Certificate of Need Legislation and the Dissemination of Robotic Surgery for Prostate Cancer

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Abbreviations and Acronyms

HSA = Health Service Area

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See Editorial on page 12.

Purpose: The uncertainty about the incremental benefit of robotic prostatectomy and its higher associated costs makes it an ideal target for state based certificate of need laws, which have been enacted in several states. We studied the relationship between certificate of need laws and market level adoption of robotic prostatectomy.

Materials and Methods: We used SEER (Surveillance, Epidemiology, and End Results)-Medicare data from 2003 through 2007 to identify men 66 years old or older treated with prostatectomy for prostate cancer. Using data from the American Health Planning Association, we categorized Health Service Areas according to the stringency of certificate of need regulations (ie low vs high stringency) presiding over that market. We assessed our outcomes (probability of adopting robotic prostatectomy and propensity for robotic prostatectomy use in adopting Health Service Areas) using Cox proportional hazards and Poisson regression models, respectively.

Results: Compared to low stringency markets, high stringency markets were more racially diverse (54% vs 15% nonwhite, $p < 0.01$), and had similar population densities (886 vs 861 people per square mile, $p = 0.97$) and median incomes ($42,344 vs $39,770, $p = 0.56$). In general, both market types had an increase in the adoption and utilization of robotic prostatectomy. However, the probability of robotic prostatectomy adoption ($p = 0.22$) did not differ based on a market's certificate of need stringency and use was lower in high stringency markets ($p < 0.01$).

Conclusions: State based certificate of need regulations were ineffective in constraining robotic surgery adoption. Despite decreased use in high stringency markets, similar adoption rates suggest that other factors impact the diffusion of robotic prostatectomy.

Key Words: prostatic neoplasms, robotics, diffusion of innovation

Prostate cancer is a common and expensive disease, accounting for approximately $11 billion in health care spending in 2011.[1] In the last decade, spending growth for prostate cancer has averaged 11% a year, and has outpaced rates for other common conditions such as cardiovascular and pulmonary diseases.[2] Many believe that medical innovation and the implementation of new health care technologies are partly to blame for this trend.[3] Indeed, there has been a recent proliferation of novel treatments that offers the potential for enhanced effectiveness and reduced morbidity.

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Chief among these treatment advances has been the introduction of robotic surgery for localized prostate cancer. Compared to the conventional approach, the advantages of robotic surgery include magnification, articulating instruments and 3-dimensional visualization, all of which facilitate operating in the small male pelvis.[4] Unfortunately for patients, evidence detailing the ability of robotics to deliver on the promise of similar cancer control with less collateral damage has been mixed.[4–6] This uncertainty about the comparative effectiveness of robotic surgery and its associated premium in requisite infrastructure (ie upwards of $2 million in start-up costs)[7] would seem to make it an ideal target for state based certificate of need legislation, which is aimed at aligning health spending with public need.[8] Certificate of need regulations are not present in all states. Furthermore, not all certificate of need regulations cover the purchase of robotic platforms. Generally, certificate of need laws are designed to balance cost, quality and access to care, and ensure that only needed services are developed.[9] However, the rapid dissemination of robotic surgery[10] would seem to question the value of such regulatory levers to curtail potentially unnecessary health care spending.

Therefore, we performed a study to better understand the relationships between certificate of need stringency and market level adoption of robotics. Furthermore, we explored the extent to which certificate of need stringency impacted the rate of growth in surgery among adopters. In the era of constrained resources, understanding the effectiveness of this regulatory lever is important for optimizing prostate cancer care, particularly given that more expensive technologies (eg proton beam therapy) are in the development pipeline.

METHODS

Data Sources and Study Population

We used SEER-Medicare data for 2003 through 2007 to identify patients with newly diagnosed prostate cancer. SEER represents approximately 26% of the United States population.[11] We identified men 66 years old or older who underwent prostatectomy (open, robotic or perineal) within the first 12 months of diagnosis using MEDPAR (Medicare Provider Analysis and Review) and carrier files. We enumerated robotic prostatectomy using the HCPCS (Healthcare Common Procedure Coding System) code 55866. We included only fee-for-service beneficiaries eligible for Medicare Parts A and B from 12 months before to 12 months after diagnosis. Men age 65 years were excluded from study to ensure accurate comorbidity estimation using Medicare claims for the 12-month period before diagnosis.[12] Using these criteria, our study population consisted of 12,351 patients.

Identifying Health Care Markets

We divided SEER registries into health care markets using 164 HSA boundaries specified by the Area Resource File. HSAs were originally defined by the National Center for Health Statistics as a single county or cluster of contiguous counties that are relatively self-contained with respect to hospital care.[13] We excluded 4 HSAs with no claims for prostatectomy during the study period.

For each HSA we characterized the level of certificate of need stringency using data from the American Health Planning Association National Directory of Health Planning, Policy and Regulatory Agencies.[14] The American Health Planning Association surveys state regulatory agencies on an annual basis to obtain information on certificate of need programs. We then contacted certificate of need agencies to confirm cost thresholds for review and to verify whether regulations applied specifically to robotic equipment. Based on previous studies,[15] we sorted HSAs into 2 groups according to the stringency of certificate of need regulations (low vs high). Low stringency was typified by markets with state defined equipment expenditure thresholds greater than $1.3 million (Connecticut, Iowa, Kentucky), markets with certificate of need regulations that did not apply specifically to robotic equipment (Michigan, New Jersey) or markets with no certificate of need regulations whatsoever (California, Louisiana, New Mexico, Utah, Washington). We chose a threshold of $1.3 million due to the approximate cost of a robotic platform.[16] Conversely, markets with equipment expenditure thresholds of $1.3 million or less were considered high stringency because purchasing robotic platforms in these markets would require prior approval (Hawaii, Georgia). Markets had stable levels of certificate of need stringency during the course of the study. In fact, certificate of need regulations were stable in these markets dating back to 2001, when robotic adoption was in its infancy.[14] We performed a sensitivity analysis for threshold values between $1.0 million and $1.4 million, and found no changes in our results. In addition, we compared low and high stringency markets after excluding HSAs with no certificate of need regulations, and found our results for adoption and utilization to be similar.

Outcomes

To measure the effects of certificate of need regulations on the dissemination of robotic surgery for prostate cancer, we first assessed the probability of adopting robotic surgery. To reduce measurement error, a market was considered an adopter if it contained 5 or more patients treated with robotic prostatectomy within a 12-month period. Since certificate of need regulations may influence the diffusion of robotic prostatectomy within an HSA even after it acquires the capability, we next measured use among adopting HSAs (67).

Statistical Analysis

We compared aggregate patient and market level characteristics using chi-square and Student t tests for categorical and continuous variables, respectively. Next, we fit a Cox proportional hazards model to assess the probability of robotic surgery adoption across the certificate of need stringency exposure. This model met the proportional haz-