


# Prostate Cancer Care Before and After Medicare Eligibility

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Marco D. Huesch, MBBS, PhD<sup>1</sup> and Michael K. Ong, MD, PhD<sup>2</sup>

## Abstract

Prior studies suggest Medicare eligibility confers significant and substantial reductions in mortality and beneficial increases in health service utilization. We compared 13 882 patients diagnosed with prostate cancer at ages 63 to 64 years with 14 774 patients diagnosed at ages 65 to 66 (controls) in 2004 to 2007. Compared with controls, patients diagnosed with prostate cancer before Medicare eligibility had no statistically significant or meaningful differences in cancer stage, time to treatment, or type of treatment.

## Keywords

uninsured, cancer, insurance, Medicare, near elderly, prostate cancer

## Introduction

Health insurance coverage is generally associated with better health outcomes and with receipt of appropriate care,<sup>1–3</sup> but whether this is true among the near elderly<sup>4–6</sup> or among cases of common, serious cancers diagnosed around the 65th year of age<sup>7</sup> is less well understood. In this brief report, to be considered in conjunction with a larger accompanying study of lung cancer, we examine prostate cancer and seek to understand whether the magnitude of beneficial insurance effects is as high as suggested by the prior literature,<sup>8,9</sup> and whether paradoxical harms caused by patient and physician moral hazard exist.

## Background and Hypotheses

Prostate cancer is typically a more slowly progressing cancer, one of the most common cancers among US men,<sup>10</sup> prevalent among patients around the time of access to relatively low cost, generous Medicare health insurance. We hypothesized that, as for lung cancer, diagnoses made before or after Medicare eligibility would be associated with different staging and treatment.

More treatment may also be obtained by some minorities who tend to present with more advanced disease,<sup>11</sup> and in whom stage at diagnosis is inversely correlated with insurance status and income.<sup>7,12,13</sup> Access to Medicare may also allow the use of potentially unwarranted aggressive therapy such as radical prostatectomy or radiotherapy in low-risk strata in response to the ability of patients to request such services or physicians to provide and bill for them.<sup>14–16</sup>

Moreover, in the absence of clearly superior treatment modalities,<sup>17–21</sup> any variation in treatment may harm patients and result in the inefficient use of scarce health care resources.

Better access to care may increase screening in response to Medicare's prostate-specific antigen (PSA) and digital rectal exam screening services.<sup>22,23</sup> We hypothesized that patients without symptoms on turning 65 years of age might receive more screening due to increased access to primary and preventive care. Access to intensive surgical or radiotherapeutic treatment options might then be more available to these patients than their younger cohort neighbors leading to higher utilization of both surgery and radiotherapy.

## Data and Methods

We analyzed a national convenience samples based on Surveillance, Epidemiology, and End Results (SEER) registry data maintained by the National Cancer Institute (NCI). The NCI administers 15 SEER registries, which cover approximately 26% of the national population. We used birth month and year and first diagnosis of prostate cancer

<sup>1</sup>University of Southern California, Los Angeles, USA

<sup>2</sup>University of California, Los Angeles, USA

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### Corresponding Author:

Marco D. Huesch, USC Leonard D. Schaeffer Center for Health Policy and Economics, University of Southern California, Verna & Peter Dauterive Hall (VPD), 635 Downey Way, Los Angeles, CA 90089-3333, USA.  
Email: huesch@usc.edu



**Table 1.** Prostate Cancer, Type of Therapy Received, and Crude and Adjusted Risk Ratios.

	No. (%)		P value	Risk ratios (95% CI) of 65- to 66-year cohort vs 63- to 64-year cohort	
	63- to 64-year cohort (n = 13882)	65- to 66-year cohort (n = 14774)		Crude	Adjusted <sup>a</sup>
Surgery received					
None	7068 (50.9)	8068 (54.6)	<.001	1.07 (1.05-1.10)	1.07 (1.05-1.10)
Local destruction <sup>b</sup>	152 (1.1)	236 (1.6)	<.001	1.46 (1.19-1.79)	1.43 (1.17-1.75)
TURP ± local destruction <sup>b</sup>	347 (2.5)	429 (2.9)	.04	1.16 (1.01-1.34)	1.15 (0.99-1.33)
Radical prostatectomy	6146 (44.3)	5846 (39.6)	<.001	0.89 (0.87-0.92)	0.90 (0.87-0.92)
Radiation received					
None	8670 (62.5)	8910 (60.3)	<.001	0.97 (0.95-0.98)	0.96 (0.94-0.98)
Beam	2675 (19.3)	3108 (21.0)	<.001	1.09 (1.04-1.14)	1.09 (1.04-1.14)
Brachytherapy	1518 (10.9)	1675 (11.3)	.28	1.04 (0.97-1.11)	1.05 (0.99-1.13)
Beam and brachytherapy	643 (4.6)	698 (4.7)	.71	1.02 (0.92-1.13)	1.06 (0.95-1.17)
Neither surgery nor radiation	2353 (17.0)	2766 (18.7)	<.001	1.10 (1.05-1.16)	1.08 (1.03-1.14)
Low-risk stratum <sup>c</sup>	(n = 3835)	(n = 4034)			
No surgery	2680 (69.9)	2931 (72.7)	.007	1.04 (1.01-1.07)	1.05 (1.02-1.08)
Radical prostatectomy	991 (25.8)	882 (21.9)	<.001	0.85 (0.78-0.92)	0.83 (0.77-0.90)
No radiation	1873 (48.8)	1858 (46.1)	.01	0.94 (0.90-0.99)	0.93 (0.88-0.97)
Beam radiotherapy	776 (20.2)	908 (22.5)	.01	1.11 (1.02-1.21)	1.12 (1.02-1.22)
Neither surgery nor radiation	775 (20.2)	833 (20.6)	.63	1.02 (0.94-1.12)	1.00 (0.92-1.10)

Note. CI = confidence interval; TURP = transurethral resection of the prostate; PSA = prostate-specific antigen.

<sup>a</sup>Adjusted for registry locations, year of diagnosis, Hispanic ethnicity, race, and marital status.

<sup>b</sup>Cryoprostectomy, laser ablation, hyperthermic, microwave, ultrasound, needle, or other local tumor destruction.

<sup>c</sup>PSA ≤ 10 ng/mL, and T2a or lower, and Gleason score of 6 or lower, where T2 NOS (not otherwise specified) staged disease classified as ≤T2a.

diagnosis month and year to construct 2 cohorts. We included 13 882 patients in a pre-Medicare-eligibility 2-year cohort aged between 63 and 64, and 14 774 patients in a post-65-year-old 2-year cohort aged between 65 and 66. We tested the significance of changes in categorical variables using chi-square tests. We used Kruskal-Wallis equality of population tests for changes in continuous variables such as tumor marker variables or ordinal biopsy score, and median tests for equality of medians. We compared proportions receiving types of treatment using Fisher's exact tests of crude risk ratios and adjusted risk ratios.

This study was approved by the institutional review board (IRB) of the study institution's Health System and declared exempt from IRB review under 45CFR46.101(b)(4).

## Results

Baseline characteristics and diagnostic characteristics were small and generally not clinically meaningful (results shown in the appendix). Risk stratification was very similar across the 2 cohorts. Testing for trend across low-risk, intermediate-risk, and high-risk strata was barely significant ( $P = .039$ ). The proportion of patients classifiable as low risk decreased slightly from 27.6% to 27.3% ( $P = .54$ ), the proportions classifiable as intermediate risk rose slightly from 22.0% to 23.0% ( $P = .028$ ), while the high-risk category saw a small decrease from 42.3% to 41.1% ( $P = .036$ ).

Overall, we found small and inconsistent, albeit significant changes in treatment comparing the 2-year-old cohort with the younger one (Table 1). In the older cohort aged 65 to 66, there was a 3.7% point decrease in the use of surgery of any sort ( $P < .001$ ); this reduction came chiefly through declining use of radical prostatectomy from 44.3% to 39.6% ( $P < .001$ ) and was present both overall and among a low-risk subset of patients (lower panel).

## Conclusions

This study used cancer registry data to detail disease, treatment, and outcome differences among the near elderly and elderly around the age of 65 years for a common and important cancer.

Our approach was designed to identify harms from underinsurance, harms from insurance due to overdiagnosis and overtreatment, and benefits from insurance due to better and more timely access to care. Nevertheless, our study failed to show substantial, consistent, or clinically meaningful differences between patients diagnosed before and immediately after eligibility for Medicare.

Improved access to insurance has been found to be associated with better access to health care and improvement in health,<sup>24</sup> with substantially improved survival after acute conditions,<sup>9</sup> and with substantially increased utilization of care.<sup>8,22,25</sup> Yet this adequately powered study was unable to

detect differences in utilization of the magnitude found by prior studies.

On the contrary, access to insurance could lead to moral hazard in the setting of prostate cancer. Of particular concern is the risk that provider preferences or provider financial self-interest could bias treatment toward more aggressive care. Widespread and growing concern exists about aggressive therapy in men who may do similarly well under more conservative “active surveillance” approaches.<sup>26-28</sup> Closely related to this is concern about the harm caused by over-detection and overtreatment of screen-detected prostate cancer.<sup>29</sup>

If easier, cheaper, and more frequent access to more cancer specialists were to lead to increased detection of low-risk disease and more aggressive treatment, then access to Medicare may tend to harm some men with indolent cancers and increase system costs. Our results cast doubt on such effects in the context of prostate cancer; no substantive evidence was found that access to Medicare led to harmful differences in care.

Our study has several major limitations, given the narrowness of our study in one condition and using data that span only a little more than 1 in 4 cancer patients nationally without sufficient power to understand regional variations in the relationship of interest.

However, the most important limitation is that our study was unable to observe prior insurance coverage, the quality of such coverage, prior health care treatment, educational levels, income, prior health status, and utilization of the comparison groups, among other relevant variables.

In consequence, while these negative results appear to imply that with prostate cancer neither the beneficial effects of more generous insurance nor the detrimental effects of overutilization were as pronounced as hypothesized, we refrain from claiming these results to be causal.

Indeed, further study is needed to build on the seminal work of Card and colleagues<sup>8,9</sup> to better understand the objective impact of insurance on treatment and outcomes in near elderly. Further study is also needed to understand whether subjective benefits of greater access and coverage nevertheless contribute to patient well-being.

## Appendix

To elaborate on relevant material in the various sections that space constraints made unfeasible, we include here amplifications and clarifications.

### Data and Methods

Our analysis required tumor marker and prostate biopsy grade data, which were only available in diagnoses made in or after 2004. Accordingly, we restricted our study to patient diagnoses made between 2004 and 2007 inclusive.

Within each cohort, we used the *American Joint Committee on Cancer* (AJCC; 6th edition) clinical T staging to classify diagnosed patients. We classified patients with T2 NOS (not otherwise specified) staged disease as belonging to the T2a or lower category. A small number of patients with unknown or missing clinical T stages were classified in the T2c or higher category. Our results were robust to both classification decisions.

We used the risk-stratification algorithm of D’Amico and colleagues<sup>30</sup> to group patients as being in a low-risk (stage  $\leq$  T2a, and PSA  $\leq$  10 ng/mL, and Gleason score  $\leq$  6), intermediate-risk (stage = T2b, or PSA > 10-20 ng/mL, or Gleason score = 7), or high-risk (stage  $\geq$  T2c, or PSA > 20 ng/mL, or Gleason score = 8-10) stratum. We distinguished a very low-risk stratum representing the subset of low-risk patients in whom the disease was screen-detected (stage T1c only). We also categorized a stratum representing patients who were not classifiable (stage  $\leq$  T2a, but missing PSA and/or missing Gleason, and thus not meeting low-risk stratum criteria). Our results were insensitive to inclusion or exclusion of these patients.

For baseline characteristics, stage and extent of disease, we present frequencies for categorical variables, and means with standard deviations or medians with interquartile ranges (IQRs) for continuous variables.

For treatment receipt variables, we present frequencies and unadjusted risks in each cohort. We compared proportions receiving types of treatment using Fisher’s exact tests of crude risk ratios. We also adjusted directly for registry location, year of diagnosis, Hispanic ethnicity, race (Caucasian, black, Asian Pacific Islander, and other/unknown), and marital status by stratifying and weighting within-stratum statistics using Mantel-Haenszel weights. We used Fisher’s exact tests in the adjusted risk ratio analyses.

## Results

Baseline characteristics showed very small but significant differences across the cohorts (Table A1). The shift toward a slightly larger representation of patients with Hispanic ethnicity is independent of the race categorization, reflecting Surveillance, Epidemiology, and End Results (SEER) coding practices. Differences in the proportions of cases diagnosed across the study years and registry locations reflect cohort differences that require adjusting of relative risks.

Diagnostic characteristics were small and significantly different, especially in terms of clinical stage, but generally not clinically meaningful (Table A2). The proportion of screen-detected disease, or T1c clinical stage, rose from 35.0% in the 63- to 64-year-old cohort to 36.6% in the 65- to 66-year-old cohort ( $P < .003$ ); more generally, we found a shift toward more early T1 disease (36.7% vs 38.5%,  $P = .001$ ) and less clinically apparent T2 disease (51.7% vs 50.4%,  $P = .028$ ). Consistent with the changes in screen-versus clinically apparent disease is data (not shown) on

**Table A1.** Prostate Cancer, Baseline Characteristics of Pre-Medicare and Post-Medicare Eligible Cohorts.

	No. (%)		P value
	63- to 64-year cohort (n = 13882)	65- to 66-year cohort (n = 14774)	
Age at diagnosis, mean (SD), y	63.5 (0.5)	65.5 (0.5)	<.001
Caucasian	10965 (79.0)	11575 (78.4)	.03
Black	1813 (13.1)	1893 (12.8)	
Asian Pacific Islander	603 (4.3)	743 (5.0)	
Other or unknown	501 (3.6)	563 (3.8)	
Hispanic	1122 (8.1)	1414 (9.6)	<.001
Never married	1259 (9.1)	1344 (9.1)	<.001
Married	9865 (71.1)	10399 (70.4)	
Separated	107 (0.8)	111 (0.8)	
Divorced	991 (7.1)	931 (6.3)	
Widowed	323 (2.3)	426 (2.9)	
Unknown marital status	1337 (9.6)	1563 (10.6)	
Diagnosed, y			
2004	3131 (22.6)	3551 (24.0)	.004
2005	2965 (21.4)	3240 (21.9)	
2006	3752 (27.0)	3816 (25.8)	
2007	4034 (29.1)	4167 (28.2)	
Registries <sup>a</sup>			.002
California <sup>b</sup>	3095 (22.3)	3465 (23.5)	.02
New Jersey	1958 (14.1)	1872 (12.7)	<.001
Los Angeles	1375 (9.9)	1577 (10.7)	.03
Detroit, metropolitan area	907 (6.5)	916 (6.2)	.25
Seattle, Puget Sound	898 (6.5)	882 (6.0)	.08

<sup>a</sup>Not shown: Alaska natives, Atlanta, Connecticut, Hawaii, Iowa, Kentucky, Louisiana, New Mexico, rural Georgia, San Francisco/Oakland, San Jose-Monterey, Utah.

<sup>b</sup>Excluding Los Angeles, San Francisco/Oakland, and San Jose-Monterey.

tumor size, essentially identical across the 2 cohorts (median diameters = 14 mm, IQR = 9-20;  $P = .98$ ). Differences in the more advanced stages were not significant (T3 disease,  $P = .08$ ; T4 disease,  $P = .83$ )/trend, aggregating across all stages, was significant ( $P = .026$ ).

Changes in PSA tumor marker were, at very slightly higher levels, consistent with a secular trend (median = 61 ng/mL vs 63 ng/mL,  $P < .001$ ), reflecting similar shifts in the proportions of patients with very low PSA  $\leq 4$  ng/mL (12.8% vs 11.5%,  $P = .001$ ) and low PSA  $\leq 10$  ng/mL (69.0% vs 66.6%,  $P < .001$ ). Consistent with a similar secular increase in cancer grade, we found a small, barely significant increase in the median Gleason score of 6 to 7 ( $P = .041$ ) and a concomitant reduction in the proportion of patients with a Gleason score of 6 or lower (48.6% vs 47.4%,  $P = .042$ ).

The combination of the countervailing trends in Gleason score and PSA value to more advanced disease and the trend to earlier clinically unapparent T1 stages balanced the changes in risk stratification to yield very similar risk stratification across the 2 cohorts. Testing for trend across low-risk, intermediate-risk, and high-risk strata was barely

significant ( $P = .039$ ). The proportion of patients classifiable as low risk decreased slightly from 27.6% to 27.3% ( $P = .54$ ), the proportions classifiable as intermediate risk rose slightly from 22.0% to 23.0% ( $P = .028$ ), while the high-risk category saw a small decrease from 42.3% to 41.1% ( $P = .036$ ).

After adjusting for differences in geographical location, year, race, ethnicity, and marital status, there remained a significantly lower rate of radical prostatectomy among the older cohort (adjusted relative risk [RR] = 0.90; 95% confidence interval [CI], 0.87-0.92). Small but significant increases in the use of local destructive techniques (cryotherapy, laser, hyperthermic therapy, microwave, ultrasound, or needle ablation) alone or in conjunction with transurethral resection of the prostate were also found. Among those who did not receive surgery, there were no statistically significant differences across the cohorts in those in whom surgery had not been recommended (82.4% vs 83.6%,  $P = .051$ ), had been recommended but was refused (15.3% vs 14.4%,  $P = .12$ ), or had been contraindicated (1.2% vs 1.0%,  $P = .25$ ).

Accompanying this net reduction in surgery was a significant increase in the use of beam radiotherapy (19.3% vs

**Table A2.** Prostate Cancer, Extent of Disease, Staging, and Risk Stratum.

	No. (%)		P value
	63- to 64-year cohort (n = 13882)	65- to 66-year cohort (n = 14774)	
PSA, median (IQR), ng/mL	6.1 (4.6-9.2)	6.3 (4.7-9.8)	<.001
≤4	1770 (12.8)	1691 (11.5)	.001
≤10	9577 (69.0)	9832 (66.6)	<.001
>10, ≤20	1511 (10.9)	1784 (12.1)	.002
>20	1132 (8.2)	1309 (8.9)	.03
Gleason score, median (IQR)	6 (6-7)	7 (6-7)	.04
≤6	6745 (48.6)	7001 (47.4)	.04
7	5050 (36.4)	5432 (36.8)	.49
≥8	1644 (11.8)	1857 (12.6)	.06
AJCC clinical T stage			
T1	5093 (36.7)	5689 (38.5)	.03
T2	7178 (51.7)	7447 (50.4)	
T3	1122 (8.1)	1111 (7.5)	
T4	156 (1.1)	162 (1.1)	
Unknown	331 (2.4)	357 (2.4)	
Stage categories <sup>a</sup>			
Screen-detected disease, T1c	4853 (35.0)	5411 (36.6)	.003
≤T2a	8956 (64.5)	9888 (66.9)	<.001
T2b	294 (2.1)	292 (2.0)	
≥T2c	4632 (33.4)	4591 (31.1)	
Risk stratum			
Low <sup>b</sup>	3835 (27.6)	4034 (27.3)	.04
Intermediate <sup>c</sup>	3048 (22.0)	3404 (23.0)	
High <sup>d</sup>	5876 (42.3)	6073 (41.1)	
Unclassifiable <sup>e</sup>	1123 (8.1)	1263 (8.6)	

Note. PSA = prostate-specific antigen; IQR = interquartile range; AJCC = American Joint Committee on Cancer.

<sup>a</sup>Clinical T2 NOS staged disease classified as ≤T2a; unknown stage disease as ≥T2c.

<sup>b</sup>Stage ≤ T2a, and PSA ≤ 10 ng/mL, and Gleason score ≤ 6.

<sup>c</sup>Stage = T2b, or PSA > 10-20 ng/mL, or Gleason score = 7.

<sup>d</sup>Stage ≥ T2c, or PSA > 20 ng/mL, or Gleason score = 8-10.

<sup>e</sup>Stage ≤ T2a, missing PSA and/or missing Gleason: not meeting low-risk stratum criteria.

21.0%,  $P < .001$ ) and a significant increase in the proportions of patients apparently managed expectantly (17.0% vs 18.7%,  $P < .001$ ).

In the low-risk stratum patients (Table 1, lower panel), a similar 3.9% reduction in the rate of radical prostatectomy from 25.8% to 21.9% was found (adjusted RR = 0.83; 95% CI, 0.77-0.90). Also accompanying this reduction in surgery was a significant increase in the use of beam radiotherapy from 20.2% to 22.5% (adjusted RR = 1.12; 95% CI, 1.02-1.22), but the proportion of patients apparently managed expectantly was indistinguishable across the cohorts (20.2% vs 20.6%,  $P = .63$ ).

Among men in the low-risk stratum who did not undergo cancer-directed surgery for their localized prostate cancer, there were no statistically significant differences in the reasons (not recommended, refused, or contraindicated) it had not been carried out.

## Robustness Checks

The level of statistical power conferred by the cohort sizes of nearly 15 000 patients represented power of 80% to detect a difference in surgery receipt of 1.7% points and in beam radiotherapy receipt of 1.3% points. The results of Card et al<sup>9</sup> suggest evidence of small 3% to 4% increases in the number of procedures at age 65 for patients with urgent, nondeferrable conditions. The earlier study by Card et al<sup>8</sup> found larger relative increases of between 11% and 23% in nonurgent medical procedures in those over 65 compared with those under 65. Relative differences of such magnitude were again ruled out by our results for prostate cancer.

The SEER data did not include number of positive cores, preventing our use of the finer Cancer of the Prostate Risk Assessment (CAPRA) score risk strata.<sup>31</sup> Substantial difficulties were also posed by prostate cancer staging schemes.



In our analysis of the low-risk stratum, we had excluded T2 NOS (not otherwise specified) clinical T staged cases. This may have impacted our low-risk stratum results. In our data, approximately 24% of low-risk stratum men had T2 NOS (not otherwise specified) staged disease, which we classified as  $\leq$ T2a disease. Excluding these 1892 cases and leaving only T1 and T2a stages left therapy receipt findings directionally similar: The proportion without surgery increased from 76.8% to 78.8% ( $P = .068$ ), those undergoing radical prostatectomy declined from 18.6% to 15.5% ( $P = .001$ ), the numbers not receiving radiation fell from 41.5% to 39.0% ( $P = .046$ ), while receipt of beam radiotherapy rose from 23.7% to 25.6% ( $P = .08$ ).

In related robustness checks necessitated by missing data, we considered the small numbers of prostate cancer cases not classifiable using the low-risk, intermediate-risk, and high-risk strata algorithm. All of these cases had clinical T stage  $\leq$  T2a but were missing one or both of PSA value or Gleason score. Changes in therapy receipt in this small group were directionally similar to the low-risk stratum itself, but crude risk ratios were not statistically different from 1 except for the relatively large proportions of patients receiving neither surgery nor radiation which rose from 37.0% to 41.6% ( $P = .024$ ).

Finally, we constructed a new low-risk stratum, a subset of the low-risk stratum reported above, in which only T1c staged screen-detected disease was included along with PSA  $\leq 10$  ng/mL and Gleason score  $\leq 6$ . In this smaller group, point estimates for reduction in radical prostatectomy and increase in beam radiotherapy were similar to the main low-risk stratum, and crude risk ratios were statistically significant, but significance was not preserved in adjusted, stratified analyses.

Current treatment guidelines<sup>10</sup> as well as guidelines<sup>31,32</sup> prevailing during the 2004-2007 period of our study allowed for substantial variation in care. Patient preferences exhibit similar large variations over the set of treatment options.<sup>10</sup> It is possible that even our small, statistically significant results represent clinically acceptable variation.

A related evidence-based dependence arises due to a large and influential Swedish trial that randomized patients between radical prostatectomy and watchful waiting found a small survival benefit only among the pre-65-year-old study participants.<sup>33,34</sup> Some have interpreted this finding as militating against the use of radical prostatectomy in the post-65 age group in general. This could explain the small but significant decrease in radical prostatectomy in our data from 44.3% to 39.6% immediately after age 65.

## Limitations

Our study focuses narrowly on 1 cancer, albeit a common, well-known, and important one. Our data are not necessarily representative of the entire US population. Currently, the SEER databases cover approximately 26% of the total US population in a nonrandom manner. Approximately 98% of

cancer cases are ascertained in that population.<sup>35</sup> Whether missing data in the cohorts we examined are missing at random is unknown.<sup>36</sup> We included patients from the 2000 calendar year, even though major registry expansion happened in 2000. We also pooled data across multiple calendar years, ignoring possible cohort effects. We did not ascertain the receipt of chemotherapy, which is separately coded in the Medicare claims for patients enrolled in fee-for-service Medicare. Information on cancer-directed surgery was limited to the most extensive procedure among planned procedure(s) performed for the primary cancer or surgery performed within a year.<sup>37</sup> We do not observe whether treatment was curative, adjuvant, or palliative. If surgery to relieve metastatic disease differs systematically across cohorts, then we will miss such differences. We were also unable to quantify cohort treatment costs which are important as cancer costs continue to rise.<sup>38</sup>

Other disease-specific limitations include the fact that this study took place in the period of time before the recommendation in May 2012 of the US Preventive Services Task Force against PSA screening. Our results might have been different in a later period in which screening was reduced. Our data also lack information on patient comorbidities or preferences, which might drive differences in therapy afforded. However, rates of patients who did not undergo surgery that had been recommended did not differ significantly across the cohorts.

## Declaration of Conflicting Interests

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