Study Title: Comparative Effectiveness of Decision Support Strategies for Joint Replacement Surgery

NCT: NCT02729831

Date: December 21, 2017

Document Title: Study Protocol (Approved Human Subjects Research Protocol)

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 R. Sepucha Ph.D.

PROTOCOL TITLE

Comparative effectiveness of decision support strategies for joint replacement surgery

FUNDING

Patient Centered Outcomes Research Institute (PCORI)

VERSION DATE

December 21, 2017

SPECIFIC AIMS

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

The orthopaedic total joint replacement care teams at Massachusetts General Hospital and Newton Wellesley Hospital have been working with the Shared Decision Making Center to integrate the delivery of patient decision aids (PDAs) to patients who are consulting with a specialist. As these efforts have materialized over the past few years, there is an increasing interest in learning which types of patient decision aids are most effective. The purpose of this study is to compare the effectiveness of two different types of decision aids for hip and knee osteoarthritis by examining the decision process and overall decision quality of patients who received either decision aids.

This study will advance our understanding of how to communicate medical evidence and how to engage both patients and health care providers in shared decision making. We plan to compare two high quality PDAs that differ in the amount of content and level of interactivity, and will examine the impact on decision quality, treatments and health outcomes. The study will also examine the impact of two different surgeon-focused interventions—a standard summary report that includes patient reported outcomes (PROs) such as pain and functional status versus an enhanced report worksheet that provides patients' goals and treatment preferences. The study will enroll 1,120 patients considering total joint replacement for hip or knee osteoarthritis in a 2X2 factorial randomized trial and will accomplish the following specific aims:

Aim 1: Evaluate comparative effectiveness of two patient decision aids (a long PDA versus a short PDA) and a surgeon-focused intervention (usual care versus intervention, a summary that includes patients' goals and treatment preferences) on their ability to achieve high decision quality.

Hypothesis 1.1: Overall, patients who receive the long PDA will have higher decision quality than those who receive the short PDA.

Hypothesis 1.2: Patients who receive the long PDA, with more comprehensive information and videos to make the information more salient, will have higher knowledge scores than those who receive the short PDA.

Hypothesis 1.3: More patients who receive the short PDA, with the explicit values clarification exercise, will have a clear treatment preference than those who receive the long PDA.

Aim 2: Follow participants for 12 months to determine the impact of the decision support strategies on treatment choices and health outcomes, specifically, overall quality of life and functional status.

Hypothesis 2.1: Patients with high decision quality (i.e. informed and received preferred treatments) at one week will have better health outcomes at one year compared to those with low decision quality.

Hypothesis 2.2: Patients with high decision quality at one week will have lower surgical rates at one year compared to those with low decision quality.

Aim 3: Identify patient-, physician- and intervention-level factors associated with effectiveness for the PDAs. These factors include (1) patient characteristics (e.g. age, gender, education level, and joint (hip or knee), (2) provider characteristics (e.g. years since graduation, surgical volume), (3) intervention compliance (e.g. whether patients reviewed the decision aids and amount of time spent reviewing the decision aids) and (4) mode of delivery (online or hardcopy).

BACKGROUND AND SIGNIFICANCE

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

Osteoarthritis is a common and debilitating disease and a leading cause of disability in the U.S. and a growing public health problem. More than one-third of adults 65 and older have OA (1) and the majority report at least some degree of limitation. A significant percentage of patients with OA (40%) report that their overall health is only “fair” or “poor” (2). Studies have also found that adults with OA have higher rates of death from all causes, cardiovascular deaths, and dementia deaths (1.6, 1.7, and 2.0 times higher respectively) compared with the general population (3).

Joint replacement surgery is a common treatment for OA and more than 1,000,000 hip and knee replacements were performed in 2010 in the U.S (4). The decision about whether or not to have joint replacement surgery requires patients and clinicians to make tradeoffs between the chance of symptom relief and potential complications. For example, total hip or knee replacement provides a high likelihood of near complete pain relief (80-90%) but carries a small chance of serious complications (1-5%) and requires considerable time and effort for recovery (5,6). Delaying or waiting for surgery does not decrease the effectiveness, so in order to determine whether or when surgery may be warranted, providers need to understand how bothered patients are by their symptoms and how concerned they are about the prospect of having surgery. The decision to have surgery depends on a complex interplay of having an appropriate clinical condition and patients’ informed preferences.

Patients are not routinely informed or engaged in decisions about total joint replacement. Clinical guidelines for treatment of OA emphasize the importance of informing patients and engaging in shared decision making (SDM) to determine the best treatment (5,7). However, studies have found little evidence of shared decision making in routine care (8,9). Patients with hip and knee osteoarthritis are not well informed about the options and outcomes, and one third

report that they were never asked about their goals or treatment preferences for this elective procedure (8,9).

There are several gaps in our understanding of how to best improve the quality of decisions. Patient decision aids (PDAs) can help inform and engage patients in medical decisions, and international standards have been created for the development of high quality decision aids (10). Recently, there has been considerable controversy around PDAs, specifically whether traditional, longer programs can be replaced by shorter, more interactive tools (11,12). Although there are more than 115 randomized controlled trials comparing the use of decision aids to usual care (without decision aids), the published literature does not include many head-to-head comparisons of different tools (13). Second, most studies focus on patient interventions, so relatively little is known about effectiveness of interventions targeted at physicians or at the visit itself. Third, few studies have examined whether using interventions to improve decision quality results in better health outcomes. This study will address each of these gaps.

As patient decision aids (PDAs) proliferate and efforts to integrate shared decision making into routine care expand, understanding the comparative effectiveness of different interventions is critical. This study will be the first study to compare effectiveness of PDAs from two leading vendors. The vendors, Health Dialog and Healthwise, employ different design features (e.g. use of video for patient narratives, interactive values clarification exercise) and the study will help advance our understanding of the relative impact of the different features on decision quality. This study will also allow us to determine the impact of a provider facing intervention through the delivery of an enhanced patient reported summary sheet.

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."

This is a randomized trial with a 2x2 factorial design to examine the comparative effectiveness of two PDAs and an in-visit intervention. In the study, patients will be surveyed shortly before their initial visit with an orthopedic specialist and again about 1 week and 1 year after the visit. Patients scheduled for an appointment with the orthopedic specialist will be screened for eligibility (criteria are listed in Table 1) and if eligible, will be randomized to receive either the Health Dialog or Healthwise decision aids to review before their visit. A computer generated randomization allocation sequence will be created for participants. Eligible patients will receive a cover letter and an information sheet about the study that includes instructions about how to opt-out in the mail before their visit. Those who do not opt out will then be enrolled in the study. The random assignment originally assigned to patients who are found ineligible after their visit will be put back to the queue and become available for the next eligible patient.

Providers will be randomly assigned to usual care or intervention group (a worksheet which includes patient's goals and preferences). Providers in the worksheet group will receive short training on the use of the worksheet.

The study will enroll patients at three sites: an academic center, the Arthroplasty Department at Massachusetts General Hospital (MGH), a community hospital, Kaplan Joint Center at Newton Wellesley Hospital (NWH), and an orthopedic specialty hospital, New England Baptist Hospital (NEBH). MGH and NWH share common resources that are critical to the conduct of the study, including patient registries which routinely collect similar patient reported data and clinical outcomes for hip and knee osteoarthritis patients. Both these sites also have access to both

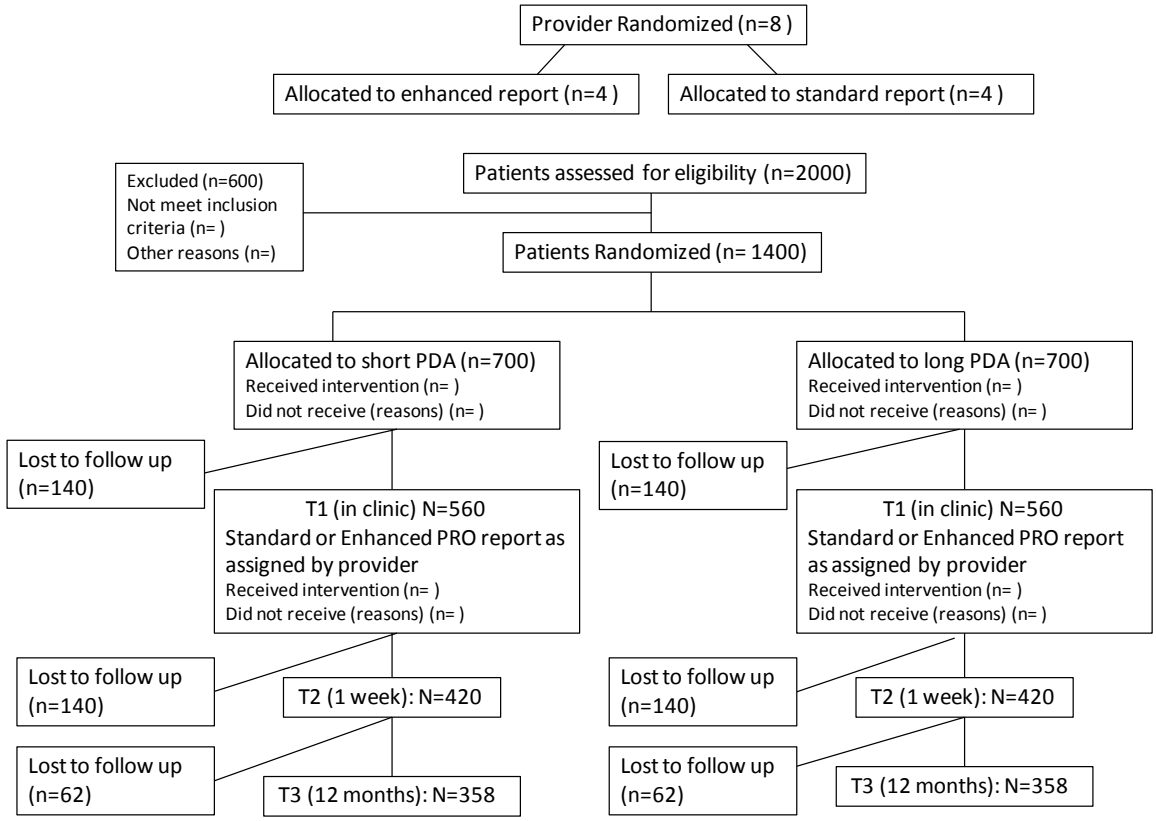
Healthwise and Health Dialog decision aids through Partners Healthcare's contracts with those vendors. NEBH is not a Partners-affiliated hospital and therefore requires separate coordination efforts to execute the research study.

Table 1: Eligibility for survey study

	Eligible	Ineligible
Knee and Hip Osteoarthritis	• Diagnosis of knee or hip OA • Adults, age 21 or older • Scheduled new patient visit with participating orthopaedic specialist	• Prior partial or total knee or hip replacement surgery on joint of concern within 5 years • Hip fracture or aseptic necrosis at any time in 12 months prior to visit • Rheumatoid arthritis or psoriatic arthritis • Does not read or write in English or Spanish • Unable to consent for self due to cognitive or other medical issue(s) • Prior decision aid order for joint of concern

Patient participants will be surveyed at three time points, before their visit with the surgeon, about one week after the visit, and again 12 months after the visit. Data from our previous studies suggests that we will have about 65 eligible new patients each month for the study enrollment period. We plan to enroll patients for about 12 months and estimate 1,120 patients will complete the first assessment in-clinic or before the visit with the surgeon, 840 (75%) will complete the second assessment one week after the visit, and 716 will complete the third assessment about one year after the visit. The sample size calculations consider both the potential for interaction effects between the interventions as well as the potential impact of clustering of patient participants within surgeons. Figure 2 offers a more detailed look at the projected screening and enrollment numbers.

Figure 2: CONSORT Flow diagram with estimates for screening, enrollment and response rates



Legend: PDA=patient decision aid, T1=in clinic before surgeon visit, PRO=patient reported outcomes; T2=1 week post visit; T3=6-12 month post visit

New patients coming to see a specialist in the Arthroplasty group at MGH complete surveys in the clinic via a computer or tablet. The surveys cover quality of life, pain, functioning and symptoms and are administered through the Harris Joint Registry (IRB # 2002-P-001823). The surveys for this study will be incorporated as an additional module in the Harris joint registry for arthroplasty patients at MGH and will be administered by paper, by computer in the clinic or via Redcap depending on the patients' preference and the timing of the visit. The new patients at NWH will similarly be offered to complete the patient reported quality and functional status surveys by paper, by computer or tablet in the clinic, or by email in advance of their visit as covered by their patient reported outcome registry protocol (IRB protocol 2014P000696). New patients at NEBH will be asked to complete the quality of life surveys as part of the initial pre-visit survey for the study.

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.

Study Procedures:

1. The principal investigator will obtain permission from participating clinicians at each site to screen their patients for eligibility and enroll eligible patients onto the study. Some, but not all, participating clinicians may also be co-investigators.
2. The statistician will generate a random allocation sequence to indicate which decision aid each participant should receive. The statistician will also group providers at each site by patient

volume and randomly assign each group to the usual care or intervention group for the in visit intervention.
3. The research coordinator, with support from the research nurse or other clinic staff, will review the schedules of participating clinicians and the Epic research report, if available, to complete the eligibility screener to the extent possible and identify potentially eligible participants
4. The research coordinator may call potentially eligible patients to clarify any information about eligibility.
5. The staff at Health Decision Sciences Center will send the assigned decision aid, cover letter, information sheet, and appropriate survey (depending on provider assignment) to eligible patients in advance of their upcoming visit in the arthroplasty service. The letter will include information about how to opt-out of the study. The packet for subjects will include the survey (T1) so they have the option of completing the survey at home and bringing it with them to the visit.
6. Two days before the scheduled visit, study staff may call subjects who did not opt out to answer any questions about the study, and to remind them to review the decision aid before the visit, and complete the survey. Study staff can administer the survey over the phone if the patient prefers to do so.
7. On the day of the visit, the study staff will discuss the study with the eligible patients who did not opt-out. If the patient agrees to participate, then study staff will administer the survey either on paper or electronically if tablet or computer is available.
8. By completing this first assessment, participants will give consent to enroll in the study.
9. Study staff will work with the Harris Joint Registry at MGH and NWH data registry to download the completed quality of life and the study questionnaires for all participants.
10. The surgeon will receive the enhanced report (depending on their study assignment) for their participating patients.
11. A research coordinator will review medical record after the visit to complete the eligibility screener, as needed, and will send the second survey (T2) by mail or email within a week of the specialist visit to all confirmed eligible patients who did not opt out. If patients have not completed the routinely collected quality of life while at their visit, it will be included with this survey.
12. Study staff will follow-up with a phone reminder about one week after sending the survey, followed by a mailed reminder or up to three email reminders, and a second phone reminder for all the participants who did not complete the surveys. Participants who are receiving the survey by email will also get one mailed reminder if it is not completed in two weeks. Patients will be given the option to complete the survey by phone.
13. All participants who complete the T2 survey will receive a thank you note.
14. About 6 months from the date of their initial visit, study staff will confirm participant surgical status and will send participants the third survey (T3) by mail or email. Non-surgical patients will receive T3 about 6 months from their consultation and surgical patients will receive T3 about 6 months from their surgery date. Study staff will follow up with a phone reminder within 1 week, a second mailing or up to three reminder emails as appropriate, and a second phone reminder for non-responders. For those who do not respond to the email reminders, we will mail them a survey before the second phone reminder.
15. All patients who receive the final survey will also be able to indicate their consent to be contacted in the future for other studies run out of the Health Decision Sciences Center. Of 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 indicated, to invite them to participate in future projects and studies.
16. Study staff will review completed surveys soon after receipt and enter survey data into the study database as needed. If there are large portions of the surveys that are missing the study coordinator will contact the participant to determine whether the items were intentionally skipped

(in which case no further action will be taken) or whether it was not intentional and in this case will provide any needed clarification and request that the items be completed.
17. All participants who complete the T3 survey will receive a thank you note including an answer key to the knowledge section of the T1 and T2 surveys.
18. Study staff will collect additional data from the medical record (including patient demographics, treatments received for the hip/knee, co-morbidities, and clinician visits related to the hip/knee) in the 12 months since the initial visit, patient-reported quality of life and functional status data from the Harris Joint Registry and Newton Wellesley Hospital's Kaplan Joint Center registry (IRB# 2014P000696) databases, and use of decision aids from the Shared Decision Making database (IRB 2005p-002282).
19. Limited data will be kept on non-responders including joint, age, gender, physician, decision aid assignment, reason for refusal (if available), and all elements in the eligibility screener. This information will be used to examine non-response bias.
20. Study data will be cleaned, surveys will be scored, analyzed and manuscripts will be prepared for publication.

Clinician surveys:
Participating clinicians will complete a short survey for a subset of their participating patients. The survey will include questions about satisfaction with the visit and rating of the quality of the decision. Research coordinators will approach the clinician in person with paper survey shortly after the initial visit. If they are not able to connect in person, they will send an email with the survey for each patient and will make up to three reminders via email to encourage the surgeon complete the survey.

All study staff are CITI certified and will receive training from the PI and program manager in the study protocol.

Outcomes:
This study will capture three main types of outcomes – these include patient-reported measures related to decision making (e.g. decision quality, decision making process and regret), patient-reported health outcomes (e.g. knee and hip pain, quality of life and functioning) and medical treatments received by participants.

We will collect the measures listed below. Table 3 shows the measures assessed at each time point as part of this study and the estimated burden on participants.

Measures:
Decision Making Measures (timing of use)
1. Hip OA and Knee OA Decision Quality Instruments (T1, T2, T3): Each DQI contains 5 decision-specific, multiple-choice knowledge items, 5 decision-specific goals and concerns (rated on an 11 point importance scale), one treatment preference item. The DQI results in a knowledge score (0-100%) and a concordance score (0-100%) indicating the percentage of patients who received treatments that matched their stated preference, and an involvement score (0-100%) with higher scores indicating more patient involvement in decision making. The minimal important changes (MIC) in knowledge and concordance scores are 10% (14).
2. Decision Process Score (T2, T3): 7 items that assess the decision-making process including whether options, outcomes and preferences were discussed. A total score is generated and scaled to (0-100%) with higher scores indicating more patient involvement in decision making. 3 items that assess general satisfaction with the visit.(9)
3. Functional goals (T2, T3): participants will list the top three things that they need or want to do but are unable to do because of their knee or hip pain (at T2). Then at T3, they will indicate to what extent they are able to do those three things.

4. SURE scale (T2): A brief, 4-item version of the widely used Decisional Conflict Scale (15) that measures patients' uncertainty about which treatment to choose and factors contributing to uncertainty (feeling uninformed, unclear values, and unsupported in decision making).
5. Decision regret (T3): 5-item Likert scale that measures distress or remorse after a decision. A total score (0-100) is calculated with higher scores indicating more regret. The scale has demonstrated strong internal consistency (0.81-0.92) and correlates with decision satisfaction and quality of life (16).

Health Outcomes Measures (timing of use)
6. EQ-5D (T1, T3) is a 6-item summary measure of health status for use in evaluating health and healthcare (17). It also generates a single index value for health status on which full health is assigned a value of 1 and death a value of 0. In conjunction with weights established for the 243 different combinations, the EQ-5D can be used to obtain quality-adjusted life years (18). The minimally important change is 0.1 points (19).
7. Knee injury and osteoarthritis score (KOOS) (T1, T3) The KOOS and HOOS questionnaires were developed to assess the patients' opinions about their knee or hip and associated problems and have been used extensively (20-28). Three subscales, pain, symptoms and functional status will be used in this study. A normalized score (100 indicating no pain/symptoms and 0 indicating extreme pain/symptoms) is calculated for each subscale.
8. Harris Hip Score (HHS) (T1, T3): The HHS assesses pain, function, range of motion and deformity for each hip. Pain receives 44 points, function 47 points, range of motion 5 points, and deformity 4 points for a total of 100 points. Function is subdivided into activities of daily living (14 points) and gait (33 points).The higher the HHS, the less dysfunction. A total score of 70 is considered a poor result; 70 – 80 is considered fair, 80 –90 is good, and 90 –100 is an excellent result. No normative values are available.

Additional items
9. PDA use (T1, T2): items will assess how much of the DVD, booklet and/or website was reviewed (all, some, a little, none) and how much time did they spend reviewing it (0-5 minutes; 6-10 minutes; 11-20 minutes; 21-30 minutes; >30 minutes).
10. Treatment received (T3, chart review): surgical and non surgical treatments tried in the twelve months after the visit will be self reported by patients and also collected via chart review.
11. Expectations (T2, T3): 4 items will assess expectations for pain relief, limitations in daily activities, overall success of surgery and complications (29).
12. Demographics (T2): information such as education, employment, marital status will be self reported.
13. Satisfaction (T2, T3): questions to assess overall satisfaction with quality of visit or treatment outcome
14. Information use (T3): 1 question to assess what sources of information patient about their health condition they found important
15. IMPACT index (T2, T3): 7 items assessing the impact of hip and knee osteoarthritis on patients' perception of their condition: worry, pain, limitation, confidence, and involvement in decision making.

Table 3: Measures including in surveys

Measures	Pre-visit (T1)	~ 1 week (T2)	~ Follow-up (T3)
Visit goals and functional goals	2 (physician intervention group only)		
		12	

Decision Quality Instrument	9		0
Decision aid use	1	1	Not asked
Decision making process	0	11	7
Functional goals	Not asked	2	1
SURE	Not asked	4	Not asked
Expectations	Not asked	10	10
Quality of life, pain and functioning (KOOS or HHS, EQ-5D)*	Routinely collected	Not asked	Routinely collected
Decision Regret	Not asked	Not asked	5
Satisfaction	Not asked	1	2
Demographics and treatment history		5	2
Health literacy	1	Not asked	Not asked
Impact Index	Not asked	7	7
Total number of items	13 (MD usual care group)/ 15 (MD intervention group)	53	34
Total time estimate	5 minutes	15 minutes	15 minutes

*These items are asked as part of routine care at this time point.

Randomization and blinding

Provider randomization will be stratified by site. Within each site, surgeons will be divided into two groups with similar patient volume. One of the two groups will be randomly assigned to usual care and the other to receive the in-visit worksheet. It will not be possible to blind the research staff, patient or providers to the group assignment for providers; however, those entering data and those analyzing the data will be blinded to group assignment.

A computer-generated randomization allocation sequence will be created for patients from each site. After confirming eligibility, the staff at the Health Decision Sciences Center that fulfills PDA orders will have access to the sequence in order to deliver the appropriate decision aid. The staff who fulfill the orders will not be the same staff that approach patients in clinic. To the extent possible, the research staff calling participants on the phone and/or approaching them in clinic will be blinded to the PDA assignment. In our pilot, several patients brought the decision aid to the clinic with them, and as a result, it was clear which intervention they received. Patient participants have the opportunity to opt-out before their visit, and those who do not opt out will be enrolled in the study. The random assignment originally assigned to subjects who are found ineligible will be put back to the queue and become available for the next eligible subject.

Patient participants will not be blinded to the PDA assigned to them; however, they will not be given any explicit information on the surgeon assignment. Likewise, surgeons will not be blinded

to their intervention group, but they will not be given any information on the type of PDA the patient used. The study staff doing chart review and data entry will be blinded to the patient and provider assignments to avoid unintended bias. The statistician analyzing the data will also be blinded to the study assignments.

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.

This study involves reviewing patient educational materials, completing surveys and conducting medical chart review. No diagnostic tests or treatments will be offered or administered as part of this study.

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

There are minimal risks to participating individuals associated with or attributable to this study. The main risks are associated with loss of privacy of their health information.

The time required for patient participants to complete the first survey is about 5 minutes and the time required to complete the follow-up surveys is about 15 minutes each.

Consent for participants will be implied by completion of the first survey. Participants may opt out of the study, may refuse to answer any question (or set of questions) and may discontinue their participation at any time. It will also be emphasized that whether or not subjects participate will not impact the medical care that they receive.

The surgeons will complete surveys for about 30% of their patient participants. Each surgeon survey should take 1-2 minutes to complete.

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 group

The participation of subjects in the study involves completing one to three surveys. Participants will be told that participating in the study and completing the survey(s) is voluntary and that they may refuse to answer any questions or set of questions and may discontinue their participation at any time.

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 infan

As stated above, there are minimal risks to individuals participating in this project. The main risks are the time and effort involved in participating (about 5 minutes for initial survey and 15 minutes for each follow up survey) and loss of privacy. The surveys will programmed into the IRB approved Harris Joint Registry (2002-P-001823), IRB approved NWH Kaplan Joint Center's registry (2014P000696) and/or REDCap web-based survey. All patient identifiers will be kept in a password protected files (Excel, Access database). Only members of the research team will have passwords to access the files and they will only access the files from Partners computers or encrypted laptops that are protected with SafeBoot. All patient information on eligibility screeners, chart reviews, and surveys collected at NEBH will be sent securely using a secure file transfer to the Partners network. To ensure confidentiality, all paper surveys will be identified by study code number only and kept in a locked file cabinet and the electronic files will be on password protected Partners server. To address issues of psychological discomfort, research assistants will inform patients that they may refuse to answer any question and may withdraw from the study at any time. Reminders will also include contact information for the PI and study staff in case participants have questions or concerns.

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.

The patients may benefit from reviewing the educational materials, as these types of tools have been shown to improve knowledge, reduce decisional conflict and help patients participate in treatment decisions. There are no direct benefits to patients from completing the surveys. By completing the decision making survey items, participants may identify some gaps in knowledge that the clinicians are able to address during or after the visit and they may clarify their goals to share with the clinician. The study will provide evidence for comparative effectiveness of two different tools, as well as an in-visit intervention. The results will help the field understand the best way to inform and engage patients in significant medical decisions.

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.

We have restricted the study to adults, both men and women. Children are not eligible as they rarely have these conditions.

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.

At this time, the patient decision aids are only available in English and Spanish so there will not be an intervention for patients who do not speak or understand English or Spanish.

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.

1. The principal investigator will obtain permission from participating clinicians at each site to screen their patients for eligibility and enroll eligible patients onto the study. Some, but not all, participating clinicians may also be co-investigators.
2. The statistician will generate a random allocation sequence to indicate which decision aid each participant should receive. The statistician will also group providers at each site by patient volume and randomly assign each group to the usual care or intervention group for the in visit intervention.
3. The research coordinator, with support from the research nurse or other clinic staff, will review the schedules of participating clinicians and the EPIC research report, if available, to complete the eligibility screener to the extent possible and identify potentially eligible participants.
4. The research coordinator may call potentially eligible patients to clarify any information about eligibility.
5. The staff at Health Decision Sciences Center will send the assigned decision aid, cover letter, information sheet, and appropriate survey (depending on provider assignment) to eligible patients in advance of their upcoming visit in the arthroplasty service. The letter will include information about how to opt-out of the study. The packet for subjects will include the survey (T1) so they have the option of completing the survey at home and bringing it with them to the visit.
6. Two days before the scheduled visit, study staff may call subjects who did not opt out to answer any questions about the study, and to remind them to review the decision aid before the visit, and complete the survey. Study staff can administer the survey over the phone if the patient prefers to do so.
7. On the day of the visit, the study staff will discuss the study with the eligible patients who did not opt-out. If the patient agrees to participate, then study staff will administer the survey either on paper or electronically if tablet or computer is available.
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12. Study staff will follow-up with a phone reminder about one week after sending the survey, followed by a mailed reminder or up to three email reminders, and a second phone reminder for all the participants who did not complete the surveys. Participants who are receiving the survey by email will also get one mailed reminder if it is not completed in two weeks. Patients will be given the option to complete the survey by phone.
13. All participants who complete the T2 survey will receive a thank you note.
14. About 6 months from the date of their initial visit, study staff will confirm participant surgical status and will send participants the third survey (T3) by mail or email. Non-surgical patients will receive T3 about 6 months from their consultation and surgical patients will receive T3 about 6 months from their surgery date. Study staff will follow up with a phone reminder within 1 week, a second mailing or up to three reminder emails as appropriate, and a second phone reminder for non-responders. For those who do not respond to the email reminders, we will mail them a survey before the second phone reminder.
15. All patients who receive the final survey will also be able to indicate their consent to be contacted in the future for other studies run out of the Health Decision Sciences Center. Of 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 indicated, to invite them to participate in future projects and studies.
16. Study staff will review completed surveys soon after receipt and enter survey data into the study database as needed. If there are large portions of the surveys that are missing the study coordinator will contact the participant to determine whether the items were intentionally skipped (in which case no further action will be taken) or whether it was not intentional and in this case will provide any needed clarification and request that the items be completed.
17. All participants who complete the T3 survey will receive a thank you note including an answer key to the knowledge section of the T1 and T2 surveys.

All study staff are CITI certified and will receive training from the PI and program manager in the study protocol. The study staff will also be supported by the research nurse, Janet Dorrwachter, for eligibility screening and patient contact.

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

Participants will be given a $5 cash incentive with both the second (T2) and third (T3) surveys.

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 study. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required. Consent for the study will be implied by completion of the first questionnaire.

A cover letter and study information sheet will be mailed prior to the initial visit along with the decision aid and first survey to eligible participants. The letter will contain information for patients to call or email to opt out of the study if they prefer. Eligible participants will be able to review the information sheet and decide whether they are interested in participating in the study. The principal investigator's name and contact information will also be available on the information sheet if participants have any questions or concerns about the study. The study staff at the time of the visit will discuss the study and answer any questions, the research nurse will be available by pager and study staff/PI will be available by phone to answer any questions.

Patients will need to give consent if they wish to receive the T2 and T3 surveys via unencrypted emails. The IRB information regarding send-secure vs. unencrypted emails will be included on the T1 survey and research staff will discuss this subject with the patients when they join the study. Patients will also be read the IRB policy and asked for verbal consent to receive unencrypted emails over the phone before they are sent the T3 survey. Participants can choose to receive the surveys via a send-secure email or on paper in the mail if they do not wish to receive unencrypted emails.

Clinicians who agree to enroll patients on the study will be informed that they will be asked to complete a short questionnaire for a subset of patients as part of their participation. By agreeing to enroll patients on the study, clinicians will give consent to be surveyed.

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.

Participation in this study involves the completion of three surveys. There are no foreseeable safety risks to participants for completing the surveys. Study staff will be instructed to review surveys within a week of receipt and will notify the PI and clinical investigators on the team about any serious events immediately and all other events at regularly scheduled meetings. Study staff will keep records of any feedback, questions, concerns and/or complaints that are received and we will address them as needed.

Patient names or any other identifying information will not be included in any paper survey and will only be referenced by study code number. The file that links the study code numbers to names and contact information will be kept separately on a Partners password protected server. The medical record chart review data will be kept on Partners password protected server and identifying information. All patient information on eligibility screeners, chart reviews, and surveys collected at NEBH will be sent securely using a secure file transfer to the Partners network.. The survey data will be collected in the IRB approved Harris Joint Registry (2002-P-001823), the NWH registry (2014P000696), or using REDCap.

REDCap (Research Electronic Data Capture) is a free, secure, HIPAA compliant web-based application hosted by the Partners HealthCare Research Computing, Enterprise Research Infrastructure & Services (ERIS) group. Vanderbilt University, with collaboration from a consortium of academic and non-profit institutional partners, has developed this software toolset and workflow methodology for electronic collection and management of research and clinical study data. Data collection projects rely on a study-specific data dictionary defined by members of the research team with planning assistance from Harvard Catalyst | The Harvard Clinical and Translational Science Center EDC Support Staff. The iterative development and testing process results in a well-planned data collection strategy for individual studies. Using REDCap, the research team can also design web-based surveys and engage potential respondents using a variety of notification methods. REDCap provides flexible features that can be used for a variety of research projects and provides an intuitive interface to enter data with real time validation (automated data type and range checks). The system offers easy data manipulation with audit trails, reports for monitoring and querying participant records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus).

For the approved NWH registry (IRB 2014P000696): All data is encrypted and stored in a relational database at a secure data center with advanced security framework safeguarding both the interior and exterior. The servers are highly secure and use HIPAA compliant anti-virus and data security procedures including multiple firewalls, intrusion detection and traffic monitoring. The system will be monitored and audited regularly to track the frequency and reasons for logging onto the system. Only IRB-approved Partners study staff members will have password access to the system.

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

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

No serious adverse events are expected. However, if a serious adverse event occurs then the principal investigator will report the event to the IRB within 24 hours and will file an HRC Adverse Event Form within 10 working days. If a mild or moderate adverse event occurs, the principal investigator will summarize the event in the progress report at continuing review.

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

MONITORING AND QUALITY ASSURANCE

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

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

The study staff and the principal investigator will have weekly meetings throughout the study and will meet at least monthly with clinician and research nurse co-investigators to ensure the project proceeds as intended per the protocol. All participant enrollment will be tracked using a password protected Access database. We will track recruitment rates, initial response rates and follow-up completion rates routinely 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.

Limited data will be kept on non-responders including joint, age, gender, physician, decision aid assignment, and all elements in the eligibility screener. This information will be used to examine non-response bias.

For guidance, refer to the following Partners policies:
Data and Safety Monitoring Plans and Quality Assurance

http://healthcare.partners.org/phsirb/guidance.htm#13

Reporting Unanticipated Problems (including Adverse Events)
http://healthcare.partners.org/phsirb/guidance.htm#7

PRIVACY AND CONFIDENTIALITY

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

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

Special efforts will be made to protect the privacy of subjects. We will have names, addresses, phone numbers and email addresses of eligible participants and this information will be kept separate from the study data. The participants who complete the surveys through the Harris registry or the NWH Kaplan Joint Center registry will follow their approved process. For the participants who receive the survey via mail or email, all patients will receive a study code number and the surveys will only be identified by code number.

Surveys sent by email will be sent either using an IRB approved mechanism through the approved Harris and NWH registries or REDCap. On the T1 survey, patients will be given the option of receiving follow-up surveys on paper, through the send-secure email system, or in an unencrypted email containing the REDCap link. For patients who have not given consent to be sent unencrypted emails earlier in the study, consent can be given over the phone to research staff before the final T3 survey. All paper or verbal consent for unencrypted surveys will be recorded in the study database. The data collected via the medical record review will also be identified by study code number only. The study code number will be used to identify who needs to be followed up for non-response. A separate password-protected electronic file will contain the codes linked to identifying information. Only the MGH and NWH 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, all study files containing personal contact information of participants will be destroyed

To ensure confidentiality, all paper surveys will be kept in a locked file cabinet or in a secure offsite file storage location.

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.

As per requirements of the funder, PCORI, the study team will create a complete, cleaned, de-identified copy of the final data set that will include pre-visit, 1 week and 12 month data. Information for investigators interested in using this data will be made available on the Health Decision Sciences website. Dr. Sepucha will share a de-identified data set with outside investigators at no cost, according to approved MGH 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, etc.

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

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

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

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

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

All patient identifiers will be kept in a password protected files (Excel, Access database, REDCap). Patient eligibility information and medical chart review data from NEBH will be collected via REDCap.

REDCap (Research Electronic Data Capture) is a free, secure, HIPAA compliant web-based application hosted by the Partners HealthCare Research Computing, Enterprise Research

Infrastructure & Services (ERIS) group. Vanderbilt University, with collaboration from a consortium of academic and non-profit institutional partners, has developed this software toolset and workflow methodology for electronic collection and management of research and clinical study data. Data collection projects rely on a study-specific data dictionary defined by members of the research team with planning assistance from Harvard Catalyst | The Harvard Clinical and Translational Science Center EDC Support Staff. The iterative development and testing process results in a well-planned data collection strategy for individual studies. Using REDCap, the research team can also design web-based surveys and engage potential respondents using a variety of notification methods. REDCap provides flexible features that can be used for a variety of research projects and provides an intuitive interface to enter data with real time validation (automated data type and range checks). The system offers easy data manipulation with audit trails, reports for monitoring and querying participant records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus).

REFERENCES:

1. Osteoarthritis. Available at: http://www.cdc.gov/arthritis/basics/osteoarthritis.

2. Guccione A, Felson D, Anderson J, Anthony J, Zhang Y, Wilson P, et al. The effects of specific medical conditions on the functional limitations of elders in the Framingham Study. Am J Pub Health 1994;84(3):351-358.

3. Nüesch E, Dieppe P, Reichenbach S, Williams S, Iff S, Jüni P. All cause and disease specific mortality in patients with knee or hip osteoarthritis: population based cohort study. BMJ 2011;342:d1165.

4. Inpatient Surgery. 2014; Available at: http://www.cdc.gov/nchs/fastats/inpatient-surgery.htm.

5. Katz JN, Earp BE, Gomoll AH. Surgical management of osteoarthritis. Arthritis Care Res (Hoboken) 2010;62(9):1220-8.

6. Mantilla CB, Horlocker TT, Schroeder DR, Berry DJ, Brown DI. Frequency of myocardial infarction, pulmonary embolism, deep vein thrombosis, and death following primary hip or knee arthroplasty. Anesthesiology 2002;96(11):40-46.

7. Jevsevar D. Treatment of osteoarthritis of the knee: evidence-based guideline, 2nd edition. J Am Acad Orthop Surg 2013;21(9):571-576.

8. Sepucha K, Feibelmann S, Chang Y, Clay C, Kearing S, Tomek I, et al. Factors associated with high decision quality for treatment of hip and knee osteoarthritis. J Am Coll Surg 2013 Oct;217(4):694-701.

9. Zikmund-Fisher BJ, Couper MP, Singer E, Ubel PA, Ziniel S, Fowler FJJ, et al. Deficits and variations in patients' experience with making 9 common medical decisions: the DECISIONS survey. Med Decis Making 2010 Sep-Oct;30(5 Suppl):85S-95S.

10. Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. BMJ 2006 Aug 26;333(7565):417.

11. Elwyn G, Lloyd A, Joseph-Williams N, Cording E, Thomson R, Durand M, et al. Option Grids Shared decision making made easier. Patient Educ Couns 2013 Feb;90(2):207-212.

12. Elwyn G, Frosch D, Volandes A, Edwards A, Montori V. Investing in deliberation: a definition and classification of decision support interventions for people facing difficult health decisions. Med Decis Making 2010 Nov-Dec;30(6):701-11.

13. Stacey D, Légaré F, Col N, Bennett C, Barry M, Eden K, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev 2014 Jan 28(1).

14. Stacey D, Bennett CL, Barry MJ, Col NF, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Légaré F, Thomson R. Decision aids for people facing health treatment or screening decisions. Cochrane Database of Systematic Reviews. 2011(10, Art. No.: CD001431):DOI: 10.1002/14651858.CD001431.pub3.

15. O'Connor AM. Validation of a decisional conflict scale. Med Decis Making 1995;15(Jan-Mar):25-30.

16. Brehaut J, O'Connor A, Wood T, Hack T, Siminoff L, Gordon E, et al. Validation of a decision regret scale. Med Decis Making 2003;23(4):281-92.

17. Rabin R and de Charro F. EQ-5D: a measure of health status from the EuroQol Group. Ann Med 2001;33(5):337-343.

18. Shaw JW, Johnson JA, Coons SJ. US valuation of the EQ-5D health states: development and testing of the D1 valuation model. Med Care 2005;43(3):203-220.

19. Jansson KA and Granath F. Health-related quality of life (EQ-5D) before and after orthopedic surgery. Acta Orthop 2011;82(1):82-89.

20. Roos EM and Toksvig-Larsen S. Knee injury and Osteoarthritis Outcome Score (KOOS) - validation and comparison to the WOMAC in total knee replacement. Health Qual Life Outcomes 2003;1:17.

21. Rodriguez-Merchan EC. Knee instruments and rating scales designed to measure outcomes. J Orthop Traumatol 2012;13(1):1-6-doi: 10.1007/s10195-011-0177-4.

22 Collins NJ, Misra D, Felson DT, Crossley KM, Roos EM. Measures of knee function: International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form, Knee Injury and Osteoarthritis Outcome Score (KOOS), Knee Injury and Ostoearthritis Outcome Score Physical Function Short Form (KOOS-PS), Knee Outcome Survey Activities of Daily Living Scale (KOS-ADL), Lysholm Knee Scoring Scale, Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Activity Rating Scale (ARS), and Tegner Activity Score (TAS). Arthritis Care Res 2011;63(Suppl 11):S208-S228-doi: 10.1002/acr.20632.

23. Alviar MJ, Olver J, Brand C, Hale T, Khan F. Do patient-reported outcome measures used in assessing outcomes in rehabilitation after hip and knee arthroplasty capture issues relevant to patients? Results of a systematic review and ICF linking process. J Rehabil Med 2011;43(5):374-381.

24. Collins NJ and Roos EM. Patient-reported outcomes for total hip and knee arthroplasty: commonly used instruments and attributes of a "good" measure. Clin Geriatr Med 2012;28(3):367-394.

25. Klassbo M, Larsson E, Mannevik E. Hip disability and osteoarthritis outcome score. An extension of the Western Ontario and McMaster Universities Osteoarthritis Index. Scan J Rheumatol 2003;32(1):46-51.

26. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. J Rheumatol 1988 Dec;15(12):1833-1840.

27. Nilsdotter A and Bremander A. Measures of hip function and symptoms: Harris Hip Score (HHS), Hip Disability and Osteoarthritis Outcome Score (HOOS), Oxford Hip Score (OHS), Lequesne Index of Severity for Osteoarthritis of the Hip (LISOH), and American Academy of Orthopedic Surgeons (AAOS) Hip and Knee Questionnaire. Arthritis Care Res (Hoboken) 2011;63(Suppl 11):S200-S207.

28. Lawless BM, Greene M, Slover J, Kwon YM, Malchau H. Does age or bilateral disease influence the value of hip arthroplasty? Clin Orthop Relat Res 2012;470(4):1073-1078.

29. Mahomed NN, Liang MH, Cook EF, Daltroy LH, Fortin PR, Fossel AH, Katz JN. The importance of patient expectations in predicting functional outcomes after total joint arthroplasty. J Rheumatol 2002;29(6):1273-1279.