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## **Title Page**

# **Quantifying severe urinary complications after radical prostatectomy: the development and validation of a surgical performance indicator using hospital administrative data**

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## **Word Count:**

Text (including abstract): 2,898 words

2 **ABSTRACT**

3 **Objectives**

4 To develop and validate a surgical performance indicator based on severe urinary  
5 complications that require an intervention within two years after radical prostatectomy (RP)  
6 identified in hospital administrative data.

7 **Patients and Methods**

8 Men who underwent RP between 2008 and 2012 in England were identified using hospital  
9 administrative data. A transparent coding-framework based on procedure codes was  
10 developed to identify severe urinary complications which were grouped into “stricture”,  
11 “incontinence” and “other”. Their validity as a performance indicator was assessed by  
12 evaluating the consistency with diagnosis codes and association with patient and surgical  
13 characteristics. Kaplan-Meier methods were used to assess time to first occurrence and  
14 multivariable logistic regression to estimate adjusted odds ratios (OR) for patient and  
15 surgical characteristics.

16 **Results**

17 17,299 men were included, 2,695 (15.6%) experienced at least one severe urinary  
18 complication within two years. High proportions of men with a complication had relevant  
19 diagnosis codes: 86% for strictures and 93% for incontinence. Urinary complications were  
20 more common in men from poorer socio-economic backgrounds(OR comparing lowest with  
21 highest quintile: 1.45; 95%CI, 1.26-1.67) and those with prolonged length of hospital stay  
22 (OR 1.54, 95% CI, 1.40-1.69) and were less common in men who had robotic surgery (OR  
23 0.65, 95% CI, 0.58-0.74).

24 **Conclusion**

25 These results demonstrate severe urinary complications identified in administrative data  
26 provide a medium-term performance indicator after RP. They can be used for research  
27 assessing outcomes of treatment modalities and for service evaluation comparing  
28 performance of prostate cancer surgery providers.

29 **INTRODUCTION**

30 Men undergoing radical prostatectomy (RP) for prostate cancer (PCa) may experience  
31 treatment-related urinary complications. Their occurrence may reflect the quality of surgical  
32 care(1) but it is essential to demonstrate that they provide a valid outcome measure before  
33 they are used as an indicator of surgical performance.

34 Studies using administrative datasets have reported the incidence of complications after  
35 PCa treatment in the United States, England and Canada (2-6). However, none define a  
36 coding system to identify these complications explicitly or assess their validity as a  
37 performance indicator.

38 In this study, a transparent coding-framework is proposed based on procedure codes to  
39 identify complications severe enough to require a hospital readmission for a surgical  
40 procedure. Comparisons with relevant diagnosis codes were performed to demonstrate  
41 coding consistency. Further validation assessed the timing of these procedures and  
42 association with patient characteristics, including age, comorbidity, socioeconomic  
43 deprivation, and surgical characteristics, including length of hospital stay post-RP and  
44 surgical approach used.

45 **PATIENTS& METHODS**

46 Patient population

47 The Hospital Episode Statistics (HES) database, an administrative database of all admissions  
48 to hospitals of the National Health Service in England was used to identify patients who  
49 underwent RP between 1 January 2008 and 31 December 2012. HES records contain a  
50 unique patient identifier that allows for longitudinal follow-up(7). Diagnoses are coded using  
51 the International classification of Diseases, 10<sup>th</sup> revision (ICD-10)(8) and procedures are  
52 coded using the UK Office for Population Census and Surveys classification, 4<sup>th</sup> revision  
53 (OPCS-4)(9).Inpatient HES records were linked to the English National Cancer Data  
54 Repository (NCDR) to verify the diagnosis of PCa (10).

55 Data items in HES records were used to determine age, Charlson comorbidity score (11),  
56 socioeconomic deprivation status (12),length of hospital stay post-RP and the surgical  
57 approach used (Appendix, Table 1 for detailed description of coding-framework).

58

59 Inclusion and exclusion criteria

60 The records of 18,761 men with a procedure code for RP (OPCS-4 “M61”) were studied.  
61 Patients were excluded if they did not have a matching NCDR record (n=22), if they could  
62 not be linked to one of the 48 regional hubs providing RP (n=345) or if we could not  
63 determine their socioeconomic deprivation status according to the national ranking from  
64 the Index of Multiple Deprivation (n=41) (12) (Figure 1).

65

66 Men with an associated diagnosis of bladder cancer (n=229, ICD-10 “C61”) were excluded as  
67 their surveillance often requires interval cystoscopies which could be incorrectly captured as  
68 a treatment of a complication of RP. Men who received adjuvant or salvage radiotherapy  
69 (n=825) were excluded because it is not possible to distinguish between complications that  
70 occurred as a consequence of RP or radiotherapy (OPCS-4 codes defined in Appendix, Table  
71 1). As a result, we included 17,299 men for whom we had complete data and at least two  
72 years of follow-up (Figure 1).

73

#### 74 Technical coding

75 All HES records of readmissions two years after RP were examined to identify medium-term  
76 urinary complications(2).This 2-year follow-up period was chosen as a preliminary time-to-  
77 event analysis demonstrated that 80% of men who experienced a severe urinary  
78 complication within 5 years following RP had experienced the complication within the first 2  
79 years. Therefore, to standardise our outcome measure we report urinary complications  
80 within 2 years of RP.

81 Based on earlier studies, a comprehensive index list of OPCS-4 procedure codes related to  
82 urinary complications after RP was pre-specified (“forward-coding”) (2-4, 6). We also  
83 examined the most frequently occurring procedure codes in records of readmissions and  
84 added these to the pre-specified list if they were not already included but likely to be  
85 related to urinary complications (“backward-coding”). These specified procedure codes  
86 were further stratified into those related to the treatment of a “stricture” or “urinary  
87 incontinence”. Procedure codes not clearly related to either complication were labelled as

88 “other”. Importantly, HES records never included both stricture and incontinence  
89 procedures in the same readmission.

90 If more than one relevant procedure code related to a specific urinary complication was  
91 present in a readmission record, the first procedure code in the record was used. Based on  
92 the above coding rules, the frequency of readmissions was separated according to type of  
93 urinary complication and by specific OPCS-4 procedures codes (Table 2).

94 Patients were considered as not having experienced a severe urinary complication if there  
95 were no hospital readmissions in the first two years after RP or if there were no relevant  
96 procedure codes in the first seven procedural fields of a readmission.

97

#### 98 Coding consistency

99 We assessed whether consistent diagnostic codes were present in the first seven diagnosis  
100 fields in records of episodes that contained procedure codes for treatment of a stricture or  
101 urinary incontinence. An index list of diagnosis codes for stricture or urinary incontinence  
102 was generated according to the ICD-10 classification using the forward-coding approach  
103 (Appendix, Table 2).

104

#### 105 Statistical analysis

106 Kaplan-Meier curves were used to assess the time to the first occurrence of a stricture,  
107 incontinence or “other” severe urinary complication or to the first occurrence of any of  
108 these complications.



109 Multivariable logistic regression modelling was used to assess the impact of patient (age,  
110 comorbidity, socioeconomic deprivation status) and surgical characteristics (length of stay  
111 and surgical approach) on the occurrence of a urinary complication in the first two years  
112 after RP as defined above. Results are reported as odds ratios and a p-value smaller than  
113 0.05 was considered statistically significant. P-values were based on the Wald test or the  
114 likelihood ratio test as appropriate.

115 A funnel plot for any medium-term severe urinary complication was generated to assess  
116 whether the study outcome measure could be used as a performance indicator comparing  
117 the proportion of patients with one or more complication across 48 specialist hubs that  
118 provide RP in England (13). Risk adjustment was performed to account for possible  
119 differences in case-mix using indirect standardisation whereby a standardised event ratio  
120 was obtained for each provider by dividing the observed by the expected number of  
121 complications(14). The adjusted rate for a provider was generated by multiplying this  
122 standardised event ratio by the national average complication rate. The expected number of  
123 complications was estimated with the multivariable logistic regression model adjusting for  
124 covariates as described earlier. The funnel plot was generated using two-sided control limits  
125 defining differences corresponding to two standard deviations (inner limits) and three  
126 standard deviations (outer limits) from the national average complication rate. If a  
127 provider's "true" complication rate is the same as the national rate, the probability that the  
128 adjusted complication rate for this provider will fall outside the funnel is 5% for the inner  
129 control limits and 0.2% for the outer control limits. Stata® version 14 (StataCorp, College  
130 Station, Texas, USA) was used for all statistical calculations.

131 **RESULTS**

132 Patient population

133 Approximately 60% of the 17,299 men included were between 60 and 69 years old, one in  
134 seven had at least one recorded comorbidity, and one in three stayed in hospital for longer  
135 than three days post-RP(Table 1).During the study period, open-RP was the most commonly  
136 used (39.7%) and robotic the least commonly used surgical approach (28.6%).

137

138 Frequency of severe urinary complications

139 2,695 men (15.6%) experienced at least one severe urinary complication within two years of  
140 RP. These men required 3,609 readmissions for complication-related procedures (1.3  
141 readmissions/man) (Table 2). The most frequent complication-related procedure (1,436 of  
142 3,609 complications, 39.8%) was an “unspecified endoscopic examination of the bladder”.  
143 The most frequent procedure for strictures (408 of 1567 complications, 26.0%) was  
144 “endoscopic incision of outlet of male bladder” and for incontinence (143 of 149  
145 complications, 96.0%) was “implantation of an artificial urinary sphincter”.

146

147 Type and timing of urinary complications

148 Within two years of RP, 6.5% of men had experienced at least one recorded readmission  
149 with a treatment code related to a stricture, 0.8% related to incontinence and 11.5% of men  
150 related to “other” complications (Figure 2). The treatment codes related to these “other”  
151 complications could be grouped into cystoscopy (1,159 out of 1860 readmissions [62.3%])  
152 and procedures addressing catheter problems (701 out of 1860 readmissions [37.7%]),

153 based on first occurring complication (Appendix, Figure 1). Approximately two thirds of men  
154 experienced a severe urinary complication within the first six months after RP (1,712 out of  
155 2,695 [63.5%]) (Figure 3).

156

#### 157 Coding consistency

158 There was high degree of consistency between the OPCS-4 codes used to capture  
159 procedures related to urinary complications and ICD-10 diagnosis codes for strictures and  
160 urinary incontinence in the records of readmission episodes. A consistent diagnosis code  
161 was observed for 1,350 out of 1,567 (86%) of records that contained a procedure code  
162 related to a stricture and for 138 out of 149 (93%) of records that related to incontinence.

163

#### 164 Association with patient and surgical characteristics

165 Multivariable analysis demonstrated that the occurrence of at least one complication in the  
166 first two years after RP was significantly lower in those from more affluent socioeconomic  
167 backgrounds, in those who stayed three days or less in hospital following RP, and in those  
168 who had a robotic approach (Table 3). The univariable analysis also demonstrated significant  
169 associations between the year in which RP was carried out, the patient's age, comorbidity  
170 status and the occurrence of urinary complications but these associations were no longer  
171 observed in the multivariable analysis, adjusting for other patient characteristics and  
172 treatment factors.

173 A risk-adjusted funnel plot was generated for two-year rates of any severe urinary  
174 complication in each of the 48 regional PCa surgery providers (Figure 4). Ten of the

175 48 providers were located outside the outer limits of the funnel (five above the upper and  
176 five below the lower outer limit).

177 **DISCUSSION**

178 A transparent coding-framework was developed to identify severe urinary complications  
179 after RP within English hospital administrative data. Because the coding-framework is solely  
180 based on procedure codes it includes complications severe enough to require a readmission  
181 to hospital. We demonstrated that the rate of complications identified in this way appears  
182 to be a valid indicator of surgical performance of RP providers given the consistency with  
183 relevant diagnosis codes, the anticipated pattern of the timing of these complications, and  
184 the association with treatment factors which have been reported to be linked to surgical  
185 complications. When this two-year complication rate was used as an indicator of the  
186 performance of PCa surgery providers we found a pattern often reported for other  
187 established surgical indicators (15).

188

189 Methodological considerations

190 We developed a comprehensive coding list that reflects current coding practice by using  
191 both a forward and a backward-coding approach. Using this methodology we were able to  
192 demonstrate that 86% of stricture-related complications and 93% of incontinence-related  
193 procedures had appropriate diagnosis codes. This high level of compatibility in operative  
194 and diagnostic coding validates our approach and is comparable to that reported in other  
195 published studies using administrative data (16).

196 Procedure codes were used in preference to diagnosis codes for two reasons. First, there is  
197 evidence that the accuracy of procedural coding is greater than diagnostic coding within  
198 administrative data (17). Second, the use of procedure codes ensured only complications

199 severe enough to require hospital-based treatments were captured. In this way, we avoided  
200 “overestimation” of the complication rate, a recognised problem when diagnosis codes are  
201 used for this purpose(18).

202 Multivariable modelling corroborated the associations between patient/surgical  
203 characteristics and urinary complications previously reported in the literature. Men who  
204 stayed in hospital three days or less after surgery and those who underwent a robotic-RP  
205 were found to be significantly less likely to experience a severe urinary complication, as  
206 reported in other studies(19-21). We also found that the complication rate was affected by  
207 the patient’s socioeconomic background which corresponds with earlier observations in  
208 men who underwent RP in the English National Health Service (NHS) between 1997 and  
209 2004(5).

210 The observed timing of the different types of complications reflects what can be expected  
211 based on pathophysiological considerations. For example, most severe urinary  
212 complications that occurred within the first month after surgery were recognised as “other”  
213 complications (i.e. those that were not grouped into stricture or incontinence) and they  
214 consisted of unplanned cystoscopies and procedures related to catheter problems. We  
215 found that stricture-related treatments occurred after the immediate post-operative period  
216 and increased steadily thereafter in keeping with the physiological process of stricture  
217 formation. Interventions for incontinence were rare in the first two years after RP with less  
218 than 1% requiring a procedure, consistent with earlier observations (22).

219 We used a classification system for procedures (OPCS-4) that is only currently used for  
220 hospital administrative data in the UK. This implies that the proposed indicator can only be  
221 applied in other health systems after the coding-framework presented in the current study

222 has been “translated” for other procedure coding classification systems. We however  
223 expect that this will have minimal effect on the validity of the surgical performance indicator  
224 presented in the current study. A number of different procedural classification systems are  
225 employed to code for procedures within datasets of a number of different countries. For  
226 example, in the US the Healthcare Common Procedure Coding System (HCPS) is used to  
227 code for operative procedures whereas in Canada, the Canadian classification of Diagnostic,  
228 Therapeutic, and Surgical procedures is employed. By using the backward coding approach  
229 presented in the current study, local coding practice within these different procedure coding  
230 systems can be determined and as such a similar surgical performance indicator to that  
231 presented in the current study can be developed.

232 A limitation of using procedure codes as a surrogate for urinary complications is that  
233 patients who were symptomatic but did not undergo an intervention for their symptoms are  
234 not captured and so absent from our analysis. We were not able to identify this cohort of  
235 patients and as such the overall burden of urinary complications is likely to be an  
236 underestimate, particularly for urinary incontinence. A further limitation is that we were not  
237 able to externally validate our study indicator using clinical records. Nonetheless we feel  
238 that the transparent coding framework and step-wise internal validation used to develop  
239 the study indicator, a process which is lacking in other studies using administrative  
240 database, justifies its validity as a surgical performance indicator.

241

242 Comparison with other studies

243 Two recent studies used physician billing codes to determine a list of “urologic minimally  
244 invasive procedures” which acted as a surrogate for urinary complications (2, 6). These  
245 studies focussed on differences in outcome between men undergoing RP versus  
246 radiotherapy. In contrast to the present study, these studies did not provide a transparent  
247 coding-framework nor did they assess the validity of this outcome as a performance  
248 indicator. Earlier studies carried out in the US (3), Canada (4) and England (5)(6) used  
249 diagnosis codes solely or in combination with procedure codes which may lead, as indicated  
250 above, to overestimation of the complication rates(18).

251

252

### 253 Applicability of study performance indicator

254 Using a funnel plot, we found that the proportion of patients who experienced a severe  
255 urinary complication according to our performance indicator was distributed among the 48  
256 regional providers of RP in England as could be expected based on results of comparisons of  
257 other outcomes of urological cancer treatment across secondary care providers (15). This  
258 provides further support that severe urinary complications identified in administrative data  
259 can be used to assess variation in surgical performance. This is of particular relevance in the  
260 UK NHS where initiatives such as the National Prostate Cancer Audit (NPCA)(23) exist to  
261 evaluate variation in the quality of prostate cancer surgery. The surgical performance  
262 indicator presented in the current study will be used alongside other outcome metrics  
263 including Patient Reported Outcome Measures (PROMs) to provide an overall assessment of  
264 the quality of prostate cancer surgical care in England. While we were not able to reliably



265 identify the operating surgeon using our existing database; it is envisaged that further data-  
266 linkage within the NPCA will allow surgeon-level reporting in the future. Moreover, given  
267 the rapid diffusion of robotic RP, this outcome measure has the potential to be used to  
268 compare the medium-term outcomes of different approaches to RP.

269

## 270 Conclusions

271 The current study provides a transparent coding-framework to capture severe urinary  
272 complications in the first two years after radical prostatectomy in hospital administrative  
273 data. These complications can be used as a performance indicator for service evaluation and  
274 research.

275

## 276 Conflicts of Interest

277 No competing interests were declared.

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288 **Table 1: Patient and surgical characteristics of men undergoing**  
 289 **radical prostatectomy (RP) (2008 – 2012)**

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293	<b>No. of men receiving RP</b>	17,299
294		
295	<b>Year of RP (%)</b>	
296	2008	2,004 (11.6)
297	2009	3,501 (20.2)
298	2010	3,694 (21.4)
299	2011	4,002 (23.1)
300	2012	4,098 (23.7)
301		
302	<b>Age (%)</b>	
303	<60	5,391 (31.2)
304	60-69	10,117 (58.5)
305	>70	1,791 (10.4)
306		
307	<b>Charlson comorbidity score (%)</b>	
308	0	14,382(83.1)
309	≥1	2,917 (16.9)
310		
311	<b>Socioeconomic deprivation (%)</b>	
312	1(least)	4,432 (25.6)
313	2	4,239 (24.5)
314	3	3,590 (20.8)
315	4	2,888 (16.7)
316	5 (most)	2,150 (12.4)
317		
318	<b>Length of stay post RP (days) (%)</b>	
319	≤3	11,597 (67.0)
320	>3	5,702 (33.0)
321		
322	<b>RP surgical approach (%)</b>	
323	Open	6,873 (39.7)
324	Laparoscopic	5,479 (31.7)
325	Robotic	4,949 (28.6)
326		

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340 **Table 2: Frequency of readmissions for treatment-related complications within two years of**  
 341 **radical prostatectomy**

342

OPCS-4 code	Description	Total readmissions	
M44.8/9	Other endoscopic operations on bladder	27	<b>“Other” urinary complication</b>
M45.5	Examination of bladder using rigid cystoscope	79	
M45.8	Other specified endoscopic examination of bladder	30	
M45.9	Unspecified endoscopic examination of bladder	1,436	
M47.1	Urethral irrigation of bladder	150	
M47.8/9	Other specified urethral catheterisation of bladder	171	
M48.1	Suprapubic aspiration of bladder	3	<b>Stricture-related complication</b>
M64.8	Other specified open operations on outlet of male bladder	28	
M65.1-5	Endoscopic resection of prostate	13	
M65.8/9	Other specified endoscopic resection of outlet of male bladder	13	
M66.9			
M66.2	Endoscopic incision of outlet of male bladder	408	
M66.8	Other specified therapeutic endoscopic operations on outlet of male bladder	115	
M76.3	Optical urethrotomy	388	
M76.4	Endoscopic dilation of urethra	368	
M76.8/9	Other therapeutic endoscopic operations on urethra	5	
M79.2	Dilation of urethra	202	
M79.4	Internal urethrotomy	24	<b>Incontinence-related complication</b>
M64.2	Implantation of artificial urinary sphincter into outlet of male bladder	143	
M64.3	Insertion of prosthetic collar around outlet of male bladder	4	
M64.6	Reconstruction of neck of male bladder	2	
	<b>Total</b>	<b>3,609</b>	

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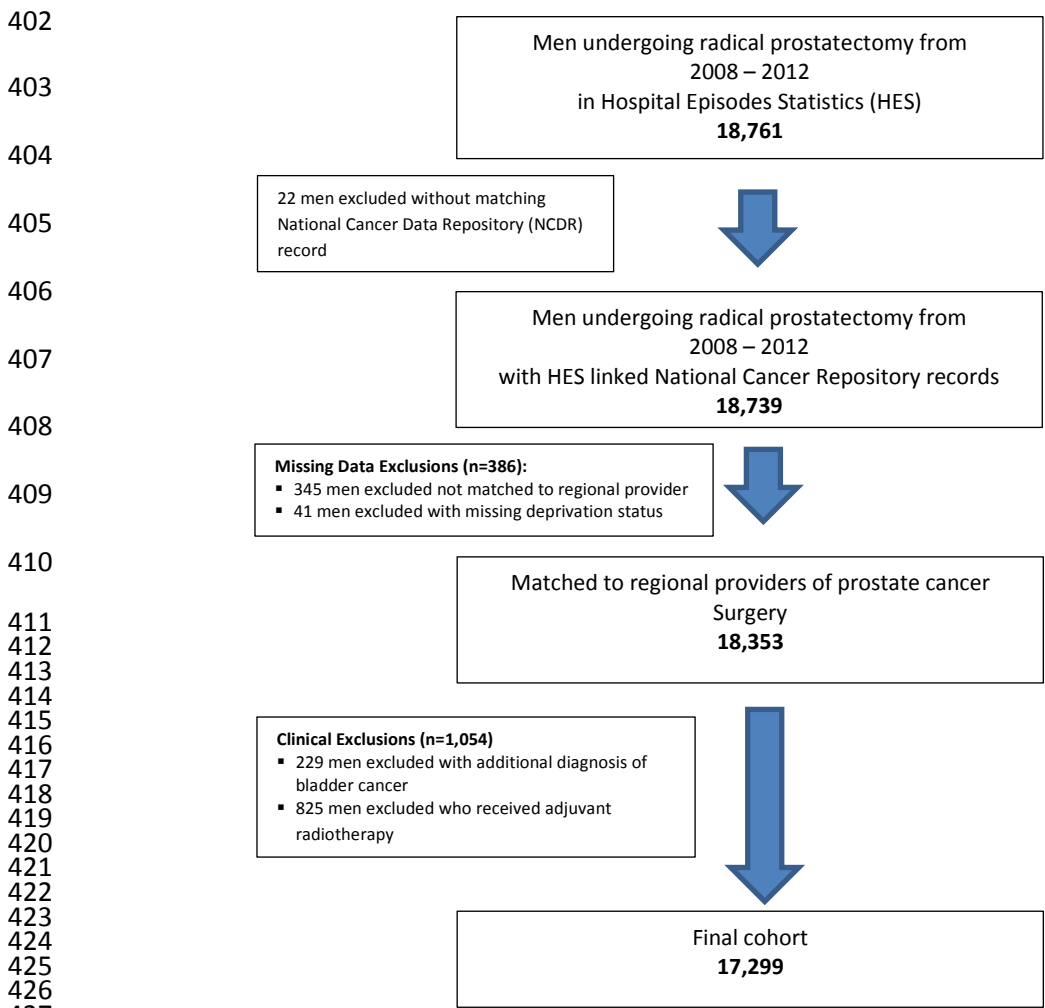
356 **Table 3: Relationship between patient and surgical characteristics and occurrence of at least one urinary complication following radical**  
 357 **prostatectomy (RP)**

360	361	362	363	364					
Patient Characteristics	No. of men with a Urinary complication (%)	Unadjusted OR (95% CI)	<i>p</i>	Adjusted OR* (95% CI)	<i>p</i>				
365 <b>Year of RP</b>									
366 2008	349 (17.4)	1.0	<0.01	1.0	0.08				
367 2009	633 (18.1)	1.05 (0.91-1.21)		1.12 (0.97-1.29)					
368 2010	581 (15.7)	0.89 (0.77-1.02)		1.00 (0.87-1.17)					
369 2011	578 (14.4)	0.81 (0.69-0.93)		0.98 (0.84-1.13)					
370 2012	554 (13.5)	0.74 (0.64-0.86)		0.94 (0.81-1.09)					
371 <b>Age</b>									
372 <60	823 (15.3)	1.0	0.04	1.0	0.11				
373 60-69	1555 (15.4)	1.01 (0.92-1.10)		0.99 (0.90-1.09)					
374 ≥70	317 (17.7)	1.19 (1.04-1.38)		1.14 (0.99-1.32)					
375 <b>Charlson comorbidity score</b>									
376 0	2196 (15.3)	1.0	0.01	1.0	0.18				
377 ≥1	499 (17.1)	1.15 (1.03-1.27)		1.08 (0.97-1.20)					
378 <b>Socioeconomic deprivation</b>									
379 1(least)	580 (13.1)	1.0	<0.01	1.0	<0.01				
380 2	661 (15.6)	1.23 (1.09-1.38)		1.18 (1.04-1.33)					
381 3	528 (14.7)	1.15 (1.01-1.30)		1.07 (0.94-1.22)					
382 4	506 (17.5)	1.41 (1.24-1.60)		1.32 (1.15-1.50)					
383 5(most)	420 (19.5)	1.61 (1.40-1.85)		1.45 (1.26-1.67)					
384 <b>Length of stay</b>									
385 ≤3	1497 (12.9)	1.0	<0.01	1.0	<0.01				
386 >3	1198 (21.0)	1.79 (1.65-1.95)		1.54 (1.40-1.70)					
387 <b>RP surgical approach</b>									
388 Open	1309 (19.1)	1.0	<0.01	1.0	<0.01				
389 Laparoscopic	866 (15.8)	0.79 (0.73-0.88)		0.98 (0.88-1.08)					
390 Robotic-assisted	520 (10.5)	0.50 (0.45-0.56)		0.65 (0.58-0.74)					

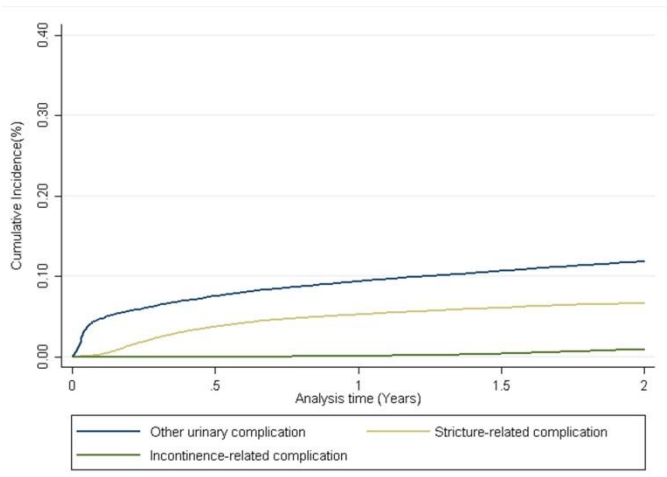
398 CI= confidence interval  
 399 \*Odds Ratio derived using multivariable logistic regression

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401 **Figure 1: Flow chart of men included in study**



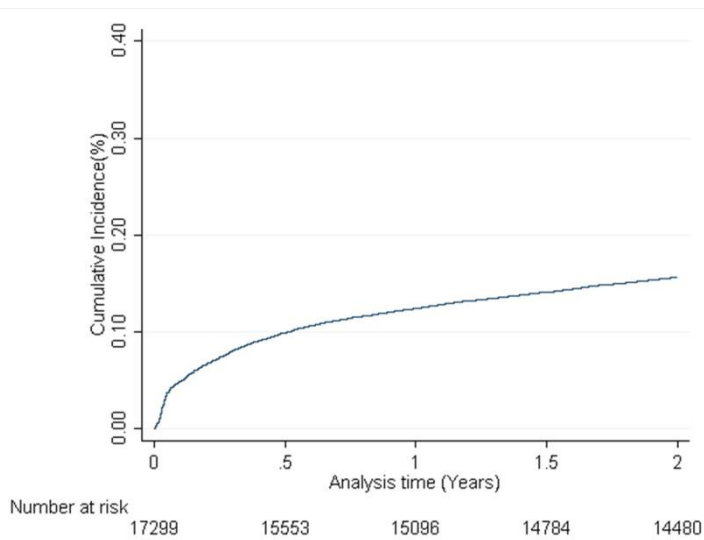
439 **Figure 2: Kaplan-Meier curves for urinary complications according to type of complication**



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442 **Figure 3: Kaplan-Meier curve for any urinary complication following radical prostatectomy**



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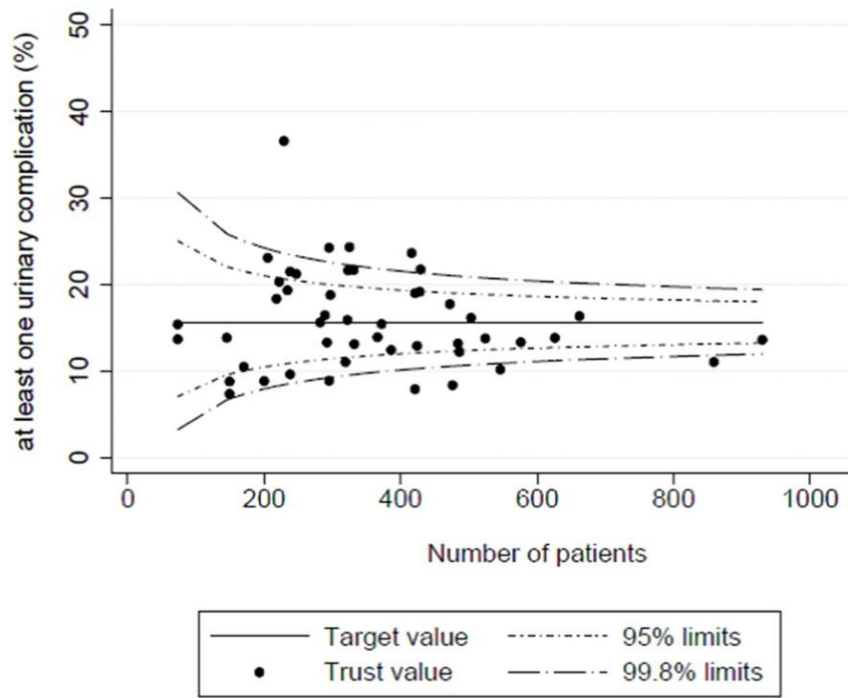
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450 **Figure 4: Risk-adjusted funnel plot of any urinary complication in 48 regional providers of**  
451 **prostate cancer surgery in England**  
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468 **Supplementary Files & Data**

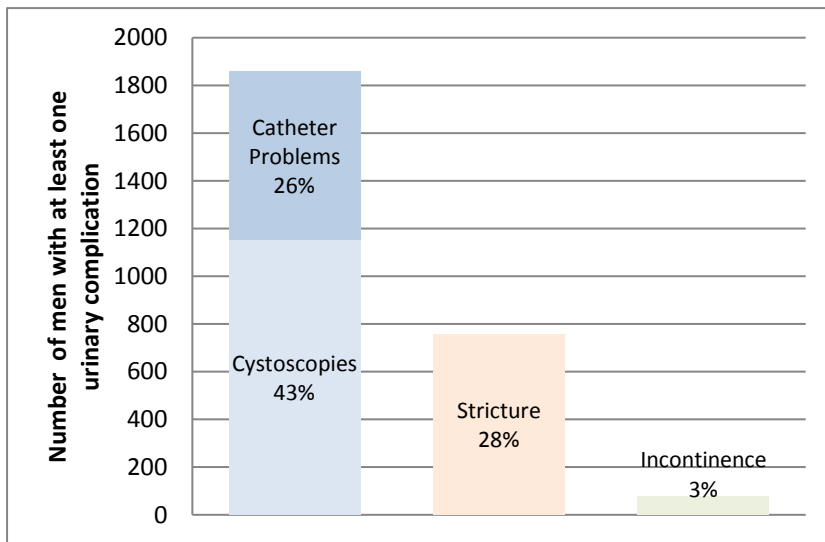
469 **Appendix**

470 **Table 1: OPCS-4 and ICD-10 codes used to identify men receiving adjuvant radiotherapy and**  
 471 **type of radical prostatectomy approach.**

Procedure Description	OPCS-4 codes	ICD-10 codes
Adjuvant Radiotherapy	X65, X67, Y91, Y92	Y842, Z0081, Z091, Z510, Z58, Z923
Robotic-assisted Prostatectomy	Y753, Y765	-
Laparoscopic Prostatectomy	Y752, Y768, Y763, Y751, Y508	-

472

473 **Figure 1: Treatment codes associated with first occurring urinary complication according to**  
 474 **type of urinary complication.**



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477 **Table 2: ICD-10 codes used to identify diagnoses of a stricture and incontinence**

ICD-10 Diagnosis Codes	Description of diagnosis
N320 N35, N991, R33	Stricture-related
N393, N394, N398, R32	Incontinence-related

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