and future use of the data, de-identified data sets will be created and will be available, by request, to outside researchers. After the study results have been published, de-identified data sets will also be deposited in an open access service such as, ICPSR (https://www.icpsr.umich.edu/icpsrweb/). On ICPSR, individuals must register and agree to ICPSR's Responsible Use statement prior to accessing datasets. Additionally, before a dataset is made available for access, ICPSR completes a detailed review of all datasets to assess disclosure risk. If necessary, ICPSR modifies data to reduce disclosure risk or limits access to datasets for which modifying the data would substantially limit their utility or the risk of disclosure remains high. No information that contains identifiers or that could be used to link an individual to the data will be included in the de-identified data set. The information sheets will contain the following language: After the study is completed, all identifiable information will be removed from the data and after removal, the de-identified information will be deposited in an open access service to promote use of the data by other researchers.

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

No identifiable data on Partners patients will be stored outside MGH. MMC patient data that is collected outside Partners will be received by the MGH research team (see details below).

MMC will have access to the clinician participant data across all sites, as needed, to schedule and conduct the simulated patient interactions. Any emails that contain identifiable clinician data will be sent using SendSecure, and any large files will be sent using secure file transfer. MMC will only have access to de-identified data sets for the Partners patients and caregivers.

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

Eligibility screeners, patient, caregiver and clinician surveys, and medical record information will be collected from participants at MMC, by MMC-affiliated study staff. This patient health information is necessary for assessing patient eligibility for participation and for administering the study protocol. As such, this patient information will be sent from MMC to MGH study staff via a secure file transfer or REDCap. The paper surveys collected at MMC will be scanned and sent to the MGH research team using a secure file transfer, and the paper copies will be transported for ultimate storage or confidential disposal at MGH.

All electronic files that contain patient identifiers will be kept Partners protected servers and will only be accessed with Partners computers or encrypted laptops.

Eligibility and medical chart review data will be collected via REDCap (Research Electronic Data Capture). REDCap is a free, secure, HIPAA compliant web-based application hosted by the Partners HealthCare Research Computing, Enterprise Research Infrastructure & Services (ERIS) group. The system offers easy data manipulation with audit trails, reports for monitoring and querying participant records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus).

[i] US Preventive Services Task Force. Screening for colorectal cancer US Preventive Services Task Force Recommendation Statement. The Journal of the American Medical Association 2016;315(23):2564-2575.
[ii] Hoffman T, Lewis CL, Pignone MP, et al. Decision-making processes for breast, colorectal, and prostate cancer screening: the DECISIONS survey. *Medical Decision Making*. 2010;30(5 Suppl):53S-64S.
[iii] Sepucha K, Stringfellow V, Fowler FJ. Shared Decision Making (SDM) Process Survey: Validity and Reliability of a Short, Patient-Reported Measure of SDM. 2017 Society for Medical Decision Making Annual Meeting abstract.
[iv] Sepucha K, Feibelmann S, Cosenza C, Levin CA, Pignone M. Development and evaluation of a new survey instrument to measure the quality of colorectal cancer screening decisions. *BMC medical informatics and decision making*. 2014;14(1):72.
[v] Hoffman RM, Elmore JG, Pignone MP, Gerstein BS, Levin CA, Fairfield KM. Knowledge and values for cancer screening decisions: Results from a national survey. Patient Educ Couns. 2016 Apr;99(4):624-30.
[vi] Health Information National Trends Survey. https://hints.cancer.gov/ Accessed December 5, 2016.
[vii] DeSalvo KB, Bloser N, Reynolds K, He J, Muntner P. Mortality Prediction with a Single General Self-Rated Health Question: A Meta-Analysis. *Journal of General Internal Medicine*. 2006;21(3):267-275. doi:10.1111/j.1525-1497.2005.00291.x.
[viii] Morris NS, MacLean, CD, Chew LD, Littenberg B. The Single Item Literacy Screener: evaluation of a brief instrument to identify limited reading ability. *BMC Family Practice*. 2006;7(1):1.
[ix] Brice JH, Foster MB, Principe S, Moss C, Shofer FS, Falk RJ, DeWalt DA. Single-item or two-item literacy screener to predict the S-TOFHLA among adult hemodialysis patients. *Patient education and counseling*. 2014;94(1):71-75.

[x] Leader A, Daskalakis C, Braddock C, Kunkel EJ, et al. Measuring Informed Decision Making about Prostate Cancer Screening in Primary Care. Med Dec Making. 2011; 32(2):327-36.
[xi] Price EL, Bereknyei S, Kuby A, Levinson W, Braddock CH. New elements for informed decision making: a qualitative study of older adults' views. Patient education and counseling. 2012;86(3):335-341.