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# Health Outcomes Research

# Patient Demographics, Quality of Life, and Disease Features of Men With Newly Diagnosed Prostate Cancer: Trends in the PSA Era

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| **OBJECTIVE** | To describe how demographic and diagnostic characteristics of men with prostate cancer in the United States have changed since 1999, using data from the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) registry. |
| **METHODS** | The medical records of patients enrolled in CaPSURE between 1999 and 2011 were evaluated. Baseline demographics, disease features, and imaging use were assessed. Mantel-Haenszel chi-square was used to test for trends across diagnostic years. |
| **RESULTS** | Between 1999 and 2011, a total of 9572 patients were diagnosed with prostate cancer and enrolled in CaPSURE at community (36), academic (3), and Veteran's Affairs (4) hospitals. Over the study period, mean age at diagnosis decreased, $P < .01$. In 2008-2011, a significant increase in diagnostic Gleason 7 or higher was observed relative to 1999-2001 (50% vs 36%, $P < .01$), congruent with recent guideline modifications of the Gleason classification system. An increase in the mean number of diagnostic biopsy cores (13.3 vs 8.3, $P < .01$) was also observed. A significant decrease in use of any imaging modality was seen (19% vs 45%, $P < .01$). Average pretreatment urinary and bowel function scores did not change, although there were significant increases in sexual function observed overall ($P < .01$). |
| **CONCLUSION** | In the United States, several trends in the demographics and disease profile of men with newly diagnosed prostate cancer were observed over the past 12 years. Decreased imaging use and increased number of cores taken during diagnostic biopsy are in line with national urologic guidelines on prostate cancer diagnosis and management.  UROLOGY 82: 60–66, 2013. © 2013 Elsevier Inc. |

Adenocarcinoma of the prostate is the most common malignancy in men as 241,740 new cases in the United States are expected to be diagnosed in 2012.[1] The prostate specific antigen (PSA) test was first approved in the United States in the mid-late 1980s for monitoring patients with known prostate cancer.[2,3] Subsequent studies supporting its utility as a first-line screening tool[4] led the Food and Drug Administration to approve PSA as an aid to early prostate cancer detection in 1994.[5] Because of widespread earlier and repeated use of PSA testing, prostate cancer is increasingly diagnosed in younger men with lower risk, early stage disease,[6] and there is now much controversy regarding rates of overdiagnosis and overtreatment. In many cases, superior oncologic efficacy of one primary management strategy over another has not been established and treatment patterns are thought to reflect a variety of factors, including physician and patient preference.[7,8] Further, men are at risk of treatment-related morbidity which can persist,[9,10] and measures of quality of life outcomes are emerging as potential tools to help guide treatment decisions.[9,11-13]

The purpose of this article was to describe how patient demographics, including comorbidity and functional quality of life status, as well as disease characteristics of men with prostate cancer in the United States have changed in the PSA era since 1999. We further aimed to describe patterns of diagnostic imaging use and primary treatment decisions.

## METHODS

The Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) is a longitudinal observational

study of men with all stages of biopsy-proven prostatic cancer. More than 14,000 patients from 36 community urology practices, 3 academic medical centers, and 4 Veteran's Affairs (VA) hospitals across the United States have enrolled since 1995. Informed consent was obtained from each patient under local institutional review board supervision. Participating sites report diagnostic, clinical, treatment, and follow up data. At enrollment and at regular intervals after primary treatment, patients report demographics, comorbid conditions, symptoms, medication usage, and resource utilization, and since 1999, health-related quality of life (HRQOL). As 1999 was also the year CaPSURE begin enrolling only men with newly diagnosed cancer, this was chosen as our initial year of data review. Additional information on CaPSURE methodology has been published previously.[14,15] The CaPSURE registry is partially funded through an independent education grant from Abbott Laboratories.

The incidence and trends of demographics, clinical characteristics, HRQOL, and diagnostic imaging of patients enrolled in CaPSURE were reviewed across 12 years of diagnosis, grouped as 1999-2001, 2002-2004, 2005-2007, and 2008-2011. Baseline, patient-reported demographics include age, ethnicity, highest level of education, insurance type, and comorbidities including cardiovascular disease (heart attack, stroke, hypertension, or coronary artery disease), diabetes mellitus, respiratory tract disease (asthma, obstructive lung disease), urinary tract disease (urinary incontinence, recurrent infection), and depression. Review of diagnostic PSA, clinical T stage, and biopsy Gleason score was performed. Clinical risk was defined by the Cancer of the Prostate Risk Assessment (CAPRA) score (0-10 scale), calculated using diagnostic PSA, biopsy Gleason score, clinical T stage, and percent biopsy cores positive, as well as patient age.[16,17] Validated CAPRA risk groups are defined as 0-2 (low), 3-5 (intermediate), and 6-10 (high).

Although primary treatment trends are not described in this article, modalities within the CaPSURE registry include watchful waiting/active surveillance, radical prostatectomy, cryotherapy, brachytherapy, external beam radiation therapy, and primary androgen deprivation therapy. Use of diagnostic (pretreatment) imaging modalities, including magnetic resonance imaging, computed tomography (CT), and bone scan was reviewed. Diagnostic imaging includes any testing before the start of primary treatment.

Prostate cancer-related quality of life was assessed with the University of California Los Angeles Prostate Cancer Index (UCLA-PCI), a validated scale[18] of urinary function, urinary bother, sexual function, sexual bother, bowel function, and bowel bother. UCLA-PCI scores range from 0-100, with higher scores representing greater quality of life. All values described are taken from patient-reported surveys completed before initiation of primary treatment. Clinically meaningful changes in baseline scores between diagnostic year categories were defined by increase or decrease of at least half an SD from 1999-2001 baseline scores.[13,19]

Frequency tables and Mantel-Haenszel chi-square were used to evaluate differences and trends of categorical variables over time. Means/medians and analysis of variance were used for continuous variables. Site participation in the CaPSURE study has varied and recruitment of new patients was suspended temporarily for 2007 and 2008 because of funding limitations. Therefore, additional sensitivity analyses were restricted to sites with patients diagnosed in at least 3 of the 4-year categories to account for fluctuations in site involvement and patient enrollment. A $P$ value $<.05$ was considered significant. Analyses were conducted using SAS version 9.1 (Cary, NC).

## RESULTS

Between 1999 and 2011, a total of 9572 patients were diagnosed with prostate adenocarcinoma and enrolled within the registry. Of these, 3395 were diagnosed in 1999-2001, 3726 in 2002-2004, 2100 in 2005-2007 and 351 in 2008-2011. These men were enrolled in 30 of the 43 CaPSURE sites in 23 states nationwide. Over 90% of patients were diagnosed in a community-based setting during the years 1999-2007. Sensitivity analyses adjusting for type of clinical site were performed, as 3 academic sites provided care for 36% of patients in 2008-2011 vs 5%-6% in preceding years. A total of 295 men (3%) were enrolled within 1 of 4 VA centers between 1999 and 2011.

### Demographic and Comorbidity Variables

Demographic features by diagnosis year are presented in Table 1. The mean age at diagnosis decreased from 66.5 ($\pm8.8$) in 1999-2001 to 63.6 ($\pm8.2$) years in 2008-2011 ($P <.01$), independent of clinical risk group. Similarly, the proportion of those $\geq65$ years old at diagnosis decreased from 59% to 44% during this time ($P <.01$) and comprised 51% of those diagnosed in community vs 35% both in academic and VA sites in 2008-2011. The majority of men enrolled were white, a finding that was consistent across time and independent of type of clinical site for the years 1999-2007. In 2008-2011, VA sites had the highest proportion of non-white men (45%) compared with academic (11%) and community (2%) sites ($P = .04$). Most men completed "some college" or "college degree," including 76% of men in 2008-2011 compared to 55% in 1999-2001 ($P <.01$). Non-Medicare insurance, including private policies and VA/government coverage, became the most common form of health care payment in 2008-2011, accounting for 73% of men at community sites, 61% of men at academic sites, and 93% of men at VA sites. The prevalence of cardiovascular disease, diabetes mellitus, respiratory tract disease, urinary tract disease, and depression at diagnosis are presented in Table 1. Cardiovascular disease was the most common comorbidity with prevalence at diagnosis ranging from 55%-62% during the study period ($P = .04$). Rates of other conditions at baseline did not statistically vary over the study period or by type of site.

**Table 1.** Baseline demographics and disease features by diagnosis year

| Diagnosis Year | 1999-2001 | 2002-2004 | 2005-2007 | 2008-2011 | P Value |
|---|---|---|---|---|---|
| Total patients | 3395 | 3726 | 2100 | 351 | |
| Age | | | | | |
|   Mean (SD) | 66.5 (8.8) | 65.2 (9.0) | 65.5 (9.2) | 63.6 (8.2) | <.01 |
|   ≥65, no. (%) | 2009 (59) | 1976 (53) | 1125 (54) | 153 (44) | <.01 |
| Race, no. (%) | | | | | |
|   White | 2975 (88) | 3182 (85) | 1755 (83) | 319 (91) | .06 |
|   African American | 287 (9) | 420 (11) | 269 (13) | 14 (4) | |
|   Latino | 49 (1) | 57 (2) | 35 (2) | 5 (1) | |
|   Asian | 34 (1) | 31 (1) | 19 (1) | 4 (1) | |
|   Other | 50 (1) | 36 (1) | 22 (1) | 9 (3) | |
| Education, no. (%)* | | | | | |
|   Some high school | 432 (18) | 338 (13) | 158 (11) | 12 (4) | <.01 |
|   High school degree | 672 (27) | 650 (25) | 397 (28) | 54 (20) | |
|   Some college | 481 (19) | 482 (19) | 302 (22) | 68 (25) | |
|   College degree | 895 (36) | 1102 (43) | 555 (39) | 141 (51) | |
| Insurance, no. (%)* | | | | | |
|   Medicare only | 570 (18) | 469 (13) | 350 (18) | 32 (10) | <.01 |
|   Medicare (supplement) | 1039 (32) | 1099 (32) | 618 (31) | 61 (19) | |
|   Other | 1583 (50) | 1901 (55) | 999 (51) | 227 (71) | |
| Comorbidities, no. (%)* | | | | | |
|   Cardiovascular | 1403 (57) | 1546 (61) | 868 (62) | 151 (55) | .04 |
|   Diabetes | 267 (11) | 300 (12) | 173 (12) | 32 (12) | .19 |
|   Respiratory | 248 (10) | 239 (9) | 126 (9) | 26 (9) | .31 |
|   Urinary | 522 (21) | 529 (21) | 276 (20) | 47 (17) | .10 |
|   Depression | 12 (<1) | 22 (1) | 15 (1) | 2 (1) | .07 |
| CAPRA, no. (%)* | | | | | |
|   Low, 0-2 | 1602 (58) | 1846 (58) | 965 (57) | 148 (58) | .17 |
|   Intermediate, 3-5 | 883 (32) | 1028 (32) | 506 (30) | 78 (30) | |
|   High, 6-10 | 282 (10) | 335 (10) | 216 (13) | 30 (12) | |
| Clinical T stage, no. (%)* | | | | | |
|   T1 | 1684 (53) | 2150 (61) | 1189 (65) | 156 (59) | <.01 |
|   T2 | 1376 (44) | 1319 (37) | 619 (34) | 103 (39) | |
|   T3 | 90 (3) | 59 (2) | 26 (1) | 4 (2) | |
|   T4 | 11 (<1) | 5 (<1) | 2 (<1) | 1 (<1) | |
| PSA (ng/mL), no. (%)* | | | | | |
|   ≤4 | 448 (14) | 574 (16) | 353 (18) | 53 (22) | <.01 |
|   4.1-10.0 | 2004 (62) | 2268 (63) | 1206 (63) | 146 (60) | |
|   10.1-20 | 520 (16) | 478 (13) | 214 (11) | 28 (12) | |
|   ≥20 | 263 (8) | 270 (8) | 146 (8) | 14 (6) | |
| Biopsy Gleason, no. (%)* | | | | | |
|   ≤6 | 2198 (66) | 2262 (62) | 1128 (57) | 140 (50) | <.01 |
|   7 (3+4) | 519 (16) | 684 (19) | 407 (20) | 82 (29) | |
|   7 (4+3) | 307 (9) | 354 (9) | 228 (11) | 31 (11) | |
|   8-10 | 292 (9) | 363 (10) | 229 (12) | 28 (10) | |
| Biopsy cores | | | | | |
|   No. positive, mean (SD) | 2.6 (2.0) | 2.8 (2.2) | 3.5 (2.8) | 3.9 (3.0) | <.01 |
|   No. taken, mean (SD) | 8.3 (3.1) | 9.6 (3.2) | 10.9 (2.9) | 13.3 (3.7) | <.01 |
|   % positive, mean (SD) | 35 (25.3) | 32 (24.6) | 34 (26.3) | 31 (23.1) | <.01 |

CAPRA, Cancer of the Prostate Risk Assessment; PSA, prostate specific antigen.

  *P* values express chi-square test or *t* test.

\* Categories may not sum to total because of missing data, percentages reflect those with complete data.

## Disease Characteristics

Baseline disease features stratified by diagnosis year are summarized in Table 1. Overall, an increase in the proportion of those with PSA ≤4 ng/mL (14% vs 22%, $P < .01$) was observed between 1999 and 2011. This trend was seen across study period within community (14% vs 26%, $P < .01$) and academic (9% vs 15%, $P = .36$) sites. The number of men with Gleason score ≤6 has decreased consistently over time, with an accompanying rise in 3+4, 4+3, and 8-10 disease, which comprised 29%, 11%,

and 10% of Gleason score, respectively, in 2008-2011 ($P < .01$). In 2008-2011, the proportion of men with a Gleason score of 7 or higher increased in community (34% vs 48%, $P < .01$) and academic centers (26% vs 52%, $P < .01$), but not at VA sites (56% vs 58%, $P = .24$). Furthermore, the mean number of cores taken at diagnostic biopsy increased across time from 8.3 (±3.1) to 13.3 (±3.7, $P < .01$). Similarly, the mean number of positive cores increased from 2.6 (±2.0) to 3.9 (±3.0, $P < .01$), whereas the percent positive decreased (mean
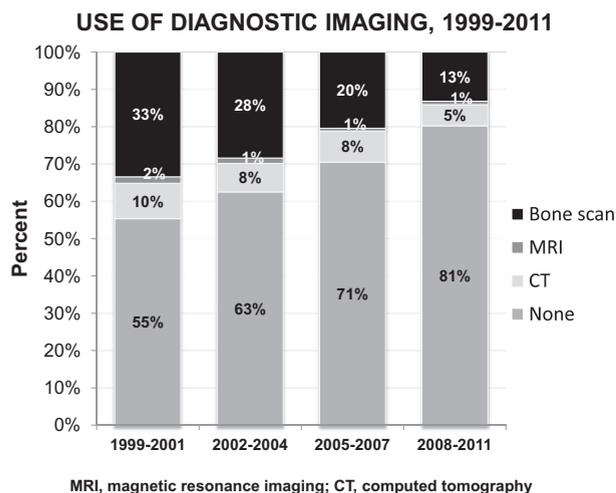
## USE OF DIAGNOSTIC IMAGING, 1999-2011



MRI, magnetic resonance imaging; CT, computed tomography

**Figure 1.** Proportion of patients who underwent diagnostic imaging by year and modality.

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35%-31%, $P$ <.01), independent of clinical site. The distribution of patients with low, intermediate, and high-risk disease did not vary between group years for overall cohort, community, or VA sites. For academic sites, the proportion of those diagnosed with low-risk disease decreased (68% vs 50%) whereas those with high-risk disease increased (3% vs 19%) between years 1999-2001 and 2008-2011 ($P$ <.01).

### Diagnostic Imaging

Figure 1 reveals pretreatment, diagnostic imaging use by year, and modality (ie, none, bone scan, magnetic resonance imaging, or CT). Across the study period, significant decreases in overall use of imaging were observed, as 45% of patients underwent 1 or more diagnostic tests in 1999-2001, compared to 19% during 2008-2011 ($P$ <.01). Similar declines were observed for community (45% vs 24%), academic (48% vs 16%), and VA cohorts (31% vs 0%, all $P$ <.01). Overall, 10% of patients had a CT scan in 1999-2001, whereas 5% had testing in 2008-2011 ($P$ <.01). Nonsignificant declines were seen in those with low (22% vs 6%, $P$ = .07) and intermediate risk (48% vs 28%, $P$ = .14) disease. Similarly, bone scan use decreased across the study period, independent of the risk group (all $P$ <.01).

### Health-related Quality of Life

Pretreatment UCLA-PCI scores by diagnosis year and clinical site were reviewed. Mean baseline sexual function, urinary function, and bowel function scores with half SDs by diagnosis year and clinical site are provided in Figure 2. Mean sexual function scores increased overall (+12 points, $P$ <.01) and for community sites (+11 points, $P$ <.01). Similarly, sexual bother scores increased overall (+7 points, $P$ = .03). For VA sites, sexual function demonstrated a decreasing trend (−24 points, $P$ = .05). No statistical differences were seen in academic sites in

scores across time. Additionally, no statistical differences were seen overall or by site type for urinary function or bowel function and urinary bother, or bowel bother scores.

## COMMENT

The CaPSURE registry provides a broad sample of men with prostate cancer within the United States, giving practitioners a sense of patient characteristics, treatment decisions, and quality of life outcomes in community-based settings. Greene et al[20] described the "average" patient with prostate cancer in 2005 as white, 65 years old, of average health, educated, and with private insurance. In a larger cohort over a greater study period, we report similar findings in patient demographics as well as several important trends across time. Men who presented more recently were younger, better educated, and a greater proportion had private insurance.

Regarding clinical features, significant trends were observed over time and were most dramatic during 2008-2011. A greater proportion of men were diagnosed with Gleason score 7 disease or higher (34% in 1999-2001 vs 50% in 2008-2011, $P$ <.01) and this finding was consistent in both community and academic sites. Biopsy sampling practices changed as well, with the average number of biopsy cores taken increasing from 8 to 13 over the past decade. These trends coincided with 2 important changes in practice guidelines. In 2005, the International Society of Urological Pathology modified their recommendations on histological grading of prostate cancer by expanding criteria of grade 4 disease. It was projected that many patients previously classified as 3+3 would now be designated as 3+4.[21] The 2009 American Urological Association Best Practice Statement[22] endorsed an extended spectrum biopsy of at least 8-12 cores as part of diagnostic workup. Saturation biopsy with laterally directed cores was found to improve cancer detection rates in a large systematic literature review.[23] Thus, our findings may reflect changes in grading and sampling standards rather than biological variation.

In contrast to higher grade findings, the proportion of men with diagnostic PSA greater than 4 ng/mL has deceased over time. Similarly, the percentage of positive biopsy cores has decreased. Although nonsignificant changes in CAPRA risk were observed for the overall cohort, academic sites had a decrease in low-risk decrease (68%-50%) and an increase in high-risk disease from 3%-19%. This finding contradicts the well-described downward stage migration of prostate cancer seen over the past several decades,[24,25] but may be related to several observed changes within academic sites, including increasing proportion of men diagnosed over age 65 and increasing rate of Gleason score 7 or higher on diagnostic biopsy. Academic sites also serve as large referral centers and increases in stage may be attributed to initial focal and nonsurgical treatment of low and intermediate risk disease.[26]
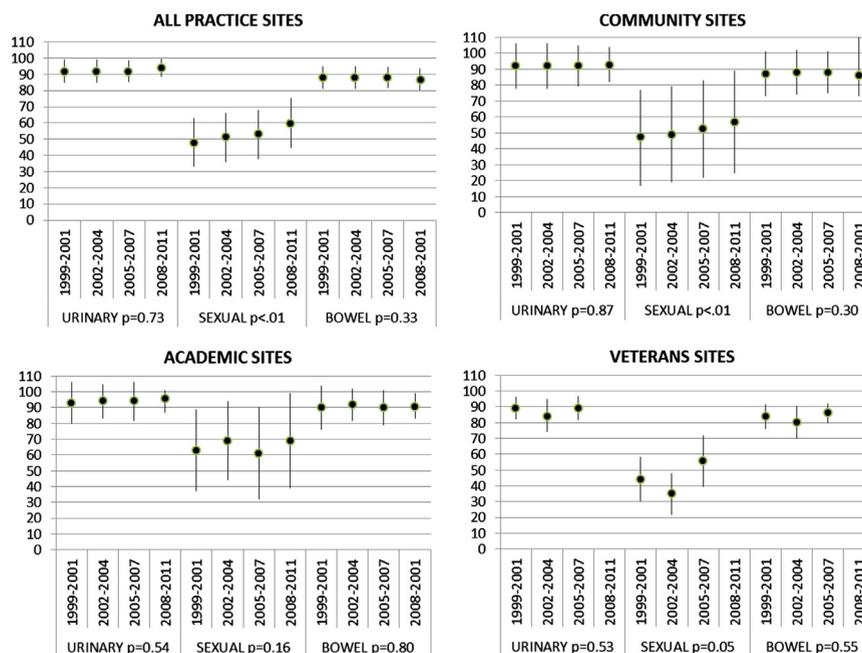
**Figure 2.** Mean pretreatment urinary, sexual, and bowel function scores for overall, community, academic, and Veteran's Affairs (VA) sites by diagnosis year groups; vertical bars represent upper and lower half SDs; *P* values reflect analysis of variance statistic. For VA sites, only scores for years 1999-2007 were available. (Color version available online.)

Several investigators have reported overuse of diagnostic imaging, especially in patients with low-risk disease.[27,28] Since 2009, national guidelines recommend that diagnostic imaging be limited to those with high-risk disease or PSA >20.0 ng/mL.[22,29] We observed dramatic decreases in use of CT and bone scan for both community and academic centers across the study period, findings that mirror suggestions in literature and national guidelines on diagnostic imaging. Changes in patient enrollment at individual CaPSURE sites also may have impacted imaging trends. Investigators reported that within a single institution, the number of new prostate cancer cases seemed to influence the rate of urologist-ordered diagnostic imaging more so than PSA, as those who saw higher numbers of patients (>20 per year) more appropriately order bone scans (ie, for men with PSA $\geq$10 ng/mL).[30]

Prior review of CaPSURE described patients presenting with average or above average HRQOL scores relative to age appropriate reference means.[20,31] We found that overall UCLA-PCI scores at the time of diagnosis consistently increased over the last 12 years, with most dramatic improvements in sexual function scores. Clinically relevant differences in quality of life measures have been previously described as a change of $\geq$0.5 SD of the mean.[13,19] Although we observed statistically significant increases in pretreatment sexual function and sexual bother over the study period, these were less than a half SD above the mean baseline scores in 1999-2001 (15.0 and 18.5 points, respectively). Significant decreases in mean patient age were also observed across the study, a possible contributor for the improvement in scores.

Baseline functional status is emerging as a key factor in predicting post-treatment morbidity patterns. Several studies report differences in long-term HRQOL outcomes when patients were stratified by pretreatment function.[9,11-13] Chamie et al[13] found that obtaining pretreatment UCLA-PCI scores resulted in lower odds of decline in sexual function, sexual bother, and bowel function in patients who underwent treatment for localized prostate cancer. Utilization of quality of life measures to improve primary treatment decision-making is an anticipated future CaPSURE study.

Several strengths of this article exist, including large cohort size and community-based multi-institution involvement with multiple practitioners. An important limitation is that the 2008-2011 cohort reflected a much smaller number of patients (N = 351) compared to all prior years. This is because of interruption in patient enrollment and participation by individual clinic sites in 2007-2009 of multiple CaPSURE sites. Many of the presented findings were most dramatic during 2008-2011 when a much higher percentage of patients were seen in academic practice sites compared to previous years (36% vs 6%). However, closer inspection of clinical site-specific data did not suggest that the greater "weight" of academic sites in 2008-2011 was responsible for overall trends that occurred in 2008-2011, including decreased age, changes in disease features, decreased use of imaging, or changes in pretreatment quality of life. Importantly, CaPSURE enrollees represent a convenience sample, and because enrollment is based on urology practices, there is concern for subspecialty bias. Additionally, race and other demographics may not be entirely reflective of national

trends in prostate cancer incidence. A recent review that used data from Surveillance, Epidemiology, and End Results of men with newly diagnosed prostate cancer enrolled between 1988 and 2005, revealed several trends across time synonymous with our findings, including decreasing mean age, rates of clinical stage T3-T4, and rates of Gleason sum 8-10, with increasing proportions of those diagnosed with Gleason 5-7 disease. This study also found evidence that racial disparities in those diagnosed with higher stage disease have narrowed considerably between 1988 and 2005.[25]

## CONCLUSION

Over the past decade, the average patient with prostate cancer has become younger, better educated, and a greater proportion carry private insurance. Although overall rates of those with low, intermediate, and high CAPRA clinical risk have remained constant, changes in disease features including greater proportion of those diagnosed with Gleason 7 or higher, have been observed in recent years. As several modern urologic controversies exist, such as the role of PSA screening, our findings suggest improved adherence by urologists to national urological guidelines on prostate cancer diagnosis and management, evidenced by the decreased use of imaging and increased number of cores taken during diagnostic biopsy. Finally, although the overdiagnosis/overtreatment dilemma remains, recognition of baseline functional quality of life status could help guide physicians and patients in treatment decisions.

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# EDITORIAL COMMENT

In this study, the authors describe trends in the demographics and pathology of men with newly diagnosed prostate cancer within the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) database from 1999 to 2011, a time period encompassing almost the entirety of the period after prostate-specific antigen (PSA) screening approval in 1994. Notably, they identified that the average age of men being diagnosed declined while confirming their previously published trends in the number of biopsy cores and use of imaging from the earlier part of the past decade continued.[1,2] As the authors note, many of the outcomes noted were most dramatic in the final 3 years of data, in which the proportion of patients seen from academic sites (rather than the community) was 6-fold greater. This is an important consideration when comparing the early and later periods in this cohort.

We hope that these findings spur additional studies to identify the impact of PSA screening on the management of prostate cancer and potentially refine its use. Although comparative data on demographic and diagnostic characteristics of men with prostate cancer before and after PSA screening approval would be quite interesting, the limitations of data collected in the pre-PSA era in a comparative analysis would be confounded by changes in pathologic classification (such as the reassignment of cribriform cancer from Gleason pattern 3 to pattern 4)[3] and increasing number of cores taken at biopsy.[1,4] Another important study that needs to be conducted would be to better understand the demographics of men being offered prostate biopsy. As we continue to refine our patient selection to minimize overdetection and subsequent overtreatment of prostate cancer, trends in the demographics of the men being biopsied (rather than only those with a new prostate cancer diagnosis) would be insightful in understanding whether urologists are increasingly selective about those men on whom they choose to perform a biopsy.

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## References

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