

# Quality of Care Received and Patient-Reported Regret in Prostate Cancer: Analysis of a Population-Based Prospective Cohort

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**BACKGROUND:** Meeting quality of care standards in oncology is recognized as important by physicians, professional organizations, and payers. Data from a population-based cohort of patients with prostate cancer were used to examine whether receipt of care was consistent with published consensus metrics and whether receiving high-quality care was associated with less patient-reported treatment decisional regret. **METHODS:** Patients with incident prostate cancer were enrolled in collaboration with the North Carolina Central Cancer Registry, with an oversampling of minority patients. Medical record abstraction was used to determine whether participants received high-quality care based on 5 standards: 1) discussion of all treatment options; 2) complete workup (prostate-specific antigen, Gleason grade, and clinical stage); 3) low-risk participants did not undergo a bone scan; 4) high-risk participants treated with radiotherapy (RT) received androgen deprivation therapy; and 5) participants treated with RT received conformal or intensity-modulated RT. Treatment decisional regret was assessed using a validated instrument. **RESULTS:** A total of 804 participants were analyzed. Overall, 66% of African American and 73% of white participants received care that met all standards ( $P = .03$ ); this racial difference was confirmed by multivariable analysis. Care that included "discussion of all treatment options" was found to be associated with less patient-reported regret on univariable analysis ( $P = .03$ ) and multivariable analysis (odds ratio, 0.59; 95% confidence interval, 0.37-0.95). **CONCLUSIONS:** The majority of participants received high-quality care, but racial disparity existed. Participants who discussed all treatment options appeared to have less treatment decisional regret. To the authors' knowledge, this is the first study to demonstrate an association between a quality of care metric and patient-reported outcome. *Cancer* 2017;123:138-43. © 2016 American Cancer Society.

**KEYWORDS:** patient-reported outcomes, prostate cancer, quality of care, racial disparities, regret.

## INTRODUCTION

Meeting quality of care (QOC) standards in oncology is increasingly recognized as important by physicians, professional organizations, and payers. An overall shift in the US health care system toward quality-based and value-based care has charged professional organizations with creating metrics of quality.

Defining and assessing high-quality care are important for prostate cancer because prostate cancer affects a large number of men. Prostate cancer is the most common malignancy diagnosed among men in the United States, and is expected to be diagnosed in an estimated 180,000 men in 2016.<sup>1</sup> In a joint effort, the American Urological Association (AUA) and the American Society for Radiation Oncology (ASTRO) formed a consensus panel to define quality guidelines for patients with newly diagnosed prostate cancer.<sup>2</sup> Five consensus quality metrics resulted: 1) patients should have a discussion of all treatment options during consultation with their physician; 2) a complete workup should include prostate-specific antigen (PSA), Gleason score, and clinical stage; 3) patients at low risk should not undergo a bone scan; 4) patients at high risk who are treated with external-beam radiotherapy (EBRT) should receive androgen deprivation therapy (ADT); and 5) patients treated with EBRT should be treated with 3-dimensional (3D) conformal or intensity-modulated RT (IMRT) techniques.

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The goal of the current study was to assess the QOC based on these 5 metrics in a population-based cohort of prostate cancer research participants. The specific research question tested whether there was a racial or socioeconomic disparity in the QOC received and whether QOC was associated with patient outcome, specifically patient-reported treatment decisional regret.

## MATERIALS AND METHODS

### Data Source

The North Carolina-Louisiana Prostate Cancer Project (PCaP) was a population-based, prospective cohort study of 2258 African American and white men with newly diagnosed prostate cancer. The research participants were enrolled from 2004 to 2009 in collaboration with the state cancer registries in North Carolina and Louisiana.<sup>3</sup> An overarching goal of the current study was to assess racial disparities in prostate cancer care and outcomes, and therefore African American men were oversampled. Subsequent funding allowed the North Carolina Health Care Access Project to gather follow-up information regarding the North Carolina PCaP participants. Of the initial 1031 participants enrolled in North Carolina, 902 (88%) were contacted for follow-up and 804 (78%) completed the follow-up survey. Data were collected prospectively and included abstracted medical record data and patient-reported outcomes.

### Measures

Baseline patient age was calculated from the participant's reported date of birth. Charlson Comorbidity Score and disease characteristics (including Gleason score, PSA, and clinical stage) were abstracted from medical records. The disease characteristics were used to classify patients into low-risk, intermediate-risk, and high-risk categories using National Comprehensive Cancer Network (NCCN) criteria.<sup>4</sup> Patient demographic information that included race, marital status, education, and household income were collected by self-report.

Each participant's care was compared with the AUA/ASTRO consensus QOC indicators using information from medical records that was obtained and abstracted by trained research staff: 1) documentation of a discussion of all treatment options (including RT and radical prostatectomy) in the consultation notes; 2) documentation of PSA level, Gleason score, and clinical stage; 3) low-risk patients did not undergo a bone scan; 4) high-risk patients treated with EBRT received ADT; and 5) patients treated with EBRT were treated using 3D conformal

**TABLE 1.** Characteristics of the Analytic Cohort

|                                     | White<br>n=450 | African American<br>n=354 |
|-------------------------------------|----------------|---------------------------|
| Characteristic                      | No. (%)        | No. (%)                   |
| Median age (range), y               | 64 (41-79)     | 60 (41-78)                |
| Marital status                      |                |                           |
| Single                              | 10 (2.2)       | 23 (6.5)                  |
| Married                             | 380 (84.4)     | 248 (70.1)                |
| Divorced, widowed                   | 60 (13.3)      | 83 (23.4)                 |
| Education                           |                |                           |
| ≤High school                        | 119 (26.4)     | 190 (53.7)                |
| College graduate or<br>some college | 200 (44.4)     | 135 (38.1)                |
| Graduate degree                     | 131 (29.1)     | 29 (8.2)                  |
| Income                              |                |                           |
| <\$20,000                           | 23 (5.4)       | 79 (23.6)                 |
| \$20,000-\$50,000                   | 130 (30.5)     | 142 (42.4)                |
| >\$50,000                           | 273 (64.1)     | 114 (34.0)                |
| Charlson Comorbidity Score          |                |                           |
| 0                                   | 255 (56.7)     | 179 (50.6)                |
| 1                                   | 94 (20.9)      | 87 (24.6)                 |
| >1                                  | 101 (23.5)     | 88 (24.9)                 |
| Gleason score                       |                |                           |
| ≤6                                  | 287 (63.9)     | 184 (52.1)                |
| 7                                   | 122 (27.2)     | 127 (36.0)                |
| 8-10                                | 40 (8.9)       | 42 (11.9)                 |
| PSA, ng/mL                          |                |                           |
| <10                                 | 383 (85.3)     | 264 (75.2)                |
| 10-20                               | 50 (11.1)      | 48 (13.7)                 |
| >20                                 | 16 (3.6)       | 39 (11.1)                 |
| Clinical stage                      |                |                           |
| T1                                  | 268 (59.8)     | 225 (64.1)                |
| T2                                  | 178 (39.7)     | 119 (33.9)                |
| T3/4                                | 2 (0.5)        | 7 (2.0)                   |
| NCCN risk group                     |                |                           |
| Low risk                            | 263 (58.4)     | 162 (45.8)                |
| Intermediate risk                   | 131 (29.1)     | 123 (34.8)                |
| High risk                           | 56 (12.5)      | 69 (19.5)                 |
| First course of treatment           |                |                           |
| Radical prostatectomy               | 300 (66.7)     | 200 (56.5)                |
| External beam RT                    | 66 (14.7)      | 83 (23.5)                 |
| Brachytherapy                       | 16 (3.6)       | 20 (5.7)                  |
| Active surveillance                 | 44 (9.8)       | 19 (5.4)                  |
| Other/unknown                       | 24 (5.3)       | 32 (9.1)                  |

Abbreviations: NCCN, National Comprehensive Cancer Network; PSA, prostate-specific antigen; RT, radiotherapy.

mal or IMRT techniques.<sup>2</sup> Each quality indicator was coded as a binary outcome (received vs not received).

Treatment decisional regret was assessed by patient report using a validated 2-item instrument from Clark et al that was specific for prostate cancer.<sup>5</sup> This outcome was collected at an average of 3 years after diagnosis. These questions were administered by mail to all participants as part of a larger survey; follow-up calls to collect these data over the telephone were required for 32% of participants who did not respond to the mail survey. The regret questions were: 1) "I would have been better off if I had chosen a different treatment from the one I had" (5-point Likert scale: definitely false, false, not true or false, true, and definitely true); and 2) "How much of the time have you

**TABLE 2.** Percentage of Participants Receiving Care Meeting Each QOC Standard

|                                  | Discussion of All Treatment Options, % | Complete Workup, % | Low-Risk Patients Did Not Undergo a Bone Scan, % | High-Risk Patients Treated With EBRT and ADT, % | Met All QOC Standards, %         |
|----------------------------------|--|--------------------|--|---|----------------------------------|
| Total                            | 77                                     | 99                 | 85   | 84  | 70                               |
| Race                             |  |                    |  |   |                                  |
| White                            | 79                                     | 99                 | 89 <sup>a</sup>                                  | 81  | 73 <sup>a</sup>                  |
| African American                 | 76                                     | 98                 | 80 <sup>a</sup> ( <i>P</i> =.01)                 | 85  | 66 <sup>a</sup> ( <i>P</i> =.03) |
| Age, y                           |  |                    |  |   |                                  |
| >65                              | 78                                     | 99                 | 84   | 85  | 70                               |
| ≤65                              | 77                                     | 99                 | 87   | 83  | 69                               |
| Household income                 |  |                    |  |   |                                  |
| >\$50,000                        | 80 <sup>a</sup>                        | 99                 | 87   | 77  | 72                               |
| ≤\$50,000                        | 75 <sup>a</sup> ( <i>P</i> =.04)       | 99                 | 85   | 89  | 68                               |
| Education                        |  |                    |  |   |                                  |
| ≤High school                     | 76                                     | 99                 | 81 <sup>a</sup>                                  | 81  | 67 <sup>a</sup>                  |
| College graduate or some college | 76                                     | 99                 | 87 <sup>a</sup>                                  | 82  | 67 <sup>a</sup>                  |
| Graduate degree                  | 83                                     | 99                 | 93 <sup>a</sup> ( <i>P</i> =.03)                 | 100   | 79 <sup>a</sup> ( <i>P</i> =.01) |

Abbreviations: ADT, androgen deprivation therapy; EBRT, external-beam radiotherapy; QOC, quality of care.

All participants treated with radiotherapy received either 3D conformal or intensity-modulated radiotherapy and therefore this measure was omitted.

<sup>a</sup>Statistically significant difference.

wished that you could change your mind about the kind of treatment you chose for your prostate cancer” (5-point Likert scale: choose a number from 1 to 5, in which 1 means NONE of the time and 5 means ALL of the time).

As per the instrument developed by Clark et al, the regret responses were combined into a single binary outcome, with an affirmative response (4 or 5) to either regret question considered positive for regret and a neutral or negative response to both questions considered negative for treatment regret.<sup>6</sup>

### Statistical Analysis

The percentages of men in the different subgroups (by race, age, household income, and education) who received care consistent with each of the 5 quality metrics were described. The statistical significance of differences among groups was compared using the Fisher exact test. The percentage of participants who received care that met all 5 quality metrics was reported. The association between race and QOC was assessed using multivariable logistic regression models with quality metrics as binary outcomes. Race was the main predictive variable, and the model was adjusted for other baseline demographic covariates that have been shown to be associated with prostate cancer care, including age, insurance status, comorbidity, and marital status.<sup>7-9</sup> A separate model was constructed with each quality metric as an outcome.

The percentage of participants who reported having regret was calculated for each QOC metric to test for an association between receipt of high-quality care and patient-reported regret. Statistical significance in the percentage of patients with regret by whether they received versus did not receive high-quality care was assessed using

the Fisher exact test. Multivariable logistic regression models were used to assess whether each quality indicator was associated with patient-reported regret, after adjusting for comorbidity, insurance status, marital status, and age. All statistical analyses were performed using STATA/IC 13 statistical software (StataCorp LP, College Station, Tex).

### RESULTS

A total of 804 men were analyzed with a median age of 62 years (Table 1). Because this cohort consisted of men with mostly screening-detected cancers, very few had locally advanced (clinical stage T3/T4) disease. African American men comprised 44% of the cohort of patients who exhibited a range of educational attainment and household income levels.

The percentages of participants who received care meeting each quality metric are summarized in Table 2. All participants treated with RT received either 3D conformal RT or IMRT; these data were omitted from Table 2. Each quality metric examined individually was met by a high percentage of participants in all subgroups. Overall, 66% to 79% of participants in different subgroups received care that met all metrics. Some differences emerged in the subgroups and are highlighted in Table 2. For example, 66% of African American versus 73% of white participants received care that met all metrics (*P* = .03). Multivariable analysis confirmed this finding (odds ratio [OR], 0.62 for African American participants; 95% confidence interval [95% CI], 0.43-0.88) (Table 3).

Overall, 13% of participants reported regret concerning their treatment decision. Participants who had all available treatment options discussed were less likely to

**TABLE 3.** Multivariable Logistic Regression Models Assessing the Association Between Race and Receipt of High-Quality Care<sup>a</sup>

| Race                        | QOC Indicators                                   |                              |  |   |                                    |
|-----------------------------|--|------------------------------|--|---|------------------------------------|
|                             | Discussion of All Treatment Options, OR (95% CI) | Complete Workup, OR (95% CI) | Low-Risk Patients Did Not Undergo a Bone Scan, OR (95% CI) | High-Risk Patients Treated With EBRT and ADT, OR (95% CI) | Met All QOC Standards, OR (95% CI) |
| White (Referent)            | 1  | 1                            | 1  | 1   | 1                                  |
| African American (adjusted) | 0.76 (0.52-1.12)                                 | 0.54 (0.13-2.30)             | 0.47 (0.25-0.89)   | 0.18 (0.00-11.74)   | 0.62 (0.43-0.88)                   |

Abbreviations: 95% CI, 95% confidence interval; ADT, androgen deprivation therapy; EBRT, external-beam radiotherapy; OR, odds ratio; QOC, quality of care.  
<sup>a</sup>Model was adjusted for comorbidity, insurance status, National Comprehensive Cancer Network risk group, first course of treatment, education, marital status, and age.

**TABLE 4.** Participant-Reported Treatment Decisional Regret Stratified by QOC Indicators

| QOC Indicators  | Participants Expressing Regret, No. (%) | <i>P</i> |
|---|---|----------|
| Discussed all treatment options                       |   |          |
| Yes   | 75 (12.1)                               | .03      |
| No  | 33 (18.1)                               |          |
| Complete workup                                       |   | .39      |
| Yes   | 106 (13.4)                              |          |
| No  | 2 (20.0)                                |          |
| Low-risk patients did not undergo bone scan           |   | .10      |
| Yes   | 48 (13.2)                               |          |
| No  | 4 (6.6)                                 |          |
| High-risk patients treated with EBRT who received ADT |   | .58      |
| Yes   | 3 (11.5)                                |          |
| No  | 0 (0)                                   |          |
| Met all quality indicators                            |   | .19      |
| Yes   | 71 (12.7)                               |          |
| No  | 37 (15.2)                               |          |

Abbreviations: ADT, androgen deprivation therapy; EBRT, external-beam radiotherapy; QOC, quality of care.

express treatment regret (12.1% vs 18.1%; *P* = .03) (Table 4). Multivariable analysis controlling for race, comorbidity, insurance status, marital status, NCCN risk group, first course of treatment, education, and age confirmed this finding (OR, 0.59; 95% CI, 0.37-0.95).

## DISCUSSION

In the current study, we examined the QOC received in a prospective, population-based cohort of patients with prostate cancer using consensus quality measures. Overall, the results indicated that a high percentage of participants received high-quality care that met all 5 published metrics. However, African American participants received an overall lower QOC, and this disparity persisted on multivariable analysis. Much of the difference in care noted between African American and white patients was driven by the measure of low-risk patients undergoing a bone scan.

Receipt of high-quality care, specifically the discussion of all available treatment options, was found to be associated with less patient regret after treatment.

Prior studies have evaluated QOC among patients with newly diagnosed, clinically localized prostate cancer using a wide array of quality metrics.<sup>10-15</sup> Schroeck et al examined QOC using Surveillance, Epidemiology, and End Results (SEER)-Medicare data and reported that 65.9% of low-risk patients did not undergo a bone scan and 76.8% of high-risk patients treated with EBRT received adjuvant ADT.<sup>10</sup> Spencer et al examined QOC received by 2775 patients at American College of Surgeons Commission on Cancer-accredited cancer institutions.<sup>12</sup> Multivariable analysis found no difference in the care received by African American versus white patients using 3 quality indicators: complete workup, discussion of treatment options, and conformal RT. Finally, Skolarus et al reported on QOC in the Veteran Affairs Central Cancer Registry using 2 overlapping quality metrics that included low-risk patients who did not undergo a bone scan and high-risk patients who were treated with EBRT and received ADT.<sup>13</sup> They found overall high quality: 80.9% to 88.9% of low-risk patients did not undergo a bone scan and 85.3% to 90.3% of high-risk patients treated with EBRT also received ADT. Consistent with these prior publications, the current study found a high percentage of participants received care that met published quality metrics. However, the current study was unique because to the best of our knowledge it is the only study to date to be able to assess all 5 of the proposed quality metrics from the consensus AUA/ASTRO physician performance measures. In addition, the current study included patients from a prospective, population-based cohort that included patients who were aged <65 years and a significant percentage of African American individuals. In this diverse cohort, we found that African American men were less likely to receive overall high-quality care, and were more

likely to undergo an unneeded bone scan for low-risk disease. The reason for the higher use of bone scans in African American patients is unknown and could be driven by an awareness that African American patients often have more aggressive cancers than white patients, although this alone does not justify the use of bone scans for low-risk patients. It is also possible that for some patients symptoms (ie, pain) could have led physicians to order bone scans for their low-risk patients.

Increasing attention has been focused on the measurement of the quality of cancer care using published metrics. However, to the best of our knowledge, the correlation between quality metrics and patient outcomes has not been well studied to date. We found 1 claims-based analysis that categorized treatment facilities into 3 tiers based on their performance on 5 metrics: 1) consultation with a urologist and radiation oncologist; 2) low-risk patients did not undergo a bone scan; 3) high-risk patients who received adjuvant ADT and RT; 4) patients treated by a high-volume (upper tertile) provider (surgeon or radiation oncologist); and 5) at least 2 follow-up visits with a treating surgeon or radiation oncologist within 1 year after receipt of treatment.<sup>15</sup> The study found that patients treated with radical prostatectomy at top-performing facilities experienced fewer perioperative complications (OR, 0.8; 95% CI, 0.64-1.0) and slightly shorter hospital stays (2.0 days vs 2.1 days;  $P = .02$ ), but were more likely to undergo a procedure for treatment-related sexual and bowel morbidity ( $P < .05$  for both). To our knowledge, the current study is the first to examine whether QOC in prostate cancer was associated with patient-reported outcomes.

Multidisciplinary cancer care is advocated by many professional organizations, including the American Society of Clinical Oncology, ASTRO, and AUA.<sup>2,16</sup> Multidisciplinary care in patients with prostate cancer appears to be a natural fit given the many treatment options available, but whether this recommendation improves patient outcomes remains uncertain. Participants in the PCaP who received multidisciplinary counseling before treatment reported less decisional regret. Regret is an important patient-centered measure for prostate cancer that may represent a patient's overall experience and subjective outcome and can affect a patient's quality of life after treatment.<sup>6,17-19</sup> Participants who did not receive multidisciplinary consultation may not have had the full opportunity to match a treatment option with their preferences and beliefs. An additional potential explanation for this finding is that a more comprehensive discussion regarding available treatment options as well as associated potential

side effects can help patients to have more realistic expectations regarding outcomes. Indeed, prior studies have shown that patients with a better understanding of expected treatment-related side effects have less regret afterward.<sup>20</sup>

The current study has potential limitations that are worth mentioning. First, some patients in the current study cohort were enrolled before publication of the consensus guidelines referenced herein. Thus, although we found a racial disparity in the care received, some of the differences in care may not have been formalized as guideline recommendations until 2007. However, the current study finding that receiving high-quality care was associated with less regret remains novel, and demonstrates the value in the guideline in that high-quality care was indeed found to be associated with better patient outcome. Another potential limitation of the current study is that there was no information regarding the patient's cancer status, although given the time of the survey, which was an average of 3 years after diagnosis, we would not expect a high percentage of patients to have active or metastatic disease. We also did not have information regarding the number of specialists (urology, radiation oncology, or medical oncology) each patient consulted before making a treatment decision, and this also could be a factor associated with regret. Furthermore, we acknowledge that treatment decisions inherently involve complex discussions and considerations, and a dichotomized quality measure regarding whether all treatment options were discussed may oversimplify the process. Despite these potential limitations, we found a novel association between QOC received and patient-reported outcome in a large, diverse cohort of patients with incident prostate cancer.

The movement of both payers and policymakers toward quality-based reimbursement and credentialing has created an urgent need for more research to generate high-quality evidence that published guidelines and quality metrics actually affect patient outcomes.<sup>21</sup> A recently published study reported that only 6% of the recommendations published in the NCCN guidelines are based on data from clinical trials.<sup>22</sup> Clinical practice guidelines, such as those of the NCCN, serve the purpose of being an easy-to-access reference for clinicians and thus facilitate care for patients, but the use of these guidelines to inform reimbursement or policy requires evidence directly tying guideline adherence to patient outcome. The current study provides an example, but more research is needed.

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## CONFLICT OF INTEREST DISCLOSURES

The authors made no disclosures.

## AUTHOR CONTRIBUTIONS

**Jordan A. Holmes:** Formal analysis and writing—original draft. **Jeannette T. Bensen:** Conceptualization, writing—review and editing, and supervision. **James L. Mohler:** Conceptualization, writing—review and editing, and supervision. **Lixin Song:** Investigation and writing—review and editing. **Merle H. Mishel:** Investigation and writing. **Ronald C. Chen:** Formal analysis and writing—original draft.

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