

Joint replacement (primary): hip, knee and shoulder

[O] Evidence review for hemiarthroplasty
proximal humeral fracture

NICE guideline

Intervention evidence review

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Draft for Consultation

*This evidence review was developed by the National Guideline
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ISBN

Contents

1	Reverse total shoulder replacement versus humeral hemiarthroplasty versus conventional shoulder replacement.....	5
1.1	Review question: In adults having primary elective shoulder replacement for pain and functional loss after a previous proximal humeral fracture (not acute trauma), what is the clinical and cost effectiveness of reverse total shoulder arthroplasty versus humeral hemiarthroplasty versus conventional total shoulder arthroplasty?	5
1.2	Introduction	5
1.3	PICO table.....	5
1.4	Clinical evidence	6
1.4.1	Included studies	6
1.4.2	Excluded studies.....	6
1.5	Economic evidence	6
1.5.1	Included studies	6
1.5.2	Excluded studies.....	6
1.5.3	Unit costs	6
1.6	Evidence statements	7
1.6.1	Clinical evidence statements.....	7
1.6.2	Health economic evidence statements.....	7
1.7	The committee's discussion of the evidence.....	7
1.7.1	Interpreting the evidence.....	7
1.7.2	Cost effectiveness and resource use	8
	Appendices.....	13
	Appendix A: Review protocols	13
	Appendix B: Literature search strategies	22
	B.1 Clinical search literature search strategy	22
	B.2 Health Economics literature search strategy.....	26
	Appendix C: Clinical evidence selection.....	29
	Appendix D: Clinical evidence tables	30
	Appendix E: Forest plots.....	31
	Appendix F: GRADE tables	32
	Appendix G: Health economic evidence selection.....	33
	Appendix H: Health economic evidence tables	36
	Appendix I: Excluded studies.....	37
	I.1 Excluded clinical studies.....	37
	I.2 Excluded health economic studies.....	38
	Appendix J: Research recommendations	39
	J.1 Procedures for shoulder replacement for people with a previous proximal humeral fracture.....	39

1 Reverse total shoulder replacement versus humeral hemiarthroplasty versus conventional shoulder replacement

1.1 Review question: In adults having primary elective shoulder replacement for pain and functional loss after a previous proximal humeral fracture (not acute trauma), what is the clinical and cost effectiveness of reverse total shoulder arthroplasty versus humeral hemiarthroplasty versus conventional total shoulder arthroplasty?

1.2 Introduction

The number of people having shoulder replacement surgery is increasing year on year with 6,526 detailed in the national joint registry in 2017.³² The majority of these are elective procedures. There have been recent changes and variations in practice about which type of shoulder replacement might offer the best outcomes for different patient groups.

For people with post traumatic shoulder pathology following a proximal humeral fracture, there is no consensus on which procedure has the best outcomes amongst these patients. National Joint Registry data indicates that an increasing number of people are being treated with a reverse total shoulder replacements as opposed to a humeral hemiarthroplasty or conventional total shoulder replacement.³² This review question was included to evaluate the published evidence on the different types of shoulder replacements in relation to patients following previous proximal humeral fractures (not acute trauma) as there is currently no consensus amongst shoulder surgeons in the UK.

24

1.3 PICO table

For full details see the review protocol in appendix A.

Table 1: PICO characteristics of review question

Population	People who have pain and functional loss after a previous proximal humeral fracture and are indicated for shoulder arthroplasty.
Interventions	<ul style="list-style-type: none">Reverse total shoulder arthroplastyConventional total shoulder arthroplastyShoulder humeral hemiarthroplasty
Comparison	Comparison of interventions
Outcomes	Critical <ul style="list-style-type: none">Mortality: life expectancy (dichotomous)Mortality: 30 day (dichotomous)Quality of life at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (continuous)Patient Reported Outcome Measures (PROMs) at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (continuous)

	<ul style="list-style-type: none"> • Revision of joint replacement (time to event) • Reoperation Patient Reported Outcome Measures (PROMs) at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (dichotomous) <p>Important</p> <ul style="list-style-type: none"> • Component failure (dichotomous) • Dislocations within 1 year, after 1 year (dichotomous) • Return to activity/sports (time to event) • Deep surgical site Infection (dichotomous) • Superficial surgical site infection (dichotomous) • Length of stay (continuous) • Major adverse events (including nerve injury, MI, VTE)
Study design	<p>Randomised controlled trials</p> <p>If no well-conducted RCTs are available, then observational studies with multivariate analysis will be investigated.</p>

1.4 1 Clinical evidence

1.4.1 2 Included studies

3 A search was conducted for randomised trials and observational studies comparing the
4 effectiveness of 3 types of shoulder arthroplasty for people who have had a previous
5 proximal humeral fracture.

6 No relevant clinical studies were identified.

7 See also the study selection flow chart in appendix C.

1.4.2 8 Excluded studies

9 See the excluded studies list in appendix I.

10

1.5 11 Economic evidence

1.5.1 12 Included studies

13 No relevant health economic studies were identified.

1.5.2 14 Excluded studies

15 One health economic study that was relevant to this question was excluded due to
16 assessment of limited applicability³⁴. The study is listed in appendix I, with reasons for
17 exclusion given.

18 See also the health economic study selection flow chart in appendix G.

1.5.3 19 Unit costs

20 Relevant unit costs are provided below to aid consideration of cost effectiveness. All three
21 procedures map the same healthcare resource group (HRG HB61) suggesting similar
22 resource use. However, there may be some difference in implant cost as illustrated in Table
23 2.

1 Table 2: Unit costs for different shoulder implants

Type of shoulder procedure	Implant cost (£)
Reverse total shoulder arthroplasty	£2,996
Conventional total shoulder arthroplasty	£2,307
Hemiarthroplasty	£1,013

2 Source: Implant costs are taken from a private provider supplied by a committee member. The magnitude of
3 difference may differ for other providers.

1.6 4 Evidence statements

1.6.1 5 Clinical evidence statements

6 No relevant published evidence was identified.

1.6.2 7 Health economic evidence statements

8 No relevant economic evaluations were identified.

9

1.7 10 The committee's discussion of the evidence

1.7.1 11 Interpreting the evidence

1.7.1.1 12 The outcomes that matter most

13 The critical outcomes were mortality, quality of life, patient reported outcomes (PROMs),
14 revision of joint replacement and reoperation.

15 The important outcomes were component failure, dislocations, return to activity or sports,
16 deep surgical site infection, superficial surgical site infection, length of stay and major
17 adverse events.

18 PROMs and quality of life are critical outcome measurements, as they are a true
19 representation of a person's subjective experience of joint replacement, which differentiates
20 them from harder objective outcomes and end points such as revision surgery. It was
21 discussed how it is easier to revise a hemiarthroplasty than a conventional total shoulder
22 arthroplasty (TSA) or reverse shoulder arthroplasty (RSA). Therefore, not all people in need
23 of a TSA revision have the surgery because it is complex with more associated risks. This
24 would be highlighted through the subjective outcomes rather than the objective outcomes.
25 Revision is a critical outcome as it is a significant operation and the lengthier the period of
26 time before one is in need of a revision, the better it is in terms of the initial replacement. The
27 return to activity or sports is important, some people in need of shoulder replacement surgery
28 are more physically active and a return to sporting activity is very important to them. Length
29 of stay is important in terms of economics and reflects the desire of people to leave hospital
30 earlier.

31

1.7.1.2 1 **The quality of the evidence**

2 No clinical studies were found for this review question.

3

1.7.1.3 4 **Benefits and harms**

5 No clinical studies were found for this review question. Most of the excluded studies found
6 concentrated on acute treatment of proximal humeral fractures. NJR data would have been
7 considered if it was adjusted for confounding factors. The committee spoke about the
8 population for this question. Proximal humeral fractures are a fracture of top end of the arm
9 bone where the ball of the shoulder joint breaks into 2, 3 or 4 pieces. It is left to heal and
10 farther down the line, mostly within 12 to 18 months, the person realises the non-operative
11 treatment has not worked. People in this situation experience a lot of pain with limited
12 movement. The treatment options are then either a hemiarthroplasty, which is replacing
13 the broken and badly healed ball with a new ball, a conventional TSA, which replaces the
14 broken ball and the shoulder socket or an RSA, which can still be done when the healed
15 fracture is very bad and the rotator cuff tendons are torn. Hemiarthroplasty and conventional
16 TSAs are not commonly done as the rotator cuff tendons still need to be working and in the
17 correct place while this is not required for RSAs. There is therefore an argument that a move
18 straight to an RSA makes sense in people whose bones and rotator cuff are damaged by
19 trauma and fractures. As long as the person's deltoid muscle is in working order, the results
20 of the RSA are expected to be good. This has led to a trend towards RSA over the past
21 decade, and it is now probably the first line treatment in this population for most surgeons in
22 the NHS. However, in people who have a lesser fracture and whose rotator cuff is still intact,
23 a hemiarthroplasty or conventional TSA can still be considered a reasonable option because
24 there still remains a future option to revise it to an RSA.

25 No clinical studies were found for this review question, and the committee could not agree on
26 a consensus recommendation on the type of surgery for this population. So a research
27 recommendation was made to answer the clinical question posed in this guideline.

28

1.7.29 **Cost effectiveness and resource use**

30 There was no published cost effectiveness studies found. The implant costs for reverse TSA
31 and conventional TSA may be more than for hemiarthroplasty given that their prosthesis
32 consists of 2 parts. However, implant costs are variable depending on the manufacturer.
33 Overall procedure costs and resource use are likely to be similar, as indicated by all 3
34 procedures mapping to the same Health Resource Group (HRG HN52) code.

35 No recommendation was made due to the lack of clinical evidence. Therefore practice is
36 likely to remain variable for this population. There are roughly 5,500 primary elective
37 shoulder operations annually, and a small proportion of these will be people with a previous
38 proximal humeral fracture. As current practice will not change for the small population size,
39 and there is similarity in costs between the interventions considered, there will not be any
40 resource impact.

41

42

43

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- 14
- 15
- 16

1 Appendices

2 Appendix A: Review protocols

3 Table 3: Review protocol: shoulder arthroplasty after previous proximal humeral fracture

ID	Field	Content
0.	PROSPERO registration number	Not registered
1.	Review title	Shoulder arthroplasty after previous proximal humeral fracture
2.	Review question	In adults having primary elective shoulder replacement for pain and functional loss after a previous proximal humeral fracture (not acute trauma), what is the clinical and cost effectiveness of reverse total shoulder replacement versus humeral hemiarthroplasty versus conventional shoulder replacement?
3.	Objective	To assess whether the most effective form of shoulder replacement is conventional total shoulder arthroplasty, hemiarthroplasty or reverse total shoulder arthroplasty in people who have pain and functional loss after a previous proximal humeral fracture.
4.	Searches	<p>The following databases will be searched:</p> <ul style="list-style-type: none"> Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Database of Systematic Reviews (CDSR) Embase MEDLINE <p>Searches will be restricted by:</p> <ul style="list-style-type: none"> English language Human studies <p>Letters and comments are excluded.</p> <p>Other searches:</p> <p>Inclusion lists of relevant systematic reviews will be checked by the reviewer.</p> <p>The searches may be re-run 6 weeks before final committee meeting and further studies retrieved for inclusion if relevant.</p>

ID	Field	Content
		The full search strategies will be published in the final review.
5.	Condition or domain being studied	Primary elective shoulder joint replacement surgery
6.	Population	<p>Inclusion: People who have pain and functional loss after a previous proximal humeral fracture and are indicated for shoulder arthroplasty.</p> <p>Exclude studies including people meeting any of the following criteria: 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.</p>
7.	Intervention/Exposure/Test	Reverse total shoulder arthroplasty Conventional total shoulder arthroplasty Shoulder humeral hemiarthroplasty
8.	Comparator/Reference standard/Confounding factors	Comparison of interventions
9.	Types of study to be included	Systematic reviews RCTs If no well-conducted RCTs are available, then observational studies with multivariate analysis will be investigated.
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
12.	Primary outcomes (critical outcomes)	Mortality: life expectancy (dichotomous) Mortality: 30 day (dichotomous) Quality of life at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (continuous) Patient Reported Outcome Measures (PROMs) at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years

ID	Field	Content
		<p>(continuous) Revision of joint replacement (time to event) Reoperation Patient Reported Outcome Measures (PROMs) at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (dichotomous)</p>
13.	Secondary outcomes (important outcomes)	<p>Component failure (dichotomous) Dislocations within 1 year, after 1 year (dichotomous) Return to activity/sports (time to event) Deep surgical site Infection (dichotomous) Superficial surgical site infection (dichotomous) Length of stay (continuous) Major adverse events (including nerve injury, MI, VTE) (dichotomous)</p> <p>To be extracted when not included within an extracted PROM: Function at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (continuous) Pain at 6 weeks or earlier, later than 6 weeks up to 1 year, at least 2 years (continuous)</p>
14.	Data extraction (selection and coding)	<p>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.</p> <p>10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer.</p> <p>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.</p> <p>A second reviewer will quality assure the extracted data. Discrepancies will be identified and resolved through discussion (with a third reviewer where necessary).</p>
15.	Risk of bias (quality) assessment	<p>Risk of bias will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual.</p>

ID	Field	Content
		<p>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)</p> <p>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.</p>
16.	Strategy for data synthesis	<p>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.</p> <p>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.</p> <p>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.</p> <p>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%.</p> <p>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.</p> <p>Where meta-analysis is not possible, data will be presented and quality assessed individually per outcome.</p> <p>If sufficient data is available to make a network of treatments, WinBUGS will be used for network meta-analysis.</p>
17.	Analysis of sub-groups	<p>Age: Working age, non-working age Humeral component: stemmed, stemless Surgical fixation: cemented, uncemented</p>

ID	Field	Content		
18.	Type and method of review	<input checked="" type="checkbox"/> Intervention		
		<input type="checkbox"/> Diagnostic		
		<input type="checkbox"/> Prognostic		
		<input type="checkbox"/> Qualitative		
		<input type="checkbox"/> Epidemiologic		
		<input type="checkbox"/> Service Delivery		
		<input type="checkbox"/> Other (please specify)		
19.	Language	English		
20.	Country	England		
21.	Anticipated or actual start date	05/12/18		
22.	Anticipated completion date	20/03/20		
23.	Stage of review at time of this submission	Review stage	Started	Completed
		Preliminary searches	<input checked="" type="checkbox"/>	<input type="checkbox"/>
		Piloting of the study selection process	<input checked="" type="checkbox"/>	<input type="checkbox"/>
		Formal screening of search results against eligibility criteria	<input type="checkbox"/>	<input type="checkbox"/>
		Data extraction	<input type="checkbox"/>	<input type="checkbox"/>
		Risk of bias (quality) assessment	<input type="checkbox"/>	<input type="checkbox"/>
		Data analysis	<input type="checkbox"/>	<input type="checkbox"/>
24.	Named contact	5a. Named contact National Guideline Centre 5b Named contact e-mail Headches@nice.org.uk		

ID	Field	Content
		<p>5e Organisational affiliation of the review National Institute for Health and Care Excellence (NICE) and the National Guideline Centre</p>
25.	Review team members	<p>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]</p>
26.	Funding sources/sponsor	<p>This systematic review is being completed by the National Guideline Centre which receives funding from NICE.</p>
27.	Conflicts of interest	<p>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.</p>
28.	Collaborators	<p>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].</p>
29.	Other registration details	
30.	Reference/URL for published protocol	
31.	Dissemination plans	<p>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.</p>

ID	Field	Content
32.	Keywords	Shoulder Joint replacement surgery, arthroplasty, proximal humeral fracture
33.	Details of existing review of same topic by same authors	N/A
34.	Current review status	<input checked="" type="checkbox"/> Ongoing
		<input type="checkbox"/> Completed but not published
		<input type="checkbox"/> Completed and published
		<input type="checkbox"/> Completed, published and being updated
		<input type="checkbox"/> Discontinued
35..	Additional information	N/A
36.	Details of final publication	www.nice.org.uk

1 **Table 4: 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	<ul style="list-style-type: none"> • 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	<p>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.</p> <p>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).³¹</p> <p>Inclusion and exclusion criteria</p> <ul style="list-style-type: none"> • 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. <p>Where there is discretion</p> <p>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.</p> <p>The health economist will be guided by the following hierarchies.</p> <p><i>Setting:</i></p> <ul style="list-style-type: none"> • 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.

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1 Appendix B: Literature search strategies

2 The literature searches for this review are detailed below and complied with the methodology
3 outlined in Developing NICE guidelines: the manual.³¹

4 *For more detailed information, please see the Methodology Review.*

B.1.5 Clinical search literature search strategy

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

11 Due to the size of retrieval, only the population was used in this search.

12 **Table 5: 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

13 **Medline (Ovid) search terms**

1.	arthroplasty, replacement, shoulder/
2.	shoulder prosthesis/
3.	(shoulder* adj4 (replace* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast* or reverse)).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.	randomized controlled trial.pt.
26.	controlled clinical trial.pt.
27.	randomi#ed.ti,ab.
28.	placebo.ab.
29.	randomly.ti,ab.
30.	Clinical Trials as topic.sh.
31.	trial.ti.
32.	or/25-31
33.	Meta-Analysis/
34.	exp Meta-Analysis as Topic/
35.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
36.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
37.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
38.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
39.	(search* adj4 literature).ab.
40.	(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.
41.	cochrane.jw.
42.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
43.	or/33-42
44.	Epidemiologic studies/
45.	Observational study/
46.	exp Cohort studies/
47.	(cohort adj (study or studies or analys* or data)).ti,ab.
48.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
49.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
50.	Controlled Before-After Studies/
51.	Historically Controlled Study/
52.	Interrupted Time Series Analysis/
53.	(before adj2 after adj2 (study or studies or data)).ti,ab.
54.	or/45-54
55.	exp case control study/
56.	case control*.ti,ab.
57.	or/56-57
58.	55 or 58

59.	Cross-sectional studies/
60.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
61.	or/60-61
62.	55 or 62
63.	55 or 58 or 62
64.	24 and (32 or 43 or 63)

1 Embase (Ovid) search terms

1.	shoulder replacement/
2.	shoulder prosthesis/
3.	(shoulder* adj4 (replac* or prosthe* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast* or reverse)).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.	random*.ti,ab.
24.	factorial*.ti,ab.
25.	(crossover* or cross over*).ti,ab.
26.	((doubl* or singl*) adj blind*).ti,ab.
27.	(assign* or allocat* or volunteer* or placebo*).ti,ab.
28.	crossover procedure/
29.	single blind procedure/
30.	randomized controlled trial/
31.	double blind procedure/
32.	or/23-31
33.	systematic review/
34.	meta-analysis/
35.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
36.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
37.	(reference list* or bibliograph* or hand search* or manual search* or relevant

	journals).ab.
38.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
39.	(search* adj4 literature).ab.
40.	(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.
41.	cochrane.jw.
42.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
43.	or/33-42
44.	Clinical study/
45.	Observational study/
46.	family study/
47.	longitudinal study/
48.	retrospective study/
49.	prospective study/
50.	cohort analysis/
51.	follow-up/
52.	cohort*.ti,ab.
53.	52 and 53
54.	(cohort adj (study or studies or analys* or data)).ti,ab.
55.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
56.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
57.	(before adj2 after adj2 (study or studies or data)).ti,ab.
58.	or/45-51,54-58
59.	exp case control study/
60.	case control*.ti,ab.
61.	or/60-61
62.	59 or 62
63.	cross-sectional study/
64.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
65.	or/64-65
66.	59 or 66
67.	59 or 62 or 66
68.	22 and (32 or 43 or 67)

1 Cochrane Library (Wiley) search terms

#1.	MeSH descriptor: [Arthroplasty, Replacement, Shoulder] this term only
#2.	MeSH descriptor: [Shoulder Prosthesis] this term only
#3.	(shoulder* near/4 (replac* or prosth* or endoprosthe* or implant* or artificial or arthroplast* or hemiarthroplast* or reverse)).ti,ab
#4.	(OR #1-#3)

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B.2.1 Health Economics literature search strategy

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

8 **Table 6: 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

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10 **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 prosth* 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

1 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

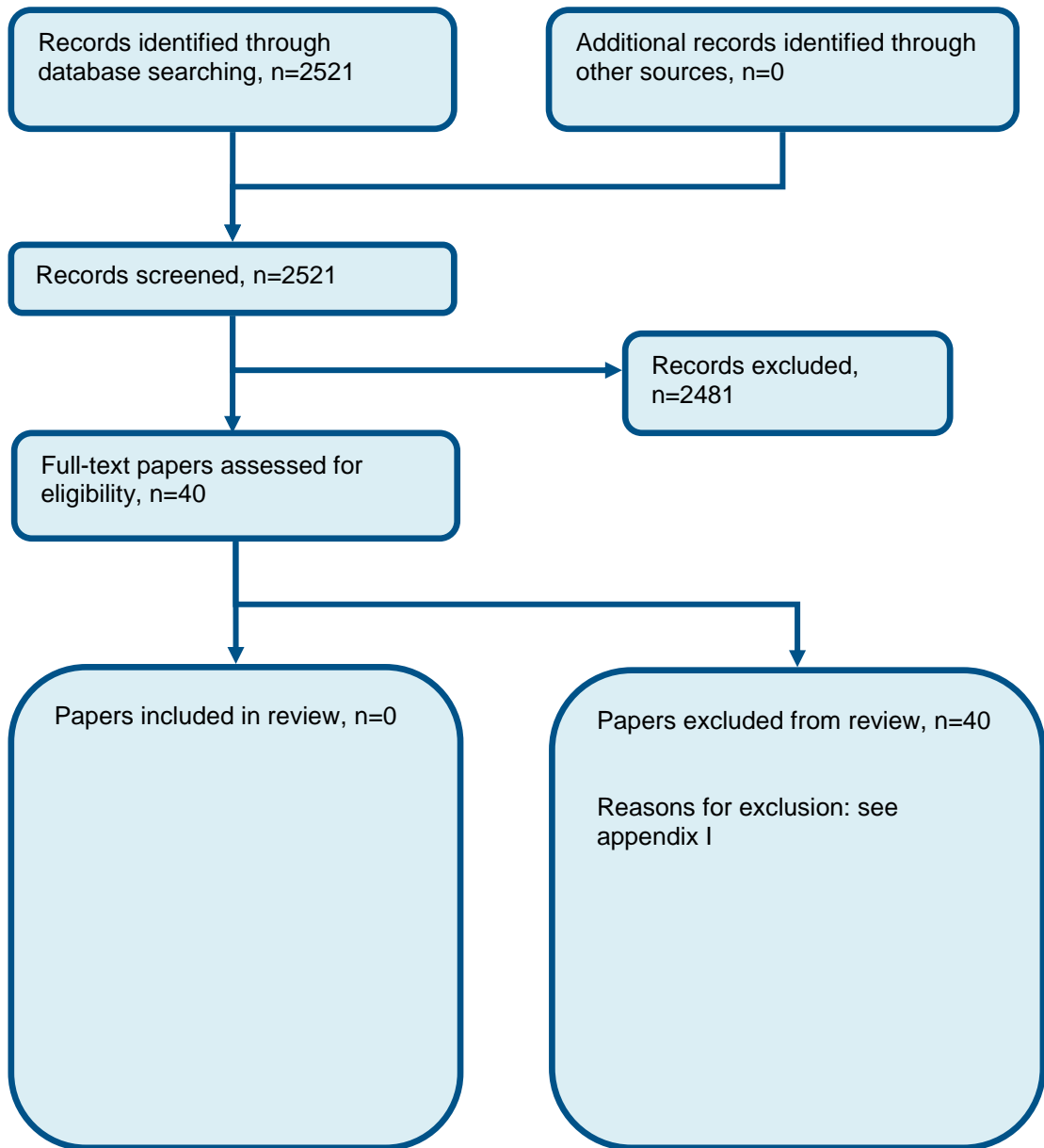
1 NHS EED and HTA (CRD) search terms

#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 prosth* or endoprosth* 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

2

1 Appendix C: Clinical evidence selection

Figure 1: Flow chart of clinical study selection for the review of shoulder arthroplasty after previous proximal humeral fracture



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1 **Appendix D: Clinical evidence tables**

2 No evidence was identified.

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1 **Appendix E: Forest plots**

2 No evidence was identified.

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1 **Appendix F: GRADE tables**

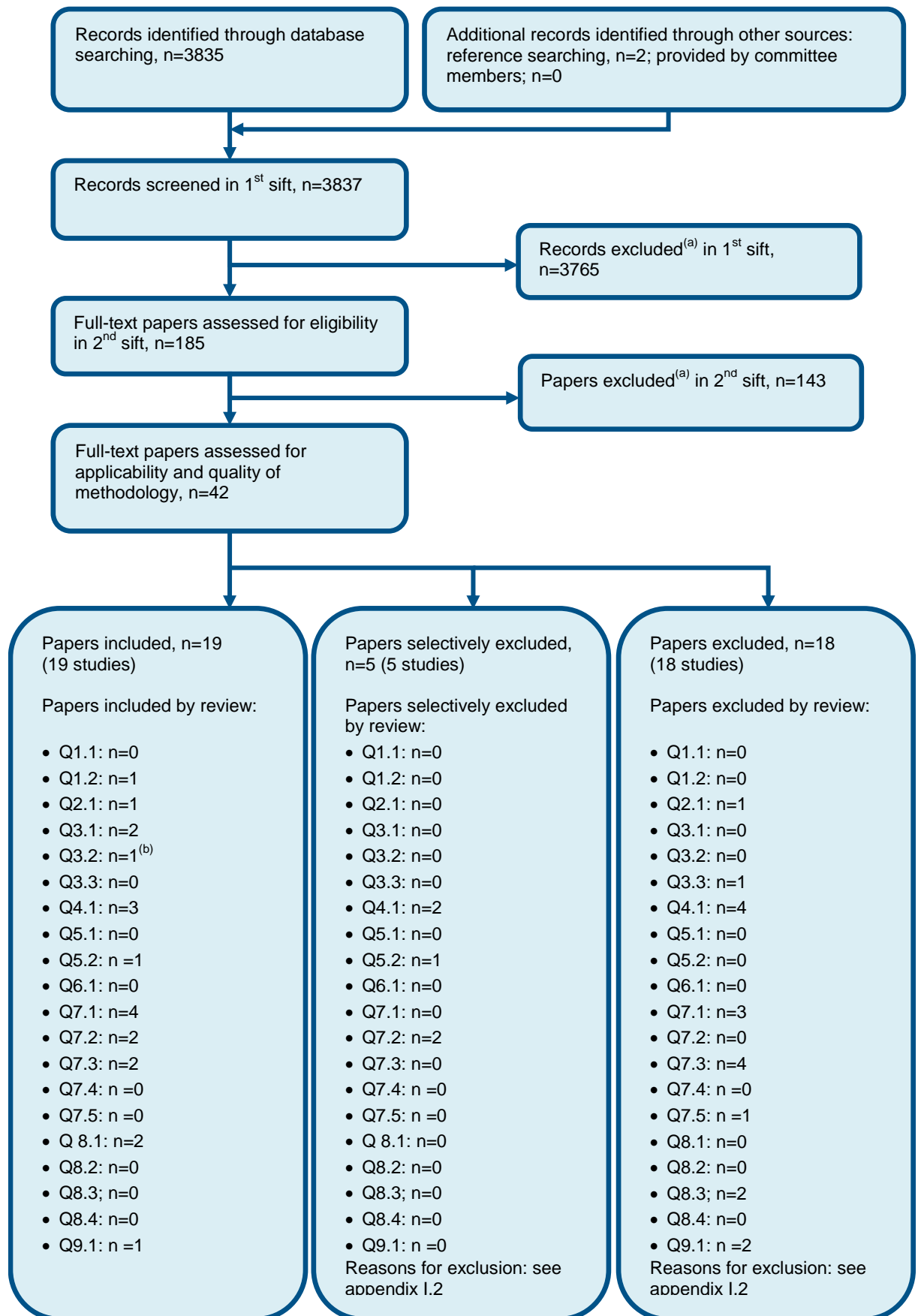
2 No evidence was identified

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1 **Appendix G: Health economic evidence** 2 **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

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1 Appendix H: Health economic evidence tables

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3 None
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2 Appendix I: Excluded studies

I.1.3 Excluded clinical studies

4 Table 7: Studies excluded from the clinical review

Study	Exclusion reason
Alentorn-geli 2015 ¹	Systematic review protocol does not match this review. Included studies were checked.
Anakwenze 2014 ²	Systematic review protocol does not match this review. Included studies were checked.
Antuna 2002 ³	Observational study that does not account for confounding factors
Baudi 2014 ⁴	Not review population
Boileau 2001 ⁵	Inappropriate comparison
Bonnevialle 2016 ⁶	Not review population
Boons 2012 ⁷	Inappropriate comparison
Boyer 2017 ⁸	Observational study without adjustment for confounding factors
Boyle 2013 ⁹	Not review population
Brorson 2013 ¹⁰	Systematic review protocol does not match this review. Included studies were checked.
Cabarcas 2018 ¹¹	Incorrect population. Included studies were checked.
Chalmers 2014 ¹²	Not review population
Chen 2016 ¹³	Systematic review protocol does not match this review. Included studies were checked.
Cuff 2013 ¹⁴	Observational study without adjustment for confounding factors
Cvetanovich 2016 ¹⁵	Not review population
Den hartog 2010 ¹⁶	Systematic review protocol does not match this review. Included studies were checked.
Du 2017 ¹⁷	Systematic review protocol does not match this review. Included studies were checked.
Farnig 2011 ¹⁸	Inappropriate comparison
Ferrel 2015 ¹⁹	Systematic review protocol does not match this review. Included studies were checked.
Fialka 2008 ²⁰	Inappropriate comparison
Gallinet 2009 ²¹	Systematic review protocol does not match this review. Included studies were checked.
Gallinet 2018 ²²	Not review population
Garrigues 2012 ²³	Not review population
Gulotta 2015 ²⁴	Incorrect study design
Handoll 2015 ²⁵	Systematic review protocol does not match this review. Included studies were checked.
Holton 2017 ²⁶	Systematic review protocol does not match this review. Included studies were checked.
Launonen 2015 ²⁷	Systematic review protocol does not match this review. Included studies were checked.
Lopiz 2016 ²⁸	Not review population
Mata-fink 2013 ²⁹	Systematic review protocol does not match this review. Included

Study	Exclusion reason
	studies were checked.
Namdari 2013 ³⁰	Systematic review protocol does not match this review. Included studies were checked.
Nijs 2009 ³³	Systematic review with incorrect population. Included studies were checked for this review.
Repetto 2017 ³⁵	Not review population
Sebastia-forcada 2014 ³⁶	Not review population
Shukla 2016 ³⁷	Systematic review protocol does not match this review. Included studies were checked.
Singh 2011 ³⁸	Not review population
Spross 2019 ³⁹	Treatment algorithm
Sumrein 2017 ⁴⁰	Not review population
Wang 2016 ⁴¹	Systematic review protocol does not match this review. Included studies were checked.
Young 2010 ⁴²	Not review population
Young 2013 ⁴³	Not review population

I.2.1 Excluded health economic studies

2 Table 8: Studies excluded from the health economic review

Reference	Reason for exclusion
Osterhoff 2017 ³⁴	This study was assessed as not applicable as it does not cover the review population

3

1 Appendix J: Research recommendations

J.1.2 Procedures for shoulder replacement for people with a previous proximal humeral fracture

4 **Research question: In adults having primary elective shoulder replacement for pain**
5 **and functional loss after a previous proximal humeral fracture (not acute trauma),**
6 **what is the clinical and cost effectiveness of reverse total shoulder replacement**
7 **compared with humeral hemiarthroplasty?**

8 **Why this is important:**

9 The number of people having shoulder replacement surgery is increasing year on year with
10 over 6,500 people having their shoulder replaced in the UK in 2017. Some of these are done
11 for acute fractures but the vast majority are elective procedures for arthritic problems. Many
12 acute fractures of the proximal humerus are treated non-operatively. A number of these go
13 onto to develop post traumatic problems such as a non-union or post traumatic arthritis. For
14 these people with post traumatic shoulder problems following a proximal humeral fracture,
15 there is no consensus on which procedure has the best outcomes. National Joint Registry
16 data now indicates that an increasing number of people are being treated with a reverse total
17 shoulder replacements as opposed to a humeral hemiarthroplasty or in some circumstances
18 a conventional total shoulder replacement. This NICE guideline was unable to find any
19 evidence to make a recommendation on which type of shoulder replacements to use in
20 patients pain and functional loss following previous proximal humeral fractures (not acute
21 trauma).

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PICO question	Population: People with pain and functional loss after a previous proximal humeral fracture (not acute trauma) in need of a shoulder replacement procedure. Intervention(s): Reverse Total Shoulder replacement Comparison: Humeral Hemiarthroplasty Outcome(s): Quality of life and Patient Reported Outcome Measures (PROMs) 2 year after surgery. Cost outcomes to enable cost-effectiveness analysis. Time to event data for revision surgery after 5 and 10 years.
Study design	Randomised controlled trial nested in NJR for longer term follow up
Other details	Decision making around which shoulder replacement type for different problems made the top 10 research priorities of the 2015 James Lind Alliance PSP on Shoulder Surgery.

23