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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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Manuscripts

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5 2 **Title:** A longitudinal study of use and cost of subacromial decompression surgery: the need for
6 3 effective evaluation of surgical procedures to prevent overtreatment and wasted resources.
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3 34 **ABSTRACT**
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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 40 **Design:** Longitudinal observational study using Hospital Episode Statistics linked to Payment by
15
16 41 Results tariffs in England, 2007/8-2016/17.

17
18 42 **Setting:** Hospital care in England, Finland, New York State USA, Florida State USA, and Western
19
20 43 Australia.

21
22 44 **Participants:** Patients with subacromial shoulder pain.

23
24 45 **Interventions:** Subacromial decompression.

25
26 46 **Main outcome measures:** National procedure rates, costs, and variation between clinical
27
28 47 commissioning groups (CCGs) in England.

29
30 48 **Results:** Without robust clinical evidence, the use of subacromial decompression in England
31
32 49 increased by 91% from 15,112 procedures (30 per 100,000 population) in 2007/8, to 28,802
33
34 50 procedures (52 per 100,000 population) in 2016/17, costing over £125 million per year. Rates of use
35
36 51 of subacromial decompression are even higher internationally: Finland (131 per 100,000 in 2011),
37
38 52 Florida State (130 per 100,000 in 2007), Western Australia (115 per 100,000 in 2013), and New York
39
40 53 State (102 per 100,000 in 2006). Two randomised trials have recently (2018) shown the procedure to
41
42 54 be no more effective than placebo or conservative approaches. Health systems appear unable to
43
44 55 avoid the rapid widespread use of procedures of unknown effectiveness, and methods for ceasing
45
46 56 ineffective treatments are under-developed.

47
48 57 **Conclusions:** Without good evidence, nearly 30,000 subacromial decompression procedures have
49
50 58 been commissioned each year in England, costing over £1 billion since 2007/8. Even higher rates of
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52 59 procedures are carried out in countries with less regulated health systems. Randomised trials need
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54 60 to be initiated before widespread adoption of promising operative procedures to avoid over-

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

For peer review only

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3 63 **ARTICLE SUMMARY**
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6 64 **Strengths and Limitations of this Study**
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- 9
10 65 • Our study used a national, longitudinal dataset over a 10-year period covering all NHS
11 secondary care providers in England, and private provision for NHS-funded patients.
12 66
13
14 67 • Hospital Episode Statistics are linked to hospital payments, which is a strong incentive to
15 provide complete data, and allowed us to explore costs of subacromial decompression in
16 68
17
18 69 England.
19
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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 subacromial decompression prior to publication of major clinical trial results (CSAW and
25 72
26
27 73 FIMPACT).
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29
30 74 • There may be additional factors influencing surgery rates which we have not controlled for
31 (e.g. private health insurance coverage).
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76 INTRODUCTION

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

83 Medicines must be licensed for use for a particular condition, requiring pharmaceutical companies
84 to provide evidence of effectiveness from clinical trials to relevant agencies such as the Medicines
85 and Healthcare products Regulatory Agency (MHRA) in the UK,⁴ European Medicines Agency (EMA)
86 in the EU, or the Food and Drug Administration (FDA) in the United States.⁵ In the UK, the National
87 Institute for Health and Care Excellence (NICE) also evaluates the cost-effectiveness of many
88 medicines and does not recommend those which do not provide value. These regulatory processes
89 have their limitations,⁶ but require robust evidence for the introduction of new treatments. The
90 quality of evidence required to introduce new surgical procedures is not as strict as for medicines,^{4,5}
91 in part because no specific product such as a drug or device is involved; it can be difficult to
92 categorise procedures as 'new' rather than modifications; and outcomes may depend on the skill of
93 the practitioner as well as the procedure itself.⁴ Once introduced, use of procedures can spread by
94 clinical consensus,⁵ and established practice and clinical evidence often take many years to be
95 updated.^{7,8}

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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3 101 bursa and tendons.^{12 13} Subacromial decompression removes the bony spur on the acromion and
4
5 102 releases the coracohumeral ligament.^{13 14} There has been a rapidly increasing use of subacromial
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7 103 decompression in England, with over 21,000 procedures carried out in 2009/10.¹³
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11 104 Two recent multi-centre randomised controlled trials (RCTs) have questioned the effectiveness of
12
13 105 subacromial decompression for shoulder pain.^{15 16} The CSAW trial,^{12 15} recruiting in England from
14
15 106 2012 to 2015, compared arthroscopic subacromial decompression surgery, placebo (investigational
16
17 107 shoulder arthroscopy), and no treatment.¹⁵ It found no difference in shoulder function after six
18
19 108 months between the arthroscopic subacromial decompression group and the arthroscopy only
20
21 109 (placebo) group, with a small, non-clinically significant benefit of surgery over the no treatment
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23 110 control. The FIMPACT trial,¹⁶ recruiting in Finland from 2005 to 2013, compared subacromial
24
25 111 decompression with placebo surgery and exercise therapy and echoed the results of CSAW,
26
27 112 extending them to two years follow-up. The CSAW and FIMPACT trials seriously question whether
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29 113 the resources invested in subacromial decompression represent good value for money for the NHS.
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31 114 As a result, a recent BMJ article made a strong recommendation against subacromial decompression
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33 115 surgery for chronic shoulder pain.¹⁷
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39 116 In this study we use subacromial decompression for shoulder pain as an example to explore the
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41 117 relationship between evolving evidence and clinical practice for hospital procedures, including how
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43 118 many procedures were performed over the last 10 years and how much money was spent before
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45 119 RCT evidence raised questions about the procedure's value; how procedure rates compare to other
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47 120 countries; and how the NHS might reduce the numbers of these procedures.
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125 **METHODS**

126 **Data sources**

127 Subacromial decompression procedures were identified using the 'admitted patient care' hospital
128 episode statistics (HES-APC). HES is a routinely collected dataset that records all episodes of care
129 provided to patients admitted (day case or inpatient) to NHS hospitals in England and NHS-funded
130 patients treated in the independent sector.^{18,19} Each episode in HES represents a period of care
131 under one consultant team. Up to 20 diagnoses are recorded per episode using the International
132 Classification of Diseases (ICD) version 10. Up to 24 clinical procedures per episode may be recorded
133 using Office of Population, Censuses and Surveys (OPCS) (fourth revision) codes. HES also includes
134 the Lower Super Output Area (LSOA) of residence for each patient.²⁰

135 **Identifying subacromial decompression**

136 We extracted anonymised, individual episodes in the HES-APC (2007/8 to 2016/17) dataset. We used
137 diagnosis and procedure codes¹³ (Figure 1) to identify subacromial decompression. A small number
138 of patients received multiple shoulder procedure episodes on the same day (0.3% of all episodes).
139 When these were for the same procedure with the same laterality (0.25% of all episodes), we
140 assumed coding error duplication so excluded the episodes. If a procedure was marked as bilateral
141 (0.6%), this was counted as two procedures. We excluded patients who were not resident in
142 England.

143 **Estimating procedure rates**

144 National trends over time were estimated using directly standardised procedure rates²¹ (per
145 100,000 population), with the population of England in 2016 as our standard population. For
146 comparison of smaller areas, we estimated indirectly standardised rates²² per 100,000 population,

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3 147 using the same standard population, and adjusting for deprivation and ethnicity (see Appendix A for
4
5 148 more details).

9 149 **Estimating procedure costs**

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12 150 Costs were estimated for each financial year by linking Healthcare Resource Group (HRG) codes for
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14 151 each admission in HES with the Department of Health Payment by Results National Tariffs for the
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16 152 appropriate financial year;²³⁻³² see Appendix A for more details.

19 153 **International comparisons**

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23 154 A search of Medline and the Cumulative Index of Nursing and Allied Health (CINAHL) databases was
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25 155 conducted for the terms “acromioplasty” or “subacromial decompression” in conjunction with
26
27 156 “incidence” or “prevalence” or “epidemiology”. One author (TJ) screened the results for articles
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29 157 including rates of subacromial decompression contemporary with our data, and further screened
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31 158 cited articles within included studies, as well as articles which cited included studies.

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35 159 All statistical analyses were conducted using Stata/MP 14.2 for Windows and we mapped variation
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37 160 in procedure rates across England in 2016/17 using ArcGIS ArcMap 10.5.1 for Desktop.

39 161 **Patient and public involvement**

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43 162 Patients involved in the CSAW trial reviewed this manuscript; they were interested by the results
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45 163 and the cost-focussed perspective.

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3 **168 RESULTS**
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6 **169 The use of subacromial decompression in England**
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10 170 There were 15,112 subacromial decompression procedures (30 per 100,000 population) in 2007/8,
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12 171 rising to 28,802 procedures (52 per 100,000 population) in 2016/17 (Figure 2), excluding those done
13
14 172 in combination with rotator cuff repair. This represents a 91% increase in the number of subacromial
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16 173 decompressions over 10 years, with 266,692 procedures carried out in total. Most of this increase
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18 174 took place before 2011/12, and procedure rates have slightly decreased between 2011/12 and
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20 175 2016/17. The use of subacromial decompression in combination with rotator cuff repair has
21
22 176 continued to increase since the early 2000s, more notably from 2006/7 onwards. Whilst the gender
23
24 177 balance and age of those having shoulder surgery have remained steady over the last decade, the
25
26 178 proportion of procedures conducted as day cases, using arthroscopy, and/or by independent (i.e.
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28 179 non-NHS) providers, have all increased (Table 1).
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34 181 Table 1: Descriptive information for subacromial decompression patients, 2007/08 and 2016/17
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	2007/08	2016/17
Procedure Count	15,112	28,802
%women	51.0	52.0
Age in years (SD)	54.94 (12.55)	54.89 (12.39)
% Arthroscopy	39.0	94.1
% Independent Providers	2.4	31.9
% Day-case	51.0	79.3

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48 **184 The cost of subacromial decompression in England**
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51 185 In 2016/17, the median cost of an elective admission for subacromial decompression alone was
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53 186 £4,476. The cost of subacromial decompression in England rose from £33 million in 2007/08 to £125
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55 187 million in 2016/17. Over the 10-year period between 2007/8 and 2016/17 just under £1.1 billion was
56
57 188 spent on subacromial decompression (excluding procedures done in combination with rotator cuff
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59 189 repair).
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190 Variation in use of subacromial decompression in England

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 90th percentile and a 'low use' CCG at the 10th 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.

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

Year	90th Pct	10th Pct	90/10 Ratio (95% 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)

201 *Confidence intervals for rate ratios³³

203 International comparison of rates of subacromial decompression

204 Table 3 shows rates of subacromial decompression in the most recent year available from England,
 205 Finland, Florida State, New York State, and Western Australia. Rates in England were lower, often
 206 only half, that of other countries. For subacromial decompression alone, the procedure rates were
 207 lower in England (52 per 100,000 in 2016/17) than Western Australia (roughly 115 per 100,000 in
 208 2013),³⁴ Florida State (130 per 100,000 in 2007),³⁵ and Finland (131 per 100,000 in 2011).³⁶

209 For subacromial decompression combined with rotator cuff repair, rates were lower in England (80
 210 per 100,000 in 2016/17) than in New York State a decade earlier (102 per 100,000 in 2006).³⁷

211 Figure 2 compares trends in rates of subacromial decompression in England, Finland, Florida State,
 212 New York State, and Western Australia. The rate of increase for subacromial decompression
 213 observed in our study (x2 between 2007/8 and 2016/17) was similar to Western Australia (x2
 214 between 2001 and 2013),³⁴ Finland (x2.2 between 1998 and 2007),³⁶ and New York State (x2.5
 215 between 1996 and 2006),³⁷ but lower than Florida State (x4.4 between 2003 and 2007).³⁵ The use of
 216 subacromial decompression in Finland peaked in 2007 and has since been declining, at least in
 217 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
Iyengar 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 Thorpe et al (2016) and Iyengar et al. (2014) were estimated from a graph; New*
 221 *York State data is for subacromial decompression with/without rotator cuff repair; SAD =*
 222 *Subacromial Decompression; RCR = Rotator Cuff Repair³⁴⁻³⁷*

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3 229 **DISCUSSION**
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6 230 **Statement of principal findings**
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9 231 NHS England carries out nearly 30,000 subacromial decompression operations per year, at an annual
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11 232 cost of over £125 million. Between 2007/08 and 2016/17, 266,692 subacromial decompression
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13 233 procedures were carried out in England costing nearly £1.1 billion, before the publication of CSAW
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15 234 and FIMPACT trial results prompted questions about the clinical benefit of the procedure. Rates of
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17 235 subacromial decompression alone in England have gradually declined since 2011/12, although an
18
19 236 increasing number are carried out in combination with rotator cuff repair. There was large variation
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21 237 between CCGs in England, even after adjustment for demographic variables, with 'high-use' areas
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23 238 carrying out nearly three times as many procedures as 'low-use' areas. Procedure rates in England
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25 239 were notably lower than other countries, arguing against any levelling of procedure rates being due
26
27 240 to saturation of 'demand' for shoulder surgery.
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33 241 **Strengths and weaknesses of the study**
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35 242 Our study used a national, longitudinal dataset over a 10-year period covering all NHS secondary
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37 243 care providers in England. Hospital Episode Statistics are administrative rather than specifically
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39 244 designed for research. However, HES is also linked to payments for hospitals, which is a strong
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41 245 incentive to provide complete data, and allowed us to produce what we believe is the first
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43 246 exploration of costs associated with subacromial decompression in England. Payment by results
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45 247 tariffs are based on average national costs and may not reflect precise costs for each hospital
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47 248 admission. Population denominators, and linkage to the indices of multiple deprivation and census
48
49 249 ethnicity data, allowed us to investigate trends and variations in procedure rates standardised on
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51 250 age, sex, deprivation and ethnicity. HES data records patients' area of residence, so we compared
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53 251 procedure rates based on place of residence rather than place of treatment. There may be other
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55 252 factors influencing rates which we have not controlled for (e.g. private health insurance coverage).
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3 253 HES does not record procedures which are privately funded and provided, meaning our surgery rates
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5 254 are an under-estimate of the population rate. We only provide cost data from 2007/08 onwards, so
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7 255 we under-estimate the amount spent on subacromial decompression prior to publication of the
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9 256 CSAW and FIMPACT trial results. International estimations of procedure rates do not use identical
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11 257 definitions of procedures and inclusion/exclusion criteria, but should be broadly comparable.
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15 258 **Implications for policymakers and clinicians**

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18 259 NHS England spent over £1 billion on subacromial decompression during the last 10 years without
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20 260 having compelling evidence of clinical effectiveness or cost-effectiveness. Rates of subacromial
21
22 261 decompression were already rising rapidly from 2000/01 onwards.¹³ It seems plausible that
23
24 262 increasing awareness of concerns about the effectiveness of subacromial decompression surgery
25
26 263 and well-known recruitment to the CSAW trial tempered the rise in use of this surgery in England,
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28 264 otherwise more may have been spent. The CSAW trial involved 51 surgeons in 30 centres
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30 265 throughout the UK and was widely advertised and discussed amongst shoulder surgeons and
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32 266 shoulder physiotherapists. Extensive consultation was carried out by the trial team prior to and
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34 267 during the trial, including presentations at national meetings surveys and visits to individual
35
36 268 surgeons and centres.³⁸ A similar plateau/decrease in procedures was observed in Finland after the
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38 269 commencement of the FIMPACT study in 2005 which involved only 3 centres in Finland (Figure 2).
39
40 270 However, it took well over a decade of increasing subacromial decompression use for clinical trial
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42 271 groups to randomise a few hundred patients (313 patients for CSAW¹⁵ and 210 in FIMPACT¹⁶) to
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44 272 investigate its effectiveness. This delay may be due to perceived difficulties in recruiting patients to
45
46 273 surgical trials with non-surgical comparators (e.g. UKUFF³⁹), as well as known challenges of
47
48 274 conducting surgical RCTs.⁴⁰ Methods to optimise recruitment, as used in CSAW and other trials,⁴¹ are
49
50 275 available to support the completion of such 'difficult' trials;⁴² this should not now be a barrier to
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52 276 rapidly initiating trials to provide robust evidence about surgical interventions before they become
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54 277 widespread. More time is needed to see the longer-term impact of publication of the CSAW and
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3 278 FIMPACT results on subacromial decompression rates, both in the UK and internationally. It is also
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5 279 worth noting the increasing tendency in England to carry out subacromial decompression in
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7 280 combination with rotator cuff repair, and any impact on this following dissemination of the
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9 281 CSAW/FIMPACT results.
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13 282 The National Institute for Health and Care Excellence (NICE) requires evidence of cost-effectiveness
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15 283 to recommend new medicines to be paid for by the NHS. It is unclear why the bar for introducing
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17 284 expensive surgical procedures should be significantly lower. A balance needs to be struck between
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19 285 supporting innovation in surgical procedures and preventing unnecessary treatment. New initiatives
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21 286 such as IDEAL (Idea, Development, Exploration, Assessment, Long-term Follow-up, Improving the
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23 287 Quality of Research in Surgery)⁴³ aim to provide such a regulatory framework for introducing new
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25 288 interventions.
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30 289 It is important that new evidence is disseminated quickly without causing inequities in access to
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32 290 care. NICE published an updated Clinical Knowledge Summary for shoulder pain in April 2017⁴⁴
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34 291 incorporating information from a commissioning guide published by the Royal College of Surgeons.⁴⁵
35
36 292 This recommended a range of conservative treatments from physiotherapy to corticosteroid
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38 293 injections, before surgery. However, many CCGs introduced their own criteria-based policies for
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40 294 access to shoulder surgery (e.g. through Individual Funding Requests)⁴⁶ at different times and with
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42 295 different details, underlining the extent to which insufficient evidence may drive clinical and
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44 296 commissioner uncertainty,⁴⁷ and possibly leading to the wide variations shown across CCGs in our
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46 297 data. Where scientific evidence is applicable nationally or internationally, it would seem more
47
48 298 efficient and appropriate to apply national policies to inform optimal use and encourage further
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50 299 research. There is a need to improve techniques for empirically-informed policy development in
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52 300 collaboration with relevant stakeholders.^{48 49} It is also important to note that certain patients may
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54 301 still benefit from surgery. Further well conducted research is needed to understand if specific sub-
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56 302 groups of patients might benefit from subacromial decompression surgery.
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3 303 Despite the criticisms provided above, England has lower rates of shoulder surgery than other
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5 304 countries. The reasons for this are uncertain but could be due to differences in the health systems
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7 305 (e.g. GP gatekeeping of services), access to surgery and hospital reimbursement. Additionally, the
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9
10 306 National Institute of Health Research in England has funded major clinical trials on shoulder
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12 307 surgery,^{15 39} as well as other procedures,^{50 51} and is about to fund a further clinical trial to compare
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14 308 surgery with placebo surgery for partial thickness rotator cuff tears.⁵² Whilst the UK's national
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16 309 regulatory processes are imperfect, they may provide examples to learn from. However, these
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18 310 processes did not sufficiently constrain the use of subacromial decompression, a procedure later
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20 311 found to have little clinical benefit.

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24 312 There have been several other controversies regarding the lack of effectiveness of procedures which
25
26 313 have become commonplace. One example is the use of stents to open narrowed arteries for
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28 314 treatment of stable angina (chest pain). Around half a million people receive stents for stable angina
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30 315 each year in the US and Europe,⁵³ but a recent (RCT) including a placebo intervention found no
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32 316 difference in chest pain outcomes between inserting a stent and using standard medications.⁵⁴
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34 317 Another example is arthroscopy to clean out the knee joint, on which around \$4 billion is spent each
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36 318 year in the US.⁵⁵ Recent RCTs,^{56 57} including one using a placebo procedure as a comparison,⁵⁷ found
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38 319 no evidence of effectiveness to justify the spending. Whilst we use subacromial decompression as an
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40 320 example in this study, our observations are likely to apply to interventional procedures more
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42 321 generally.

43 44 45 46 47 322 **Unanswered questions and future research**

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51 323 The example of subacromial decompression highlights that, in the absence of rigorous evaluation,
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53 324 costly interventions can proliferate over a long period of time. To maximise limited resources, it is
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55 325 vital that methods are developed to identify promising procedures early and commission trials to
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57 326 examine their value, as well as identify existing health technologies that may be ineffective, leading
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59 327 to over-treatment and wasting of resources.

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3 328 There is an opportunity for a natural experiment exploring the impact of the results of the CSAW and
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5 329 FIMPACT trials^{15 16} on the development of CCG policies, national guidelines, and clinical decision-
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7 330 making with surgeons and patients. It is arguable that we should now see swift reductions in the use
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9 331 of subacromial decompression; research studies could help enhance the transfer of knowledge from
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11 332 trials into clinical practice.
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15 333 **Conclusions**
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18 334 NHS England pays for nearly 30,000 shoulder subacromial decompression procedures each year at
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20 335 an annual cost of over £125 million, with little evidence that they are effective or cost-effective. The
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22 336 rates of this operation in other countries are even higher. This raises serious questions around the
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24 337 regulatory and professional processes governing the adoption and widespread use of surgical
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26 338 interventions. High quality RCTs should be funded early to examine the effectiveness and cost-
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28 339 effectiveness of expensive procedures using methods to optimise recruitment, and robust processes
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30 340 should be developed to reduce the use of ineffective procedures.
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3 350 **Author Statement**
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6 351 This publication is the work of the authors, who serve as guarantors for the contents of this paper. TJ
7
8 352 contributed to study design, data cleaning, data analysis, interpretation of results and writing the
9
10 353 manuscript. MJL contributed to study design, data cleaning, interpretation of results and writing the
11
12 354 manuscript. AC contributed to study design, interpretation of results and writing the manuscript. DB,
13
14 355 LR, and JD contributed to interpretation of results and writing the manuscript. WH contributed to
15
16 356 study conceptualization, study design, interpretation of results and writing the manuscript. TJ had
17
18 357 full access to the data in the study and takes responsibility for the integrity of the data and the
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33
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35
36 364 Department of Health and Social Care.
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39 365 **Ethical Approval**
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42 366 We were provided with routinely-collected Hospital Episode Statistics data under licence from NHS
43
44 367 Digital (DARS-NIC-17875-X7K1V). The licence allows us to use the information under Section 261 of
45
46 368 the Health and Social Care Act 2012, 2(b)(ii): "after taking into account the public interest as well as
47
48 369 the interests of the relevant person, considers that it is appropriate for the information to be
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50 370 disseminated".
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54 371 **Data Sharing**
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57 372 This study is based in part on data from the Hospital Episode Statistics (HES) obtained under licence
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59 373 (DARS-NIC-17875-X7K1V) from NHS Digital (previously the Health and Social Care Information
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3 374 Centre); Copyright © 2018, re-used with the permission of The Health & Social Care Information

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5 375 Centre. All rights reserved. The data are provided by patients and collected by the NHS as part of

6
7 376 their care and support. HES data can be accessed via NHS Digital:

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10 377 <https://digital.nhs.uk/services/data-access-request-service-dars>

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13 378 **Transparency**

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15 379 The manuscript's guarantor (TJ) affirms that the manuscript is an honest, accurate, and transparent

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17 380 account of the study being reported; that no important aspects of the study have been omitted; and

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19 381 that any discrepancies from the study as originally planned have been explained.

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23 382 **Competing Interests**

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25 383 All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf

26
27 384 and declare: TJ and JD had financial support from NIHR CLAHRC West for the submitted work; no

28
29 385 financial relationships with any organisations that might have an interest in the submitted work in

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31 386 the previous three years; no other relationships or activities that could appear to have influenced

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33 387 the submitted work.

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For peer review only

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 alone³⁴⁻³⁷; RCR = Rotator Cuff Repair

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

For peer review only

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

OR

<i>This procedure code in any position</i>
O29.1 Subacromial decompression

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

102x65mm (300 x 300 DPI)

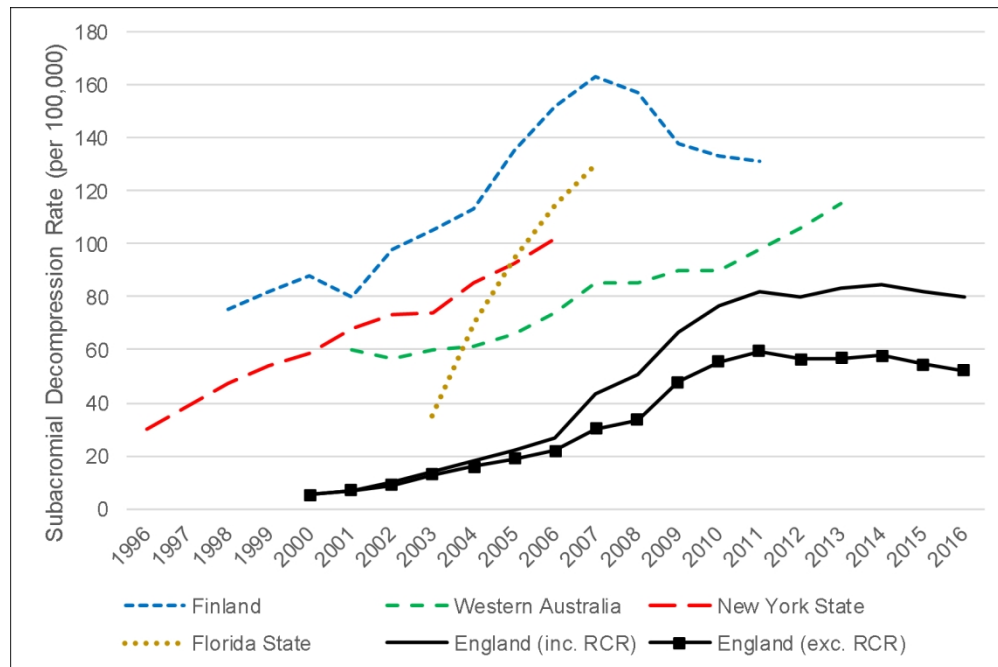


Figure 2. Directly standardised rates (per 100,000 people) of subacromial decompression in England, Finland, New York State USA, Florida State USA, and Western Australia

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 alone³⁴⁻³⁷; RCR = Rotator Cuff Repair

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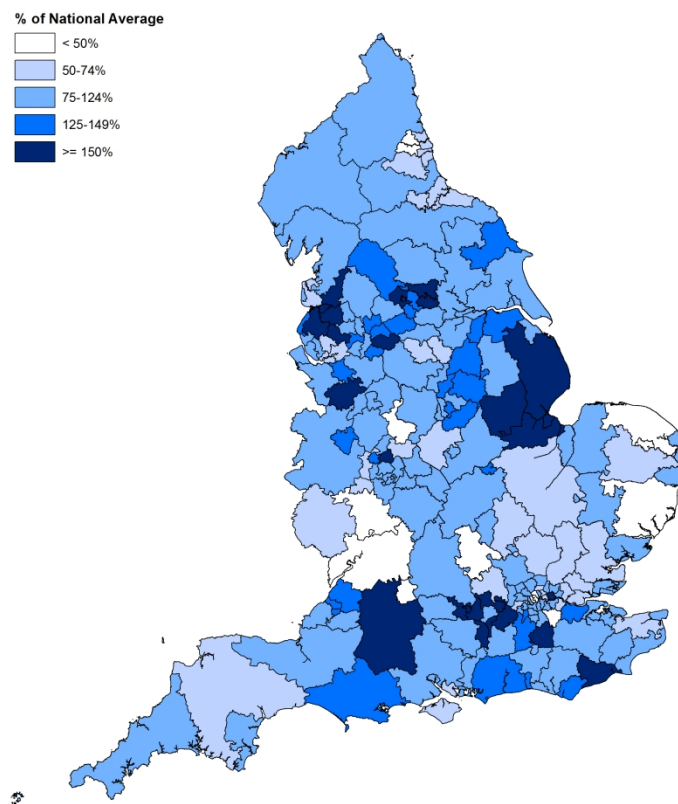


Figure 3. Indirectly standardised rates of subacromial decompression by CCG in England, 2016/17

210x296mm (300 x 300 DPI)

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).

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

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.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-030229.R1
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Primary Subject Heading:	Surgery
Secondary Subject Heading:	Epidemiology, Health economics
Keywords:	subacromial decompression, shoulder surgery, England, commissioning, arthroscopy

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Manuscripts

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5 2 **Title:** A longitudinal study of use and cost of subacromial decompression surgery: the need for
6 3 effective evaluation of surgical procedures to prevent overtreatment and wasted resources.
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61 48 **Keywords:**

62 49 Subacromial decompression; arthroscopy; shoulder surgery; England; commissioning
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2
3 34 **ABSTRACT**
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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 40 **Design:** Longitudinal observational study using Hospital Episode Statistics linked to Payment by
15
16 41 Results tariffs in England, 2007/8-2016/17.

17
18 42 **Setting:** Hospital care in England, Finland, New York State USA, Florida State USA, and Western
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20 43 Australia.

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22 44 **Participants:** Patients with subacromial shoulder pain.

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24 45 **Interventions:** Subacromial decompression.

25
26 46 **Main outcome measures:** National procedure rates, costs, and variation between clinical
27
28 47 commissioning groups (CCGs) in England.

29
30 48 **Results:** Without robust clinical evidence, the use of subacromial decompression in England
31
32 49 increased by 91% from 15,112 procedures (30 per 100,000 population) in 2007/8, to 28,802
33
34 50 procedures (52 per 100,000 population) in 2016/17, costing over £125 million per year. Rates of use
35
36 51 of subacromial decompression are even higher internationally: Finland (131 per 100,000 in 2011),
37
38 52 Florida State (130 per 100,000 in 2007), Western Australia (115 per 100,000 in 2013), and New York
39
40 53 State (102 per 100,000 in 2006). Two randomised placebo-controlled trials have recently (2018)
41
42 54 shown the procedure to be no more effective than placebo or conservative approaches. Health
43
44 55 systems appear unable to avoid the rapid widespread use of procedures of unknown effectiveness,
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46 56 and methods for ceasing ineffective treatments are under-developed.

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48 57 **Conclusions:** Without good evidence, nearly 30,000 subacromial decompression procedures have
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50 58 been commissioned each year in England, costing over £1 billion since 2007/8. Even higher rates of
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52 59 procedures are carried out in countries with less regulated health systems. High quality randomised
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54 60 trials need to be initiated before widespread adoption of promising operative procedures to avoid
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61 over-treatment and wasted resources, and methods to prevent or desist the use of ineffective
62 procedures need to be expedited.

For peer review only

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3 63 **ARTICLE SUMMARY**
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6 64 **Strengths and Limitations of this Study**
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10 65 • Our study used a national, longitudinal dataset over a 10-year period covering all NHS
11
12 66 secondary care providers in England, and private provision for NHS-funded patients.
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14 67 • Hospital Episode Statistics are linked to hospital payments, which is a strong incentive to
15
16 68 provide complete data, and allowed us to explore costs of subacromial decompression in
17
18 69 England.
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20 70 • We provide international comparisons of the use of subacromial decompression surgery.
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23 71 • Our data are from 2007/08 onwards, so we under-estimate the amount spent on
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25 72 subacromial decompression prior to publication of major clinical trial results (CSAW and
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27 73 FIMPACT).
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30 74 • There may be additional factors influencing surgery rates which we have not controlled for
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32 75 (e.g. private health insurance coverage).
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76 INTRODUCTION

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

83 Medicines must be licensed for use for a particular condition, requiring pharmaceutical companies
84 to provide evidence of effectiveness from clinical trials to relevant agencies such as the Medicines
85 and Healthcare products Regulatory Agency (MHRA) in the UK,⁴ European Medicines Agency (EMA)
86 in the EU, or the Food and Drug Administration (FDA) in the United States.⁵ In the UK, the National
87 Institute for Health and Care Excellence (NICE) also evaluates the cost-effectiveness of many
88 medicines and does not recommend those which do not provide value. These regulatory processes
89 have their limitations,⁶ but require robust evidence for the introduction of new treatments. The
90 quality of evidence required to introduce new surgical procedures is not as strict as for medicines,^{4,5}
91 in part because no specific product such as a drug or device is involved; it can be difficult to
92 categorise procedures as 'new' rather than modifications; and outcomes may depend on the skill of
93 the practitioner as well as the procedure itself.⁴ Once introduced, use of procedures can spread by
94 clinical consensus,⁵ and established practice and clinical evidence often take many years to be
95 updated.^{7,8}

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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3 101 bursa and tendons.^{12 13} Subacromial decompression removes the bony spur on the acromion and
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5 102 releases the coracohumeral ligament.^{13 14} There has been a rapidly increasing use of subacromial
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7 103 decompression in England, with over 21,000 procedures carried out in 2009/10.¹³
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11 104 Several randomised controlled trials (RCTs) since the early 1990s have compared subacromial
12
13 105 decompression to non-operative treatment (e.g. exercise) for shoulder pain and found no evidence
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15 106 of effectiveness.¹⁵⁻¹⁷ Two recent multi-centre RCTs including a placebo surgery arm have further
16
17 107 questioned the effectiveness of subacromial decompression for shoulder pain.^{18 19} The CSAW trial,¹²
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19 108 ¹⁸ recruiting in England from 2012 to 2015, compared arthroscopic subacromial decompression
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21 109 surgery, placebo (investigational shoulder arthroscopy), and no treatment.¹⁸ It found no difference
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23 110 in shoulder function after six months between the arthroscopic subacromial decompression group
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25 111 and the arthroscopy only (placebo) group, with a small, non-clinically significant benefit of surgery
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27 112 over the no treatment control. The FIMPACT trial,¹⁹ recruiting in Finland from 2005 to 2013,
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29 113 compared subacromial decompression with placebo surgery and exercise therapy and echoed the
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31 114 results of CSAW, extending them to two years follow-up. A recent Cochrane review including CSAW,
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33 115 FIMPACT, and earlier RCTs, found high-certainty evidence that subacromial decompression does not
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35 116 improve pain, function, or health-related quality of life.²⁰ This seriously questions whether the
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37 117 resources invested in subacromial decompression represent good value for money for the NHS. As a
38
39 118 result, a recent BMJ article made a strong recommendation against subacromial decompression
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41 119 surgery for chronic shoulder pain.²¹

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43 120 In this study we use subacromial decompression for shoulder pain as an example to explore the
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45 121 relationship between evolving evidence and clinical practice for hospital procedures, including how
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47 122 many procedures were performed over the last 10 years and how much money was spent before
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49 123 RCT evidence raised questions about the procedure's value; how procedure rates compare to other
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51 124 countries; and how the NHS might reduce the numbers of these procedures.
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3 126 **METHODS**
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6 127 **Data sources**
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10 128 Subacromial decompression procedures were identified using the 'admitted patient care' hospital
11 episode statistics (HES-APC). HES is a routinely collected dataset that records all episodes of care
12 provided to patients admitted (day case or inpatient) to NHS hospitals in England and NHS-funded
13 patients treated in the independent sector.^{22 23} Each episode in HES represents a period of care
14 under one consultant team. Up to 20 diagnoses are recorded per episode using the International
15 Classification of Diseases (ICD) version 10. Up to 24 clinical procedures per episode may be recorded
16 using Office of Population, Censuses and Surveys (OPCS) (fourth revision) codes. HES also includes
17 the Lower Super Output Area (LSOA) of residence for each patient.²⁴
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28 136 **Identifying subacromial decompression**
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31 137 We extracted anonymised, individual episodes in the HES-APC (2007/8 to 2016/17) dataset. We used
32 diagnosis and procedure codes¹³ (Figure 1) to identify subacromial decompression. A small number
33 of patients received multiple shoulder procedure episodes on the same day (0.3% of all episodes).
34 When these were for the same procedure with the same laterality (0.25% of all episodes), we
35 assumed coding error duplication so excluded the episodes. If a procedure was marked as bilateral
36 (0.6%), this was counted as two procedures. We excluded patients who were not resident in
37 England.
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48 144 **Estimating procedure rates**
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51 145 National trends over time were estimated using directly standardised procedure rates²⁵ (per
52 100,000 population), with the population of England in 2016 as our standard population. For
53 comparison of smaller areas, we estimated indirectly standardised rates²⁶ per 100,000 population,
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3 148 using the same standard population, and adjusting for deprivation and ethnicity (see Appendix A for
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5 149 more details).

9 150 **Estimating procedure costs**

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12 151 Costs were estimated for each financial year by linking Healthcare Resource Group (HRG) codes for
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14 152 each admission in HES with the Department of Health Payment by Results National Tariffs for the
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16 153 appropriate financial year;²⁷⁻³⁶ see Appendix A for more details.

19 154 **International comparisons**

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23 155 A search of Medline and the Cumulative Index of Nursing and Allied Health (CINAHL) databases was
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25 156 conducted for the terms “acromioplasty” or “subacromial decompression” in conjunction with
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27 157 “incidence” or “prevalence” or “epidemiology”. One author (TJ) screened the results for articles
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29 158 including rates of subacromial decompression contemporary with our data, and further screened
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31 159 cited articles within included studies, as well as articles which cited included studies.

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35 160 All statistical analyses were conducted using Stata/MP 14.2 for Windows and we mapped variation
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37 161 in procedure rates across England in 2016/17 using ArcGIS ArcMap 10.5.1 for Desktop.

39 162 **Patient and public involvement**

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43 163 There was no patient involvement in the design or conduct of this study. Two patients involved in
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45 164 the CSAW trial reviewed this manuscript; they were interested by the results and the cost-focused
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3 **169 RESULTS**
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6 **170 The use of subacromial decompression in England**
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10 171 There were 15,112 subacromial decompression procedures (30 per 100,000 population) in 2007/8,
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12 172 rising to 28,802 procedures (52 per 100,000 population) in 2016/17 (Figure 2), excluding those done
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14 173 in combination with rotator cuff repair. This represents a 91% increase in the number of subacromial
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16 174 decompressions over 10 years, with 266,692 procedures carried out in total. Most of this increase
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18 175 took place before 2011/12, and procedure rates have slightly decreased between 2011/12 and
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20 176 2016/17. Whilst the gender balance and age of those having shoulder surgery have remained steady
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22 177 over the last decade, the proportion of procedures conducted as day cases, using arthroscopy,
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24 178 and/or by independent (i.e. non-NHS) providers, have all increased (Table 1).
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30 180 Table 1: Descriptive information for subacromial decompression patients, 2007/08 and 2016/17

	2007/08	2016/17
Procedure Count	15,112	28,802
%women	51.0	52.0
Age in years (SD)	54.94 (12.55)	54.89 (12.39)
% Arthroscopy	39.0	94.1
% Independent Providers	2.4	31.9
% Day-case	51.0	79.3

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43 **183 The cost of subacromial decompression in England**
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46 184 In 2016/17, the median cost of an elective admission for subacromial decompression alone was
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48 185 £4,476. The cost of subacromial decompression in England rose from £33 million in 2007/08 to £125
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50 186 million in 2016/17. Over the 10-year period between 2007/8 and 2016/17 just under £1.1 billion was
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52 187 spent on subacromial decompression (excluding procedures done in combination with rotator cuff
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54 188 repair).
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58 **189 Variation in use of subacromial decompression in England**
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3 190 In 2016/17 there was substantial variation in procedure rates between CCGs, after adjusting for age,
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5 191 sex, deprivation, and ethnicity profiles (Figure 3). The map demonstrates pockets of very high use
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7 192 (>150% of the expected rate), for example in the Reading area, Wiltshire, and East Lincolnshire.
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10 193 There were also areas where procedure rates were less than 50% of the expected rate, such as in
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12 194 Worcestershire, Gloucestershire, Swindon, and North Norfolk. In 2016/17 the ratio of procedure
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14 195 rates between a 'high use' CCG at the 90th percentile and a 'low use' CCG at the 10th percentile was
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16 196 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
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19 197 overlapping confidence intervals suggest this may be due to chance variation; see Table 2.
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22 198 Table 2: 90/10 percentile ratios for directly age-sex standardised rates of subacromial
23 199 decompression by CCG, England, 2007/8-2016/17

Year	90th Pct	10th Pct	90/10 Ratio (95% 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)

39 200 *Confidence intervals for rate ratios³⁷
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42 202 International comparison of rates of subacromial decompression

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46 203 Table 3 shows rates of subacromial decompression in the most recent year available from England,
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48 204 Finland, Florida State, New York State, and Western Australia. Rates in England were lower, often
49
50 205 only half, that of other countries. For subacromial decompression alone, the procedure rates were
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52 206 lower in England (52 per 100,000 in 2016/17) than Western Australia (roughly 115 per 100,000 in
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54 207 2013),³⁸ Florida State (130 per 100,000 in 2007),³⁹ and Finland (131 per 100,000 in 2011).⁴⁰
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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 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

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
Iyengar et al. (2014)	Florida State	2007	~130
Our Data	England	2016/17	52

Notes: Numbers for Thorpe et al (2016) and Iyengar et al. (2014) were estimated from a graph; New York State data is for subacromial decompression with/without rotator cuff repair; SAD = Subacromial Decompression³⁸⁻⁴¹

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3 228 **DISCUSSION**
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6 229 **Statement of principal findings**
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9 230 NHS England carries out nearly 30,000 subacromial decompression operations per year, at an annual
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11 231 cost of over £125 million. Between 2007/08 and 2016/17, 266,692 subacromial decompression
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13 232 procedures were carried out in England costing nearly £1.1 billion, before the addition of the CSAW
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15 233 and FIMPACT placebo-controlled trial results to the existing evidence prompted serious questions
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17 234 about the clinical benefit of the procedure. Rates of subacromial decompression alone in England
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19 235 have gradually declined since 2011/12, although an increasing number are carried out in
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21 236 combination with rotator cuff repair. There was large variation between CCGs in England, even after
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23 237 adjustment for demographic variables, with 'high-use' areas carrying out nearly three times as many
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25 238 procedures as 'low-use' areas. Procedure rates in England were notably lower than other countries,
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27 239 arguing against any levelling of procedure rates being due to saturation of 'demand' for shoulder
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29 240 surgery.
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35 241 **Strengths and weaknesses of the study**
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38 242 Our study used a national, longitudinal dataset over a 10-year period covering all NHS secondary
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40 243 care providers in England. Hospital Episode Statistics are administrative rather than specifically
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42 244 designed for research. However, HES is also linked to payments for hospitals, which is a strong
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44 245 incentive to provide complete data, and allowed us to produce what we believe is the first
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46 246 exploration of costs associated with subacromial decompression in England. Payment by results
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48 247 tariffs are based on average national costs and may not reflect precise costs for each hospital
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50 248 admission. Population denominators, and linkage to the indices of multiple deprivation and census
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52 249 ethnicity data, allowed us to investigate trends and variations in procedure rates standardised on
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54 250 age, sex, deprivation and ethnicity. HES data records patients' area of residence, so we compared
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56 251 procedure rates based on place of residence rather than place of treatment. There may be other
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3 252 factors influencing rates which we have not controlled for (e.g. private health insurance coverage).
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5 253 HES does not record procedures which are privately funded and provided, meaning our surgery rates
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7 254 are an under-estimate of the population rate. We only provide cost data from 2007/08 onwards, so
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10 255 we under-estimate the amount spent on subacromial decompression prior to publication of the
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12 256 CSAW and FIMPACT trial results. International estimations of procedure rates do not use identical
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14 257 definitions of procedures and inclusion/exclusion criteria, but should be broadly comparable.
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17 258 **Implications for policymakers and clinicians**

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21 259 NHS England spent over £1 billion on subacromial decompression during the last 10 years without
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23 260 having compelling evidence of clinical effectiveness or cost-effectiveness. Rates of subacromial
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25 261 decompression were already rising rapidly from 2000/01 onwards.¹³ It seems plausible that
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27 262 increasing awareness of concerns about the effectiveness of subacromial decompression surgery¹⁵⁻¹⁷
28
29 263 and well-known recruitment to the CSAW trial tempered the rise in use of this surgery in England,
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31 264 otherwise more may have been spent. The CSAW trial involved 51 surgeons in 30 centres
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33 265 throughout the UK and was widely advertised and discussed amongst shoulder surgeons and
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35 266 shoulder physiotherapists. Extensive consultation was carried out by the trial team prior to and
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37 267 during the trial, including presentations at national meetings surveys and visits to individual
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39 268 surgeons and centres.⁴² A similar plateau/decrease in procedures was observed in Finland after the
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41 269 commencement of the FIMPACT study in 2005 which involved only 3 centres in Finland (Figure 2). It
42
43 270 is likely that awareness of a potential lack of effectiveness of subacromial decompression had been
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45 271 growing in the years before CSAW and FIMPACT, based on earlier trial results.¹⁵⁻¹⁷ However, it took
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47 272 well over a decade of increasing subacromial decompression use for clinical trial groups to run high
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49 273 quality, low risk-of-bias, placebo-controlled studies randomising a few hundred patients (313
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51 274 patients for CSAW¹⁸ and 210 in FIMPACT¹⁹) to investigate its effectiveness. This delay may be due to
52
53 275 perceived difficulties in recruiting patients to surgical trials with non-surgical comparators (e.g.
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55 276 UKUFF⁴³), as well as known challenges of conducting surgical RCTs.⁴⁴ Methods to optimise
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3 277 recruitment, as used in CSAW and other trials,⁴⁵ are available to support the completion of such
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5 278 'difficult' trials;⁴⁶ this should not now be a barrier to rapidly initiating trials to provide robust
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7 279 evidence about surgical interventions before they become widespread. More time is needed to see
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10 280 the longer-term impact of publication of the CSAW and FIMPACT results on subacromial
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12 281 decompression rates, both in the UK and internationally.

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15 282 The National Institute for Health and Care Excellence (NICE) requires evidence of cost-effectiveness
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17 283 to recommend new medicines to be paid for by the NHS. It is unclear why the bar for introducing
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19 284 expensive surgical procedures should be significantly lower. A balance needs to be struck between
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21 285 supporting innovation in surgical procedures and preventing unnecessary treatment. New initiatives
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23 286 such as IDEAL (Idea, Development, Exploration, Assessment, Long-term Follow-up, Improving the
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25 287 Quality of Research in Surgery)⁴⁷ aim to provide such a regulatory framework for introducing new
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27 288 interventions.

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32 289 It is important that new evidence is disseminated quickly without causing inequities in access to
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34 290 care. NICE published an updated Clinical Knowledge Summary for shoulder pain in April 2017⁴⁸
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36 291 incorporating information from a commissioning guide published by the Royal College of Surgeons.⁴⁹
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38 292 This recommended a range of conservative treatments from physiotherapy to corticosteroid
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40 293 injections, before surgery. However, many CCGs introduced their own criteria-based policies for
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42 294 access to shoulder surgery (e.g. through Individual Funding Requests)⁵⁰, essentially meaning that
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44 295 commissioners would only pay providers for surgery under particular circumstances. These were
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46 296 implemented at different times and with different details, underlining the extent to which
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48 297 insufficient evidence may drive clinical and commissioner uncertainty,⁵¹ and possibly leading to the
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50 298 wide variations shown across CCGs in our data. Where scientific evidence is applicable nationally or
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52 299 internationally, it would seem more efficient and appropriate to apply national policies to inform
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54 300 optimal use and encourage further research. There is a need to improve techniques for empirically-
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56 301 informed policy development in collaboration with relevant stakeholders.^{52 53}
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3 302 Despite the criticisms provided above, England has lower rates of shoulder surgery than other
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5 303 countries. The reasons for this are uncertain but could be due to differences in the health systems
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7 304 (e.g. GP gatekeeping of services), access to surgery and hospital reimbursement. Additionally, the
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10 305 National Institute of Health Research in England has funded major clinical trials on shoulder
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12 306 surgery,^{18 43} as well as other procedures,^{54 55} and is about to fund a further clinical trial to compare
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14 307 surgery with placebo surgery for partial thickness rotator cuff tears.⁵⁶ Whilst the UK's national
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16 308 regulatory processes are imperfect, they may provide examples to learn from. However, these
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18 309 processes did not sufficiently constrain the use of subacromial decompression, a procedure later
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21 310 found to have little clinical benefit.

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23
24 311 There have been several other controversies regarding the lack of effectiveness of procedures which
25
26 312 have become commonplace. One example is the use of stents to open narrowed arteries for
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28 313 treatment of stable angina (chest pain). Around half a million people receive stents for stable angina
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30 314 each year in the US and Europe,⁵⁷ but a recent (RCT) including a placebo intervention found no
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32 315 difference in chest pain outcomes between inserting a stent and using standard medications.⁵⁸
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34 316 Another example is arthroscopy to clean out the knee joint, on which around \$4 billion is spent each
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36 317 year in the US.⁵⁹ Recent RCTs,^{60 61} including one using a placebo procedure as a comparison,⁶¹ found
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38 318 no evidence of effectiveness to justify the spending. Whilst we use subacromial decompression as an
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40 319 example in this study, our observations are likely to apply to interventional procedures more
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42 320 generally.

43 44 45 46 47 321 **Unanswered questions and future research**

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51 322 The example of subacromial decompression highlights that, in the absence of rigorous evaluation,
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53 323 costly interventions can proliferate over a long period of time. To maximise limited resources, it is
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55 324 vital that methods are developed to identify promising procedures early and commission trials to
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57 325 examine their value, as well as identify existing health technologies that may be ineffective, leading
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59 326 to over-treatment and wasting of resources.

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3 327 There is an opportunity for a natural experiment exploring the impact of the results of the CSAW and
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5 328 FIMPACT trials^{18 19} on the development of CCG policies, national guidelines, and clinical decision-
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7 329 making with surgeons and patients. It is arguable that we should now see swift reductions in the use
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10 330 of subacromial decompression; research studies could help enhance the transfer of knowledge from
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12 331 trials into clinical practice.

15 332 **Conclusions**

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18 333 NHS England pays for nearly 30,000 shoulder subacromial decompression procedures each year at
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20 334 an annual cost of over £125 million, with little evidence that they are effective or cost-effective. The
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22 335 rates of this operation in other countries are even higher. This raises serious questions around the
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24 336 regulatory and professional processes governing the adoption and widespread use of surgical
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26 337 interventions. High quality RCTs should be funded early to examine the effectiveness and cost-
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28 338 effectiveness of expensive procedures using methods to optimise recruitment, and robust processes
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30 339 should be developed to reduce the use of ineffective procedures.

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3 349 **Author Statement**
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6 350 This publication is the work of the authors, who serve as guarantors for the contents of this paper. TJ
7
8 351 contributed to study design, data cleaning, data analysis, interpretation of results and writing the
9
10 352 manuscript. MJL contributed to study design, data cleaning, interpretation of results and writing the
11
12 353 manuscript. AC contributed to study design, interpretation of results and writing the manuscript. DB,
13
14 354 LR, and JD contributed to interpretation of results and writing the manuscript. WH contributed to
15
16 355 study conceptualization, study design, interpretation of results and writing the manuscript. TJ had
17
18 356 full access to the data in the study and takes responsibility for the integrity of the data and the
19
20 357 accuracy of the data analysis.
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26

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38
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41 365 Department of Health and Social Care.
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45 366 **Ethnical Approval**
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47
48 367 We were provided with routinely-collected Hospital Episode Statistics data under licence from NHS
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50 368 Digital (DARS-NIC-17875-X7K1V). The licence allows us to use the information under Section 261 of
51
52 369 the Health and Social Care Act 2012, 2(b)(ii): "after taking into account the public interest as well as
53
54 370 the interests of the relevant person, considers that it is appropriate for the information to be
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56 371 disseminated".
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60 372 **Data Sharing**

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3 373 This study is based in part on data from the Hospital Episode Statistics (HES) obtained under licence
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5 374 (DARS-NIC-17875-X7K1V) from NHS Digital (previously the Health and Social Care Information
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7 375 Centre); *Copyright © 2018, re-used with the permission of The Health & Social Care Information*
8
9 376 *Centre. All rights reserved.* The data are provided by patients and collected by the NHS as part of
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11 377 their care and support. HES data can be accessed via NHS Digital:
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14 378 <https://digital.nhs.uk/services/data-access-request-service-dars>

17 379 **Transparency**

20 380 The manuscript's guarantor (TJ) affirms that the manuscript is an honest, accurate, and transparent
21
22 381 account of the study being reported; that no important aspects of the study have been omitted; and
23
24 382 that any discrepancies from the study as originally planned have been explained.

27 383 **Competing Interests**

30 384 All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf
31
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33
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35
36 387 the previous three years; no other relationships or activities that could appear to have influenced
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38 388 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 alone³⁸⁻⁴¹

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

For peer review only

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

OR

<i>This procedure code in any position</i>
O29.1 Subacromial decompression

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

102x65mm (300 x 300 DPI)

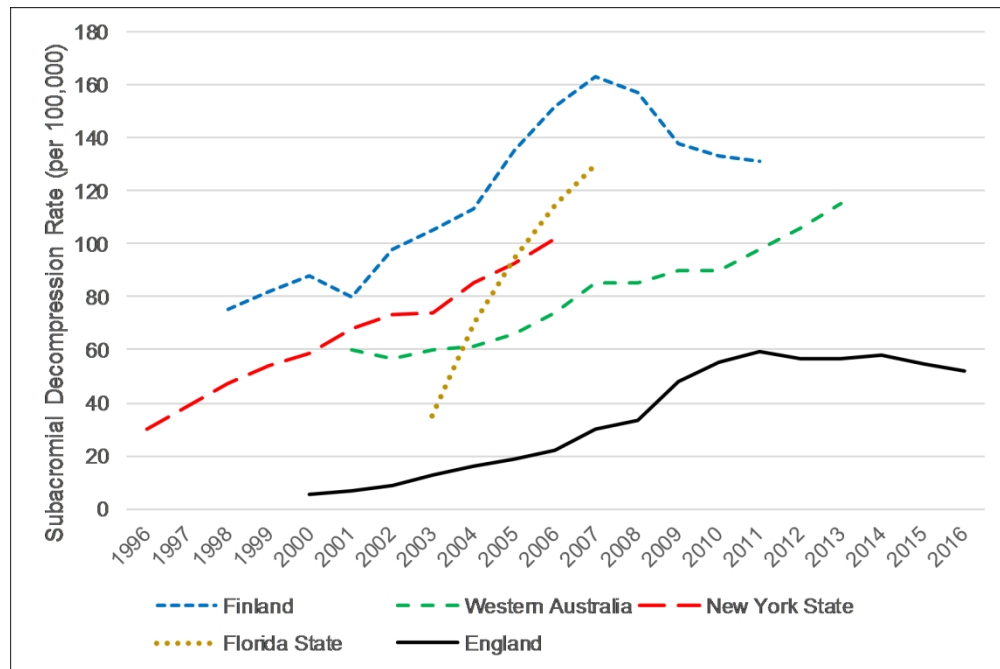


Figure 2. Directly standardised rates (per 100,000 people) of subacromial decompression in England, Finland, New York State USA, Florida State USA, and Western Australia. Notes for Figure 2. England data prior to 2007 is taken from Judge et al.¹³; New York State data is for subacromial decompression with or without rotator cuff repair, whilst data for Florida State, Finland and Western Australia is for subacromial decompression alone.³⁴⁻³⁷

150x99mm (300 x 300 DPI)

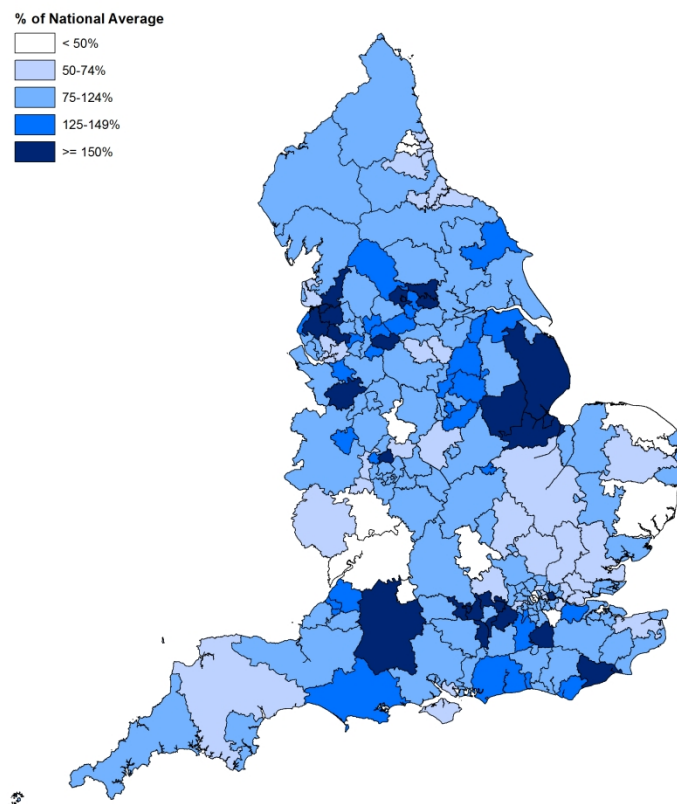


Figure 3. Indirectly standardised rates of subacromial decompression by CCG in England, 2016/17

210x296mm (300 x 300 DPI)

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 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 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).

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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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	Location in manuscript where items are reported
Title and abstract					
	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 summary of what was done and what was found		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. RECORD 1.2: If applicable, the geographic region and timeframe within which the study took place should be reported in the title or abstract. RECORD 1.3: If linkage between databases was conducted for the study, this should be clearly stated in the title or abstract.	40, 41 37, 40, 41, 42 40, 41
Introduction					
Background rationale	2	Explain the scientific background and rationale for the investigation being reported			77-115
Objectives	3	State specific objectives, including any prespecified hypotheses			116-120
Methods					
Study Design	4	Present key elements of study design early in the paper			126-163
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection			127-142

<p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27</p> <p>Participants</p>	<p>6</p>	<p>(a) <i>Cohort study</i> - Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> - Give the eligibility criteria, and the 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 of participants</p> <p>(b) <i>Cohort study</i> - For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> - For matched studies, give matching criteria and the number of controls per case</p>		<p>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.</p> <p>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.</p> <p>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.</p>	<p>136-142 and Figure 1</p> <p>Previous paper using same codes referenced: 137</p> <p>Linked to payment-by-results tariffs by HRG code (150-152), more of a lookup table than a core linkage; also Appendix A</p>
<p>28 29 30 31 32 33 34</p> <p>Variables</p>	<p>7</p>	<p>Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.</p>		<p>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.</p>	<p>136-142 and Figure 1</p>
<p>35 36 37 38 39 40 41 42</p> <p>Data sources/ measurement</p>	<p>8</p>	<p>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</p>			<p>136-152</p>

1 2 3 4	Bias	9	Describe any efforts to address potential sources of bias		136-148; standardisation
5 6 7 8 9	Study size	10	Explain how the study size was arrived at		136-142, 170-173
10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34	Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why		143-160
35 36 37 38 39 40 41 42 43 44	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		143-160
45 46 47	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: Authors should provide information on the data cleaning methods used in the study.	136-142
Linkage		..		RECORD 12.3: State whether the 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.	Linked to payment-by-results tariffs by HRG code (150-152), more of a lookup table than a core linkage; also Appendix A
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		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.	170-179, Table 1, Appendix A
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)			Table 1, 181-182
Outcome data	15	<i>Cohort study</i> - Report numbers of outcome events or summary measures over time			170-179

		<p><i>Case-control study</i> - Report numbers in each exposure category, or summary measures of exposure</p> <p><i>Cross-sectional study</i> - Report numbers of outcome events or summary measures</p>			
Main results	16	<p>(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</p> <p>(b) Report category boundaries when continuous variables were categorized</p> <p>(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period</p>			170-200
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses			204-218
Discussion					
Key results	18	Summarise key results with reference to study objectives			231-240
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.	242-257

1 2 3 4 5 6 7	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence		259-321
8 9 10 11	Generalisability	21	Discuss the generalisability (external validity) of the study results		319-321
12	Other Information				
13 14 15 16 17 18	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		361-364
19 20 21 22 23 24	Accessibility of protocol, raw data, and programming code		..	RECORD 22.1: Authors should provide information on how to access any supplemental information such as the study protocol, raw data, or programming code.	372-377

*Reference: Benchimol EI, Smeeth L, Guttman 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.

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