

BMJ Open Protocol for a randomised trial evaluating the comparative effectiveness of strategies to promote shared decision making for hip and knee osteoarthritis (DECIDE-OA study)

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ABSTRACT

Introduction There are several different interventions available to promote shared decision making (SDM); however, little is known about the comparative effectiveness of different approaches.

Objective To examine the impact of patient-directed and physician-directed decision support strategies on the quality of treatment decisions for hip and knee osteoarthritis (OA).

Trial design A 2×2 factorial randomised controlled trial.

Setting One academic medical centre, one community hospital and one orthopaedic specialty hospital.

Participants and interventions The enrolment targets were 8 surgeons and 1120 patients diagnosed with hip or knee OA. Patients were randomly assigned to receive one of two different decision aids (DAs) stratified by site. The DAs varied in length, content and the level of detail regarding treatment options. Both DAs were available by paper or online. Surgeons were randomly assigned to receive a report detailing patients' goals and treatment preferences at the time of the visit or not. Eligible patients received their assigned DA before their visit and completed three surveys: before the visit (timepoint (T)1), 1-week postvisit (T2) and 6 months from either the visit date or surgery date for patients who underwent surgery (T3). Study staff and participating surgeons were not blinded, but the statistician conducting the analyses was blinded to the arms.

Main outcome measure and analysis The primary study outcome was decision quality, the percentage of patients who were well informed and received their preferred treatment. Secondary outcomes included involvement in decision making, surgical rates, health outcomes, decision regret and satisfaction. A logistic regression model with the generalised estimating equations approach was used to compare rates of decision quality between the groups and account for the clustering of patients within providers.

Ethics and dissemination Ethics approval was obtained through the institutional review board at the main site. The findings will be published in peer-reviewed journals.

Trial registration number NCT02729831; Pre-results.

Strengths and limitations of this study

- The DECIDE-OA study is a large, multisite randomised controlled trial and will provide important evidence on the comparative effectiveness of two leading patient decision aids that vary in the amount of detail, level of interactivity and use of patient narratives.
- The study also includes a clinician-focused intervention, as the literature suggests that intervention strategies directed at both patients and clinicians may have the biggest impact.
- Data will be collected from patients before the initial visit with the surgeon, shortly after the visit with the surgeon, and again about 6 months later to shed light on short-term and long-term impacts of the decision support strategies.
- The study is adequately powered to examine the impact in key subgroups, including older patients and patients with low literacy, as well as to examine whether there are differences in those who review the patient decision aids online versus on paper.
- The study staff and participating surgeons are not blinded to the interventions which is a limitation; however, the statistician conducting the analyses will be blinded to the arms.

INTRODUCTION

Hip and knee osteoarthritis (OA) are among the most prevalent chronic diseases in the USA.¹ Joint replacement surgery is a common treatment for OA with a recent estimate indicating that 600 000 knee replacements are performed in the USA each year alone.² Clinical guidelines for the treatment of OA highlight the importance of informing patients about their surgical and non-surgical treatment options.^{3,4} Engaging in shared decision making (SDM) is recognised as an integral strategy to help patients choose the best treatment for them.⁵

Patient decision aids (DAs) can help inform patients about their relevant treatment options and promote SDM.^{6,7} There are >105 randomised controlled trials of DAs that find the tools improve knowledge, accuracy of risk perceptions, reduce decisional conflict and increase the match between choices and values.⁸ Although considerable evidence exists to support effectiveness over usual care, the literature comparing different DAs is sparse.^{8,9} Furthermore, while DAs can help prepare patients to participate in SDM, it is also important to support surgeons to engage in SDM during a medical visit.¹⁰ There is only one small randomised controlled trial that has examined the impact of patient-directed and surgeon-directed interventions on decision making in hip and knee OA.¹¹

The purpose of this randomised controlled trial (DECIDE-OA study) is to compare the effectiveness of two DAs for treatment of hip and knee OA and a surgeon-directed intervention.

METHODS AND ANALYSIS

This clinical trial protocol follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (see SPIRIT checklist in online supplemental files).^{12,13} The underlying protocol follows the Consolidated Standards of Reporting Trials (CONSORT) guidelines and the Standards for Universal Reporting of Decision Aid Evaluations (SUNDAE) guidelines (see SUNDAE checklist in online supplemental files).^{14–17} The trial was registered on clinicaltrials.gov (NCT02729831).

Study design

The DECIDE-OA study compared two high-quality DAs that differ in the format, amount of content and level of interactivity, and will examine the impact on decision quality, treatment selection and health outcomes. Patients were randomly assigned to receive one of two different DAs stratified by site. The study also examined the impact of a surgeon-focused intervention—a patient preference report (PPR) detailing patients' goals and treatment preferences—versus usual care. Because the patient DA and the provider PPR may work together to improve decisions better than each on their own, we selected a 2×2 factorial randomised trial design to compare the interventions. Factorial studies allow for efficient examination of multiple interventions and are also particularly well-suited when two interventions have a potential interaction, as the design enables the examination of the benefits of each intervention separately as well as both interventions together.¹⁸

Specific aims

Aim 1: evaluate comparative effectiveness of two patient DAs (DA-A vs DA-B) and a surgeon-focused intervention (usual care vs PPR), which includes patients' goals and treatment preferences, on their ability to achieve high decision quality.

Hypothesis 1.1: overall, patients who receive DA-A will have higher decision quality than those who receive DA-B.

Hypothesis 1.2: patients who receive DA-A, with more comprehensive information and videos to make the information more salient, will have higher knowledge scores than those who receive DA-B.

Hypothesis 1.3: more patients who receive DA-B, with the explicit values clarification exercise, will have a clear treatment preference than those who receive DA-A.

Hypotheses 1.4: the PPR group will have higher rate of concordance, that is, more patients who receive treatments that match their goals, compared with usual care group.

Aim 2: follow participants for 6–12 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 (ie, informed and received preferred treatments) at 1 week from their visit will have better health outcomes at 1 year compared with those with low decision quality.

Hypothesis 2.2: patients with high decision quality at 1 week will have lower surgical rates at 1 year compared with those with low decision quality.

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

Conceptual framework

The study was based on the conceptual framework of SDM as outlined in the studies by Mulley¹⁹ and Sepucha and Mulley^{20,21} that view SDM as a systems approach to enable continuous improvement in clinical decision making. The framework recognises the fundamentally social nature of the decision-making task; it cannot be completed by the healthcare provider or patient alone but rather requires productive interactions between them. The interventions chosen for this study address the key elements of the conceptual framework. The DAs help surgeons convey the evidence to patients in ways that they can access and understand. The surgeon intervention will help patients communicate their treatment preferences to the surgeons in a structured manner. Together, these interventions will work to ensure high-quality decisions that are evidence-based and patient-centred.

Participants, interventions and outcomes

Participants and setting

Patients and physicians were recruited from the orthopaedic departments of three sites: a large academic medical centre in an urban setting, a community hospital in suburban environment and an orthopaedic specialty

hospital in an urban setting. Two of the three sites were selected because of their access and use of DAs as part of routine care, as well as their common electronic medical record (EMR). A third site was added to meet recruitment targets.

Patients scheduled for an appointment with an orthopaedic surgeon were screened 2 weeks prior to their visit date (previsit screening) for study eligibility. Study staff called patients, as needed, to collect eligibility information that was not available in the EMR.

The eligibility criteria for patients are:

- ▶ Diagnosis of knee or hip OA (confirmed via X-ray or visit note);
- ▶ Age 21 or older;
- ▶ Attends visit with a participating orthopaedic specialist.

Patients with the following will be ineligible:

- ▶ Partial or total knee or hip replacement surgery within 5 years of being screened;
- ▶ Received patient DA within 1 year of visit;
- ▶ Hip fracture or aseptic necrosis in 12 months prior to visit;
- ▶ Rheumatoid arthritis or psoriatic arthritis diagnosis;
- ▶ Does not read or write in English or Spanish;
- ▶ Cognitive impairment (unable to consent for self);
- ▶ Non-OA-related reason for visit.

Interventions

The DAs are not publicly available. Two of the sites had existing licenses to use the DAs, and the Principal Investigator (PI) obtained a licensing agreement to use the DAs as part of the study at all sites. These DAs were selected because they are commercially available, have been certified by Washington state for use with hip and knee patients and vary in content and format. Table 1 provides details of the various elements of the two DAs.

- ▶ DA-A: *Treatment Choices for Knee Osteoarthritis* Health Dialogue is a 42min DVD and 38-page booklet (over the course of the study the DA was updated, and the following versions were used: English: Booklet V08/DVD V07 2016 and Booklet V07A/DVD V06A 2014; Spanish Booklet V07/DVD V07 2014; Booklet V08/DVD V08 2016) and *Treatment Choices for Hip Osteoarthritis* Health Dialog is a 44min DVD and 40-page booklet (English: booklet V06A/DVD V06A 2014 and booklet V07/DVD V07 2016; Spanish: booklet V06/DVD V07 2014 and booklet V07/DVD V08 2016). The same content is also available online through Health Dialog's secure website. Health Dialog has 40 different DAs that have been evaluated in 20 randomised controlled trials. The DAs have been shown to increase knowledge, reduce decisional conflict and increase decision quality. Spanish language versions were also available online or in paper booklet form.²² The authors reviewed the DAs for International Patient Decision Aid Standards (IPDAS) criteria and found they met seven of seven qualifying criteria to be defined as a DA and eight out of nine criteria to lower the risk of making a biased decision.

- ▶ DA-B: *Knee Osteoarthritis: Is it time to think about surgery?* Healthwise 2016 and *Hip Osteoarthritis: Is it time to think about surgery?* Healthwise 2016 DAs are available online or as a 17-page printed brochure. They include six sections (get facts, compare options, your feelings, your decision, quiz and summary).^{23 24} Healthwise has >180 *Decision Points* and these were accessed over 5 million times in 2014. The knee and hip arthritis *Decision Points* were among the top five accessed topics. The Ottawa inventory of decision aids published IPDAS ratings for these DAs and found they met seven out of seven criteria to be defined as a DA and eight out of nine criteria to lower the risk of making a biased decision.^{25 26} English and Spanish versions of Healthwise DAs were made available for this trial.
- ▶ PPR: a one-page sheet that includes patients' goals for the visit, impact of disease on activities and treatment preference (see online supplemental files). The sheet was developed with input from a patient advisory group (n=6), an expert in decisions sciences, a primary care physician, a nurse practitioner and two orthopaedic surgeons.

Sample size

The sample size calculations considered both the potential for interaction effects between the two sets of interventions as well as the potential impact of clustering of patient participants within surgeons. In the situation where an interaction between DAs and PPR report is unlikely, the patients from both usual care and PPR groups will be combined for the comparisons between the two DAs. We planned to have 8 surgeons at the sites enrol a total of 1120 of their patients (T2). We anticipated a 25% attrition rate at T2 (n=840), and another 15% attrition rate at T3 (n=716). Based on our previous estimate, we assumed an intraclass correlation coefficient (ICC) of 0.01.^{6 27} Using the formula of design factor = $1 + (m - 1) \times ICC$, where m is the average number of observations in each cluster, a sample size of 280 participants in each group at the time-point (T)1 survey is equivalent to an effective sample size of 117, a sample size of 210 per group at the T2 survey is equivalent to an effective sample size of 103 patients and a sample size of 178 participants in each group at T3 survey is equivalent to an effective sample size of 95 patients. Thus, the effective sample size varies depending on the hypotheses within each aim as dictated by analysis plan. Using hypothesis 1.1 as an example, it is plausible that an interaction between DAs and type of surgeon report exists for this analysis. As a result, the effective sample size will be limited to 117 per group when the comparisons are stratified by the type of surgeon report. The study will have 89% power to detect a difference in the percentage of patients with high decision quality of 18%, from 65% in DA-B group to 83% in DA-A group. Details on sample size and power calculations for hypotheses within each aim are included in the analysis plan.

Table 1 Design features of decision aid-A and decision aid-B

Design feature	Decision aid-A	Decision aid-B
Format	Paper and DVD or online	Paper or online
Treatment options	<i>Non-surgical options:</i> ► Lifestyle changes; physical therapy; walking aids; pain medications; injections (<i>knee only</i>); complementary approaches <i>Total joint replacement</i> <i>Partial joint Replacement (knee only)</i>	<i>Non-surgical options:</i> ► Generic discussion of non-surgical options <i>Total joint replacement</i>
Essential information by itself, first*		X
Video to improve salience of patient narratives and information*	X	
Components in decision aid		
Explicit description of the decision	X	X
Description of health problem	X	X
Information on options and their benefits, harms and consequences	X	X
Values clarification (implicit or explicit)	Implicit, patient narratives	Explicit, rating of goals and concerns
Numerical probabilities	X	X
Tailoring of information or probabilities		
Guidance in deliberation	X	X
Guidance in communication	X	X
Personal stories	X	
Reading level or other strategies to help understanding	Not available	Not available

*These design features have been shown to be effective in low literacy populations.⁵⁶

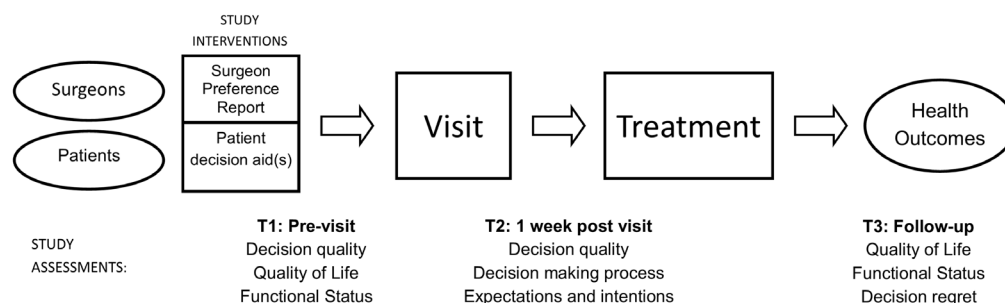


Figure 1 Flow of study interventions and assessments.

Outcomes

Our primary outcome is decision quality, defined as the percentage of patients who are well informed (at least three out of five knowledge questions correct) and received their preferred treatment (surgical or non-surgical). The hip or knee decision quality instruments (DQI) were used to measure the primary outcome.²⁸ Secondary outcomes include involvement in decision making, surgical rates, patient-reported health outcome measures, decision regret and satisfaction.

- **Hip OA and knee OA DQI (T1, T2):** each DQI contains 5 decision-specific, multiple-choice knowledge items, 5 decision-specific goals and concerns (rated on an 11-point importance scale) and one treatment preference item. The DQIs were developed with considerable input from patients and a multidisciplinary team of providers²⁹ and followed best practices in survey research methods.^{30–31} They have demonstrated strong psychometric properties (eg, retest reliability, validity, sensitivity to change) and clinical sensibility (eg, acceptability and feasibility).^{7, 28, 32} Respondents get a knowledge score (0%–100%) and a concordance indicator (yes or no) depending on whether the patient received treatment that matched their stated preference. High decision quality is a binary indicator variable calculated as the percentage of patients whose knowledge score met or exceeded the knowledge threshold and received treatment that matched their preference. The minimal important changes in knowledge and concordance scores are 10%.²⁸
- **Shared decision-making process survey (T2, T3):** 7 items that assess discussion of four elements of SDM: options, pros, cons and preferences. A total score is generated (0–4) with higher scores indicating more SDM.⁶
- **Functional goals (T1/T2, T3):** participants listed the top three things that they needed or wanted to do but were unable to do because of their knee or hip pain (at T1 for the PPR group and at T2 for the usual care group). Then at T3, they indicated to what extent they were able to do those three things and how important those goals still were.
- **Sure of myself; Understand information; Risk-benefit ratio; Encouragement (SURE) scale (T2):** a brief, 4-item version of the widely used Decisional Conflict Scale that

measures patients' uncertainty about which treatment to choose and factors contributing to uncertainty (feeling uninformed, unclear values and unsupported in decision making).^{33, 34}

- **Decision regret (T3):** a 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.³⁵
- **EuroQol-5D (EQ-5D) (T1, T3):** a 6-item summary measure of overall health status.³⁶ It 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.³⁷ The minimum important change is 0.1 points.³⁸
- **Knee injury and osteoarthritis score (KOOS) (T1, T3):** KOOS was developed to assess patients' opinions about their knee and associated problems and has been used extensively.^{39–45} Three subscales were used in this study: pain, symptoms and functional status. A normalised score (100 indicating no pain/symptoms and 0 indicating extreme pain/symptoms) is calculated for each subscale.
- **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; 70–79 is considered fair, 80–89 is good and 90–100 is an excellent result. No normative values are available.^{46–49}
- **DA usage (T1, T2):** 1 item assessed how much of the DVD, booklet and/or website was reviewed (all, most, some, none).
- **Treatment received (T3, chart review):** surgical and non-surgical treatments tried since the consultation visit were self-reported by patients and collected via chart review.
- **Expectations (T2, T3):** 10 items assessed expectations at T2 for pain relief and limitations in daily activities. At

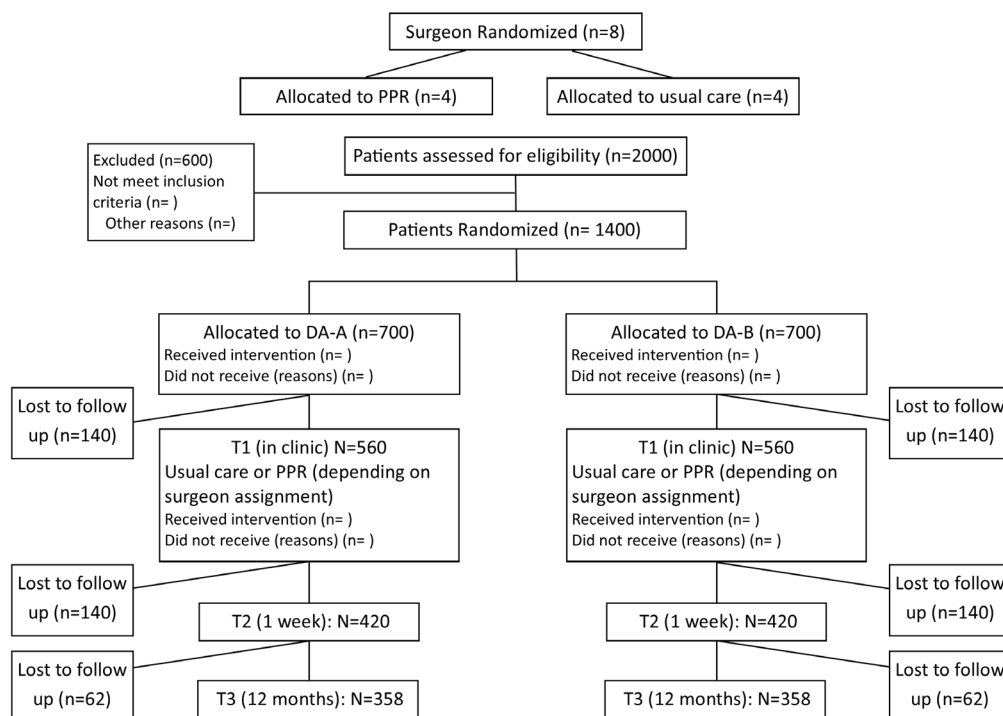


Figure 2 Consolidated Standards of Reporting Trials flow diagram estimating patient screening, enrolment and response rate. DA, decision aid; PPR, patient preference report; T1, previsit/in clinic before surgeon visit; T2, 1 week postvisit; T3, 6–12 months postvisit.

T3, patients were asked if their function after surgical or non-surgical treatment is worse, about or better than they expected.⁵⁰

- *Demographics (T2)*: information such as age, gender and insurance were collected from the EMR and education, race and ethnicity were self-reported.
- *Satisfaction (T3)*: two questions assess overall satisfaction with quality of visit and treatment outcome.
- *Collaborate score (T2)*: three item patient-reported measure of SDM and patient satisfaction at a clinical encounter.⁵¹
- *Single-item literacy screener (T1)*: one question assessing how often patients need help reading and understanding medical paperwork.⁵²

Delivery of interventions and assessments

The study activities included screening, recruitment and intervention and survey delivery. The sequence of activities within the orthopaedic clinic flow is illustrated in figure 1.

- *DA delivery*: trained study staff screened new patients from the orthopaedic clinical schedule across the three sites. Eligible patients received their assigned DA 2 weeks prior to their visit. The DA was sent electronically to patients who are enrolled in the site's online patient portal and mailed to all others.
- *First survey at T1*: 2 weeks before the initial visit, a mailed packet was sent to all participants which included a cover letter, information sheet and the T1 survey. The DA was included in the same packet as

the T1 survey for patients receiving a paper copy. For patients receiving the DA online, instructions for how to access the online portal was included with the T1 survey. The T1 survey was collected from the patient on the day of the visit in the waiting room before they saw the surgeon.

- *PPR delivery*: for patients seeing a surgeon in the PPR group, the PPR was included as part of the T1 survey. In the waiting room before the patient's visit, study staff collected the completed survey from patients, made two copies of the PPR page and gave one to the patient and the other to the surgeon in advance of the visit.
- *Second survey at T2*: after the visit, study staff screened visit notes for enrolled patients to confirm eligibility. Eligible patients received the T2 survey either via mail or email (depending on patient preference as indicated on the T1 survey) approximately 1 week after their visit.
- *Third survey at T3*: follow-up assessment was collected between 6 and 12 months postinitial visit. Approximately 6 months after initial visit, study staff called patients to remind them about the study follow-up assessment, confirm surgical status and their preferred method for receiving the T3 survey (mail or email). Patients who did not have surgery within 6 months were sent the T3 survey at this time; patients who had surgery were sent the T3 survey 6 months after their date of surgery.

Recruitment strategies

Figure 2 is the CONSORT flow diagram and includes estimates for screening, enrolment and response rates. To meet our sample size requirements, we needed 1120 patients to complete the T1 survey, 840 to complete the T2 survey and 716 to complete the T3 survey. Several strategies were implemented during the enrolment period to achieve the target sample size. After sending out the DA with the invitation to participate, study staff called patients who did not opt out prior to their visit date to answer any questions about the study. This call also served as a reminder to the patients to review the DA before the visit and to complete the T1 survey. Study staff also offered to administer the survey over the phone. On the day of the visit, the study staff met with eligible patients in clinic waiting room. Staff answered questions and brought extra copies of the T1 surveys to administer the survey in clinic if needed.

Recruitment status and trial dates

Patient enrolment started April 2016 at sites 1 and 2 and July 2017 at site 3 and was completed in December 2017. The T3 surveys were collected from December 2016 through November 2018.

Randomisation and blinding

Two randomisations occurred: one at the patient-level and one at the surgeon-level. Within each site, surgeons were divided into two groups stratified by years in practice and patient volume, then the two groups were randomly assigned to usual care or PPR by the statistician. Patients were randomised to DA-A or DA-B, using a computer-generated allocation sequence, prior to enrolment in the study.

A study database was set up to support allocation and concealment. Study staff entered information for each eligible patient one at a time and the randomisation assignment was revealed once the study staff clicked the 'randomise' button for each patient. Study staff did not know in advance what the assignment was. For any patient participant found to be ineligible for the study after randomisation, the original assignment was put back into the study database and re-assigned to the next eligible patient. Study staff did not know when this re-assignment occurred as the allocation sequence was kept hidden.

Patient participants were not blinded to the DA assigned to them; however, they were not given any explicit information on the other DA or their surgeon's assignment. Likewise, surgeons were not blinded to their intervention group, but they were not given any specific information on the type of DA the patient received. It was possible for surgeons to find out their patients' assignment; patients may have brought the DA with them to the visit, or surgeons could have opened the patient education note in the EMR that included the specific title of the DA.

Study staff who recruited participants and approached them in clinic were not blinded to the DA assignment, as they were responsible for mailing the DAs to patients.

Table 2 Outcomes collected at different timepoints

Outcomes	T1	T2	T3
Hip osteoarthritis and knee osteoarthritis decision quality instruments	X	X	
Shared decision-making process survey		X	X
Functional goals	X*	X*	X
SURE scale		X	
Decision regret			X
EuroQol-5D	X		X
Knee injury and osteoarthritis score	X		X
Harris hip score	X		X
Decision aid usage	X	X	
Treatment received			X
Expectations		X	X
Demographics		X	
Satisfaction			X
CollaboRATE score		X	
Single-item literary screener	X		

*T1 for patient preference report group, T2 for usual care group.

However, the study staff responsible for data entry did not have information on the DA assignment when entering the paper surveys. The analytic data set will be de-identified to maintain blinding during the analysis process.

Data collection, management and analysis

Data collection

Paper and online surveys were used to collect patient-reported outcomes. The first (T1) survey was mailed to patients before their visit. The second (T2) and third (T3) surveys were sent to patients either via mail or email based on patient preference. Study staff followed-up with a phone reminder about 1 week after sending the surveys, 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 received the surveys by email also got the survey in the mail if they did not complete it online within 2 weeks. During the reminder calls, study staff gave participants the option to complete the survey by phone. A cash incentive of US\$5 was included with the T2 and T3 assessments. A study database tracked all participant contact and was used to monitor the consistency of the reminder protocols. Table 2 shows which outcomes were administered at each timepoint.

Data management

Study staff reviewed surveys within a week of receipt and flagged any missing answers or comments that suggested a problem with the survey to discuss with the PI and study team. The staff contacted patient participants up to three times to acquire answers to missing items. Study staff were responsible for data entry of the paper surveys into

Research Electronic Data Capture (REDCap), a Health Insurance Portability and Accountability Act (HIPAA)-approved web application.⁵³ Study staff conducted double coding on 10% of surveys collected over the first 6 months of the recruitment period. We stopped double coding after a 99.5% rate of agreement between entered and double-coded surveys was achieved.

Analysis plan

For patient-reported outcomes (decision quality, quality of life, etc), missing data items will be handled according to established protocols for the validated surveys (eg, missing knowledge items are considered incorrect). For item-specific analysis, our primary analyses will be conducted excluding patients with missing data. The treatment received (surgical vs non-surgical) will be assessed through chart review and confirmed via patient report (T3); therefore is not subject to missing data.

Even though we cannot test the missing at random assumption, we will first compare patients with and without missing data to gain insights. As a sensitivity analysis, we will conduct several missing imputation techniques: (1) last value carried forward (LVCF), (2) single imputation with EM algorithm and (3) multiple imputation. The LVCF approach applies to follow-up missing data, which is essentially the same as assuming no change over time. Compared with single imputation, the appealing aspect of the multiple imputation approach is incorporating the variability across imputation so that the statistical uncertainty due to missing is more properly accounted for. We will compare our findings from the primary analyses with the findings from different imputation strategies to determine whether our findings are stable across different assumptions. We will also report the uncertainty associated with the treatment effect as indicated in the SE estimates from the multiple imputation analysis.

As the first step, responders and non-responders will be compared across groups to examine non-response bias. For patient-reported outcomes, missing data will be handled according to established protocols for the validated surveys. We will conduct sensitivity analyses to determine the impact of missing imputation.⁵⁴ The hypotheses will be evaluated using an intention-to-treat approach. The analysis plan for the primary outcome (hypothesis 1.1) will first calculate the rate of decision quality in each group, as the percentage of patients who meet or exceed the knowledge threshold *and* receive treatment that matches their preference. A logistic regression model with the generalised estimating equations (GEE) approach will be used to compare the rates of decision quality of the DA-A and DA-B groups and account for the clustering of patients within providers.⁵⁵ Analysis will start by testing the interaction between the two intervention factors. It is plausible that an interaction between DAs and type of surgeon report exists for this analysis. As a result, the effective sample size will be limited to 117 per group when the comparisons are stratified by the type of surgeon report. The study has 89% power to detect a

difference in the percentage of patients with high decision quality of 18%, from 65% in DA-B group to 83% in DA-A group.

For hypothesis 1.2, an interaction between DAs and PPR report is unlikely so there is no need to account for clustering within the same provider, as a result, we will use a two-sample t-test to compare the mean knowledge score between the two groups. With approximately 560 patients from each group, we can invoke the Central Limit Theorem and use a two-sample t-test to compare mean knowledge score between the two groups, even if the knowledge score is not normally distributed. The study will have 80% power to detect a difference as small as 3.3% in total knowledge scores assuming the SD is 20%.

For hypothesis 1.3, patient's treatment preference will be assessed before the surgeon visit so again, there is no need to account for clustering. A χ^2 test will be used to compare the percentage of patients with clear treatment preference between the two groups. Hypothesis 2.1 will use a linear regression model with the GEE approach and hypothesis 2.2 will use logistic regression with GEE approach to account for clustering of patients within surgeons for these analyses.

The heterogeneity of the treatment effect will be explored by testing the interaction between interventions and different factors on study outcomes. These factors include (1) patient characteristics (eg, age, gender, education level, joint (hip or knee), health literacy and severity of disease), (2) provider characteristics (gender, years since graduation, surgical volume), (3) intervention compliance (whether patients reviewed the DAs) and (4) mode of DA delivery (online or paper). Linear or logistic regression models (with the GEE approach in the case of clustering within providers) will be used to test the interaction between interventions and these factors. We will also report treatment effect in each subpopulation if there are strong evidence of interactions between interventions and these factors. Some of the hypothesis testing here might be exploratory in nature. The study will have sufficient power for testing interaction for continuous outcomes (eg, detecting meaningful 'differences in differences' for knowledge scores, EQ-5D scores) but not categorical outcomes (eg, rate of high decision quality, surgical rate).

Data monitoring

Data monitoring and auditing

Due to the minimal risk nature of the study, there is no external data and safety monitoring board. The PI, co-investigators and study staff monitored data internally. Study staff, co-investigators and PI met weekly in person or by phone to ensure the project proceeded as intended, per protocol. All participant enrolment was tracked including recruitment rates and survey response rates. The study staff completed all required items required by the institutional review board (IRB) regarding data monitoring. The internal data monitoring committee is independent from the funder. Reports detailing study progress and

milestones were submitted every 6 months to Patient-Centred Outcomes Research Institute (PCORI), the funder.

The central site controlled the randomisation and data storage for the study. Limited data were kept on all non-responders across sites including joint, age, gender, physician, DA assignment and all elements in the eligibility screener. This information will be used to examine non-response bias. There are no planned interim analyses for this study. Study outcomes will be analysed by the statistician who will have a de-identified, blinded dataset.

Adverse events

There were minimal risks to participating individuals; the main risks were the time and effort involved in completing the surveys. Study staff reviewed surveys within a week of receipt and notified the PI and clinical investigators about any adverse events at regularly scheduled meetings. Study staff kept records of any feedback, questions, concerns and/or complaints that were received and addressed them as needed. Staff were trained on how to address adverse events with the PI according to IRB protocol.

Patient and public involvement

We have the ongoing participation of a patient advisory committee (PAC) throughout this study. The group includes six orthopaedic patients recommended by physicians from one site who showed interest in contributing to patient-centred research in orthopaedic care. The PAC meets quarterly with the study team and members provide feedback on the design of workflows, the communication and messaging to patients, and the type of data to collect. Specifically, this study question was informed by the views of our PAC who wanted to explore the variation in how new orthopaedic patients educate themselves about their treatment options. They showed interest in how different DAs might influence patients' treatment decisions differently. The PAC reviewed all the interventions—both DAs, patient surveys and the surgeons' PPR. They were particularly involved in designing our patient outreach plan, including how we would send study materials and contact study patients. The PAC offered insight on the best ways to engage patients over phone and email. Through their recommendation, when the trial is completed, study data will be shared on our website in our 'For Patients and Families' section so participants can see the results of their involvement.

Limitations

There are some potential limitations to note in this study. First, study staff are not blinded to the interventions as they are responsible for mailing them to patients. However, staff entering the survey data will be blinded to the DA assignment, and the statistician will also be blinded to the arms. Second, we expect a number of postrandomisation exclusions due to patients not showing up for their appointment and due to limited data available to assess eligibility before the visit. Third, we expect a modest amount of attrition over the course of the study

and have put into place standard protocols to maximise response rates to all surveys. Fourth, the follow-up period of 6 months may be too short to capture the full benefit of surgery on quality of life. Finally, the surgeons at two of the sites had prior exposure to patients using one of the DAs.

ETHICS AND DISSEMINATION

Ethics approval and consent to participate

Protocol version

This study protocol was approved on 15 March 2016 and this manuscript details the protocol on the latest version approved on 21 December 2017.

Protocol amendments to IRB

All changes to the study protocol were reviewed by the IRB and then reported to funder at the 6 month reports. The participating providers and co-investigators were sent regular emails with updates on the study recruitment timeline and any major protocol changes during the enrolment period. All significant protocol changes were noted on ClinicalTrials.gov.

Study participant consent

- *Surgeon consent:* the PI and co-investigators met with potential surgeons individually or as part of faculty meetings to discuss the study and to answer any questions. The surgeons were given a copy of the PPR, the patient and surgeon surveys and both DAs to review. Surgeons provided verbal and email consent to the PI to indicate their willingness to participate.
- *Patient consent:* there are no formal written consent procedures for patients as 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 patient participants was implied by completion of the first survey. Two weeks prior to their surgical consultation, eligible patients were mailed (1) a cover letter from the patient's surgeon inviting them to be part of the study; (2) an information sheet explaining the study involvement, risks and benefits, and how to 'opt out' prior to the visit; (3) their assigned DA and (4) the T1 survey. Three days prior to the visit, study staff called all patients who did not opt out to answer any questions about the study, and to remind them to review the DA and complete the survey. On the day of the visit, the study staff met the patients in clinic, answered any questions and collected T1 surveys.

Confidentiality

Special efforts are made to protect the privacy of subjects. All personal identifying information (PII), such as names, addresses, phone numbers and email addresses are kept in a secure Access database. PII on eligibility screeners collected at each site are sent securely using a secure file transfer to

the central study staff. Any paper that includes PII is kept in a locked cabinet or at a secure offsite storage facility.

Data management for the study was done through REDCap. Study staff assigned to manage data have access to the REDCap application and are required to login via an individualised username and password combination. Study staff located at other institutions only have access to the data collected at their sites. De-identified survey data are entered into REDCap. All paper surveys and electronic surveys (collected via REDCap) include a patient study ID number and do not have any identifying information. The access database that links the study ID number to patient name and contact information is kept separately on a password-protected server.

Dissemination plan

The PI and study team have developed a plan to promote dissemination and implementation of the study findings to consumer, clinical and payer stakeholders. The PAC will facilitate dissemination of the study and results to patient, advocate and community audiences. One key role the PAC will play is to develop and maintain relationships with local and regional organisations that may assist in disseminating the results. Presentations at local meetings (eg, grand rounds), at national meetings (eg, American Academy of Orthopaedic Surgeons) as well as publications in leading journals will be used to reach physicians more broadly. In addition, the team will convene an external advisory board made up of clinician, payer, researcher and consumer representatives to guide dissemination and implementation efforts. This group will convene for one in-person meeting and two calls over the study period. These external advisors are experts across different domains (clinical care, payers, patient advocacy and consumer groups) who can help disseminate study findings more broadly.

Availability of data and material

Within 3 months of the end of the final year of funding a description of the study dataset, including a code book, a SAS file of the code used for creating the final study sample, the final study variables and plan for conducting the outcomes analyses outlined in the study protocol will be made available. The investigators will create a complete, cleaned, de-identified copy of the final data set that will include T1, T2 and T3 data. A section in the MGH Health Decision Sciences Center website will be created to hold study materials and it will include information for investigators interested in accessing these materials and replicating the findings. The PI will share a de-identified data set with outside investigators according to the policies in the approved IRB protocol. Investigators may be required to provide evidence of IRB approval (or exemption) and/or complete a data sharing agreement.

Process evaluation

A process evaluation was designed to help understand how and why the interventions work. The study staff gathered data on differences in clinic structure and operations,

institutional processes, clinicians and staff that may influence study outcomes. Before enrolling patients, study staff observed the clinic at each surgeon's practice and documented the standard patient flow, who patients met with during a visit, any patient information available at intake and any standard patient education materials provided to support the visit and the decision-making process. Staff tracked delivery and receipt of the interventions including patient DAs and surgeon PPR sheets and documented any deviations in a study database along with reasons for the deviations. Participating surgeons were surveyed for a random sample of about 30% of their study patients. The surgeon survey had six questions including the surgeon's treatment recommendation, satisfaction and their perception of the patient's preferred treatment. Orthopaedic fellows who were involved in the initial visit with participating patients also completed a short survey assessing their confidence in certain SDM skills such as risk communication and eliciting patients' goals and preferences, as well as their perceptions of the attending surgeons' SDM skills. Exit interviews are also planned with surgeons, administrators and clinic staff to assess gather reflections on the study protocol, acceptability and feasibility to support dissemination and implementation of findings.

DISCUSSION

This study protocol outlines the methodology for the DECIDE-OA study, a multicentred, randomised trial comparing two different DAs and a PPR on SDM in orthopaedic care. DAs are tools that communicate complex medical information to patients and families and have been shown to improve decision quality. As DAs proliferate and efforts to integrate SDM into routine care expand, understanding the comparative effectiveness of different interventions is critical. While the value of DA delivery in orthopaedics has been highlighted in past studies, this study builds on those findings and will provide rigorous data on the impact of variations in DA format. The study will help answer several key questions that are aligned with the funder, PCORI's mission as well as our patient partners and stakeholders, including (1) Which DA is most effective for patients who are considering elective hip or knee replacement surgery? Does the effectiveness vary by patient characteristics (such as age or literacy) or other factors? (2) What is the impact of providing surgeons information about their patients' experience with the disease and their goals for treatment? Does it help ensure more patient-centred treatment decisions? (3) Do patients who make high-quality decisions have better health-related outcomes? Does it change the kind of treatments received?

In general, to assure that patients get the treatment they need and no less—and the treatment they want and no more—doctors and patients must share in decision making and collaborate in the care that follows. By contributing evidence on the value of patient and provider

decision support strategies, we are eager to offer insights on promoting patient engagement and more patient-centred care. This fits with recent trends in healthcare policy that emphasise increasing consumer involvement in many aspects of care, from selecting a plan or provider to selecting treatments. The results of this study will provide critical evidence for healthcare administrators who are often tasked with making decisions about offering decision support technologies.

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Contributors Each author has contributed significantly to, and is willing to take public responsibility for, one or more aspects of the study. KS, AAF, HB and YC participated integrally in the study design. All authors contributed to implementation of the study protocol, data acquisition and analysis and interpretation of the study data. MM, SD, SM, HV and KS drafted the initial manuscript; all other authors including MD and CT provided critical revisions and approved the final revisions.

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Competing interests KS (PI) has received salary support as a medical editor for the Informed Medical Decisions Foundation (IMDF). From 1997 to 2014, the IMDF was associated with Health Dialog; from 2014 to 2017, the IMDF was part of Healthwise and in 2017, the IMDF became part of Massachusetts General Hospital. AAF reports other from Zimmer Biomet, ArthroSurface, CeramTec and Orthopaedic Technology Group, outside the submitted work. HB reports personal fees from Smith & Nephew and Conformis, outside the submitted work.

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REFERENCES

- Jevsevar DS. Treatment of osteoarthritis of the knee: evidence-based guideline, 2nd edition. *J Am Acad Orthop Surg* 2013;21:571–6.
- Ruiz D, Koenig L, Dall TM, et al. The direct and indirect costs to society of treatment for end-stage knee osteoarthritis. *J Bone Joint Surg Am* 2013;95:1473–80.
- Katz JN, Earp BE, Gomoll AH. Surgical management of osteoarthritis. *Arthritis Care Res* 2010;62:1220–8.
- Slover J, Shue J, Koenig K. Shared decision-making in orthopaedic surgery. *Clin Orthop Relat Res* 2012;470:1046–53.
- Zikmund-Fisher BJ, Couper MP, Singer E, et al. The DECISIONS study: a nationwide survey of United States adults regarding 9 common medical decisions. *Med Decis Making* 2010;30:20–34.
- Sepucha K, Atlas SJ, Chang Y, et al. Patient decision aids improve decision quality and patient experience and reduce surgical rates in routine orthopaedic care: a prospective cohort study. *J Bone Joint Surg Am* 2017;99:1253–60.
- Sepucha K, Feibelman S, Chang Y, et al. Factors associated with the quality of patients' surgical decisions for treatment of hip and knee osteoarthritis. *J Am Coll Surg* 2013;217:694–701.
- Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2017;4:CD001431.
- Shue J, Karia RJ, Cardone D, et al. A randomized controlled trial of two distinct shared decision-making aids for hip and knee osteoarthritis in an ethnically diverse patient population. *Value in Health* 2016;19:487–93.
- Weinstein JN, Clay K, Morgan TS. Informed patient choice: patient-centered valuing of surgical risks and benefits. *Health Aff* 2007;26:726–30.
- Stacey D, Taljaard M, Dervin G, et al. Impact of patient decision aids on appropriate and timely access to hip or knee arthroplasty for osteoarthritis: a randomized controlled trial. *Osteoarthritis Cartilage* 2015;24:1.
- Chan AW, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.
- Chan AW, Tetzlaff JM, Gotzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* 2013;346:e7586.
- Moher D, Schulz KF, Altman DG. CONSORT. The CONSORT statement: revised recommendations for improving the quality of reports of parallel group randomized trials. *BMC Med Res Methodol* 2001;1:2.
- Altman DG, Schulz KF, Moher D, et al. The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Ann Intern Med* 2001;134:663–94.
- Sepucha KR, Abhyankar P, Hoffman AS, et al. Standards for Universal reporting of patient Decision Aid Evaluation studies: the development of SUNDAE Checklist. *BMJ Qual Saf* 2018;27:380–8.
- Hoffman AS, Sepucha KR, Abhyankar P, et al. Explanation and elaboration of the Standards for Universal reporting of patient Decision Aid Evaluations (SUNDAE) guidelines: examples of reporting SUNDAE items from patient decision aid evaluation literature. *BMJ Qual Saf* 2018;27:389–412.
- Montgomery AA, Peters TJ, Little P. Design, analysis and presentation of factorial randomised controlled trials. *BMC Med Res Methodol* 2003;3:26.
- Mulley A. Methodological issues in the application of effectiveness and outcomes research to clinical practice. *Effectiveness and outcomes in health care*. Washington, DC: National Academy Press, 1990.
- Sepucha K, Mulley AG. A perspective on the patient's role in treatment decisions. *Med Care Res Rev* 2009;66:53S–74.
- Sepucha KR, Mulley AG. Extending decision support: preparation and implementation. *Patient Educ Couns* 2003;50:269–71.
- Health Dialog: Shared Decision Making Video Versions. 2018. <https://www.healthdialog.com/sites/default/files/resources/Shared-Decision-Making-%20Video-%20Versions.pdf>
- A to Z Summary Results - Patient Decision Aids - Ottawa Hospital Research Institute. Decision Aid Summary: Arthritis: Should I Have Knee Replacement Surgery? <https://decisionaid.ohri.ca/AZsumm.php?ID=1191> (cited 27 Mar 2018).
- A to Z Summary Results - Patient Decision Aids - Ottawa Hospital Research Institute. Decision Aid Summary: Arthritis: Should I Have Hip Replacement Surgery? <https://decisionaid.ohri.ca/AZsumm.php?ID=1112> (cited 27 Mar 2018).
- Ottawa Hospital Research Institute. Decision aid Summary - Arthritis: Should I have knee replacement surgery [Internet]. 2017. <https://decisionaid.ohri.ca/Azsumm.php?ID=1191> (cited 20 Nov 2018).
- Ottawa Hospital Research Institute. Decision aid Summary - Arthritis: Should I have hip replacement surgery [Internet]. 2017. <https://decisionaid.ohri.ca/Azsumm.php?ID=1112> (cited 20 Nov 2018).
- Bland M. *Cluster randomized trials in the medical literature. Notes for talks presented at University of York*: University of York, 2005.
- Sepucha KR, Stacey D, Clay CF, et al. Decision quality instrument for treatment of hip and knee osteoarthritis: a psychometric evaluation. *BMC Musculoskelet Disord* 2011;12:149.

29. Sepucha KR, Levin CA, Uzogara EE, *et al.* Developing instruments to measure the quality of decisions: early results for a set of symptom-driven decisions. *Patient Educ Couns* 2008;73:504–10.
30. Fowler FJ. *Survey research methods*. Thousand Oaks, CA: Sage Publications, Inc, 1993.
31. DeVellis R. *Scale development theory and applications*. 2nd edn. Thousand Oaks, CA: Sage Publications, 2003.
32. Sepucha KR, Feibelmann S, Abdu WA, *et al.* Psychometric evaluation of a decision quality instrument for treatment of lumbar herniated disc. *Spine* 2012;37:1609–16.
33. O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making* 1995;15:25–30.
34. Légaré F, Kearing S, Clay K, *et al.* Are you SURE?: assessing patient decisional conflict with a 4-item screening test. *Can Fam Physician Med Fam Can* 2010;56:e308–14.
35. Brehaut JC, O'Connor AM, Wood TJ, *et al.* Validation of a decision regret scale. *Med Decis Making* 2003;23:281–92.
36. Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. *Ann Med* 2001;33:337–43.
37. 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;43:203–20.
38. Jansson KÅ, Granath F. Health-related quality of life (EQ-5D) before and after orthopedic surgery. *Acta Orthop* 2011;82:82–9.
39. Roos EM, 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.
40. Rodriguez-Merchan EC. Knee instruments and rating scales designed to measure outcomes. *J Orthop Traumatol* 2012;13:1–6.
41. Collins NJ, Misra D, Felson DT, *et al.* Measures of knee function: international knee documentation committee (IKDC) subjective knee evaluation form, knee injury and osteoarthritis outcome score (KOOS), knee injury and osteoarthritis 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):S208–28.
42. Alviar MJ, Olver J, Brand C, *et al.* 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;43:374–81.
43. Collins NJ, Roos EM. Patient-reported outcomes for total hip and knee arthroplasty: commonly used instruments and attributes of a “good” measure. *Clin Geriatr Med* 2012;28:367–94.
44. Klässbo M, Larsson E, Mannevik E. Hip disability and osteoarthritis outcome score. An extension of the Western Ontario and McMaster Universities Osteoarthritis Index. *Scand J Rheumatol* 2003;32:46–51.
45. Bellamy N, Buchanan WW, Goldsmith CH, *et al.* 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;15:1833–40.
46. Nilsdotter A, 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 (A. *Arthritis Care Res* 2011;63:S200–S207.
47. Lawless BM, Greene M, Slover J, *et al.* Does age or bilateral disease influence the value of hip arthroplasty? *Clin Orthop Relat Res* 2012;470:1073–8.
48. Mahomed NN, Arndt DC, McGrory BJ, *et al.* The Harris hip score: comparison of patient self-report with surgeon assessment. *J Arthroplasty* 2001;16:575–80.
49. Harris WH. Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. An end-result study using a new method of result evaluation. *J Bone Joint Surg Am* 1969;51:737–55.
50. Mahomed NN, Liang MH, Cook EF, *et al.* The importance of patient expectations in predicting functional outcomes after total joint arthroplasty. *J Rheumatol* 2002;29:1273–9.
51. Barr PJ, Thompson R, Walsh T, *et al.* The psychometric properties of CollaboRATE: a fast and frugal patient-reported measure of the shared decision-making process. *J Med Internet Res* 2014;16:e2.
52. Morris NS, MacLean CD, Chew LD, *et al.* The single item literacy screener: evaluation of a brief instrument to identify limited reading ability. *BMC Fam Pract* 2006;7:21.
53. Harris PA, Taylor R, Thielke R, *et al.* Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
54. Dempster AP, Laird NM, Rubin DB. Maximum likelihood from incomplete data via the EM Algorithm. *Journal of the Royal Statistical Society: Series B* 1977;39:1–22.
55. Hardin JW, Hilbe JM. *Generalized estimating equations*. 2nd edn. Boca Raton, FL: Chapman and Hall/CRC, 2012.
56. McCaffery KJ, Holmes-Rovner M, Smith SK, *et al.* Addressing health literacy in patient decision aids. *BMC Med Inform Decis Mak* 2013;13(Suppl 2):S10.