National Institute for Health and Care Excellence

Final

Joint replacement (primary): hip, knee and shoulder

[B] Evidence review for decision aids

NICE guideline NG157

Intervention evidence review underpinning the research recommendation in the NICE guideline

June 2020

Final

This evidence review was developed by the National Guideline Centre, hosted by the Royal College of Physicians

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1 Decision aids

1.1 Review question: How useful are decision aids in helping people who are referred for primary elective joint replacement make decisions about their treatment (for example, the type of procedure, timing and implant choice)?

1.2 Introduction

NICE guideline Patient experience in adult NHS services provides clear guidance on the principles of shared decision- making when people are offered treatments. These include the value of decision aids and other forms of decision support.

Deciding on when and if to have joint replacement surgery can be a difficult decision for a person. Using a decision aid may allow information to be given in a format that is easy to understand, engage the person more fully in the decision making process, highlight considerations about surgery that a person was not previously aware of, prompt a better discussion between the individual and clinician, and ultimately help the person to make a more informed choice.

Decision aids should ideally summarise the best available evidence which relates to the effectiveness, safety and practical factors relating to surgery and present the information in a way that makes it easier to weigh up the pros and cons of surgery and surgical options with support from a health care practitioner.

The aim of the review is to assess effectiveness of decision aids for people who are referred for elective joint replacement make a decision about their treatment.

2Quantitative review

2.1 PICO table

For full details see the review protocol in Appendix A:

Table 1: PICO characteristics of review question

Population	• Adults referred for primary elective joint replacement • People with cognitive impairment referred for primary elective joint replacement
Intervention	Patient decision aid: designed to help patients make an informed choices between 2 or more relevant treatment options
Comparison	Usual care
Outcomes	Critical • Quality of life (continuous) • Patient Reported Outcome Measures (PROMs) (continuous) • Patient-clinician communication (continuous) • Participation in decision making (dichotomous) • Accurate risk perceptions (continuous) • Knowledge of the surgery (continuous) • Decisional Conflict Scale (continuous) • Satisfaction with care/decision-making (continuous) Important • Proportion undecided (dichotomous) • Adherence to chosen option (dichotomous)
Study design	Randomised controlled trials If no well-conducted RCTs are available, then observational studies with multivariate analysis will be investigated.

2.2 Clinical evidence

2.2.1 Included studies

Nine RCTs were included in the review; [13, 14, 27, 33, 37, 38, 63, 65, 66, 71, 77] these are summarised in Table 2 below. Evidence from these studies is summarised in the clinical evidence summary below (Table 3). As there was a sufficient number of RCTs included, observational studies were therefore not included.

See also the study selection flow chart in Appendix C: study evidence tables in Appendix D: forest plots in Appendix E: and GRADE tables in Appendix H:

2.2.2 Excluded studies

See the excluded studies list in Appendix I:

2.2.3 Summary of clinical studies included in the evidence review

Table 2: Summary of studies included in the evidence review

Study	Intervention and comparison	Population	Outcomes	Comments
Bozic 2013[14] and Youm 2015[77]	**Decision aids (n=95)** Patients given a combination of decision and communication aids via a DVD and booklet. A question-listing telephone consultation with a trained health coach to assist in constructing a list of questions they'd like to ask their surgeon in an organised focussed one page document. **Versus** **Usual care (n=103)** Subjects mailed existing materials used in surgeons' practices to review before their appointment, which consisted of a map and directions to the clinic and a one page informational handout about signs and symptoms, diagnosis and treatment options for hip/ knee osteoarthritis.	Adults referred for primary elective hip/knee joint replacement Majority aged over 60 years	Decision made by patient	USA Patients choosing between surgery and no surgery.
De Achaval 2012[27]	**Decision aids (n=70)** Patients given a video booklet decision aid, which included a DVD and booklet to follow along with while viewing the DVD. The video was 45 minutes long.	Adults referred for primary elective knee joint replacement Mean age (SD) = 62.8 years (9.0)	Decisional conflict scale	USA Patients choosing between surgery and no surgery.

Study	Intervention and comparison	Population	Outcomes	Comments
	Versus **Versus** **Usual care (71)** Subjects given a printed booklet about treatment choices for knee osteoarthritis, including medical management and surgery.			
Groves 2010[33]	**Decision aids (n=59)** Patients received an envelope of useful websites that were chosen as they provided information about anaesthesia, particularly with respect to hip/knee arthroplasty. **Versus** **Usual care (n=59)** Patients received an envelope containing a letter thanking them for their participation.	Adults referred for primary elective hip/knee joint replacement Mean age (SD) = 60.4 years (9.8)	Change in decision made	UK Patients choosing between general anaesthesia and neuraxia.
Ibrahim 2013[38]	**Decision aids (n=168)** Patients received the knee OA patient decision aid which discussed treatment options, including lifestyle changes, medications, injections, complementary therapy and surgery. The risks and benefits and known efficacy of options were outlined. It also covers clinical indications, operative duration,	Adults referred for primary elective knee joint replacement Mean age (SD) Decision group = 60.70 years (9.27) Control group = 61.28 years (8.29)	Patient-clinician communication	USA Patients choosing between surgery and no surgery.

Study	Intervention and comparison	Population	Outcomes	Comments
	hospital duration, and need for rehabilitative care, physical therapy, recovery time and effort, and cost. Also, the risks of knee replacement surgery, including risk of death, how long a single prosthesis lasts, and consideration of whether to have both knees replaced at the same time or one at a time are discussed. The video was 40 minutes long. **Versus** **Usual care (n=167)** Patients received an educational booklet about osteoarthritis which provided a brief educational program summarising how to live with knee osteoarthritis but not specifically mentioning joint replacement.			
Ibrahim 2017[37]	**Decision aids (n=168)** Patients received the knee OA patient decision aid which discussed treatment options, including lifestyle changes, medications, injections, complementary therapy and surgery. The risks and benefits and known efficacy of options were outlined. It also covers clinical indications, operative duration, hospital duration, and need for rehabilitative care, physical therapy, recovery time and effort, and cost.	Adults referred for primary elective knee joint replacement Mean age (SD) Decision group = 58.9 years (7.0) Control group = 59.3 years (7.5)	Decision made	USA Patients choosing between surgery and no surgery.

Study	Intervention and comparison	Population	Outcomes	Comments
	Also, the risks of knee replacement surgery, including risk of death, how long a single prosthesis lasts, and consideration of whether to have both knees replaced at the same time or one at a time are discussed. The video was 40 minutes long. **Versus** **Usual care (n=168)** Patients received an educational booklet about osteoarthritis which provided a brief educational program summarising how to live with knee osteoarthritis but not specifically mentioning joint replacement.			
Sepucha 2011[63]	**Decision aids (n=61)** Patients received a standard information booklet prepared by the hospital for patients undergoing joint replacement and a video/DVD booklet, describing osteoarthritis and the different treatment options. It included interviews with patients discussing their experiences using surgical/non-surgical approaches to managing their disease. **Versus** **Usual care (n=66)** Patients received a standard information booklet prepared by the	Adults referred for primary elective hip/knee joint replacement Mean age (SD) Decision group = 64.3 years (10.16) Control group = 66.1 years (9.49)	Knowledge score	USA Patients choosing between surgery and no surgery.

Study	Intervention and comparison	Population	Outcomes	Comments
	hospital for patients undergoing joint replacement.			
Stacey 2014[65]	**Decision aids (n=71)** Patients received a video and booklet that provided information on various treatment options for knee osteoarthritis including lifestyle changes, non-drug treatments, pain medication, injections, complementary therapies, and surgery. A description of the options, probabilities of benefits and harms for each option, and video-clips of patient experiences allows patients to clarify their values associated with outcomes of options. The video was 50 minutes long. **Versus** **Usual care (n=71)** Patients received a standard information booklet prepared by the participating hospital for all patients undergoing joint replacement surgery. Information included preparation for surgery, recovery after surgery, and discharge plans. There was no information on benefits and harms of surgery or alterative options that could be used for decision making.	Adults referred for primary elective knee joint replacement Mean age (SD) Decision group = 67.1 years (10.85) Control group = 67.3 years (12.16)	Patient-clinician communication Decision made	Canada Patients choosing between surgery and no surgery.
Stacey 2016[66] and Boland 2018[13]	**Decision aids (n=174)**	Adults referred for primary elective hip/knee joint replacement	Patient-clinician	Canada

Study	Intervention and comparison	Population	Outcomes	Comments
	Patients received standard patient education and a video and booklet that made explicit the decision and provided evidence-based information on treatment options, benefits and risks, and related probabilities. They included patients' testimonials (e.g., describing treatment options, their decision making process experiences, and outcomes) that help patients clarify their values associated with option outcomes. The video was 50 minutes long. **Versus** **Usual care (n=169)** Patients received standard patient education.	Mean age (SD) Decision group = 66.1 years (9.8) Control group = 66.9 years (9.8)	communication Knowledge score Change in decision made Decisional conflict scale	Patients choosing between surgery and no surgery.
Vina 2016[71]	**Decision aids (n=240)** Patients watched a video that discussed the benefits and risks of various pharmacologic and surgical treatment options for knee osteoarthritis. It also covered clinical indications for joint replacement, anticipated clinical course during surgery, and postoperative expectations. It described the potential complications of undergoing joint replacement surgery and the anticipated lifespan of a prosthesis. They then underwent face to face counselling	Adults referred for primary elective hip/knee joint replacement Mean age (SD) Decision group = 62.02 years (8.09) Control group = 61.14 years (7.86)	No relevant outcomes to extract	USA Patients choosing between surgery and no surgery.

Study	Intervention and comparison	Population	Outcomes	Comments
	regarding TKA using a motivational interviewing strategy. Participants were asked about their thoughts regarding TKA, and their goals and values regarding their arthritis. Information regarding TKA and how to engage the patients' primary care providers in discussing their knee pain also were provided. The video lasted 40 minutes and the counselling 30 minutes. **Versus** **Usual care (n=253)** Patients received an educational booklet that summarized how to live with knee OA. It did not specifically mention joint replacement as a treatment option but provided examples of exercises one could do to improve knee pain and stiffness.			

See Appendix D: for full evidence tables.

2.2.4 Quality assessment of clinical studies included in the evidence review

Table 3: Clinical evidence summary: Decision aids versus usual care

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Decision aids versus usual care (95% CI)
Quality of life	Not reported				

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Decision aids versus usual care (95% CI)
Patient Reported Outcome Measures (PROMs)	Not reported				
Decisional conflict total score Scale from: 0 to 100.	138 (1 study)	LOW[1,2] due to risk of bias, imprecision		The mean decisional conflict total score in the control groups was 29.2	The mean decisional conflict total score in the intervention groups was 5.8 lower (11.07 to 0.53 lower)
Decisional conflict present	253 (1 study) 6 months	LOW[1,2] due to risk of bias, imprecision	RR 0.71 (0.40 to 1.26)	189 per 1000	55 fewer per 1000 (from 113 fewer to 49 more)
Patients made an informed decision	593 (3 studies)	VERY LOW[1,2] due to risk of bias, inconsistency	RR 0.99 (0.84 to 1.18)	355 per 1000	4 fewer per 1000 (from 57 fewer to 64 more)
Knowledge score - validity of decision quality instrument Scale: 0-100, 0-18	441 (2 studies)	LOW[1,3] due to risk of bias, imprecision		The mean knowledge score - validity of decision quality instrument in the control groups was 32.5	The mean knowledge score - validity of decision quality instrument in the intervention groups was 0.54 standard deviations higher (0.35 to 0.73 higher)
Patient-clinician communication, prepared to talk to doctor about what matters most Scale: 1-5	443 (2 studies) 2 weeks	HIGH		The mean patient-clinician communication, prepared to talk to doctor about what matters most in the control groups was 4.167	The mean patient-clinician communication, prepared to talk to doctor about what matters most in the intervention groups was 0.3 higher (0.13 to 0.48 higher)
Appointment with an orthopaedic surgeon	323 (1 study) 12 months	HIGH	OR 1.27 (0.54 to 3)	Not reported	Unable to calculate absolute effect because the underlying numbers experiencing the outcome were not reported

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Decision aids versus usual care (95% CI)
Satisfaction with care/decision-making	Not reported				
Proportion undecided	372 (2 studies)	VERY LOW[2,3] due to inconsistency, imprecision	Peto OR 0.44 (0.13 to 1.54)	38 per 1000	20 fewer per 1000 (from 60 fewer to 10 more)

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
[2] Downgraded by 1 or 2 increments because the point estimate varied widely across studies, unexplained by subgroup analysis.
[3] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

See Appendix F: for full GRADE tables.

2.3 Economic evidence

2.3.1 Included studies

One health economic study was identified with the relevant comparison and has been included in this review.[70] The study is summarised in the health economic evidence profile below (Table 4) and the health economic evidence table in Appendix H:

2.3.2 Excluded studies

No health economic studies that were relevant to this question were excluded due to assessment of limited applicability or methodological limitations.

See also the health economic study selection flow chart in Appendix G:

2.3.3 Summary of studies included in the economic evidence review

Table 4: Health economic evidence profile: Decision aids versus usual care

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Trenaman 2017[70] [Canada]	Partially applicable[(a)]	Potentially serious limitations[(b)]	A within-trial (RCT) cost-utility analysis with a 2-year follow-up comparing the use of decision aid to usual care	Decision aids saved £286 per person	Decision aids gave 0.02 extra QALYs per person	Decision aids dominate (less costly and more effective) usual care	Decision aids remained dominant in all sensitivity analyses which included a probabilistic analysis and series of one-way deterministic analyses

Abbreviations: QALY= quality-adjusted life years; RCT= randomised controlled trial

(a) A cost-utility analysis that used EQ-5D to calculate QALYs from a Canadian healthcare perspective

(b) Only 158/334 people had complete data at follow-up although this was imputed. Outcomes are derived from only 1 RCT out of 10 included in the clinical review. The reported incremental cost and utility is not same as the difference in reported mean cost and utility values for using a decision aid and usual care. A discount rate of 5% was used.

3Qualitative review

3.1 Characteristics table

For full details see the review protocol in Appendix A:

Table 5: Characteristics of review question

Objective	To find out about experiences of using decision aids from both the person undergoing surgery and the surgical team.
Population and setting	Healthcare staff involved in the joint replacement procedure, adults who have undergone primary elective joint replacement, and the carers or family of those who have undergone joint replacement surgery.
Context	People's views on the requirements for effective collaborative decision-making between the surgical team and the person undergoing joint replacement surgery and their carers'.
Review strategy	Synthesis of qualitative research. Results presented in narrative and table format. Quality of the evidence will be assessed by a GRADE CerQual approach for each review finding.

3.2 Qualitative evidence

3.2.1 Included studies

We searched for qualitative studies exploring the perceptions of patients' who have undergone primary elective joint replacement, the healthcare staff involved in the joint replacement procedure and family and carers' of those who have undergone joint replacement surgery and their experiences of using decision aids.

One qualitative study was included in the review; [18] which is summarised in Table 6 below. The aim of the study was to explore the barriers and facilitators to decision aid uptake among orthopaedic surgeons. Face to face interviews were used as their data collection method and a variety of qualitative methodologies were used to inform the research.

Key findings from these studies are summarised in Section Table 7 below. See also the study selection flow chart in Appendix C: study evidence tables in Appendix D: and excluded studies lists in Appendix E:

3.2.2 Excluded studies

See the excluded studies list in Appendix E:

3.2.3 Summary of qualitative studies included in the evidence review

Table 6: Summary of studies included in the review

Study	Design	Population	Research aim	Comments
Bunzli 2017[18]	Structured one to one interviews with grounded theory analysis	All orthopaedic surgeons performing TKA at one tertiary teaching hospital in Australia were eligible. 15 consultant surgeons and 5 registrars were included in the analysis	The aim of this study was to explore the barriers and facilitators to decision aid uptake among orthopaedic surgeons.	

See Appendix D: for full evidence tables.

3.2.4 Qualitative evidence synthesis

Table 7: Review findings

Main findings	Statement of finding
Knowledge of one's own patient outcomes	Most participants were aware of the literature that up to 20% of patients undergoing TKA have no clinically meaningful improvement from surgery, however most believed this percentage was significantly lower in the patients they operated on.
Behavioural regulation	Some participants explained how they were aware the feedback from patients may be biased and all stated how they would be interested in the feedback from those who achieved a clinically meaningful improvement.
Memory, attention and decision processes	All participants described that patient expectations are an important consideration in surgical decision making.
Beliefs about capabilities and skills	Some participants stated how they found it difficult to assess the patient-related factors that can influence TKA outcome. Most participants saw themselves as reasonably good at picking the patients who will do well.
Social/professional role and identity	Participants described how surgery is an art and a science, and not just about the evidence.
Beliefs/attitudes towards a decision aid	Most participants would use a decision aid to support, not replace their decision making.
Beliefs about consequences	Participants stated reasons of how decision aids can be useful but also stated how they could have disadvantages.
Environmental context and resources (how the tool might be implemented)	Most participants would not like to see a decision aid with mandatory cut-offs implemented and do not think surgeons could agree on a cut off level for a decision aid. Some participants stated that time would be a key concern to using a decision aid in their practice.
Reinforcement	Some participants stated that evidence that the tool had been widely validated would not convince them to use it and would need it correlated with their own clinical decision making.
Goals	All of the participants' goals were to optimise patient outcomes.

3.2.5 Narrative summary of review findings

Review finding 1: Knowledge of one's own patient outcomes

Most participants were aware of the literature concerning 20% of patients do not have a clinically meaningful improvement from TKA, with one stating that '22 per cent is the high end. But there are a lot of papers that all suggest 10, 15, and 20 per cent'. Furthermore, a high majority of surgeons believed that number to be lower in their own patients, with one explaining 'I don't count it, but I think around 10 per cent would be saying they aren't entirely satisfied by surgery'. A potential barrier discussed by some participants was around how any improvement in pain is still an improvement, and how it depends on how you define 'meaningful'.

Review finding 2: Behavioural regulation

All participants stated they would be interested to know the percentage of their patients achieved a clinically meaningful improvement, with one stating 'there's always a difference between how well you

think you are doing and you are doing'. With surgeons having formal feedback it would allow them the opportunity to change things if they are not doing as well as they want to.

Review finding 3: Memory, attention and decision processes

All participants discussed how they find patient expectations an important consideration in surgical decision making, with one stating they won't do the operation 'if patients' expectations are not meeting mine, because then the patient isn't happy'. A high amount of participants also explained how the lack of effective non-operative alternatives influence their surgical decision making with one stating how they think 'there are limitations on what you can improve with non-operative measures'. Some also felt it important to be able to say 'although we don't think you would benefit from surgery, we're going to put you in this intense physiotherapy program with dieticians to improve your knee pain. They need to be offered something'. A high number of participants thought their 'threshold of acceptable risk for surgery is >80% likelihood of a good outcome' and their level of acceptable risk is patient dependent.

Review finding 4: Beliefs about capabilities and skills

Most participants believed themselves to be reasonably good at picking the patients who will do well with one stating 'I think I am reasonably good… I do have a little bit of a gut feeling about patients'. Some participants explained how they find it difficult to assess the patient-related factors that can influence TKA outcome, with one describing how they 'don't know how to identify them pre-operatively. Something is happening from my assessment to the patients' outcome and I don't know what the link is'. Some also explained how they find it difficult to say no to patients.

Half the participants described how they rely mostly on their experience when it comes to surgical decision making, with one stating 'I don't use any formal tools. I use I guess old fashioned clinical acumen is what I would call it…I have been doing this for a while and you develop a way of assessing people'.

Review finding 5: Social/professional role and identity

Half the participants thought surgery to be an art and a science and not just about the evidence. One explained how they thought 'medicine is not about numbers, it is about patients. Each patient has their own different pathology and own different personality'.

Review finding 6: Beliefs/attitudes towards a decision aid

Most participants discussed they would use a decision aid to support but not replace their decision making. One participant explained how they didn't think 'it would really influence my surgical decision making; I think it would more affirm my decision to not offer a patient an operation'. Another described how if they 'if I think they are ok and they score badly I will relook at it and say why is that? Am I missing something obvious? But at the end of the day if an aid says one thing and my sniff test says there is something not right, I'm still following my nose'.

Review finding 7: Beliefs about consequences

Most participants stated a disadvantage of decision aids is that it may not capture the nuances of the individual patient and some patients may miss out on surgery. Some thought it would be a useful objective tool to help them say no to patients or useful for gaining patient informed consent and shared decision making. Some also thought decision aids has the potential to improve the use of resources and save costs. A number of participants expressed concern regarding the legal and ethical implications of a decision aid, with one stating 'I guess the ethicists would say you are denying patient-centred care, so that is where there is a potential for a can of worms'. Some had medicolegal concerns about documenting specific risk values in patient records, with some believing such information would have to be deliberately withheld from patients in case it fell into the 'wrong' hands. 'You have to think the medico-legal implications of a patient having a risk value documented in their notes. If they don't have a good result and then some have the lawyers look through and say you had this tool that was validated and you still went ahead where would we lie medico-legally?'.

Review finding 8: Environmental context and resources (how the tool might be implemented)

Most participants expressed concerns in making decision aids compulsory with set cut-offs, and would not like to see a decision aid with a mandatory cut-off implemented, further explaining how they do not think surgeons could agree on a cut-off level. One participant commented they do not think 'there are things that can become compulsory in terms of a decision aid as I mentioned because it takes away patient-centred care'. Although a handful commented they could see the benefit of decision aids, specifically an electronic or online tool, some also stated how they believed time would be a key concern to using decision aids. Most believed it would be best used within the patient-surgeon consultation, with a few suggesting it could be designed for patients to use on their own or with a support network to save time during the clinical consultation.

Review finding 9: Reinforcement

Almost half of participants shared the opinion of the importance of their own clinical decision making, as solely evidence of the tool being widely validated would not convince them to use it, they would need it correlated with their own decision making. One participant stated the reason being although they trust the research, they 'want their own data no doubt about it because I think I am better… I know lots of faults in techniques or little things that really can comprise outcome'. Moreover, one stated how the evidence may apply to a 'certain situation in a certain individual at a period in time and there is always variations or exceptions around that', so they would then correlate the results in their mind as well as visually observing the patient. A few participants also stated they would be more likely to trust a tool developed and implemented by their peers.

Review finding 10: Goals

All participants agreed their goal is to optimise patient outcomes as they all would like good results for patients.

Explanation of quality assessment

All the themes came from one study which was conducted in one centre which involved the potential use of a decision aid. While this raises concerns about adequacy of the findings the themes were internally coherent. There was a judgement of moderate confidence in each of the themes.

3.2.6 Qualitative evidence summary

Table 8: Summary of evidence

Study design and sample size		Finding	Quality assessment		
Number of studies contributing to the finding	Design		Criteria	Rating	Overall assessment of confidence
Knowledge					
1	Interviews	Nearly all participants are aware of the literature concerning that up to 20% of patients do not have a clinically meaningful improvement from surgery, with a vast majority believing this number is lower when it comes to their patients.	Limitations	Very minor concerns about methodological limitations	MODERATE
			Coherence	Very minor concerns about coherence	
			Relevance	Very minor concerns about relevance	
			Adequacy	Moderate concerns about adequacy	
Behavioural regulation					
1	Interviews	All participants were interested in receiving feedback to observe which of their patients achieved a clinically meaningful improvement.	Limitations	Very minor concerns about methodological limitations	MODERATE
			Coherence	Very minor concerns about coherence	
			Relevance	Very minor concerns about relevance	
			Adequacy	Moderate concerns about adequacy	

Study design and sample size		Finding	Quality assessment		
Number of studies contributing to the finding	Design		Criteria	Rating	Overall assessment of confidence
Memory, attention and decision processes					
1	Interviews	All participants believed patient expectations are an important consideration in surgical decision making.	Limitations	Very minor concerns about methodological limitations	MODERATE
			Coherence	Very minor concerns about coherence	
			Relevance	Very minor concerns about relevance	
			Adequacy	Moderate concerns about adequacy	
Beliefs about capabilities and skills					
1	Interviews	Although most participants believed themselves to be reasonably good at selecting patients who would do well, a fair amount found it difficult to assess the patient-related factors that can influence TKA outcome. Half of the participants rely on their experience when it comes to surgical decision making.	Limitations	Very minor concerns about methodological limitations	MODERATE
			Coherence	Very minor concerns about coherence	
			Relevance	Very minor concerns about relevance	
			Adequacy	Moderate concerns about adequacy	
Social/professional role and identity					
1	Interviews	Half of participants believed surgery is an art and a science, and not just about the evidence.	Limitations	Very minor concerns about methodological limitations	MODERATE
			Coherence	Very minor concerns	

Study design and sample size		Finding	Quality assessment		
Number of studies contributing to the finding	Design		Criteria	Rating	Overall assessment of confidence
				about coherence	
			Relevance	Very minor concerns about relevance	
			Adequacy	Moderate concerns about adequacy	
Beliefs/attitudes towards a decision aid					
1	Interviews	The majority of participants would use a decision aid to support, not replace their decision-making.	Limitations	Very minor concerns about methodological limitations	MODERATE
			Coherence	Very minor concerns about coherence	
			Relevance	Very minor concerns about relevance	
			Adequacy	Moderate concerns about adequacy	
Beliefs about consequences					
1	Interviews	Participants thought a decision aid would be useful for gaining patient informed consent and shared decision making, but also thought it may not capture the nuances of the individual patient and some patients may miss out on surgery.	Limitations	Very minor concerns about methodological limitations	MODERATE
			Coherence	Very minor concerns about coherence	
			Relevance	Very minor concerns about relevance	
			Adequacy	Moderate concerns about adequacy	

Study design and sample size		Finding	Quality assessment		
Number of studies contributing to the finding	Design		Criteria	Rating	Overall assessment of confidence
Environmental context and resources (how the tool might be implemented)					
1	Interviews	A number of participants could see electronic decision aids working well in their practice, but also largely agreed mandatory cut-off's would be hard for surgeons to agree on.	Limitations	Very minor concerns about methodological limitations	MODERATE
			Coherence	Very minor concerns about coherence	
			Relevance	Very minor concerns about relevance	
			Adequacy	Moderate concerns about adequacy	
Reinforcement					
1	Interviews	A large number of participants stated that evidence the tool had been widely validated would not convince them to use it, preferring to trust a tool developed and implemented by their peers.	Limitations	Very minor concerns about methodological limitations	MODERATE
			Coherence	Very minor concerns about coherence	
			Relevance	Very minor concerns about relevance	
			Adequacy	Moderate concerns about adequacy	
Goals					
1	Interviews	All participants stated their goal was to optimise patient outcomes.	Limitations	Very minor concerns about methodological limitations	MODERATE
			Coherence	Very minor concerns	

Study design and sample size		Finding	Quality assessment		
Number of studies contributing to the finding	Design		Criteria	Rating	Overall assessment of confidence
				about coherence	
			Relevance	Very minor concerns about relevance	
			Adequacy	Moderate concerns about adequacy	

4 Evidence statements

4.1 Clinical evidence statements

Decision aids versus usual care

Evidence from 9 RCTs was included to assess the effectiveness of decision aids compared to usual care. A benefit for decision aids was seen in decisional conflict present, knowledge score, discussion with primary care provider, and proportion undecided (high to very low quality, n=253 to441). No outcomes favoured usual care. No difference in interventions was found for decisional conflict total score, patients made an informed decision and patient-clinician communication outcomes (high to very low quality, n=138 to 593).

4.2 Health economic evidence statements

One cost-utility analysis found that using decision aids were dominant (less costly and more effective) compared to usual care for people considering primary elective total hip or knee replacement. This study was assessed as partially applicable with potentially serious limitations.

4.3 Qualitative evidence statements

1 qualitative study with 20 participants utilising semi structured interviews, suggested 11 areas on thoughts of using decision aids (moderate confidence).

Knowledge of one's own patient outcomes

- Participants were aware of the literature concerning 20% of patients do not have a clinically meaningful improvement from TKA, with a high majority believing that number to be lower in their own patients.

Behavioural regulation

- All participants would be interested to know the percentage of their patients achieved a clinically meaningful improvement.

Memory, attention and decision processes

- All participants discussed how patient expectations are an important consideration in surgical decision making. Some also felt it important to be able to say their opinion if they did not think people would benefit from surgery.

Beliefs about capabilities and skills

- Most believed themselves to be reasonably good at picking the patients who will do well and half the participants described they rely mostly on their experience when it comes to surgical decision making.

Social/professional role and identity

- Half the participants thought surgery to be an art and a science and not just about the evidence.

Beliefs/attitudes towards a decision aid

- Most discussed they would use a decision aid to support but not replace their decision making.

Beliefs about consequences

- Most stated a disadvantage of decision aids being it may not capture the nuances of the individual patient and some patients may miss out on surgery. Some thought it would be a useful objective tool to help them say no to patients or useful for gaining patient informed consent and shared decision making.

Environmental context and resources (how the tool might be implemented)

- Most expressed concerns in making decision aids compulsory with set cut-offs, and would not like to see a decision aid with a mandatory cut-off implemented. Although a handful commented they could see the benefit of decision aids, specifically an electronic or online tool, some also stated how they believed time would be a key concern to using decision aids.

Reinforcement

- Almost half of participants shared the opinion of the importance of their own clinical decision making, as sole evidence of the tool being widely validated would not convince them to use it. A few participants also stated they would be more likely to trust a tool developed and implemented by their peers.

Goals

- All agreed their goal is to optimise patient outcomes as they all would like results.

5The committee's discussion of the evidence

5.1.1 Interpreting the evidence

5.1.1.1 The outcomes that matter most

Quantitative review

The critical outcomes were; quality of life, Patient Reported Outcome Measures (PROMs), patient clinician communication, participation in decision making, accurate risk perceptions, knowledge of the surgery, decisional conflict scale and satisfaction with care/decision making. The decisional conflict scale measures one's personal perceptions of uncertainty in choosing options, modifiable factors contributing to uncertainty such as feeling uninformed, and effective decision making such as feeling the choice is informed. Patient clinician communication and discussion with primary care provider reflect interaction with healthcare professionals and feeling able to discuss topics such as what matters most to them.

The important outcomes were proportion undecided and adherence to chosen option. Proportion undecided reflects those who were unsure after receiving the intervention on which approach to choose, i.e. surgery or no surgery.

Qualitative review

The outcome for this review was people's views on the requirements for effective collaborative decision-making between the surgical team and the person undergoing joint replacement surgery and their carers'.

5.1.1.2 The quality of the evidence

Quantitative review

Eleven studies were included in the review, showing outcomes ranging from very low to high quality due to risk of bias, inconsistency and imprecision. The majority of the evidence was very low quality, mainly due to lack of allocation concealment and blinding, contributing to a higher risk of bias. There was often imprecision due to confidence intervals crossing the default minimal important difference (MID) lines. Inconsistency was present in several outcomes due to heterogeneity unexplained by subgroup analysis or the number of zero events varying across arms.

Qualitative review

1 study was included in this review. The quality of all of the evidence was deemed moderate due to moderate adequacy related to only one study in the analysis. This was the only relevant study available at the time of the review.

5.1.1.3 Benefits and harms

Quantitative review

All of the studies compared decision aids to usual care. 7 of the studies involved people with hip or knee joint replacements, while 4 involved those with just knee replacements.

A clinically important benefit of decision aids over usual care was found in decisional conflict total score, 3 knowledge score subscale outcomes, discussion with primary care provider and the proportion undecided. No outcomes favoured usual care. No clinically important difference was found for decisional conflict being present, patients made an informed

decision, 3 knowledge score subscales, and clear about benefits and risks that mattered most (SURE test).

There are biases issues inherent studies of decision aid use. It is not possible to blind people to decision aids and engagement with them may well be higher if a person knows they are involved in a study evaluating decision aids. This increased engagement could lead to more positive views of decision aids. Usual care in some of the included studies was considered less than is expected of current NHS care and this may artificially benefit outcomes in decision aid groups.

Qualitative review

This qualitative review identified a number of important themes that arose from healthcare professionals views of decision aids.

The included study was designed around the development of a decision aid and the participants were not given a specific decision aid to assess.

The committee noted how it seemed the study participants saw decision aids as a threat to their expertise. The majority of participants described they would use a decision aid to support but not replace their decision making, with some explaining they did not feel it would really influence their surgical decision making, but may affirm their decision to not offer a person joint replacement surgery. Half of the participants described how they relied mostly on their personal experience when it came to surgical decision making, as they felt they developed their own way of assessing people.

Most participants stated a disadvantage of decision aids is that they may not capture the nuances of an individual patient and some may unnecessarily miss out on surgery.

The committee discussed how the participants may have been considering a decision aid as more of a triage type tool rather than decision aid with information for the person having surgery.

5.1.2 Cost effectiveness and resource use

Quantitative review

One cost utility analysis was presented. The results suggested using a decision aid was dominant (less costly and more effective) when compared to usual care. However, the committee acknowledged that given the study had only 46% complete cases at follow-up; it was difficult to draw any firm conclusions regarding decision aids from the paper. Furthermore, this study represented only 1 form of decision aid.

There was much discussion over the definition of a decision aid. Given that they can take other forms than what was included in the economic study, no recommendation could be made about the cost-effectiveness of decision aids given their broad definition. Consequently, a research recommendation was made with the intention of understanding what components an effective decision aid consists of.

Qualitative review

Economic evidence to inform recommendations in this area was sought in the previous quantitative question.

5.1.3 Other factors the committee took into account

The committee recognised the importance of shared decision-making and the principles of this. Joint replacement is an elective procedure and among the decisions to be made are alternative therapies to address pain and improve function, the benefits and risks of various

types of joint replacement surgery, the types of implants the orthopaedic team can offer in that centre, and the options around anaesthesia.

Discussions and information around these decisions can begin from the first meeting with the orthopaedic team and continue from there. Interventions that help the patient to make an informed choice are welcome and the committee considered that patient decision aids are potentially useful for this.

The evidence review found variation between studies on what constitutes a decision aid. The committee considered they should be more than an information-giving tool as they appear to be in some of the included studies. The committee concluded from the clinical evidence that people who have more information tend to feel less conflicted and more comfortable with their decisions around joint replacement surgery. This supports the idea providing comprehensive information and from the experience of committee surgeons people can come to their first appointment without any understanding of joint replacement surgery. These people can be anxious because they may feel under pressure to make quick decisions and not have prepared questions that they would like to ask.

The committee supported the aims of NICE decision aids as tools to:[58]

- summarise the best available evidence relating to the effectiveness, safety and practical factors relating to the treatment or care options and
- present that information in a way that is easy for people facing the decision (and their carers, as appropriate) to understand, with support from their health or care practitioner, so that they can weigh up the options' pros, cons and trade-offs.

The committee considered it important that a decision aid should not be seen as the end of discussion and that people may want the option to change their mind.

The committee discussed how decision aids may not cover the many individual aspects of people's situations such as social and psychological aspects, such as the patients' journey and what they are going through, importance of returning to work, or cultural or religious aspects that are also important in terms of decision making. Individualised discussion is important the observation skills of a clinician may be important as non-verbal behaviour may be present that may be missed with the sole use of a decision aid.

There are potential equality issues around the use of decision aids for example for people with learning or cognitive disabilities and people without English as a first language.

The committee stressed it is necessary to make the shared decision making process accessible to all people. Further research around making decision aids that are appropriate for different people and situations may be of use

The committee considered they could not make a recommendation on specific 'decision aids' for joint replacement decision. It was agreed to cross refer to the current Patient experience in adult NHS services: improving the experience of care for people using adult NHS services guideline[56] as this covers much of what this review was aiming to explore. This resulted in the committee forming a research recommendation, resulting in a question to address what are the components of a decision aid tool specific to joint replacement. This will in turn help to define decision aids for research going forward, resulting in a more uniform concept of decision aids across future studies.

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Appendices

Appendix A: Review protocols

Table 9: Review protocol: Decision aids – quantitative and qualitative review

ID	Field	Content
0.	PROSPERO registration number	Not registered
1.	Review title	Use of decision aids during joint replacement
2.	Review question	How useful are decision aids in helping people who are referred for primary elective joint replacement make decisions about their treatment (for example, the type of procedure, timing and implant choice)?
3.	Objective	The process of deciding the specifics of the surgery is collaboration between the joint replacement surgeon and the person having the replacement. Patient decision aids are designed to help patients understand relevant evidence-based information, to clarify their attitudes towards potential benefits and harms and to aid communication. This review seeks to find a decision aid to support the shared decision-making process. The qualitative review seeks to find out about experiences of using decision aids from both the person undergoing surgery and the surgical team.
4.	Searches	The following databases will be searched: Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Database of Systematic Reviews (CDSR) Embase MEDLINE CINAHL, Current Nursing and Allied Health Literature PsycINFO Searches will be restricted by: English language Human studies Letters and comments are excluded. Other searches: Inclusion lists of relevant systematic reviews will be checked by the reviewer.

ID	Field	Content
		The searches may be re-run 6 weeks before final committee meeting and further studies retrieved for inclusion if relevant. The full search strategies will be published in the final review.
5.	Condition or domain being studied	Use of decision aids during joint replacement
6.	Population	Intervention review • Adults referred for primary elective joint replacement • People with cognitive impairments referred for primary elective joint replacement Qualitative review • The views of healthcare staff involved in the joint replacement procedure, adults who have undergone primary elective joint replacement, and the carers or family of those who have undergone joint replacement surgery. Exclusion: • Adults having joint replacement as immediate treatment following fracture. • Adults having revision joint replacement. • Adults having joint replacement as treatment for primary or secondary cancer affecting the bones.
7.	Intervention/Exposure/Test	Patient decision aid: designed to help patients make an informed choices between 2 or more relevant treatment options
8.	Comparator/Reference standard/Confounding factors	Usual care
9.	Types of study to be included	Intervention review Randomised controlled trials If no well-conducted RCTs are available, then observational studies with multivariate analysis will be investigated. Qualitative review Qualitative studies utilising qualitative analysis (for example, interviews, focus groups, observations)studies
10.	Other exclusion	Non-English language studies.

ID	Field	Content
	criteria	Abstracts will be excluded as it is expected there will be sufficient full text published studies available.
11.	Context	For qualitative review; • People's views on the requirements for effective collaborative decision-making between the surgical team and the person undergoing joint replacement surgery and their carers. Data synthesis • Synthesis of qualitative research: thematic analysis – information synthesised into main review findings. Results presented in a detailed narrative [with accompanying diagrams] and in table format with summary statements of main review findings. Data extraction will be stopped once saturation has been reached. This is the point when no new information emerges from studies that match the review protocol.
12.	Primary outcomes (critical outcomes)	Quality of life (continuous) Patient Reported Outcome Measures (PROMs) (continuous) Patient-clinician communication (continuous) Participation in decision making (dichotomous) Accurate risk perceptions (continuous) Knowledge of the surgery (continuous) Decisional Conflict Scale (continuous) Satisfaction with care/decision-making (continuous))
13.	Secondary outcomes (important outcomes)	Proportion undecided (dichotomous) Adherence to chosen option (dichotomous) Cochrane review: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001431.pub5/full Primary outcomes Evaluation criteria that map onto the IPDAS criteria: • Attributes of the choice made: does the patient decision aid improve the match between the chosen option and the features that matter most to the informed patient (demonstrated by outcomes such as knowledge, accurate risk perceptions, values-choice congruence)? • Attributes of the decision-making process: does the patient decision aid help patients to recognize that a decision needs to be made, feel informed about the options and their features, be clear about the option features that matter most, discuss values with their clinician, and become involved in decision making?

ID	Field	Content
		Other decision-making process variables • Decisional conflict • Patient-clinician communication • Participation in decision making • Proportion undecided • Satisfaction with the choice, with the process of decision making, and with the preparation for decision making Secondary outcomes • Behaviour • Choice (the actual choice implemented; if not reported, the participants' preferred option was used as a surrogate measure) • Adherence to chosen option Health outcomes • Health status and quality of life (generic and condition-specific) • Anxiety, depression, emotional distress, regret, confidence Healthcare system • Costs, cost-effectiveness • Consultation length • Litigation rates
14.	Data extraction (selection and coding)	EndNote will be used for reference management, sifting, citations and bibliographies. Titles and/or abstracts of studies retrieved using the search strategy and those from additional sources will be screened for inclusion. The full text of potentially eligible studies will be retrieved and will be assessed for eligibility in line with the criteria outlined above. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. An in-house developed database; EviBase, will be used for data extraction. A standardised form is followed to extract data from studies (see Developing NICE guidelines: the manual section 6.4) and for undertaking assessment of study quality. Summary evidence tables will be produced including information on: study setting; study population and participant demographics and baseline characteristics; details of the intervention and control interventions; study methodology'

ID	Field	Content
		recruitment and missing data rates; outcomes and times of measurement; critical appraisal ratings. A second reviewer will quality assure the extracted data. Discrepancies will be identified and resolved through discussion (with a third reviewer where necessary). Qualitative review The methodological quality of each study will be assessed using NGC modified NICE checklists and the quality of the body of evidence as a whole will be assessed by a GRADE CERQual approach for each review finding.
15.	Risk of bias (quality) assessment	Risk of bias will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual. For Intervention reviews the following checklist will be used according to study design being assessed: Systematic reviews: Risk of Bias in Systematic Reviews (ROBIS) Randomised Controlled Trial: Cochrane RoB (2.0) Disagreements between the review authors over the risk of bias in particular studies will be resolved by discussion, with involvement of a third review author where necessary.
16.	Strategy for data synthesis	Where possible, data will be meta-analysed. Pairwise meta-analyses will be performed using Cochrane Review Manager (RevMan5) to combine the data given in all studies for each of the outcomes stated above. A fixed effect meta-analysis, with weighted mean differences for continuous outcomes and risk ratios for binary outcomes will be used, and 95% confidence intervals will be calculated for each outcome. Heterogeneity between the studies in effect measures will be assessed using the I^2 statistic and visually inspected. We will consider an I^2 value greater than 50% indicative of substantial heterogeneity. Sensitivity analyses will be conducted based on pre-specified subgroups using stratified meta-analysis to explore the heterogeneity in effect estimates. If this does not explain the heterogeneity, the results will be presented using random-effects. GRADE pro will be used to assess the quality of each outcome, taking into account individual study quality and the meta-analysis results. The 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) will be appraised for each outcome. If the population included in an individual study includes children aged under 12, it will be included if the majority of the population is aged over 12, and downgraded for indirectness if the overlap into those aged less than 12 is greater than 20%. Publication bias is tested for when there are more than 5 studies for an outcome. Other bias will only be taken into consideration in the quality assessment if it is apparent.

ID	Field	Content			
		Where meta-analysis is not possible, data will be presented and quality assessed individually per outcome. If sufficient data is available to make a network of treatments, WinBUGS will be used for network meta-analysis.			
17.	Analysis of sub-groups	Site of joint replacement: knee shoulder hip			
18.	Type and method of review	☒	Intervention		
		☐	Diagnostic		
		☐	Prognostic		
		☒	Qualitative		
		☐	Epidemiologic		
		☐	Service Delivery		
		☐	Other (please specify)		
19.	Language	English			
20.	Country	England			
21.	Anticipated or actual start date	15/03/19			
22.	Anticipated completion date	20/03/20			
23.	Stage of review at time of this submission	Review stage		Started	Completed
		Preliminary searches		☐	☑
		Piloting of the study selection process		☐	☑
		Formal screening of search results against eligibility criteria		☐	☑
		Data extraction		☐	☑
		Risk of bias (quality) assessment		☐	☑

ID	Field	Content
		Data analysis ☐ ☑
24.	Named contact	5a. Named contact National Guideline Centre 5b Named contact e-mail TBC 5e Organisational affiliation of the review National Institute for Health and Care Excellence (NICE) and the National Guideline Centre
25.	Review team members	From the National Guideline Centre: Carlos Sharpin [Guideline lead] Alex Allen [Senior Systematic Reviewer] Rafina Yarde [Systematic reviewer] Robert King [Health economist] Agnès Cuyàs [Information specialist] Eleanor Priestnall [Project Manager]
26.	Funding sources/sponsor	This systematic review is being completed by the National Guideline Centre which receives funding from NICE.
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: [NICE guideline webpage].
29.	Other registration details	
30.	Reference/URL for	

ID	Field	Content	
	published protocol		
31.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: notifying registered stakeholders of publication publicising the guideline through NICE's newsletter and alerts issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.	
32.	Keywords	Decision aids, joint replacement, usual care, qualitative, focus groups, semi structured interviews, quantitative	
33.	Details of existing review of same topic by same authors	N/A	
34.	Current review status	☐	Ongoing
		☒	Completed but not published
		☐	Completed and published
		☐	Completed, published and being updated
		☐	Discontinued
35..	Additional information	N/A	
36.	Details of final publication	www.nice.org.uk	

Table 10: Health economic review protocol – quantitative review

Review question	All questions – health economic evidence
Objectives	To identify health economic studies relevant to any of the review questions.
Search criteria	• Populations, interventions and comparators must be as specified in the clinical review protocol above. • Studies must be of a relevant health economic study design (cost–utility analysis, cost-effectiveness analysis, cost–benefit analysis, cost–consequences analysis, comparative cost analysis). • Studies must not be a letter, editorial or commentary, or a review of health economic evaluations. (Recent reviews will be ordered although not reviewed. The bibliographies will be checked for relevant studies, which will then be ordered.) • Unpublished reports will not be considered unless submitted as part of a call for evidence. • Studies must be in English.
Search strategy	A health economic study search will be undertaken using population-specific terms and a health economic study filter – see appendix B below.
Review strategy	Studies not meeting any of the search criteria above will be excluded. Studies published before 2003, abstract-only studies and studies from low or middle-income countries (e.g. most non-OECD countries) or the USA will also be excluded. Each remaining study will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist which can be found in appendix H of Developing NICE guidelines: the manual (2014).[57] **Inclusion and exclusion criteria** • If a study is rated as both 'Directly applicable' and with 'Minor limitations' then it will be included in the guideline. A health economic evidence table will be completed and it will be included in the health economic evidence profile. • If a study is rated as either 'Not applicable' or with 'Very serious limitations' then it will usually be excluded from the guideline. If it is excluded then a health economic evidence table will not be completed and it will not be included in the health economic evidence profile. • If a study is rated as 'Partially applicable', with 'Potentially serious limitations' or both then there is discretion over whether it should be included. **Where there is discretion** The health economist will make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the guideline committee if required. The ultimate aim is to include health economic studies that are helpful for decision-making in the context of the guideline and the current NHS setting. If several studies are considered of sufficiently high applicability and methodological quality that they could all be included, then the health economist, in discussion with the committee if required, may decide to include only the most applicable studies and to selectively exclude the remaining studies. All studies excluded on the basis of applicability or methodological limitations will be listed with explanation in the excluded health economic studies appendix below. The health economist will be guided by the following hierarchies. *Setting:* • UK NHS (most applicable). • OECD countries with predominantly public health insurance systems (for example, France, Germany, Sweden). • OECD countries with predominantly private health insurance systems (for example,

	Switzerland). • Studies set in non-OECD countries or in the USA will be excluded before being assessed for applicability and methodological limitations. *Health economic study type:* • Cost–utility analysis (most applicable). • Other type of full economic evaluation (cost–benefit analysis, cost-effectiveness analysis, cost–consequences analysis). • Comparative cost analysis. • Non-comparative cost analyses including cost-of-illness studies will be excluded before being assessed for applicability and methodological limitations. *Year of analysis:* • The more recent the study, the more applicable it will be. • Studies published in 2003 or later but that depend on unit costs and resource data entirely or predominantly from before 2003 will be rated as 'Not applicable'. • Studies published before 2003 will be excluded before being assessed for applicability and methodological limitations. *Quality and relevance of effectiveness data used in the health economic analysis:* • The more closely the clinical effectiveness data used in the health economic analysis match with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline.

Appendix B: Literature search strategies

The literature searches for this review are detailed below and complied with the methodology outlined in Developing NICE guidelines: the manual.[57]

For more detailed information, please see the Methodology Review.

B.1 Clinical search literature search strategy

Searches were constructed using a PICO framework where population (P) terms were combined with Intervention (I) and in some cases Comparison (C) terms. Outcomes (O) are rarely used in search strategies for interventions as these concepts may not be well described in title, abstract or indexes and therefore difficult to retrieve. Search filters were applied to the search where appropriate.

Searches for patient views were run in Medline (OVID), Embase (OVID), CINAHL, Current Nursing and Allied Health Literature (EBSCO) and PsycINFO (ProQuest). Search filters were applied to the searches where appropriate.

Table 11: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline (OVID)	1946 – 01 May 2019	Exclusions Randomised controlled trials Systematic review studies Observational studies Qualitative studies
Embase (OVID)	1974 – 01 May 2019	Exclusions Randomised controlled trials Systematic review studies Observational studies Qualitative studies
The Cochrane Library (Wiley)	Cochrane Reviews to 2019 Issue 5 of 12 CENTRAL to 2019 Issue 5 of 12 DARE, and NHSEED to 2015 Issue 2 of 4 HTA to 2016 Issue 4 of 4	None
CINAHL, Current Nursing and Allied Health Literature (EBSCO)	Inception – 01 May 2019	Exclusions
PsycINFO (ProQuest)	Inception – 01 May 2019	Exclusions

Medline (Ovid) search terms

1.	arthroplasty/ or arthroplasty, replacement/ or arthroplasty, replacement, hip/ or arthroplasty, replacement, knee/ or arthroplasty, replacement, shoulder/ or hemiarthroplasty/
2.	joint prosthesis/ or hip prosthesis/ or knee prosthesis/ or shoulder prosthesis/
3.	((joint* or knee* or shoulder* or hip*) adj5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*)).ti,ab.
4.	or/1-3
5.	letter/

6.	editorial/
7.	news/
8.	exp historical article/
9.	Anecdotes as Topic/
10.	comment/
11.	case report/
12.	(letter or comment*).ti.
13.	or/5-12
14.	randomized controlled trial/ or random*.ti,ab.
15.	13 not 14
16.	animals/ not humans/
17.	exp Animals, Laboratory/
18.	exp Animal Experimentation/
19.	exp Models, Animal/
20.	exp Rodentia/
21.	(rat or rats or mouse or mice).ti.
22.	or/15-21
23.	4 not 22
24.	limit 23 to English language
25.	Decision Support Techniques/
26.	Decision Support Systems, Clinical/
27.	Decision Making/ or Choice behavior/ or informed consent/
28.	Patient participation/
29.	Physician-patient relations/ or Professional-Patient Relations/
30.	(decision making or ((choice* or option*) adj (behavior* or behaviour*))).ti,ab.
31.	((decision* or decid*) adj4 (option* or support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).ti,ab.
32.	((share* or sharing or making or made or agree* or participat* or support* or collaborat* or joint) adj2 (decision* or decid* or make*)).ti,ab.
33.	((decision or decid*) adj3 (board* or guide* or counseling or counselling)).ti,ab.
34.	((risk communication or risk assessment or risk information) adj4 (tool* or method*)).ti,ab.
35.	(informed adj (choice* or decision*)).ti,ab.
36.	((communicat* or discuss* or speak* or talk* or converse* or conversat*) adj3 (treatment* or procedure* or timing* or implant*)).ti,ab.
37.	(patient-cent* adj3 (decision* or tool* or choice*)).ti,ab.
38.	or/25-37
39.	24 and 38
40.	randomized controlled trial.pt.
41.	controlled clinical trial.pt.
42.	randomi#ed.ti,ab.
43.	placebo.ab.
44.	randomly.ti,ab.
45.	Clinical Trials as topic.sh.
46.	trial.ti.
47.	or/40-46
48.	Meta-Analysis/

49.	exp Meta-Analysis as Topic/
50.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
51.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
52.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
53.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
54.	(search* adj4 literature).ab.
55.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
56.	cochrane.jw.
57.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
58.	or/48-57
59.	Epidemiologic studies/
60.	Observational study/
61.	exp Cohort studies/
62.	(cohort adj (study or studies or analys* or data)).ti,ab.
63.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
64.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
65.	Controlled Before-After Studies/
66.	Historically Controlled Study/
67.	Interrupted Time Series Analysis/
68.	(before adj2 after adj2 (study or studies or data)).ti,ab.
69.	or/59-68
70.	exp case control study/
71.	case control*.ti,ab.
72.	or/70-71
73.	69 or 72
74.	Cross-sectional studies/
75.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
76.	or/74-75
77.	69 or 76
78.	69 or 72 or 76
79.	health survey/ or exp questionnaire/ or exp interview/ or qualitative research/ or narrative/
80.	(qualitative or interview* or focus group* or theme* or questionnaire* or survey*).ti,ab.
81.	(metasynthes* or meta-synthes* or metasummar* or meta-summar* or metastud* or meta-stud* or metathem* or meta-them* or ethno* or emic or etic or phenomenolog* or grounded theory or constant compar* or (thematic* adj3 analys*) or theoretical sampl* or purposive sampl* or hermeneutic* or heidegger* or husserl* or colaizzi* or van kaam* or van manen* or giorgi* or glaser* or strauss* or ricoeur* or spiegelberg* or merleau*).ti,ab.
82.	or/79-81
83.	39 and (47 or 58 or 78 or 82)

Embase (Ovid) search terms

1.	*arthroplasty/ or *replacement arthroplasty/ or *hip replacement/ or *knee replacement/ or *shoulder replacement/ or *hemiarthroplasty/

2.	*joint prosthesis/ or *hip prosthesis/ or *knee prosthesis/ or *shoulder prosthesis/
3.	((joint* or knee* or shoulder* or hip*) adj5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*)).ti,ab.
4.	or/1-3
5.	letter.pt. or letter/
6.	note.pt.
7.	editorial.pt.
8.	case report/ or case study/
9.	(letter or comment*).ti.
10.	or/5-9
11.	randomized controlled trial/ or random*.ti,ab.
12.	10 not 11
13.	animal/ not human/
14.	nonhuman/
15.	exp Animal Experiment/
16.	exp Experimental Animal/
17.	animal model/
18.	exp Rodent/
19.	(rat or rats or mouse or mice).ti.
20.	or/12-19
21.	4 not 20
22.	limit 21 to English language
23.	decision support system/
24.	*decision making/ or informed consent/
25.	patient participation/
26.	*doctor patient relation/ or professional-patient relationship/
27.	(decision making or ((choice* or option*) adj (behavior* or behaviour*))).ti,ab.
28.	((decision* or decid*) adj4 (option* or support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).ti,ab.
29.	((share* or sharing or making or made or agree* or participat* or support* or collaborat* or joint) adj2 (decision* or decid* or make*)).ti,ab.
30.	((decision or decid*) adj3 (board* or guide* or counseling or counselling)).ti,ab.
31.	((risk communication or risk assessment or risk information) adj4 (tool* or method*)).ti,ab.
32.	(informed adj (choice* or decision*)).ti,ab.
33.	((communicat* or discuss* or speak* or talk* or converse* or conversat*) adj3 (treatment* or procedure* or timing* or implant*)).ti,ab.
34.	(patient-cent* adj3 (decision* or tool* or choice*)).ti,ab.
35.	or/23-34
36.	22 and 35
37.	random*.ti,ab.
38.	factorial*.ti,ab.
39.	(crossover* or cross over*).ti,ab.
40.	((doubl* or singl*) adj blind*).ti,ab.
41.	(assign* or allocat* or volunteer* or placebo*).ti,ab.
42.	crossover procedure/
43.	single blind procedure/

44.	randomized controlled trial/
45.	double blind procedure/
46.	or/37-45
47.	systematic review/
48.	meta-analysis/
49.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
50.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
51.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
52.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
53.	(search* adj4 literature).ab.
54.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
55.	cochrane.jw.
56.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
57.	or/47-56
58.	Clinical study/
59.	Observational study/
60.	family study/
61.	longitudinal study/
62.	retrospective study/
63.	prospective study/
64.	cohort analysis/
65.	follow-up/
66.	cohort*.ti,ab.
67.	65 and 66
68.	(cohort adj (study or studies or analys* or data)).ti,ab.
69.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
70.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
71.	(before adj2 after adj2 (study or studies or data)).ti,ab.
72.	or/58-64,67-71
73.	exp case control study/
74.	case control*.ti,ab.
75.	or/73-74
76.	72 or 75
77.	cross-sectional study/
78.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
79.	or/77-78
80.	72 or 79
81.	72 or 75 or 79
82.	health survey/ or exp questionnaire/ or exp interview/ or qualitative research/ or narrative/
83.	(qualitative or interview* or focus group* or theme* or questionnaire* or survey*).ti,ab.
84.	(metasynthes* or meta-synthes* or metasummar* or meta-summar* or metastud* or meta-stud* or metathem* or meta-them* or ethno* or emic or etic or phenomenolog* or grounded theory or constant compar* or (thematic* adj3 analys*) or theoretical sampl*

	or purposive sampl* or hermeneutic* or heidegger* or husserl* or colaizzi* or van kaam* or van manen* or giorgi* or glaser* or strauss* or ricoeur* or spiegelberg* or merleau*).ti,ab.
85.	or/82-84
86.	36 and (46 or 57 or 81 or 85)

Cochrane Library (Wiley) search terms

#1.	MeSH descriptor: [Arthroplasty] this term only
#2.	MeSH descriptor: [Arthroplasty, Replacement] this term only
#3.	MeSH descriptor: [Arthroplasty, Replacement, Hip] this term only
#4.	MeSH descriptor: [Arthroplasty, Replacement, Knee] this term only
#5.	MeSH descriptor: [Arthroplasty, Replacement, Shoulder] this term only
#6.	MeSH descriptor: [Hemiarthroplasty] this term only
#7.	(or #1-#6)
#8.	MeSH descriptor: [Joint Prosthesis] this term only
#9.	MeSH descriptor: [Hip Prosthesis] this term only
#10.	MeSH descriptor: [Knee Prosthesis] this term only
#11.	MeSH descriptor: [Shoulder Prosthesis] this term only
#12.	(or #8-#11)
#13.	((joint* or knee* or shoulder* or hip*) near/5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*)):ti,ab
#14.	(or #7, #12-#13)
#15.	MeSH descriptor: [Decision Support Techniques] this term only
#16.	MeSH descriptor: [Decision Support Systems, Clinical] this term only
#17.	MeSH descriptor: [Decision Making] this term only
#18.	MeSH descriptor: [Choice Behavior] this term only
#19.	MeSH descriptor: [Informed Consent] this term only
#20.	MeSH descriptor: [Patient Participation] this term only
#21.	MeSH descriptor: [Physician-Patient Relations] this term only
#22.	MeSH descriptor: [Professional-Patient Relations] this term only
#23.	(decision making or ((choice* or option*) near/1 (behavior* or behaviour*))):ti,ab
#24.	((decision* or decid*) near/4 (option* or support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)):ti,ab
#25.	((share* or sharing or making or made or agree* or participat* or support* or collaborat* or joint) near/2 (decision* or decid* or make*)):ti,ab
#26.	((decision or decid*) near/3 (board* or guide* or counseling or counselling)):ti,ab
#27.	((risk communication or risk assessment or risk information) near/4 (tool* or method*)):ti,ab
#28.	(informed near/1 (choice* or decision*)):ti,ab
#29.	((communicat* or discuss* or speak* or talk* or converse* or conversat*) near/3 (treatment* or procedure* or timing* or implant*)):ti,ab
#30.	(patient-cent* near/3 (decision* or tool* or choice*)):ti,ab
#31.	(OR #15-#30)
#32.	#14 AND #31

CINAHL (EBSCO) search terms

S1.	(MH "Arthroplasty") OR (MH "Arthroplasty, Replacement") OR (MH "Arthroplasty, Replacement, Hip") OR (MH "Arthroplasty, Replacement, Knee") OR (MH

	"Arthroplasty, Replacement, Shoulder") OR (MH "Hemiarthroplasty")
S2.	(MH "Joint Prosthesis") OR (MH "Shoulder Prosthesis")
S3.	TI ((joint* or knee* or shoulder* or hip*) n5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*))
S4.	AB ((joint* or knee* or shoulder* or hip*) n5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*))
S5.	S1 OR S2 OR S3 OR S4
S6.	PT anecdote or PT audiovisual or PT bibliography or PT biography or PT book or PT book review or PT brief item or PT cartoon or PT commentary or PT computer program or PT editorial or PT games or PT glossary or PT historical material or PT interview or PT letter or PT listservs or PT masters thesis or PT obituary or PT pamphlet or PT pamphlet chapter or PT pictorial or PT poetry or PT proceedings or PT "questions and answers" or PT response or PT software or PT teaching materials or PT website
S7.	S5 NOT S6
S8.	(MH "Decision Support Techniques") OR (MH "Decision Support Systems, Clinical")
S9.	(MH "Decision Making") OR (MH "Consent+")
S10.	(MH "Consumer Participation")
S11.	(MH "Physician-Patient Relations") OR (MH "Professional-Patient Relations")
S12.	TI (decision making or ((choice* or option*) n1 (behavior* or behaviour*)))
S13.	AB (decision making or ((choice* or option*) n1 (behavior* or behaviour*)))
S14.	TI ((decision* or decid*) n4 (option* or support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*))
S15.	AB ((decision* or decid*) n4 (option* or support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*))
S16.	TI ((share* or sharing or making or made or agree* or participat* or support* or collaborat* or joint) n2 (decision* or decid* or make*))
S17.	AB ((share* or sharing or making or made or agree* or participat* or support* or collaborat* or joint) n2 (decision* or decid* or make*))
S18.	TI ((decision or decid*) n3 (board* or guide* or counseling or counselling))
S19.	AB ((decision or decid*) n3 (board* or guide* or counseling or counselling))
S20.	TI ((risk communication or risk assessment or risk information) n4 (tool* or method*))
S21.	AB ((risk communication or risk assessment or risk information) n4 (tool* or method*))
S22.	TI (informed n1 (choice* or decision*))
S23.	AB (informed n1 (choice* or decision*))
S24.	TI ((communicat* or discuss* or speak* or talk* or converse* or conversat*) n3 (treatment* or procedure* or timing* or implant*))
S25.	AB ((communicat* or discuss* or speak* or talk* or converse* or conversat*) n3 (treatment* or procedure* or timing* or implant*))
S26.	TI (patient-cent* n3 (decision* or tool* or choice*))
S27.	AB (patient-cent* n3 (decision* or tool* or choice*))
S28.	S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S27
S29.	S7 AND S28

PsycINFO (ProQuest) search terms

1.	((ti,ab((joint* OR knee* OR shoulder* OR hip*) NEAR/5 (surger* OR replace* OR prosthe* OR endoprosthe* OR implant* OR artificial OR arthroplast* OR hemiarthroplast*)) NOT (su.exact.explode("rodents") OR su.exact.explode("mice") OR (su.exact("animals") NOT (su.exact("human males") OR su.exact("human females"))) OR ti(rat OR rats OR mouse OR mice))) AND ((MAINSUBJECT.EXACT("Decision

	Support Systems") OR MAINSUBJECT.EXACT("Choice Behavior") OR MAINSUBJECT.EXACT("Informed Consent") OR MAINSUBJECT.EXACT("Decision Making") OR MAINSUBJECT.EXACT("Client Participation")) OR ti,ab((decision* OR decid*) NEAR/4 (option* OR support* OR aid* OR tool* OR instrument* OR technolog* OR technique* OR system* OR program* OR algorithm* OR process* OR method* OR intervention* OR material*)) OR ti,ab((share* OR sharing OR making OR made OR agree* OR participat* OR support* OR collaborat* OR joint) NEAR/2 (decision* OR decid* OR make*)) OR ti,ab((decision OR decid*) NEAR/3 (board* OR guide* OR counseling OR counselling)) OR (informed NEAR/1 (choice* OR decision*)))) AND la.exact("English")

B.2 Health Economics literature search strategy

Health economic evidence was identified by conducting a broad search relating to the joint replacement population in NHS Economic Evaluation Database (NHS EED – this ceased to be updated after March 2015) and the Health Technology Assessment database (HTA) with no date restrictions. NHS EED and HTA databases are hosted by the Centre for Research and Dissemination (CRD). Additional health economics searches were run in Medline and Embase..

Table 12: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline	2014 – 01 May 2019	Exclusions Health economics studies
Embase	2014 – 01 May 2019	Exclusions Health economics studies
Centre for Research and Dissemination (CRD)	HTA - Inception – 01 May 2019 NHSEED - Inception to March 2015	None

Medline (Ovid) search terms

1.	arthroplasty/ or arthroplasty, replacement/ or arthroplasty, replacement, hip/ or arthroplasty, replacement, knee/ or arthroplasty, replacement, shoulder/ or hemiarthroplasty/
2.	joint prosthesis/ or hip prosthesis/ or knee prosthesis/ or shoulder prosthesis/
3.	((joint* or knee* or shoulder* or hip*) adj5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*)).ti,ab.
4.	or/1-3
5.	letter/
6.	editorial/
7.	news/
8.	exp historical article/
9.	Anecdotes as Topic/
10.	comment/
11.	case report/
12.	(letter or comment*).ti.
13.	or/5-12
14.	randomized controlled trial/ or random*.ti,ab.
15.	13 not 14

16.	animals/ not humans/
17.	exp Animals, Laboratory/
18.	exp Animal Experimentation/
19.	exp Models, Animal/
20.	exp Rodentia/
21.	(rat or rats or mouse or mice).ti.
22.	or/15-21
23.	4 not 22
24.	limit 23 to English language
25.	Economics/
26.	Value of life/
27.	exp "Costs and Cost Analysis"/
28.	exp Economics, Hospital/
29.	exp Economics, Medical/
30.	Economics, Nursing/
31.	Economics, Pharmaceutical/
32.	exp "Fees and Charges"/
33.	exp Budgets/
34.	budget*.ti,ab.
35.	cost*.ti.
36.	(economic* or pharmaco?economic*).ti.
37.	(price* or pricing*).ti,ab.
38.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
39.	(financ* or fee or fees).ti,ab.
40.	(value adj2 (money or monetary)).ti,ab.
41.	or/25-40
42.	24 and 41

Embase (Ovid) search terms

1.	*arthroplasty/ or *replacement arthroplasty/ or *hip replacement/ or *knee replacement/ or *shoulder replacement/ or *hemiarthroplasty/
2.	*joint prosthesis/ or *hip prosthesis/ or *knee prosthesis/ or *shoulder prosthesis/
3.	((joint* or knee* or shoulder* or hip*) adj5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*)).ti,ab.
4.	or/1-3
5.	letter.pt. or letter/
6.	note.pt.
7.	editorial.pt.7
8.	case report/ or case study/
9.	(letter or comment*).ti.
10.	or/5-9
11.	randomized controlled trial/ or random*.ti,ab.
12.	10 not 11
13.	animal/ not human/
14.	nonhuman/
15.	exp Animal Experiment/

16.	exp Experimental Animal/
17.	animal model/
18.	exp Rodent/
19.	(rat or rats or mouse or mice).ti.
20.	or/12-19
21.	4 not 20
22.	limit 21 to English language
23.	health economics/
24.	exp economic evaluation/
25.	exp health care cost/
26.	exp fee/
27.	budget/
28.	funding/
29.	budget*.ti,ab.
30.	cost*.ti.
31.	(economic* or pharmaco?economic*).ti.
32.	(price* or pricing*).ti,ab.
33.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
34.	(financ* or fee or fees).ti,ab.
35.	(value adj2 (money or monetary)).ti,ab.
36.	or/23-35
37.	22 and 36

NHS EED and HTA (CRD) search terms

#1.	MeSH DESCRIPTOR arthroplasty
#2.	MeSH DESCRIPTOR arthroplasty, replacement
#3.	MeSH DESCRIPTOR arthroplasty, replacement, hip
#4.	MeSH DESCRIPTOR arthroplasty, replacement, knee
#5.	MeSH DESCRIPTOR arthroplasty, replacement, shoulder
#6.	MeSH DESCRIPTOR hemiarthroplasty
#7.	MeSH DESCRIPTOR joint prosthesis
#8.	MeSH DESCRIPTOR hip prosthesis
#9.	MeSH DESCRIPTOR knee prosthesis
#10.	MeSH DESCRIPTOR shoulder prosthesis
#11.	(((joint* or knee* or shoulder* or hip*) adj5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*)))
#12.	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11) IN NHSEED
#13.	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11) IN HTA

Appendix C: Clinical evidence selection

Figure 1: Flow chart of clinical study selection for the review of decision aids – quantitative review

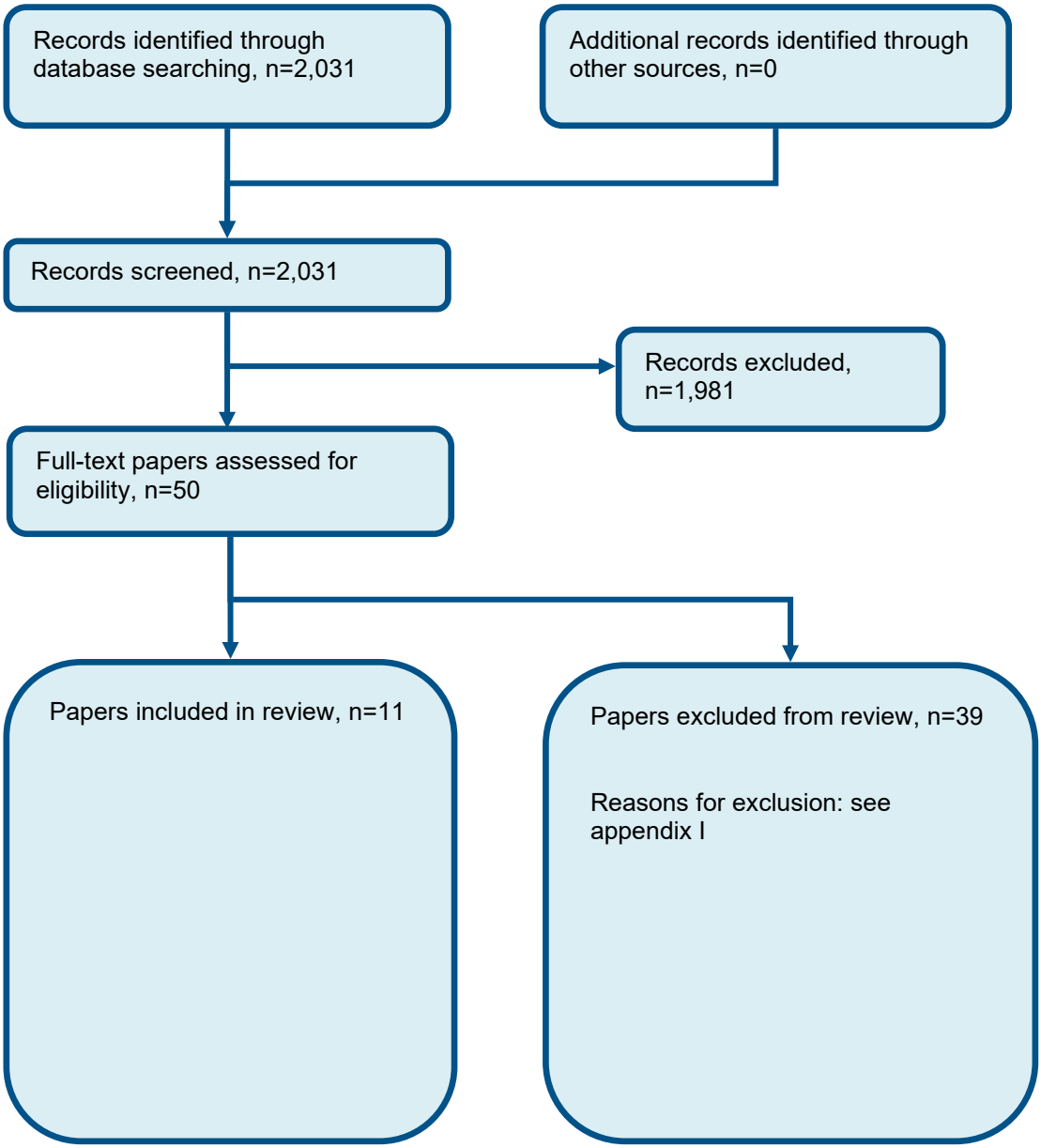
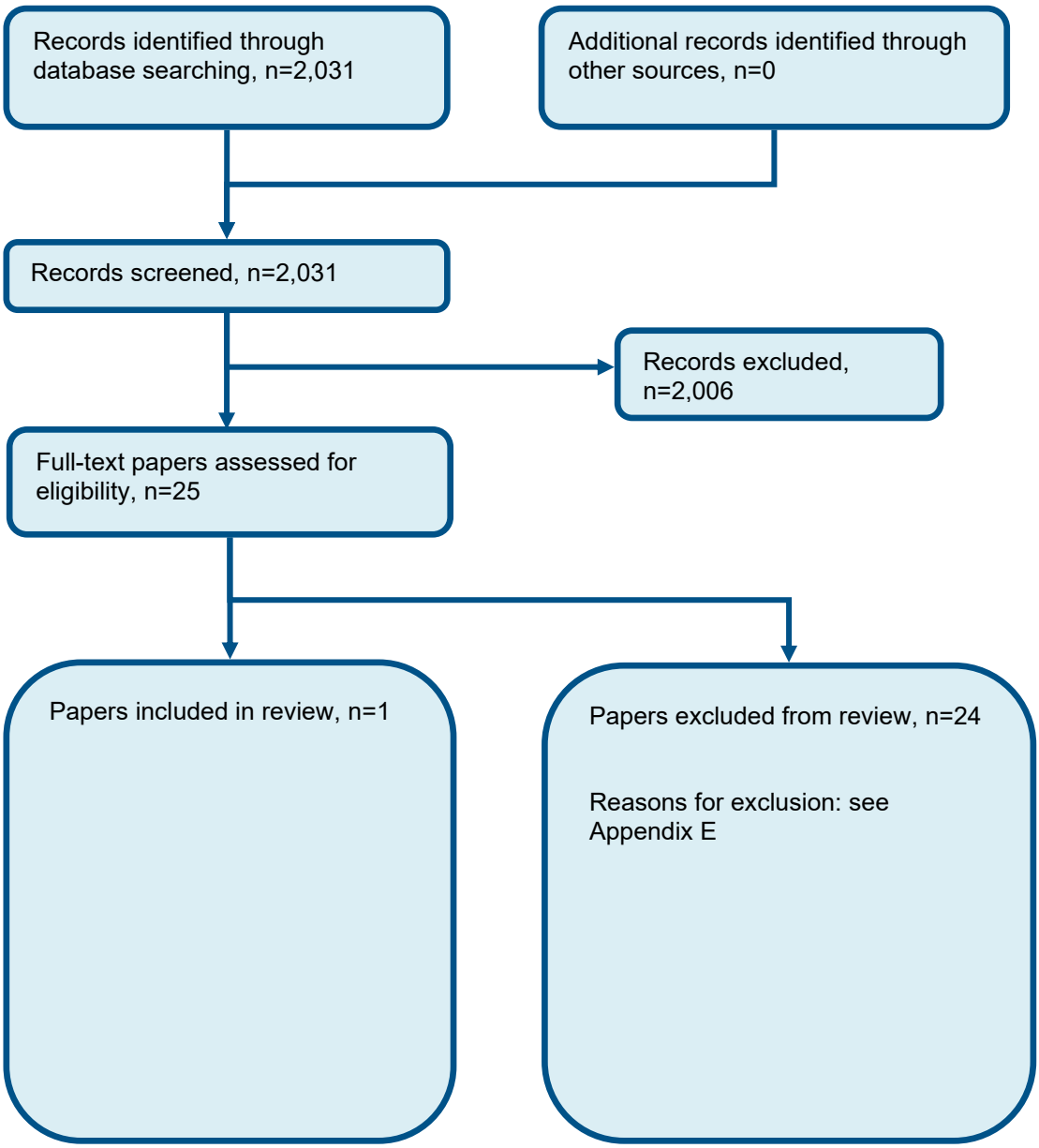


Figure 2: Flow chart of qualitative study selection for the review of decision aids – qualitative review



Appendix D: Clinical evidence tables

Quantitative review

Study (subsidiary papers)	Bozic 2013[14] (Youm 2015[77])
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=198)
Countries and setting	Conducted in USA
Line of therapy	Not applicable
Duration of study	Intervention + follow up:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients were eligible for the study if they had a primary osteoarthritis of the hip or knee, it was their first time seeing an orthopaedic surgeon for this problem, and they had no history of a lower extremity joint arthroplasty.
Exclusion criteria	Patients were ineligible if they could not read or speak English or had a previous appointment with another orthopaedic surgeon for evaluation of the arthritic hip or knee. Eligibility was also limited to patients who were considered medically appropriate for total joint arthroplasty on the basis of well-established clinical and radiographic criteria, including a history of pain refractory to non-operative management and radiographic findings consistent with advanced osteoarthritis of the hip or knee.
Recruitment/selection of patients	Patients referred to two academic medical centres
Age, gender and ethnicity	Age - --: Majority over 60 years. Gender (M:F): N/A. Ethnicity: N/A
Further population details	
Indirectness of population	No indirectness

Interventions	(n=95) Intervention 1: Decision aids - Video based. Decision aids - Intervention was a combination of decision and communication aids of the type shown in systematic reviews to increase patient knowledge, question asking and information recall. The decision aid was a digital video disc (DVD) and booklet regarding the natural history and treatment alternatives for osteoarthritis of the hip and knee produced by the Informed Medical Decisions Foundation and Health Dialog. It explicitly compares the risks and benefits of surgical and non-surgical options in a balanced fashion. A second component of our intervention was a question-listing telephone consultation with a trained heal coach to assist the patient in constructing a list of questions that he or she would like to ask his or her surgeon into an organised, focussed, one page document with the use of the situation, choices, objectives, people, evaluation and decisions (SCOPED) question listing intervention. . Duration N/A. Concurrent medication/care: Both groups completed surveys assessing their knowledge, preferences and stage in decision making before and immediately after their initial consultation with the surgeon and again six weeks after their appointment. For all, the health coach was present in the examination room during the consultation to audio record the consultation, to record the length of the patients time in the examination room, to record the time that the surgeon spent in the examination room and to make notes on observations regarding the interaction between the patient and the surgeon. . Indirectness: No indirectness Further details: 1. Joint replaced: (n=103) Intervention 2: Usual care. Usual care - Subjects were mailed existing materials used in the surgeons practices to review before their appointment. These materials consisted of a map and directions to the clinic and a one-page informational handout about the signs and symptoms, diagnosis and treatment options for hip and knee osteoarthritis. Control subjects were called the day before their appointment to confirm their appointment and to verify that they had received the materials. . Duration N/A. Concurrent medication/care: Both groups completed surveys assessing their knowledge, preferences and stage in decision making before and immediately after their initial consultation with the surgeon and again six weeks after their appointment. For all, the health coach was present in the examination room during the consultation to audio record the consultation, to record the length of the patients time in the examination room, to record the time that the surgeon spent in the examination room and to make notes on observations regarding the interaction between the patient and the surgeon. . Indirectness: No indirectness Further details: 1. Joint replaced:
Funding	Academic or government funding (This work was supported by a grant from the Robert Wood Johnson Foundation. Funds were used to pay for salaries, employee benefits, and other direct costs such as office operations, communications, meetings, travel, surveys and contracts. The funding source did not play a role in the investigation. One or more of the authors received payments or services, either directly or indirectly from a third party in support of an aspect of this work. In addition one or more of the authors or his or her institution has had a financial relationship, in the 36 months prior to submission of this work, with an entity in the biomedical arena

	that could be perceived to influence or have the potential to influence what is written in this work.)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DECISION AIDS versus USUAL CARE Protocol outcome 1: Proportion undecided at N/A - Actual outcome: Informed decision made at 6 weeks; Group 1: 20/60, Group 2: 35/60; Comments: Patients who arrived at an informed decision after the first office consultations. Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness; Group 1 Number missing: 34, Reason: 11 excluded due to insufficient time for intervention, appointment cancellation or patient chose to withdraw. 23 were withdrawn by principal investigators due to no primary diagnosis of osteoarthritis, not considered surgical candidates, deemed cognitively unfit to participate or had Workers compensation insurance. ; Group 2 Number missing: 41, Reason: 14 were excluded due to appointment cancellation or patient chose to withdraw. 27 patients were withdrawn by principal investigators due to no primary diagnosis of osteoarthritis, not considered surgical candidates, deemed cognitively unfit to participate, had previously seen another surgeon for the hip or knee osteoarthritis or had participated in the shared decision-making study at the other study site.	
Protocol outcomes not reported by the study	Quality of life at N/A; Patient Reported Outcome Measures (PROMs) at N/A; Patient-clinician communication at N/A; Participation in decision making at N/A; Accurate risk perceptions at N/A; Knowledge of the surgery at N/A; Decisional Conflict Scale at N/A; Satisfaction with care/decision making at N/A; Adherence to chosen option at N/A

Study	De achaval 2012[27]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=141)
Countries and setting	Conducted in USA
Line of therapy	Not applicable
Duration of study	Intervention + follow up:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Participants were considered eligible if: 1) a physician had told them they had OA of the knee diagnosed with a radiograph at least 2 years before screening, 2) their knee OA interfered with their activities of daily living, 3) they experienced pain (at least a 4 on a scale of 1–10) on most days in the last 3 months, and 4) they had ever considered or talked to a doctor about TKA.
Exclusion criteria	Patients were excluded if they had rheumatoid arthritis, had not had radiographs of their knees, had undergone TKA or were currently scheduled for TKA, if they were not comfortable reading and communicating in English, or if they were not comfortable answering questions on a computer using a mouse.
Recruitment/selection of patients	Participants were recruited using multiple methods, including advertisements in several local newspapers, on Facebook, and by contacting participants of a previous research study.
Age, gender and ethnicity	Age - Mean (SD): 62.8 (9.0). Gender (M:F): 141 female, 67 male. Ethnicity: 66% white, 24% African American, 7% Hispanic, 3% other
Further population details	
Indirectness of population	No indirectness
Interventions	(n=71) Intervention 1: Usual care. Group 1 (control) were given a printed booklet about treatment choices for knee OA, including medical management and surgery, published by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (24). Participants were asked to read the booklet, which took ~20 minutes. Duration N/A. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Joint replaced: (n=70) Intervention 2: Decision aids - Video based. Subjects randomized to group 2 (videobooklet) were given a videobooklet decision aid developed by Health Dialog with the Foundation for Informed Medical Decision-Making (FIMDM) entitled “Treatment Choices for Knee Osteoarthritis,” including a DVD and a booklet to follow along while viewing the DVD. The Shared Decision-Making video was □45 minutes long

	and met criteria created by the International Patient Decision Aids Standards Collaboration in the areas of content, development process, and effectiveness. . Duration N/A. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Joint replaced:
Funding	Academic or government funding (Supported by the Agency for Healthcare Research and Quality through the Center for Education and Research on Therapeutics (grant U18-HS016093). Dr. Fraenkel's work was supported by an NIH/National Institute of Arthritis and Musculoskeletal and Skin Diseases K23 award (AR-048826-05). Dr. Suarez-Almazor holds a K24 career award from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (AR-53593-06) and is the Director of the Houston Center for Education and Research on Therapeutics funded by the Agency for Healthcare Research and Quality.)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: USUAL CARE versus DECISION AIDS - GROUP 2 Protocol outcome 1: Decisional Conflict Scale at N/A - Actual outcome: Decisional conflict scale - total score at N/A; Group 1: mean 29.2 (SD 16.61); n=69, Group 2: mean 21.6 (SD 12.55); n=70 Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0, Reason: N/A; Group 2 Number missing: 1, Reason: No post questionnaire RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: USUAL CARE versus DECISION AIDS - GROUP 3 Protocol outcome 1: Decisional Conflict Scale at N/A - Actual outcome: Decisional conflict scale - total score at N/A; Group 1: mean 29.2 (SD 16.61); n=69, Group 2: mean 23.4 (SD 14.95); n=69 Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 1, Reason: No post questionnaire ; Group 2 Number missing: 1, Reason: No DCS form	
Protocol outcomes not reported by the study	Quality of life at N/A; Patient Reported Outcome Measures (PROMs) at N/A; Patient-clinician communication at N/A; Participation in decision making at N/A; Accurate risk perceptions at N/A; Knowledge of the surgery at N/A; Satisfaction with care/decision making at N/A; Proportion undecided at N/A; Adherence to chosen option at N/A

Study	Groves 2010[33]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=118)
Countries and setting	Conducted in United Kingdom
Line of therapy	Unclear
Duration of study	Intervention + follow up:
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Inclusion criteria were all patients presenting to the orthopaedic pre-admission clinic, before inpatient admission for hip or knee arthroplasty, who had internet access either at home, or via friends or relatives.
Exclusion criteria	Exclusion criteria were as follows and are comparable to work done previously: visual impairment that would prevent reading the questionnaires; more than three previous anaesthetics; previous neuraxial anaesthesia; learning difficulties; psychotic mental illness; dementia; age >18 or <80 years.
Age, gender and ethnicity	Age - Mean (SD): 60.4 (9.8). Gender (M:F): 67 female, 51 male. Ethnicity: N/A
Further population details	
Indirectness of population	No indirectness
Interventions	(n=59) Intervention 1: Usual care. The envelope for patients in both control groups contained a letter, thanking them for their participation in the study, and reminding them of the second questionnaire, which they would be asked to complete at the time of admission for surgery. . Duration N/A. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Joint replaced: (n=59) Intervention 2: Decision aids - Video based. The envelope in the intervention group contained, in addition, addresses of a number of useful internet websites. These websites were chosen as they provide information about anaesthesia, particularly with respect to hip and knee arthroplasty. In addition, the credibility and reliability of these websites have been reviewed in previous literature. . Duration N/A. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Joint replaced:
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DECISION AIDS versus USUAL CARE Protocol outcome 1: Proportion undecided at N/A - - Actual outcome: Proportion that don't know after intervention at N/A; Group 1: 0/59, Group 2: 5/59 Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Quality of life at N/A; Adherence to chosen option, Patient Reported Outcome Measures (PROMs) at N/A; Patient-clinician communication at N/A; Participation in decision making at N/A; Accurate risk perceptions at N/A; Knowledge of the surgery at N/A; Decisional Conflict Scale at N/A; Satisfaction with care/decision making at N/A

Study	Ibrahim 2013[38]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=663)
Countries and setting	Conducted in USA; Setting:
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 12 months follow up
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	African American primary care patients older than 55 years with knee OA, defined as chronic, frequent knee pain based on the National Health and Nutrition Examination Survey (NHANES) questions, a Western Ontario and McMaster Universities OA Index (WOMAC) score ≥39, and radiographic evidence of knee OA, were eligible for the study.
Exclusion criteria	Exclusion criteria were the following: prior history of any major joint replacement, terminal illness (e.g., end-stage cancer), physician-diagnosed inflammatory arthritis (i.e., rheumatoid arthritis, connective tissue disease, ankylosing spondylitis or other seronegative spondyloarthritis, or any crystal-induced arthropathy, such as gout or pseudogout), or contraindications to joint replacement surgery (e.g., lower extremity paralysis as a result of stroke).
Recruitment/selection of patients	Potential participants were identified from the VA clinical databases at 3 academic VA medical centers (Pittsburgh, Cleveland, and Philadelphia VA medical centers) between March 2007 and February 2009.
Age, gender and ethnicity	Age - Mean (SD): control - 61.28 (8.29), decision aid 60.70 (9.27). Gender (M:F): 302 male, 21 female. Ethnicity: African American
Further population details	
Indirectness of population	No indirectness
Interventions	(n=168) Intervention 1: Decision aids - Web-based. This study used the knee OA patient decision aid developed by the Foundation for Informed Medical Decision Making as a vehicle to deliver high-quality, relevant, and timely information on knee OA and joint replacement. The knee OA decision aid is a 40-minute video. It discusses treatment options, including lifestyle changes, medications, injections, complementary therapy, and surgery. The risks, benefits, and known efficacy of each treatment option are outlined. It also covers clinical indications, operative duration, hospital duration, and need for rehabilitative care, physical therapy, recovery time and effort, and cost. Also, the risks of knee replacement surgery, including risk of death, how long a single prosthesis lasts, and consideration of whether to have both knees replaced at the

	same time or one at a time are discussed.. Duration N/A. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Joint replaced: (n=167) Intervention 2: Usual care. Attention control. Subjects randomized to the attention control arm received a patient educational booklet about OA published by the National Institute of Arthritis and Musculoskeletal and Skin Diseases. This booklet provides a brief educational program that summarizes how to live with knee OA but does not specifically mention joint replacement.. Duration N/A. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Joint replaced:
Funding	Academic or government funding (Supported by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Health Services Research and Development Service (grant IIR 05-234-2 to Dr. Ibrahim). Dr. Ibrahim's work also was supported by the NIH (National Institute of Arthritis and Musculoskeletal and Skin Diseases grant 1K24-AR-055259-01).)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DECISION AIDS versus USUAL CARE Protocol outcome 1: Patient-clinician communication at N/A - Actual outcome: Appointment with an orthopaedic surgeon at 12 months at 12 months; OR; 1.27 (95%CI 0.54 to 3 Comments: control group is reference group); Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 6/167, Reason: did not receive intervention ; Group 2 Number missing: 6/168, Reason: did not receive intervention	
Protocol outcomes not reported by the study	Quality of life at N/A; Proportion undecided, Patient Reported Outcome Measures (PROMs) at N/A; Participation in decision making at N/A; Accurate risk perceptions at N/A; Knowledge of the surgery at N/A; Decisional Conflict Scale at N/A; Satisfaction with care/decision making at N/A; Adherence to chosen option at N/A

Study	Ibrahim 2017[37]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=336)
Countries and setting	Conducted in USA
Line of therapy	Unclear
Duration of study	Intervention + follow up: 12 month follow up
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Eligible participants were those who self-identified as black, were 50 years or older, had chronic and frequent knee pain based on the National Health and Nutrition Examination Survey questionnaire, had a Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) score of at least 39 (range, 0-100, with higher scores indicating increased pain, stiffness, and functional limitations), and had radiographic evidence of OA of the knee.
Exclusion criteria	Exclusion criteria consisted of a history of major joint replacement, diagnosis of a terminal illness (e.g., end-stage cancer), physician diagnosis of inflammatory arthritis (i.e., rheumatoid arthritis, connective tissue disease, ankylosing spondylitis, or other seronegative spondyloarthropathy), contraindications to replacement surgery (e.g., lower extremity paralysis as a result of stroke), having a prosthetic leg, cognitive impairment (e.g., dementia), and not having home telephone service.
Age, gender and ethnicity	Age - Mean (SD): control - 59.3 (7.5), decision aids - 58.9 (7.0). Gender (M:F): 101 male, 235 female. Ethnicity: African American
Further population details	
Indirectness of population	No indirectness
Interventions	(n=168) Intervention 1: Decision aids - Written format. This study used the patient decision aid for OA of the knee developed by the Foundation for Informed Medical Decision Making as a vehicle to deliver high-quality, relevant, and timely information on knee OA and joint replacement. The decision aid consists of a 40-minute video that discusses treatment options, including lifestyle changes, medications, injections, complementary therapy, and surgery. The risks, benefits, and known efficacy of each treatment option are outlined. Clinical indications, operative duration, hospital duration, the need for rehabilitative care and physical therapy, recovery time and effort, and cost are also covered. The risks of knee replacement surgery, including death, how long a single prosthesis lasts, and consideration of whether to have both knees replaced at the same time or one at a time are discussed. Duration N/A. Concurrent medication/care: N/A. Indirectness: No indirectness

	Further details: 1. Joint replaced: (n=168) Intervention 2: Usual care. Participants randomly assigned to the control group received an educational booklet developed by the National Institute of Arthritis and Musculoskeletal and Skin Diseases that summarizes how to live with knee OA but does not mention joint replacement. The purpose of the booklet was to offer patients some benefit in participating in the study. Duration N/A. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Joint replaced:
Funding	Academic or government funding (This study was supported by grant 1R01AR059615-0 from the National Institute of Arthritis and Musculoskeletal Skin Diseases, National Institutes of Health. Dr Ibrahim reports receiving Mid-Career Development Award K24AR055259 from the National Institute of Arthritis and Musculoskeletal and Skin Diseases.)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DECISION AIDS versus USUAL CARE Protocol outcome 1: Adherence to chosen option at N/A - Actual outcome: TKR at 12 months at 12 months; OR; 2.10 (95%CI 1.04 to 4.27, Comments: Site adjusted OR comparing intervention (168 people) to control (168 people)); Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 18, Reason: did not receive intervention ; Group 2 Number missing: 14, Reason: did not receive booklet - Actual outcome: TKR at 12 months at 12 months; Group 1: 25/168, Group 2: 13/168 Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 18, Reason: did not receive intervention ; Group 2 Number missing: 14, Reason: did not receive booklet	
Protocol outcomes not reported by the study	Quality of life at N/A; Patient Reported Outcome Measures (PROMs) at N/A; Patient-clinician communication at N/A; Participation in decision making at N/A; Accurate risk perceptions at N/A; Knowledge of the surgery at N/A; Decisional Conflict Scale at N/A; Satisfaction with care/decision making at N/A; Proportion undecided at N/A

Study	Sepucha 2011[63]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=127)
Countries and setting	Conducted in USA; Setting:
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 1 week after recruitment
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Adult patients with osteoarthritis of the hip or knee who met the guidelines for referral to an orthopaedic surgeon for TJR and had access to a TV with a VCR or DVD player were recruited for participation.
Exclusion criteria	Patients with inflammatory arthritis; a previous total joint replacement; or who were deaf, blind, cognitively impaired, or had a language barrier were excluded.
Age, gender and ethnicity	Age - Mean (SD): control - 66.1 (9.49), decision aid - 64.3 (10.16). Gender (M:F): 52 male, 75 female. Ethnicity: N/A
Further population details	
Indirectness of population	No indirectness
Interventions	(n=66) Intervention 1: Usual care. Patients allocated to the usual care group received a standard information booklet prepared by the hospital for patients undergoing joint replacement. Duration N/A. Concurrent medication/care: Both groups were instructed to review the information at home and complete the HK-DQI. Approximately one week after recruitment, a research assistant telephoned participants to record the answers to the HK-DQI over the phone. . Indirectness: No indirectness Further details: 1. Joint replaced: (n=61) Intervention 2: Decision aids - Video based. The decision aid group received the same information booklet and a decision aid (video/DVD and booklet) titled Treatment Choices for Knee Osteoarthritis (©Health Dialog and Foundation for Informed Medical Decision Making, 2007). The decision aid describes osteoarthritis and the different treatment options and includes interviews with patients who discuss their experiences using surgical and non-surgical approaches to managing their disease. Duration N/A. Concurrent medication/care: Both groups were instructed to review the information at home and complete the HK-DQI. Approximately one week after recruitment, a research assistant telephoned participants to record the answers to the HK-DQI over the phone. . Indirectness: No indirectness Further details: 1. Joint replaced:

Funding	Academic or government funding (The work was supported by two grants from the Foundation for Informed Medical Decision Making (FIMDM) (one to K.S. and one to D.S.). The research involved collaboration between the Massachusetts General Hospital (MGH) research team/Ottawa research team and representatives from the funder. The research grant was awarded in compliance with MGH's policies which bar funder interference in scholarly work. During this research, Dr. Levin was Director of Research at the funder, the Foundation for Informed Medical Decision Making. She provided input on the research design, feedback on analyses, and constructive comments on manuscript drafts consistent with her listed co-authorship role. Dr. Katz has funding supported in part of NIH K24 AR 02123, NIH P60 AR 47782.)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: USUAL CARE versus DECISION AIDS Protocol outcome 1: Knowledge of the surgery at N/A - Actual outcome: Knowledge - validity of decision quality instrument (DQI) knowledge score at 1 week; Group 1: mean 54 (SD 19); n=66, Group 2: mean 68 (SD 18); n=61; Comments: Percentages Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing:	
Protocol outcomes not reported by the study	Quality of life at N/A; Patient Reported Outcome Measures (PROMs) at N/A; Patient-clinician communication at N/A; Participation in decision making at N/A; Accurate risk perceptions at N/A; Decisional Conflict Scale at N/A; Satisfaction with care/decision making at N/A; Proportion undecided at N/A; Adherence to chosen option at N/A

Study	Stacey 2014[65]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=142)
Countries and setting	Conducted in Canada
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 1 year follow up
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Eligible knee osteoarthritis patients were those with access to a television with a VCR or DVD player.
Exclusion criteria	Those with inflammatory arthritis, previous TJA, uncorrected hearing or visual impairment, or unable to read, or understand English, were excluded.
Age, gender and ethnicity	Age - Mean (SD): control - 67.3 (12.16), decision aid - 67.1 (10.85). Gender (M:F): 44 male, 96 female. Ethnicity: N/A
Further population details	
Indirectness of population	No indirectness
Interventions	(n=71) Intervention 1: Decision aids - Web-based. The patient decision aid (PtDA), developed by the Informed Medical Decisions Foundation and distributed through Health Dialog, is entitled Treatment Choices for Knee Osteoarthritis. It consists of a 50-minute video and accompanying booklet that provides information on various treatment options for knee osteoarthritis, including lifestyle changes, non-drug treatments, pain medication, injections, complementary therapies, and surgery. A description of the options, probabilities of benefits and harms for each option, and video-clips of patient experiences allows patients to clarify their values associated with outcomes of options. According to the International Patient Decision Aid Standards, this PtDA meets most criteria for content (12 of 15), development process (8 of 9), and effectiveness (1 of 2). For more details on the IPDAS score card and the PtDA go to: http://decisionaid.ohri.ca/AZsumm.php?ID=1191. Patients received a questionnaire, formatted as user-friendly booklet, assessing their knowledge, values, preferred treatment choice, decisional conflict, and comments or questions. These results were combined with the patients' clinical assessment findings to create a one-page preference report for the surgeon. Duration N/A. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Joint replaced: (n=71) Intervention 2: Usual care. Patients in the usual education group received a standard information

	booklet prepared by the participating hospital for all patients undergoing joint replacement surgery. Information included preparation for surgery, recovery after surgery, and discharge plans. There was no information on benefits and harms of surgery or alterative options that could be used for decision making. Surgeons for patients in the control group received a half-page summary of patients' clinical assessment findings only. Duration N/A. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Joint replaced:
Funding	Academic or government funding (The study was funded using D Stacey's research start-up funds from the University of Ottawa, in Ottawa, Canada. The PtDAs were provided free of charge by the Informed Medical Decisions Foundation.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DECISION AIDS versus USUAL CARE

Protocol outcome 2: Patient-clinician communication at N/A
- Actual outcome: Prepare you to talk to your doctor about what matters most at 2 weeks; Group 1: mean 4.364 (SD 0.905); n=66, Group 2: mean 4.234 (SD 1.035); n=64
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2, Reason: withdrew and were excluded from analysis ; Group 2 Number missing: 3, Reason: Lost to follow up

Protocol outcome 3: Adherence to chosen option at N/A
- Actual outcome: High quality decision at 2 weeks; Group 1: 31/55, Group 2: 14/56
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2, Reason: withdrew and were excluded from analysis ; Group 2 Number missing: 3, Reason: Lost to follow up
- Actual outcome: Uptake of chosen option at 1 year - TJA surgery at 1 year; Group 1: 55/69, Group 2: 48/68
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: withdrew and were excluded from analysis, died; Group 2 Number missing: 4, Reason: Lost to follow up, died
- Actual outcome: Uptake of chosen option at 1 year - No surgery at 1 year; Group 1: 5/69, Group 2: 9/68
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: withdrew and were excluded from analysis, died; Group 2 Number missing: 4, Reason: Lost to follow up, died

Protocol outcomes not reported by the study	Quality of life at N/A; Patient Reported Outcome Measures (PROMs), Participation in decision making at N/A; Accurate risk perceptions at N/A; Knowledge of the surgery at N/A; Decisional Conflict Scale at N/A;

Satisfaction with care/decision making at N/A; Proportion undecided at N/A

Study	Stacey 2016[66]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=343)
Countries and setting	Conducted in Canada
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 2 years follow up
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Eligible adults aged 18 or over had moderate or severe hip or knee radiographic osteoarthritis and were determined at the orthopaedic screening clinic to be appropriate for surgical consultation about joint arthroplasty.
Exclusion criteria	Patients with inflammatory arthritis, previous joint arthroplasty surgical consultation, or osteotomy were ineligible. In addition, patients were excluded if they had non-corrected hearing or visual impairment, were unable to read or understand English, or did not have access to a television with a VCR or DVD player.
Age, gender and ethnicity	Age - Mean (SD): control - 66.9 (9.8), decision aids - 66.1 (9.8). Gender (M:F): 142 male, 192 female. Ethnicity: N/A
Further population details	
Indirectness of population	No indirectness
Interventions	(n=174) Intervention 1: Decision aids - Web-based. The intervention group received standard patient education, a PtDA and a preference report for the surgeon. The PtDAs were titled Treatment choices for hip osteoarthritis and Treatment choices for knee osteoarthritis; 50-min videos and booklets produced by the Informed Medical Decisions Foundation. Both PtDAs met the International Patient Decision Aid Standards criteria by making explicit the decision and providing evidence-based information on treatment options, benefits and risks, and related probabilities. They included patients' testimonials (e.g., describing treatment options, their decision making process experiences, and outcomes) that help patients clarify their values associated with option outcomes. Patients' knowledge, values, preferred treatment choice, and decisional conflict were assessed using a questionnaire formatted as a user-friendly leaflet. These findings were combined with patients' clinical assessment results to create a one-page preference report for the surgeon. . Duration N/A. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Joint replaced: (n=169) Intervention 2: Usual care. The control intervention consisted of standard patient education and

	surgeons received a half-page summary of patients' clinical assessment findings only.. Duration N/A. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Joint replaced:
Funding	Academic or government funding (This work was supported by funding and access to the PtDA from the not-for-profit Informed Medical Decisions Foundation (Grant #0099-1). Funding for graduate students was from the Faculty of Health Sciences, University of Ottawa. The study sponsors had no involvement in the study design, collection, analysis and interpretation of data; in the writing of the manuscript; or in the decision to submit the manuscript for publication.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DECISION AIDS versus USUAL CARE

Protocol outcome 2: Patient-clinician communication at N/A
- Actual outcome: Prepared to talk to your doctor about what matters most post intervention (pre-surgeon consult) at 2 weeks; Group 1: mean 4.47 (SD 0.68); n=156, Group 2: mean 4.1 (SD 1.14); n=157
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 9, Reason: No data for primary outcome, 5 ineligible ; Group 2 Number missing: 6, Reason: No data for primary outcome, 2 ineligible, 1 withdrawn

Protocol outcome 3: Knowledge of the surgery at N/A
- Actual outcome: Mean total knowledge score at 2 years; Group 1: mean 12.4 (SD 2.79); n=156, Group 2: mean 11 (SD 3.25); n=158
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 9, Reason: No data for primary outcome, 5 ineligible ; Group 2 Number missing: 6, Reason: No data for primary outcome, 2 ineligible, 1 withdrawn

Protocol outcome 4: Decisional Conflict Scale at N/A
- Actual outcome: Total 4 out of 4 SURE test score post-surgical consultation at 6 months; Group 1: 109/126, Group 2: 103/127
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 9, Reason: No data for primary outcome, 5 ineligible ; Group 2 Number missing: 6, Reason: No data for primary outcome, 2 ineligible, 1 withdrawn
- Actual outcome: Total 4 out of 4 SURE test score post-intervention at 2 weeks; Group 1: 104/156, Group 2: 96/157
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 9, Reason: No data for primary outcome, 5 ineligible ; Group 2 Number missing: 6, Reason: No data for primary outcome, 2 ineligible, 1 withdrawn

Protocol outcome 5: Proportion undecided at N/A

- Actual outcome: Patient unsure of preference post-surgical consultation at 6 months; Group 1: 3/127, Group 2: 2/127 Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 9, Reason: No data for primary outcome, 5 ineligible ; Group 2 Number missing: 6, Reason: No data for primary outcome, 2 ineligible, 1 withdrawn	
Protocol outcomes not reported by the study	Quality of life at N/A; Patient Reported Outcome Measures (PROMs), Participation in decision making at N/A; Accurate risk perceptions at N/A; Satisfaction with care/decision making at N/A

Study	Vina 2016[71]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=493)
Countries and setting	Conducted in USA
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 12 months follow up
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Eligible participants were those who self-identified as black, were 50 years or older, had chronic and frequent knee pain, a WOMAC score of 39 or greater, and had radiographic evidence of knee OA. Only those who previously self-identified themselves as black/African-American and at least 50 years old based on medical records or registries were screened, along with those who responded to advertisements that asked for potentially eligible participants based on the study eligibility criteria.
Exclusion criteria	Exclusion criteria were prior history of joint replacement, a diagnosis of terminal illness, diagnosis of inflammatory arthritis (e.g., rheumatoid arthritis), contraindications to joint replacement surgery (e.g., lower extremity paralysis), had a prosthetic leg, cognitive impairment, and did not have a telephone.
Recruitment/selection of patients	Potentially eligible participants were identified by screening medical records of patients in primary care clinics. They also were identified via existing research and clinic registries. Additional participants were sought via local advertisements.
Age, gender and ethnicity	Age - Mean (SD): control - 61.14 (7.86), intervention - 62.02 (8.09) . Gender (M:F): 242 male, 251 female . Ethnicity: African American
Further population details	
Indirectness of population	No indirectness
Interventions	(n=253) Intervention 1: Usual care. Participants randomly assigned to the control group received an educational booklet, developed by the NIH National Institute of Arthritis and Musculoskeletal and Skin Diseases (Bethesda,MD,USA), that summarized how to live with knee OA. It did not specifically mention joint replacement as a treatment option but provided examples of exercises one could do to improve knee pain and stiffness. Many physicians provide educational materials to patients when considering various treatments for OA; therefore, it would be appropriate to compare the intervention treatment with this clinically relevant alternative. . Duration 12 months. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Joint replaced:

	(n=240) Intervention 2: Decision aids - Web-based. Participants randomly assigned to the treatment group received a two-phase series of a patient-centred educational intervention. First, participants in the treatment group watched a 40-minute decision-aid video. Developed by the Foundation for Informed Medical Decision-Making (Boston, MA, USA), the video discussed the benefits and risks of various pharmacologic (e.g., medications, injections, complementary therapy) and surgical treatment options for knee OA. It also covered clinical indications for joint replacement, anticipated clinical course during surgery, and postoperative expectations. It described the potential complications of undergoing joint replacement surgery and the anticipated lifespan of a prosthesis. Second, participants in the treatment group underwent counselling regarding TKA using a motivational interviewing strategy. Participants were asked about their thoughts regarding TKA, and their goals and values regarding their arthritis. Information regarding TKA and how to engage the patients' primary care providers in discussing their knee pain also were provided. Trained, certified interventionists in motivational interviewing conducted each face-to-face counselling session which lasted approximately 30 minutes. Duration 12 months. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Joint replaced:
Funding	Academic or government funding (Funding was received from the NIH/National Institute of Arthritis and Musculoskeletal Skin Diseases Grant# 1-RO1-AR-054474-5 (SI) and K24AR055259 (SI).)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DECISION AIDS versus USUAL CARE

Protocol outcome 1: Patient Reported Outcome Measures (PROMs) at N/A
- Actual outcome: Change in willingness by treatment group - number increased at 2 weeks at 2 weeks; Group 1: 67/200, Group 2: 68/208; Comments: OR (95% CI) - 1.06 (0.70 to 1.60)
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2, Reason: missing referral data; Group 2 Number missing: 1, Reason: missing referral data
- Actual outcome: Change in willingness by treatment group - number increased at 12 months at 12 months; Group 1: 49/174, Group 2: 51/191; Comments: OR (95% CI) - 1.10 (0.70 to 1.75)
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2, Reason: missing referral data; Group 2 Number missing: 1, Reason: missing referral data

Protocol outcomes not reported by the study	Quality of life at N/A; Patient-clinician communication at N/A; Participation in decision making at N/A; Accurate risk perceptions at N/A; Knowledge of the surgery at N/A; Decisional Conflict Scale at N/A;

Satisfaction with care/decision making at N/A; Proportion undecided at N/A; Adherence to chosen option at N/A	

Qualitative review

Study	Bunzli 2017[18]
Aim	The aim of this study was to explore the barriers and facilitators to decision aid uptake among orthopaedic surgeons.
Population	15 consultant surgeons and 5 registrars. The surgeons' total experience performing TKA ranged from 6 months to 30 years (mean±SD: 12.9±9.3), and the number of TKAs performed each month ranged from less than 1 to 12 (mean±SD: 5.9±3.0).
Setting	In a private office
Study design	Qualitative interview study
Methods and analysis	Structured one-to-one interviews with grounded theory analysis. In the first part of the interview, questions aimed to elicit current decision-making processes and biases. In the second part, questions aimed to identify beliefs and attitudes towards decision aids and factors that may influence decisions to use one. Data saturation was considered complete when the beliefs and attitudes of all 20 surgeons working in this setting had been elicited. Face-to-face interviews were conducted with 18 participants in a private office; phone interviews were conducted with two participants. Interviews lasted 20–30 min. Nineteen interviews were audio recorded and transcribed verbatim. One participant did not wish the interview to be recorded; therefore hand-written notes were made during the interview. Participant anonymity was ensured at all times. All transcripts were deidentified prior to data analysis. All participants had the opportunity to review the study findings during a presentation at a scheduled surgical meeting. There was consensus agreement with the researchers' interpretations and no adjustments were made to the study themes. Adopting an implementation approach, three stages of data analysis were conducted. In the first stage, two researchers (SB and EN) independently coded interview transcripts by classifying each interview response or utterance into one of the 14 TDF domains. Definitions for each domain were derived from the literature and adapted to the study context. Pilot coding was performed in which the two researchers independently coded two transcripts. Intercoder comparisons resulted in the refinement of domain definitions (see online supplementary file). This process was conducted three times, until the two researchers were confident that all relevant interview responses could be clearly coded into one domain. The two researchers then independently coded all 20 transcripts. Disagreements were discussed, and consensus was reached in each instance. Coded responses were uploaded into qualitative data sorting software (Codesort) to facilitate further analysis. In the second stage of analysis, one researcher (SB) generated 'belief statements' based on the coded interview responses. Belief statements were worded such that they could describe similar responses from different participants. Belief statements were reviewed by two further researchers (EN and MD), before being interpreted as a likely 'facilitator' or 'barrier' to surgeon's uptake of a decision aid. In the third stage of analysis, we identified the domains most likely to influence surgeon's behaviour (ie, using a decision aid or not). This was determined by: (1) frequency of beliefs across transcripts and (2) the perceived strength of beliefs in influencing behaviour. Where the researchers considered that beliefs within and between domains represented similar barriers/facilitators, these were grouped into themes. We present frequencies of beliefs (see table 2) to provide the reader with a better

Study	Bunzli 2017[18]
	understanding of the range of interview responses and to assist us in identifying 'relevant' domains of the TDF. However, readers should be cognisant that the absence of a belief in a transcript is not the same as a lack of endorsement
Findings	**a) Knowledge of one's own patient outcomes.** The goal of participants was to optimise outcomes for their patients.
	b) **Reliance on 'clinical intuition'**. Participants relied on their 'clinical intuition' for patients who were less likely to do well. A 'gut-feeling' for patients was developed with experience over time.
	c) The role of aids in supporting clinical decision making. All participants expected to be provided with evidence that a decision aid had been rigorously validated and shown to have high specificity and sensitivity before considering using it. Participants were more likely to trust this evidence if it came from their own institution.
	d) Implications of a decision aid for patient–surgeon communication and shared decision making. A decision aid was seen as a valuable support to shared decision making.
	e) Ethical and legal concerns about decision aids. While some participants believed it would be unethical not to use a decision aid if it had been shown to improve patient outcomes, others were concerned about the ethical implications of a tool if imposed cut-offs were used to deny patients' surgery.
	f) Available resources and organisational culture as barriers to uptake. Almost all participants expressed concerns about making an aid compulsory and imposing mandatory cut-off levels.
	g) **Format and content of a decision aid.** Most believed that an aid would be best used within the patient–surgeon consultation, while a couple suggested that an aid could be designed for patients to use on their own or with a support network to save time in the clinical consultation.
Limitations and applicability of evidence	The researchers followed clear methods to ensure the validity and rigour of their qualitative analysis. The researchers detailed their professional backgrounds, the interview and analysis process. The researchers provided an in-depth analysis of the themes that emerged in participants' talk about their time as surgeons.

Appendix E: Forest plots in quantitative review

E.1 Decision aids versus usual care

Figure 3: Decisional conflict score, total score, 0-100

Study or Subgroup	Decision aids Mean	SD	Total	Usual care Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
De Achaval 2012	23.4	14.95	69	29.2	16.61	69	-5.80 [-11.07, -0.53]

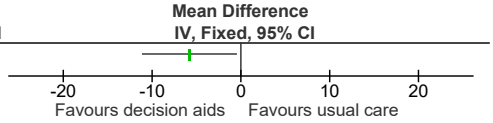


Figure 4: Decisional conflict present within 6 months

Study or Subgroup	Decision aids Events	Total	Usual care Events	Total	Risk Ratio M-H, Fixed, 95% CI
Stacey 2016	17	126	24	127	0.71 [0.40, 1.26]

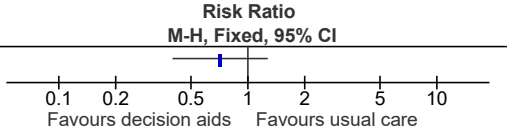


Figure 5: Patients made an informed decision (after first office consultations)

Study or Subgroup	Decision aids Events	Total	Usual care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bozic 2013	20	60	35	60	33.2%	0.57 [0.38, 0.87]
Ibrahim 2017	25	168	13	168	12.3%	1.92 [1.02, 3.63]
Stacey 2014	60	69	57	68	54.5%	1.04 [0.90, 1.19]
Total (95% CI)		**297**		**296**	**100.0%**	**0.99 [0.84, 1.18]**
Total events	105		105			

Heterogeneity: Chi² = 11.30, df = 2 (P = 0.004); I² = 82%
Test for overall effect: Z = 0.09 (P = 0.93)

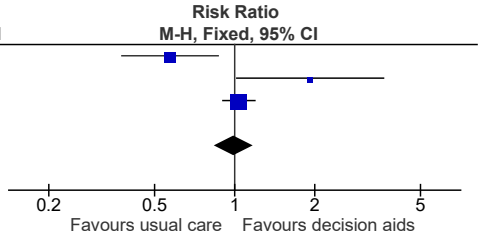


Figure 6: Knowledge score - validity of decision quality instrument

Study or Subgroup	Decision aids Mean	SD	Total	Usual care Mean	SD	Total	Weight	Std. Mean Difference IV, Fixed, 95% CI
Sepucha 2011	68	18	61	54	19	66	27.9%	0.75 [0.39, 1.11]
Stacey 2016	12.4	2.79	156	11	3.25	158	72.1%	0.46 [0.24, 0.69]
Total (95% CI)			**217**			**224**	**100.0%**	**0.54 [0.35, 0.73]**

Heterogeneity: Chi² = 1.80, df = 1 (P = 0.18); I² = 44%
Test for overall effect: Z = 5.58 (P < 0.00001)

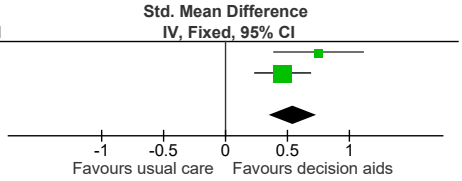


Figure 7: Patient-clinician communication, prepared to talk to doctor about what matters most at 2 weeks

Study or Subgroup	Decision aids Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Stacey 2014	4.364	0.905	66	4.234	1.035	64	27.8%	0.13 [-0.20, 0.46]
Stacey 2016	4.47	0.68	156	4.1	1.14	157	72.2%	0.37 [0.16, 0.58]
Total (95% CI)			**222**			**221**	**100.0%**	**0.30 [0.13, 0.48]**

Heterogeneity: Chi² = 1.43, df = 1 (P = 0.23); I² = 30%
Test for overall effect: Z = 3.37 (P = 0.0008)

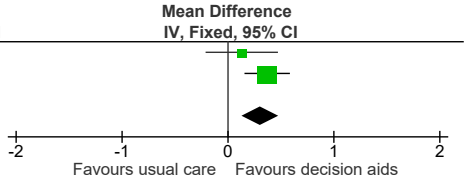


Figure 8: Appointment with an orthopaedic surgeon at 12 months

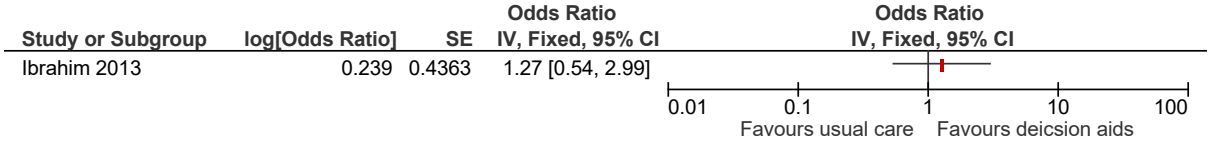
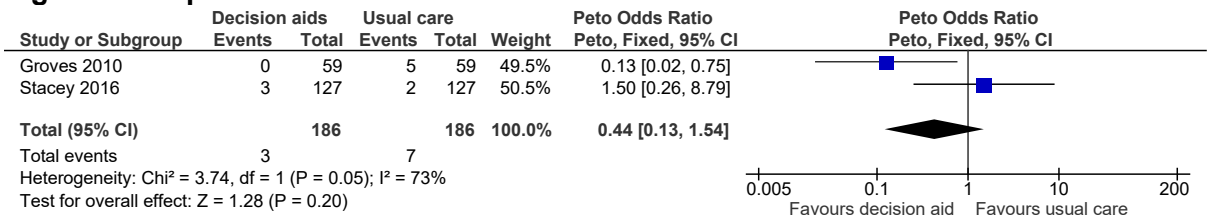


Figure 9: Proportion undecided



Appendix F: GRADE tables from quantitative review

Table 13: Clinical evidence profile: decision aids versus usual care

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Decision aids versus usual care	Control	Relative (95% CI)	Absolute		
Decisional conflict total score (range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	69	69	-	MD 5.8 lower (11.07 to 0.53 lower)	⊕⊕OO LOW	CRITICAL
Decisional conflict present (follow-up 6 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	17/126 (13.5%)	24/127 (18.9%)	RR 0.71 (0.4 to 1.26)	55 fewer per 1000 (from 113 fewer to 49 more)	⊕⊕OO LOW	CRITICAL
Patients made an informed decision												
3	randomised trials	serious[1]	very serious[3]	no serious indirectness	no serious imprecision	none	105/297 (35.4%)	105/296 (35.5%)	RR 0.99 (0.84 to 1.18)	4 fewer per 1000 (from 57 fewer to 64 more)	⊕OOO VERY LOW	CRITICAL
Knowledge score - validity of decision quality instrument (Better indicated by higher values)												
2	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	217	224	-	SMD 0.54 higher (0.35 to 0.73 higher)	⊕⊕OO LOW	CRITICAL
Patient-clinician communication, prepared to talk to doctor about what matters most (follow-up 2 weeks; Better indicated by higher values)												
2	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	222	221	-	MD 0.3 higher (0.13 to 0.48 higher)	⊕⊕⊕⊕ HIGH	IMPORTANT
Discussion with primary care provider (follow-up 12 months)												

1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/162 (0%)	0/161 (0%)	Not estimable	-	⊕⊕⊕⊕ HIGH	IMPORTANT
Proportion undecided												
2	randomised trials	no serious risk of bias	serious[3]	no serious indirectness	very serious[2]	none	3/186 (1.6%)	7/186 (3.8%)	Peto OR 0.44 (0.13 to 1.54)	20 fewer per 1000 (from 60 fewer to 10 more)	⊕OOO VERY LOW	IMPORTANT

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
[2] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.
[3] Downgraded by 1 or 2 increments because the point estimate varied widely across studies, unexplained by subgroup analysis.

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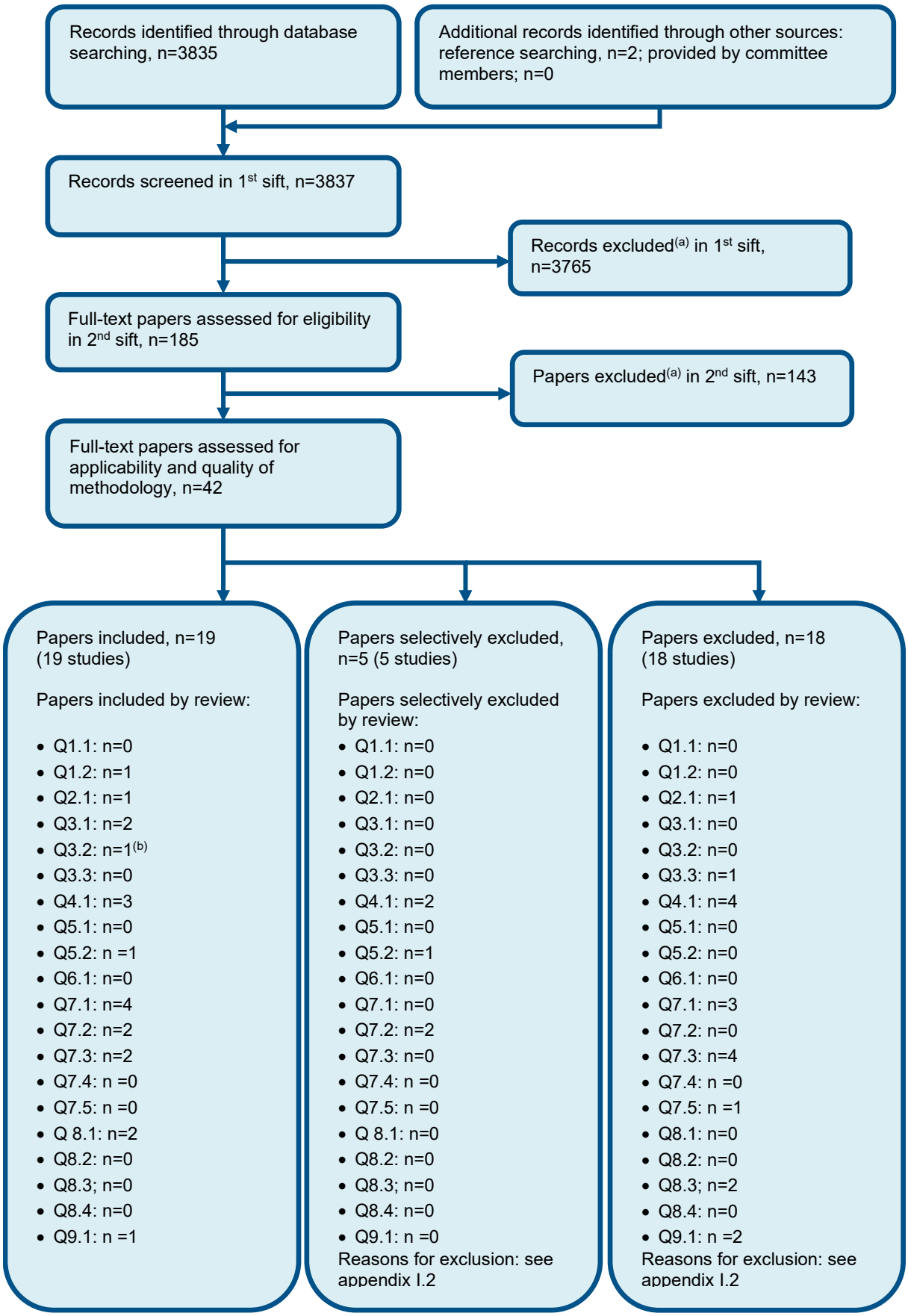
Appendix G: Health economic evidence selection

Figure 10: Flow chart of health economic study selection for the guideline



a) Non-relevant population, intervention, comparison, design or setting; non-English language
b) One study was applicable to both Q3.1 and Q3.2

Appendix H: Health economic evidence tables

Study	Trenaman 2017[70]			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: Cost-utility analysis (health outcome: QALYs) **Study design:** within trial (alongside the Stacey 2016 [66] RCT) **Approach to analysis:** Patients from two orthopaedic screening centres were randomised to receive a decision aid or usual care. Individual resource use was recorded. **Perspective:** Canadian healthcare **Follow-up**: 2 years **Discounting:** Costs: 5%; Outcomes: 5%	**Population:** 334 patients deciding whether to have primary TJR **Cohort characteristics:** Intervention 1 and 2 Mean age: 66.9 and 66.1 Male: 46.7% and 38.3% **Intervention 1:** Usual care **Intervention 2:** Patient decision aid (video and a booklet) plus surgeon preference report	**Total costs (mean per patient):** Intervention 1: £4,557 Intervention 2: £4,271 Incremental (2−1): Intervention saves £286[(a)] (95% CI: -£770 to -£242; p=NR) **Currency & cost year:** 2014 Canadian dollars, presented here as 2014 British pounds[(b)] **Cost components incorporated:** Consultations, surgical procedure costs and intervention costs including the time for the surgeon to compile the surgeon preference report and DVD/booklet cost	**QALYs (mean per patient):** Intervention 1: 1.21 Intervention 2: 1.23 Incremental (2−1): 0.02[(a)] (95% CI: -0.04 to 0.13; p=NR)	**Use of a decision aid dominated (less costly and more effective) usual care** **Analysis of uncertainty:** A probabilistic sensitivity analysis was conducted. Although the exact probability of cost effectiveness is not reported, a figure is presented that shows a large majority of simulations being either dominant or cost effective. A series of deterministic analyses were conducted for; complete case data; varying the cost of the intervention; varying the discount rate (to 0% and 3%); including only those with knee osteoarthritis and lastly; using different mapping algorithms from WOMAC to EQ-5D. Using a decision aid remained dominant in all scenarios.
Data sources				
Health outcomes: QALYs were obtained from the RCT **Quality-of-life weights:** WOMAC mapped to EQ-5D **Cost sources:** Resource use collected from individuals participating in the RCT; Ontario healthcare unit costs applied were applied to the reported resource use.				
Comments				
Source of funding: Informed Medical Decisions Foundation **Limitations:** Only 158/334 people had complete data at follow-up although this was imputed. Outcomes are derived from only 1 RCT out of 10 included in the clinical review. The reported incremental cost and utility is not same as the difference in reported mean cost and utility values for interventions 1 and 2. A 5% discount rate was used that differs from the recommended 3.5% rate recommended by NICE.				

Overall applicability:[c] Partially applicable **Overall quality:**[d] Potentially serious limitations

Abbreviations: 95% CI= 95% confidence interval; EQ-5D= Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); ICER= incremental cost-effectiveness ratio; NR= not reported; pa= probabilistic analysis; QALYs= quality-adjusted life years; TJR: total joint replacement

(a) The incremental cost and utility have been changed to equal the difference in reported costs and utilities of the two interventions. These are not the reported incremental values in the paper

(b) Converted using 2014 purchasing power parities[61]

(c) Directly applicable / Partially applicable / Not applicable

(d) Minor limitations / Potentially serious limitations / Very serious limitations

Appendix I: Excluded studies

I.1 Excluded clinical studies

Table 14: Studies excluded from the quantitative clinical review

Study	Exclusion reason
Abdel 2014[1]	Incorrect interventions
Adam 2008[2]	Incorrect study design
Akbaba 2015[3]	Inappropriate comparison
Arterburn 2012[5]	Incorrect study design
Atkinson smith 2016[6]	Incorrect study design
Bay 2018[10]	Systematic review not suitable for inclusion; references individually checked
Beamond 2009[11]	Incorrect interventions
Bozic 2011[16]	Trial protocol
Bozic 2014[15]	Incorrect study design
Briggs 2004[17]	Incorrect interventions
Buttigieg 2018[19]	Incorrect interventions
Clavel 2016[21]	Incorrect interventions
Copanitsanou 2015[22]	Unavailable
Cornoiu 2011[23]	Not review population.
Coudeyre 2009[24]	Incorrect interventions
Daltroy 1998[25]	Incorrect interventions
Das nair 2016[26]	Trial protocol
Dowsey 2016[29]	Trial protocol
Fraenkel 2019[30]	Inappropriate comparison
Hoffmann 2014[34]	Not review population
Horwood 2016[35]	Incorrect interventions
Huang 2017[36]	Incorrect interventions
Johnson 2011[40]	Inappropriate comparison
Jones 2017[41]	Incorrect study design
Kesternich 2016[43]	Incorrect study design.
Langdon 2002[47]	Inappropriate comparison
Lange 2017[48]	Incorrect interventions
Lansdown 2018[49]	Incorrect study design
Leal-blanquet 2013[50]	Inappropriate comparison
Mangla 2018[53]	Not review population
Mcdonald 2014[54]	Conference abstract
Slover 2016[64]	Incorrect study design
Stanton 2012[67]	Incorrect study design
Traumer 2018[69]	Incorrect interventions
Trenaman 2017[70]	Inappropriate comparison
Walker 2017[72]	Incorrect interventions
Werner 2017[74]	Incorrect interventions
Zheng 2017[79]	Incorrect interventions

Study	Exclusion reason
Zheng 2018[78]	Incorrect interventions

Table 15: Studies excluded from the qualitative review

Reference	Reason for exclusion
Al-Taiar 2013[4]	Incorrect intervention; not decision aids
Barlow 2015[7]	Systematic review not suitable for inclusion; references individually checked
Barlow 2016[8]	Incorrect intervention; not decision aids
Barlow 2018[9]	Incorrect intervention; not decision aids
Beard 2012[12]	Incorrect intervention; not decision aids
Clark 2004[20]	Incorrect intervention; not decision aids
Dosanjh 2009[28]	Incorrect intervention; not decision aids
Gillespie 2007[31]	Incorrect intervention; not decision aids
Grove 2015[32]	Trial protocol
Johnson 2016[39]	Incorrect intervention; not decision aids
Karlson 1997[42]	Incorrect intervention; not decision aids
Khatri 2011[44]	Incorrect intervention; not decision aids
Kroll 2007[45]	Incorrect intervention; not decision aids
Lane-Carlson 2012[46]	Incorrect intervention; not decision aids
Maillefert 2008[51]	Incorrect intervention; not decision aids
Malley 2018[52]	Incorrect intervention; not decision aids
Moore 2017[55]	Incorrect intervention; not decision aids
Nemes 2018[59]	Incorrect intervention; not decision aids
O'Neill 2007[60]	Incorrect intervention; not decision aids
Riffin 2018[62]	Incorrect study design; telephone survey
Strickland 2018[68]	Incorrect intervention; not decision aids
Weng 2007[73]	Quantitative - survey
Wiering 2017[75]	Incorrect intervention; not decision aids
Wright 1994[76]	Incorrect intervention; not decision aids

I.2 Excluded health economic studies

Table 16: Studies excluded from the health economic review

Reference	Reason for exclusion
None	

Appendix J: Research recommendations

J.1 Decision aids

Research question: What are the components of a decision aid to support people referred for elective joint replacement in making decisions about their treatment (for example, the type of procedure, timing and implant choice)?

Why this is important:

Decision aids are designed to enable shared decision-making between the person undergoing surgery and the orthopaedic team. This could include a number of decisions such as whether to have joint replacement surgery, when to have surgery, the specific type of joint replacement, and decisions such as the type of anaesthesia to be used during surgery. However there is no standard for what a decision aid for joint replacement surgery would consist of and this question seeks to assess this. Decision aids could be informational brochures, DVDs, questionnaires, decision-making software, presentations, value cards, individual or group discussions and combinations of all of these. It would be useful for commissioners to know the most effective form of decision aid.

PICO question	Population: Focus groups of people referred for joint replacement surgery and who have undergone joint replacement surgery within the last 2 years, focus groups of surgeons who undertake joint replacement surgery, focus groups of healthcare professionals, such as nurses and therapists, who are involved in the care of those undergoing joint replacement surgery Context: Questions designed to elicit the necessary components of a decision aid in relation to joint replacement surgery Outcome: Components of a decision aid established through thematic analysis of data elicited from the focus groups - which could then be compared against standard care in a further study/ final stage of the study - for each type of joint replacement.
Study design	Primary qualitative research
Other details	Importance to patients or the population: to allow development of a decision aid, in regard to joint replacement surgery, to potentially improve patient experience in regard to factors that need to be considered when making decision around surgery; which they may otherwise not be aware of. This, in turn, should help provide a structure, or pointers, for shared decision making with the surgical team.' Relevance to NICE guidance: this research would be in keeping with NICE guidance on patient experience (CG) and shared decision making. Current evidence base: there are studies which seem to show the potential benefits of decision aids in joint replacement surgery, none of these studies provide a consistent view of what a decision aid for joint replacement surgery is. Equality: - It is important to address people with cognitive impairments and their family or carers in the design of this trial. There may be differing effectiveness of the types of component in this group of people.