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 Ph.D.

PROTOCOL TITLE

Improving Patient Involvement in Decision-Making in Primary Care

FUNDING

Massachusetts General Physicians Organization, The Donaghue Foundation

VERSION DATE

November 30, 2021

SPECIFIC AIMS

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

1. Demonstrate the ability to introduce and disseminate shared decision-making (SDM) programs to patients within the Partners Healthcare System. We will measure the volume and type of programs that are "prescribed" to patients.

2. Assess "prescribing" utilization, trends and patterns by clinician and across practices, and identify and understand the barriers and problems faced by clinicians in making the SDM programs an integrated part of the clinical practice of primary and specialty care. Identification and understanding of the barriers will be gained through clinician interviews.

3. Gain feedback from the patients about: their experiences, perceptions and satisfaction with receiving SDM programs; the effect the program has on their decision preference; what they think about the available options; and how they feel about making a decision. This feedback will be obtained through written and online surveys, and telephone interviews.

4. Surgery shared decision making survey: Integrate new measures to assess the quality of elective surgical decisions across the Partners Healthcare network for patients with knee and hip osteoarthritis, herniated disc and spinal stenosis and test the hypothesis that routinely measuring shared decision making for these elective surgical decisions, and reporting that data back to clinicians and administrators, has the potential to make a positive impact on the value of care provided to patients.

BACKGROUND AND SIGNIFICANCE

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

Multiple studies assessing the value of decision aids, such as the shared decision-making programs produced by the Informed Medical Decisions Foundation, have found that these tools reduce uncertainty and decisional conflict, and increase knowledge and patient's desire to participate in decision-making, without increasing anxiety. Decision aids have been

shown to increase patient involvement in treatment decisions, and are particularly helpful when the clinical evidence supports more than one treatment or testing option. Decision aids improve the ability of patients to take into account their own values when making such decisions, increase patient satisfaction and improve health outcomes. High quality decision aids present the evidence about treatment and testing options in a fashion that most patients understand. However, despite the multiple studies investigating the quality and value of decision aids and shared decision-making, their integration into the practice setting has been slow. Questions remain as to how to successfully and efficiently incorporate decision aids into the office visit and how physicians can gain the knowledge, skills, and proper attitude to promote this process where appropriate. Additionally, further information is needed about the impact of these tools and processes on the care experience from the patient and provider perspectives and on the actual care that patients receive.

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 dissemination of the programs will occur as part of routine care and will vary depending on the provider group and program. They may be sent in advance of the visit, or prescribed after the visit. The programs may also be put online and accessed by patients with a password. One common way the programs are distributed is outlined as follows:

1. Patient has visit with primary care clinician.
2. Clinician determines patient is clinically eligible for one of the SDM programs and discusses it with the patient.
3. Clinician "prescribes" program through the electronic medical record, and gives patient the one-page description of the program that automatically prints when the program is ordered. The "prescription" function in the electronic medical record triggers an email message with the order information to be sent to the Blum Patient and Family Learning Center.
4. The program is sent (or given, in the case of the "pick-up" option) to the patient with a questionnaire and pre-paid, addressed envelope. The goal of the questionnaire is to assess the patient's intentions with regard to the topic and the patient's opinion about shared decision-making prior to viewing the decision aid. After viewing the decision aid, patients will also be asked a series of general knowledge questions about the target topic and a few questions evaluating the content and comprehensiveness of the decision aid itself.
5. Some patients will receive a follow-up "post-visit" survey in the mail and a pre-paid addressed envelope several months after receiving a decision aid. The purpose of this questionnaire is to learn the extent to which viewing decision aids impacts patients' conversations with their providers and ultimately their treatment decisions.

It is difficult to anticipate the total number of patients who will receive a SDM program because the "prescription" of the program is incorporated into routine clinical care, similar to clinicians giving a pamphlet or other written patient education materials to their patients. We anticipate the target enrollment of patients to be 80,000. Patients who are eligible are:

- Adult patients in the Partners Healthcare System primary or specialty care practices.
- Patients, for whom a SDM program is clinically appropriate, based on the clinical judgment of the clinician. This includes patients with the following health

problems/concerns: general healthcare options, low back pain (chronic, acute, spinal stenosis, and herniated disc), osteoarthritis of the knee or hip, coronary artery/heart disease, benign prostatic hyperplasia, abnormal uterine bleeding, uterine fibroids, symptoms of menopause, obesity, depression, ovarian cancer screening, prostate cancer screening, colorectal cancer screening, advance directives, heart failure, diabetes, breast cancer treatment, prostate cancer treatment, insomnia, carotid artery disease, and chronic pain.

Patient decision aids are all available in English and Spanish except for 4 programs that are only available in English: *Prediabetes: Choices you can make to prevent diabetes, Pregnancy: Birth Options if your baby is getting too big, and Pregnancy: Your birth options after cesarean, Prostate Cancer: Is radiation or surgery right for you*.

The staff maintain a program log as part of their standard operating procedures so they can keep track of the programs that are sent to patients. Routine follow-up with patients who received a program is important to ensure proper "close the loop" process. Follow-up may include a phone call, post-card or email reminder to patients. Follow-up will occur within 2 weeks of the initial survey. Reminder survey packets will be mailed within 4 weeks if the patient has yet to return the survey. These patients will also receive reminder phone calls within 2 weeks of the reminder mailing. It will be mentioned to the patient as a reminder that they can return the questionnaire, if they wish, or complete the questionnaire by telephone during the phone call. Patients willing to complete the questionnaire and who have not yet viewed the decision aid will be asked only pre-viewing questions, and will be encouraged to view the decision aid and follow up for administration of the post-viewing questions.

Questionnaires will include solely, a coded unique numeric identifier for each patient. Therefore, all completed questionnaires will be stripped of any personal identifiers and/or HIPAA related information. Only MGH approved study staff for this protocol will have access to the information crosswalk needed to link this unique identifier with confidential personal information. The completed, coded questionnaires will be returned, where study staff will enter the de-indentified data into a secured online data warehouse. The online surveys will be entered directly into the data warehouse. The operating processes are as follows:

- Study staff provides questionnaires, which are then assigned a systematic unique 7-digit study ID.
- Study staff provides a tracking log for each title that is "prescribed."
- Staff will record in a secured, restricted-access tracking log the primary care practice name (of the prescribing clinician); patient's name, address, and phone number; program topic; date sent; and date returned.
- Once questionnaires have been returned, a study staff will enter the coded de-identified data into a secured online data warehouse separate from the information crosswalk with no ability to link the data back to patient's personal and HIPAA related information.

The providers' perspectives will also be collected, periodically, through questionnaires or individual interviews. An email invitation will be sent to all eligible Partners Healthcare System primary care physicians, specialists, nurses and other clinic staff involved in a patient's care to complete either the questionnaire or participate in an interview. The providers and staff will be able to choose to complete the questionnaire online or by paper. A reminder email will be sent to those who haven't completed the questionnaire within a 2-week timeframe. Study staff will work individually with those interested in the interviews, at the time of a specific project.

Patients who have indicated their consent to be contacted in the future for other studies will be contacted to see if they would be interested in participating in a pilot study examining the effectiveness of mental health decisions aids: sleeping better, depression, and anxiety. Patients will be contacted first by telephone and asked if they would be interested in participating in a survey study. If they agree to participate they will be asked to review some additional patient educational materials either online or on paper. After the patient reviews the materials, they will be asked to complete and answer the questions via phone with study staff at a scheduled time. Consent will be implied by the completion of the questionnaire. If a patient would like to complete the questionnaire via paper, an information sheet, questionnaire, and return-envelope will be sent to the patient. The project goal is to have approximately 30 eligible patients complete the survey.

Patients who have indicated their consent to be contacted in the future for other studies will be contacted to see if they would be interested in participating in a structured interview either in-person or via telephone to learn more about decision making for older adults about whether to continue colorectal cancer screening. We may also have primary care physicians (PCP) identify patients who they believe would good candidates to participate in the interviews. The PCP will provide the patient with the information sheet and if the patient is interested, the PCP will provide the research staff contact information for the subject to call to indicate their interest in participating. Subjects will be contacted first by telephone and asked their interest to participate in an interview. If they agree to participate they will be asked whether they prefer to conduct the interview in-person or via telephone and study staff will schedule a mutually convenient time. Consent will be implied by the completion of the interview. A cover letter and an information sheet will be sent by mail or email (if subjects provide verbal consent to use personal email) for those interested in an interview. The project goal is to have approximately 20 eligible subjects complete the interview.

We will conduct 60 interviews with up to 20 patients and physicians to evaluate how they interact with the patient decision aid accessed through Patient Gateway. The interviews will be conducted in-person or remotely using a videoconference approved by MGH Brigham (such as Healthcare Secure Zoom or Enterprise Zoom). Each interview using the videoconference will require a waiting room and secure password for that specific meeting. During the interview, the moderator and research subject (physician or patient) will review all the steps in the process. We will audiotape the interviews and a research coordinator will be present during the interview to take notes on the interaction. The interviews will take place at a location on the MGH campus convenient to the participant or via the approved videoconference platform. The interviews will follow structured guides.

Patients will be recruited from the database of patients who have received decision aids. For patients who have given consent to be re-contacted, study staff will telephone the patient and invite them to participate in the interview. For patients who were not asked about being recontacted for future studies, we will send the patient an invitation letter letting them know about the study opportunity and how to opt-out if they do not want to be contacted. We will also include the study information sheet with the mailing. If the person does not opt-out, study staff will call the patient and ask if she/he is interested in participating. If they agree to participate, study staff will schedule a remote interview using a secure videoconference at a mutually convenient time. The patient will be asked to consent to participating in a secure videoconference and will be asked permission for the researcher to audiotape the call. Consent will be implied by completion of the interview. A letter indicating the date and time of the interview will be sent by mail or email (if the subjects provide verbal consent to use personal email). We will include English-speaking men and women aged 40-80 years. Patients will be asked if they are enrolled in Patient Gateway. If not, they will not be eligible.

Physicians will be recruited from the database of patients who were prescribed a patient decision aid at MGH in the past. We will recruit physicians across a range of practices and specialties.

Patients who received a specialty referral where their physician provisionally ordered a decision aid will also be contacted for feedback. Their feedback on the referral process will be collected through individual interviews or surveys. A cover letter and information sheet describing the study will be mailed to the patients so that they may choose to participate or not. A reminder phone call will be placed for those who haven't completed the questionnaire within a 2-week timeframe. The patients' demographic information will be collected through an RPDR data collection.

The patients' feedback will also be collected, periodically, through individual or group interviews. An email or mailed invitation to participate in interviews will be sent to a sample of patients who indicated their consent to be re-contacted. The patients will be able to choose to participate in an individual or group interview. Participants will receive $20 for participation in the 45-minute individual interview, $40 for the 90-minute individual interview, and $60 for participation in the group interview.

A medical chart abstraction will be conducted looking at patients who have both received a decision aid and who have not. For patients who have not received a decision aid, the patients' medical records will be pulled based on the relevant ICD-9, ICD-10, or procedure (CPT) codes associated with a visit within the study timeframe.

In collaboration with Partners Center for Population Health, patients across PHS who have a surgical procedure for one of the 4 identified clinical diagnoses: hip osteoarthritis, knee osteoarthritis, lumbar herniated disc and lumbar spinal stenosis, will be surveyed about shared decision making. The shared decision making surveys will be integrated into the routine patient reported outcomes measurement (PROMS) assessments that are in current clinical practice at these sites for these clinical situations. The PROMs platform does not capture or include the shared decision making survey for all surgeons and all patients and; as a result, study staff will track all potentially eligible patients and will mail the survey to a randomly selected sample of patients who are eligible, but who did not complete the questions as part of the PROMs platform. Patients who complete the mailed survey will be asked if they are interested in participating in a short phone interview to discuss their survey responses. The patient can indicate their interest in the interview on the survey. For patients who completed the shared decision making items via the PROMS system, an invitation letter will be sent to the patient who completed the PROMs questionnaire to invite them to participate in a phone interview.

A report of surgical patients will be created by the eCare team to support identification of eligible patients. The report will identify adults across the four hospitals who are scheduled for, or who have recently had, one of the surgical procedures for the targeted diagnoses.~~,~~ We will supplement the eCare report with a query from the Research Patient Data Registry (RPDR) to identify and confirm eligible patients using their MRNs (from eCare report) or using relevant ICD-10 and CPT codes to identify patients and get required data. The RPDR query will pull information from the medical record about surgeon visits, diagnoses and treatments related to the index diagnosis (hip or knee osteoarthritis, spinal stenosis or herniated disc), imaging reports (X-Ray and MRI), pathology reports (post-surgical bone pathology), clinical and patient features (e.g. BMI, disease severity), patient demographics and contact information (to support mailing survey as needed). Specific diagnoses that may indicate that the procedure is not elective, or it's for a different diagnosis, will also be

included in the eCare report and RPDR queries to help identify patients who should be excluded (e.g. to identify patients who had a hip replacement to treat a hip fracture as opposed to hip osteoarthritis) as outlined in Table 1. The list of patients generated by the eCare report will be compared to the list from the RPDR query in order to identify any potentially eligible patients missing from either list. For patients who are not captured by the RPDR query or for whom RPDR is missing data (e.g., patient-reported outcomes data), a limited review of that patient's electronic medical record will be conducted, only covering the information listed above. These data will help study staff identify a cohort of surgical patients who are potentially eligible for the shared decision making survey. Table 1 has the specific eligibility criteria.

To ensure that the RPDR and eCare reports are providing a complete, accurate list of eligible patients, a limited review of the surgical schedules for the participating surgeons will also be conducted. We estimate that staff will need to review about 2 months for hip and knee surgeons and up to 6 months for spine surgeons to ensure a minimum number of about 300 procedures for each of the four conditions. When the review of surgical schedules identifies a patient that is not included in the RPDR query or eCare report, a review of the visit and imaging notes from their surgical consults and surgical report in their EHR chart will be conducted to determine eligibility and reasons why the patient was not identified by the eCare or RPDR reports. This limited review will be used to establish validity of the approach (i.e., eCare report and RPDR query) that we are using to identify elective surgical patients for these four clinical areas.

Based on estimates from RPDR and from analysts at Center for Population Health, we anticipate that 5,880 patients have one of the procedures for the targeted diagnoses each year and will be included in the eCare reports and RPDR queries. About 40% will have completed a PROMs assessment pre-operatively and 38% will have completed a PROMs assessment post-operatively. Our target is to receive 1,200 completed shared decision making surveys across the hospitals and four conditions over the three-year project. Ideally, we will have about 300 surveys per diagnosis and about 300 per hospital. If the shared decision making survey completions from the PROMs system are not balanced across sites or across diagnoses, we will purposively select a sample of eligible patients to receive a mailed survey in order to meet the minimum targets.

Cancer Screening Study 2020:
A subset of patients who received decision aids on: breast cancer screening, colorectal cancer screening, prostate cancer screening, or lung cancer screening will be eligible for this study. The goal of the study is to understand the decision making process between patients and providers related to cancer screening tests. The research study will be a one-time survey asking patients to reflect on conversations with their providers regarding the decision to screen for breast cancer, colorectal cancer, prostate cancer, or lung cancer in the last 2 years. Our target is to receive 400 completed surveys across all 4 clinical contexts. Eligible patients (see Table 2) will be identified and study staff will use RPDR queries to capture contact information for the study invitation packet and information on relevant cancer screening tests that the patient had completed. A chart review will be conducted to collect information related to cancer screening tests and visit notes related to cancer screening tests. This project is funded by the Agency for Healthcare Research and Quality (AHRQ).

Path to Lifestyle Change: Patients who are eligible for the research study will be participants in the *Path to Lifestyle Change* program offered through the MGH Diabetes Center. As part of the *Path to Lifestyle Change* program, the Healthwise® Decision Aid entitled "Pre-Diabetes: Which Treatment Should I Use to Prevent Type 2 Diabetes?" will be sent to participants at enrollment in the clinical program. The goal of this research study is to survey patients using a secure

REDCap link at 5 time points over 2 years (one-week post-baseline visit, 6 months, 12 months, 18 months and 24 months) to collect patient-reported outcomes related to treatment decisions. The *Path to Lifestyle Change* program is planning to recruit up to 200 participants. Once a patient has been enrolled in the *Path to Lifestyle Change* clinical program, he/she will be asked permission to use their email to send them a fact sheet and recruitment letter about a research project. The clinician from the MGH Diabetes Center who enrolls the patient in *the Path to Lifestyle Change* program will obtain permission to send the information by email. For patients who do not provide their email, they will not be sent information about the study.

Table 1: Eligibility Criteria

Eligible	Ineligible
• Adults 21 and older • Able to read and speak English • Scheduled for an elective primary total hip or knee replacement, spinal fusion, laminectomy, or discectomy or had procedure in past 4 weeks. • Primary or secondary diagnosis of hip or knee osteoarthritis, lumbar spinal stenosis or herniated disc for the procedure	• Patients with severe cognitive impairment who cannot consent for themselves • Hip and knee patients who had a hip or knee fracture within the last 12 months • Hip and knee patients with or aseptic necrosis in the past 12 months-Spine patients with severe weakness in leg/ foot, or bladder or bowel changes • Spine patients who had a spine fracture within the last 12 months • Any patients who had a possible or confirmed tumor at the surgery site within the last 12 months • Unable to confirm primarily language is English

Surgeons who see patients with these conditions across the participating sites will be eligible for a survey. Study staff will give the paper survey to surgeons in person or send via email. The survey will ask for participant's name as it may be provided in a meeting. Once we get the survey we will mark each with a code and use the study ID code as the identifier. As needed, study staff will make up to three reminders via email. The brief survey will contain questions about the surgeon's attitudes toward shared decision making, use of decision aids, and confidence in shared decision making skills. The survey participation is voluntary and surgeon implies consent by completing the survey and providing it back to study staff.

Table 2: Eligibility Criteria for Cancer Screening Study 2020

Clinical Context	Eligibility Criteria	Ineligibility Criteria
Colon Cancer Screening	• Between the ages of 45-75 • Received a decision aid for colon cancer screening	• Previous diagnosis of colon cancer • Patients with severe cognitive impairment who cannot consent for themselves • Unable to confirm primary language is English

Breast Cancer Screening	• Female • Between the ages of 35-55 • Received decision aid for breast cancer screening	• Previous diagnosis of breast cancer • Patients with severe cognitive impairment who cannot consent for themselves • Unable to confirm primary language is English
Prostate Cancer Screening	• Male • Between the ages of 45-74 • Received decision aid for prostate cancer screening	• Previous diagnosis of prostate cancer • Patients with severe cognitive impairment who cannot consent for themselves • Unable to confirm primary language is English
Lung Cancer Screening	• Between the ages of 50-80 • Received decision aid for lung cancer screening	• Previous diagnosis of lung cancer • Patients with severe cognitive impairment who cannot consent for themselves • Unable to confirm primary language is English

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.

See above section for study procedures.

Study endpoints include: 1) demonstration of the ability to introduce and disseminate SDM programs to patients, 2) assessment and understanding of "prescribing" utilization, trends and patterns by clinician and across practices, 3) feedback from patients about receiving SDM programs, and their decision preferences and comfort with making a decision and 4) Assess the quality of shared decision making for elective surgical decisions.

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.

No diagnosis or treatments will be offered or administered as part of this study. There is no medical intervention as part of this study. The standard of care is that clinicians discuss appropriate treatment options, including their benefits and risks with each patient. The standard of care at these sites is also to engage patients in shared decision making and to assess patient-reported outcomes periodically to measure the quality of care.

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 no known risks to participating individuals associated with or attributable to this project. Clinicians will provide their patients with evidence-based decision aids in much the same way they currently provide other educational materials to their patients. Additionally, completed questionnaires do not capture personal identifiers nor HIPAA related information. Only MGH approved study staff will have access to the information crosswalk.

For the mailed surgery shared decision making surveys, participants will be informed that they may refuse to answer any question. It will also be emphasized that whether participants complete the survey or not, will not impact the medical care that they receive.

If the patient completes the surgery shared decision making questions as part of the PROMs platform, the responses will be made available in their medical record per standard practice. If the patient completes the PROMs by paper, the responses will not be put in the medical record. Patients who complete the PROMs questions will also be sent an invitation letter to participate in a 30-45 minute phone interview discussing their experience with elective surgery.

Cancer Screening Project 2020:
For the cancer screening decision making surveys, participants will be informed that they may refuse to answer any question. It will also be emphasized that whether participants complete the survey or not, it will not impact the medical care that they receive. Participants who wish to complete the survey electronically will be provided with a link to the secure Mass General Brigham REDCap survey platform. Participants may also request the REDCAP survey link be sent to them via email. 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 Mass General Brigham 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 Mass General Brigham. 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, Mass General Brigham 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 Mass General Brigham 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.

There are minimal risks to participating in interviews. Participants may refuse to answer any questions and may discontinue their participation at any time. Participants’ names will not be identified in any reports or manuscript.

Path to Lifestyle Change. Patients will be informed that they may refuse to answer any question. It will also be emphasized that whether patients complete the survey or not, will not impact the medical care that they receive. Surveys will be sent electronically using the Partners REDCap platform.

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.

As stated above, there are no known risks to participating individuals in this project. The clinicians discuss with their patients, who are clinically eligible for one of the SDM programs, whether or not such a decision aid is something they are interested in receiving and watching. This is done in the same manner in which other patient educational information in more traditional medium (i.e., handouts, brochures, pamphlets) is given to patients. During the course of the discussion, if the patient expresses that he/she is not interested in program, it will not be sent to the patient. It is the patient's decision whether or not to view the programs.

The questionnaires that are included with the program or that are mailed to patients separately are optional. Patients can voluntarily complete them and send them back, but are not required to do so. An information sheet will accompany the questionnaire that explains the study in detail, including how we protect patient privacy, and explains that returning the completed surveys indicates their consent to participate in the project. We inform patients that we may share their survey data with their clinicians, as some providers have requested the feedback to make sure that their patients understand the key information in the program and to guide future conversations about the decision. We also explain that we may look at their medical record to examine whether specific tests or treatments were done (for example, to examine whether someone who viewed the knee osteoarthritis program had a knee replacement).

All patients who receive a decision aid or a study survey will also be able to indicate their consent to be contacted in the future for other studies or to discuss their decision making experiences. Of those patients who've given consent to be contacted: study staff may contact these patients via email or telephone, depending on their preferred method, to solicit feedback on all aspects of programming. The feedback may be obtained over the telephone, via email, or via focus groups. Participation in any future contact is voluntary; patients may choose to not participate at any time.

The completion of the provider and patient questionnaire or interview is also voluntary, and they may choose to skip any question they wish not to answer. No information will be shared that will permit identification of any individual.

For patients involved in the medical chart abstraction, each patient's information will be coded with a study ID to protect their privacy.

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.

As stated above, there are minimal known risks to participating individuals associated with or attributable to this project. This is a project in which patients are provided with evidence-based decision aids in the form of DVD programs or online versions of these program, which aim to help them make better, more informed decisions about the screening, management, and treatment options available to them.

For patients that are invited to complete the surgery shared decision making survey, it is estimated that it will take <5 minutes to complete the 10-12 items. The PROMs, that are part of standard of care, are measured at the same time and take about 10-20 minutes, depending on the clinical area. For patients who are interested in the phone interview it should take about 20 minutes.

All reasonable measures will be taken to protect the privacy of the data gathered to ensure that the protection of personal information. An analytic data set will be created that does not contain any personal identifiers. All data from the ECare reports, RPDR queries, and patient surveys will be kept on Partners password protected computers in a limited access shared drive folder. Only approved study staff will have access to the folder.

The paper surveys will only contain a study ID. Participant information is linked to a study ID will be kept in a password-protected file on Partners shared folder and only study staff will have access to the folder.

Cancer Screening Project 2020:
For patients who are invited to complete the cancer screening survey, it is estimated that it will take 10-15 minutes to complete. All reasonable measures will be taken to protect the privacy of the data gathered to ensure to ensure that the protection of personal information. An analytic data set will be created that does not contain any personal identifiers. All data from RPDR queries and patient surveys will be kept on Partners password protected computers in a limited access shared drive folder. Only approved study staff will have access to the folder. The paper surveys will only contain a study ID. Participant information is linked to a study ID will be kept in a password-protected file on Partners shared folder and only study staff will have access to the folder.

In interviews, participants will be told that completing the interview is voluntary and that they may refuse to answer any question, at any time and can stop at any time. The major risk to participants will be discomfort with the interview questions.

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.

Potential benefits to participants include:

- Increased knowledge (i.e. better understanding of treatment/screening options and the risks and benefits of the different options)
- Better decision quality; reduced uncertainty and decisional conflict
- Feeling more comfortable with decision
- Increased patient involvement in treatment and screening decisions
- Improved ability for patients to take into account their own values and preferences when making healthcare decisions
- Improved health outcomes

- Increased patient satisfaction

There is no direct benefit to participants who are included in the RPDR query and eCare reports or who complete the surgery **s**hared decision making survey.

The knowledge we expect to gain from this project include: 1) a demonstration of the ability to introduce and disseminate SDM programs to patients, 2) assessment and understanding of "prescribing" utilization, trends and patterns by clinician and across practices, 3) insight from patients about receiving SDM programs, and their decision preferences and comfort with making a decision, 4) a more comprehensive analysis of the quality of decisions for patients undergoing elective joint replacement and spine procedures and 5) identification of practices and surgeons who are able to achieve shared decision making.

Cancer Screening Project 2020:
There is no direct benefit to participants who complete the cancer screening shared decision making survey.

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.

Participants in this project will be adult patients with a provider in the Partners Healthcare System adult primary and specialty care practices. Patient decision aids are all available in English and Spanish except for 4 programs that are only available in English: *Prediabetes: Choices you can make to prevent diabetes, Pregnancy: Birth Options if your baby is getting too big, and Pregnancy: Your birth options after cesarean, Prostate Cancer: Is radiation or surgery right for you*.

Participants will also be limited to those for whom a SDM program is clinically appropriate. This includes men and women with the following health problems and concerns: general healthcare options, low back pain (chronic, acute, spinal stenosis, and herniated disc), osteoarthritis of the knee or hip, coronary artery/heart disease, benign prostatic hyperplasia, abnormal uterine bleeding, uterine fibroids, symptoms of menopause, obesity, depression, ovarian cancer screening, prostate cancer screening, colorectal cancer screening, advance directives, diabetes, breast cancer treatment, heart failure, insomnia, carotid artery disease, and chronic pain.

Only participants who have consented to be contacted will be included to provide feedback over the telephone, via email or via focus groups. Study staff will only reach out to those participants who have provided this consent.

Patients for whom a decision aid was provisionally ordered for a specialty referral will be contacted to provide feedback through questionnaires and individual interviews.

Providers who made a specialty referral for a patient will be emailed a survey to complete online or by paper regarding that specific referral. Also, all eligible Partners Healthcare System primary care physicians, specialists, nurses and other clinic staff involved in a patient's care may be asked to complete either the questionnaire or participate in an

interview. Study staff will work individually with those interested in the interviews, at the time of a specific project.

Participants in the surgery shared decision making project will be adult patients who had surgery at a Partners Hospital for one of the four identified clinical conditions during the recruitment period who have been confirmed that primarily language is English. Participants will also be limited to those who meet the eligibility criteria laid out in Table 1. Children will be excluded as these conditions and procedures are not relevant for children.

Cancer Screening Project 2020:
Participants in the cancer screening shared decision making project will be adults who received a decision aid at a Partners Hospital for one of the four identified clinical conditions in the last 2 years, and English is their confirmed primary language. Participants will also be limited to those who meet the eligibility criteria laid out in Table 2. Children will be excluded as these conditions and procedures are not relevant for children.

Patients in the interviews will be recruited from the database of those who received a decision aid in the past. Patients must also be on Patient Gateway. Physicians will be recruited from the same database and they will be eligible if they prescribed a patient decision aid in the past.

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.

Participants in this project will be adult patients with a provider in the Partners Healthcare System adult primary and specialty care practices. Patient decision aids are all available in English and Spanish except for 4 programs that are only available in English: *Prediabetes: Choices you can make to prevent diabetes, Pregnancy: Birth Options if your baby is getting too big, and Pregnancy: Your birth options after cesarean, Prostate Cancer: Is radiation or surgery right for you*.

There are plans for more of the programs to be created in other languages; however they are not available at this time. We plan to include all of the non-English versions as they become available in the future.

Currently, the PROMs surveys are not available in Spanish. When they become available in Spanish, we will modify our protocol to include Spanish-speaking patients in our surgery shared decision making survey portion of this study.

For guidance, refer to the following Partners policy:
Obtaining and Documenting Informed Consent of Subjects who do not Speak English
http://healthcare.partners.org/phsirb/nonengco.htm

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.

Patient participants in this project will be patients in the Partners Healthcare System adult primary and specialty care practices. There is no formal recruitment of patient participants, as this is driven purely by appropriate clinical care. The distribution of SDM programs will vary by practice and program. One common method is that during an office visit, clinicians will discuss the program with the patient to determine if he or she is interested in watching it, in much the same way clinicians currently discuss any patient education material they provide their patients. Those patients who are interested will then receive the program, either via the mail, email, or by picking it up from the Blum Patient and Family Learning Center, depending on the patient's preference.

Clinicians are interested in automating the distribution of decision aids. To accomplish this, we will work with clinicians and practices to identify patients at a decision point. Data will be collected regarding the general practice patterns for the conditions covered to understand the number of eligible patients. The investigators will work with Steve Atlas who has an IRB approved protocol to examine practice patterns for quality improvement. For example, we may examine the number of men seen in MGH primary care practices who have never had a PSA test, and then work with providers to ensure that those men receive the appropriate decision aid in advance of their next visit. The data will enable automation of distribution as well as evaluation of distribution rates to determine the proportion of eligible patients we are reaching with each program.

Quantitative data will be collected for the number and type of programs "prescribed," both overall and by physician and practice. This data will be strictly quantitative and will not be associated with any individual patient or identifying information. Nothing about the patients will be associated with these numbers. Furthermore, this data will be independent of active patient participation in the evaluation and feedback (i.e., patient questionnaires) portion of the project.

All patients who receive a SDM program will be eligible to participate in the qualitative (evaluation and feedback) portion of the pilot. A questionnaire will be included with all SDM programs that are sent or given to patients. The questionnaires may also be incorporated into standard patient intake procedures at clinics, such as the touch screen computers or kiosks that patients use to complete standard assessments before seeing a provider in the orthopedic clinic. Patients can choose to complete the questionnaire and mail it back or complete the questionnaire over the telephone or online, thus providing implied consent (i.e., voluntary completion of survey or questionnaire), or they can choose to not complete the questionnaire. Patients who have not returned the questionnaire within 2 weeks of the initial survey will receive a follow-up phone call. Reminder survey packets will be mailed within 4 weeks if the patient has yet to return the survey. These patients will also receive reminder phone calls within 2 weeks of the reminder mailing. Patients may complete the questionnaire by telephone during the follow-up phone call. Patients willing to complete the questionnaire and who have not yet viewed the decision aid will be asked only pre-viewing questions, and will be encouraged to view the decision aid and follow up for administration of the post-viewing questions.

All patients who receive a decision aid will also be able to indicate their consent to be contacted in the future. Of those patients who've given consent to be contacted: study staff may contact these patients via email or telephone, depending on their preferred method, to solicit feedback on all aspects of programming. The feedback may be obtained by staff through individual interviews or group interviews. The information will help us make improvements to the patient education materials. All emails that are sent for recruitment will be sent in accordance with Partners' institutional guidelines for information security. Any

information provided by patients will be kept confidential. Participation in any future contact is voluntary; patients may choose to not participate at any time.

Patients who have indicated their consent to be contacted in the future for other studies will be contacted to see if they would be interested in participating in a pilot study examining the effectiveness of mental health decisions aids: sleeping better, depression, and anxiety. Patients will be contacted first by telephone and asked if they would be interested in participating in a survey study. If they agree to participate they will be asked to review some additional patient educational materials either online or on paper. After the patient reviews the materials, they will be asked to complete and answer the questions via phone with study staff at a scheduled time. Consent will be implied by the completion of the questionnaire. If a patient would like to complete the questionnaire via paper, an information sheet, questionnaire, and return-envelope will be sent to the patient. The project goal is to have approximately 30 eligible patients complete the survey.

Patients who have indicated their consent to be contacted in the future for other studies will be contacted to see if they would be interested in participating in a structured interview either in-person or via telephone to learn more about decision making for older adults about whether to continue colorectal cancer screening. We may also have primary care physicians (PCP) identify patients who they believe would good candidates to participate in the interviews. The PCP will provide the patient with the information sheet and if the patient is interested, the PCP will provide the research staff contact information for the subject to call to indicate their interest in participating. Subjects will be contacted first by telephone and asked their interest to participate in an interview. If they agree to participate they will be asked whether they prefer to conduct the interview in-person or via telephone and study staff will schedule a mutually convenient time. Consent will be implied by the completion of the interview. A cover letter and an information sheet will be sent by mail or email (if subjects provide verbal consent to use personal email) for those interested in an interview. All emails that are sent for recruitment will be sent in accordance with Partners' institutional guidelines for information security. The project goal is to have approximately 20 eligible subjects complete the interview.

Patients who received a decision aid in the past will be sent a letter and information sheet to let them know about an upcoming research project and that if they do not want to be contacted about participating, they can opt-out by phone. Potentially eligible patients will be asked if they are users of Patient Gateway. If so, the patient will be asked about their interest in participating in the interview. If the patient is not on Patient Gateway, he/she will not be eligible. If the patient agrees to participate he/she will be sent an information sheet describing the study and a mutually convenient time will be scheduled for the patient to participate in the interview. Consent will be implied by the completion of the interview.

Physicians who prescribed a patient decision aid in the past will be sent a recruitment email asking if they would like to participate in the 60-minute interview. The information sheet will also be included. The physician will be asked to reply to the email to indicate if he/she is interested. For physicians who respond to the email, a mutually convenient time will be scheduled for the physician to participate in the interview. We will recruit physicians across a range of practices and specialties. All emails that are sent for recruitment will be sent in accordance with Partners' institutional guidelines for information security. Consent will be implied by the completion of the interview.

Patients who received a specialty referral where their physician provisionally ordered a decision aid through the Clinical Referral Management System will also be contacted by the study staff for feedback on the referral process. Their feedback will be collected through

individual interviews or surveys. The information will help us to better understand decisions around the referral process. A cover letter and information sheet describing the study will be mailed to the patients so that they may choose to participate or not. Any information provided by patients will be kept confidential. The patients' demographic information will be collected through an RPDR data collection.

Physicians who have placed the referral for patients through the Clinical Referral Management System will also be contacted by study staff for their feedback on the referral process. Their feedback will be collected through an email survey. A cover letter and information sheet describing the study will be included in the email so that they may choose to participate or not. Any information provided by these providers will be kept confidential. All emails that are sent for recruitment will be sent in accordance with Partners' institutional guidelines for information security.

All eligible Partners Healthcare System primary care physicians, specialists, nurses and other clinic staff involved in a patient's care may be asked to complete either the questionnaire or participate in an interview. The email may also include an information sheet describing the study. All emails that are sent for recruitment will be sent in accordance with Partners' institutional guidelines for information security. Study staff will work individually with those interested in the interviews, at the time of a specific project.

Medical chart abstraction will examine visits, testing and treatment decisions for patients who have both received a decision aid and those with target condition who have not. For patients who have not received a decision aid, the patients' medical records will be pulled based on the relevant ICD-9, ICD-10, CPT codes associated with a visit, or with a provider within the study timeframe.

For the surgery shared decision making surveys, the procedures are as follows:

1. Work with PROMs team to schedule patients to receive the shared decision-making survey as part of their routine orthopedic PROMs assessment at a post-operative visit between 4-26 weeks post-procedure.
2. Use eCare report and RPDR queries to generate a list of patients who are scheduled for or who have recently had the target procedures across the Partners hospitals, along with selected details about the patients, the surgery and their interactions with specialists.
3. Study staff will run the report periodically and review results to confirm eligibility. A database of eligible surgical patients will be created and updated throughout the study period. Study staff may use RPDR to pull data for eligible patients that was not available from the eCare report. Staff may also access EHR to pull data (e.g. PROMs completion and responses) that is not available through RPDR.
4. Study staff will track shared decision-making survey completion rates on the PROMs platform and upload survey data into the database.
5. Staff will compare completion data to targets across topics and hospitals and if needed, staff will use a computer-generated allocation scheme to randomly select a subset of eligible surgical patients who did not receive the shared decision making survey on the PROMs platform to receive it in the mail.
6. The mailing will contain a cover letter signed by the PI and Clinical Chief at each site inviting patients to complete the survey, an information sheet about the study, the survey, a $2 incentive, and self-addressed stamped return envelope. The cover letter will include instructions for how to opt out of the survey if subjects are not interested.
7. About two weeks after the mailing, research staff will make up to three attempts to call subjects who did not opt out to answer questions and encourage subjects to complete the survey.

8. One reminder mailing will be sent about three weeks after the initial to non responders and that will be followed by up to two reminder phone calls.
9. For patients who have completed the PROMs questions or survey, they will be sent an invitation letter to participate in a 30-45 minute phone interview discussing their experience with elective surgery.
10. One week after mailing, study staff will call patients who did not opt out to ask them if they are interested in participating in a 30-45 minute interview.
11. Patients who complete a phone interview, will be sent a thank you letter and $20 cash compensation.

Surgeons who see patients with these conditions across the participating sites will be eligible for a survey. Study staff will give the paper survey to surgeons in person or send via email. The survey will ask for participant's name as it may be provided in a meeting. Once we get the survey we will mark each with a code and use the study ID code as the identifier. As needed, study staff will make up to three reminders via email. The brief survey will contain questions about the surgeon's attitudes toward shared decision making, use of decision aids, and confidence in shared decision making skills. The survey participation is voluntary and surgeon implies consent by completing the survey and providing it back to study staff. All emails that are sent for recruitment will be sent in accordance with Partners' institutional guidelines for information security.

Cancer Screening Project 2020:
For the cancer screening shared decision making surveys, the procedures are as follows:

1. Study staff will identify patients through the prescription log of individuals who received patient education materials in the form of decision aids on cancer screening for: breast cancer, colorectal cancer, prostate cancer, lung cancer over the last 2 years.
2. Study staff will mail eligible study participants a cover letter, information sheet describing the study, a copy of the first page of the educational materials they received through their Patient Gateway, a one time survey and $2 USD for their consideration of completing the study.
3. Participants can choose to complete the survey and mail it back, complete the survey over the telephone, or online via a REDCap survey link, thus providing implied consent (i.e., voluntary completion of survey or questionnaire). Participants can also choose not to complete the survey.
4. Study staff will make up to three reminder calls to patients regarding the survey within 2 weeks of the initial mailing.
5. Study staff will send reminder survey packets within 4 weeks if the patient has yet to return the survey and receive up to three reminder phone calls within 2 weeks of the reminder mailing.
6. Study staff will conduct a chart review to collect information on cancer screening tests and review visit notes related to cancer screening.
7. Participants will be sent a thank-you letter for their participation following completion and research staff's receipt of completed survey.

Path to Lifestyle Change
Patients eligible for the research study will be participants in the *Path to Lifestyle Change* program offered through the MGH Diabetes Center. The clinician in the MGH Diabetes Center will obtain permission to send the study information by email. In addition, the clinician will be available to answer questions about the study. For patients who give permission to use their email to send the study information, they may opt-out of the research by contacting the study coordinator by phone or email. For patients who do not opt-out, consent will be implied by

survey completion. Patients who did not opt-out will receive a secure REDCap survey link by email at 5 time points: one-week post baseline visit, 6 months, 12 month, 18 months and 24 months. The protocol for following up at each time point will be the same: 1) the patients will receive an automated reminder from REDCap one week after each survey is sent if the patient has not responded, 2) one reminder phone call will be made one week after the automated response is sent if the patient has not responded. Study staff will offer to complete the survey over the phone, if the patient would prefer.

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

Those patients participating in an individual interview will receive $20 after completion of the 45-minute interview. Patients completing a 1 hour audiotaped interview will receive $40. Focus group participants will receive $60 after completion of the 90 minute session. Participants will not receive any remuneration for completing questionnaires, including the specialty referral interview. Participants who will be participating in a 90-minute individual interview will receive $40 after completion of the interview. Patients participating in the recontract survey mental health study will not receive compensation.

Participants in the interviews about the patient decision aids prescribed through EPIC and accessed through Patient Gateway will receive $50 in cash to thank them for their time

Participants who receive the surgery shared decision making survey in the mail will receive $2 cash as an incentive to promote survey completion.

Cancer Screening Project 2020:
Participants who receive the cancer screening shared decision making survey by mail will receive $2 as an incentive to promote survey completion.

Clinician's participating in surveys or interviews will not be compensated.

Participants in the *Path to Lifestyle Change* program will not receive any incentives.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
http://healthcare.partners.org/phsirb/recruit.htm

Guidelines for Advertisements for Recruiting Subjects
http://healthcare.partners.org/phsirb/advert.htm

Remuneration for Research Subjects
http://healthcare.partners.org/phsirb/remun.htm

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. Whether or not a patient receives one of the SDM programs is determined by appropriate clinical care and the patient's desire to receive information about his or her health problem/screening in the form of a shared decision-making program. This occurs through a discussion between the patient and clinician during the office visit, much like any conversation that occurs when a physician gives educational material to a patient.

Patients who receive a SDM program will also receive an information sheet describing the study and a questionnaire. Patients can choose to complete the questionnaire and mail it back, online, or complete the questionnaire over the telephone, thus providing implied consent (i.e., voluntary completion of survey or questionnaire), or they can choose to not complete the questionnaire. There will be routine post-card reminders and follow-up phone calls made to patients who have not returned the questionnaire within 2 weeks of the initial survey. Reminder survey packets will be mailed within 4 weeks if the patient has yet to return the survey. These patients will also receive reminder phone calls within 2 weeks of the reminder mailing. It will be mentioned to the patient as a reminder that they can return the questionnaire, if they wish, or complete the questionnaire over the telephone. Patients willing to complete the questionnaire and who have not yet viewed the decision aid will be asked only pre-viewing questions, and will be encouraged to view the decision aid and follow up for administration of the post-viewing questions.

The data collected in the questionnaires pertains to the processes of shared decision-making and receiving the program, how helpful the program was to the patient in making their decision, the effect the program had on decision preference, what the patient thinks about the available options, and how they feel about making a decision.

The provider survey, and specialty referral survey, will not have formal written consent either, and consent will be implied by the return of the completed survey. The provider questionnaire will provide us with valuable feedback regarding the dissemination of the SDM programs, as well as their perspective barriers and/or benefits to prescribe and refer to eligible patients. Clinician consent will be implied by agreeing to participate in the interviews or completing a survey. Clinicians will be provided with a study information sheet as well.

For the patients in the specialty referral survey, no formal written consent will be collected. Patients' consent will be implied by the return of the completed survey or completion of a telephone interview. A cover letter and information sheet describing the purpose and time commitment of the study will be mailed to the patients so that they may choose to participate or not. A reminder phone call will be placed for those who haven't completed the questionnaire within a 2-week timeframe. They can choose to complete the survey over the phone at that point.

For those patients who've given consent to be re-contacted: study staff may contact these patients via email or telephone, depending on their preferred method, to invite them to participate in an individual or group interview or via survey. An information sheet describing the interview study, time commitment and remuneration (if applicable) will be provided. If

interested, patients will contact staff and schedule an interview or participate in the phone survey. Consent to participate will be implied by completion of the interview and/or survey.

For the surgery shared decision making surveys, there are no formal written consent procedures in this project. When the survey is included as part of the PROMs application, it is part of the standard of care. When surveys are mailed to patients, consent is implied by the completion and return of the survey. Study staff will protect the privacy of research study participants. Patients can skip any question and may stop at any time. There are no procedures in this research for which written consent is normally required. For the mailed survey, eligible participants will receive a cover letter signed by the chief of orthopedic surgery or medical director of the specific service from each site and the principal investigator inviting them to complete the survey, as well as an information sheet that will provide details about the survey study. Participants can review the questions and choose whether or not they wish to participate. Surgeons who receive a surgery shared decision making survey will have implied consent by completing and returning the survey. Survey participation is voluntary.

Cancer Screening Study 2020:
No formal written consent will be obtained for participants of the cancer screening study survey. Potential participants will be mailed an information sheet containing information about the study and inviting participation. Participants may review the questions and the information provided in the mailing packet and choose whether or not they wish to participate. Participants may also contact study staff to opt out of the study. Consent for participation will be implied by the return of completed survey by mail or online via the REDCap survey link. Participants may request the REDCAP survey link be sent to their email. Study staff will read the IRB policy regarding send-secure vs. unencrypted emails and obtain verbal consent from participants via telephone to send the survey link via email based on participant email preference. Survey participation is voluntary.

All participants in the *Path to Lifestyle Change* program will be asked permission to send them an email about this research project. If the participant gives permission to use their email, he/she will be emailed a cover letter and fact sheet explaining the research project per Partners guidelines. The cover letter will ask participants to opt-out if they do not want to participate in the survey research. For participants who do not opt-out, they will be sent an email with a secure link to a REDCap survey at each of the four timepoints. Consent will be implied by completion of the REDCap surveys.

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:
http://healthcare.partners.org/phsirb/newapp.htm#Newapp

For guidance, refer to the following Partners policy:
Informed Consent of Research Subjects
http://healthcare.partners.org/phsirb/infcons.htm

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.

While there are no known risks or safety concerns to participating individuals associated with or attributable to viewing information about health topics and voluntarily answering questionnaires, we will monitor patient feedback obtained in the questionnaires and any conversations they might have with their clinician in which they express complaints or problems related to the project. The Stoeckle Center staff are available to answer questions or concerns that patients might have. We plan to keep records of any feedback, questions, concerns and/or complaints received about the project and will address them as necessary.

The main risks to patients will be loss of privacy. Questionnaires will include solely, a coded unique numeric identifier for each patient and provider. Therefore, all completed questionnaires will be stripped of any personal identifiers and/or HIPAA related information. Only MGH approved study staff for this protocol will have access to the information crosswalk needed to link this unique identifier with confidential personal information. The completed, coded questionnaires will be returned, where study staff will enter the de-identified data into a secured online data warehouse. Data will be stored using a secure, online data warehouse hosted by the DatStat Company. All DatStat servers used for data collection are housed in a server room. The server room is in a building with 24/7 alarm security. Any building compromise will sound the alarm and generate a call to the building supervisor and police, who will subsequently notify DatStat personnel of the intrusion. Protection of servers from remote attacks is accomplished with a dedicated hardware Watchguard firewall with auditing enabled at the recommended settings. Watchguard LiveSecurity keeps IT staff advised of all known security alerts. The firewall ensures that all traffic is closely monitored and suspicious packets blocked from access to the production systems. Security patches are applied to DatStat servers on a timely and ongoing basis. Logs are created by the web servers to increase the accountability and are essential in investigating incidents after the fact. Access to data stored in the server is available only to MGH approved study staffs that are assigned specified usernames and passwords within which to log in. Study staff at the sponsor and participating sites are also assigned specified user names and passwords and can access only the aggregated study data. Users are logged out after a period of time. A listing of the users with a description of their access privileges is available within the application. The following are logged: failed and successful logins, attempts to access files/directories without authority, successful and failed attempts to access sensitive data.

All emails that are sent for recruitment will be sent in accordance with Partners' institutional guidelines for information security.

Only approved study staff will have contact with the patients who've consented to participate in the qualitative feedback sessions. Any information provided by these patients will be kept confidential. Individual interviews will be hosted by two study staff. One will

follow a prepared interview script and the other will take detailed notes. There will also be at least two study staff, one acting as facilitator who will follow similar script as the phone interview, and one as note-taker, during the group sessions. All notes will be stripped of any personal identifiers and/or HIPAA related information. The individual interviews that will be conducted for the weblink decision aid videos will have two study staff, one as a note-taker and the other as a guide to assist the participate in viewing the online video. The videos will be viewed through the Healthwise website. No personal information will be captured during the qualitative feedback sessions. It will be stated upfront during the focus group sessions that no personal information discussed is to leave the room.

The medical chart abstraction data will be stored in a database on a Partners password protected computer. Only study staff will have access to this database. A study code will be used to protect the confidentiality of patients.

Data collection for surgery shared decision making survey, will be from the medical record and patient surveys and surgeon surveys. There are no foreseeable safety risks to participants for completing the survey. Study staff will protect the privacy of research study participants as described in the Privacy and Confidentiality section.

Cancer Screening Survey Study 2020:
Data collection for the cancer screening survey will be from medical records and patient surveys. There are no risks to participant safety in completing the survey. To mitigate risk of loss to patient privacy all surveys will be coded with unique numeric identifier for each patient. The medical chart abstraction data will be stored in a database on a Partners password protected computer. Only study staff will have access to this database. 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 prior experience using these questionnaires with patients who have knee osteoarthritis or low back pain have found that it is very rare for participants to be upset. Nevertheless, study staff will screen surveys for adverse events and address them as described in the next section.

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

Any adverse event or patient complaint that occurs as a result of or related to this pilot project will be addressed immediately upon receiving it. We will also relay any such event to the Informed Medical Decisions Foundation if it pertains directly to the SDM program. Again, the Health Decision Sciences Center (HDSC) staff are available to address any questions or concerns that are received from the patients, either directly or through the

patients' clinician. We will keep records of any feedback, questions, concerns and/or complaints that are received, and we will address them immediately and appropriately.

The HDSC have clinical co-investigators in primary care and surgery who will be able to consult with study staff on any clinical issues that become apparent. For example, if patients raise a clinical issue with study staff during the course of phone reminders or on the written 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.

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 will routinely review the program "prescription" log as well as all incoming questionnaires for monitoring purposes. Monitoring of the prescription log will also be done by the HDSC staff, as they are the ones who receive and process all requests for SDM programs. Other quality assurance monitoring will be accomplished through the patient and provider questionnaires and interviews. The study staff and the principal investigator will have routine meetings during the study period to ensure the project proceeds as intended per the protocol. 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 principal investigator.

The principal investigator will speak with the study staff on a weekly basis and as-needed to ensure that the protocol is being followed. This research does not entail physical risks. We have procedures in place to minimize risks to loss of privacy.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
http://healthcare.partners.org/phsirb/datasafe.htm

Adverse Event Reporting Guidelines
http://healthcare.partners.org/phsirb/adverse.htm

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.

As the goals of this study are to 1) demonstrate the ability to introduce and disseminate SDM programs to patients, 2) assess and understand "prescribing" utilization, trends and patterns by clinician and across practices, 3) obtain feedback from patients about receiving SDM programs, their decision preferences and comfort with making a decision, and 4) assess the quality of shared decision making for elective surgical decisions.

The study staff will process and manage the distribution and return of programs and questionnaires. Once questionnaires have been returned, the study IDs will be removed so that any ability to link the questionnaires back to patients is removed prior to any review, database entry or analysis of the data. Patient identifiers on the program log (name, address and phone number) will be removed before a copy of it is given to study staff. The study database will not contain any patient information. In this way, the privacy of the subjects and confidentiality of the data collected will be maintained.

No personal information will be captured during the qualitative feedback sessions. Patient privacy will be maintained. All notes will be stripped of any personal identifiers and/or HIPAA related information.

The interviews will be recorded. The interview data will be identified by a code only. Once the interview is completed, we will not keep the link that ties the participant to the interview. To ensure confidentiality, all study materials will be kept in locked file cabinets and on electronic drives on a Partners password-protected computer to which only the study staff has access.

For the surgery shared decision making survey, study staff will run eCare reports and RPDR queries to gather information on potentially eligible subjects and will review the subject's medical record to confirm eligibility. We will have names and addresses of eligible participants and this information will be kept separate from the study data (e.g. PROMs patient survey data). A separate file on a password-protected Partners shared drive 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.

Cancer Screening Study 2020:
For the cancer screening study, researchers will identify patients who received a decision aid in the HDSC database and will run RPDR queries to gather contact information on potentially eligible subjects and confirm eligibility. We will have names and addresses of eligible participants and this information will be kept separate from the study data (e.g. patient surveys). All patients will receive a code number and the surveys will only be identified by code number. A separate file on a password-protected Partners shared drive 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 paper 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.

The de-identified program and decision aid survey data will be shared with the sponsor, the Informed Medical Decisions Foundation. The sponsor is hosting the data warehouse described in detail above and it will aggregate de-identified data from other sites that are funded to collect the same data on implementation of the DVDs/booklets at primary care sites across the country. The data will not contain any identifiers and other investigators, including the sponsor, will not be able to link the data to individual subjects.

A written summary of the interviews that does not contain any personal identifiers will be shared with the Healthwise, who is the funder.

Cancer screening study 2020:
The research team is committed to making resources and data from this proposed research study available to other investigators in the research community. The patient information sheet states the data will be de-identified and made available to others for analysis and research following study completion. The study team will create a clean and de-identified copy of the final data set which will include patient survey data in addition to the limited demographics and cancer screening test. Information for investigators interested in using this data will be made available on the Health Decision Sciences Center website and in publications of the data. Dr. Sepucha will share a de-identified data set with outside investigators at no cost, per approved MGH/Partners policies for data sharing. We will never share the key that will enable an investigator to link the coded data to an individual. Investigators from other sites will be able to request the data and will be required to complete a data use agreement that ensures that all local IRB requirements are met before using the data, that they will not attempt to identify any data in the dataset, and that they will not share the data set with anyone outside their project team. We will also make information necessary to interpret the data, such as study protocols, data dictionaries, and survey tools available to interested investigators.

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/). This is to promote research replicability, transparency and future use of the data. 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.

Since there will be no identifying information in the data submitted to the sponsor it will not be possible for an individual to withdraw their information. We have submitted the approval for the protocol held by the sponsor that covers the aggregation of data from MGH and other participating sites.

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.

Study staff at MGH will be able to access the aggregated data that the sponsor has collected from other participating sites. MGH study staff will not be able to link data to individual subjects from other participating sites. We have attached the IRB approval held by the sponsor that covers the aggregation of data from MGH and the other participating sites.