Facilitators and Barriers to Cancer Screening: Stakeholder Perspectives on Implementation

NCT04683744

December 8, 2020

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Support Provided by:
Patient-Centered Outcomes Research Institute (CDR-2018C3-14715)

Affected sections	Summary of revision/change	Date

Co-Investigators/Key Personnel	Removed investigators: Stanley Taylor, Abigail Garcia, Abigail Sachs, and Katie Claxton. Added investigators: Heather L. Anderson, Heather M. Kinney, Judy Kline, and Samantha Vershaw.	July 21, 2021
2.0 Objectives; 4.0 Research Plan; 5.0 Data Analysis Plan	Addition of provider survey	July 21, 2021
4.0 Research Plan	Removed plan to recruit patients who completed the randomized clinical trial for Aim 3 study procedures.	July 21, 2021
4.0 Research Plan	Clarified inclusion and exclusion criteria for patients enrolled for Aim 3 study procedures	July 21, 2021

1.0 Background & Rationale

CRC Screening: Colorectal cancer (CRC) is the second-largest cancer killer in the U.S., and low screening rates leads to thousands of preventable deaths. Each year, over 140,000 people are diagnosed with CRC and more than 50,000 die.[1] Under 65% of eligible adults are current with screening, a rate that pales in comparison to breast and cervical cancer screening.[1-3] Raising the CRC screening rate to 80% by 2018, which was the Colorectal Cancer Roundtable's goal, would have prevented over 20,000 deaths from CRC per year and 203,000 deaths by 2030.[4]

"Precision prevention" in this area is a promising way to motivate screening and help patients choose the best test for them. Leading guidelines approve multiple testing strategies, including colonoscopy every 10 years, flexible sigmoidoscopy every five years, annual stool testing with high-sensitivity fecal occult blood testing (FOBT) or fecal immunochemical testing (FIT), or stool testing for high risk DNA.[3,5,6] Colonoscopy is the most sensitive and specific for identifying polyps or cancers,[6-8] and is best known. But it is an invasive procedure involving a lengthy preparation, IV sedation, and the need to take a day off. There are significant risks, including hemorrhage and perforation.[5]

Stool (or fecal) blood testing is the second most commonly utilized approach, and many patients prefer stool testing to colonoscopy when they are informed about both tests.[9-15] We concentrate here on FIT since it is widely used and available nationwide, and is recommended by all major guideline organizations.[3,5,6] Stool blood testing may be done in the privacy of one's home, is low cost, and requires no preparation. The main limitations are that it must be done annually, it requires the patient to handle stool, and all positive tests require evaluation with colonoscopy. Newer forms of stool testing, such as Cologuard, which combines FIT with testing for high risk DNA, are being used relatively rarely, and they can be considered similarly to FIT for this application, except that they may be performed every 3 years.[5]

In a recent study, an outreach program that recommended just colonoscopy for screening resulted in a 38% uptake, while recommending a stool test or offering a choice between colonoscopy and stool test resulted in uptake of 67% and 69%, respectively.[16] Multiple national organizations recommend that providers describe and explain the alternatives to colonoscopy. A slogan used by the 80 by 2018 initiative declares that "The best CRC screening test is the one that gets done."[17,18]

Precision prevention: Guidelines recommend only colonoscopy for patients with particularly high risk for CRC, such as those with a significant family history, a genetic condition such as Lynch syndrome, or inflammatory bowel disease.[3,19] Approximately 90% of patients lack these risk factors and are considered "average risk," so can choose any CRC screening test, according to guidelines. But even within this average risk group, people have varying chances of having an "advanced colorectal neoplasm" (ACN), i.e. a colorectal cancer or precancerous polyp.[20,21] A

polyp counts as “advanced” if it is greater than 1 cm or has high-risk pathology (villous histology or high-grade dysplasia).

An individual’s chance of currently having an ACN affects the comparative effectiveness of CRC screening tests, and, thus, is relevant information for making a screening test decision. Colonoscopy has higher effectiveness in patients who have a high probability of having a current ACN because of the larger chance that colonoscopy will identify a dangerous that should be removed.[20,22] Nearly all ACN are polyps rather than cancers (15:1 ratio in a recent study),[20] and polyps are considered the prime target of screening since they can be removed to prevent cancer.[23]

In patients whose probability of having a current ACN is lower, the burdens associated with colonoscopy may be difficult to justify since the chance of finding a lesion that should be removed is lower. And the chance that FIT or Cologuard will fail to identify a dangerous polyp or cancer is lower in a patient with lower baseline risk of ACN. FIT and Cologuard are approved for all average risk patients because they provide long-term risk reduction in colorectal cancer that rivals colonoscopy.[24,25] Still, failing to identify a polyp or cancer in the colon is a negative outcome of screening (a “false negative”),[25] so it is important that the chance of this occurring is smaller in patients with lower baseline risk of ACN.

Validated, usable rules for estimating the probability of current ACN in average risk patients are available. A prediction rule developed and validated by Dr. Tom Imperiale, a member of the study team uses five variables (gender, age, CRC family history, waist circumference, and smoking history) and identifies a wide range of risk for current ACN among average risk patients. For patients with “high-average” risk (22%), personalized messages in our decision aid and provider notification highlight the advantage of colonoscopy because of the likelihood of finding and removing an ACN. For patients at low risk for ACN (2% or 4%), personalized messages highlight the advantage of stool testing, due to the relatively low chance of failing to detect ACN.

Disclosing information about a patient’s risk of having a current ACN has potential to increase uptake of screening. Letting patients know that their chance of having an ACN is low can support decisions to choose and complete the FIT test. Knowing that a patient who prefers FIT has low ACN risk may help providers overcome their hesitancy to order this test, by reassuring them that the chance of FIT’s missing a cancer or dangerous polyp for this patient is low. Informing patients and providers that the patient has a high-average risk for an ACN can motivate discussion of screening colonoscopy and completion of that test.

At a system level, guiding patients at high-average risk toward colonoscopy and those with low-average risk to FIT could improve the efficiency of screening.[20,26,27,28] While colonoscopy is an effective screening test for all individuals with average risk from ages 50 to 75, it is more cost-

effective for those with higher chance of ACN. If all eligible patients chose colonoscopy, endoscopy centers would be overwhelmed.[29-31] Given that the recently validated rule found that over 50% of the population had low- or very-low risk of having an ACN, the impact on reducing over-use of colonoscopy and the cost of CRC screening could be substantial. (RQ-3)(RQ-4)

Current clinical practice involves calculating patient risk in other areas. More complicated calculators, such as the Atherosclerotic Cardiovascular Disease risk estimator used to determine need for statins, are already in common use. Calculating risk is relatively easy using the short version of the Imperiale rule, since it relies on just five variables that are either recorded in the medical record (age, gender) or are easy to collect from patients and could be placed in the medical record (smoking history, waist circumference, family history).

Decision Aids: Informing patients about their options for CRC screening could produce higher quality decisions, improve the match between patient preferences and tests performed, and increase uptake of CRC screening. Decision aids (DAs) are a promising tool for accomplishing this goal. While DAs are not widely used in clinical medicine, a 2014 Cochrane review identified 115 randomized, controlled trials of DAs. These studies show that compared to usual care, DAs increase patient knowledge, improve patient-provider communication, and increase uptake of recommended interventions in many areas.[32] Ten randomized trials have tested a total of 7 different DAs designed for CRC screening.[33-39]

A big challenge has been getting decision aids to patients; despite studies showing benefits of decision aids in many areas, relatively few patients receive these aids. Promising recent developments include incentivizing healthcare systems to provide decision aids, including reimbursement for patient use of approved decision aids.[40] Encouraging providers to "prescribe" decision aids to their patients also has promising results.[41]

COVID-19 Pandemic: Since the COVID pandemic began in the United States in March 2020, cancer screenings and other preventive services, such as Hgba1c and BP checks, have plummeted, and rates have remained depressed even with re-opening of clinical services. These challenges for screening and prevention may continue for many reasons, including increased telemedicine, decreased patient willingness to come to health centers, severe work and living stress for patients, and changes in patient perceptions of health risks and prevention.

Clinics are already trying to adapt, for instance by finding ways to offer preventive services outside clinic, such as home stool testing for CRC screening and telephone outreach to provide social services, health reminders, and reassurance that infection risk at clinic is low. These efforts have only begun and are poorly understood. Moreover, patient perceptions of disease risk and risk from COVID19 are unknown. If we fail to identify ways to effectively deliver

screening and prevention during the COVID19 pandemic, many patients will die unnecessarily from non-COVID19 conditions.

Randomized Clinical Trial *Helping Patients and Providers Make Better Decisions about Colorectal Cancer Screening* (Indiana University IRB# 2004109966) The study team is currently conducting a randomized clinical trial testing whether providing patients and their healthcare providers with personalized messages about ACN risk results in higher screening uptake and higher decision quality (i.e, informed choice and receipt of the preferred screening test), compared to an approach that does not utilize ACN risk. In this clinical trial, all patient-participants are viewing a decision aid that provides basic information about CRC screening. For half the patients, the decision aid also includes their chance of currently having an ACN, the predicted frequency of ACN (icon chart), and implications for screening test effectiveness and choice. All healthcare provider-participants are being sent a message through their respective Electronic Health Record (EHR) system notifying them that their patient is due for CRC screening. For half the healthcare providers, the message also includes their patient's chance of currently having an ACN and implications for screening test effectiveness and choice.

Engagement (PC-1), Dissemination, and Implementation:
The trial also provides an opportunity to conduct observational and qualitative work to study the barriers and facilitators to implementing decision aids, provider notifications, and personalized risk analysis for colorectal cancer screening. In addition, we have the opportunity to use qualitative and observational methods to assess the impact of the COVID pandemic on CRC screening and on other recommended, evidence-based screening, and to assess perspectives of leadership, providers, staff, and patients. Finally, we can use similar observational and qualitative methods to identify responses by clinics and healthcare to the COVID pandemic, and assess their impact and facilitators and barriers to their implementation.

We have worked closely with leadership, quality improvement, and information technology teams at both our partner healthcare institutions to develop and pilot the system we are studying in the randomized trial. We are building on this engagement to identify effective methods for providing decision aids and provider messages through an EHR. Staff and providers involved will potentially become champions and "super users" for future implementation of decision aids and provider notifications in their clinics. (PC-4) These efforts will be overseen by co-investigator Dr. Damush, who has extensive experience performing stakeholder and key informant formative and summative evaluations to understand the current state, existing barriers, and potential facilitators to overcome contextual barriers in implementation strategies.[42,43] (PC-1)

2.0 Objectives

Our study team will engage with the leadership, staff, and providers in our partner healthcare systems, to identify facilitators and barriers to implementing patient decision aids and provider notifications as well as cancer risk assessment tools, for colorectal cancer screening, and for other evidence-based cancer screening during the COVID pandemic and, potentially, after the conclusion of the pandemic.

At the conclusion of our study, we will have extensive information regarding how best to provide decision aids through an EHR portal, with or without personalized information, and to deliver provider notifications, which can guide broader implementation.

Our study will involve, first, interviews with staff and providers at our partner healthcare systems to identify facilitators and barriers to implementing decision aids and provider notifications for colorectal cancer screening. In addition to the interviews, providers enrolled in randomized clinical trial *Helping Patients and Providers Make Better Decisions about Colorectal Cancer Screening* (Indiana University IRB# 2004109966) and were sent a screening reminder and personalized message will be surveyed via email to evaluate the provider notification.

Secondly, we will interview patients to identify perceptions of prevention during the COVID19 pandemic including risk perception and barriers to screening, perceptions of risk from both the pandemic and disease, and patient cancer screening and risk prevention behaviors engaged in or postponed during the pandemic and patient rationales for their decisions. This part of our study will suggest potentially promising approaches for providing prevention and disease management during the COVID19 pandemic, which can then be tested in comparative effectiveness and implementation studies.

Thirdly, we plan to collect data from both health systems about their screening rates and volume of in-person vs. telehealth visits prior to the COVID-19 pandemic and compare with data during the COVID-19 pandemic. And to provide context to this data, we will also collect data about local, regional, and state COVID-19 cases, restrictions, executive orders, and COVID-19 vaccine development from public resources such as the Regenstrief COVID-19 Dashboard, Indiana COVID-19 Data Report, and the CDC website.

3.0 Aims

Aim 1: Identify facilitators and barriers to implementing decision aids, provider notifications, and personal risk calculation using an electronic health record to promote colorectal cancer screening.

Aim 2: Identify the challenges and facilitators of effective cancer screening and prevention in primary care during the COVID19 pandemic among leadership, providers, and staff at two healthcare systems.

Aim 3: Identify patient knowledge, attitudes, and beliefs that influence decisions to engage in cancer screening and prevention at two healthcare organizations during the COVID19 pandemic, and barriers to uptake**.**

4.0 Research Plan

Decision Aid and Provider Notification Implementation (Aim 1):
Leadership, providers, and staff at IU Health and Eskenazi Health have always worked closely with our research team on colorectal cancer screening projects due to our shared interest in increasing CRC screening uptake rate. More recently, we have developed the proposal and currently conducting the randomized trial to provide decision aids through the patient portal of the EHR systems (Epic at Eskenazi, Cerner at IU Health). Both institutions wish to use these portals more frequently in patient care. (PC-1)

We will study the facilitators and barriers of delivering decision aids to patients, systems for carrying out risk assessments and notifying providers, also through the EHR, by soliciting input from patients, providers, and staff through interviews and surveys.

Interviews
We plan to meet with providers, staff, and leadership at our partner healthcare systems every 3-4 months for approximately two years. During these interviews, we will ask for their thoughts about implementing decision aids, provider notifications, and using cancer risk assessment tools in their health center or healthcare system. The questions will be specific to colorectal cancer screening and may also be about other cancer screenings as well as preventive healthcare services. We plan to share experiences and findings of our randomized trial being conducted concurrently with this study and ask for reactions and feedback.

These interviews can be held individually with a member of our research team, or if there are other participating providers or staff from the same healthcare system and they all agree, the interviews can be held in a group meeting.

We can conduct these interviews or meetings by phone, videoconferencing platform, or in-person according to the participants' preference and COVID-19 pandemic restriction guidelines.

We expect the interviews to vary in length especially if they are conducted individually or in a group; however, we estimate the meetings will take no longer than an hour.

Participants will be given a $100 gift card after each interview or meeting.

Enrollment: Our IU Health and Eskenazi Health provider, staff, and leadership stakeholders are scheduling times for the PI and Co-I's to attend quality improvement and population health meetings. These meetings focus on identifying improvement goals for their practice, including increasing colorectal cancer screening rates. During these meetings, we will briefly describe our study and ask if anyone is interested in learning more. Those individuals who express interest will be contacted by a study team member by phone or email based on the interested persons' preference. We will email the study information sheet to the interested person and follow-up by email or phone, again based on the interested persons' preference. We will answer all questions to the persons satisfaction. We will then obtain verbal consent at the first scheduled meeting prior to initiating the interview and recording.

We will also use a snowball approach to recruit additional participants by asking participants to assist in identifying other potentially interested providers or staff at their health center or healthcare system. A study team member will contact these recommended individuals by email with a brief description of the study and instructions to respond within two week if they do not wish to be further contacted. After two weeks, we will follow up with the remaining potential participants to gauge their interest and availability in participating. If the potential participant is interested, we will email them the study information sheet and follow-up by email or phone to answer questions. Because the risk of this study is low, we will obtain verbal consent to participate at the first scheduled meeting prior to initiating the interview and recording.

Throughout the study, we will confirm interest and continued willingness to participate at the end of each interview and meeting.

Eligibility: Individuals will be eligible if they are employed by one of our partner healthcare systems (IU Health or Eskenazi Health)

Data Collection: We plan to record all meetings/interviews as well as take detailed notes. The research team will review the notes after each meeting and determine if the recordings need transcribing for more detailed review. All recordings will be transcribed and de-identified. A cross walk file will be kept password protected by key staff with limited access. Recordings will be kept on the study project folder.

Surveys

Our randomized clinical trial *Helping Patients and Providers Make Better Decisions about Colorectal Cancer Screening* (Indiana University IRB# 2004109966) enrolls providers to participate in the study. Half the providers are randomized to receive a reminder that their patient is due for colorectal cancer screening, and their patient's chance of currently having an ACN and implications for screening test effectiveness and choice. We plan to invite providers who were sent at least one of these notifications to complete a survey after their completion in the randomized trial.

The survey data will be collected by emailing the providers a link to complete the survey directly in a web-based, HIPAA-aligned data collection system (REDCap). Data will be collected with an investigator created measure to evaluate the notification. Satisfaction will be measure with an 11-item scale using Likert-type response options where 4 = strongly agree to 1 = strongly disagree, and usability will be measure with five multiple choice questions. At the end of these 16 items, providers will be invited to share additional thoughts in a text box field. We will program REDCap to resend the survey 2 more times if the provider does not complete.

We expect the survey will take less than 3 minutes to complete, and the providers will be mailed a $20 gift card after completing the survey.

Enrollment: Study staff working with the clinical trial monitor patient enrollment. When study staff determine that patients from a provider are no longer being recruited and enrolled, that provider's participation in the trial will end. Within approximately 1 month of the provider coming off the clinical trial, study staff will send the provider the survey through REDCap. The body of the email containing the survey link will inform the provider that they are being asked to complete a survey, the purpose of the survey, a statement regarding any potential risks and benefits, a statement that completing the survey is voluntary, and the Principal Investigator's name and contact information. Clicking on the link to access the survey will confirm consent.

Eligibility: Providers who enrolled in the clinical trial *Helping Patients and Providers Make Better Decisions about Colorectal Cancer Screening* (Indiana University IRB# 2004109966), and received at least one notification containing the reminder that their patient is due for colorectal cancer screening, and their patient's chance of currently having an ACN and implications for screening test effectiveness and choice.

Cancer screening and prevention in primary care during COVID19 (Aim 2):
We will expand our planned Aim 1 interviews with leadership, providers, and staff to cover cancer screening beyond colorectal cancer and cancer screening during the COVID-19 pandemic. While we will be interested in all health system participants' comments, we anticipate that a subset of these participants will have more knowledge about the impact COVID-19 had on their health center and health system. With this subset of health system participants, we will spend more time asking them to reflect on challenges in prevention during the COVID-19 pandemic, initiatives that have been tried to promote screening and prevention, and barriers and facilitators of the initiatives.

Health system leadership, providers, and staff will be informed of these COVID-19 focused interviews when they enroll in the study as part of Aim 1.

As with the interviews in Aim 1, these interviews will be conducted by trained project staff over the phone, video conferencing, or in-person according to the participants' preference and

pandemic restrictions. Project staff will be located in a private area and the interviewees will be encouraged to locate in a private area as well. These interviews are planned to take an hour and will be audio recorded. All recordings will be transcribed and de-identified. Participants will be mailed a $100 gift card to thank them for their time.

Data analysists from both our health system partners will query their respective EHRs' for cancer screening rates, types of screening tests, and primary care visit volume and type of visits. This data will be shared with health system leadership, providers, and staff to help them remember the time periods during the interviews and meetings.

Patient engagement in cancer screening and prevention during COVID19 (Aim 3):
We will identify patients receiving primary care from two healthcare organizations: Eskenazi Health and IU Health who were due for cancer screening at the start of the COVID pandemic.

We will identify adults age eligible for screening in the electronic health records from these two healthcare organizations who previously had either breast, cervical, or lung cancer screening and became eligible for repeat screening in April or May 2020. We will also identify patients who were scheduled for a screening colonoscopy in April or May 2020 and had the procedure cancelled due to the COVID pandemic. We will identify some individuals who completed the cancer screening after May 2020 and some who did not complete indicated screening. We will aim to enroll a convenience sample with diverse sex, race, ethnicity, and range of participation in cancer screening and prevention.

Inclusion criteria:
Patients will be eligible if they:

- completed cervical cancer screening in April or May 2017; completed breast cancer screening in April or May 2018; completed lung cancer screening in April or May 2019; or had a scheduled screening colonoscopy cancelled in April or May 2020 as noted in electronic health record
- age 50 – 75 years* for individuals screened for breast cancer; age 50 – 80 years* for individuals screened for lung cancer; age 25 – 75 years* for individuals screened for cervical cancer; age 50 – 75 years* for individuals scheduled for screening colonoscopy in April/May 2020
- Speaks English
- Able to provide verbal consent
- Accessible by phone

*age as of April/May 2020

Exclusion criteria:
Patients will be excluded if they:

- Self-report they no longer receive primary care at either of our partner health systems (IU Health or Eskenazi Health)
- Self-report that they completed the repeat screening prior to April/May 2020 and therefore, were not eligible to be screened again in April/May 2020
- For patients identified as not having the repeat screening after May 2020, self-report that they did complete the indicated screening
- Are unable to speak or read English
- Previously participated in any research projects conducted by the Principal Investigator (Peter H. Schwartz, MD, PhD)

Methods: We will mail potentially eligible patients an invitation letter to participate in a one-time interview. The invitation will include a phone number to call our research team if the patient does not wish to be further contacted. After about 1 week, we will follow up with a telephone call for all remaining patients to assess interest in our study participation. We will review the Study Information Sheet (SIS) and HIPAA authorization with the patient and email the participant both forms, arranging for a follow-up phone call as needed to further discuss and answer any participant questions. After the patient verbally agrees to participate, we will schedule a one time, phone/virtual platform (Zoom) meeting to administer a semi-structured interview. Prior to starting the interview, we will confirm verbal consent to participate and to audiotape(telephone)/videotape (Virtual Platform) the interview. The interview will take approximately 45 minutes and will be transcribed and de-identified. Participants will be compensated with a $100 gift card for completing an interview.

We will employ a semi-structured, telephone/virtual platform interview. The interview guide will be developed based on materials such as the current US preventive task force guidelines, other relevant literature, and research on perceived risk and preventive behaviors. We will continue interviews until we achieve content saturation.

We will assess patients' participation in screening and prevention and healthcare more generally during the COVID19 pandemic, planned future participation, perceived facilitators and barriers, risk perception, and sources of information. In each area, we will ask participants for reflection on changes from before the pandemic.

5.0 Data Analysis Plan

Decision Aid and Provider Notification Implementation (Aim 1):

All interviews will be audio recorded, transcribed, and de-identified. We will first conduct rapid qualitative analysis using notes taken during the interviews to identify key themes. Next we will qualitatively code using Nvivo software, with separate coding and analysis for the patient and

the leadership/provider/ staff interviews. The codebooks will include both apriori including planned constructs around risk communications, local context and adaptations and emergent codes from the stakeholders. We will run a series of planned matrices evaluating risk assessment barriers and facilitators by healthcare organization (IU and Eskenazi).

Descriptive methods will be used to analyze the quantitative survey data. The satisfaction questions have Likert-type response options, and the usability items have multiple choice response options. We will calculate the counts and percentages of each response option for each question.

Cancer screening and prevention in primary care during COVID19 (Aim 2) and Patient engagement in cancer screening and prevention during COVID19 (Aim 3):
All interviews will be audio recorded, transcribed, and de-identified. We will first conduct rapid qualitative analysis using notes taken during the interviews to identify key themes. Next we will qualitatively code using Nvivo12 software, with separate coding and analysis for the patient and the leadership/provider/ staff interviews. The codebooks will include both apriori including planned constructs around risk communications and referrals, clinical preventive services received or postponed, local context and adaptations and emergent codes from the stakeholders. We will run a series of planned matrices evaluating perceived risk and preventive services received by healthcare organization, and by consumer patient age and sex. Furthermore, we will explore contextual elements by change rates in preventive services delivered in 2020 to understand local adaptation to preventive health services amid COVID19 pandemic. We will construct flow maps of the adapted CRC screening clinical processes amid the COVID19 pandemic.

For each of the three aims, we will feedback the results to the key stakeholders for their interpretations and perceptions including the healthcare organizations, our patient advisory panel, and our investigator/staff team.

6.0 Deliverables

Decision Aid and Provider Notification Implementation (Aim 1):
At the conclusion of our study, we will have extensive information regarding how best to provide decision aids through an EHR portal, with or without personalized information, and to deliver provider notifications, which can guide broader implementation. We have worked closely with our patient and community partners, as well as the leadership, quality improvement, and IT teams at our health system partners to develop systems that can be implemented effectively and affordably in clinical care. Beyond publication and presentation, this information and the decision aids and systems will be made available to all healthcare

systems that wish to adopt approaches supported by our findings.

The broader dissemination of our results will also be supported by the involvement of national leaders and policymakers who have been involved in planning the study and will serve on an external advisory board during the study (3x per year teleconference). These include:

- Richard Wender, MD, chief cancer control officer of the American Cancer Society and chair of the National Colorectal Cancer Roundtable,
- David Lieberman, MD, President of the American Gastroenterology Association,
- Jon Keevil, VP for Clinical Decision Support at EBSCO, and
- Michael Barry, MD, former chief science officer at Healthwise.

These supplement the members of our research team -- Brian Zikmund-Fisher, PhD, and Paul Han, MA, MD – who play leadership roles in the International Patient Decision Aids Standards consortium.

Cancer screening and prevention in primary care during COVID19 (Aim 2) and Patient engagement in cancer screening and prevention during COVID19 (Aim 3):
In addition to publications and presentations of findings, we aim to identify at least four initiatives that hold promise for responding to the challenges of prevention in the COVID19 pandemic, including facilitators and barriers and patient factors. Examples could include variations in settings to accommodate level of virus risk (surgical facility; clinic; community based (e.g.pharmacy), drive throughs, and home-based systems. We will report these initiatives back to our leadership, provider, and staff participants for feedback and reflection. These initiatives would be candidates for implementation and future comparative effectiveness research.

7.0 Study Timeline

Decision Aid and Provider Notification Implementation (Aim 1):
November 1, 2020 – July 30, 2023

Cancer screening and prevention in primary care during COVID19 (Aim 2) and Patient engagement in cancer screening and prevention during COVID19 (Aim 3):
October 1, 2020 – December 31, 2021 (15 months). Initialization: October 1 – Nov. 30, 2020. Interviews: Dec. 2020 – August 2021. Data analysis: Oct. 2021 – Dec. 2021

8.0 Data Management Plan

Reportable Events: If a participant experiences an adverse event that occurs in greater frequency or severity than previously known, this will be reported to the IRB either as a prompt report if it meets reporting criteria, or at time of study closure.

Data Safety Monitoring: Dr. Peter H. Schwartz, principal investigator will have ultimate responsibility for monitoring the safety and security of the participants and data. Dr. Schwartz and his study team will engage in quality improvement practices beginning with development and then with ongoing review of study procedures. The Co-Investigators will be actively involved in quality assurance activities including monitoring of recruitment, adherence to study protocol, and adherence to any adverse event reporting.

Potential Risks: A breach of confidentiality is always a risk with minimal risk studies. In addition, participating in a research study and answering questions may cause anxiety.

Protecting against or Minimizing Potential Risks**:** For both patient and healthcare system participants, all information required for recruitment and tracking will be stored in a HIPAA-aligned database accessible only by authorized study team members. All team members will adhere to our institution's HIPAA policy and use of protected health information. All data provided by the patient and healthcare system participants will be collected and stored in a separate HIPAA-aligned database accessible only by authorized study team members. Authorization to access both databases will be managed and overseen by the project manager and the principal investigator. Audio recordings will be saved on a Department of Medicine servers. The PI and project manager will coordinate with the Department IT staff to control access to these folders. Processes and procedures have been documented and implemented to ensure the security and protection of the data within the computer operations centers, the servers, and the databases.

Participants will be assigned a unique identification number and using this number to identify the participant in all transcripts. We will keep all paper documents locked in lockable cabinets in a locked office suite.

All participants will be fully informed about the study prior to enrollment and be given the opportunity to decline to answer any questions or to discuss any issues they find troubling. They will be told that they can terminate participation at any time for any reason.

Research team members will be trained in procedures to allow participant to withdraw from the study. All study team members including those involved with the recruitment, informed consent process, and data collection will be adequately trained. Training will include passing of our institution's required Collaborative Institutional Training Initiative (CITI) modules and ongoing study-specific training from study personnel.

Protections for Research Data: Most of the data will be entered directly into one of several instruments in the study's REDCap project, a HIPAA aligned web environment. Privileges to the instruments will be granted or restricted by the PI or project manager based on what user rights are necessary to do the job. This could include no access, read only, or read and edit the data. Audio files that are created during the course of the study will be saved on the Department's servers. The PI or project manager will coordinate with the Department's IT to control access to these folders.

Protections for Participant Privacy: Initial contact with healthcare system providers and staff will be during a quality or population health meeting, or by email. Providers and staff generally are in a private area for these meetings. Providers and staff will choose their location for the follow-up emails or phone calls. The study interviews and meetings will be held in private locations. The research team member will be in a private area to conduct a phone or videoconferencing interview or meeting.

Initial contact with the patient will be a recruitment letter mailed through the US Postal Service to the address provided by the patient to be included in the EHR. The recruitment phone calls will be made from a private office to the phone number listed in the EHR and if additional phone calls are required, the recruiter will confirm with the potential participant their preferred contact number and time; the study team will make arrangements to comply with the potential participant's wishes.

Research staff will encourage the patient-participants to be in a quiet, private area for the interview; however, the participants ultimately will choose the location. The research team member conducting the interview will be in a private location.

9.0 References

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