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# Examining Potential Colorectal Cancer Care Disparities in the Veterans Affairs Health Care System

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A B S T R A C T

#### Purpose

Racial disparities in cancer treatment and outcomes are a national problem. The nationwide Veterans Affairs (VA) health system seeks to provide equal access to quality care. However, the relationship between race and care quality for veterans with colorectal cancer (CRC) treated within the VA is poorly understood. We examined the association between race and receipt of National Comprehensive Cancer Network guideline–concordant CRC care.

### Patients and Methods

This was an observational, retrospective medical record abstraction of patients with CRC treated in the VA. Two thousand twenty-two patients (white, n = 1,712; African American, n = 310) diagnosed with incident CRC between October 1, 2003, and March 31, 2006, from 128 VA medical centers, were included. We used multivariable logistic regression to examine associations between race and receipt of guideline-concordant care (computed tomography scan, preoperative carcinoembryonic antigen, clear surgical margins, medical oncology referral for stages II and III, fluorouracil-based adjuvant chemotherapy for stage III, and surveillance colonoscopy for stages I to III). Explanatory variables included demographic and disease characteristics.

#### Results

There were no significant racial differences for receipt of guideline-concordant CRC care. Older age at diagnosis was associated with reduced odds of medical oncology referral and surveillance colonoscopy. Presence of cardiovascular comorbid conditions was associated with reduced odds of medical oncology referral (odds ratio, 0.65; 95% Cl, 0.50 to 0.89).

#### Conclusion

In these data, we observed no evidence of racial disparities in CRC care quality. Future studies could examine causal pathways for the VA's equal, quality care and ways to translate the VA's success into other hospital systems.

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# INTRODUCTION

The Veterans Affairs (VA) health care system is the largest provider of integrated cancer care in the United States, treating approximately 3% of newly diagnosed patients with cancer nationwide.<sup>1</sup> Among VA patients, colorectal cancer (CRC) is a common disease.<sup>1</sup> In fact, CRC is the third most commonly diagnosed cancer and third most common cause of cancer-related death nationwide.<sup>2</sup> In nonfederal US health care systems, racial differences in CRC diagnosis, treatment, and mortality have been documented.<sup>3-13</sup> For example, fewer African Americans receive adjuvant chemotherapy for CRC compared with whites.5,7,14 Compared with white patients, cancer surveillance is lower and cancerrelated mortality is higher among African American patients.<sup>5,9,10</sup> Unequal access to health care services

has been attributed as a contributing factor for racial disparities in care.<sup>3,15,16</sup> The VA health care system provides a good context in which to study racial disparities because of standard VA eligibility criteria and narrow distribution of family income among VA patients, making access issues among individuals of different races narrower than for non-VA systems.<sup>17</sup> Although racial health care disparities have been noted for some conditions, the degree of racial disparities identified in the quality of VA health care is often less than what is found in other health care systems.<sup>18,19</sup>

There is paucity of information regarding racial disparities in VA CRC care quality for patients of diverse race. Previous studies suggest that racial differences in CRC treatment may be diminished in the VA.<sup>16,20,21</sup> However, these studies were based on a limited number of quality measures that can

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be evaluated based solely on administrative data. We extend previous research by including additional data sources (ie, a comprehensive review of electronic health record data, supplemented with administrative data) to examine racial differences for receipt of guidelineconcordant CRC care.

# **PATIENTS AND METHODS**

#### **Data Sources**

Data were from the External Peer Review Program (EPRP), the national program for tracking quality of VA health care.<sup>22</sup> Between July and August 2007, medical record abstraction was conducted under the guidance of the VA Office of Quality and Performance to assess CRC care quality. Abstractors accessed the electronic medical record (EMR) remotely, collecting data on disease characteristics and health care delivery provided to individuals across the VA nationwide. We supplemented EPRP with clinical comorbidity and demographic information from the VA Central Cancer Registry (VACCR) and administrative data. The institutional review boards at the Durham VA Medical Center and at the University of North Carolina at Chapel Hill approved this project.

#### Patient Sample

The sample has previously been described in detail.<sup>23</sup> Briefly, patients were identified for EPRP inclusion based on a search algorithm defining a representative sample of VA patients diagnosed with CRC between October 1, 2003, and March 31, 2006, using administrative diagnosis, procedure, and encounter data.<sup>23,24</sup> Eligible patients had an International Classification of Diseases code for colon and/or rectal cancer within 3 months of the study diagnosis time period.<sup>23,25</sup> Eligible patients must have had a clinic visit, surgical procedure, or pathology report in the VA that corresponded with a specific visit or receipt of medical services within the aforementioned time frame. To be in the final analytic data set, patients also must have had nonmetastatic CRC (stages I to III), had an incident occurrence (first diagnosis of CRC occurred during the study time period), and received definitive CRC surgical resection. Because their recommended patterns of health care and life expectancy are different than patients with earlier stage disease, those with metastatic disease (stage IV) were excluded. Furthermore, to be included in this analysis, patients must have successfully linked with the VA administrative data sources. In other words, patients must have had matching records in both the EPRP quality tracking data source as well as the VA administrative data. The administrative data are generated when a patient interacts with the VA health care system, either in an inpatient or outpatient setting, to receive health care. Because of the small number of non-African American minorities and women, we restricted the study to white and African American male patients (Fig 1).

#### **Dependent Variables**

We used six distinct CRC quality indicators based on 2003 National Comprehensive Cancer Network guidelines<sup>26,27</sup> that have scientific evidence and/or National Comprehensive Cancer Network panel consensus.<sup>23,26,27</sup>

Included in EPRP (N = 2,896)	Excluded Noninvasive/stage 0	(n = 874) (n = 119)
	Missing comorbidity information	(n = 285) (n = 8)
	Missing age at diagnosis Missing marital status Missing race	(n = 11) (n = 35) (n = 314)
Available for analysis	Other minority race Women	(n = 59) (n = 43)
(n = 2,022)		

Fig 1. Colorectal cancer cohort assembly. EPRP, External Peer Review Program.

Each indicator applied to a subset of patients as determined by stage and other factors. The specific quality indicators, by stage, were as follows. For stages II and III CRC, the quality indicators were preoperative computed tomography (CT) scan of the abdomen and pelvis before definitive surgical resection; preoperative carcinoembryonic antigen determination before definitive surgical resection; documented radial margins free of tumor at the time of definitive surgical resection; and referral to a medical oncologist. Because our intent was to evaluate equity in access to quality care, patients with documentation of a refusal (eg, refused CT scan) in the EMR were included in the quality indicator as having received guideline-concordant care. For stage III CRC, the quality indicator was receipt of adjuvant fluorouracil- (FU) or capecitabine-based chemotherapy administered after definitive surgical resection. If the EMR contained a documented reason why FU was not administered, that was included in the quality indicator calculation as having received guidelineconcordant care. For patients with stage I to III CRC who did not have documentation of an obstructing preoperative lesion, the quality indicator was receipt of surveillance colonoscopy within 7 to 18 months after definitive surgical resection. Consistent with previous analyses,<sup>23</sup> 7 months was used as a minimum because colonoscopies performed earlier might not be intended for surveillance, and 18 months was chosen because surveillance colonoscopies may not occur exactly within 1 year. To be included in the surveillance colonoscopy measure, patients must have survived at least 1 year after surgical resection.

Table 1. Key Variables						
Variable	No. of Patients/Total No.	%				
Dependent variables						
CT scan	1,022/1,410	72.48				
Preoperative CEA	1,175/1,410	83.33				
Clear surgical margins	1,155/1,393	82.91				
Referral to a medical oncologist	1,103/1,410	78.23				
Adjuvant FU chemotherapy	487/653	74.58				
Surveillance colonoscopy	869/2,006	43.32				
Independent variable						
White race	1,712/2,022	84.67				
Other control variables						
Age at diagnosis, years						
< 55	180/2,022	8.90				
55-64	615/2,022	30.42				
65-74	576/2,022	28.49				
75+	651/2,022	32.20				
Married	1,045/2,022	51.68				
Region						
South	760/2,022	37.59				
North	386/2,022	19.09				
Central	451/2,022	22.30				
West	425/2,022	21.02				
Stage at diagnosis						
I	612/2,022	30.27				
II	757/2,022	37.44				
III	653/2,022	32.29				
Individual comorbid conditions						
Liver disease	11/2,022	0.54				
Rheumatoid disease or AIDS	23/2,022	1.14				
Renal disease	53/2,022	2.62				
Dementia or paralysis	5/2,022	0.25				
CHF, acute MI, CVD, or						
COPD	485/2,022	23.99				
Diabetes	541/2,022	26.76				

Abbreviations: CEA, carcinoembryonic antigen; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; CT, computed tomography; CVD, cardiovascular disease; FU, fluorouracil; MI, myocardial infarction.

#### Independent Variables

The primary independent variable of interest was race. We used a hierarchy of sources to determine the most accurate race measure. Because data were obtained through EMR review by trained cancer registrars, the VACCR was considered the most valid source. If race was not reported in the VACCR, then race was extracted from the inpatient medical record, followed by outpatient medical record information.

Other covariates included marital status (married or not), age at diagnosis (< 55, 55 to 64, 65 to 74, or  $\geq$  75 years), geographic region (west, south, east, or central), comorbid conditions, and, when applicable, stage of disease (I, II, or III). The included comorbid conditions were based on the National Cancer Institute Combined Comorbidity Index, which has been validated in patients with CRC.28 We identified diagnoses for comorbid conditions with International Classification of Diseases codes from medical inpatient and outpatient administrative data files.<sup>25</sup> To be included, comorbid conditions must have been diagnosed within the year before the CRC diagnosis, excluding those comorbidities occurring in the 30 days leading up to diagnosis. This is because the 30 days before a cancer diagnosis often involve multiple interactions with the health care system, and patients may be diagnosed, sometimes erroneously, with comorbidities that are actually cancer symptoms or sequelae. To ensure that analyses had adequate statistical power to address the study question, we aggregated conditions based on consultation with a medical oncologist and statistical examination to ensure no valuable information was lost (eg, collapsing a positively correlated condition with a negatively correlated condition).29 Individual comorbid conditions included the following: liver disease; rheumatoid disease/AIDS; renal disease; dementia/paralysis; congestive heart failure, acute myocardial infarction, cardiovascular disease, or chronic obstructive pulmonary disease; and diabetes. This approach enabled examination of the effect of specific conditions on receipt of guidelineconcordant care, an advantage over an aggregate comorbidity score.

#### Data Analysis

Multivariable logistic regression was used to determine the association between race and receipt of guideline-concordant CRC care. Pearson's  $\chi^2$  tests were used to determine whether there were significant differences between groups for background demographic and clinical characteristics. Because this analysis examines multiple comparisons (eg, race, age at diagnosis), we used the Bonferroni adjustment to control for family-wise error. Therefore, associations between independent variables and quality indicators were considered statistically significant if P < .01. Stata 11 (StataCorp LP, College Station, TX) and SAS version 9.2 (SAS Institute, Cary, NC) were used for data management and analyses.

# RESULTS

The final sample consisted of 2,022 men with incident CRC (Fig 1). The mean age at diagnosis was 68 years (range, 34 to 94 years). Reflecting the overall VA patient population, the sample was predominately white (85%) and married (52%) and lived in the south (38%). Stage was approximately evenly distributed. The most commonly diagnosed comorbid conditions were diabetes (27%) and cardiovascular-related diseases (24%; Table 1).

There were no significant racial differences in receipt of quality CRC care in the VA (Tables 2 and 3). In these data, race was not associated with receipt of guideline-concordant care for the examined quality indicators.

Compared with patients age 75 years or older at diagnosis, patients age 55 to 64 years at diagnosis had marginally greater odds of

Table 2. Multivariable Logistic Regression Results for Measures Involving Patients With Stage II or III CRC												
	Preoperative CT Scan (n = 1,410)		Preoperative CEA $(n = 1,410)$			Clear Surgical Margins $(n = 1,393)$			Medical Oncologist Referral $(n = 1,410)$			
Variable	OR	95% CI	Ρ	OR	95% CI	Ρ	OR	95% CI	Ρ	OR	95% CI	Ρ
Demographic												
White	1.22	0.88 to 1.70	.23	1.17	0.80 to 1.72	.41	0.71	0.43 to 1.19	.19	1.46	1.00 to 2.13	.05
Married	0.82	0.64 to 1.04	.11	1.13	0.84 to 1.50	.42	1.02	0.73 to 1.44	.90	0.85	0.64 to 1.11	.23
Age at diagnosis, years												
< 55	1.03	0.67 to 1.58	.88	1.04	0.62 to 1.80	.87	0.70	0.39 to 1.25	.23	2.45	1.42 to 4.23	< .01*
55-64	1.51	1.11 to 2.05	.01	1.33	0.91 to 1.93	.14	0.90	0.58 to 1.38	.62	1.89	1.34 to 2.65	< .01*
65-74	1.20	0.59 to 1.63	.24	0.87	0.61 to 1.24	.44	1.00	0.63 to 1.60	1.00	1.66	1.18 to 2.35	< .01*
75+ (referent)												
Region												
North	1.71	1.20 to 2.43	< .01*	1.32	0.88 to 1.98	.18	2.25	1.22 to 4.14	.01	3.22	1.96 to 5.30	< .01*
Central	1.91	1.37 to 2.67	< .01*	0.98	0.69 to 1.41	.93	0.93	0.60 to 1.43	.73	1.25	0.86 to 1.82	.23
West	1.21	0.88 to 1.66	.24	2.88	1.79 to 4.64	< .01*	0.85	0.55 to 1.31	.46	0.42	0.30 to 0.58	< .01*
South (referent)												
Comorbidity												
Liver disease	1.15	0.23 to 5.82	.86	0.37	0.08 to 1.61	.18	0.47	0.09 to 2.48	.38	0.78	0.14 to 4.34	.78
Rheumatoid disease or AIDS	0.99	0.34 to 2.91	.99	0.63	0.20 to 1.99	.43	_†			1.53	0.42 to 5.59	.52
Renal disease	0.60	0.30 to 1.24	.17	3.43	0.80 to 14.65	.10	1.80	0.41 to 7.85	.43	1.08	0.46 to 2.54	.85
Dementia or paralysis	0.67	0.11 to 4.20	.67	0.13	0.02 to 0.83	.03	0.18	0.03 to 1.15	.07	1.27	0.13 to 12.15	.84
CHF, acute MI, CVD, or COPD	0.82	0.63 to 1.09	.19	0.96	0.69 to 1.35	.82	0.86	0.58 to 1.29	.47	0.65	0.50 to 0.89	.01
Diabetes	0.93	0.71 to 1.23	.62	1.03	0.73 to 1.43	.88	1.20	0.80 to 1.80	.38	1.02	0.74 to 1.40	.90
Stage at diagnosis												
III	1.06	0.83 to 1.35	.63	1.04	0.78 to 1.38	.81	0.44	0.31 to 0.62	< .01*	2.70	2.03 to 3.60	< .01*
II (referent)												

Abbreviations: CEA, carcinoembryonic antigen; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; CRC, colorectal cancer; CT, computed tomography; CVD, cardiovascular disease; MI, myocardial infarction; OR, odds ratio.

\*Indicates statistical significance of P < .01.

†Because of perfect prediction between rheumatoid disease and AIDS, 17 observations were excluded.

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	Adjuva	nt FU Chemotherapy* (n =	= 653)	Sur	Surveillance Colonoscopy (n = $2006$ )			
Variable	OR	95% CI	Р	OR	95% CI	Р		
Demographic								
White	1.23	0.77 to 1.97	.40	1.32	1.01 to 1.73	.04		
Married	1.30	0.90 to 1.88	.16	1.00	0.82 to 1.22	1.00		
Age at diagnosis, years								
< 55	1.70	0.86 to 3.38	.13	1.12	0.77 to 1.62	.55		
55-64	1.03	0.65 to 1.62	.91	1.20	0.93 to 1.53	.16		
65-74	1.15	0.71 to 1.87	.57	1.47	1.14 to 1.89	<.01†		
75+ (referent)								
Region								
North	1.75	1.00 to 3.07	.05	1.28	0.96 to 1.71	.09		
Central	1.52	0.95 to 2.42	.08	0.84	0.65 to 1.08	.18		
West	1.30	0.79 to 2.14	.31	1.01	0.77 to 1.33	.93		
South (referent)								
Comorbidity								
Liver disease	0.28	0.04 to 2.11	.22	—‡				
Rheumatoid disease or AIDS	1.11	0.20 to 6.17	.90	1.00	0.40 to 2.46	.99		
Renal disease	0.68	0.22 to 2.14	.51	0.87	0.49 to 1.56	.65		
Dementia or paralysis	0.17	0.01 to 2.03	.16	—§				
CHF, acute MI, CVD, or COPD	0.82	0.53 to 1.25	.35	0.84	0.67 to 1.06	.14		
Diabetes	0.84	0.56 to 1.26	.40	0.86	0.69 to 1.08	.20		
Stage at diagnosis								
1				0.71	0.56 to 0.90	< .01†		
II (referent)								
III				0.97	0.77 to 1.24	.83		

Abbreviations: CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; FU, fluorouracil; MI, myocardial infarction; OR, odds ratio.

\*Stage is not included because only patients with stage III colorectal cancer were included per National Comprehensive Cancer Network guidelines. †Indicates statistical significance of *P* < .01.

#Because of issues of perfect prediction with liver disease, 11 observations were excluded.

\$Because of perfect prediction with dementia/paralysis, five observations were excluded.

having a preoperative CT scan (odds ratio [OR], 1.51; 95% CI, 1.11 to 2.05). Similarly, compared with patients age 75 years or older, younger patients had greater odds of a medical oncology referral (age < 55 years: OR, 2.45; 95% CI, 1.42 to 4.23; age 55 to 64 years: OR, 1.89; 95% CI, 1.34 to 2.65; age 65 to 74 years: OR, 1.66; 95% CI, 1.18 to 2.35; Table 2). Patients who were age 65 to 74 years old had greater odds of receiving surveillance colonoscopy than patients who were age 75 years or older (OR, 1.47; 95% CI, 1.14 to 1.89; Table 3).

For the majority of quality indicators, there was no association between individual comorbid conditions and receipt of guidelineconcordant care. Patients with cardiovascular-related comorbidities had lower odds of referral to a medical oncologist (OR, 0.65; 95% CI, 0.50 to 0.89) than patients without cardiovascular conditions (Table 2).

Limited associations between stage and receipt of guidelineconcordant care may reflect disease severity. Patients with stage III disease had lower odds of clear surgical margins (OR, 0.44; 95% CI, 0.31 to 0.62) than those with stage II disease (Table 2). Patients with stage III disease had increased odds of referral to medical oncology (OR, 2.70; 95% CI, 2.03 to 3.60). Odds of receiving surveillance colonoscopy were lower among patients with stage I disease (OR, 0.71; 95% CI, 0.56 to 0.90) compared with patients with stage II disease (Table 3).

Bivariate analyses indicated that patient refusals and/or physician documentation of a clinical contraindication for therapy were not

masking racial disparities in care. One white patient refused preoperative CT scan. The association between race and CT refusal was not statistically significant (P = .36). Regarding receipt of adjuvant FUbased chemotherapy for patients with stage III disease, 11 patients (one African American and 10 white patients) refused treatment and 32 patients (five African American and 27 white patients) had physician documentation of a clinical contraindication precluding receipt of chemotherapy. This represented 3% of the sample for the FU-based chemotherapy measure (43 of 1,410 patients), and the association with race was not significant (P = .37).

## DISCUSSION

Historically, the VA was criticized for its overall organization and management and providing poor care quality.<sup>30,31</sup> In 1995, the VA began a system-wide transformational redesign with emphasis on using information technology, reporting quality performance, and integrating medical services.<sup>32-35</sup> Recent reports suggest that the VA is now a leader in information technology and delivery of high-quality care.<sup>23,35-37</sup> The question that we address is whether this overall quality transformation has also reduced racial disparities in guideline-concordant CRC care.

We found a lack of evidence of racial disparities in receipt of guideline-concordant CRC care. This contrasts with prior studies in

nonfederal hospitals that observed racial differences in receipt of CRC care, for example, in receipt of screening colonoscopies.<sup>3,38,39</sup> However, there is a dearth of information about racial differences in surveillance colonoscopy receipt after surgery. We identified no racial differences for surveillance colonoscopy.

Colonoscopy is not without risks; differences in receipt of surveillance colonoscopy based on stage and age at diagnosis may be appropriate. There is evidence that intensive postsurgery surveillance can increase survival,<sup>40-42</sup> but a direct clinical benefit for surveillance colonoscopy alone has not been established. Despite this, clinical guidelines assert that surveillance colonoscopy is an important component of guideline-concordant CRC surveillance.<sup>26,27,43</sup>

Studies from the Surveillance, Epidemiology, and End Results– Medicare registry found differences in oncologist evaluation rates between white and African American patients, but the gap decreased substantially over time. Contingent on consulting with a medical oncologist, there were no racial differences in treatment receipt.<sup>44</sup> However, there are differences based on age at diagnosis. Clinical trials generally do not enroll elderly people; the clinical benefit of adjuvant chemotherapy on older people has not been tested extensively in a trial setting, and older patients often do not receive FU-based chemotherapy in the private health care setting.<sup>45</sup> Regarding race, there is evidence that the clinical benefit of FU may be lower for African American patients than for white patients.<sup>14,46</sup>

In our analysis, age and stage at diagnosis were associated with medical oncology referral. The difference in stage, where patients with stage III disease have greater odds of referral than patients with stage II disease, is likely clinically appropriate. Our study sample was diagnosed in 2003 to 2006. At the time these patients received treatment, chemotherapy for patients with stage II disease was controversial. This association may reflect clinicians' knowledge of clinical practice guidelines. However, differences in referral patterns based on stage, age, and cancer type require further examination. We found no association between race and medical oncology referral. Medical oncology referral typically precedes chemotherapy. In this VA population, we also found no association between race or age and FU-based chemotherapy receipt.

We found differences in receipt of care based on the presence of specific comorbid conditions—patients with cardiovascular conditions were less likely to be referred to a medical oncologist. This may be a result of contraindications for chemotherapy. Clinical appropriateness of referral was not addressed in our analysis.

There are several limitations to this study. First, we were unable to control for potentially confounding sociodemographic status, which may mediate associations between race and care quality. This potential omission bias is likely mitigated because VA patients receive care on a sliding fee scale based on ability to pay and by service-connected status.<sup>47</sup> Nearly one half of VA patients have family incomes of less than \$20,000.<sup>17</sup> Second, we did not have information regarding Hispanic ethnicity. Third, data were abstracted from the VA EMR and administrative data; we lacked data on care received outside of the VA health care system or care not documented in the available data sources. We could not address possible reasons for the VA's lack of disparities. The VA strives to be an equalaccess system, which may be one reason for the success in this area. Other reports have hypothesized that this is a potential reason for reduced levels of health care disparities in the VA.<sup>21,48,49</sup> Generalizability of findings has been questioned in studies of VA populations; however, it is notable that our sample population is of similar age (eg, 68 years in our sample, 69 years nationally) and stage distribution to that of the US population of male patients with colon cancer. Additionally, we examined the data for specific situations, such as patients' refusal of care or physicians' documentation of clinical contraindications precluding care, that might impact our findings and mask potential racial disparities. Although these data suggest that this is not an issue, it remains possible that there may be unmeasured racial discrimination.<sup>50,51</sup>

In summary, we observed no evidence of racial disparities in receipt of quality CRC care provided by the VA health care system. As other clinical programs within the VA seek to strengthen their approach to quality management, they may evaluate the lessons that can be learned from successful CRC programs and specific changes such as electronic reminder systems, multidisciplinary collaborative improvement groups, and electronic tools for quality monitoring. Given that the VA treats 3% of newly diagnosed patients with cancer annually,<sup>1</sup> it is plausible that the benefit of widespread quality improvement within the VA would influence the landscape of cancer care and outcomes nationally. Other health care systems could also consider aspects of VA care that could be translatable to reduce racial disparities in cancer care. Future studies with larger sample sizes are needed to examine causal pathways for the VA's equal, quality care and ways to translate the VA's success into other hospital systems.

## AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Although all authors completed the disclosure declaration, the following author(s) and/or an author's immediate family member(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a "U" are those for which no compensation was received; those relationships marked with a "C" were compensated. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

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# **AUTHOR CONTRIBUTIONS**

Conception and design: All authors Financial support: Leah L. Zullig Administrative support: Leah L. Zullig, William R. Carpenter Provision of study materials or patients: Dawn Provenzale, George L. Jackson Collection and assembly of data: Leah L. Zullig, Dawn Provenzale, George L. Jackson Data analysis and interpretation: All authors Manuscript writing: All authors

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