

# The current status of daycase hip and knee arthroplasty within the English National Health Service – A retrospective analysis of Hospital Episode Statistic data

Journal:	Annals Journal & Bulletin Journal
Manuscript ID	RCSJ-2020-0433
Manuscript Type:	Original research – Annals (clinical)
Date Submitted by the Author:	18-May-2020
Complete List of Authors:	Wainwright, Thomas; Bournemouth University, Orthopaedic Research Institute; The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust, Physiotherapy Department
Keywords – Go to <a href="http://www.ncbi.nlm.nih.gov/mesh" target="_blank"&gt;MeSH to find your keywords.:</a 	hip arthroplasty, knee arthroplasty, Daycase surgery, Enhanced Recovery after Surgery
	,

SCHOLARONE™ Manuscripts

Word count - 1927

1	Title:
2	The current status of daycase hip and knee arthroplasty within the English National
3	Health Service – A retrospective analysis of Hospital Episode Statistic data
4	
5	Author:
6	Thomas W. Wainwright <sup>a,b</sup>
7	
8	a. Bournemouth University, Bournemouth, UK
9	b. The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust.
10	
11	
12	Corresponding Author:
13	Thomas Wainwright
14	Orthopaedic Research Institute
15	Bournemouth University
16	Executive Business Centre
17	89 Holdenhurst Road
18	Bournemouth
19	BH8 8EB
20	Email: twainwright@bournemouth.ac.uk
21	Phone: (+44) 01202 961656
22	
23	

### Abstract

#### Introduction

- A high volume of total hip, total knee, and unicompartmental knee arthroplasty (THA,
- 29 TKA, UKA) procedures, an aging population, and ongoing financial pressures within
- 30 the English National Health Service (NHS) mean that strategies to reduce length of
- stay (LOS) are attractive. Enhanced Recovery after Surgery (ERAS) protocols are one
- 32 such intervention, and have advanced so that daycase arthroplasty is now possible.
- 33 This study examines the current rate of daycase arthroplasty within the English NHS.

## 34 Patients and Methods

- 35 Hospital Episode Statistics data from all English NHS providers of arthroplasty
- 36 procedures was analysed. Activity, daycase rate, length of stay (LOS), and
- readmission rates were recorded. All THA, TKA, and UKA operations undertaken
- within the time period 1 July 2018 to 30 June 2019 were examined.

#### 39 Results

- 40 LOS was analysed for 162,966 patients, and 74,665 (46%) were THA, 79,252 (49%)
- were TKA, and 9,049 were UTKA (5%). Mean LOS was 4.08 days for THA, 4.11 days
- for TKA, and 2.64 days for UTKA. Daycase rate for THA was 0.55%, 0.52% for TKA,
- 43 and 5.44% for UKA. The percentage of patients staying in hospital for longer than 4
- days (a LOS of 5 days or more) was 18.61% of THA spells, 20.54% of TKA spells, and
- 45 5.48% of UTKA spells.

#### 46 Discussion

- 47 This large observational study of unselected hip and knee arthroplasty patients
- demonstrates that the national daycase rate for arthroplasty across providers in the
- 49 NHS is low, and mean LOS remains higher than international comparators.

## Introduction

Total hip arthroplasty (THA), total knee arthroplasty (TKA), and unicompartmental knee arthroplasty (UKA) are high volume elective surgical procedures in the English National Health Service (NHS) (1). An aging population is contributing to a year-on-year rise of the number of procedures performed (1). This in combination with the considerable ongoing economic and capacity challenges that the NHS faces means that strategies to reduce length of stay (LOS) in hospital are extremely attractive to NHS hospitals.

Over the past ten years, the implementation of Enhanced Recovery after Surgery (ERAS) protocols has been a strategy to improve perioperative care, and create capacity by reducing LOS. The evidence-base confirms that ERAS can improve clinical and economic outcomes, however widescale implementation and adoption is not yet complete (2). Within the NHS, a national enhanced recovery partnership program ran between 2009 and 2011 with the aim to spread the best practice from early ERAS adopters (3, 4). Whilst LOS continues to gradually decline, recently the independent effect of the national enhanced recovery partnership programme on decreasing LOS has been questioned (5).

However, implementing ERAS successfully within individual NHS hospitals is possible and has occurred, with exemplar hospitals now further developing protocols to perform daycase arthroplasty (6). This evolution is the next step towards the ultimate goal of ERAS, namely the achievement of ambulatory surgery that is "pain and risk free" (2). The concept of daycase THA and TKA is not new. Studies on selected patients demonstrating its feasibility were first published over 10 years ago (7). More recently,

there has been an increasing number of publications describing the introduction of daycase arthroplasty. It has been shown to be feasible for 15% of patients in unselected cohorts within socialized health systems, with no increase to complications or re-admissions (8, 9). Daycase surgery is an attractive concept for the NHS at a time when capacity is required and financial savings continue to be required (10). This combined with the clinical and patient benefits of optimising the perioperative pathway, has led to THA, TKA and UKA being included within the latest British Association of Day Surgery Directory of Procedures (11). However, despite enthusiasm for the approach within the NHS, and promotion of its adoption within the media, it is unclear to what extent daycase arthroplasty is actually occurring.

The primary outcome of this analysis was therefore to identify the proportion of patients currently undergoing daycase THA, TKA, and UKA within the English NHS. Secondary outcomes were to establish current mean length of stay, readmission rate, and percentage of patients staying longer than 4 days in hospital, for THA, TKA, and UKA patents within the English NHS.

## **Materials and Methods**

This is a retrospective analysis of English NHS providers of THA, TKA, and UKA reported using The Reporting of Studies Conducted using Observational Routinely-collected health Data (RECORD) statement. The analysis was performed using Hospital Episode Statistic data (HES data) collected between 1 July 2018 and 30 June 2019 (the last available twelve months to include LOS and re-admission at the time of data collection). HES data are a valuable resource for research and allow for comparisons of outcomes (12). The HES data were accessed via the Dr Foster "Health

Intelligence Portal Tool (HIP)" (13), an online tool that receives clean data from HES, that can be used for presenting and comparing healthcare data. The online NHS Health Research Authority decision tool (http://www.hradecisiontools.org.uk/research/) advised that ethical approval was not required.

All (NHS and independent) providers of NHS procedures were included in the analysis. All elective primary THA, TKA, and UKA procedures were included in the analysis, and the Office of Population censuses and Survey (OPCS-4) classification of intervention and procedures codes were used. The OPCS-4 codes used to identify procedures are presented in Table 1. UKA procedures were identified and separated from TKA using previously described criteria (14).

The primary outcome measure (the number of daycase procedures performed) was calculated by including all patients coded as daycase as well as all patients coded as an inpatient who had zero day LOS (admission and discharge the same date with a procedure performed). The secondary outcome measures of this study were LOS, recorded as the number of midnights between admission and discharge home, and readmission rate (7, 14, 30 day). Emergency Readmissions were calculated using the superspell and are presented as crude readmission rates, and do not take into account the case-mix of individual patients. Definitions of each outcome measure can be found in Table 2.

Descriptive statistics were calculated using IBM SPSS Statistics version 26 (SPSS Inc., Chicago, USA). The percentage of patients discharged on the day of surgery, and by day four was calculated. The median, mean, and standard deviation, along

with the minimum and maximum values, were determined for length of stay in hospital and 7, 14, and 30-day readmission rate.

## Results

162,966 spells were included for the LOS analysis and 162,283 superspells for the analysis of re-admissions (readmissions within the HIP tool are superspell-based which will result in a smaller denominator value as there may be multiple spells across a superspell if for instance a patient is transferred between hospitals). Of all the spells included in the LOS analysis, 74,665 (46%) were THA, 79,252 (49%) were TKA, and 9,049 were UTKA (5%). The percentage of procedures in the superspells analysed for readmission were equivalent to those for LOS.

Across NHS providers, the daycase rate for THA was 0.55%, 0.52% for TKA, and 5.44% for UKA. The mean LOS was 4.08 days for THA (range 2.09-12.86, SD 1.12), 4.11 days for TKA (range 1.98-9.53, SD 1.36), and 2.64 days for UTKA (range 1-8.74, Standard Deviation (SD) 0.92). The mean and median LOS by hospital for THA, TKA and UTKA are shown in *Figures 1-3* respectively. The percentage of patients staying in hospital for longer than 4 days (a LOS of 5 days or more) was 18.61% of THA spells, 20.54% of TKA spells, and 5.48% of UTKA spells. The percentage of patients discharged on each post-operative day up until day 5 is presented in *Table 3*. The percentage of patients discharged on each post-operative day for hospitals found to have the lowest median LOS and highest volume of each procedure is shown in *Figure 4*. The crude 30 day readmission rate for THA was 5.27%, 5.88% for TKA, and 3.41% for UKA. The crude 7, 14, and 30 day readmission rates are presented in *Table 4*.

## **Discussion**

Despite recent media and industry reports, and an increased focus on daycase arthroplasty within the medical literature, the results from this national analysis of English NHS providers show that the percentage of patients undergoing daycase arthroplasty is actually very low on a national level. The overall national mean LOS across providers is comparable with recent data from Spain (15), but considerably higher than some international comparators. For example, in Denmark (16) and the USA (17), mean LOS is now 2 days for both THA and TKA, and daycase arthroplasty is now well documented internationally (18). In addition, approximately a fifth of patients will stay in hospital 5 days or longer after a TKA (20.54%) or THA (18.61%).

However, the data also demonstrates that daycase surgery is possible and being successfully delivered by some providers such as Northumbria Healthcare NHS Foundation Trust where 6% of THA and 5% TKA patients are treated as a daycase. For UTKA, the national daycase rate (5.44%) is considerably higher than for THA and TKA. In the centre (Oxford University Hospitals NHS Foundation Trust) with the highest volume of procedures and a median LOS of one day, the daycase rate was 49%. These examples show that daycase surgery is possible for some centres, but the national mean LOS across providers for THA, TKA, and UTKA demonstrates that routine daycase arthroplasty is far from a reality for most hospitals, and there is considerable variation in LOS across providers. This variation is unlikely to be due to case-mix alone, but instead likely to represent differences in local care pathways, as has been reported in previous reports of ERAS implementation (5).

The challenges to improve care pathways and implement strategies such as ERAS protocols within surgical pathways have been previously acknowledged (19). However, the concept of daycase arthroplasty is providing a renewed focus within orthopaedic teams to improve care pathways, and this should be encouraged, and facilitated by teams utilising clinical guidelines (20) and recognised quality improvement methods to successfully implement new surgical pathways (21). For example, the daycase pathway at Northumbria Healthcare NHS Foundation Trust, has evolved from early adoption of ERAS principles in 2008 (3), and ongoing and continued multi-disciplinary quality improvement efforts since then. Their daycase pathway was launched in 2016 (6) and they have subsequently disseminated their protocols (6), and run a series of training courses for daycase arthroplasty in conjunction with the British Association for Day Surgery. Their current daycase rate of 6% for THA and 5% for TKA, may not be the important point, but rather the fact that now 52% of THA and 46% of TKA patients go home on day 1. They are the only provider within the analysis with a median LOS of one day for all procedures.

The concept of ERAS should be considered a dynamic process and was first introduced as a multi-modal approach that challenged the traditions of surgical pathways. This data set is consistent with previous data (5), illustrating that ERAS implementation is still not widespread within the English NHS despite the general perception that it has been implemented. The concept of daycase surgery is appealing to surgical teams and has generated enthusiasm, and it may be the catalyst to renew efforts to successfully implement ERAS protocols. This is at a time when the NHS could benefit greatly from the associated capacity and economic gains.

## **Strengths and Limitations**

This study presents the current daycase rate, LOS, and re-admission rate across all NHS providers completing arthroplasty procedures. It includes all registered procedures for the most recent 12 months available at the time of analysis. This independent analysis of all NHS arthroplasty procedures, provides data on an unselected cohort, and is therefore a hugely valuable data reference point, that reflects current practice. HES data are a valuable resource for the analysis of activity and outcomes within the NHS, but it is a secondary dataset, and so it is reliant on local coding accuracy. However, it is the mandated data set that each hospital is required to supply to the Health and Social Care Information Centre. For the outcome measures examined within this study it can be judged reliable and also representative of current national practice.

#### Conclusion

Daycase arthroplasty is feasible within the English NHS, and exemplar centres are now demonstrating that is possible. However, the national daycase rate is very low, and it is far from standard practice for most hospitals. National mean LOS for THA and TKA is still significantly higher than international comparators and large epidemiological studies within the ERAS literature. However, the daycase concept is generating enthusiasm amongst surgical teams and reinvigorating ERAS concepts. It should therefore be encouraged, because whilst day of surgery discharge mat not be possible or suitable for all patients, optimised and evidenced based ERAS perioperative care pathways will improve patient care and reduce LOS.

#### Reference list

- 1. National Joint Registry. National joint registry for England, Wales, Northern Ireland and the Isle of Man 16th annual report. online. NJR: Hemel Hempstead; 2019.
- 227 2. Wainwright TW, Kehlet H. Fast-track hip and knee arthroplasty have we reached the goal? Acta Orthop. 2019;90(1):3-5.
  - 3. Malviya A, Martin K, Harper I, Muller SD, Emmerson KP, Partington PF, et al. Enhanced recovery program for hip and knee replacement reduces death rate. Acta Orthop.
- 231 2011;82(5):577-81.
- Wainwright T, Middleton R. An orthopaedic enhanced recovery pathway. Curr Anaesth Crit Care. 2010;21(3):114-20.
- 5. Judge A, Carr A, Price A, Garriga C, Cooper C, Prieto-Alhambra D, et al. The impact of the enhanced recovery pathway and other factors on outcomes and costs following hip and knee replacement: routine data study. Health Services and Delivery Research 8.4.
- 237 Southampton: NIHR Journals Library; 2020.
- 238 6. Jain S, Paice SE, Reed MR, Partington PF. Is day case hip and knee replacement surgery possible in the NHS? Journal of Trauma & Orthopaedics. 2019;7(4):32-4.
- 7. Berger RA. A comprehensive approach to outpatient total hip arthroplasty. Am J Orthop (Belle Mead NJ). 2007;36(9 Suppl):4-5.
- 8. Gromov K, Jorgensen CC, Petersen PB, Kjaersgaard-Andersen P, Revald P, Troelsen
- A, et al. Complications and readmissions following outpatient total hip and knee arthroplasty: a prospective 2-center study with matched controls. Acta Orthop. 2019;90(3):281-5.
- 9. Gromov K, Kjærsgaard-Andersen P, Revald P, Kehlet H, Husted H. Feasibility of outpatient total hip and knee arthroplasty in unselected patients. Acta Orthop. 2017;88(5):516-247 21.
- 32 248 10. Appleby J. Day case surgery: a good news story for the NHS. BMJ: British Medical 33 249 Journal. 2015;351:h4060.
  - 250 11. British Association of Day Surgery. BADS directory of procedures. 6th ed. London: 251 BADS; 2020.
  - 252 12. Slavin JP, Deakin M, Wilson R. Surgical research and activity analysis using Hospital Episode Statistics. Ann R Coll Surg Engl. 2012;94(8):537-8.
  - 254 13. Dr Foster. Quality and outcomes measurement [online]. London: Dr Foster 255 Intelligence; [Available from: https://drfoster.com/service/quality-and-outcomes-
  - 256 measurement/#product-hip-quality.
  - 257 14. Middleton R, Wilson HA, Alvand A, Abram SGF, Bottomley N, Jackson W, et al. Outcome-based commissioning of knee arthroplasty in the NHS: system error in a national
  - 259 monitoring programme and the unintended consequences on achieving the Best Practice Tariff.
  - 260 Bone Joint J. 2018;100-b(12):1572-8.
  - 261 15. Ripollés-Melchor J, Abad-Motos A, Díez-Remesal Y, Aseguinolaza-Pagola M, Padin-
  - Barreiro L, Sánchez-Martín R, et al. Association Between Use of Enhanced Recovery After
  - Surgery Protocol and Postoperative Complications in Total Hip and Knee Arthroplasty in the
  - Postoperative Outcomes Within Enhanced Recovery After Surgery Protocol in Elective Total Hip and Knee Arthroplasty Study (POWER2). JAMA Surgery. 2020;155(4):e196024-e.
- 52 265 Hip and Knee Arthropiasty Study (POWER2). JAINA Surgery. 2020,133(4):e190024-e.
  53 266 16. Petersen PB, Jorgensen CC, Kehlet H. Temporal trends in length of stay and
  54 267 readmissions after fast-track hip and knee arthroplasty. Dan Med J. 2019;66(7):1-4.
  - 268 17. Liu J, Elkassabany N, Poeran J, Gonzalez Della Valle A, Kim DH, Maalouf D, et al.
  - Association between same day discharge total knee and total hip arthroplasty and risks of
  - cardiac/pulmonary complications and readmission: a population-based observational study.
    - 271 BMJ Open. 2019;9(12):e031260.

- Vehmeijer SBW, Husted H, Kehlet H. Outpatient total hip and knee arthroplasty. Acta Orthop. 2018;89(2):141-4.
- 274 19. Stone AB, Yuan CT, Rosen MA, Grant MC, Benishek LE, Hanahan E, et al. Barriers 275 to and facilitators of implementing enhanced recovery pathways using an implementation 276 framework: a systematic review. JAMA Surg. 2018;153(3):270-9.
- 277 20. Wainwright TW, Gill M, McDonald DA, Middleton RG, Reed M, Sahota O, et al.
  278 Consensus statement for perioperative care in total hip replacement and total knee replacement
  279 surgery: Enhanced Recovery After Surgery (ERAS®) Society recommendations. Acta Orthop.
  280 2020;91(1):3-19.
- 281 21. Jones EL, Lees N, Martin G, Dixon-Woods M. How well is quality improvement 282 described in the perioperative care literature? a systematic review. Jt Comm J Qual Patient Saf. 283 2016;42(5):196-206.



## **Figures**

Figure 1 - THA mean and median LOS by provider

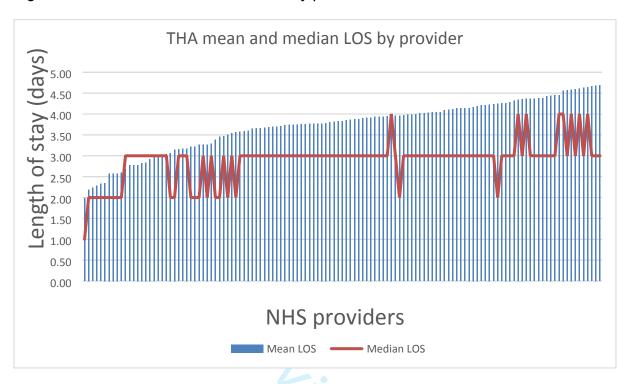


Figure 2 - TKA mean and median LOS by provider

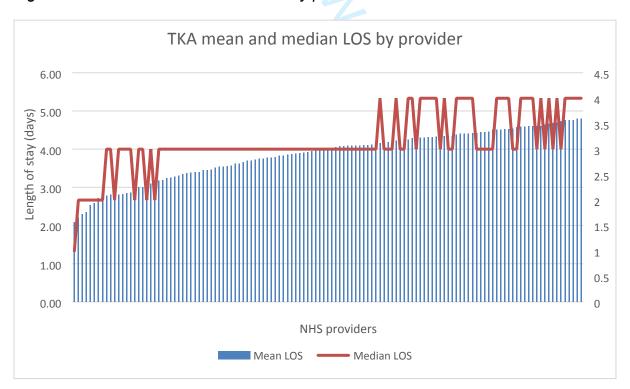


Figure 3 - UTKA mean and median LOS by provider

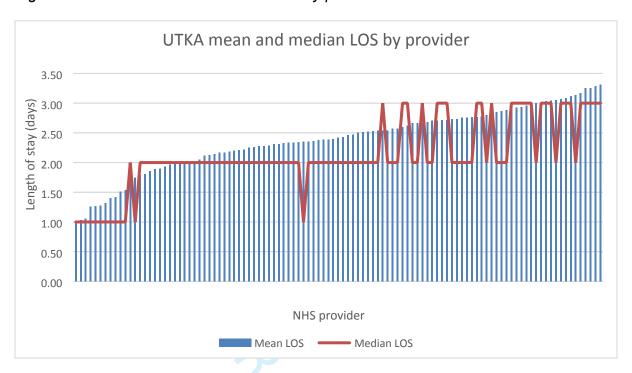


Figure 4 - Northumbria Healthcare NHS Foundation Trust

Percentage of THA and TKA patients discharged per post-operative day

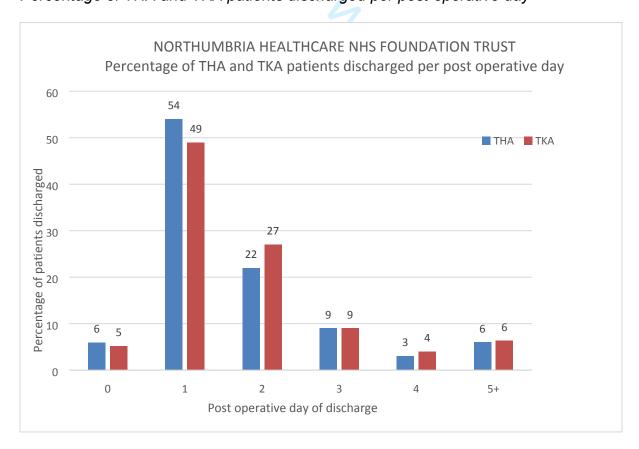
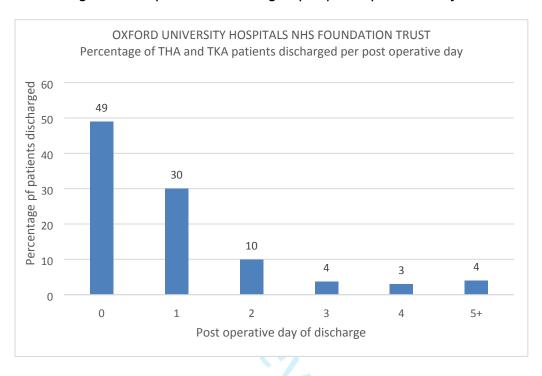


Figure 5 – Oxford University Hospitals NHS Foundation Trust

Percentage of UKA patients discharged per post-operative day



## **Tables**

## Table 1 – OPCS (4-char) procedure codes

Procedure	OPCS4 (4-char)			
	O 181 Primary hybrid prosthetic replacement of knee joint using cement			
	O189 Unspecified hybrid prosthetic replacement of knee joint using cement			
	W401 Primary total prosthetic replacement of knee joint using cement			
	W408 Other specified total prosthetic replacement of knee joint using cement			
	W409 Unspecified total prosthetic replacement of knee joint using cement			
TKA	W411 Primary total prosthetic replacement of knee joint not using cement			
TION	W418 Other specified total prosthetic replacement of knee joint not using cement			
	W419 Unspecified total prosthetic replacement of knee joint not using cement			
	W421 Primary total prosthetic replacement of knee joint NEC			
	W426 Arthrolysis of total prosthetic replacement of knee joint			
	W428 Other specified other total prosthetic replacement of knee joint			
	W429 Unspecified other total prosthetic replacement of knee joint			
	W521 Primary prosthetic replacement of articulation of bone using cement NEC			
	W523 Revision of prosthetic replacement of articulation of bone using cement NEC			
UTKA	W528 Other specified prosthetic replacement of articulation of other bone using cement			
UIM	W531 Primary prosthetic replacement of articulation of bone not using cement NEC			
	W541 Primary prosthetic replacement of articulation of bone NEC			
	W581 Primary resurfacing arthroplasty of joint			
	W371 Primary total prosthetic replacement of hip joint using cement			
	W378 Other specified total prosthetic replacement of hip joint using cement			
	W379 Unspecified total prosthetic replacement of hip joint using cement			
	W381 Primary total prosthetic replacement of hip joint not using cement			
	W388 Other specified total prosthetic replacement of hip joint not using cement			
	W389 Unspecified total prosthetic replacement of hip joint not using cement			
	W391 Primary total prosthetic replacement of hip joint NEC			
	W396 Closed reduction of dislocated total prosthetic replacement of hip joint			
THA	W398 Other specified other total prosthetic replacement of hip joint			
THA:	W399 Unspecified other total prosthetic replacement of hip joint			
	W581 Primary resurfacing arthroplasty of joint			
	W931 Primary hybrid prosthetic replacement of hip joint using cemented acetabular component			
	W941 Primary hybrid prosthetic replacement of hip joint using cemented femoral component			
	W948 Other specified hybrid prosthetic replacement of hip joint using cemented femoral component			
	W949 Unspecified hybrid prosthetic replacement of hip joint using cemented femoral component			
	W951 Primary hybrid prosthetic replacement of hip joint using cement NEC			
	W958 Other specified hybrid prosthetic replacement of hip joint using cement			

Table 2 – Outcome definitions

Definitions of outcomes (adapted from Dr Foster)
The total continuous stay of a patient using a hospital bed on premises controlled by a health care provider, during which
medical care is the responsibility of one or more consultants, or patients is receiving care under one or more nursing
episodes or midwife episodes on a ward.
A superspell is the collected term of all the related, or linked, spells for a single patient. A spell of care is the period of time a
patient spends within one hospital trust before being discharged. Spells of care are linked to superspells when:
They have the same patient ID, or HESID in HES years where this is available.
The discharge date of the first spell is within two days of the next spell.
Either the discharge destination of the first spell or the admission source of the next spell is in the range of 49 to 53
("NHS other hospital provider") or the admission method of the next spell is 81 ("Transfer of any admitted patient
from another hospital to provide other than in emergency")
Only valid spells (i.e. complete spells without severe data problems) can be linked into superspells. Anything with a spell
value of 0 or a quality value of above 200 will not be in a multiple-spell superspell.
For spells this is the number of midnights between the date of admission and the date of discharge.
A readmission is defined as being readmitted to an English trust as a non-elective emergency admission within a defined
period following discharge from the spinal spell in the superspell. Readmission is a superspell based analysis. The
Healthcare Intelligence Portal (HIP) benchmarks and monitors readmissions within 28 days of discharge, whilst the

	efficiency module within the HIP tool details volume and rate of readmission within 7, 14, 28 and 30 days of discharge. The
	benchmark is case-mix adjusted and based on the average readmission rate in England.
Crude rate	The crude rate is the number of new cases occurring in the population. It is calculated by: the numerator divided by the
	denominator, multiplied by 100.

Table 3 – Number and Percentage of patients discharged on each post-operative day

Procedure Total S				Number and Percentage of patients discharged on each post operative day											
	7-1-16	Mean	0 (da	ycase)	1	.00	0 2.00	2.00 3.00		.00 4		.00		5+	
	Procedure	Total Spells	LOS	Spells	Percentage of spells	Spells	Percentage of spells	Spells	Percentage of spells	Spells	Percentage of spells	Spells	Percentage of spells	Spells	Percentage of spells
TKA	79252.00	4.11	415.00	0.52	3140.00	3.96	19157.00	24.17	27819.00	35.10	12446.00	15.70	16275.00	20.54	
UTKA	9049.00	2.64	492.00	5.44	1634.00	18.06	3251.00	35.93	2442.00	26.99	734.00	8.11	496.00	5.48	
THA	74665.00	4.08	410.00	0.55	4125.00	5.52	22466.00	30.09	23764.00	31.83	10007.00	13.40	13893.00	18.61	

Table 4 – Number and Percentage of patients discharged on each post-operative day

		Readmissions								
ALL	Total Superspells	7 days	7-day rate (%)	14 days	14-day rate (%)	30 days	30-day rate (%)			
TKA	78943	1836	2.33	3063	3.88	4644	5.88			
UTKA	9005	139	1.54	205	2.28	307	3.41			
THA	74335	1587	2.13	2673	3.60	3919	5.27			



RECORD checklist (extended from the STROBE statement) for the manuscript "The current status of daycase hip and knee arthroplasty within the English National Health Service – A retrospective analysis of Hospital Episode Statistic data"

	Item No.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
Title and abstrac	ct				
	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced		RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included.	Title – line 2 Abstract – line 35
		summary of what was done and what was found	erien	RECORD 1.2: If applicable, the geographic region and timeframe within which the study took place should be reported in the title or abstract.	Title – line 3 Abstract – line 35 and line 38
			Ch	RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract.	N/A
Introduction					
Background rationale	2	Explain the scientific background and rationale for the investigation being reported			Lines 52-89
Objectives	3	State specific objectives, including any prespecified hypotheses			Lines 91-95
Methods					
Study Design	4	Present key elements of study design early in the paper			Lines 98-100
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection			Lines 98-123

Participants	6	(a) Cohort study - Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Case-control study - Give the eligibility criteria, and the		RECORD 6.1: The methods of study population selection (such as codes or algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided.	Lines 108-113 and Table 1
		sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> - Give the eligibility criteria, and the sources and methods of selection		RECORD 6.2: Any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and results should be provided.	Line 112 (to justify codes for UTKA)
		of participants  (b) Cohort study - For matched studies, give matching criteria and number of exposed and unexposed  Case-control study - For matched studies, give matching criteria and the number of controls per case	e Lieh	RECORD 6.3: If the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage.	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.		RECORD 7.1: A complete list of codes and algorithms used to classify exposures, outcomes, confounders, and effect modifiers should be provided. If these cannot be reported, an explanation should be provided.	Lines 115-123 and Table 2
Data sources/ measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement).  Describe comparability of assessment methods if there is more than one group			Lines 115-123 and Table 2

Bias	9	Describe any efforts to address potential sources of bias			N/A
Study size	10	Explain how the study size was arrived at			Lines 101-103
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why			N/A
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data	e Lieh		Lines 125-129
Data access and cleaning methods				RECORD 12.1: Authors should describe the extent to which the investigators had access to the database population used to create the study population.	Lines 104-106

Linkage				RECORD 12.2: Authors should provide information on the data cleaning methods used in the study.  RECORD 12.3: State whether the	Lines 105-106 N/A
				study included person-level, institutional-level, or other data linkage across two or more databases. The methods of linkage and methods of linkage quality evaluation should be provided.	
Results					
Participants	13	(a) Report the numbers of individuals at each stage of the study ( <i>e.g.</i> , numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed) (b) Give reasons for non-participation at each stage. (c) Consider use of a flow diagram	erien	RECORD 13.1: Describe in detail the selection of the persons included in the study ( <i>i.e.</i> , study population selection) including filtering based on data quality, data availability and linkage. The selection of included persons can be described in the text and/or by means of the study flow diagram.	Lines 100-114
Descriptive data	14	(a) Give characteristics of study participants ( <i>e.g.</i> , demographic, clinical, social) and information on exposures and potential confounders (b) Indicate the number of participants with missing data for each variable of interest (c) <i>Cohort study</i> - summarise follow-up time ( <i>e.g.</i> , average and total amount)			N/A
Outcome data	15	Cohort study - Report numbers of outcome events or summary measures over time  Case-control study - Report numbers in each exposure			Lines 135-141

		category, or summary measures of exposure			
		Cross-sectional study - Report			
		numbers of outcome events or			
		summary measures			
Main results	16	(a) Give unadjusted estimates and, if applicable, confounderadjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	OL;		N/A
Other analyses	17	Report other analyses done— e.g., analyses of subgroups and interactions, and sensitivity analyses	10/2		N/A
Discussion	<u>'</u>				
Key results	18	Summarise key results with reference to study objectives			158-166
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision.  Discuss both direction and magnitude of any potential bias		RECORD 19.1: Discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of misclassification bias, unmeasured confounding, missing data, and changing eligibility over time, as they pertain to the study being reported.	Lines 208-218
Interpretation	20	Give a cautious overall interpretation of results considering objectives,			Lines 221-229

		limitations, multiplicity of analyses, results from similar studies, and other relevant evidence			
Generalisability	21	Discuss the generalisability (external validity) of the study results			Discussion – first paragraph
Other Information					
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based			N/A
Accessibility of protocol, raw data, and programming code			0	RECORD 22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code.	N/A

<sup>\*</sup>Reference: Benchimol EI, Smeeth L, Guttmann A, Harron K, Moher D, Petersen I, Sørensen HT, von Elm E, Langan SM, the RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. *PLoS Medicine* 2015; in press.

<sup>\*</sup>Checklist is protected under Creative Commons Attribution (<u>CC BY</u>) license.