

# BMJ Open Relationship between hospital or surgeon volume and outcomes in joint arthroplasty: protocol for a suite of systematic reviews and dose-response meta-analyses

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## ABSTRACT

**Introduction** Joint arthroplasty is a particularly complex orthopaedic surgical procedure performed on joints, including the hip, knee, shoulder, ankle, elbow, wrist and even digit joints. Increasing evidence from volume-outcomes research supports the finding that patients undergoing joint arthroplasty in high-volume hospitals or by high-volume surgeons achieve better outcomes, and minimum case load requirements have been established in some areas. However, the relationships between hospital/surgeon volume and outcomes in patients undergoing arthroplasty are not fully understood. Furthermore, whether elective arthroplasty should be restricted to high-volume hospitals or surgeons remains in dispute, and little is known regarding where the thresholds should be set for different types of joint arthroplasties.

**Methods and analyses** This is a protocol for a suite of systematic reviews and dose-response meta-analyses, which will be amended and updated in conjunction with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols. Electronic databases, including PubMed and Embase, will be searched for observational studies examining the relationship between the hospital or surgeon volume and clinical outcomes in adult patients undergoing primary or revision of joint arthroplasty. We will use records management software for study selection and a predefined standardised file for data extraction and management. Quality will be assessed using the Newcastle-Ottawa Scale, and the meta-analysis, subgroup analysis and sensitivity analysis will be performed using Stata statistical software. Once the volume-outcome relationships are established, we will examine the potential non-linear relationships between hospital/surgeon volume and outcomes and detect whether thresholds or turning points exist.

**Ethics and dissemination** Ethical approval is not required, because these studies are based on aggregated published data. The results of this suite of systematic reviews and meta-analyses will be submitted to peer-reviewed journals for publication.

**PROSPERO registration number** CRD42017056639.

## Strengths and limitations of this study

- To the best of our knowledge, this will be the first suite of systematic reviews and dose-response meta-analyses to explore the relationship between the hospital/surgeon volume and outcomes of the dominant types of arthroplasties.
- Once the volume-outcome relationships are established, we will examine the potential non-linear relationships between hospital/surgeon volume and outcomes, and determine whether thresholds or turning points exist.
- A comprehensive literature search, developed in consultation with a librarian with experience in systematic review search strategies, will be performed to include all eligible studies to present comprehensive systematic reviews and meta-analyses of the currently available evidence.
- It is highly likely that many studies will be included in the systematic reviews but excluded from the meta-analyses due to a paucity of data, which will introduce some bias.

## INTRODUCTION

In previous decades, the relationships between the number of patients treated by a physician/surgeon (physician/surgeon volume) or in a hospital (hospital volume) and patient outcomes have been extensively documented under many medical and surgical conditions.<sup>1–14</sup> In these relationships, patients admitted to a higher volume hospital or treated by a higher volume physician/surgeon are thought to be associated with a lower rate of adverse events and better health outcomes.<sup>3</sup> And a posteriori defined volume threshold for such an association usually is artificially determined to optimise the correlation when the volume-outcome relationship has been established, indicating that there is a hospital/surgeon volume above

which any increase will no longer be associated with improved outcomes. However, controversy pertaining to such volume–outcome relationships persists, and recent published studies have conveyed inconsistent results, thus fuelling a continuing debate.<sup>2</sup>

Supporters believe that volume–outcome relationship may be a sensible surrogate for quality assessment when choosing where to obtain surgical and interventional care,<sup>15</sup> while opponents argue that such volume–outcome relationship is an imperfect indicator of healthcare quality and that generalisability of these results is uncertain.<sup>16 17</sup> Despite the heated controversy that it provokes, the volume–outcome relationship remains a good point of departure in the exploration of optimal care in health services delivery. Understanding these relationships remains critical for clinicians and policy-makers because they are under increasing pressure to elucidate the performances of hospitals/surgeons, analyse the processes of care that lead to optimal outcomes and identify strategies to improve the quality of care.<sup>18 19</sup> Considering that volume is not an immutable determinant of the incidence of adverse events and that the volume–outcome relationship can change with the development of the healthcare provider and improvements in the quality of care, updating these volume–outcome relationships should be a priority when new research released.

Joint arthroplasty or joint replacement surgery is a particularly complex orthopaedic surgical procedure that is performed when severe joint pain or dysfunction cannot be alleviated by less invasive therapies. The goal of this procedure is to relieve pain, restore joint function and enhance quality of life.<sup>20–23</sup> Until now, joint arthroplasty has been performed on joints including the hip, knee, shoulder, ankle, elbow, wrist and even digit joints.

Hip and knee arthroplasties are the most common types of procedures performed.<sup>24</sup> According to estimates for the USA, the demands for primary total hip arthroplasty (THA) and revision THA will reach 572 000 and 96 700, respectively, by 2030, while the demands for primary total knee arthroplasty (TKA) and revision TKA will reach 3.48 million and 268 000, respectively.<sup>25 26</sup> Although shoulder arthroplasty is less common than hip and knee arthroplasties, it is still an exceptional procedure with excellent results,<sup>27</sup> and more than 53 000 shoulder arthroplasties are performed each year in the USA.<sup>28</sup> Because ankle arthrodesis has long been considered the gold standard of surgical treatment for ankle arthritis, total ankle arthroplasty is not frequently performed.<sup>29</sup> Only 2608 procedures were performed in the USA in 2010.<sup>30</sup> The elbow joint cannot be easily replaced or bypassed by external aids as can the lower extremity joints, and total elbow arthroplasty remains a relatively uncommon surgical procedure.<sup>31 32</sup> Approximately 3000 procedures were performed in the USA in 2015.<sup>33</sup> Similar to the ankle joint, wrist arthrodesis is the most frequently recommended treatment,<sup>34</sup> with only approximately 1000 total wrist arthroplasty procedures performed annually in the USA.<sup>35</sup>

Increasing evidence from volume–outcome research supports the finding that patients undergoing arthroplasty in high-volume hospitals or by high-volume surgeons achieve better outcomes,<sup>36–49</sup> but the actual definitions of high-volume hospitals and surgeons are highly variable among studies.<sup>50</sup> To improve clinical outcomes and deliver the best healthcare, the German Federal Joint Committee has established minimum case load requirements. The volume standards for primary TKA proposed by the Committee are 25 TKAs per year for surgeons and 50 TKAs per year for hospitals.<sup>51</sup> Although accumulating evidence supports these interventions, many researchers question how the minimum case load requirements should be exactly determined in clinical practice.<sup>50 52</sup>

The relationships between the hospital/surgeon volume and the outcomes in patients undergoing arthroplasty are not fully understood; whether elective arthroplasty should be restricted to high-volume hospitals or surgeons remains in dispute; and little is known regarding where exactly the thresholds should fall for different types of joint arthroplasties. Therefore, we decided to explore the volume–outcome relationships and thresholds to address this issue.

## OBJECTIVE

This is a protocol for a suite of systematic reviews and dose–response meta-analyses to explore the relationship between hospital/surgeon volume and outcomes in patients undergoing arthroplasty with the following objectives:

1. To examine the relationships between hospital/surgeon volume and outcomes in different types of joint arthroplasties.
2. To investigate the dose–response relationship between the volume and outcomes and to propose meaningful hospital/surgeon arthroplasty volume thresholds.
3. To compare the volume–outcome relationships among different procedure volumes for joint arthroplasties (primary hip and knee arthroplasties *vs* revision hip and knee arthroplasties *vs* shoulder arthroplasty *vs* ankle, elbow and wrist arthroplasties).

## METHODS AND ANALYSIS

Our systematic reviews and meta-analyses will be performed in accordance with guidelines from the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group and the methods prescribed in the Cochrane Handbook for Systematic Reviews of Interventions and will be reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement.<sup>53 54</sup>

## Registration information

This protocol will be amended and updated in conjunction with the PRISMA-Protocols.<sup>55</sup>

### Eligibility criteria

#### Types of studies

We will include observational studies that examined the relationship between hospital or surgeon volume and clinical outcomes, mainly including prospective cohort studies, retrospective cohort studies, case-control studies and cross-sectional studies, and meeting abstracts will also be included if eligible. There will be no restrictions regarding publication status or language.

#### Types of participants

Adult patients undergoing primary or revision joint arthroplasty will be eligible, and will specifically include those undergoing primary and revision THA, primary and revision TKA, and primary shoulder, ankle, elbow or wrist arthroplasty.

#### Types of outcome measures

The outcomes of interest are as follows: rate of mortality, readmission, periprosthetic joint infection, dislocation, revision, as well as wound complication, urinary tract infection, length of hospital stay, hospitalisation cost and functional score. The list is not exhaustive and will be modified based on the evidence compiled from the systematic reviews. We will not exclude studies due to paucity of data and we will include these studies in systematic reviews.

#### Patient and public involvement

In this study, data will not be collected directly from patients but instead will be obtained from published studies available in the main databases. Therefore, patients will not be involved in the completion of the systematic review protocol or subsequent research.

#### Information sources

We will search the electronic bibliographic databases PubMed and Embase from inception to March 2018 to ensure that all recent relevant studies are captured. No language restrictions will be imposed. In addition, we will search the clinical trial registry for ongoing and unpublished studies. Reference lists of all the identified studies as well as relevant reviews will be manually searched for potentially relevant studies. Potential grey literature sources (eg, conference abstracts) will be screened to identify any eligible published and unpublished studies.

#### Search strategy

Electronic search terms for each part will include both exploded Medical Subject Headings (MeSHs) terms and corresponding keywords. Search terms will include those related to ‘Volume’, ‘Caseload’, ‘Arthroplasty’, ‘Replacement’ and their variants. The search will be broad, and no restrictions will be applied. After retrieving and combining the corresponding subject terms using ‘OR’, the two parts will be combined using ‘AND’. The detailed librarian-assisted search strategy is shown in [table 1](#).

**Table 1** Search strategy

PubMed	Search	Query
#1		‘Arthroplasty’[Mesh]
#2		Arthroplasty[Title/Abstract]
#3		Replacement[Title/Abstract]
#4		‘Arthroplasty, Replacement’[Mesh]
#5		#1 OR #2 OR #3 OR #4
#6		‘Hospitals, High-Volume’[Mesh]
#7		‘Hospitals, Low-Volume’[Mesh]
#8		Volume[Title/Abstract]
#9		Volumes[Title/Abstract]
#10		Caseload[Title/Abstract]
#11		Caseloads[Title/Abstract]
#12		#6 OR #7 OR #8 OR #9 OR #10 OR #11
#13		hemofiltration[Title/Abstract]
#14		hematoma[Title/Abstract]
#15		Brain[Title/Abstract]
#16		Blood[Title/Abstract]
#17		Search Platelet[Title/Abstract]
#18		Gastric[Title/Abstract]
#19		Ventricule[Title/Abstract]
#20		Pressure[Title/Abstract]
#21		Lung[Title/Abstract]
#22		Stroke[Title/Abstract]
#23		hemodialysis[Title/Abstract]
#24		Tidal[Title/Abstract]
#25		#12 NOT #13 NOT #14 NOT #15 NOT #16 NOT #17 NOT #18 NOT #19 NOT #20 NOT #21 NOT #22 NOT #23 NOT #24
#26		#12 AND #25
Embase	Search	Query
#1		arthroplasty'/exp
#2		replacement arthroplasty'/exp
#3		arthroplasty:ti,ab
#4		replacement:ti,ab
#5		#1 OR #2 OR #3 OR #4
#6		volume'/exp
#7		volume:ti,ab
#8		volumes:ti,ab
#9		caseload:ti,ab
#10		caseloads:ti,ab
#11		#6 OR #7 OR #8 OR #9 OR #10
#12		hemofiltration:ti,ab
#13		hematoma:ti,ab
#14		brain:ti,ab
#15		blood:ti,ab
#16		platelet:ti,ab
#17		gastric:ti,ab
#18		ventricule:ti,ab

Continued

**Table 1** Continued

Embase	Search	Query
	#19	pressure:ti,ab
	#20	lung:ti,ab
	#21	stroke:ti,ab
	#22	hemodialysis:ti,ab
	#23	tidal:ti,ab
	#24	#12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23
	#25	#11 NOT #24
	#26	#5 AND #25

## Data collection and synthesis

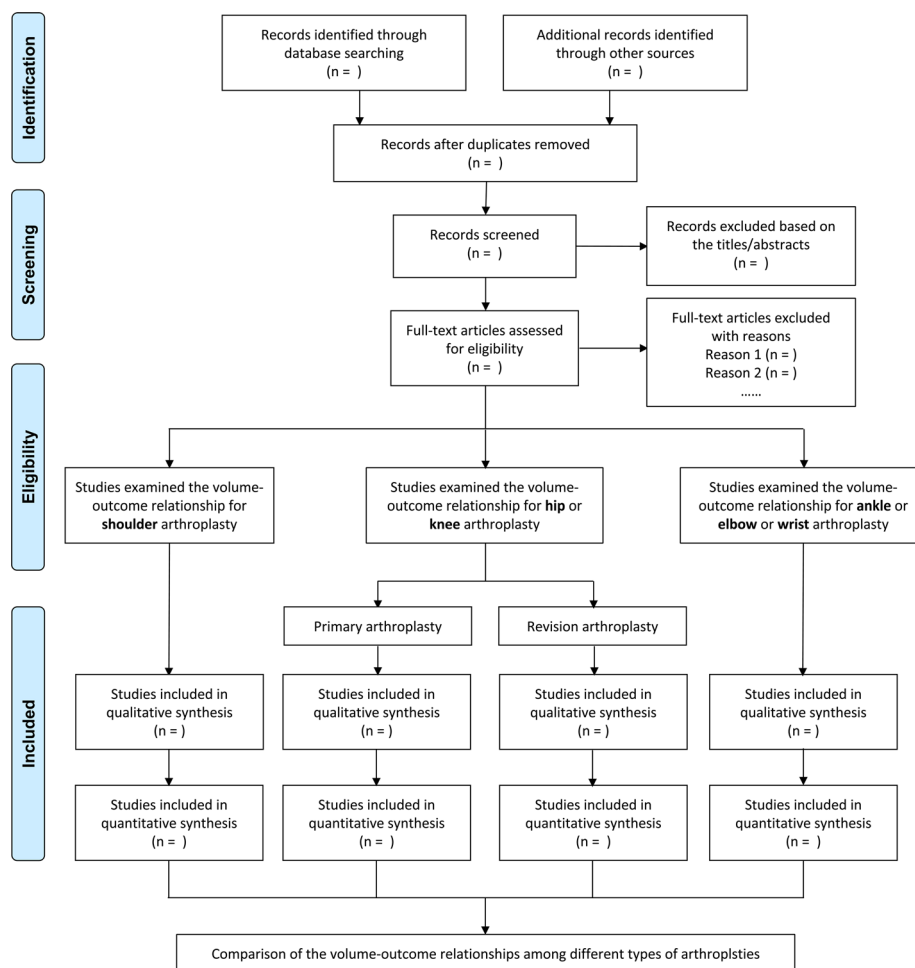
### Study selection

The obtained study records will be exported from medical databases and imported into a software package (EndNote V.X7, Thomson Reuters, California, USA) for records management. We will use a three-stage process for study screening and selection using standardised and piloted screening forms (figure 1). First, two reviewers

(X-DW and YYS) will jointly remove duplicate records from the initial search results. Second, the two reviewers will independently screen the titles and abstracts of each record to determine the eligibility, and identify the studies as included, excluded or requiring further assessment. Third, the full text of potentially eligible records will be retrieved and reviewed independently with reference to the predetermined inclusion and exclusion criteria. Differences of opinions will be resolved by discussion and consensus with a third reviewer (WH).

### Data extraction and management

A predefined standardised Excel (Microsoft Corporation, Washington, USA) file will be applied for data extraction, and separate sheets will be applied for each type of arthroplasty. Two independent reviewers (Z-HZ and YH) will extract the following information from each included study: first author, publication year, study location, study design, database, study period, number of patients, volume grouping and category, multivariate effect estimate, covariates in the fully adjusted model, as well as outcome measures mentioned above. The online supplementary files of the included studies will



**Figure 1** PRISMA flow diagram showing the process of literature screening, study selection and reasons for study exclusion. The PRISMA statement is used worldwide to improve the reporting of systematic reviews and meta-analyses. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.



also be examined for data extraction. In cases of missing data, we will contact the authors of the study. If we fail to obtain the missing data, the study will not be included in data analysis. Any discrepancies between the two reviewers will be resolved through consensus by discussion with an independent adjudicator (WH) as required.

### Quality assessment

As recommended by the MOOSE checklist, the quality of the included studies will be assessed using the Newcastle-Ottawa Scale, which is a validated scale for evaluating the quality of non-randomised studies in meta-analyses. This scale contains eight items with a maximum score of nine stars, which are awarded based on three domains: four stars for selection, two stars for comparability and three stars for outcomes. We will assign studies with scores of 0–3, 4–6 and 7–9 as low, moderate and high-quality studies, respectively. Two authors (MT and WX) will independently perform the quality appraisal, and disagreements will be resolved by a third investigator (WH).

### Data synthesis

Included studies that provide sufficient data to calculate an effect size measure will be included in the quantitative analysis. To quantify the degree of heterogeneity across studies, we will use Cochran's  $Q$  test with its  $p$  value and the Higgins  $I^2$  statistic with its 95% CI.<sup>56 57</sup> The  $I^2$  statistic is used to quantify the proportion of total variation in the effect estimation that is due to between-study variation.  $I^2$  values of 25%, 50% and 75% will be used as indicators of low, moderate and high heterogeneity, respectively.<sup>57 58</sup> Multivariate ORs with corresponding 95% CIs between extreme levels of hospital/surgeon volume (highest *vs* lowest) will be pooled using a random-effects model accounting for clinical heterogeneity. We will evaluate the possible presence of publication bias by using a funnel plot for meta-analyses including at least 10 studies.<sup>59</sup> We will also use tests proposed by Egger *et al.*, and by Begg and Mazumdar to measure funnel plot asymmetry.<sup>60 61</sup>

### Subgroup analysis and sensitivity analysis

To explore the potential sources of heterogeneity among the studies and to test the robustness of the volume–outcome relationships, we will further carry out subgroup analyses, primarily including the study design (cohort studies *vs* cross-sectional studies), adjusted factors (uncertain), sample size (uncertain) and period (?–1998 *vs* 1999–2008 *vs* 2009–2018). Additional 'leave-one-out' sensitivity analyses will be performed to explore whether the results are dominated by a single study; this issue will be investigated by omitting each study in turn and examining the influence of each individual study on the overall risk estimate (the 'leave-one-out' approach). This approach will enable an evaluation of the influence of individual studies on the overall risk estimate, and a two-sided  $p < 0.05$  will be considered as statistically significant. All of the above analyses will be performed using the Stata statistical software V.13.0 (StataCorp).

### Dose–response analysis and threshold effect analysis

Once the volume–outcome relationships are established, we will use two-step random-effects meta-regression models to examine potential non-linear relationships between hospital/surgeon volume and outcomes. To derive the dose–response curve, study-specific slopes (non-linear trends) with 95% CIs from the natural logs of the reported ORs and CIs across the hospital/surgeon volume categories will be calculated. The details of the methods that will be used have been described by Greenland and Longnecker and Orsini *et al.*<sup>62 63</sup> In particular, the mean or median level of volume for each category of the annual hospital/surgeon volume will be assigned to each corresponding OR for each study. If the data are not available, we will assign the midpoint of the upper and lower boundaries in each category as the annual hospital/surgeon volume. In cases where the upper or lower boundary of the category is open ended or extreme upper or lower values are present, we will assume that the absent boundary has the same amplitude as the adjacent category, meaning that the highest boundary has the same amplitude as the closest category, and the lowest boundary will be assumed to be 0. Additionally, only studies that report the number of events and control subjects (rather than the event rate), and the OR and its variance estimate for at least three categories will be eligible for the dose–response analysis.

For different types of arthroplasties, if the dose–response relationships are available, we will further develop a two-piecewise linear regression model to detect whether there exist thresholds or turning points of the annual hospital/surgeon volume on outcome using a smoothing function. The threshold level will be determined using trial and error, primarily by including the selection of turning points along a predefined interval and choosing the turning point that yields the maximum model likelihood. All analyses will be performed using Empower (R) (www.empowerstats.com, X&Y solutions, Massachusetts, USA).

### DISCUSSION

The relationship between hospital/surgeon volume and clinical outcomes has been proposed in arthroplasty for more than two decades.<sup>39</sup> Currently, minimum case load requirements or certificate-of-need programmes have been implemented to improve healthcare quality or to prevent overutilisation of healthcare resources. These measures are intended to align the supply of facilities with demand, but the advantages and disadvantages of regionalisation or centralisation in joint arthroplasty have not been fully elaborated. Therefore, this suite of systematic reviews and meta-analyses will provide new knowledge that is essential for healthcare service planning as well as knowledge on the implementation process and adjustment of programmes to improve the quality of care.

We anticipate challenges in conducting this research. First, it is highly likely that many studies will be included

in the systematic reviews but excluded from the meta-analyses due to a paucity of data, which will introduce some bias. Second, most of the included studies will be retrospective, which will limit the ability to control for confounders. Additionally, the numbers of eligible studies for ankle, elbow and wrist arthroplasties are predicted to be small, and the findings of the meta-analyses may be restricted.

## ETHICS AND DISSEMINATION

The findings will be disseminated in peer-reviewed journals and will also be shared with all stakeholders. Knowledge dissemination workshops will be conducted with relevant stakeholders to transfer the evidence, which will be tailored to the stakeholder (eg, policy briefs, publications and information booklets).

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**Contributors** X-DW and WH conceived and designed the study. X-DW drafted the protocol. M-ML, Y-YS, Z-HZ, QZ, JSWK, WX, MT, YH and WH revised the protocol. X-DW and Y-YS will search for and select eligible studies. Z-HZ and MT will extract the data. M-ML will check the data. YH and WX will assess the risk of bias. QZ and JSWK will perform the data synthesis. X-DW and WH act as guarantors of the protocol. All authors approved the publication of the protocol.

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**Competing interests** None declared.

**Patient consent** Not required.

**Ethics approval** Because this suite of systematic reviews and dose-response meta-analyses involves analysis of anonymous secondary data that are available in the public domain, and does not involve human participants or encroach on the privacy of individual patients, ethical approval is not required.

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