










## ORIGINAL ARTICLE

# Assessing sociodemographic and regional disparities in Oncotype DX Genomic Prostate Score uptake

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## Abstract

**Background:** The Oncotype DX Genomic Prostate Score (ODX-GPS) is a gene expression assay that predicts disease aggressiveness. The objective of this study was to identify sociodemographic and regional factors associated with ODX-GPS uptake.

**Methods:** Data from Surveillance Epidemiology and End Results registries on men with localized prostate cancer with a Gleason score of 3 + 3 or 3 + 4, PSA  $\leq 20$  ng/mL, and stage T1c to T2c disease from 2013 through 2017 were linked with ODX-GPS data. Census-tract level neighborhood socioeconomic status (nSES) quintiles were constructed using a composite socioeconomic score. Multivariable logistic regression was used to estimate the associations of ODX-GPS uptake with age at diagnosis, race and ethnicity, nSES, geographic region, insurance type, and marital status, accounting for National Comprehensive Cancer Network risk group, year of diagnosis, and clustering by census tract.

**Results:** Among 111,434 eligible men, 5.5% had ODX-GPS test uptake. Of these, 78.3% were non-Hispanic White, 9.6% were Black, 6.7% were Hispanic, and 3.6% were Asian American. Black men had the lowest odds of ODX-GPS uptake (odds ratio, 0.70; 95% confidence interval [CI], 0.63–0.76). Those in the highest versus lowest quintile of nSES were 1.64 times more likely (95% CI, 1.38–2.94) to have ODX-GPS uptake. The odds of ODX-GPS uptake were statistically significantly higher among men residing in the Northeast, West, and Midwest compared to the South.

**Conclusions:** Disparities in ODX-GPS uptake by race, ethnicity, nSES, and geographical region were identified. Concerted efforts should be made to ensure that this clinical test is equitably available.

**KEYWORDS**

genomic medicine, health inequities, health services accessibility, prostatic neoplasms, social determinants of health, socioeconomic disparities and health

## INTRODUCTION

Precision medicine has become an important component of prostate cancer management.<sup>1</sup> Tumor genomic profiling is an emerging tool in precision medicine, which in conjunction with clinicopathologic characteristics, can aid in making treatment decisions.<sup>2</sup> For men with very low, low, or intermediate risk prostate cancer who are candidates for active surveillance (AS), tumor genomics provide additional prognostic information when choosing an optimal approach for disease management.

Oncotype DX Genomic Prostate Score (ODX-GPS) is a gene expression assay that was launched in 2013.<sup>3</sup> ODX-GPS uses tissue from prostate biopsies to calculate a genomic risk score that, in conjunction with clinical characteristics, aids in estimating the likelihood of adverse pathology at radical prostatectomy. Higher (worse) ODX-GPS scores have been associated with distant metastasis and prostate cancer-specific mortality.<sup>4</sup> Tumor-based molecular assays, including ODX-GPS, were first incorporated into the 2015 National Comprehensive Cancer Network (NCCN) prostate cancer guidelines as an option that could be considered for patients with clinically localized disease.<sup>5</sup> Since 2018, molecular assays, which also include Decipher, Prolaris, and Promark, have been included in the NCCN risk stratification and staging workup guidelines for patients with very low, low, and favorable intermediate risk prostate cancer.<sup>6</sup> Specifically, genomic tests like ODX-GPS may be administered at time of prostate cancer diagnosis to patients with localized disease as defined by the NCCN and a life expectancy of at least 10 years. For some patients, the additional information provided by genomic tests can impact their treatment plan. In a study of 158 prostate cancer patients from three high-volume urology practices, 30% of patients with NCCN low risk prostate cancer who were initially recommended radical prostatectomy switched to AS after ODX-GPS testing.<sup>7</sup> Another study evaluating the impact of ODX-GPS on treatment decisions that included 200 men (70% African American) with very low-, low-, and low intermediate-risk prostate cancer found that men with lower health literacy who received ODX-GPS were 7-fold less likely to choose active surveillance than controls, whereas no difference was seen in men with higher health literacy.<sup>8</sup>

Although racial and ethnic disparities in prostate cancer treatment have been identified, there is a paucity of information on variation in the use of prostate cancer genomic tests.<sup>9,10</sup> In the era of precision medicine, it is critical to ensure that all patients have equitable access to genomic tools that can aid in making informed

management decisions for their disease. By leveraging a unique linkage of national population-based cancer registry data with genomic testing data, our objective was to examine whether the uptake of ODX-GPS differs by racial, ethnic, sociodemographic, and regional characteristics.

## MATERIALS AND METHODS

Our study used data from the National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) population-based cancer registry program,<sup>11</sup> which linked its data to genomic testing data from ODX-GPS. We included prostate cancer cases from the following SEER registries: California, Connecticut, Detroit, Georgia, Hawaii, Idaho, Iowa, Kentucky, Louisiana, Massachusetts, New Jersey, New Mexico, New York, Seattle-Puget Sound, and Utah. The linkage was performed using a similar method previously described that linked the 21-gene Oncotype DX Breast Recurrence Score with SEER data.<sup>12</sup>

Individuals eligible for this study included 137,980 men in the SEER database diagnosed with localized prostate cancer stage T1c-T2c from 2013 through 2017 with a Gleason score of 3 + 3 or 3 + 4, and a prostate-specific antigen (PSA) of  $\leq 20$  ng/mL. It was assumed that prostate cancer cases not linked to ODX-GPS did not have the test ordered. The outcome, ODX-GPS uptake, was defined as whether a patient had the test ordered by a clinician. Men were excluded from the analysis if they were diagnosed with prior cancers, a nonepithelial tumor, or if their cancer was diagnosed at autopsy or death certificate or reported by a nursing home, convalescent home, or hospice ( $n = 4717$ ). Cases with unknown initial prostate cancer treatment/management were also excluded ( $n = 21,829$ ). A total of 111,434 men with prostate cancer were included in the final analysis cohort.

We examined sociodemographic and regional characteristics as follows. Race and ethnicity were characterized as the following mutually exclusive categories: non-Hispanic American Indian or Alaska Native, non-Hispanic Asian American, non-Hispanic Black, Hispanic that includes all races, non-Hispanic Native Hawaiian or Pacific Islander, non-Hispanic White, and non-Hispanic unknown race. These groups will herein be referred to as American Indian or Alaska Native, Asian American, Black, Hispanic, Native Hawaiian or Pacific Islander, White, and unknown race, respectively. Neighborhood socioeconomic status (nSES) quintiles were constructed using

a composite socioeconomic score, for census tracts of addresses at diagnosis, based on American Community Survey 5-year estimates for 2013–2017.<sup>13</sup> The composite score uses the distribution across the study region for the following variables: median household income, median home value, median rent, percent below 150% of the poverty line, an education index, percent working class, and percent unemployed.<sup>14</sup> The first quintile represented census tracts with the lowest nSES and the fifth quintile represented the highest SES neighborhoods. Registries were grouped into four designated US Census regions and cases were assigned to regions based on their residence at diagnosis.<sup>15</sup> The Northeast region included Connecticut, Massachusetts, New Jersey, and New York registries. The Midwest region included the Detroit and Iowa registries. The South region included the Georgia, Kentucky, and Louisiana registries. The West region included the California, Hawaii, Idaho, New Mexico, Seattle-Puget Sound, and Utah registries. Age at diagnosis was categorized into four groups: under 55, 55–64, 65–74, and over 75 years old. Insurance status was categorized as any Medicaid (including Indian/Public Health Service), insured (private insurance [fee-for-service, managed care, health maintenance organization, preferred provider organization, TRICARE], Medicare, Medicare with supplement, and military), uninsured, and unknown.<sup>16</sup> Marital status was categorized as married, unmarried, or unknown. Cases were classified as having low, favorable intermediate, and unfavorable intermediate risk based on 2016 NCCN Prostate Cancer guidelines (version 1).<sup>17</sup> During the study period, Idaho, Massachusetts, and New York were not yet included in the SEER registry and thus followed only data standards set by the North American Association of Central Cancer Registries, which have slightly different standards than SEER for some variables.<sup>18</sup> This study was approved as part of the Greater Bay Area Cancer Registry protocol by the institutional review board at the University of California, San Francisco.

We used logistic regression to estimate adjusted odds ratios (OR) and 95% confidence intervals (CI) of the associations of ODX-GPS uptake with race and ethnicity, nSES, geographic region, age at diagnosis, insurance type, and marital status, adjusting for NCCN risk group and year of diagnosis. In addition, we accounted for clustering using a pseudo census tract identifier using the `glm.cluster` function for the `miceadds` package.<sup>19</sup> Stratified analysis were conducted by racial and ethnic group and year of diagnosis. All tests were two-sided with a pre-specified  $\alpha$  of 0.05. Statistical analysis was conducted using R version 4.2.1<sup>20</sup> and STATA 17.<sup>21</sup>

## RESULTS

Descriptive characteristics of the 111,434 men diagnosed with very low, low, or intermediate risk prostate cancer by linkage to ODX-GPS uptake are shown in Table 1. The mean age was 63.8 years with a standard deviation of 7.7 years and ranged from 29 to 102

years; the majority was 55–64 (39.9%) and 65–74 (40.0%) years old. Most men in the study were White (70.5%), followed by Black (15.2%), Hispanic (9.0%), Asian American (3.7%), Native Hawaiian or Pacific Islander (0.3%), and American Indian or Alaska Native (0.2%). There was a higher uptake of ODX-GPS among White men (6%) compared to Black (3.4%), Hispanic (3.9%), and Asian (5.3%) men. Approximately 31.7% resided in the highest quintile of nSES whereas 11.4% resided in the lowest nSES quintile. ODX-GPS uptake increased monotonically with increasing nSES and with decreasing NCCN risk category. The distribution of NCCN risk category varied by race and ethnicity (Table S1). For unfavorable intermediate disease in comparison to other risk categories, Native Hawaiian or other Pacific Islander men were diagnosed with the largest proportion (28.6%) followed by Black men (27.0%), American Indian or Alaska Native men (24.6%), Hispanic men (23.7%), Asian men (23.2%), and White men (23.1%). Men in this study resided largely in the Northeast (39.6%) and West (35.6%), followed by the South (17.4%) and Midwest (7.4%) (Table 1). The majority were married (69.6%) and insured (86.9%). Uptake was lower among uninsured men (2.3%) and men residing in the South (2.6%).

The odds of ODX-GPS uptake varied by race and ethnicity, adjusted for year of diagnosis and NCCN category. Compared to White men with prostate cancer, the odds of ODX-GPS uptake were statistically significantly lower among Black (OR, 0.70; 95% CI, 0.64–0.76) and Hispanic men (OR, 0.70; 95% CI, 0.62–0.78) (Table 2). Native Hawaiian or Pacific Islander (OR, 0.78; 95% CI, 0.42–1.45), and Asian men (OR, 0.91; 95% CI, 0.79–1.06) also had lower odds of ODX-GPS uptake, but the observed differences were not statistically significant. In stratified analyses by year of diagnosis, Black and Hispanic men had a consistently lower odds of uptake compared to White men, suggesting that the racial disparity did not change over this time period (Table S2).

Overall, increasing nSES quintile was associated with increasing odds of ODX-GPS uptake. Men residing in the highest nSES quintile had 62% higher odds (OR, 1.62; 95% CI, 1.44–1.83) of test uptake compared to those in the lowest nSES quintile (Table 2). When stratified by race and ethnicity, only two groups, Black and Hispanic men, experienced statistically significantly higher odds of ODX-GPS uptake in the highest nSES quintile when compared to other Black and Hispanic men, respectively, residing in the lowest quintile nSES census tracts (Table S3). In contrast, White men in the third, fourth, and fifth nSES quintiles all had statistically significantly higher odds of ODX-GPS uptake than White men in the lowest nSES quintile. We also identified regional variation. In comparison to the South, the odds of ODX-GPS uptake among men in the Northeast was 2.57-times higher (OR, 2.57; 95% CI, 2.30–2.87), followed by those in the Midwest (OR, 2.08; 95% CI, 1.80–2.41) and West (OR, 1.49; 95% CI, 1.33–1.67) (Table 2). Uninsured men had approximately half the odds of ODX-GPS uptake compared to those with insurance (OR, 0.56; 95% CI, 0.36–0.87).

**TABLE 1** Characteristics of 111,434 men diagnosed with low/intermediate risk prostate cancer in 20 SEER registries from 2013 through 2017 by ODX-GPX uptake.

	ODX-GPS test, No. (%) <sup>c</sup>	No ODX-GPS, No. (%) <sup>c</sup>	Total, No. (%) <sup>d</sup>
Cases	6014 (5.4)	105,420 (94.6)	111,434
Mean age (SD), years	63.8 (7.5)	63.8 (7.8)	63.8 (7.7)
Age at diagnosis, years			
<55	689 (5.1)	12,714 (94.9)	13,403 (12.0)
55–64	2414 (5.4)	42,101 (94.6)	44,515 (39.9)
65–74	2477 (5.6)	42,058 (94.4)	44,535 (40.0)
75+	434 (4.8)	8547 (95.2)	8981 (8.1)
Race and ethnicity			
American Indian or Alaska Native	<15	263	276 (0.2)
Asian	218 (5.3)	3922 (94.7)	4140 (3.7)
Black	580 (3.4)	16,314 (96.6)	16,894 (15.2)
Hispanic	394 (3.9)	9625 (96.1%)	10,019 (9.0)
Native Hawaiian or other Pacific Islander	<15	279	290 (0.3)
Unknown	89 (7.0)	1174 (93.0)	1263 (1.1)
White	4709 (6.0)	73,843 (94.0)	78,552 (70.5)
Neighborhood SES quintile (census tract)			
Q1–Low	405 (3.2)	12,295 (96.8)	12,700 (11.4)
Q2	511 (3.6)	13,602 (96.4)	14,113 (12.7)
Q3	792 (4.4)	17,254 (95.6)	18,046 (16.2)
Q4	1227 (5.1)	23,035 (94.9)	24,262 (21.8)
Q5–High	2550 (7.2)	32,743 (92.8)	35,293 (31.7)
Missing	529 (7.5)	6491 (92.5)	7020 (6.3)
US census region			
South	505 (2.6)	18,901 (97.4)	19,406 (17.4)
Midwest	434 (5.2)	7836 (94.8)	8270 (7.4)
Northeast	3319 (7.5)	40,778 (92.5)	44,097 (39.6)
West	1756 (4.4)	37,905 (95.6)	39,661 (35.6)
Insurance status			
Insured <sup>a</sup>	5197 (5.4)	91,682 (94.6)	96,879 (86.9)
Any Medicaid	263 (4.2)	6024 (95.8)	6287 (5.6)
Uninsured	21 (2.3)	883 (97.7)	904 (0.8)
Unknown	533 (7.2)	6831 (92.8)	7364 (6.6)
Marital status			
Married	4239 (5.5)	73,269 (94.5)	77,508 (69.6)
Unmarried	1207 (4.9)	23,196 (95.1)	24,403 (21.9)
Unknown	568 (6.0)	8955 (94.0)	9523 (8.5)

**TABLE 1** (Continued)

	ODX-GPS test, No. (%) <sup>c</sup>	No ODX-GPS, No. (%) <sup>c</sup>	Total, No. (%) <sup>d</sup>
NCCN risk category <sup>b</sup>			
Very low and low	3778 (7.2)	48,629 (92.8)	52,407 (47.0)
Favorable intermediate	1617 (5.0)	30,910 (95.0)	32,527 (29.2)
Unfavorable intermediate	619 (2.3)	25,881 (97.7)	26,500 (23.8)
Diagnosis year			
2013	588 (2.6)	22,105 (97.4)	22,693 (20.4)
2014	934 (4.4)	20,229 (95.6)	21,163 (19.0)
2015	1349 (6.2)	20,416 (93.8)	21,765 (19.5)
2016	1501 (6.6)	21,350 (93.4)	22,851 (20.5)
2017	1642 (7.2)	21,320 (92.8)	22,962 (20.6)

Abbreviations: NCCN, National Comprehensive Cancer Network; ODX-GPX, Oncotype DX Genomic Prostate Score; PSA, prostate-specific antigen; SEER, Surveillance, Epidemiology and End Results; SES, socioeconomic status; US, United States.

<sup>a</sup>Insured includes fee-for-service, managed care, health maintenance organization, preferred provider organization, TRICARE, Medicare, Medicare with supplement, and military.

<sup>b</sup>Very low/low: T1–T2a, Gleason score ≤6, PSA <10 ng/mL; favorable intermediate: none of the following Gleason score ≤8, T3 or higher, or PSA >10, and one of the following T2b–T2c, Gleason score 3 + 4, or PSA 10–20 ng/mL; unfavorable intermediate: none of the following Gleason score ≤8, T3 or higher, or PSA >10, and two of the following T2b–T2c, Gleason score 3 + 4, or PSA 10–20 ng/mL.

<sup>c</sup>Row percentages.

<sup>d</sup>Column percentages.

## DISCUSSION

This large population-based study of men with very low, low, and intermediate risk prostate cancer, eligible for an emerging genomic test for prostate cancer risk stratification, ODX-GPS, identified racial, ethnic, socioeconomic, and regional differences in its uptake. Although uptake has increased slightly since the ODX-GPS test was first introduced, it remained low, at 7.2%, in 2017, with substantial regional variations from 7.5% in the Northeast to 2.6% in the South. Almost all racial and ethnic minoritized groups had lower odds of ODX-GPS uptake compared to White men, with statistically significant disparities observed for Black and Hispanic men that did not vary over the study period. ODX-GPS uptake increased with increasing nSES and was 62% higher for men residing in the highest vs. lowest neighborhoods. Among Black and Hispanic men, only those in the highest nSES quintile experienced a statistically significant increased odds of ODX-GPS uptake compared to those in the lowest nSES quintile. In contrast, White men who resided in neighborhoods that were in the upper three quintiles of nSES had a higher odds of ODX-GPS uptake. The odds of ODX-GPS uptake was nearly half among uninsured men relative to insured men, yet those with Medicaid insurance has statistically similar

**TABLE 2** Adjusted odds of ODX-GPS uptake among men diagnosed with low/intermediate risk prostate cancer in 20 SEER registries from 2013 through 2017.

	No. of cases	Adjusted OR <sup>a</sup> (95% CI)
Age at diagnosis, years		
<55	13,403	Reference
55–64	44,515	1.01 (0.93–1.10)
65–74	44,535	1.07 (0.98–1.16)
75+	8981	0.98 (0.86–1.10)
Race and ethnicity		
White	78,552	Reference
American Indian or Alaska Native	276	1.02 (0.59–1.76)
Asian	4140	0.91 (0.79–1.06)
Black	16,894	0.70 (0.64–0.76)
Hispanic	10,019	0.70 (0.62–0.78)
Native Hawaiian or other Pacific Islander	290	0.78 (0.42–1.45)
Unknown race	1263	1.06 (0.85–1.32)
Neighborhood SES quintile (census tract)		
Q1–Low	12,700	Reference
Q2	14,113	0.97 (0.85–1.12)
Q3	18,046	1.09 (0.95–1.24)
Q4	24,262	1.17 (1.03–1.33)
Q5–High	35,293	1.62 (1.44–1.83)
Missing	7020	1.25 (0.94–1.65)
US census region		
South	19,406	Reference
Midwest	8270	2.08 (1.80–2.41)
Northeast	44,097	2.57 (2.30–2.87)
West	39,661	1.49 (1.33–1.67)
Insurance status		
Insured <sup>b</sup>	96,879	Reference
Any Medicaid	6287	0.93 (0.82–1.06)
Uninsured	904	0.56 (0.36–0.87)
Unknown	7364	1.26 (1.13–1.40)
Marital status		
Married	77,508	Reference
Unmarried	24,403	1.01 (0.95–1.08)
Unknown	9523	1.07 (0.97–1.19)

Abbreviations: CI, confidence interval; NCCN, National Comprehensive Cancer Network; ODX-GPX, Oncotype DX Genomic Prostate Score; OR, odds ratio; SEER, Surveillance, Epidemiology and End Results; SES, socioeconomic status; US, United States.

<sup>a</sup>Adjusted for diagnosis year, NCCN risk category, age category, race and ethnicity, neighborhood SES, US census region, insurance status, and marital status.

<sup>b</sup>Insured includes fee-for-service, managed care, health maintenance organization, preferred provider organization, TRICARE, Medicare, Medicare with supplement, and military.

adjusted odds of test uptake (crude proportions were slightly lower) compared to insured men.

Patient factors may affect ODX-GPS use through limited awareness of testing, an unfavorable perceived risk-benefit profile, medical mistrust, and limited health care access. A study from outpatient oncology clinics at Yale New Haven Medical center found White participants and those with prior knowledge of genomic tumor profiling were more willing to undergo genomic tumor testing. In a survey of Black cancer patients at outpatient oncology clinics in Philadelphia, PA, patients expressed concerns over tumor genomic profiling cost, results, accuracy, and the prospect of insurance discrimination.<sup>22</sup> In contrast, a small cohort study on the use of ODX-GPS among 390 patients in six Veterans Affairs (VA) medical centers found no racial and ethnic differences in receipt of ODX-GPS testing.<sup>23</sup> This is likely related to reduced barriers to testing as well as standard implementation of guidelines within an equal access health care system. Unlike the VA study, we identified differences in a national population-based setting in the odds of ODX-GPS test uptake by race and ethnicity. Additionally, although most of our study population was insured, we identified a lower odds of ODX-GPS uptake among those without insurance, even with adjustment for race, ethnicity, nSES, and other characteristics; having Medicaid was not statistically significantly associated with ODX-GPS uptake.

We identified increasing adjusted odds of ODX-GPS uptake with increasing nSES. This is likely due to a confluence of ecological-level factors including differential access to and quality of health care services. Our findings are consistent with the findings from two previous studies on uptake of genomic prostate tissue testing from 2012 through 2018 by Leapman and colleagues<sup>9,10</sup> among privately insured men, which also used a combination of patient-level demographic factors and area-level social determinants of health. They used trajectory modeling that divided the hospital referral regions into quartiles based on the percent increase of ODX-GPS testing over the study period and found that increasing quartile of uptake in prostate genomic testing was associated with increasing median household income at the hospital referral region level. They also found that higher educational attainment at the hospital referral region level was associated with increasing test uptake.<sup>10</sup>

We found statistically significant differences in the odds of ODX-GPS testing by geographic region, with the Northeast having the highest adjusted odds followed by the Midwest and West, and the South having the lowest. There are several possible pathways that may be contributing to these regional differences in ODX-GPS uptake. Provider density may play a role. In 2018, the Northeast had the highest density of urologists and the South had the lowest.<sup>24</sup> Median travel time to a National Cancer Institute–designated cancer center takes five times longer in the South, compared to the Northeast, which may affect test referral and access,<sup>25</sup> as tumor genomic tests may be more commonly administered in academic than community practices. The lower use of ODX-GPS in the South may also be related to rurality, as the 2011–2015 American Community Survey found that nearly half of all people living in rural areas resided in the South.<sup>26</sup> Rural oncology practices have less access to on-site pathology, protocols for genomic tests and molecular tumor boards.<sup>27</sup>



Provider access to and perceived utility of genomic testing may also play a role in ODX-GPS uptake variation. A cross-sectional, 2022 survey of 38 genitourinary malignancy specialists in Canada found that only 58% had access to genomic testing.<sup>28</sup> Of 33 physicians who offered genomic testing, only two (6%) did so at diagnosis. This proportion increased when the patient had a family history of prostate cancer (9%) or had high risk localized disease (18%). Physicians also reported that testing was most commonly arranged through clinical trials and provincially (government) funded testing, suggesting that utilization may be influenced by access. Medical practice setting may also play a role. One U.S. study found that urologists at Columbia University had a higher satisfaction with ODX-GPS testing utility (95%) than urologists at two community practices (85% and 41%).<sup>7</sup> The 2017 National Survey of Precision Medicine in Cancer Treatment, which is a nationally representative survey of oncologists and hematologists, found that multi-specialty group academic practices were more likely to have genomic testing protocols compared to other practice settings.<sup>27</sup> Provider perception of biological differences in prostate cancer aggressiveness by race and ethnicity may also influence treatment decisions, including ODX-GPS ordering.<sup>29</sup>

To our knowledge, this is the first population-based study on variation in the use of a tissue-based genomic prostate risk stratification tool. Leveraging the SEER data resource enhanced with genomic data allowed us to evaluate disparities in ODX-GPS use among over a hundred thousand men with prostate cancer. The comprehensiveness of these data allowed for the study of important patient characteristics in detail, including race and ethnicity, insurance status, and nSES. Our findings on the association of insurance status and geographic region with ODX-GPS uptake fill an important research gap in our understanding of access to tissue-based genomic prostate risk stratification tools.

Our study has some limitations. We were only able to assess the use of one prostate cancer tissue-based genomic test, although there are several of them on the market.<sup>30</sup> Over the study period, less than 6% of the cases used ODX-GPS, which is approximately half the proportion of men who used ODX-GPS, Decipher, Prolaris, or Promark combined, as reported in a 2021 study of commercially insured men.<sup>9</sup> We were unable to distinguish between those who were not tested due to ODX-GPS not being offered versus declining testing. Given available coding in cancer registry data, the inclusion criteria did not exclude patients with unfavorable intermediate-risk prostate cancer who were not eligible for the ODX-GPS assay during the study period. The prostate cancer risk groups in this study were based on NCCN guidelines, and although commonly used, they are not the only guidelines for prostate cancer management. The joint guidelines issued by the American Urological Association, the American Society for Radiation Oncology, and the Society of Urologic Oncology also issued guidelines for prostate cancer management.<sup>31</sup> The study period, 2013 through 2017, covers the early stages of ODX-GPS adoption and thus may not reflect its current use patterns. Further study of more recent ODX-GPS is necessary to understand its use with insurance coverage. This study did not assess the impact of the ODX-GPS test on the treatment outcomes. We were unable to assess factors that likely

influence ODX-GPS uptake including provider and health care characteristics that are not included in the SEER database. Given our findings on regional variation, further exploration of variation of smaller geographies is warranted but was infeasible for this analysis as we were limited to geographic identifiers of census region and pseudo identifications of census tracts. Additionally, we were unable to estimate associations for rurality due to missing data.

The use of prostate cancer tumor genomic testing is a relatively new entrant to the treatment paradigm. As with any health service, understanding variations in its use is essential in identifying possible inequities. We identified racial and ethnic, socioeconomic, and regional variations in ODX-GPS uptake. Future studies should include other prostate cancer genomic tests to determine if these disparities are pervasive. Additionally, detailed research into the role and effectiveness of ODX-GPS results in treatment decision-making is warranted.

## AUTHOR CONTRIBUTIONS

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## CONFLICT OF INTEREST STATEMENT

John Bennett reports stock holdings with Exact Sciences. Benjamin I. Chung reports consulting fees from Johnson & Johnson Health Care Systems Inc and VPIX; and travel funding from Intuitive Surgical, Inc. John T. Leppert reports consulting fees from Telix. The other authors declare no conflicts of interest.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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