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A longitudinal study of use and cost of subacromial decompression surgery: the need for effective evaluation of surgical procedures to prevent overtreatment and wasted resources.

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6	3	effective evaluation of surgical procedures to prevent overtreatment and wasted resources.
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2 3 4	34	ABSTRACT
5	35	
7	36	Objectives: To illustrate the need for better evaluation of surgical procedures, we investigated the
8 9	37	use and cost of subacromial decompression in England over the last decade compared with other
10 11	38	countries and explored how this related to the conduct and outcomes of randomised, placebo-
12 13	39	controlled clinical trials.
14	40	Design: Longitudinal observational study using Hospital Episode Statistics linked to Payment by
16 17	41	Results tariffs in England, 2007/8-2016/17.
17	42	Setting: Hospital care in England, Finland, New York State USA, Florida State USA, and Western
20	43	Australia.
21 22 23	44	Participants: Patients with subacromial shoulder pain.
24 25	45	Interventions: Subacromial decompression.
26 27	46	Main outcome measures: National procedure rates, costs, and variation between clinical
28 29	47	commissioning groups (CCGs) in England.
30 31	48	Results: Without robust clinical evidence, the use of subacromial decompression in England
32 33	49	increased by 91% from 15,112 procedures (30 per 100,000 population) in 2007/8, to 28,802
34 35	50	procedures (52 per 100,000 population) in 2016/17, costing over £125 million per year. Rates of use
36 37 38	51	of subacromial decompression are even higher internationally: Finland (131 per 100,000 in 2011),
39 40	52	Florida State (130 per 100,000 in 2007), Western Australia (115 per 100,000 in 2013), and New York
41 42	53	State (102 per 100,000 in 2006). Two randomised trials have recently (2018) shown the procedure to
43 44	54	be no more effective than placebo or conservative approaches. Health systems appear unable to
45 46 47	55	avoid the rapid widespread use of procedures of unknown effectiveness, and methods for ceasing
47 48 49	56	ineffective treatments are under-developed.
50 51	57	Conclusions: Without good evidence, nearly 30,000 subacromial decompression procedures have
52 53	58	been commissioned each year in England, costing over £1 billion since 2007/8. Even higher rates of
54 55	59	procedures are carried out in countries with less regulated health systems. Randomised trials need
57 58 59 60	60	to be initiated before widespread adoption of promising operative procedures to avoid over-

61	treatment and wasted resources, and methods to prevent or desist the use of ineffective procedure
62	need to be expedited.

ARTICLE SUMMARY

Strengths and Limitations of this Study

9		
10	65	 Our study used a national, longitudinal dataset over a 10-year period covering all NHS
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12	66	secondary care providers in England, and private provision for NHS-funded patients.
13		
14	67	• Hospital Episode Statistics are linked to hospital payments, which is a strong incentive to
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16	68	provide complete data, and allowed us to explore costs of subacromial decompression in
17	00	provide complete data, and anowed us to explore costs of subactornial decomplession in
18	60	Factored
19	69	England.
20		
21	70	 We provide international comparisons of the use of subacromial decompression surgery.
22		
23	71	 Our data are from 2007/08 onwards, so we under-estimate the amount spent on
24 25		
25	72	subacromial decompression prior to publication of major clinical trial results (CSAW and
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27 20	73	ΕΙΜΡΔ(Τ)
20	/5	Thui Act J.
30	74	There may be additional factors influencing surgery rates which we have not controlled for
31	74	There may be additional factors influencing surgery rates which we have not controlled for
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33	75	(e.g. private health insurance coverage).
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76 INTRODUCTION

Health and social care services are 'straining at the seams' following increasing demand for services
from an ageing population with more complex needs.¹ In England, over 200 Clinical Commissioning
Groups (CCGs) have a budget to purchase health services for their local populations.² Hospital care
currently accounts for 48.5% (£74 billion) of government health expenditure in the UK.³ It is vital that
commissioners make evidence-based decisions to maximise the effectiveness of this hospital care
budget to benefit the overall health of the population.

Medicines must be licensed for use for a particular condition, requiring pharmaceutical companies to provide evidence of effectiveness from clinical trials to relevant agencies such as the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK,⁴ European Medicines Agency (EMA) in the EU, or the Food and Drug Administration (FDA) in the United States.⁵ In the UK, the National Institute for Health and Care Excellence (NICE) also evaluates the cost-effectiveness of many medicines and does not recommend those which do not provide value. These regulatory processes have their limitations,⁶ but require robust evidence for the introduction of new treatments. The quality of evidence required to introduce new surgical procedures is not as strict as for medicines,⁴⁵ in part because no specific product such as a drug or device is involved; it can be difficult to categorise procedures as 'new' rather than modifications; and outcomes may depend on the skill of the practitioner as well as the procedure itself.⁴ Once introduced, use of procedures can spread by clinical consensus,⁵ and established practice and clinical evidence often take many years to be updated.78

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96 NHS England has recently commissioned a consultation regarding the use of 17 hospital procedures,⁹
97 one of which is subacromial decompression for shoulder pain. Shoulder pain is common, with a
98 lifetime prevalence of up to 66.7% ¹⁰. Most of these cases (up to 70%) are related to rotator cuff
99 tears or subacromial pain.¹¹ Subacromial pain is often considered to be caused by bony 'spurs'
100 forming on the acromion, part of the shoulder blade, leading to inflammation in the surrounding

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bursa and tendons.^{12 13} Subacromial decompression removes the bony spur on the acromion and releases the coracohumeral ligament.^{13 14} There has been a rapidly increasing use of subacromial decompression in England, with over 21,000 procedures carried out in 2009/10.13 Two recent multi-centre randomised controlled trials (RCTs) have guestioned the effectiveness of subacromial decompression for shoulder pain.^{15 16} The CSAW trial,^{12 15} recruiting in England from 2012 to 2015, compared arthroscopic subacromial decompression surgery, placebo (investigational shoulder arthroscopy), and no treatment.¹⁵ It found no difference in shoulder function after six months between the arthroscopic subacromial decompression group and the arthroscopy only (placebo) group, with a small, non-clinically significant benefit of surgery over the no treatment control. The FIMPACT trial,¹⁶ recruiting in Finland from 2005 to 2013, compared subacromial decompression with placebo surgery and exercise therapy and echoed the results of CSAW, extending them to two years follow-up. The CSAW and FIMPACT trials seriously question whether the resources invested in subacromial decompression represent good value for money for the NHS. As a result, a recent BMJ article made a strong recommendation against subacromial decompression surgery for chronic shoulder pain.¹⁷ In this study we use subacromial decompression for shoulder pain as an example to explore the relationship between evolving evidence and clinical practice for hospital procedures, including how many procedures were performed over the last 10 years and how much money was spent before RCT evidence raised questions about the procedure's value; how procedure rates compare to other countries; and how the NHS might reduce the numbers of these procedures.

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2 3 4	125	METHODS
5 6 7 8	126	Data sources
9 10	127	Subacromial decompression procedures were identified using the 'admitted patient care' hospital
11 12 13	128	episode statistics (HES-APC). HES is a routinely collected dataset that records all episodes of care
14 15	129	provided to patients admitted (day case or inpatient) to NHS hospitals in England and NHS-funded
16 17	130	patients treated in the independent sector. ^{18 19} Each episode in HES represents a period of care
18 19 20	131	under one consultant team. Up to 20 diagnoses are recorded per episode using the International
20 21 22	132	Classification of Diseases (ICD) version 10. Up to 24 clinical procedures per episode may be recorded
23 24	133	using Office of Population, Censuses and Surveys (OPCS) (fourth revision) codes. HES also includes
25 26	134	the Lower Super Output Area (LSOA) of residence for each patient. ²⁰
27 28 29 30	135	Identifying subacromial decompression
31 32	136	We extracted anonymised, individual episodes in the HES-APC (2007/8 to 2016/17) dataset. We used
33 34 35	137	diagnosis and procedure codes ¹³ (Figure 1) to identify subacromial decompression. A small number
36 37	138	of patients received multiple shoulder procedure episodes on the same day (0.3% of all episodes).
38 39	139	When these were for the same procedure with the same laterality (0.25% of all episodes), we
40 41 42	140	assumed coding error duplication so excluded the episodes. If a procedure was marked as bilateral
42 43 44	141	(0.6%), this was counted as two procedures. We excluded patients who were not resident in
45 46	142	England.
47 48 49 50	143	Estimating procedure rates
51 52	144	National trends over time were estimated using directly standardised procedure rates ²¹ (per
53 54 55	145	100,000 population), with the population of England in 2016 as our standard population. For
56 57 58 59 60	146	comparison of smaller areas, we estimated indirectly standardised rates ²² per 100,000 population,

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147	using the same standard population, and adjusting for deprivation and ethnicity (see Appendix A for
148	more details).
149	Estimating procedure costs
150	Costs were estimated for each financial year by linking Healthcare Resource Group (HRG) codes for
151	each admission in HES with the Department of Health Payment by Results National Tariffs for the
152	appropriate financial year; ²³⁻³² see Appendix A for more details.
153	International comparisons
154	A search of Medline and the Cumulative Index of Nursing and Allied Health (CINAHL) databases was
155	conducted for the terms "acromioplasty" or "subacromial decompression" in conjunction with
156	"incidence" or "prevalence" or "epidemiology". One author (TJ) screened the results for articles
157	including rates of subacromial decompression contemporary with our data, and further screened
158	cited articles within included studies, as well as articles which cited included studies.
159	All statistical analyses were conducted using Stata/MP 14.2 for Windows and we mapped variation
160	in procedure rates across England in 2016/17 using ArcGIS ArcMap 10.5.1 for Desktop.
161	Patient and public involvement
162	Patients involved in the CSAW trial reviewed this manuscript; they were interested by the results
163	and the cost-focussed perspective.
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1 2 3	168	RESULTS			
4 5					
6 7 8	169	The use of subacromial deco	mpression in Engla	nd	
9 10 11	170	There were 15,112 subacrom	ial decompression	procedures (30 per	100,000 population) in 2007/8,
12 13	171	rising to 28,802 procedures (52 per 100,000 pop	ulation) in 2016/17	(Figure 2), excluding those done
14 15	172	in combination with rotator c	uff repair. This rep	resents a 91% incre	ase in the number of subacromial
16 17	173	decompressions over 10 year	s, with 266,692 pro	ocedures carried ou	t in total. Most of this increase
18 19 20	174	took place before 2011/12, a	nd procedure rates	have slightly decre	ased between 2011/12 and
20 21 22	175	2016/17. The use of subacror	nial decompressior	in combination wi	th rotator cuff repair has
23 24	176	continued to increase since the	ne early 2000s, moi	re notably from 200	6/7 onwards. Whilst the gender
25 26	177	balance and age of those having shoulder surgery have remained steady over the last decade, the			
27 28	178	proportion of procedures conducted as day cases, using arthroscopy, and/or by independent (i.e.			
29 30 21	179	non-NHS) providers, have all increased (Table 1).			
32 33	180				
34	181	Table 1: Descriptive informat	ion for subacromial	decompression pa	tients. 2007/08 and 2016/17
35 36			2007/08	2016/17	,
37		Procedure Count	15,112	28,802	
38		%women	51.0	52.0	
39		Age in vears (SD)	54.94 (12.55)	54.89 (12.39)	
40 41		% Arthroscopy	39.0	94.1	
42		% Independent Providers	2.4	31.9	
43		% Day-case	51.0	79.3	
44	182		51.0	/ 5.5	
45	183				
46	105				
47 48 49 50	184	The cost of subacromial deco	ompression in Engla	and	
50 51 52	185	In 2016/17, the median cost of an elective admission for subacromial decompression alone was			
53 54	186	£4,476. The cost of subacromial decompression in England rose from £33 million in 2007/08 to £125			
55 56	187	million in 2016/17. Over the 2	10-year period betv	veen 2007/8 and 20	016/17 just under £1.1 billion was
 57 58 188 spent on subacromial decompression (excluding procedures 				procedures done in	n combination with rotator cuff
60	189	repair).			

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190	Variation in use of subacromia	I decompression i	in England
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191	In 2016/17 there was substantial variation in procedure rates between CCGs, after adjusting for age
192	sex, deprivation, and ethnicity profiles (Figure 3). The map demonstrates pockets of very high use
193	(>150% of the expected rate), for example in the Reading area, Wiltshire, and East Lincolnshire.
194	There were also areas where procedure rates were less than 50% of the expected rate, such as in
195	Worcestershire, Gloucestershire, Swindon, and North Norfolk. In 2016/17 the ratio of procedure
196	rates between a 'high use' CCG at the 90 th percentile and a 'low use' CCG at the 10 th percentile was
197	2.7 (95% CI: 2.2-3.4). This ratio has decreased since 2007/8, when the ratio was 3.6 (95% CI: 2.2-
198	6.1); see Table 2.

Table 2: 90/10 percentile ratios for directly age-sex standardised rates of subacromial
 decompression by CCG, England, 2007/8-2016/17

		10th	90/10 Ratio (95%
Year	90th Pct	Pct	CI*)
2007/08	53	15	3.6 (2.2-6.1)
2008/09	55	16	3.3 (2.1-5.2)
2009/10	72	27	2.6 (2.0-3.5)
2010/11	87	33	2.6 (1.9-3.6)
2011/12	89	36	2.5 (2.0-3.1)
2012/13	90	33	2.7 (2.0-3.7)
2013/14	88	34	2.6 (2.1-3.3)
2014/15	89	33	2.7 (2.0-3.7)
2015/16	81	33	2.5 (1.4-4.3)
2016/17	83	30	2.7 (2.2-3.4)

203 International comparison of rates of subacromial decompression

Table 3 shows rates of subacromial decompression in the most recent year available from England,
Finland, Florida State, New York State, and Western Australia. Rates in England were lower, often
only half, that of other countries. For subacromial decompression alone, the procedure rates were
lower in England (52 per 100,000 in 2016/17) than Western Australia (roughly 115 per 100,000 in
2013),³⁴ Florida State (130 per 100,000 in 2007),³⁵ and Finland (131 per 100,000 in 2011).³⁶

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09 For subacromial decompression combined with rotator cuff repair, rates were lower in England (80 10 per 100,000 in 2016/17) than in New York State a decade earlier (102 per 100,000 in 2006).³⁷ Figure 2 compares trends in rates of subacromial decompression in England, Finland, Florida State, 11 12 New York State, and Western Australia. The rate of increase for subacromial decompression 13 observed in our study (x2 between 2007/8 and 2016/17) was similar to Western Australia (x2 14 between 2001 and 2013),³⁴ Finland (x2.2 between 1998 and 2007),³⁶ and New York State (x2.5 between 1996 and 2006),³⁷ but lower than Florida State (x4.4 between 2003 and 2007).³⁵ The use of 15 subacromial decompression in Finland peaked in 2007 and has since been declining, at least in 16 17 publicly-funded hospitals, which has been attributed to accumulating evidence that it is no more

218 clinically effective than non-surgical alternatives.³⁶

219 Table 3: International comparisons of age-sex-standardised rates of subacromial decompression

	Article	Country	Data Year	SAD Rate (per 100,000 population)
	Thorpe et al. (2016)	Western Australia	2013	~115
	Paloneva et al. (2015)	Finland	2011	131
	Vitale et al. (2010)	New York State	2006	102
	lyengar et al. (2014)	Florida State	2007	~130
	Our Data (inc. RCR)	England	2016/17	80
	Our Data (exc. RCR)	England	2016/17	52
220	Notes: Numbers for Thorp	e et al (2016) and lyeng	ar et al. (202	14) were estimated from
221	York State data is for sub	acromial decompression	with/withou	ut rotator cuff repair; SA
222	Subacromial Decompressi	ion; RCR = Rotator Cuff I	Repair ³⁴⁻³⁷	
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DISCUSSION

Statement of principal findings

NHS England carries out nearly 30,000 subacromial decompression operations per year, at an annual cost of over £125 million. Between 2007/08 and 2016/17, 266,692 subacromial decompression procedures were carried out in England costing nearly £1.1 billion, before the publication of CSAW and FIMPACT trial results prompted questions about the clinical benefit of the procedure. Rates of subacromial decompression alone in England have gradually declined since 2011/12, although an increasing number are carried out in combination with rotator cuff repair. There was large variation between CCGs in England, even after adjustment for demographic variables, with 'high-use' areas carrying out nearly three times as many procedures as 'low-use' areas. Procedure rates in England were notably lower than other countries, arguing against any levelling of procedure rates being due to saturation of 'demand' for shoulder surgery.

Strengths and weaknesses of the study

Our study used a national, longitudinal dataset over a 10-year period covering all NHS secondary care providers in England. Hospital Episode Statistics are administrative rather than specifically designed for research. However, HES is also linked to payments for hospitals, which is a strong incentive to provide complete data, and allowed us to produce what we believe is the first exploration of costs associated with subacromial decompression in England. Payment by results tariffs are based on average national costs and may not reflect precise costs for each hospital admission. Population denominators, and linkage to the indices of multiple deprivation and census ethnicity data, allowed us to investigate trends and variations in procedure rates standardised on age, sex, deprivation and ethnicity. HES data records patients' area of residence, so we compared procedure rates based on place of residence rather than place of treatment. There may be other factors influencing rates which we have not controlled for (e.g. private health insurance coverage).

HES does not record procedures which are privately funded and provided, meaning our surgery rates are an under-estimate of the population rate. We only provide cost data from 2007/08 onwards, so we under-estimate the amount spent on subacromial decompression prior to publication of the CSAW and FIMPACT trial results. International estimations of procedure rates do not use identical definitions of procedures and inclusion/exclusion criteria, but should be broadly comparable. Implications for policymakers and clinicians NHS England spent over £1 billion on subacromial decompression during the last 10 years without having compelling evidence of clinical effectiveness or cost-effectiveness. Rates of subacromial decompression were already rising rapidly from 2000/01 onwards.¹³ It seems plausible that increasing awareness of concerns about the effectiveness of subacromial decompression surgery and well-known recruitment to the CSAW trial tempered the rise in use of this surgery in England, otherwise more may have been spent. The CSAW trial involved 51 surgeons in 30 centres throughout the UK and was widely advertised and discussed amongst shoulder surgeons and shoulder physiotherapists. Extensive consultation was carried out by the trial team prior to and during the trial, including presentations at national meetings surveys and visits to individual surgeons and centres.³⁸ A similar plateau/decrease in procedures was observed in Finland after the commencement of the FIMPACT study in 2005 which involved only 3 centres in Finland (Figure 2). However, it took well over a decade of increasing subacromial decompression use for clinical trial groups to randomise a few hundred patients (313 patients for CSAW ¹⁵ and 210 in FIMPACT¹⁶) to investigate its effectiveness. This delay may be due to perceived difficulties in recruiting patients to surgical trials with non-surgical comparators (e.g. UKUFF³⁹), as well as known challenges of conducting surgical RCTs.⁴⁰ Methods to optimise recruitment, as used in CSAW and other trials,⁴¹ are

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276 rapidly initiating trials to provide robust evidence about surgical interventions before they become

available to support the completion of such 'difficult' trials;⁴² this should not now be a barrier to

59 277 widespread. More time is needed to see the longer-term impact of publication of the CSAW and

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FIMPACT results on subacromial decompression rates, both in the UK and internationally. It is also
 worth noting the increasing tendency in England to carry out subacromial decompression in
 combination with rotator cuff repair, and any impact on this following dissemination of the
 CSAW/FIMPACT results.

The National Institute for Health and Care Excellence (NICE) requires evidence of cost-effectiveness
to recommend new medicines to be paid for by the NHS. It is unclear why the bar for introducing
expensive surgical procedures should be significantly lower. A balance needs to be struck between
supporting innovation in surgical procedures and preventing unnecessary treatment. New initiatives
such as IDEAL (Idea, Development, Exploration, Assessment, Long-term Follow-up, Improving the
Quality of Research in Surgery)⁴³ aim to provide such a regulatory framework for introducing new
interventions.

It is important that new evidence is disseminated quickly without causing inequities in access to care. NICE published an updated Clinical Knowledge Summary for shoulder pain in April 2017⁴⁴ incorporating information from a commissioning guide published by the Royal College of Surgeons.⁴⁵ This recommended a range of conservative treatments from physiotherapy to corticosteroid injections, before surgery. However, many CCGs introduced their own criteria-based policies for access to shoulder surgery (e.g. through Individual Funding Requests)⁴⁶ at different times and with different details, underlining the extent to which insufficient evidence may drive clinical and commissioner uncertainty,⁴⁷ and possibly leading to the wide variations shown across CCGs in our data. Where scientific evidence is applicable nationally or internationally, it would seem more efficient and appropriate to apply national policies to inform optimal use and encourage further research. There is a need to improve techniques for empirically-informed policy development in collaboration with relevant stakeholders.^{48 49} It is also important to note that certain patients may still benefit from surgery. Further well conducted research is needed to understand if specific sub-groups of patients might benefit from subacromial decompression surgery.

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303 Despite the criticisms provided above, England has lower rates of shoulder surgery than other 304 countries. The reasons for this are uncertain but could be due to differences in the health systems 305 (e.g. GP gatekeeping of services), access to surgery and hospital reimbursement. Additionally, the 306 National Institute of Health Research in England has funded major clinical trials on shoulder surgery,^{15 39} as well as other procedures;^{50 51} and is about to fund a further clinical trial to compare 307 308 surgery with placebo surgery for partial thickness rotator cuff tears.⁵² Whilst the UK's national 309 regulatory processes are imperfect, they may provide examples to learn from. However, these 310 processes did not sufficiently constrain the use of subacromial decompression, a procedure later 311 found to have little clinical benefit.

312 There have been several other controversies regarding the lack of effectiveness of procedures which 313 have become commonplace. One example is the use of stents to open narrowed arteries for 314 treatment of stable angina (chest pain). Around half a million people receive stents for stable angina each year in the US and Europe,⁵³ but a recent (RCT) including a placebo intervention found no 315 difference in chest pain outcomes between inserting a stent and using standard medications.⁵⁴ 316 317 Another example is arthroscopy to clean out the knee joint, on which around \$4 billion is spent each 318 year in the US.⁵⁵ Recent RCTs,^{56 57} including one using a placebo procedure as a comparison,⁵⁷ found 319 no evidence of effectiveness to justify the spending. Whilst we use subacromial decompression as an 320 example in this study, our observations are likely to apply to interventional procedures more 321 generally.

322 Unanswered questions and future research

323 The example of subacromial decompression highlights that, in the absence of rigorous evaluation, 324 costly interventions can proliferate over a long period of time. To maximise limited resources, it is 325 vital that methods are developed to identify promising procedures early and commission trials to examine their value, as well as identify existing health technologies that may be ineffective, leading 326 to over-treatment and wasting of resources. 327

There is an opportunity for a natural experiment exploring the impact of the results of the CSAW and FIMPACT trials^{15 16} on the development of CCG policies, national guidelines, and clinical decision-making with surgeons and patients. It is arguable that we should now see swift reductions in the use of subacromial decompression; research studies could help enhance the transfer of knowledge from trials into clinical practice.

Conclusions

18 19	334	NHS England pays for nearly 30,000 shoulder subacromial decompression procedures each year at
20 21 22	335	an annual cost of over £125 million, with little evidence that they are effective or cost-effective. The
23 24	336	rates of this operation in other countries are even higher. This raises serious questions around the
25 26	337	regulatory and professional processes governing the adoption and widespread use of surgical
27 28 20	338	interventions. High quality RCTs should be funded early to examine the effectiveness and cost-
29 30 31	339	effectiveness of expensive procedures using methods to optimise recruitment, and robust processes
32 33 34	340	should be developed to reduce the use of ineffective procedures.
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350 **Author Statement**

	352	contributed to study design, data cleaning, data analysis, interpretation of results and writing the
) 1	353	manuscript. MJL contributed to study design, data cleaning, interpretation of results and writing the
2 3 4	354	manuscript. AC contributed to study design, interpretation of results and writing the manuscript. DB,
5	355	LR, and JD contributed to interpretation of results and writing the manuscript. WH contributed to
7 8	356	study conceptualization, study design, interpretation of results and writing the manuscript. TJ had
9	357	full access to the data in the study and takes responsibility for the integrity of the data and the
1 2 2	358	accuracy of the data analysis. The authors would like to thank two patients from the CSAW trial,
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4 5	363	this article are those of the author(s) and not necessarily those of the NHS, the NIHR, or the
5 7	364	Department of Health and Social Care.
9 0 1	365	Ethnical Approval
2 3	366	We were provided with routinely-collected Hospital Episode Statistics data under licence from NHS
4 5	367	Digital (DARS-NIC-17875-X7K1V). The licence allows us to use the information under Section 261 of
5 7 8	368	the Health and Social Care Act 2012, 2(b)(ii): "after taking into account the public interest as well as
9 0	369	the interests of the relevant person, considers that it is appropriate for the information to be
1 2	370	disseminated".
3 4 5 5	371	Data Sharing
7 8	372	This study is based in part on data from the Hospital Episode Statistics (HES) obtained under licence
9 0	373	(DARS-NIC-17875-X7K1V) from NHS Digital (previously the Health and Social Care Information
		17

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374	Centre); Copyright © 2018, re-used with the permission of The Health & Social Care Information
375	Centre. All rights reserved. The data are provided by patients and collected by the NHS as part of
376	their care and support. HES data can be accessed via NHS Digital:
377	https://digital.nhs.uk/services/data-access-request-service-dars
378	Transparency
379	The manuscript's guarantor (TJ) affirms that the manuscript is an honest, accurate, and transparent
380	account of the study being reported; that no important aspects of the study have been omitted; and
381	that any discrepancies from the study as originally planned have been explained.
382	Competing Interests
383	All authors have completed the ICMJE uniform disclosure form at www.icmje.org/ coi_disclosure.pdf
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386	the previous three years; no other relationships or activities that could appear to have influenced
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FIGURE CAPTIONS

Figure 1. ICD-10 and OPCS-4 codes used to define subacromial decompression¹³

Figure 2. Directly standardised rates (per 100,000 people) of subacromial decompression in England, Finland, New York State USA, Florida State USA, and Western Australia

Notes for Figure 2. England data prior to 2007 is taken from Judge et al.¹³; New York State data is for subacromial decompression with or without rotator cuff repair, whilst data for Florida State, Finland and Western Australia is for subacromial decompression alone ³⁴⁻³⁷; RCR = Rotator Cuff Repair

Figure 3. Indirectly standardised rates of subacromial decompression by CCG in England, 2016/17

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Any of these diagnosis codes		Any of these procedure
in any position	In combination with	codes in any position
		W84.8 Other specified
M75.1 Rotator cuff		therapeutic endoscopic
syndrome		operations on other joint
		structure
M7E 2 Calaifia tandinitia af		Y52.8 Other specified
WI75.3 Calcific tendinitis of		approach to organ through
shoulder		other opening
M75.4 Impingement		Y76.7 Arthroscopic approach
syndrome of shoulder		to joint
		W84.4 Endoscopic
W1/5.5 Bursitis of shoulder		decompression of joint

OR

This procedure code in any
position
O29.1 Subacromial
decompression

Figure 1. ICD-10 and OPCS-4 codes used to define subacromial decompression¹³

102x65mm (300 x 300 DPI)





Notes for Figure 2. England data prior to 2007 is taken from Judge et al.¹³; New York State data is for subacromial decompression with or without rotator cuff repair, whilst data for Florida State, Finland and Western Australia is for subacromial decompression alone ³⁴⁻³⁷; RCR = Rotator Cuff Repair

150x99mm (300 x 300 DPI)

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APPENDIX A: METHODOLOGICAL DETAILS

Estimating Procedure Rates

National trends over time were estimated using directly standardised procedure rates(1) (per 100,000 population), with the population of England in 2016 as our standard population. We first summed the number of shoulder procedures, grouped by sex, quintiles of age, and financial year. These procedure counts were used to calculate annual age-sex-specific rates, by dividing by the appropriate age-sex-specific mid-year populations of England(2) (e.g. for the 2012/13 financial year, the mid-2012 populations were used). We weighted the annual age-sex-specific rates according to the population distribution of England in 2016, to produce directly standardised rates for each year. The standardised rates for 2016/17 are the same as the crude rates.

For comparison of smaller areas, we estimated indirectly standardised rates(3) per 100,000 population. We first calculated age-sex-specific rates for England in 2016/17, then multiplied these rates by the age-sex-specific population for the area of interest(2, 4, 5) (e.g. CCG) and summed the results. This produced the expected number of patients and procedures for that area, if it were to have the same age-sex-specific rates as England. The expected number was then compared to the observed number of patients and procedures for that area. A Poisson regression model was fitted to the observed counts for each year, with the expected counts as an offset and socio-economic deprivation (using the overall score from the English Indices of Multiple Deprivation(6)) and ethnicity (% white British(7)) as predictive factors. The model was then used to predict new expected counts for each area based on deprivation and ethnicity, and form indirectly standardised procedure ratios (observed / expected).

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Estimating Procedure Costs

Costs were estimated for each financial year by linking HRG codes for each admission in HES with the Department of Health Payment by Results National Tariffs for the appropriate financial year.(8-17) Enhanced Tariff Option (ETO) tariffs were applied for 2015/16 as, following a dispute, 88% of providers agreed to use ETO tariffs for that financial year.(18) The National Tariffs provide costs for day cases and longer stays, for both elective and non-elective admissions. They also provide additional daily costs for admissions that go above a threshold number of days (termed excess bed days), which varies for different types of admission. To calculate the cost of admission, we excluded admissions without a discharge date (used to calculate number of bed days) or without a HRG code that matched to the National Tariffs (0.7% excluded). We then applied the relevant national tariff or alternatively the best practice tariff where applicable (only for HRG code HB62C under specified circumstances) and added excess bed day costs (if there were any). Following this, the special service top-up for orthopaedic procedures was applied for each year.

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A longitudinal study of use and cost of subacromial decompression surgery: the need for effective evaluation of surgical procedures to prevent overtreatment and wasted resources.

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Keywords:	subacromial decompression, shoulder surgery, England, commissioning, arthroscopy

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6 7	3	effective evaluation of surgical procedures to prevent overtreatment and wasted resources.
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9 10	F	Authors, Tim Jonos 12 Androw Carr ³ , David Board ³ , Mules Jay Linton 12, Joila Booshonas ² , Jonny J
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2 3	21	ABSTRACT
4	54	ADSTRACT
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7	36	Objectives: To illustrate the need for better evaluation of surgical procedures, we investigated the
8 9	37	use and cost of subacromial decompression in England over the last decade compared with other
10 11	38	countries and explored how this related to the conduct and outcomes of randomised, placebo-
12 13	39	controlled clinical trials.
14 15	40	Design: Longitudinal observational study using Hospital Episode Statistics linked to Payment by
16 17	41	Results tariffs in England, 2007/8-2016/17.
17 18 19	42	Setting: Hospital care in England, Finland, New York State USA, Florida State USA, and Western
20 21	43	Australia.
22	44	Participants: Patients with subacromial shoulder pain.
23 24 25	45	Interventions: Subacromial decompression.
26 27	46	Main outcome measures: National procedure rates, costs, and variation between clinical
27 28 29	47	commissioning groups (CCGs) in England.
30 31	48	Results: Without robust clinical evidence, the use of subacromial decompression in England
32 33	49	increased by 91% from 15,112 procedures (30 per 100,000 population) in 2007/8, to 28,802
34 35	50	procedures (52 per 100,000 population) in 2016/17, costing over £125 million per year. Rates of use
36 37 20	51	of subacromial decompression are even higher internationally: Finland (131 per 100,000 in 2011),
38 39 40	52	Florida State (130 per 100,000 in 2007), Western Australia (115 per 100,000 in 2013), and New York
41 42	53	State (102 per 100,000 in 2006). Two randomised placebo-controlled trials have recently (2018)
43 44	54	shown the procedure to be no more effective than placebo or conservative approaches. Health
45 46	55	systems appear unable to avoid the rapid widespread use of procedures of unknown effectiveness,
47 48 49	56	and methods for ceasing ineffective treatments are under-developed.
50 51	57	Conclusions: Without good evidence, nearly 30,000 subacromial decompression procedures have
52 53	58	been commissioned each year in England, costing over £1 billion since 2007/8. Even higher rates of
54 55	59	procedures are carried out in countries with less regulated health systems. High quality randomised
50 57 58 59 60	60	trials need to be initiated before widespread adoption of promising operative procedures to avoid

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2 3	61	over treatment and wasted resources, and methods to prevent or desist the use of ineffective
4	01	over-treatment and wasted resources, and methods to prevent or desist the use of menective
5 6	62	procedures need to be expedited.
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ARTICLE SUMMARY

Strengths and Limitations of this Study

9		
10	65	• Our study used a national, longitudinal dataset over a 10-year period covering all NHS
11 12 13	66	secondary care providers in England, and private provision for NHS-funded patients.
14 15	67	Hospital Episode Statistics are linked to hospital payments, which is a strong incentive to
16 17	68	provide complete data, and allowed us to explore costs of subacromial decompression in
18 19 20	69	England.
20 21 22	70	• We provide international comparisons of the use of subacromial decompression surgery.
23 24	71	• Our data are from 2007/08 onwards, so we under-estimate the amount spent on
25 26	72	subacromial decompression prior to publication of major clinical trial results (CSAW and
27 28 29	73	FIMPACT).
30 31	74	• There may be additional factors influencing surgery rates which we have not controlled for
32 33	75	(e.g. private health insurance coverage).
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76 INTRODUCTION

Health and social care services are 'straining at the seams' following increasing demand for services
from an ageing population with more complex needs.¹ In England, over 200 Clinical Commissioning
Groups (CCGs) have a budget to purchase health services for their local populations.² Hospital care
currently accounts for 48.5% (£74 billion) of government health expenditure in the UK.³ It is vital that
commissioners make evidence-based decisions to maximise the effectiveness of this hospital care
budget to benefit the overall health of the population.

Medicines must be licensed for use for a particular condition, requiring pharmaceutical companies to provide evidence of effectiveness from clinical trials to relevant agencies such as the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK,⁴ European Medicines Agency (EMA) in the EU, or the Food and Drug Administration (FDA) in the United States.⁵ In the UK, the National Institute for Health and Care Excellence (NICE) also evaluates the cost-effectiveness of many medicines and does not recommend those which do not provide value. These regulatory processes have their limitations,⁶ but require robust evidence for the introduction of new treatments. The quality of evidence required to introduce new surgical procedures is not as strict as for medicines,⁴⁵ in part because no specific product such as a drug or device is involved; it can be difficult to categorise procedures as 'new' rather than modifications; and outcomes may depend on the skill of the practitioner as well as the procedure itself.⁴ Once introduced, use of procedures can spread by clinical consensus,⁵ and established practice and clinical evidence often take many years to be updated.78

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96 NHS England has recently commissioned a consultation regarding the use of 17 hospital procedures,⁹
97 one of which is subacromial decompression for shoulder pain. Shoulder pain is common, with a
98 lifetime prevalence of up to 66.7% ¹⁰. Most of these cases (up to 70%) are related to rotator cuff
99 tears or subacromial pain.¹¹ Subacromial pain is often considered to be caused by bony 'spurs'
100 forming on the acromion, part of the shoulder blade, leading to inflammation in the surrounding

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3 4	101	bursa and tendons. ^{12 13} Subacromial decompression removes the bony spur on the acromion and
5 6	102	releases the coracohumeral ligament. ^{13 14} There has been a rapidly increasing use of subacromial
7 8 9	103	decompression in England, with over 21,000 procedures carried out in 2009/10.13
10 11 12	104	Several randomised controlled trials (RCTs) since the early 1990s have compared subacromial
13 14	105	decompression to non-operative treatment (e.g. exercise) for shoulder pain and found no evidence
15 16	106	of effectiveness. ¹⁵⁻¹⁷ Two recent multi-centre RCTs including a placebo surgery arm have further
17 18 19	107	questioned the effectiveness of subacromial decompression for shoulder pain. ^{18 19} The CSAW trial, ¹²
20 21	108	¹⁸ recruiting in England from 2012 to 2015, compared arthroscopic subacromial decompression
22 23	109	surgery, placebo (investigational shoulder arthroscopy), and no treatment. ¹⁸ It found no difference
24 25	110	in shoulder function after six months between the arthroscopic subacromial decompression group
26 27	111	and the arthroscopy only (placebo) group, with a small, non-clinically significant benefit of surgery
28 29 30	112	over the no treatment control. The FIMPACT trial, ¹⁹ recruiting in Finland from 2005 to 2013,
31 32	113	compared subacromial decompression with placebo surgery and exercise therapy and echoed the
33 34	114	results of CSAW, extending them to two years follow-up. A recent Cochrane review including CSAW,
35 36	115	FIMPACT, and earlier RCTs, found high-certainty evidence that subacromial decompression does not
37 38 30	116	improve pain, function, or health-related quality of life. ²⁰ This seriously questions whether the
39 40 41	117	resources invested in subacromial decompression represent good value for money for the NHS. As a
42 43	118	result, a recent BMJ article made a strong recommendation against subacromial decompression
44 45	119	surgery for chronic shoulder pain. ²¹
46 47 48	120	In this study we use subacromial decompression for shoulder pain as an example to explore the
49 50	121	relationship between evolving evidence and clinical practice for hospital procedures, including how
51 52	122	many procedures were performed over the last 10 years and how much money was spent before
53 54	123	RCT evidence raised questions about the procedure's value: how procedure rates compare to other
55 56	124	countries: and how the NHS might reduce the numbers of these procedures
57 58	125	countries, and now the Mris might reduce the numbers of these procedures.
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2 3	126	METHODS
4 5		
6 7 8	127	Data sources
9 10 11	128	Subacromial decompression procedures were identified using the 'admitted patient care' hospital
12 13	129	episode statistics (HES-APC). HES is a routinely collected dataset that records all episodes of care
14 15	130	provided to patients admitted (day case or inpatient) to NHS hospitals in England and NHS-funded
16 17 18	131	patients treated in the independent sector. ^{22 23} Each episode in HES represents a period of care
19 20	132	under one consultant team. Up to 20 diagnoses are recorded per episode using the International
21 22	133	Classification of Diseases (ICD) version 10. Up to 24 clinical procedures per episode may be recorded
23 24	134	using Office of Population, Censuses and Surveys (OPCS) (fourth revision) codes. HES also includes
25 26 27	135	the Lower Super Output Area (LSOA) of residence for each patient. ²⁴
28 29 30	136	Identifying subacromial decompression
31 32 33	137	We extracted anonymised, individual episodes in the HES-APC (2007/8 to 2016/17) dataset. We used
34 35	138	diagnosis and procedure codes ¹³ (Figure 1) to identify subacromial decompression. A small number
36 37	139	of patients received multiple shoulder procedure episodes on the same day (0.3% of all episodes).
38 39 40	140	When these were for the same procedure with the same laterality (0.25% of all episodes), we
41 42	141	assumed coding error duplication so excluded the episodes. If a procedure was marked as bilateral
43 44	142	(0.6%), this was counted as two procedures. We excluded patients who were not resident in
45 46 47	143	England.
48 49 50	144	Estimating procedure rates
51 52 53	145	National trends over time were estimated using directly standardised procedure rates 25 (per
54 55	146	100,000 population), with the population of England in 2016 as our standard population. For
56 57 58 59 60	147	comparison of smaller areas, we estimated indirectly standardised rates ²⁶ per 100,000 population,

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148	using the same standard population, and adjusting for deprivation and ethnicity (see Appendix A for
149	more details).
150	Estimating procedure costs
151	Costs were estimated for each financial year by linking Healthcare Resource Group (HRG) codes for
152	each admission in HES with the Department of Health Payment by Results National Tariffs for the
153	appropriate financial year; ²⁷⁻³⁶ see Appendix A for more details.
154	International comparisons
155	A search of Medline and the Cumulative Index of Nursing and Allied Health (CINAHL) databases was
156	conducted for the terms "acromioplasty" or "subacromial decompression" in conjunction with
157	"incidence" or "prevalence" or "epidemiology". One author (TJ) screened the results for articles
158	including rates of subacromial decompression contemporary with our data, and further screened
159	cited articles within included studies, as well as articles which cited included studies.
160	All statistical analyses were conducted using Stata/MP 14.2 for Windows and we mapped variation
161	in procedure rates across England in 2016/17 using ArcGIS ArcMap 10.5.1 for Desktop.
162	Patient and public involvement
163	There was no patient involvement in the design or conduct of this study. Two patients involved in
164	the CSAW trial reviewed this manuscript; they were interested by the results and the cost-focussed
165	perspective.
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2 3 4	169	RESULTS
5 6 7 8	170	The use of subacromial decompression in England
9 10	171	There were 15,112 subacromial decompression procedures (30 per 100,000 population) in 2007/8,
11 12 13	172	rising to 28,802 procedures (52 per 100,000 population) in 2016/17 (Figure 2), excluding those done
14 15	173	in combination with rotator cuff repair. This represents a 91% increase in the number of subacromial
16 17 18	174	decompressions over 10 years, with 266,692 procedures carried out in total. Most of this increase
19 20	175	took place before 2011/12, and procedure rates have slightly decreased between 2011/12 and
21 22	176	2016/17. Whilst the gender balance and age of those having shoulder surgery have remained steady
23 24	177	over the last decade, the proportion of procedures conducted as day cases, using arthroscopy,
25 26	178	and/or by independent (i.e. non-NHS) providers, have all increased (Table 1).
27 28	179	
29 30 31	180	Table 1: Descriptive information for subacromial decompression patients, 2007/08 and 2016/17 2007/08 2016/17
32		Procedure Count 15,112 28,802
33 34		%women 51.0 52.0
35		Age in years (SD) 54.94 (12.55) 54.89 (12.39)
36		% Arthroscopy 39.0 94.1
37		% Independent Providers 2.4 31.9
38 39		% Dav-case 51.0 79.3
40	181	
41 42	182	
43 44 45	183	The cost of subacromial decompression in England
46 47 48	184	In 2016/17, the median cost of an elective admission for subacromial decompression alone was
49 50	185	£4,476. The cost of subacromial decompression in England rose from £33 million in 2007/08 to £125
51 52	186	million in 2016/17. Over the 10-year period between 2007/8 and 2016/17 just under ± 1.1 billion was
53 54	187	spent on subacromial decompression (excluding procedures done in combination with rotator cuff
55 56 57	188	repair).
58 59 60	189	Variation in use of subacromial decompression in England

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190	In 2016/17 there was substantial variation in procedure rates between CCGs, after adjusting for age
191	sex, deprivation, and ethnicity profiles (Figure 3). The map demonstrates pockets of very high use
192	(>150% of the expected rate), for example in the Reading area, Wiltshire, and East Lincolnshire.
193	There were also areas where procedure rates were less than 50% of the expected rate, such as in
194	Worcestershire, Gloucestershire, Swindon, and North Norfolk. In 2016/17 the ratio of procedure
195	rates between a 'high use' CCG at the 90 th percentile and a 'low use' CCG at the 10 th percentile was
196	2.7 (95% CI: 2.2-3.4). This ratio is lower than the 2007/8 ratio of 3.6 (95% CI: 2.2-6.1), although
197	overlapping confidence intervals suggest this may be due to chance variation; see Table 2.

Table 2: 90/10 percentile ratios for directly age-sex standardised rates of subacromial
 decompression by CCG, England, 2007/8-2016/17

decompression by CCG, England, 2007/8-2010/17			
		10th	90/10 Ratio (95%
Year	90th Pct	Pct	CI*)
2007/08	53	15	3.6 (2.2-6.1)
2008/09	55	16	3.3 (2.1-5.2)
2009/10	72	27	2.6 (2.0-3.5)
2010/11	87	33	2.6 (1.9-3.6)
2011/12	89	36	2.5 (2.0-3.1)
2012/13	90	33	2.7 (2.0-3.7)
2013/14	88	34	2.6 (2.1-3.3)
2014/15	89	33	2.7 (2.0-3.7)
2015/16	81	33	2.5 (1.4-4.3)
2016/17	83	30	27(22-34)

200 *Confidence intervals for rate ratios³⁷

202 International comparison of rates of subacromial decompression

Table 3 shows rates of subacromial decompression in the most recent year available from England,
Finland, Florida State, New York State, and Western Australia. Rates in England were lower, often
only half, that of other countries. For subacromial decompression alone, the procedure rates were
lower in England (52 per 100,000 in 2016/17) than Western Australia (roughly 115 per 100,000 in
2013),³⁸ Florida State (130 per 100,000 in 2007),³⁹ and Finland (131 per 100,000 in 2011).⁴⁰

Figure 2 compares trends in rates of subacromial decompression in England, Finland, Florida State,

New York State, and Western Australia. The rate of increase for subacromial decompression

observed in our study (x2 between 2007/8 and 2016/17) was similar to Western Australia (x2

between 2001 and 2013),³⁸ Finland (x2.2 between 1998 and 2007),⁴⁰ and New York State (x2.5

between 1996 and 2006),⁴¹ but lower than Florida State (x4.4 between 2003 and 2007).³⁹ The use of

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subacromial decompression in Finland peaked in 2007 and has since been declining, at least in
publicly-funded hospitals, which has been attributed to accumulating evidence that it is no more
clinically effective than non-surgical alternatives. ⁴⁰

216 Table 3: International comparisons of age-sex-standardised rates of subacromial decompression

Article	Country	Data Year	SAD Rate (per 100,000 population)
Thorpe et al. (2016)	Western Australia	2013	~115
Paloneva et al. (2015)	Finland	2011	131
Vitale et al. (2010)	New York State	2006	102
lyengar et al. (2014)	Florida State	2007	~130
Our Data	England	2016/17	52

217	Notes: Numbers for Thorpe et al (2016) and Iyengar et al. (2014) were estimated from a graph; New
218	York State data is for subacromial decompression with/without rotator cuff repair; SAD =
219	Subacromial Decompression ³⁸⁻⁴¹
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228 DISCUSSION

229 Statement of principal findings

NHS England carries out nearly 30,000 subacromial decompression operations per year, at an annual cost of over £125 million. Between 2007/08 and 2016/17, 266,692 subacromial decompression procedures were carried out in England costing nearly £1.1 billion, before the addition of the CSAW and FIMPACT placebo-controlled trial results to the existing evidence prompted serious questions about the clinical benefit of the procedure. Rates of subacromial decompression alone in England have gradually declined since 2011/12, although an increasing number are carried out in combination with rotator cuff repair. There was large variation between CCGs in England, even after adjustment for demographic variables, with 'high-use' areas carrying out nearly three times as many procedures as 'low-use' areas. Procedure rates in England were notably lower than other countries, arguing against any levelling of procedure rates being due to saturation of 'demand' for shoulder surgery.

35 241 Strengths and weaknesses of the study

Our study used a national, longitudinal dataset over a 10-year period covering all NHS secondary care providers in England. Hospital Episode Statistics are administrative rather than specifically designed for research. However, HES is also linked to payments for hospitals, which is a strong incentive to provide complete data, and allowed us to produce what we believe is the first exploration of costs associated with subacromial decompression in England. Payment by results tariffs are based on average national costs and may not reflect precise costs for each hospital admission. Population denominators, and linkage to the indices of multiple deprivation and census ethnicity data, allowed us to investigate trends and variations in procedure rates standardised on age, sex, deprivation and ethnicity. HES data records patients' area of residence, so we compared procedure rates based on place of residence rather than place of treatment. There may be other

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252 factors influencing rates which we have not controlled for (e.g. private health insurance coverage). 253 HES does not record procedures which are privately funded and provided, meaning our surgery rates 254 are an under-estimate of the population rate. We only provide cost data from 2007/08 onwards, so 255 we under-estimate the amount spent on subacromial decompression prior to publication of the 256 CSAW and FIMPACT trial results. International estimations of procedure rates do not use identical 257 definitions of procedures and inclusion/exclusion criteria, but should be broadly comparable.

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Implications for policymakers and clinicians

259 NHS England spent over £1 billion on subacromial decompression during the last 10 years without 260 having compelling evidence of clinical effectiveness or cost-effectiveness. Rates of subacromial 261 decompression were already rising rapidly from 2000/01 onwards.¹³ It seems plausible that increasing awareness of concerns about the effectiveness of subacromial decompression surgery¹⁵⁻¹⁷ 262 263 and well-known recruitment to the CSAW trial tempered the rise in use of this surgery in England, 264 otherwise more may have been spent. The CSAW trial involved 51 surgeons in 30 centres 265 throughout the UK and was widely advertised and discussed amongst shoulder surgeons and 266 shoulder physiotherapists. Extensive consultation was carried out by the trial team prior to and 267 during the trial, including presentations at national meetings surveys and visits to individual 268 surgeons and centres.⁴² A similar plateau/decrease in procedures was observed in Finland after the 269 commencement of the FIMPACT study in 2005 which involved only 3 centres in Finland (Figure 2). It 270 is likely that awareness of a potential lack of effectiveness of subacromial decompression had been growing in the years before CSAW and FIMPACT, based on earlier trial results.¹⁵⁻¹⁷ However, it took 271 272 well over a decade of increasing subacromial decompression use for clinical trial groups to run high 273 quality, low risk-of-bias, placebo-controlled studies randomising a few hundred patients (313 274 patients for CSAW ¹⁸ and 210 in FIMPACT¹⁹) to investigate its effectiveness. This delay may be due to 275 perceived difficulties in recruiting patients to surgical trials with non-surgical comparators (e.g. 276 UKUFF⁴³), as well as known challenges of conducting surgical RCTs.⁴⁴ Methods to optimise 60

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recruitment, as used in CSAW and other trials,⁴⁵ are available to support the completion of such
'difficult' trials;⁴⁶ this should not now be a barrier to rapidly initiating trials to provide robust
evidence about surgical interventions before they become widespread. More time is needed to see
the longer-term impact of publication of the CSAW and FIMPACT results on subacromial
decompression rates, both in the UK and internationally.
The National Institute for Health and Care Excellence (NICE) requires evidence of cost-effectiveness

to recommend new medicines to be paid for by the NHS. It is unclear why the bar for introducing
expensive surgical procedures should be significantly lower. A balance needs to be struck between
supporting innovation in surgical procedures and preventing unnecessary treatment. New initiatives
such as IDEAL (Idea, Development, Exploration, Assessment, Long-term Follow-up, Improving the
Quality of Research in Surgery)⁴⁷ aim to provide such a regulatory framework for introducing new
interventions.

It is important that new evidence is disseminated quickly without causing inequities in access to care. NICE published an updated Clinical Knowledge Summary for shoulder pain in April 2017⁴⁸ incorporating information from a commissioning guide published by the Royal College of Surgeons.⁴⁹ This recommended a range of conservative treatments from physiotherapy to corticosteroid injections, before surgery. However, many CCGs introduced their own criteria-based policies for access to shoulder surgery (e.g. through Individual Funding Requests)⁵⁰, essentially meaning that commissioners would only pay providers for surgery under particular circumstances. These were implemented at different times and with different details, underlining the extent to which insufficient evidence may drive clinical and commissioner uncertainty,⁵¹ and possibly leading to the wide variations shown across CCGs in our data. Where scientific evidence is applicable nationally or internationally, it would seem more efficient and appropriate to apply national policies to inform optimal use and encourage further research. There is a need to improve techniques for empirically-informed policy development in collaboration with relevant stakeholders.^{52 53}

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302 Despite the criticisms provided above, England has lower rates of shoulder surgery than other 303 countries. The reasons for this are uncertain but could be due to differences in the health systems 304 (e.g. GP gatekeeping of services), access to surgery and hospital reimbursement. Additionally, the 305 National Institute of Health Research in England has funded major clinical trials on shoulder surgery,^{18 43} as well as other procedures;^{54 55} and is about to fund a further clinical trial to compare 306 307 surgery with placebo surgery for partial thickness rotator cuff tears.⁵⁶ Whilst the UK's national 308 regulatory processes are imperfect, they may provide examples to learn from. However, these 309 processes did not sufficiently constrain the use of subacromial decompression, a procedure later 310 found to have little clinical benefit.

311 There have been several other controversies regarding the lack of effectiveness of procedures which 312 have become commonplace. One example is the use of stents to open narrowed arteries for 313 treatment of stable angina (chest pain). Around half a million people receive stents for stable angina each year in the US and Europe,⁵⁷ but a recent (RCT) including a placebo intervention found no 314 difference in chest pain outcomes between inserting a stent and using standard medications.⁵⁸ 315 316 Another example is arthroscopy to clean out the knee joint, on which around \$4 billion is spent each year in the US.⁵⁹ Recent RCTs,^{60 61} including one using a placebo procedure as a comparison,⁶¹ found 317 318 no evidence of effectiveness to justify the spending. Whilst we use subacromial decompression as an 319 example in this study, our observations are likely to apply to interventional procedures more 320 generally.

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321 Unanswered questions and future research

322 The example of subacromial decompression highlights that, in the absence of rigorous evaluation, 323 costly interventions can proliferate over a long period of time. To maximise limited resources, it is 324 vital that methods are developed to identify promising procedures early and commission trials to examine their value, as well as identify existing health technologies that may be ineffective, leading 325 to over-treatment and wasting of resources. 60 326

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> There is an opportunity for a natural experiment exploring the impact of the results of the CSAW and FIMPACT trials^{18 19} on the development of CCG policies, national guidelines, and clinical decision-making with surgeons and patients. It is arguable that we should now see swift reductions in the use of subacromial decompression; research studies could help enhance the transfer of knowledge from trials into clinical practice.

Conclusions

18 19	333	NHS England pays for nearly 30,000 shoulder subacromial decompression procedures each year at
20 21 22	334	an annual cost of over £125 million, with little evidence that they are effective or cost-effective. The
22 23 24	335	rates of this operation in other countries are even higher. This raises serious questions around the
25 26	336	regulatory and professional processes governing the adoption and widespread use of surgical
27 28 20	337	interventions. High quality RCTs should be funded early to examine the effectiveness and cost-
29 30 31	338	effectiveness of expensive procedures using methods to optimise recruitment, and robust processes
32 33 34	339	should be developed to reduce the use of ineffective procedures.
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349	Author Statement
350	This publication is the work of the authors, who serve as guarantors for the contents of this paper. TJ
351	contributed to study design, data cleaning, data analysis, interpretation of results and writing the
352	manuscript. MJL contributed to study design, data cleaning, interpretation of results and writing the
353	manuscript. AC contributed to study design, interpretation of results and writing the manuscript. DB,
354	LR, and JD contributed to interpretation of results and writing the manuscript. WH contributed to
355	study conceptualization, study design, interpretation of results and writing the manuscript. TJ had
356	full access to the data in the study and takes responsibility for the integrity of the data and the
357	accuracy of the data analysis.
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365	Department of Health and Social Care.
366	Ethnical Approval
367	We were provided with routinely-collected Hospital Episode Statistics data under licence from NHS
368	Digital (DARS-NIC-17875-X7K1V). The licence allows us to use the information under Section 261 of

369 the Health and Social Care Act 2012, 2(b)(ii): "after taking into account the public interest as well as

370 the interests of the relevant person, considers that it is appropriate for the information to be

371 disseminated".

372 **Data Sharing**

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373 This study is based in part on data from the Hospital Episode Statistics (HES) obtained under licence

374 (DARS-NIC-17875-X7K1V) from NHS Digital (previously the Health and Social Care Information

375 Centre); Copyright © 2018, re-used with the permission of The Health & Social Care Information

Centre. All rights reserved. The data are provided by patients and collected by the NHS as part of

377 their care and support. HES data can be accessed via NHS Digital:

378 <u>https://digital.nhs.uk/services/data-access-request-service-dars</u>

379 Transparency

The manuscript's guarantor (TJ) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned have been explained.

383 Competing Interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/ coi_disclosure.pdf
and declare: TJ and JD had financial support from NIHR CLAHRC West for the submitted work; no
financial relationships with any organisations that might have an interest in the submitted work in
the previous three years; no other relationships or activities that could appear to have influenced
the submitted work.

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FIGURE CAPTIONS

Figure 1. ICD-10 and OPCS-4 codes used to define subacromial decompression¹³

Figure 2. Directly standardised rates (per 100,000 people) of subacromial decompression in England, Finland, New York State USA, Florida State USA, and Western Australia

Notes for Figure 2. England data prior to 2007 is taken from Judge et al.¹³; New York State data is for subacromial decompression with or without rotator cuff repair, whilst data for Florida State, Finland and Western Australia is for subacromial decompression alone ³⁸⁻⁴¹

Figure 3. Indirectly standardised rates of subacromial decompression by CCG in England, 2016/17

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Any of these diagnosis codes in any position M75.1 Rotator cuff syndrome M75.3 Calcific tendinitis of shoulder	In combination with	Any of these procedure codes in any position W84.8 Other specified therapeutic endoscopic operations on other joint structure Y52.8 Other specified approach to organ through
M75.4 Impingement syndrome of shoulder		other opening Y76.7 Arthroscopic approach to joint
M75.5 Bursitis of shoulder		W84.4 Endoscopic decompression of joint

OR

This procedure code in any
position
O29.1 Subacromial
decompression

Figure 1. ICD-10 and OPCS-4 codes used to define subacromial decompression¹³

102x65mm (300 x 300 DPI)



Figure 2. Directly standardised rates (per 100,000 people) of subacromial decompression in England, Finland, New York State USA, Florida State USA, and Western AustraliaNotes for Figure 2. England data prior to 2007 is taken from Judge et al.13; New York State data is for subacromial decompression with or without rotator cuff repair, whilst data for Florida State, Finland and Western Australia is for subacromial decompression alone ³⁴⁻³⁷ BMJ Open: first published as 10.1136/bmjopen-2019-030229 on 28 August 2019. Downloaded from http://bmjopen.bmj.com/ on May 14, 2025 at Department GEZ-LTA Erasmushogeschool

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APPENDIX A: METHODOLOGICAL DETAILS

Estimating Procedure Rates

National trends over time were estimated using directly standardised procedure rates¹ (per 100,000 population), with the population of England in 2016 as our standard population. We first summed the number of shoulder procedures, grouped by sex, quintiles of age, and financial year. These procedure counts were used to calculate annual age-sex-specific rates, by dividing by the appropriate age-sex-specific mid-year populations of England² (e.g. for the 2012/13 financial year, the mid-2012 populations were used). We weighted the annual age-sex-specific rates according to the population distribution of England in 2016, to produce directly standardised rates for each year. The standardised rates for 2016/17 are the same as the crude rates.

For comparison of smaller areas, we estimated indirectly standardised rates³ per 100,000 population. We first calculated age-sex-specific rates for England in 2016/17, then multiplied these rates by the age-sex-specific population for the area of interest²⁴⁵ (e.g. CCG) and summed the results. This produced the expected number of patients and procedures for that area, if it were to have the same age-sex-specific rates as England. The expected number was then compared to the observed number of patients and procedures for that area. A Poisson regression model was fitted to the observed counts for each year, with the expected counts as an offset and socio-economic deprivation (using the overall score from the English Indices of Multiple Deprivation⁶) and ethnicity (% white British⁷) as predictive factors. The model was then used to predict new expected counts for each area based on deprivation and ethnicity, and form indirectly standardised procedure ratios (observed / expected). Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

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Estimating Procedure Costs

Costs were estimated for each financial year by linking HRG codes for each admission in HES with the Department of Health Payment by Results National Tariffs for the appropriate financial year.⁸⁻¹⁷ Enhanced Tariff Option (ETO) tariffs were applied for 2015/16 as, following a dispute, 88% of providers agreed to use ETO tariffs for that financial year.¹⁸ The National Tariffs provide costs for day cases and longer stays, for both elective and non-elective admissions. They also provide additional daily costs for admissions that go above a threshold number of days (termed excess bed days), which varies for different types of admission. To calculate the cost of admission, we excluded admissions without a discharge date (used to calculate number of bed days) or without a HRG code that matched to the National Tariffs (0.7% excluded). We then applied the relevant national tariff or alternatively the best practice tariff where applicable (only for HRG code HB62C under specified circumstances) and added excess bed day costs (if there were any). Following this, the special service top-up for orthopaedic procedures was applied for each year.

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BMJ Open Page 3 The RECORD statement – checklist of items, extended from the STROBE statement, that should be reported in observational studies using routinely collected health data.

	Item No.	STROBE items	Location in manuscript where items are reported	RECORD items in 19-030 229 on for the second	Location in manuscript where items are reported
Title and abstra	ct			r us	
	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 time or abstract. When possible, the databases used should be specified.	40, 41
		summary of what was done and what was found	Pris	RECORD 1.2: If applications is the geographic region and time tame within which the study that a place should be reported in the stiller or abstract.	37, 40, 41, 42
Introduction			ev.e	RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract.	40, 41
Dealsground	2	Explain the acientific			77 115
rationale	2	background and rationale for the investigation being reported		nilar tec	//-115
Objectives	3	State specific objectives, including any prespecified hypotheses		May 14, 20 hnologies.	116-120
Methods				25	
Study Design	4	Present key elements of study design early in the paper		rt Depa	126-163
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection		artment GEZ-	127-142

Participants	6	(a) Cohort study - Give the	RECORD 6.1: The methods of study	136-142 and
1		eligibility criteria, and the	population selection (sugh a codes or	Figure 1
		sources and methods of selection	algorithms used to identify subjects)	
		of participants. Describe	should be listed in details If this is not	
		methods of follow-up	possible, an explanation showed be	
		<i>Case-control study</i> - Give the	provided.	
		eligibility criteria, and the	u fo	
		sources and methods of case	RECORD 6.2: Any validation studies	
		ascertainment and control	of the codes or algorithn is used to	Previous paper
		selection. Give the rationale for	select the population should be	using same cod
		the choice of cases and controls	referenced. If validation	referenced: 137
		Cross-sectional study - Give the	for this study and not public fed	
		eligibility criteria, and the	elsewhere, detailed methors and results	
		sources and methods of selection	should be provided.	
		of participants		
			RECORD 6.3: If the sture of the	
		(b) Cohort study - For matched	linkage of databases, consider use of a	Linked to
		studies, give matching criteria	flow diagram or other graphical display	payment-by-
		and number of exposed and	to demonstrate the data finkage	results tariffs b
		unexposed	process, including the number of	HRG code (150
		<i>Case-control study</i> - For	individuals with linked data at each	152), more of a
		matched studies, give matching	stage.	lookup table the
		criteria and the number of	an	a core linkage;
		controls per case		also Appendix
Variables	7	Clearly define all outcomes,	RECORD 7.1: A complete list of codes	136-142 and
		exposures, predictors, potential	and algorithms used to chassify	Figure 1
		confounders, and effect	exposures, outcomes, conformed formed exposures, and	
		modifiers. Give diagnostic	effect modifiers should be provided. If	
		criteria, if applicable.	these cannot be reported and	
			explanation should be provided.	
Data sources/	8	For each variable of interest,	25 8	136-152
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		(measurement).		
		Describe comparability of		
		assessment methods if there is	n n n n n n n n n n n n n n n n n n n	
		more than one group		

			BMJ Open	.1136/b sted by	Page 3
Bias	9	Describe any efforts to address potential sources of bias		copyrij	136-148; standardisation
Study size	10	Explain how the study size was arrived at		9ht, inc	136-142, 170-173
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why		030229 on 28 Au Iuding for uses	143-160
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 were addressed (d) <i>Cohort study</i> - If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> - If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> - If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses 	Pr revie	ugust 2019. Downloaded from http://bmjopen.bmj.com/ on May 14, 20 Erasmushogeschool . related to text and data mining, Al training, and similar technologies	143-160
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.	366-370

				RECORD 12.2: Authorseshort	136-142
				provide information on the cata	150 112
				cleaning methods used in the study	
Linkage				RECORD 12.3. State whether the	Linked to
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				linkage quality evaluation should be	lookup table th
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Main results16(a) Give unadjusted estimates and, if applicable, confounder- adjusted 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 period170-200Other analyses17Report other analyses done— e.g., analyses of subgroups and interactions, and sensitivity analyses204-218Discussion18Summarise key results with reference to study objectivesRECORD 19.1: Discussed integrations of using data that were not created or collected to answite the specific research questions?231-240Limitations19Discuss initiations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential biasRECORD 19.1: Discussed specific research questions?242-257			Case-control study - Reportnumbers in each exposurecategory, or summary measuresof exposureCross-sectional study - Reportnumbers of outcome events orsummary measures		njopen-2019-030229 on copyright, including fo	
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