INVESTIGATOR STUDY PLAN
12.14.2021

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Development of an Osteoarthritis (OA) Careplan to improve process and quality of OA treatment decisions and the quality of OA care.

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1. TITLE
Development of an Osteoarthritis (OA) Careplan to improve process and quality of OA treatment decisions and the quality of OA care.

2. EXTERNAL IRB REVIEW HISTORY*
Participating surgeon sites will cede to the UMASS Medical School IRB. As surgeons are recruited, IAA agreements will be initiated.

3. PRIOR APPROVALS:
NA

4. OBJECTIVES*
We propose to prospectively randomize orthopedists, with their patients, to receive (or not) a real-time, web-based system intervention: the OA Care plan. The OA Care plan will include individualized, patient-centric information: (1) trended patient-reported OA pain and function, (2) tailored estimates of likely TJR benefits and risks based on a contemporary US cohort of 25,000 TJR patients (FORCE-TJR Registry), (3) evidence-based information for non-operative care, and (4) individual patient goals.
Specific Aims include:
Aim 1. Patients and their Caregivers/Trusted Others will refine the design, content, and usability of a real-time, web-based individual OA Care plan to guide TJR and non-operative OA care decisions.
Aim 2. Randomize 40 orthopedists, and their patients, to receive the OA Care plan at the time of orthopedic consultation (intervention) vs. usual care (control) and compare (a) OA care decision process and quality and (b) quality of OA care as measured by pain relief and functional gain in the two arms at 6 and 12 months after the decision, and assess the impact of decision quality on quality of OA care.
Aim 3. Randomize 36-40 orthopedists, and their patients, to receive the OA Care plan plus peer, family, and primary care physician support (OA Care plan+Support; intervention called A.S.K. Coaching) vs. the OA Care plan alone and compare the quality of OA care decision and quality of care (pain relief, functional gain) in the two arms.

When moving the PCORI contract to Northwestern in early 2019, we revised the sample size estimates required to meet the same study power and analytic plan for both Aim 2 and Aim 3. Using the early study data, we determined that n=3000 patients in Aim 2 and n=3000 patients in Aim 3 was adequate to meet statistical goals. We also determined that fewer surgeons (N= 36-40) would be required in Aim 3 to consent 3000 patients. PCORI agreed to the changes in number of surgeons and patients. We clarified this change in the ISP.

Based on the components of the Chronic Care Model, this technology-delivered, individualized OA Care plan will enable patients and clinicians to make treatment decisions based on patient symptoms, goals, and comparative effectiveness evidence. We hypothesize that OA Care plan users, as compared to usual care, will report greater decision quality for both TJR or non-

operative care, and better quality of care (less OA pain, greater function). Further, we anticipate incremental effectiveness of the OA Care plan+Support (peer, family, and primary care support) on the same outcomes. Study results will guide future OA Care plan implementation to assure optimal healthcare for patients with advanced knee and hip OA. Finally, lessons learned from the evaluation of this automated patient-centric decision support system can be extended beyond OA and TJR to other elective surgical procedures to engage informed patients to make optimal individual decisions.

5. BACKGROUND*

Knee and hip osteoarthritis (OA) is the most common cause of disability in the U.S. and affects more than 60% of adults over 65 years.[1] OA has no cure so as arthritis pain progresses, chronic pain medications and physical therapy are prescribed to limit the pain and associated disability.[1] When these therapies no longer relieve arthritis pain, total joint replacement (TJR) surgery is the most common treatment.[2] TJR effectively eliminates arthritis pain and, in the majority of patients, improves physical function. Because of the growing prevalence of OA, TJR surgery is the highest volume inpatient procedure in the US today with over one million procedures each year.[2, 3] As the burden of knee and hip OA increases among aging adults, more patients elect TJR. However, no clear guidelines exist *for patients* to determine <u>if</u> or <u>when</u> to undergo TJR.

While TJR effectively relieves OA pain, improvement in function varies by pre-operative patient factors. Recent analyses of TJR patients found that patients with very low or high function have limited functional gains after TJR. [4, 5] Today, younger patients experience more advanced knee and hip OA and must decide if TJR is appropriate. Over 45% of TJR patients are under 65 years of age and working age patients are the fastest growing TJR patient sub-group.[6] However, younger patients will use the knee or hip implant for a longer period of time and face a greater risk of revision surgery if the implant wears out. By 2030, the utilization of hip and knee replacement surgery is projected to increase by 174% and 630%, respectively.[7] Patients, clinicians, and payers need new tools to guide decisions regarding need for TJR and optimal timing to assure safe and effective OA care. Optimal OA care, including TJR, is a public health priority.

Chronic diseases, such as diabetes, blood levels (HgA1c) are monitored over time to guide medication and disease progression. OA has no comparable biomarker to monitor. While x-rays confirm the presence of knee and hip OA, x-rays cannot quantify the pain or functional limitations associated with OA.[8] In contrast, patient-reported symptom severity informs treatment plans. The patient must report pain, stiffness and swelling that limit knee and hip function and compare his/her limitations with his/her personal activity demands and goals. The orthopedist relies on the patient to assess the OA severity, its progression over time, and the effectiveness (or lack thereof) of non-operative treatments. When a patient is referred for evaluation of knee or hip OA, the surgeon and patient determine if TJR is the next treatment or if non-operative care is indicated. The use of TJR is a collaborative decision between the patient and surgeon, when non-surgical alternatives are exhausted.

A 2014 editorial called for strategies to assure optimal TJR patient selection using clinician-patient shared decision---making based on research evidence and individual patient symptoms.[9] More recently, a 2015 NEJM editorial concluded, "For most patients, the dramatic pain relief associated with total knee replacement provides a compelling rationale to choose surgery. Other patients, particularly those who are more risk-averse, may prefer nonsurgical care. Since patients vary considerably in their preferences, physicians should present the relevant data to their patients and then listen carefully." [10,11] Anticipating this need, the Function and Outcomes Research orthopedic network (FORCE-TJR) designed a prototype system of real-time scored patient-reported pain and function assessments and tested it in two surgeon offices. The scored, trended data were available at the clinical encounter when the patient discussed possible TJR with the surgeon. The patient users concluded that the "OA Care plan" successfully prepared them for TJR conversations with their surgeon, while providing objective benchmarks to guide surgeon recommendations.

Based on this feedback, we propose to refine and test a web-based system intervention that provides individualized patient OA Care plans including (1) trended patient-reported OA pain and symptoms, (2) estimates of likely TJR outcomes tailored to patient risk factors, (3) evidence-based information for non-operative care, and (4) patient goals. We hypothesize that the OA Care plan will improve the process and quality of OA treatment decisions and the quality of OA care.

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6. INCLUSION AND EXCLUSION CRITERIA*

Aim 1 Individual Stakeholder Interviews (in place of Focus Groups)

Inclusion criteria

Patients from 3 participating sites with a diagnosis of OA in the knee and/or hip, identified by the surgeon or designated staff.

Caregivers or trusted others of patients with OA in the knee and/or hip from 3 participating sites, identified by the surgeon, designated staff or by patients participating in the patient interviews.

Patients must be 18 years of age or older and able to provide informed consent.

Exclusion criteria

Inflammatory arthritis, such as rheumatoid or psoriatic arthritis
Pregnant women
Prisoners
Non-English speaking subjects as the interview guide and tools for patient review are only available in English.

Aim 2 and 3

Inclusion Criteria

*Aim 3 modification: We proposed to PCORI (and they agreed) that we expand beyond "new" patients as these are only patients who are new to the surgeon's practice. We did this for staff training simplicity, not because these are the only appropriate patients to use the report. NOW: Enroll all patients who are not "follow-up" appointments to surgery or other treatment, so that both (a) patients **new to the practice** (already in ISP) and (b) existing patients who have seen surgeon before but are **here for a new evaluation** are eligible.*

Patients must be 40 years of age or older and able to provide informed consent.

Because only new office patients are enrolled, patients enrolled in Aim 2 will not be eligible for enrollment in Aim 3. (Even with the updated definition of "new" patients, patients enrolled in Aim 2 will not be eligible for enrollment in Aim 3.)

Non-English (Spanish) speaking subjects will be included in aim 2 of the study;
Non-English speaking patients will not be included in Aim 3 (with funder approval). The OA Careplan + Support program (now called A.S.K. Coaching) will only be available with an English speaking health educator and we learned in Aim 2 that <1% of eligible patients were primarily Spanish language speakers.

Exclusion criteria

Inflammatory arthritis, such as rheumatoid or psoriatic arthritis

Recent knee or hip injury as purpose for visit
Contraindications to TJR surgery including co-existing conditions that negate functional improvement with OA treatment/surgery and terminal illness with a life expectancy of less than 6 months
Pregnant women
Prisoners
Inability to comprehend written English or Spanish surveys
Inability to provide assent due to cognitive impairment or dementia

Additional inclusion criteria for Aim 3 patient qualitative interviews:

- English-speaking since the A.S.K. Coaching intervention is only offered in English
- Self-reported receipt of OA Care plan as per response on 1-month survey
- Patients in sites randomized to the OA Care plan + Support arm must also consent to and participate in A.S.K. Coaching

7. STUDY-WIDE NUMBER OF SUBJECTS*

Aim 1 Patient Interviews= 30 participants
Caregiver/Trusted Other Interviews = 30 participants

Aims 2 and 3 6000 patients total, 3000 in Aim 2 and 3000 in Aim 3
20-30 surgeon offices will have 1-2 surgeons for each office (total 40 surgeons) contribute 100 consecutive new patients to the study for Aim 2 and an additional 100 patients for Aim 3.

For surgeon qualitative interviews: up to 35 MD surgeons. MD surgeons are not subjects in the ASK study (patients are).

For Aim 3 patient qualitative interviews: Up to 50 patients, with an approximately even breakdown from each of the following groups

- Participated in A.S.K. Coaching + self-reported (on 1-month survey) surgery planned and use of OA Care plan with MD.
- Participated in A.S.K. Coaching + self-reported (on 1-month survey) non-surgical treatment planned and use of OA Care plan with MD.
- Participated in A.S.K. Coaching + self-reported (on 1-month survey) surgery planned and no use of OA Care plan with MD.
- Participated in A.S.K. Coaching + self-reported (on 1-month survey) non-surgical treatment planned and no use of OA Care plan with MD.
- Usual Care arm + self-reported (on 1-month survey) surgery planned and use of OA Care plan with MD.
- Usual Care arm + self-reported (on 1-month survey) non-surgical treatment planned and use of OA Care plan with MD.

8. STUDY-WIDE RECRUITMENT METHODS*

All recruitment methods are local.

Aim 1

Patient Interviews (in place of focus groups)

Potential participants with a potential diagnosis of OA in the knee and/or hip will be identified by the surgeon or designated staff. Potential participants will be provided a letter of invitation from their surgeon during a clinic visit or mailed a letter of invitation (see Patient Interview Letter of Invitation). The Patient Letter of Invitation includes a toll free opt-out telephone number for potential participants to call if they do not want to be contacted in the future to receive additional information. Individuals who opt-out will not be contacted for participation. The study will only retain information pertaining to site, gender, age and reason for opting out.

Approximately 1 to 2 weeks after the Interview Letter of Invitation has been sent, a packet of materials will be mailed to potential participants who did not opt-out of the study. This packet will include: a copy of the Patient Letter of Invitation and the Patient Interview Fact Sheet (see Patient Interview Fact Sheet). UMMHC patients will also receive a HIPAA Authorization form without signature form (see Interview HIPAA Authorization form without signature form).

Approximately 1 week after the packet has been mailed, the Project Director will review the eligibility criteria (see Interview Recruitment Script and Eligibility Screening Tool) and if eligible will call potential participants who did not opt-out after receiving the packet. The Project Director will review the Fact sheet and HIPAA Authorization form (if applicable). She/he will answer any questions, determine interest in participating and obtain informed verbal consent. An interview time will be scheduled at the convenience of the participant. Interviews will be conducted either over the phone or in person. For phone interviews, materials for review and discussion will be sent via overnight mail or email to the participant. These materials will include: screen shots of pain and function reports; decision aids and; feedback reports (see attached Interview Materials). In person interviews participants will receive the materials at the time of the interview as well a HIPAA Authorization Form with signature (see In person Interview HIPAA Authorization form with signature form) if applicable . Individuals who opt-out or refuse to participate will have all identifying information destroyed. Only information pertaining to gender, age and reason for opting out or refusing will be retained.

Caregiver/Trusted Other Interviews

Caregivers or trusted others of patients with OA in the knee and/or hip from 3 participating sites, identified by the surgeon, designated staff or by patients participating in the patient interviews. Surgeons or designated staff will identify potential Caregiver/Trusted Others by their attendance at an office visit for a patient under the surgeon's care. Potential participants will be provided a letter of invitation from the surgeon during a clinic visit or mailed a letter of invitation (see Caregiver/Trusted Other Interview Letter of Invitation). The Caregiver/Trusted Other Letter of Invitation includes a toll free opt-out telephone number for potential participants to call if they do not want to be contacted in the future to receive additional information. Individuals who opt-out will have all identifying information

destroyed. Only information pertaining to gender, age and reason for opting out will be retained.

Approximately 1 to 2 weeks after the Caregiver/Trusted Other Interview Letter of Invitation has been sent, a packet of materials will be mailed to potential participants who did not opt-out of the study. This packet will include: a copy of the Caregiver/Trusted Other Letter of Invitation and the Caregiver/Trusted Other Interview Fact Sheet (see Caregiver/Trusted Other Interview Fact Sheet). UMMHC patients will also receive a HIPAA Authorization form without signature form (see Interview HIPAA Authorization form without signature form).

Approximately 1 week after the packet has been mailed, the Project Director will call potential participants who did not opt-out after receiving the packet, using the Recruitment Script (see Recruitment Script and Eligibility Screening Tool). The Project Director will review the Fact sheet and HIPAA Authorization form (if applicable). She/he will answer any questions, determine interest in participating and obtain informed verbal consent. An interview time will be scheduled at the convenience of the participant. Interviews will be conducted either over the phone or in person. For phone interviews, materials for review and discussion will be sent via overnight mail or email to the participant. These materials will include: screen shots of pain and function reports; decision aids and; feedback reports (see attached Interview Materials). In person interviews participants will receive the materials at the time of the interview as well a HIPAA Authorization Form with signature (see In person Interview HIPAA Authorization form with signature form) if applicable. Individuals who opt-out or refuse to participate will have all identifying information destroyed. Only information pertaining to gender, age and reason for opting out will be retained.

Patient and Caregiver/Trusted Other Interviews will be conducted via telephone or in person and digitally recorded. Interviews will last approximately 60 minutes. Participants will receive a $25 gift card for their time. Patient Interview Guide and Caregiver/Trusted Other Interview Guide are attached. In person interviews will be conducted in a private setting.

Aims 2 and 3

Sites and surgeons with a Business Associate Agreement in place

Participating surgeons will be provided the OA Care Plan Web-based system to use with all their patients. As collection of Patient Reported Outcomes (PROs) is considered standard of care in orthopedics (CMS mandate, Bundled Payment requirements, and reporting for Qualified Clinical Data Registry requirement for example), Business Associate Agreements with participating sites will be in place and will allow for PRO short term data collection follow-up (up to 12 months) by the OA Care Plan Data Coordinating Center (DCC), located at the University of Massachusetts Medical School, for surgeon office reporting purposes and Quality Improvement. The surgeon offices will be responsible for entering patients into the web-based system at their clinic visits and facilitating patient completion of PROs.

The OA Care Plan Web-based system allows for identification of new OA patients as the survey for new patients is slightly different to allow patients to report on the pain and function

of the joint or joints that is of most concern to them. (see New Patient Baseline survey [Knee/Hip])

At the beginning of the New Patient Baseline survey, potential participants will view the OA Care Plan Surgeon Letter of Invitation with BAA (see attached).
This letter includes an opt-out radio button for potential participants to click if they do not want to be contacted in the future to receive additional information about the study of their treatment decision. Individuals who opt-out will not be contacted by the DCC. Only information pertaining to site, gender, age and severity of pain and function (measured at baseline by HOOS/KOOS) will be retained for the research study. It is important to keep information regarding the pain and function of those refusing, opting out or ineligible to understand if the level of pain or level of function differs between those who agree or are eligible and those who do not agree or are ineligible, as these differences could impact the results of the study.

<u>Sites and surgeons without a Business Associate Agreement in place</u>
Participating surgeons will be provided the OA Care Plan Web-based system to use with all their new patients. At the beginning of the New Patient Baseline web survey, potential participants will view the OA Care Plan Surgeon Letter of Invitation without BAA (see attached). This letter includes an opt-out radio button for potential participants to click if they do not want to be contacted in the future to receive additional information about the study of their treatment decision. If a patient opts out, the New Patient Baseline survey will close and patients will not be able to complete the survey. This will prevent any information being shared with the DCC.

Option 1
An Authorization to contact (see attached Authorization to Contact) and an ASK Brochure will be presented to patients prior to completing the survey. If a patient completes the Authorization to Contact, new patients will be presented with the New Patient Baseline survey and follow all procedures as listed above depending on whether they are a BAA site or non-BAA site.

Option 2
Office staff within the surgeon's office will mail the Mailed Invitation Letter and a ASK brochure to all eligible patients. The Mailed Invitation Letter provides an option to opt out of the study. If UMMS is contacted by someone who wants to opt out, this information is recorded and also conveyed to the office staff at the surgeon's office. This minimizes the chance that offices will send patient phone numbers for individuals who do not want to hear more about the study. Sites are instructed to provide the FORCE-TJR team with phone numbers for all eligible patients approximately one week after the providers send the Mailed Invitation Letter and ASK brochure.
For potential participants who do not opt out after receiving the Mailed Invitation Letter, a research coordinator from the UMMS coordinating center will call the patient and assist them with completing the New Patient Survey (see Phone Script to complete new patient survey).If

after completing the survey patients decline to be contacted after their appointment, they will be documented as an opt out and not called.

Option 2b (Northwestern Medicine (NM) only)
Research staff at Northwestern University (where the PI is now a faculty member) will assist Northwestern Medicine Healthcare (NM) clinical staff in identifying potential participants by reviewing the real-time medical orthopedic clinic schedules via the Northwestern Medicine Epic/ Enterprise Data Warehouse. (These NM staff have been added to the UMMS IRB with CITI documentation and have NM approval to access the clinical data warehouse). Only patients of NM participating surgeons will be screened. If the NM patient meets the study eligibility criteria, the study team will send the Mailed Invitation Letter with an ASK brochure and follow the steps as outlined in 2 (above).

The DCC will identify all new patients who did not opt out that are included in the OA Care Plan Web-based system for the two participating surgeons at each office. Potential participants will be mailed and/or emailed a packet of materials. This packet will include: a copy of the Cover Letter (see Cover letter for mailing) and 1 copy of the OA Care Plan Consent Form.

Approximately 1 day to 1 week after the packet has been mailed/emailed (depending on method of delivery), the Research Coordinator will call potential participants who did not opt-out after receiving the packet. The Research Coordinator will review the eligibility criteria (see Recruitment Script and Eligibility Screening Tool) and if eligible will review the OA Care Plan Consent Form. She/he will answer any questions, determine interest in participating and obtain verbal informed consent. For consented patients, the consent form also contains information about being contacted for future research activities. When applicable, individuals who opt-out, are not eligible or refuse to participate will have all identifying information destroyed from the research study. Only information pertaining to gender, age, severity of pain and function (measured at baseline by HOOS/KOOS) and reason for opting out, being ineligible or refusing will be retained. It is important to keep information regarding the pain and function of those refusing, opting out or ineligible to understand if the level of pain or level of function differs between those who agree or are eligible and those who do not agree or are ineligible, as this difference could impact the results of the study.

If the Research Coordinator is unable to reach the potential participant by phone, the Final contact Recruitment and Follow-up-e-mail-snail mail 2-14-18 letter will be sent to the patient either by email or snail mail (see attached). This letter will also be used if consented participants do not return follow-up surveys.

Surgeon offices will be randomized to Usual Care or Intervention sites. During Aim 2, after completing the surveys in the clinic, usual care patients and surgeons will have the ability to see PRO scores, but will NOT receive feedback (no OA Care Plan). This is the current standard of care in orthopedic clinics. For intervention sites, the patient and surgeon will receive the OA Care Plan (named the A.S.K. Report).

The DCC will follow-up with patients at 3 time points: 1-month Decisional Conflict Scale and Shared Decision Making Process Survey; 6 months and 12 months after surgery or decision to use non-surgical method of managing OA. (see 1-month Decisional Conflict Scale, 6 and12-month [Knee/Hip] surveys attached). Surveys will be mailed and/or emailed based on participant preference. The 12 month surveys are standard clinical care; the 1 month, and 6 month contact are for the research. After receiving IRB approval (hopefully September 2020), newly enrolled patients will also respond to Covid-19 measures via the same web-based data capture system used in the rest of the study at 1-month, 6 months and 12 months.

Participants will receive a $20 gift card after completing the 1-month Decisional Conflict Scale for their time

During Aim 3, Usual Care sites will receive the OA Care Plan (A.S.K. Report), and Intervention sites will receive the Enhanced OA Care Plan, including access to Patient Peer Support website and PCP reports. All surgeons that used the OA Care plan in Aim 2 will be invited to participate in the Enhanced OA Care plan in Aim 3.

When patients are contacted to complete the post-visit 1-month Decisional Conflict Scale, we will inquire as to whether the surgeon and patient reviewed the A.S.K. Report together. This allows us to understand report use rates for all patients.

See modification to 1-month Decision Conflict Scale (attached – 'Addendums to 1-Month Decision Conflict Scale' and 'SPANISH Addendums to 1-Month Decision Conflict Scale') with the addition of a question about understanding of the OA Care Plan for all patients. Those in the Enhanced Care Arm will also be asked to complete questions in the 1-month Decision Conflict Scale about their confidence to manage treatments (attached – 'Addendums to 1-Month Decision Conflict Scale'). A Spanish translation of the confidence questions is not included as only English-speaking patients are enrolled in the Coaching session as previously approved.

Note: Spanish language enrollment was implemented as planned, but discontinued in the last 9 months of subject enrollment when the Spanish language research coordinator left the study to pursue alternate work).
Aim 3 Enhanced Intervention (or A.S.K. Coaching Session).

Aim 3 patients receiving care with one of the surgeons randomized to receive the ASK report will follow procedures as described for Aim 2 (above).

Aim 3 patients receiving care with one of the surgeons randomized to the Enhanced intervention will follow the procedures described above for Aim 2 AND the procedures developed for the ASK Coaching session and website.

<u>Procedures to invite patients to participate in the ASK Coaching Session (Aim 3 intervention)</u>

The recruitment packet for patients receiving care by an Enhanced intervention surgeon will be the same as described above and will also include: (1) the Fact Sheet describing the ASK Coaching Session (see attached Coaching Session Fact Sheet) and (2) the 'Join Us for ASK Coaching' flyer (see attached).

After the research coordinator completes the verbal consent process and the 1-month Decisional conflict assessment, s/he will then invite the patient to participate in the one-hour ASK Coaching session. (See attached Aim 3 additions to invitation phone call Coaching invitation). The coordinator will review the Coaching session Fact Sheet and answer questions. Participation in the Coaching session is not mandatory, but is encouraged as a way to review the information in the ASK report, and coach patients to use the information when discussing treatment options with their medical team. The session is 1 hour and uses a virtual Zoom web-platform. Participants can also opt to join by phone alone. Sessions will be scheduled weekly, alternating between mid-day and early evening to meet participant needs, and led by a trained health educator. The session will not offer clinical advice. (See Coaching session script and ASK Coaching Power-point slides.)

Participants scheduled to attend the Coaching session will receive a mailing with another copy of their ASK report to refer to during the session, and (1) a welcome letter, (2) a copy of the Coaching Powerpoint slides, (3) the "I have a voice" patient handout to prepare for medical visits, and (4) instructions for using the Zoom conferencing system. (See attachments – Coaching session welcome letter, ASK Coaching Powerpoint Slides, I Have a Voice patient handout, and Zoom Instructions).

At the end of the Coaching session, participants will be introduced to a study website that integrates for easy access publicly available patient information about managing arthritis. See attached ASK Website Outline, including both text and informational web-links as well as the ASK Annotate Report for Patients, which will be available on the site. The website links patients to professional society information (e.g., American Association of Orthopedic Surgeons, American Physical Therapy Association) and patient advocacy information (e.g., Arthritis Foundation).

After the Coaching session, participants will receive two emails and one postcard:

(1) Sharing the link to the study website, and asking participants if they choose to share the ASK report with their primary care provider. If they choose to share it, participants will reply to the email granting permission and include the name and email address of the provider. If they choose not to share, they will do nothing.
(1) Asking participants to complete a brief web-based evaluation of the Coaching session. The assessment will ask questions about what was learned from the coaching session, confidence related to managing treatment, and understanding of the OA Care plan. (Attached – 'Post-Coaching Evaluation Email' and 'Post-Coaching Evaluation Survey'). Up to 3 reminder emails (Attached – 'Post-Coaching Evaluation Email Reminder') and a phone call to complete the coaching evaluation may be sent/made.

In addition to phone calls, we will also use text messages to schedule calls with patients. Participants will not complete any study documents through text so no protected health information will be transferred. Patients have been requesting text communication and already provide their phone number at the initial enrollment. We will use existing scripts, emails and letters that have already been approved by the IRB in our text message communication.

(SEE REVISED DETAILS BELOW)
We will also provide participating sites/surgeon offices with a poster that includes their site name (see attached ASK poster) to hang in patient waiting rooms and patient brochures (see attached ASK patient brochure) for sites to distribute as they wish, including in waiting rooms or in clinic materials mailed to new patients in anticipation of their appointment.

From time to time surgical office staff members take time off, so at these times we will train additional office staff to enter new-visit patients into the study's web-system. With PCORI's support, we may offer cookies or other edible item for office staff to share following re-training if they continued to meet the enrollment standards. We ensure that the enrollment standards are attainable based on reviewing our detailed records of historical enrollment rates at each site. This case finding step is viewed as "usual care," and the office staff who receive the edible item are distinct from the research staff who invite study participation (consent). In total, up to $60 (cookies or other edible item) *10 offices =$600 per year may be allocated to these costs.

Procedures to invite patients to participate in the Aim 3 Patient Qualitative Interviews

Goals:

- Understand patients' perspectives of OA Care plan when choosing surgery or non-surgical care.
- Understand patients' perspectives of A.S.K. Coaching session.
- Compare patients' perspectives of OA Care plan with and without Enhanced support (coaching).

Methods:

For patients in Usual Care sites (no coaching):
'Aim 3 Patient Interview Fact Sheet' (see attached) will be included in mailing/e-mailing of initial consent packets for all Aim 3 patients in the Usual Care arm until interviews are completed.

We plan to invite for an interview approximately 2 participants from this arm per week, for up to 17 participants total.

After the research coordinator completes the verbal consent process and 1-month Decisional Conflict assessment, the coordinator will invite the patient to the interview (See 'Aim 3 Patient Interview – Additions to Invitation Phone Call'). The coordinator will review the Aim 3 Patient Interview Fact Sheet and answer questions. The modified recruitment script will be

used until interviews are completed. Interviews will take place within 4-6 weeks of the office visit with surgeon. Patients who schedule an interview will receive 2 additional emails: 1 with a copy of their personalized report for reference during the interview ('Aim 3 Patient Interview – Report Email') and 1 as a reminder of their session ('Aim 3 Patient Interview – Reminder Email').

For patients in Enhanced Intervention sites (Coaching):
'Aim 3 Patient Interview Fact Sheet' (see attached) will be included in mailing/e-mailing of initial consent packets for all Aim 3 patients in the Enhanced Intervention arm until interviews are completed.

We plan to invite for an interview approximately 5 participants from this arm per week, for up to 33 participants total.

After the research coordinator completes the verbal consent process, the 1-month Decisional conflict assessment, and the invitation to the ASK Coaching session AND the patient schedules a Coaching session, the coordinator will invite the patient to the Interview (See 'Aim 3 Patient Interview – Additions to Invitation Phone Call'). The coordinator will review the Aim 3 Patient Interview Fact Sheet and answer questions. The modified recruitment script will be used until interviews are completed. Interviews will take place within 2-4 weeks of coaching session and within 6-8 weeks of office visit with surgeon. Patients who schedule an interview will receive 2 additional emails: 1 with a copy of their personalized report for reference during the interview ('Aim 3 Patient Interview – Report Email') and 1 as a reminder of their session ('Aim 3 Patient Interview – Reminder Email').

For all patients:
Participation in interviews is voluntary. The interview is 1:1, will take up to 1 hour (estimated 30-60 minutes), and uses a virtual web-platform (Zoom). Participants can also opt to join by phone alone. Sessions will be scheduled at various times of day to meet patients' needs. Trained interviewers will use a semi-structured discussion guide (see attached 'Aim 3 Patient Interview Guide'). With participants' verbal consent, interviews will be audio-recorded. Participants will receive a $20 gift card after completing the interview in appreciation for their time.

Twenty-five interviews were completed as planned in 2021. In 2022, we plan to interview an additional twenty-five patients at two time points, pre and post coaching. The consent plan and reminder emails will match the initial twenty-five interviews. An updated interview guide is attached.

Qualitative interview of the surgeons to get their feedback on the report.

Goals: Conduct interviews of all participating surgeons, as possible, to:

1. Assess surgeon use of *each component* of the ASK report- how was it used? in which patients?

p1- descriptive data: (a) symptom severity/PROs, (b) clinical risk profile
p2- predictive data for surgical treatment: (a) predicted scores, (b) predicted symptoms
p3- comparative grid of non-operative options

2. When ASK report is not used; why not? (office flow or time? patient factors? report content?) If due to report- what modifications (if any) would improve the report?

3. What office systems facilitated use? limited use?

Methods: Two study investigators will conduct up to 35 interviews via telephone with orthopedic surgeons participating in the A.S.K. study to understand their experiences using the A.S.K. predictive reports. Participation in interviews is voluntary. Interviews will follow a semi-structured discussion guide (see attached 'Qualitative Interview Guide Surgeons FINAL') and last approximately 30-45 minutes. With verbal consent, interviews will be audio-recorded. No remuneration will be provided to surgeons for their participation. This work is part of the study evaluation with the aim of understanding the context of report use and opportunities for future improvement.

9. STUDY TIMELINES*

Aim 1 Interviews (in place of Focus Groups)
Individual participants will complete an interview lasting approximately 60 minutes.
We anticipate that we can recruit within 6 months.
We anticipate an additional 6 months to complete data analyses.

Aims 2 and 3
Participants will participate in the study for approximately 1 year, from the time of treatment decision to completion of the 12 month FU survey.
We anticipate that it will take approximately 1.5 years to recruit 3000 for Aim 2 and 1.5 years to recruit for Aim 3.
We anticipate that primary analyses will be completed in 5 years (2022).

10. STUDY ENDPOINTS*

Primary Outcomes Measures:
1. To assess the effect of OA Careplan on (a) decision quality using a validated Decisional Conflict Scale and (b) pre-to-post decision pain relief and functional gain, using the HOOS (for hip patients) or KOOS (for knee patients).
2. To evaluate the effect of the OA Careplan+Support on (a) decision quality using Decisional Conflict Scale and (b) pre-to-post decision pain relief and functional gain, using the HOOS or KOOS.

11. PROCEDURES INVOLVED*

See #8 above
Surgeon offices will be randomized to Usual Care or Intervention sites. During Aim 2, after completing the surveys in the clinic, usual care patients and surgeons will have the ability to

see PRO scores, but will NOT receive feedback (no OA Care Plan) as PROs are the current standard of care in orthopedic clinics. For intervention sites, the patient and surgeon will receive the OA Care Plan (now called A.S.K. report). In Aim 3 (see details above), all patients (both study arms) will receive the A.S.K. report. In addition, patients at intervention sites will be invited to attend the ASK Coaching session to review the content of the report, discuss how to use the report in communication with the medical team, and to learn more about arthritis self-care.

Data collected include the following: New Patient Baseline [Knee/Hip] surveys; 1-month Decisional Conflict Scale;), 6-month and 12-month [Knee/Hip] surveys attached).
These data collection sheets will be submitted to the IRB once they are developed.

12. DATA AND SPECIMEN BANKING*

No specimens will be banked for future use. See #13, Data Management, for data retention and access.

13. Data Analysis and Management*

Responsibility for 6 month and 12 month outcome data collection was transferred from UMMS to Northwestern during 2021. At the completion of study enrollment (on or about March 1, 2022), the UMMS data enrollment and collection services will be completed. At that date, the UMMS data center will have already, or will then, transfer all enrollment, patient-reported, and study data to Northwestern for the analytic team to manage and analyze. The UMMS data center will confirm that they expunged all ASK study data from the web-based data capture systems (DatStat, RedCap) and UMMS data storage files within UMMS.

Aim 1
We will transcribe recorded interviews and code using content analysis techniques to identify themes. We expect to achieve data saturation at or before completing 30 interviews with patients and 30 with caregivers.
AIM 2 and 3. Sample size and effect size estimates:
The trial is designed with ≥80% statistical power at 5% significance level to detect intervention effects that are meaningful to both patients and surgeons, and health systems. In total, 40 (Aim 2) or 54 (Aim 3) surgeons will be randomized equally to treatment and control arms with an average of 100 patients/surgeon. Based on data from FORCE-TJR, the intraclass correlation within surgeon is approximately 0.02. Using two independent group t-tests adjusting for within surgeon clustering, the trial can detect an intervention effect of (a) improved decision quality of >0.16 SD ; (b) improved quality of OA care defined in two ways: 6 month post-decision pain relief (KOOS/HOOS) of ≥3.3 points for TKR patients (34.1 vs. 37.4; SD=20.8) and ≥3.3 for THR patients (45.7 vs. 49.0; SD=20.9) or greater proportion of patients with meaningful pain relief (17 points in HOOS/KOOS pain score) of ≥6.1% more TKR patients (77.9% vs. 84.0%) and ≥4.2% more THR patients (90% vs. 94.2%).

Aims 2 and 3: Overview of analytic approach**.** We hypothesize (Aim 2) that patient/clinician use of the OA Careplan will improve decision quality as well as

satisfaction with the OA care decision, as compared to usual care. Further, we hypothesize that improved decision quality will mediate quality of OA care as measured by lower pain and higher function at 6 and 12 months (KOOS/HOOS) after decision for both TJR and non-operative care. In Aim 3, we hypothesize that the OA Careplan+Support (vs. OA Careplan alone) will incrementally enhance decision quality and quality of OA care (for those who choose to use the Support) with the same measures used in Aim 2.

The general analytic approaches for Aims 2 and 3 are similar and summarized here. The underlying models extend our previous award-winning TKR outcome prediction model where discrete outcome sub-groups were identified. We will adhere to the intent-to-treat principle to analyze the trial data; the intervention status of the surgeon/site and their patients will be analyzed according to their status at the time of intervention. First, descriptive statistics for all relevant outcomes will be tabulated by treatment arm. Select patient factors (e.g., race, sex, function; comorbid factors) that may contribute to heterogeneity of treatment effects will be compared using univariate methods such as t-test for normally distributed variables, Wilcoxon rank sum test for skewed continuous variables, or Chi2 test for categorical variables. We will examine distributions of outcomes, identify proper distribution assumptions, and determine whether or what types of transformations are indicated.

Because the trial data are hierarchical in nature (repeated measures of the same patient nested within participating surgeons/sites), we will use hierarchical generalized linear latent and mixed models (GLLAMM) to analyze the trial data. The model will consider information at the patient and surgeon levels. The basic unit of analysis is at the patient level. Patients nested within the surgeon/site will be considered exchangeable, and sites/surgeons are considered independent from each other. To account for potential imbalance in site/surgeon and patient characteristics, we will adjust for surgeon/site and patient factors in the regression models. Candidate patient level covariables include joint pain severity, pre-decision physical function level, and comorbid conditions, such as diabetes, renal disease, pulmonary disease, depression, obesity, or congestive health failure. Candidate surgeon variables for adjustment include annual surgical volume, procedure type, or geographic region of US. We will follow the parsimonious principle to derive the final models for evaluating intervention effects. First, we will use GLLAMM models to analyze the association of each plausible patient-and site/surgeon-level factor with the outcomes (quality of decision, change in pain severity, function). Those statistically significant variables ($p<0.10$) will be included in a subsequent analysis using multivariable models to identify a parsimonious set of independent patient-and site/surgeon-level covariates. Model development will be guided by clinicians and patient advisors to assure that clinically important variables are included. To identify independent site/surgeon-level variables, we will include each of the significant variables separately while forcing the patient-level covariates into the models. The significance of each site/surgeon-level variable will be determined using (partial) likelihood ratio tests. We will identify a subset of site/surgeon indicators that contribute to outcomes ($p<0.10$), independent of individual-level factors. Furthermore, this subset of significant indicators

will be entered into the same model in order to assess their contributions to the outcome under analysis, after adjusting for each other, as well as the patient-level covariates. Model assumptions will be carefully examined. In these model-building processes, effect modifications will be examined by including interaction terms between relevant covariates, and to ensure the heterogeneity of the intervention effects among patient subgroups are adequately considered. The analyses will be conducted with all patients; and then for TKR and THR patients separately. While the primary goal is to understand patient-level covariates with outcomes, it is critical to assess surgeon/site factors that may influence outcome for all, or sub-groups of patients. For example, obese, diabetic patients with cardiac disease may have more positive decision quality and pain relief with a more experienced high-volume surgeon.

Aim 2: To assess the effect of OA Careplan on (a) decision quality and (b) pre-to- post decision pain relief and functional gain, we will do the following. We expect 20 surgeons and 2000 patients will receive the OA Careplan intervention, and another 20 surgeons and 2000 patients will receive usual care. The analyses will be conducted with all patients; and then for TKR and THR patients separately. First, we will tabulate the decision quality and care outcomes by arm and for select patient subgroups (e.g., sex, age, race/ethnicity). Second, we will use GLLAMM to estimate adjusted Careplan intervention effects by including in the models a Careplan indicator (Careplan intervention=1 vs. usual care=0) and a set of site/surgeon and patient variables for adjustment. A statistically significant coefficient of the Careplan indicator signals possible intervention effect. In this analysis, interaction terms between the Careplan indicator and surgeon or patient factors will be examined, statistically significant interaction terms may suggest the existence of heterogeneity in intervention effects. If present, intervention effects will be analyzed and presented by subgroups.

Aim 3: To evaluate the effect of the OA Careplan+Support (Coaching) on (a) decision quality and (b) pre-to-post decision pain relief and functional gain, we will do the following. The 20 surgeons (and their patients) who received usual care in Aim 2 will receive the OA Careplan intervention (n=2,000) in Aim 3. The 20 surgeons who received the OA Careplan in Aim 2 will now receive the OA Careplan+Support (n=2,000 new patients) in Aim 3. Additional surgeons will be recruited and randomized to the 2 arms. First, we will compare patient characteristics between users and non-users of the SUPPORT. We will then identify patient as well as site/surgeon determinants of the use of the SUPPORT using multi-level logistic regression models, and estimate individual patient's probability (propensity) for any use of SUPPORT strategies. Because use of the SUPPORT is not randomized, we will use inverse propensity weighting approach to estimate the effects of the SUPPORT on outcomes (decision quality, pain, function).

We will begin with descriptive analysis, and estimation of crude OA Careplan+Support intervention effects, overall and by select patient subgroups. We will further use GLLAMM to estimate covariate---adjusted intervention effects, overall and by patient

subgroup, and adjust for propensity scores, plausible surgeon and patient factors. Statistically significant differences between the two arms indicate possible incremental SUPPORT intervention effect beyond the OA Careplan alone. We will conduct pre-post comparisons of the outcomes (decision quality, pain relief) for patients of the 20 surgeons who were in the OA Careplan intervention arm in Aim 2 and are now in the OA Careplan+Support arm.

Statistically significant pre-post changes in outcomes support possible incremental effects of the SUPPORT intervention. We will derive a usage score of the SUPPORT system (e.g., frequency and duration of use) as an indicator of "dosage" of use and use it to estimate a possible "dose-response" relationship between level of use and patient outcomes in the GLLAMM. We will also identify relevant patient-and site/surgeon predictors of any and higher levels of usage.

Second, we will use GLLAMM to analyze the differences in joint pain and function at 6 and 12 months after the care decision between OA Careplan and comparison arms. We will pool data from both arms in the two phases. We will include an indicator variable to represent intervention status (usual care, OA Careplan, or OA Careplan+Support). We will assess whether 6 and 12 month pain differ between intervention arms. Next, we will repeat this process for the patients with meaningful (>17 point) change in HOOS/KOOS pain score. We expect pain relief will be significantly improved in the OA Careplan arm, with greater improvement to occur in the OA Careplan+Support, compared to the usual care group. Finally, we will formally test the mediation effects of Careplan and Careplan+Support on pain relief and functions at 6 and 12 months, using the two level structural equation models with mediation effects by Krull and MacKinnon (2001) and Preacher, Zyphur and Zhang (2010).

Only those listed in our IRB application will have access to identified data.

At this time, there is no plan to destroy the Patient Reported Outcome (PROs) data because of the value to this data regarding national norms for PROs for patients electing to have surgery and those electing non-surgical management of OA.

PHI including individual contact information for follow-up date collection will be destroyed after all surveys have been completed by individual patients 3 years after the completion of the study.

Published data derived from this study will consist of statistical analyses collapsed (averaged) across participants. Under no circumstances will data from individual participants be identifiable in reports or published manuscripts.

Qualitative Interviews of Patients, Analyses: We will transcribe recorded interviews and check transcripts for accuracy. We will code transcripts using content analysis techniques to identify themes. All identifiers will be removed from transcripts before they are uploaded to a web-based qualitative analysis program Dedoose (http://www.dedoose.com/). Two members of the research team will review an initial subset of transcripts and independently generate an initial code book. The code list will be discussed with the research team prior to finalizing. An additional subset of transcripts will be coded using the code book by a pair of coders who will compare their results periodically to reconcile their independent applications of codes. All transcripts will then be coded, and the research team will organize the codes into content areas to summarize findings. Personal identifiable data from individual participants will not be included in reports or published manuscripts.

Qualitative Interviews of Surgeons, Analyses: Interviews will be qualitatively analyzed. Transcripts will be checked for accuracy before being uploaded into the web-based qualitative analysis program Dedoose (http://www.dedoose.com/). All identifiers will be removed from transcripts before they are uploaded. Two members of the research team will begin by reviewing transcripts as they are uploaded to Dedoose and independently generating an initial code list. The code list will be discussed with the research team prior to finalizing. Pairs of coders will apply codes to transcripts and compare their results periodically to reconcile their independent applications of codes. In cases where coder pairs are not able to reconcile code applications, the codes will be presented to the research team during weekly study meetings to examine and adjudicate codes together. Individual coders will be free to propose new codes they feel are not adequately represented on the operational coding list. These proposals will be made at weekly study meetings and accepted codes will be applied to the dataset by coder pairs accordingly. Once coding is complete, the research team will organize the codes into content areas to summarize findings.

14. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS*

Not applicable as this is a minimal risk study.

15. WITHDRAWAL OF SUBJECTS WITHOUT THEIR CONSENT*

Not applicable

16. RISKS TO SUBJECTS*

For participants participating in Interviews, a possible risk is that some questions we ask during the interview could make participants upset. This is highly unlikely as we will asking about opinions, however participants will be encouraged to skip any question they do not want to answer or stop the interview at any time.

No risks are anticipated to the health or wellbeing of the patient participating in this study. The OA Careplan (with or without support) are based on best practices of decision support. However, a theoretical risk to confidentiality exists whenever data are collected for research. All means possible will assure that the patient reported data remain anonymous and confidential in any future analysis or reports. There have been no documented confidentiality breaches in the prior UMMS Orthopedic studies. However, there is a rare chance that one

could occur.

If a breach of the database releases identifiable information, the participating surgeons and the sponsor (PCORI) will be notified immediately. However, we have a protocol to minimize or prevent a breach in confidentiality, including keeping the patient identifiers separate from the analytic dataset. Data management strategies meet HIPAA and research privacy and confidentiality standards. However, if any unanticipated problems or adverse events occur, these will be reported to the UMass IRB as per policy.

17. POTENTIAL DIRECT BENEFITS TO SUBJECTS*

NA

18. VULNERABLE POPULATIONS*

NA

19. MULTI-SITE RESEARCH*

All recruitment methods are local.
See #8 above.

20. COMMUNITY-BASED PARTICIPATORY RESEARCH*

NA

21. SHARING OF RESEARCH RESULTS WITH SUBJECTS*

We will not be sharing research results with individual subjects.

22. SETTING

See #8 above

23. RESOURCES AVAILABLE

Staff training: All project staff will pass the CITI exam on ethical conduct of research. Any newly hired study staff will pass the web-based CITI exam as required by the University of Massachusetts Medical School Institutional Review Board for the Protection of Human Subjects. All project personnel that are engaged in research will have completed the CITI GCP training prior to their involvement in the conduct of the research. In addition, study staff will receive training and supervision regarding patient confidentiality. This training will be directed by Drs. Franklin and Zheng (co-investigator; informatics). The training will address the rights of patients to keep participation decision (yes or no) and health assessment data private and confidential. Research process training will emphasize patient confidentiality, including procedures for separating patient data from identifying information. Training will also emphasize that discussion or disclosure of any information obtained from research participants during the course of the study is strictly prohibited. Prior to having any direct contact with research participants, the on-site coordinators and the UMMS DCC will receive extensive training in recruitment and assessment procedures.

Only those listed in our IRB application will have access to identified data.

- Principle Investigator – The PI will be responsible for the overall organization and completion of this study. She will oversee the collaboration with the surgical groups, and to assure patients are enrolled and retained. As supervisor of the data coordinating center at UMass, she will oversee the web-system development (with Co-I for Informatics). She will also collaborate in the analysis and interpretation of the findings, manuscript preparation. Finally, with the Senior Project Principal Investigator: oversees and manages the entire study
- Co-Investigators: assists and advises the PI about the overall study on research procedures and research questions
- Statisticians: Reviews and analyzes study data and produces reports
- Project Director: Manages the Research Coordinators; reviews and adapts the study processes and operations on going; development of process and protocol relating to medical reporting and follow up including medical chart review, surgeon practice review; oversees analysis and dissemination of clinical and research data. Reviews and implements process in regard to retention; contacts study pts/ppts for recruitment, enrollment, follow up, and retention;
- Verbally consents interview subjects and conducts interviews for Aim 1.
- Research Coordinator-A: Screens, recruits, enrolls, follows up with participants and reviews and processes all patient/participant data
- Research Coordinator-B- reviews, processes, all patient/participant data related to the study such as outgoing and ingoing mail, data entry, data reports,follows up with participants for complete data; mails and receives surveys, files, copies participant materials, reviews all materials related to participant medical event reporting and follow up to this such as chart review, surgeon practice review
- Research Assistant-A: mails and receives surveys, files, copies participant materials
- Co-I of Informatics and Research Database Director: develops, updates, manages databases and processes related to the study databases. Oversees all database development and reporting
- Database Developer: develops, updates and tracks databases used for the study under the Informatics and Research Database Director direction

24. LOCAL RECRUITMENT METHODS

SEE #8 ABOVE

26. CONFIDENTIALITY

Aim 1

Participants will be encouraged to not use any identifiers during the interview, including surgeon name, location or their own name. Once interviews have been transcribed, all recording will be destroyed.

Aim 3 Patient Interviews: Identifiers (such as surgeon name, patient name, hospital name) will be removed from transcripts. Audio recordings will be destroyed after all have

transcribed and all transcripts have been checked for accuracy and deidentified. Original transcripts with identifiers will also be destroyed once all transcripts are checked for accuracy and deidentified.

Confidentiality. The following steps will be taken to insure that all patient data remain confidential. These steps have been used successfully in our prior work.
(a) Use of numeric identifiers: To increase confidentiality, study assessments, including paper data collection forms and electronically stored data will be linked to a unique identifier generated by the programmer.
(b) Data storage: All paper data collection documents will be kept in locked file cabinets within locked offices that are accessible only to the project investigators and staff. Access to the electronic data will be restricted to project investigators and data entry staff. Databases will be password protected to guard against unauthorized access. The servers used for data collection are highly fault-tolerant and are equipped with redundant, hot-pluggable power supplies, redundant network interfaces, and RAID 1/5 hot-pluggable disk storage. Data are encrypted while stored, at a minimum, key sizes of 128 bits for symmetric keys and 1024 bits for asymmetric keys.
(c) Staff training: This training has been the standard of operations for the our previous studies. All project staff have passed the CITI exam on ethical conduct of research. Any newly hired study staff will pass the CITI exam as required by the University of Massachusetts Medical School Institutional Review Board for the Protection of Human Subjects. In addition, study staff will receive training and supervision regarding patient confidentiality. This training will be directed by Drs. Franklin and Zheng. The training will address the rights of patients to keep participation decision (yes or no) private and confidential. Research process training will emphasize patient confidentiality, including procedures for separating patient data from identifying information. Training will also emphasize that discussion or disclosure of any information obtained from research participants during the course of the study is strictly prohibited. Prior to having any direct contact with research participants, the study coordinator will receive extensive training in recruitment and assessment procedures.
(d) Handling of published data and reports: Published data derived from this study will consist of statistical analyses collapsed (averaged) across participants. Under no circumstances will data from individual participants be identifiable in reports or published manuscripts.

We will use the same IRB approved platform for electronic data collection and storage that is used for previously IRB approved studies. This system includes DatStat for web survey data capture and Cogitas (now called Precision Health) or a UMass IT and privacy approved vendor) for secure data hosting. An overview is summarized below:
Data Transmission
Survey responses are encrypted while in-transit between the patient's browser and our servers using SSL (Secure Sockets Layer) 256 or 128-bit Public Key Encryption. The matter of 256 or 128-bit encryption via SSL is dependent on the browser and the server.
Data Availability
Application and data availability is maintained by redundant servers to insure maximum uptime for all hosted applications.

Data Backup
Our database backups are conducted on a daily basis. Backups are encrypted and streamed over on a private network to a secure offsite location. Backups are encrypted using 256-bit AES encryption.
Data Access
Physical access to servers and data backup is restricted to a minimal number of IT professionals. Such access is provided only with strong passwords that regularly expire to minimize the chance that inadvertently and unknowingly distributed passwords could cause inappropriate data access. Access to data stored in servers is available only to designated users who log in with specified usernames and complex passwords. Users are logged out after a period of time.

27. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS

Aim 1
Transcripts will not include any identifiers. Participants will be informed that they do not have to answer any questions that cause discomfort.

For UMass/Memorial patients that are interviewed over the phone, we are submitting a HIPAA Authorization form without signature form for case finding purposes (see Interview HIPAA Authorization form without signature form) and a HIPAA waiver of signature..

For UMass patients interviewed in person, we are submitting a HIPAA Authorization Form with signature (see In person Interview HIPAA Authorization form with signature form)

Aim 2 and 3
All patients and surgeons will be asked to provide verbal informed consent to allow the researchers to maintain individual contact information for follow-up data collection.

Aim 3 Patient Interviews: Identifiers will be removed from transcripts. Participants will be informed that they do not have to answer any questions that cause discomfort.

28. COMPENSATION FOR RESEARCH-RELATED INJURY

No risks are anticipated to the health or well-being of the patients or surgeons participating in this study, and no funds have been set aside**.**

29. ECONOMIC BURDEN TO SUBJECTS

N/A- no additional costs.

30. CONSENT PROCESS

Aim 1
We are requesting a waiver of written documentation of informed consent. The research proposed:

Presents no more than Minimal Risk of harm to subjects

The research involves no procedures for which written consent is normally required outside of the research context
The investigator will provide a written statement regarding the research that embodies the elements of consent
The investigator will provide subjects with that written statement

Written information describing the research will be provided to the subject (i.e., the Patient Interview Fact Sheet or the Caregiver/Trusted Other Interview Fact Sheet will be mailed to subjects in advance and discussed over the phone or in person. The patient will provide Verbal Consent before the patient is enrolled in the project.

Aim 2 and 3
We are requesting a waiver of written documentation of informed consent. The research proposed:

Presents no more than Minimal Risk of harm to subjects
The research involves no procedures for which written consent is normally required outside of the research context
The investigator will provide a written statement regarding the research that embodies the elements of consent
The investigator will provide subjects with that written statement

Written information describing the research will be provided to the subject (i.e., OA Care Plan Consent Form) and will be mailed and emailed to subjects in advance and discussed over the phone. The patient will provide verbal consent over the phone.

See #8 above.

31. PROCESS TO DOCUMENT CONSENT IN WRITING
See # 30 above. We will document receipt of verbal consent.

32. DRUGS OR DEVICES
Not applicable