National Institute for Health and Care Excellence

Final

Joint replacement (primary): hip, knee and shoulder

[J] Evidence review for wrong implant selection

NICE guideline NG157

Intervention evidence review underpinning recommendations 1.6.1, 1.6.2 and the research recommendation in the NICE guideline

March 2020

Final

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

Disclaimer

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and, where appropriate, their carer or guardian.

Local commissioners and providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

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Contents

1 Wrong implant selection

1.1 Review question: What interventions would reduce the number of intraoperative implant selection errors, including systems and processes for selection, in adults having primary elective joint replacement?

1.2 Introduction

Wrong implant selection for primary elective joint replacement refers to a situation when the prosthesis implanted into a patient by the surgeon is the incorrect size, wrong side or where parts of the prosthesis used are incompatible with each other. This is often termed a 'mismatch' and is a rare event. Sometimes this is recognised by the surgeon and operating theatre team and can be addressed at the time of the person's replacement, but often it requires a revision. If not recognised at the time, the situation is picked up by the National Joint Register as a 'Never Event' and the person informed.

This review seeks to establish what systems or processes could be implemented to prevent any never events in relation to wrong implant selection.

1.3 PICO table

For full details see the review protocol in Appendix A:

Table 1: PICO characteristics of review question

Population	• Adults having primary elective joint replacement. Indirect populations that will be considered: • People having a pacemaker fitted • People having maxillofacial implant surgery • People having ocular prosthesis surgery
Intervention(s)	Interventions to reduce incorrect implant use. For example: • Clearer labelling on the implant packaging • Regimen for implant verification • Use of new technology • Colour coding • Shared learning/training • Scan for safety • Unique device identifiers
Comparison(s)	Usual care
Outcomes	**Critical** • Incorrect implant use (dichotomous) • Revision rate • Revision surgery (time to event) • Mortality: life expectancy (time to event) • Mortality: 30 day (dichotomous) • Quality of life (continuous) **Important** • Hospital readmission (dichotomous)

	• Length of stay (continuous) • Enhanced follow up – recommend blood tests, cross sectional imaging (dichotomous)
Study design	Randomised controlled trials

1.4 Clinical evidence

1.4.1 Included studies

A search was conducted for randomised trials comparing interventions to reduce wrong implant selection with usual care, and no relevant clinical studies were identified.

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:

1.4.2 Excluded studies

See the excluded studies list in Table 6.

1.5 Economic evidence

1.5.1 Included studies

No health economic studies were included.

1.5.2 Excluded studies

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

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

1.6 Evidence statements

1.6.1 Clinical evidence statements

No relevant published evidence was identified.

1.6.2 Health economic evidence statements

No relevant economic evaluations were identified.

1.7 The committee's discussion of the evidence

1.7.1 Interpreting the evidence

1.7.1.1 The outcomes that matter most

The critical outcomes were incorrect implant use, revision rate, revision surgery, mortality and quality of life. The most critical outcome was incorrect implant selection and use as this is the issue this evidence review seeks to address. The other outcomes are thought likely to be affected by incorrect implant use such as earlier revision surgery and reduced quality of life that might be associated with revision surgery or a joint replacement that is not

functioning as well as it could if the correct implant was used. The important outcomes were hospital readmission, length of stay and enhanced follow up.

1.7.1.2 The quality of the evidence

No evidence was found comparing interventions to reduce incorrect implant use with usual care.

1.7.1.3 Benefits and harms

The committee agreed that wrong implant selection and implantation is a very rare event but the implications of such an error are potentially significant for the person who has undergone joint replacement surgery. These are often referred to as “never events” because they are viewed as preventable and caused by human and process error. It was noted that this is an issue that exists in a wider context than simply orthopaedic surgery and indeed the evidence review was expanded to look for studies in people who are having other implant surgery such as having a pacemaker fitted, maxillofacial implant surgery, or ocular prosthesis surgery.

How implant selection errors can occur was discussed by the committee. The implant should be ultimately checked by the surgeon before implantation, after initial checks by the scrub nurse, runner, and sometimes by an industry representative supporting the case. However despite multiple parties checking the prosthesis, implant selection errors still occur. The committee agreed that there is unlikely to be a single intervention that will solve this and it should be approached from multiple angles.

The committee discussed the work that has been done to reduce or eradicate implant selection errors. Two national safety initiatives have provided guidance in this area. The National Safety Standards for Invasive Procedures[48] (NatSSIPs), an NHS Improvement initiative to reduce the number of patient safety incidents related to invasive procedures in which surgical never events could occur. Recommendations have been for prosthesis verification before the procedure, during the procedure, and after the procedure. The Healthcare Safety Investigation Branch (HSIB) published a report on its investigation into the implantation of wrong prostheses during joint replacement surgery.[31] This made 5 safety recommendations aimed at reducing wrong implant selection.

Current joint replacement surgery practice requires the use of the WHO surgical safety checklist to address local and national safety data which could include Never Events and National Patient Safety Agency (NPSA) alerts.

The evidence review found no relevant evidence, resulting in the committee using their experience and knowledge of current evidence to make consensus recommendations to reduce implant selection errors. They spoke of the importance of stop moments during surgery. This is where other actions are ceased by all staff and the details of the prosthesis components are checked so everyone agrees the correct prostheses are going to be implanted. The committee believe these time outs are common practice but are uncertain it is universal and stated how important it is to formally undertake them.

The 2nd recommendation is to use real time data entry before implantation using a system that will highlight some instances of wrong selection. The committee spoke about NJR Data collection forms that are normally completed after the surgery is completed. All hip and knee joint replacement operations undertaken in the UK are put into this database. When these data collection forms are inputted onto the NJR database incorrect combinations of implants are highlighted. However at this point the joint replacement operation has already occurred and any changes would require revision surgery. The committee considered the advantage of detecting incorrect combinations of implants intraoperatively so they could be prevented from occurring and made a recommendation to consider this.

The committee were aware that undertaking this intraoperative data entry has process implications for the orthopaedic centres undertaking the surgery. The committee were keen not to be prescriptive in terms of the specific system used whether it is the NJR database or an alternative system or how the data is entered, the method of data entry be it barcode, RFID or manual entry, or indeed the person entering the data be it OR staff or a HCA data collection clerk. The key result is “real time” warnings of wrong implant selection that can be acted on prior to implantation.

The committee agreed that there could be technological solutions to supplement current manual checks that may help reduce errors and therefore the made a research recommendation.

1.7.2 Cost effectiveness and resource use

No economic evidence was found for this review question. The first recommendation would not represent any significant additional use of resources. An intraoperative pause to check implant details and compatibility would not require additional personal and could also be conducted in a matter of seconds.

It was noted there may be economic implications to entering data intraoperatively, depending on how this is done. One option would be to install scanners that can inform the surgeons if the correct components are being used. This option is likely to have a large resource impact as there is national variability in terms of technology and IT infrastructure in hospitals. Therefore if technological investments were required for real time scanning, the costs incurred for some hospitals may be more than for others. There is also the option of having this check done manually. Component details are already entered into the NJR manually post-operatively for all procedures, however, it could be possible to move or copy this process during the intraoperative period. This would represent less of a resource impact and is better than no check; however, the implementation of technology would be the safest choice.

Given there was no clinical or cost effectiveness evidence, the committee did not specify how the real time scanning should be done.

References

1. Actrn. Visual images to assist in positioning for spinal and epidural anaesthesia. 2016. Available from: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01867625/full Last accessed: 09/04/2019

2. Al-Bataineh M, Sajadi S, Fontaine JM, Kutalek S. Axillary subpectoral approach for pacemaker or defibrillator implantation in patients with ipsilateral prepectoral infection and limited venous access. Journal of Interventional Cardiac Electrophysiology. 2010; 27(2):137-142

3. Asada S, Mori S, Matsushita T, Nakagawa K, Tsukamoto I, Akagi M. Comparison of MRI- and CT-based patient-specific guides for total knee arthroplasty. Knee. 2014; 21(6):1238-43

4. Ast MP, Mayman DJ, Bostrom MP, Gonzalez Della Valle A, Haas SB. Can we avoid implant-selection errors in total joint arthroplasty? Clinical Orthopaedics and Related Research. 2019; 477:130-133

5. Bai G, He D, Yang C, Chen M, Yuan J, Wilson JJ. Application of digital templates to guide total alloplastic joint replacement surgery with biomet standard replacement system. Journal of Oral and Maxillofacial Surgery. 2014; 72(12):2440-52

6. Ballas R, Philippot R, Cartier JL, Boyer B, Farizon F. Computer-assisted total knee arthroplasty: Impact of the surgeon's experience on the component placement. Archives of Orthopaedic and Trauma Surgery. 2013; 133(3):397-403

7. Bandeira F, Morral M, Elies D, Eguiza S, Souki S, Manero F et al. Transitional conic toric intraocular lens for the management of corneal astigmatism in cataract surgery. Clinical Ophthalmology. 2018; 12:1071-1079

8. Bargar WL, Bauer A, Borner M. Primary and revision total hip replacement using the Robodoc system. Clinical Orthopaedics and Related Research. 1998; (354):82-91

9. Bell SW, Anthony I, Jones B, MacLean A, Rowe P, Blyth M. Improved accuracy of component positioning with robotic-assisted unicompartmental knee arthroplasty: Data from a prospective, randomized controlled study. Journal of Bone and Joint Surgery (American Volume). 2016; 98(8):627-35

10. Bellemans J, Vandenneucker H, Vanlauwe J. Robot-assisted total knee arthroplasty. Clinical Orthopaedics and Related Research. 2007; (464):111-6

11. Benedek ZM, Furman S. The role of the computer in cardiac pacemaker technology. Pacing and Clinical Electrophysiology. 1984; 7(6 Pt 2):1217-27

12. Bernstein AD, Parsonnet V. Computer-assisted measurements in pacemaker follow-up. Pacing and Clinical Electrophysiology. 1986; 9(3):392-400

13. Bjorkenheim JM, Pajarinen J, Savolainen V. Internal fixation of proximal humeral fractures with a locking compression plate: A retrospective evaluation of 72 patients followed for a minimum of 1 year. Acta Orthopaedica Scandinavica. 2004; 75(6):741-5

14. Bove JC. Computer-assisted total knee arthroplasty: Does the tibial component remain at malposition risk? Orthopaedics & Traumatology, Surgery & Research. 2010; 96(5):536-42

15. Brandicourt P, Delanoe F, Roux FE, Jalbert F, Brauge D, Lauwers F. Reconstruction of cranial vault defect with polyetheretherketone implants. World Neurosurgery. 2017; 105:783-789

16. Buchbender C, Hartung-Knemeyer V, Forsting M, Antoch G, Heusner TA. Positron emission tomography (PET) attenuation correction artefacts in PET/CT and PET/MRI. British Journal of Radiology. 2013; 86:20120570

17. Cobb J, Henckel J, Gomes P, Harris S, Jakopec M, Rodriguez F et al. Hands-on robotic unicompartmental knee replacement: A prospective, randomised controlled study of the acrobot system. Journal of Bone and Joint Surgery (British Volume). 2006; 88(2):188-97

18. Elmallah RK, Cherian JJ, Jauregui JJ, Padden DA, Harwin SF, Mont MA. Robotic-arm assisted surgery in total hip arthroplasty. Surgical Technology International. 2015; 26:283-8

19. Fu J, Wang Y, Li X, Yu B, Ni M, Chai W et al. Robot-assisted vs. conventional unicompartmental knee arthroplasty: Systematic review and meta-analysis. Orthopade. 2018; 47(12):1006-1014

20. Gan Y, Ding J, Xu Y, Hou C. Accuracy and efficacy of osteotomy in total knee arthroplasty with patient-specific navigational template. International Journal of Clinical and Experimental Medicine. 2015; 8(8):12192-201

21. Gandhi RR, Manzotti A, Confalonieri N, Cerveri P. Comparison of CT-based patient-specific templating and digital radiography templating in total knee arthroplasty. Journal of Arthroscopy and Joint Surgery. 2016; 3(1):17-21

22. Gauci MO, Boileau P, Baba M, Chaoui J, Walch G. Patient-specific glenoid guides provide accuracy and reproducibility in total shoulder arthroplasty. Bone & Joint Journal. 2016; 98-B(8):1080-5

23. Goebel M, Burgkart R, Gerdesmeyer L, Diehl P, Schmitt-Sody M, Plötz W et al. Diagnosis specific differences in knee joint geometry. A challenge for the correct axial implantation of long stems in total knee arthroplasty. Der Orthopade. 2005; 34(11):1150-2, 1154-9

24. Hafez MA, Chelule KL, Seedhom BB, Sherman KP. Computer-assisted total knee arthroplasty using patient-specific templating. Clinical Orthopaedics and Related Research. 2006; (444):184-192

25. Hampp EL, Chughtai M, Scholl LY, Sodhi N, Bhowmik-Stoker M, Jacofsky DJ et al. Robotic-arm assisted total knee arthroplasty demonstrated greater accuracy and precision to plan compared with manual techniques. Journal of Knee Surgery. 2019; 32(3):239-250

26. Harrison AK, Gioe TJ, Simonelli C, Tatman PJ, Schoeller MC. Do porous tantalum implants help preserve bone? Evaluation of tibial bone density surrounding tantalum tibial implants in TKA. Clinical Orthopaedics and Related Research. 2010; 468:2739-45

27. Hashemian SJ, Farrokhi H, Foroutan A, Jafari ME, Hashemian SM, Alemzadeh SA et al. Ocular higher-order aberrations changes after implantable collamer lens implantation for high myopic astigmatism. Journal of Current Ophthalmology. 2018; 30(2):136-141

28. Hassan DM, Johnston GH, Dust WN, Watson G, Dolovich AT. Accuracy of intraoperative assessment of acetabular prosthesis placement. Journal of Arthroplasty. 1998; 13(1):80-4

29. Hassanein AG, Abdel Mabood AM. Can submandibular tracheal intubation be an alternative to tracheotomy during surgery for major maxillofacial fractures? Journal of Oral and Maxillofacial Surgery. 2017; 75(3):508.e1-508.e7

30. Hayward RM, Dewland TA, Moyers B, Vittinghoff E, Tanel RE, Marcus GM et al. Device complications in adult congenital heart disease. Heart Rhythm. 2015; 12(2):338-44

31. Healthcare Safety Investigation Branch. Investigation into the implantation of wrong prostheses during joint replacement surgery. Independent report by the Healthcare Safety Investigation Branch. Farnborough. Healthcare Safety Investigation Branch, 2018. Available from: https://www.hsib.org.uk/investigations-cases/implantation-wrong-prostheses-during-joint-replacement-surgery/final-report/

32. Hoenecke HR, Jr., Hermida JC, Flores-Hernandez C, D'Lima DD. Accuracy of CT-based measurements of glenoid version for total shoulder arthroplasty. Journal of Shoulder and Elbow Surgery. 2010; 19(2):166-71

33. Holt P, Crick JC, Sowton E. Antitachycardia pacing: A comparison of burst overdrive, self-searching and adaptive table scanning programs. Pacing and Clinical Electrophysiology. 1986; 9(4):490-7

34. Hourlier H, Fennema P. Intraoperative fluoroscopy improves surgical precision in conventional TKA. Knee Surgery, Sports Traumatology, Arthroscopy. 2014; 22(7):1619-25

35. Isrctn. Total vs Robotic bi-UniCompartmental Knee (TRUCK)Trial. 2014. Available from: http://apps.who.int/trialsearch/trial2.aspx?Trialid=isrctn12151461 Last accessed: 09/04/2019

36. Issa K, Rifai A, McGrath MS, Callaghan JJ, Wright C, Malkani AL et al. Reliability of templating with patient-specific instrumentation in total knee arthroplasty. Journal of Knee Surgery. 2013; 26(6):429-33

37. Jacobs MJ, Edmondson MJ, Lowry JC. Accuracy of diagnosis of fractures by maxillofacial and accident and emergency doctors using plain radiography compared with a telemedicine system: a prospective study. British Journal of Oral and Maxillofacial Surgery. 2002; 40(2):156-62

38. Jacquot A, Gauci MO, Chaoui J, Baba M, Deransart P, Boileau P et al. Proper benefit of a three dimensional pre-operative planning software for glenoid component positioning in total shoulder arthroplasty. International Orthopaedics. 2018; 42(12):2897-2906

39. Knafo Y, Houfani F, Zaharia B, Egrise F, Clerc-Urmes I, Mainard D. Value of 3D preoperative planning for primary total hip arthroplasty based on biplanar weightbearing radiographs. BioMed Research International. 2019; 2019:1932191

40. Lin F, Lim D, Wixson RL, Milos S, Hendrix RW, Makhsous M. Limitations of imageless computer-assisted navigation for total hip arthroplasty. Journal of Arthroplasty. 2011; 26(4):596-605

41. Liow MH, Chin PL, Tay KJ, Chia SL, Lo NN, Yeo SJ. Early experiences with robot-assisted total knee arthroplasty using the DigiMatchTM ROBODOC surgical system. Singapore Medical Journal. 2014; 55(10):529-34

42. Martelli M, Marcacci M, Nofrini L, La Palombara F, Malvisi A, Iacono F et al. Computer- and robot-assisted total knee replacement: Analysis of a new surgical procedure. Annals of Biomedical Engineering. 2000; 28(9):1146-1153

43. Marx A, von Knoch M, Pfortner J, Wiese M, Saxler G. Misinterpretation of cup anteversion in total hip arthroplasty using planar radiography. Archives of Orthopaedic and Trauma Surgery. 2006; 126(7):487-92

44. Michaels RK, Makary MA, Dahab Y, Frassica FJ, Heitmiller E, Rowen LC et al. Achieving the National Quality Forum's "Never Events": Prevention of wrong site, wrong procedure, and wrong patient operations. Annals of Surgery. 2007; 245(4):526-32

45. Naqvi ZG, Markhand JA, Ahmed SK, Chinoy A, Khan MA. Intra-operative implantation errors during Austin Moore Hemiarthroplasty. Journal of the Pakistan Medical Association. 2016; 66(Suppl 3):S90-S92

46. National Institute for Health and Care Excellence. Developing NICE guidelines: the manual [updated 2018]. London. National Institute for Health and Care Excellence, 2014. Available from: http://www.nice.org.uk/article/PMG20/chapter/1%20Introduction%20and%20overview

47. Nguyen D, Ferreira LM, Brownhill JR, King GJ, Drosdowech DS, Faber KJ et al. Improved accuracy of computer assisted glenoid implantation in total shoulder arthroplasty: An in-vitro randomized controlled trial. Journal of Shoulder and Elbow Surgery. 2009; 18(6):907-14

48. NHS England Patient Safety Domain, National Safety Standards for Invasive Procedures Group. National safety standards for invasive procedures (NatSSIPs). NHS England, 2015. Available from: https://improvement.nhs.uk/documents/5405/NatSSIPs_Final_updated_June_2019.pdf

49. Ozsoy U, Demirel BM, Yildirim FB, Tosun O, Sarikcioglu L. Method selection in craniofacial measurements: Advantages and disadvantages of 3D digitization method. Journal of Cranio-Maxillofacial Surgery. 2009; 37(5):285-290

50. Pagkalos J, Chaudary MI, Davis ET. Navigating the reaming of the acetabular cavity in total hip arthroplasty: Does it improve implantation accuracy? Journal of Arthroplasty. 2014; 29(9):1749-52

51. Parsonnet V, Myers GH, Gilbert L, Zucker IR. Followup of implanted pacemakers: An evaluation of surveillance methods. Cardiovascular Clinics. 1975; 6(3):431-46

52. Parsonnet V, Myers GH, Gilbert L, Zucker IR, Shilling E. Follow-up of implanted pacemakers. American Heart Journal. 1974; 87(5):642-53

53. Riddick A, Smith A, Thomas DP. Accuracy of preoperative templating in total hip arthroplasty. Journal of Orthopaedic Surgery. 2014; 22(2):173-6

54. Rodriguez F, Harris S, Jakopec M, Barrett A, Gomes P, Henckel J et al. Robotic clinical trials of uni-condylar arthroplasty. International Journal of Medical Robotics + Computer Assisted Surgery. 2005; 1(4):20-8

55. Schulz N, Puschel K, Turk EE. Fatal complications of pacemaker and implantable cardioverter-defibrillator implantation: Medical malpractice? Interactive Cardiovascular and Thoracic Surgery. 2009; 8(4):444-8

56. Sendtner E, Schuster T, Worner M, Kalteis T, Grifka J, Renkawitz T. Accuracy of acetabular cup placement in computer-assisted, minimally-invasive THR in a lateral decubitus position. International Orthopaedics. 2011; 35(6):809-15

57. Seyler TM, Lai LP, Sprinkle DI, Ward WG, Jinnah RH. Does computer-assisted surgery improve accuracy and decrease the learning curve in hip resurfacing? A

radiographic analysis. Journal of Bone and Joint Surgery (American Volume). 2008; 90(Suppl 3):71-80

58. Steppacher SD, Kowal JH, Murphy SB. Improving cup positioning using a mechanical navigation instrument. Clinical Orthopaedics and Related Research. 2011; 469:423-8

59. Stockl B, Nogler M, Rosiek R, Fischer M, Krismer M, Kessler O. Navigation improves accuracy of rotational alignment in total knee arthroplasty. Clinical Orthopaedics and Related Research. 2004; (426):180-6

60. Strik M, Frontera A, Eschalier R, Defaye P, Mondoly P, Ritter P et al. Accuracy of the pacemaker-mediated tachycardia algorithm in Boston Scientific devices. Journal of Electrocardiology. 2016; 49(4):522-9

61. Wirtz DC, Stargardt A, Prescher A, Forst R. Errors of computer-assisted migration analysis in conventional radiographs of femoral hip implants--an experimental study. Archives of Orthopaedic and Trauma Surgery. 1999; 119(1-2):50-6

Appendices

Appendix A: Review protocols

Table 2: Review protocol: Wrong implant selection

ID	Field	Content
0.	PROSPERO registration number	Not registered
1.	Review title	Reducing wrong implant selection during joint replacement
2.	Review question	What interventions would reduce the number of intraoperative implant selection errors, including systems and processes for selection, in adults having primary elective joint replacement?
3.	Objective	Surgical placement of the wrong implant or prosthesis where the implant/prosthesis placed in the patient is other than that specified in the surgical plan. This review seeks to find systems, processes or methods that will reduce these errors.
4.	Searches	The following databases will be searched: Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Database of Systematic Reviews (CDSR) Embase MEDLINE 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. 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	Methods to reduce wrong implant selection during joint replacement

ID	Field	Content
6.	Population	Inclusion: • Adults having primary elective joint replacement. Indirect populations that will be considered: • People having a pacemaker fitted • People having maxillofacial implant surgery • People having ocular prosthesis surgery Include mixed studies with adults having primary elective joint replacement and: • 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. Exclusion: N/A
7.	Intervention/Exposure/Test	Interventions to reduce incorrect implant use. For example: Clearer labelling on the implant packaging Regimen for implant verification Use of new technology Colour coding Shared learning/training Scan for safety Unique device identifiers
8.	Comparator/Reference standard/Confounding factors	Usual care
9.	Types of study to be included	Randomised controlled trials
10.	Other exclusion criteria	Non-English language studies. Abstracts will be excluded as it is expected there will be sufficient full text published studies available.
11.	Context	N/A

ID	Field	Content
12.	Primary outcomes (critical outcomes)	Incorrect implant use (dichotomous) Revision rate Revision surgery (time to event) Mortality: life expectancy (time to event) Mortality: 30 day (dichotomous) Quality of life (continuous)
13.	Secondary outcomes (important outcomes)	Hospital readmission (dichotomous) Length of stay (continuous) Enhanced follow up – recommend blood tests, cross sectional imaging (dichotomous)
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' 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).
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	Where possible, data will be meta-analysed. Pairwise meta-analyses will be performed using Cochrane Review Manager

ID	Field	Content	
	synthesis	(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. 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

ID	Field	Content		
		☐	Service Delivery	
		☐	Other (please specify)	
19.	Language	English		
20.	Country	England		
21.	Anticipated or actual start date	25/04/19		
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	☐	☑
		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: Mr Carlos Sharpin [Guideline lead] Mr Alex Allen [Senior Systematic Reviewer]		

ID	Field	Content	
		Ms Rafina Yarde [Systematic reviewer] Mr Robert King [Health economist] Ms Agnès Cuyàs [Information specialist] Ms 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 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	Wrong implant, prosthesis, joint replacement, clear labelling, checking, data entry	
33.	Details of existing review of same topic by same authors	N/A	
34.	Current review status	☐	Ongoing
		☒	Completed but not published

ID	Field	Content	
		☐	Completed and published
		☐	Completed, published and being updated
		☐	Discontinued
35..	Additional information	N/A	
36.	Details of final publication	www.nice.org.uk	

Table 3: Health economic review protocol

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).[46] **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.[46]

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 searches where appropriate.

Table 4: 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
Embase (OVID)	1974 – 01 May 2019	Exclusions Randomised controlled trials Systematic review studies Observational studies
The Cochrane Library (Wiley)	Cochrane Reviews to 2019 Issue 5 of 12 CENTRAL to 2019 Issue 5 of 12	None

Medline (Ovid) search terms

1.	arthroplasty/ or arthroplasty, replacement/ or arthroplasty, replacement, hip/ or arthroplasty, replacement, knee/ or arthroplasty, replacement, shoulder/ or hemiarthroplasty/ or exp Maxillofacial Prosthesis Implantation/
2.	joint prosthesis/ or hip prosthesis/ or knee prosthesis/ or shoulder prosthesis/ or eye, artificial/ or exp maxillofacial prosthesis/
3.	((joint* or knee* or shoulder* or hip* or ocular* or maxillofacial*) adj5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*)).ti,ab.
4.	((femoral or patellar or polyethylene or tibial or humeral or glenoid) adj2 component*).ti,ab.
5.	(((femoral or humeral) adj2 (steam or head)) or (acetabular or liner)).ti,ab.
6.	Pacemaker, Artificial/ or Cardiac Pacing, Artificial/
7.	(pacemaker* adj3 (implant* or fit* or surg*)).ti,ab.
8.	or/1-7
9.	letter/
10.	editorial/
11.	news/
12.	exp historical article/
13.	Anecdotes as Topic/
14.	comment/

15.	case report/
16.	(letter or comment*).ti.
17.	or/9-16
18.	randomized controlled trial/ or random*.ti,ab.
19.	17 not 18
20.	animals/ not humans/
21.	exp Animals, Laboratory/
22.	exp Animal Experimentation/
23.	exp Models, Animal/
24.	exp Rodentia/
25.	(rat or rats or mouse or mice).ti.
26.	or/19-25
27.	8 not 26
28.	limit 27 to English language
29.	"Prostheses and Implants"/ae, st [Adverse Effects, Standards]
30.	(wrong* or incorrect* or erroneous or error* or mistak* or unsuitabl* or incompatibl*).ti,ab.
31.	medical errors/ or diagnostic errors/
32.	exp Malpractice/
33.	(malpractice* or negligen*).ti,ab.
34.	(confus* or disorganiz* or disorganis* or distract*).ti,ab.
35.	((never or sentinel) adj4 event*).ti,ab.
36.	or/29-35
37.	28 and 36
38.	randomized controlled trial.pt.
39.	controlled clinical trial.pt.
40.	randomi#ed.ti,ab.
41.	placebo.ab.
42.	randomly.ti,ab.
43.	Clinical Trials as topic.sh.
44.	trial.ti.
45.	or/38-44
46.	Meta-Analysis/
47.	exp Meta-Analysis as Topic/
48.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
49.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
50.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
51.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
52.	(search* adj4 literature).ab.
53.	(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.
54.	cochrane.jw.
55.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
56.	or/46-55

57.	Epidemiologic studies/
58.	Observational study/
59.	exp Cohort studies/
60.	(cohort adj (study or studies or analys* or data)).ti,ab.
61.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
62.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
63.	Controlled Before-After Studies/
64.	Historically Controlled Study/
65.	Interrupted Time Series Analysis/
66.	(before adj2 after adj2 (study or studies or data)).ti,ab.
67.	or/57-66
68.	exp case control study/
69.	case control*.ti,ab.
70.	or/68-69
71.	67 or 70
72.	Cross-sectional studies/
73.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
74.	or/72-73
75.	67 or 74
76.	67 or 70 or 74
77.	37 and (45 or 56 or 76)

Embase (Ovid) search terms

1.	*arthroplasty/ or *replacement arthroplasty/ or *hip replacement/ or *knee replacement/ or *shoulder replacement/ or *hemiarthroplasty/ or *maxillofacial implant/
2.	*joint prosthesis/ or *hip prosthesis/ or *knee prosthesis/ or *shoulder prosthesis/ or *maxillofacial prosthesis/
3.	((joint* or knee* or shoulder* or hip* or ocular* or maxillofacial*) adj5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*)).ti,ab.
4.	((femoral or patellar or polyethylene or tibial or humeral or glenoid) adj2 component*).ti,ab.
5.	(((femoral or humeral) adj2 (steam or head)) or (acetabular or liner)).ti,ab.
6.	*artificial heart pacemaker/ or *heart pacing/
7.	(pacemaker* adj3 (implant* or fit* or surg*)).ti,ab.
8.	or/1-7
9.	letter.pt. or letter/
10.	note.pt.
11.	editorial.pt.
12.	case report/ or case study/
13.	(letter or comment*).ti.
14.	or/9-13
15.	randomized controlled trial/ or random*.ti,ab.
16.	14 not 15
17.	animal/ not human/
18.	nonhuman/

19.	exp Animal Experiment/
20.	exp Experimental Animal/
21.	animal model/
22.	exp Rodent/
23.	(rat or rats or mouse or mice).ti.
24.	or/16-23
25.	8 not 24
26.	limit 25 to English language
27.	(wrong* or incorrect* or erroneous or error* or mistak* or unsuitabl* or incompatibl*).ti,ab.
28.	*medical error/ or *diagnostic error/
29.	*malpractice/
30.	(malpractice* or negligen*).ti,ab.
31.	(confus* or disorganiz* or disorganis* or distract*).ti,ab.
32.	((never or sentinel) adj4 event*).ti,ab.
33.	or/27-32
34.	26 and 33
35.	random*.ti,ab.
36.	factorial*.ti,ab.
37.	(crossover* or cross over*).ti,ab.
38.	((doubl* or singl*) adj blind*).ti,ab.
39.	(assign* or allocat* or volunteer* or placebo*).ti,ab.
40.	crossover procedure/
41.	single blind procedure/
42.	randomized controlled trial/
43.	double blind procedure/
44.	or/35-43
45.	systematic review/
46.	meta-analysis/
47.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
48.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
49.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
50.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
51.	(search* adj4 literature).ab.
52.	(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.
53.	cochrane.jw.
54.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
55.	or/45-54
56.	Clinical study/
57.	Observational study/
58.	family study/
59.	longitudinal study/
60.	retrospective study/

61.	prospective study/
62.	cohort analysis/
63.	follow-up/
64.	cohort*.ti,ab.
65.	63 and 64
66.	(cohort adj (study or studies or analys* or data)).ti,ab.
67.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
68.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
69.	(before adj2 after adj2 (study or studies or data)).ti,ab.
70.	or/56-62,65-69
71.	exp case control study/
72.	case control*.ti,ab.
73.	or/71-72
74.	70 or 73
75.	cross-sectional study/
76.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
77.	or/75-76
78.	70 or 77
79.	70 or 73 or 77
80.	34 and (44 or 55 or 79)

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.	MeSH descriptor: [Maxillofacial Prosthesis Implantation] explode all trees
#8.	(or #1-#7)
#9.	MeSH descriptor: [Joint Prosthesis] this term only
#10.	MeSH descriptor: [Hip Prosthesis] this term only
#11.	MeSH descriptor: [Knee Prosthesis] this term only
#12.	MeSH descriptor: [Shoulder Prosthesis] this term only
#13.	MeSH descriptor: [Maxillofacial Prosthesis] explode all trees
#14.	(or #9-#13)
#15.	((joint* or knee* or shoulder* or hip* or ocular* or maxillofacial*) near/5 (surger* or replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast*)):ti,ab
#16.	(((femoral or humeral) near/2 (steam or head)) or (acetabular or liner)):ti,ab
#17.	((femoral or patellar or polyethylene or tibial or humeral or glenoid) near/2 component*):ti,ab
#18.	MeSH descriptor: [Pacemaker, Artificial] this term only
#19.	MeSH descriptor: [Cardiac Pacing, Artificial] this term only
#20.	(pacemaker* near/3 (implant* or fit* or surg*)):ti,ab

#21.	(or #15-#20)
#22.	(or #8, #14, #21)
#23.	(wrong* or incorrect* or erroneous or error* or mistak* or unsuitabl* or incompatibl*):ti,ab
#24.	MeSH descriptor: [Medical Errors] this term only
#25.	MeSH descriptor: [Diagnostic Errors] this term only
#26.	MeSH descriptor: [Malpractice] this term only
#27.	(malpractice* or negligen*):ti,ab
#28.	(confus* or disorganiz* or disorganis* or distract*):ti,ab
#29.	((never or sentinel) near/4 event*):ti,ab
#30.	(or #23-#29)
#31.	#22 AND #30

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 5: 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.
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

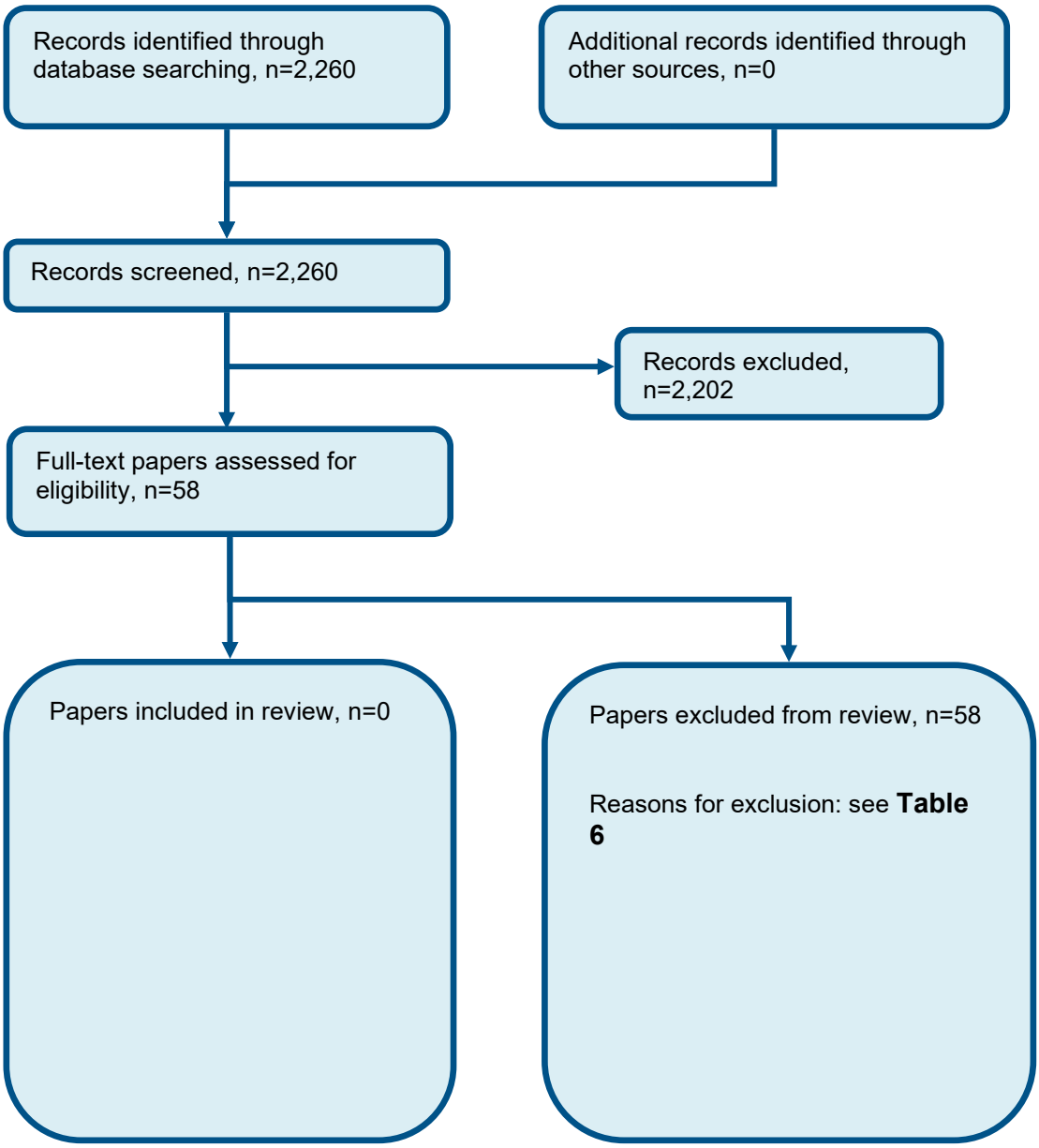
NHS EED and HTA (CRD) search terms

#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 wrong implant selection



Appendix D: Clinical evidence tables

No clinical studies were included in this review

Appendix E: Forest plots

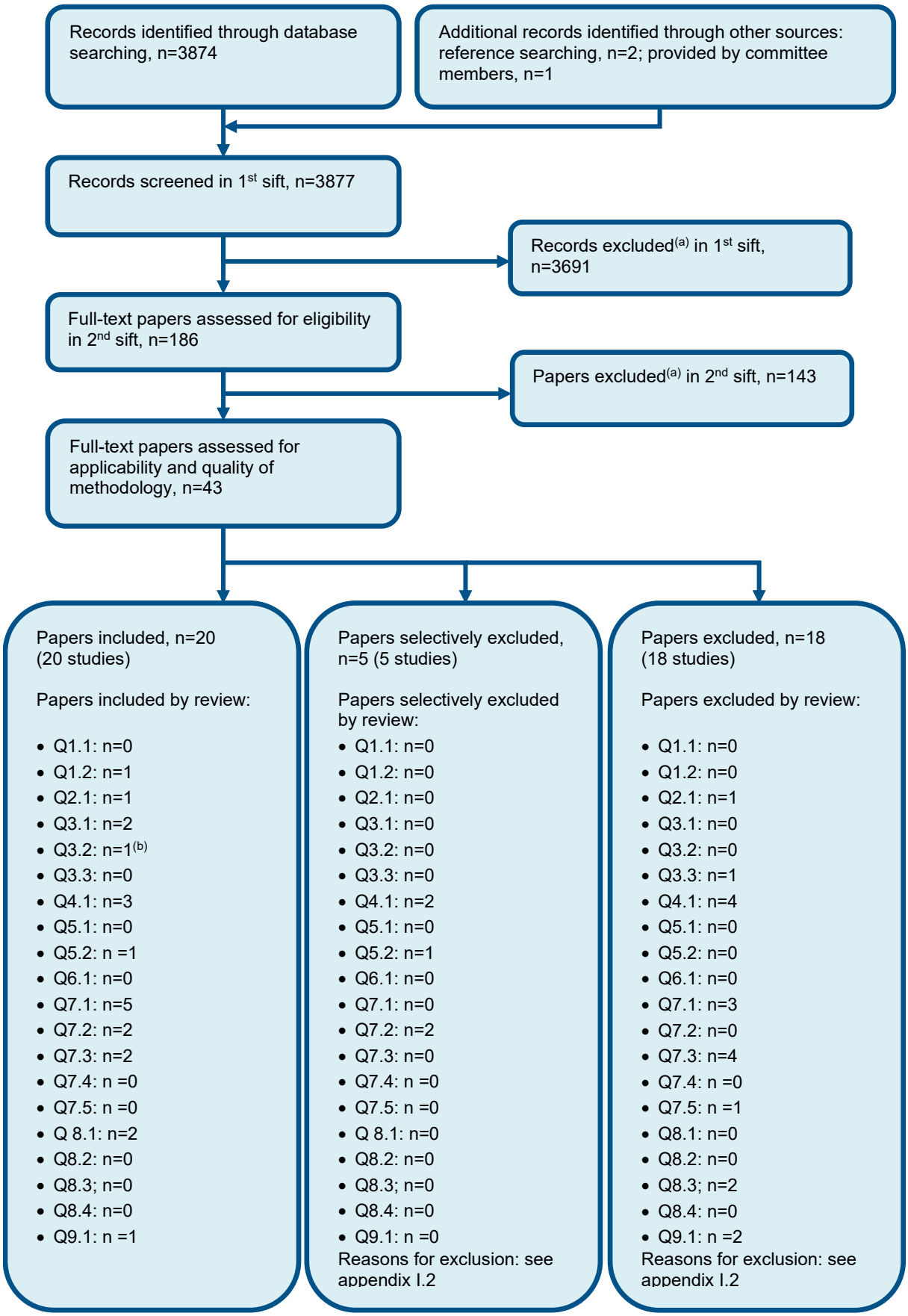
No clinical studies were included in this review

Appendix F: GRADE tables

No clinical studies were included in this review

Appendix G: Health economic evidence selection

Figure 2: 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

No health economic studies were included in this review

Appendix I: Excluded studies

I.1 Excluded clinical studies

Table 6: Studies excluded from the clinical review

Actrn 2016[1]	Trial web page
Al-Bataineh 2010[2]	Incorrect study design, incorrect intervention
Asada 2014[3]	Incorrect study design
Ast 2019[4]	Incorrect study design
Bai 2014[5]	Incorrect study design
Ballas 2013[6]	Incorrect study design, incorrect comparisons
Bandeira 2018[7]	Incorrect study design
Bargar 1998[8]	Incorrect intervention
Bell 2016[9]	Incorrect intervention
Bellemans 2007[10]	Incorrect study design
Benedek 1984[11]	Incorrect study design, incorrect intervention
Bernstein 1986[12]	Incorrect study design
Bjorkenheim 2004[13]	Incorrect study design
Bove 2010[14]	Incorrect study design
Brandicourt 2017[15]	Incorrect study design
Buchbender 2013[16]	Incorrect study design, incorrect intervention, incorrect population
Cobb 2006[17]	Incorrect intervention
Elmallah 2015[18]	Incorrect comparisons
Fu 2018[19]	Systematic review; references individually checked
Gan 2015[20]	Incorrect intervention
Gandhi 2016[21]	Incorrect study design
Gauci 2016[22]	Incorrect study design
Goebel 2005[23]	Not in English
Hafez 2006[24]	Incorrect study population
Hampp 2019[25]	Incorrect study population
Harrison 2010[26]	Incorrect study design
Hashemian 2018[27]	Incorrect study design
Hassan 1998[28]	Incorrect study design
Hassanein 2017[29]	Incorrect study design, incorrect population
Hayward 2015[30]	Incorrect intervention, incorrect study design
Hoenecke 2010[32]	Incorrect study design
Holt 1986[33]	Incorrect comparisons
Hourlier 2014[34]	Incorrect intervention
Isrctn 2014[35]	Trial web page
Issa 2013[36]	Incorrect study design
Jacobs 2002[37]	Incorrect comparisons
Jacquot 2018[38]	Incorrect comparisons
Knafo 2019[39]	Incorrect intervention

Lin 2011[40]	Incorrect intervention
Liow 2014[41]	Incorrect study design
Martelli 2000[42]	Incorrect study design
Marx 2006[43]	Incorrect study design
Michaels 2007[44]	Incorrect study design
Naqvi 2016[45]	Incorrect study design
Nguyen 2009[47]	Incorrect population
Ozsoy 2009[49]	Incorrect comparisons
Pagkalos 2014[50]	Incorrect study design
Parsonnet 1974[52]	Incorrect study design, incorrect intervention
Parsonnet 1975[51]	Incorrect comparisons
Riddick 2014[53]	Incorrect study design
Rodriguez 2005[54]	Incorrect study design
Schulz 2009[55]	Incorrect study design
Sendtner 2011[56]	Incorrect intervention
Seyler 2008[57]	Incorrect study design
Steppacher 2011[58]	Incorrect study design
Stockl 2004[59]	Incorrect intervention
Strik 2016[60]	Incorrect study design, incorrect comparisons
Wirtz 1999[61]	Incorrect study population

I.2 Excluded health economic studies

Table 7: Studies excluded from the health economic review

Reference	Reason for exclusion
No studies	

Appendix J: Research recommendations

J.1 Avoiding implant selection errors

Research question: What is the most effective technological solution for minimising wrong implant selection during joint replacement surgery?

Why this is important:

The committee agreed that wrong implant selection and implantation is a very rare event but the implications of such an error are potentially significant for the person who has undergone joint replacement surgery. These are often referred to as “never events” because they are viewed as preventable and caused by human and process error.

PICO question	Population: Adults undergoing primary hip, knee or shoulder joint replacement surgery Intervention(s): technological solution to prevent implant selection errors Comparison: Usual care Outcome(s): Implant selection errors and the resulting reduction in quality of life and economic costs
Study design	Randomised controlled trial
Other details	Two national safety initiatives have been asked to provide guidance in this area. The National Safety Standards for Invasive Procedures (NatSSIPs) and the Healthcare Safety Investigation Branch (HSIB). NatSSIPs is an NHS Improvement initiative that aims to reduce the number of patient safety incidents related to invasive procedures in which surgical never events could occur.