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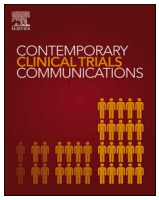

Access to urologists for participation in research: An analysis of NCI's Community Oncology Research Program landscape survey

Shellie D. Ellis [a,*], Riha Vaidya [b], Joseph M. Unger [b], Kelly Stratton [c], Jessie Gills [d], Peter Van Veldhuizen [e], Eileen Mederos [d], Emily V. Dressler [f], Matthew F. Hudson [g], Charles Kamen [e], Heather B. Neuman [h], Anne E. Kazak [i], Ruth C. Carlos [j], Kathryn E. Weaver [k]

[a] University of Kansas Cancer Center, University of Kansas Medical Center, USA
[b] SWOG Statistics and Data Management Center, Fred Hutchinson Cancer Research Center, Seattle, USA
[c] Stephenson Cancer Center, University of Oklahoma Health Sciences Center, USA
[d] Gulf South NCORP, Louisiana State University Health Sciences Center, USA
[e] University of Rochester Medical Center, USA
[f] Wake Forest School of Medicine, Department of Biostatistics and Data Science, Winston-Salem, NC, USA
[g] Prisma Health, Greenville, SC, USA
[h] University of Wisconsin School of Medicine and Public Health, Madison, USA
[i] Nemours Children's Health, USA
[j] University of Michigan School of Medicine, Ann Arbor, USA
[k] Wake Forest Baptist Comprehensive Cancer Center, Wake Forest School of Medicine, Winston-Salem, NC, USA

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ABSTRACT

Purpose: Urological cancer clinical trials face accrual challenges, which may stem from structural barriers within cancer programs. We sought to describe the extent to which urology cancer care providers are available within community cancer research programs and explore the role of oncology practice group ownership in their access to urology practices to participate in research.

Materials and methods: We conducted secondary analysis of organizational survey data collected in 2017 among National Cancer Institute Community Oncology Research Program practice groups. We used logistic regression to assess the association of self-reported access to urologists to participate in research and oncology practice group ownership type: independent, payor-provider, health-system, or public ownership.

Results: Of the 209 community oncology practice groups in the analysis sample, 133 (63.6%) had access to urologists for research participation. Ownership was not statistically significantly associated with access to urology practices after controlling for other covariates ($p = 0.4$). Instead, having a hospital outpatient clinic ($p = 0.008$) and identifying as a safety-net hospital ($p = 0.035$) were both positively significantly associated with access to urologists to participate in research.

Conclusions: Two-thirds of community cancer research groups have access to urology. Oncology ownership status was not associated with access to urologists for research. Research groups may need support to increase their capacity to engage non-oncology cancer care providers in research.

1. Introduction

Approximately 1 in 6 urological cancer trials fail due to low accrual and rates may be higher for late phase trials. [1,2] Failed clinical trials are costly (median: $19 million/trial, maximum: $345 million/trial [3]) and can delay or compromise access to beneficial therapies. [4] Sponsors, institutions overseeing trials, and patients not only accrue financial costs, but also opportunity costs: >48,000 participants are enrolled annually in trials unable to answer the primary research question. [5–7] Trial suspensions prohibit conclusions regarding clinical benefit and consume effort participants could otherwise expend enhancing quantity or quality of life. [6] Unenrolled patients also incur costs as untimely completion delays beneficial therapies. [8,9] Urological trials are particularly vulnerable to poor accrual and accrue participants more

* Corresponding author. University of Kansas School of Medicine, 3901 Rainbow Blvd., MS 3044 Kansas City, KS, 66160, USA.
E-mail address: Sellis4@kumc.edu (S.D. Ellis).

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slowly than other cancer trials. [2,10–15]

Trialists often attribute suboptimal accrual to patient refusal and limited physician engagement in the trial process; [11,16–20] however, more recent systems-level research proposes an alternative explanation. Noting that >50% of trial-eligible patients agree to participate in trials when asked, [21] this research suggests organizational factors in cancer care delivery, not patient refusal, more directly influence low patient participation. [9,22] More than half of cancer patients lack access to disease-relevant trials. [23] Care delivery barriers may particularly predict low enrollment to urological cancer trials: 63–81% of urological cancer patients receive treatment in community settings with no or minor academic affiliation. [24,25] In contrast, academic medical centers and teaching hospitals conduct the majority of clinical trials. [26] Although urology-specific networks bring urological cancer research directly to urology practices, [27] the US Oncology Network and the NCI Community Oncology Research Program (NCORP) also provide access to many urologic cancer trials. [27–29] NCORP contributes approximately one-third of all accruals to NCI-sponsored trials. These networks primarily target medical oncologists, yet medical oncologists treat relatively few urological cancer patients. [11] Urological cancer is routinely diagnosed and treated by urologists. Compared to other specialties, multi-disciplinary care is less common in urology, particularly in community settings. [30,31] Further, unlike other surgical oncologists, urologists routinely provide both surgical and medical treatments to patients and increasingly do so for cancer. [32–34] Consequently, urological cancer patients often receive care exclusively in urology practices (excluding referral to radiation oncology), bypassing interaction with medical oncologists. [35] Despite this, little empirical data describes the degree to which underrepresentation of urologists in oncology networks limits urological trial accrual. [36]

Likewise, little is known regarding factors that contribute to an organization's ability to include urology practices in research, but oncology practice size and ownership may be among them. [36,37] Larger practice size may allow an organization to cost share research staff and infrastructure, thereby reducing cost burden to other specialty providers. Hospital or payor ownership, compared to private ownership, has been associated with lower costs, higher quality, and greater access to care, [38,39] which may extend to research participation. Community oncology practices noted weak leverage over urology practices as a particular barrier to some types of accrual [40] and private practice ownership among urology groups is high (58.6% of urologists practices in a private practice or hospital in 2020). [41]

We sought to describe research-amenable hospital organizations' access to urologists for research participation in a large cancer research network and explore the association between oncology practice ownership and access to urologists to participate in research.

2. Materials and methods

We conducted a secondary analysis of organizational survey data. The survey protocol was reviewed by the Institutional Review Board at Wake Forest Health Sciences and was deemed exempt from review.

Setting. NCORP comprises nearly 1000 oncology practices, hospitals, and other cancer care providers in the U.S., organized into 46 NCORPs. The National Cancer Institute (NCI) has funded the network since 1982, originally to.support participation in NCI-sponsored cancer clinical trials, and more recently to support cancer prevention research, and cancer care delivery research (CCDR). [28] NCORP practices are distributed across the United States [40] and may include up to half of U. S. oncology practices. [40,42]

Data. The NCI Community Oncology Research Program (NCORP) Landscape Capacity Assessment collected institutional capacity germane to CCDR. The NCI's Division of Cancer Prevention convened a multidisciplinary committee to design the survey and authorized its collection and analysis by the Wake Forest Research Base in 2015 and 2017. The current study is drawn from the 2017 response. The web-based survey asked NCORP administrators and research staff to describe structural characteristics of the group of hospitals, health systems and/or clinical practices associated with each NCORP grantee. Survey data are available at the practice group level, which serves as the unit of analysis in this study. Each NCORP component, usually a practice or a hospital, is identified by a Cancer Therapy Evaluation Program (CTEP) institution code, used by institutions when participating in NCI-sponsored clinical research. Practices are further categorized at the *practice group* level, uniform with respect to providers, patient population, and services. [36] Respondents self-identified their practice groups within each NCORP by selecting the practices that shared providers, patients, and infrastructure and generally had a common electronic health record. [43] Most practice groups represent a single practice or hospital, but some represent a group of practices. We included all practice groups serving adult cancer patients.

Measures. The outcome of the analysis is self-reported access to urologists to participate in CCDR within the practice groups. We defined access to urologists from a specific item on the Landscape Assessment: "Consider the relationship of your component/subcomponent to the clinic/practice where patients are seen for the following services (for majority of providers). Which of the following are available to participate in NCORP CCDR studies? Urology." Practice groups could select one of three response options: yes, no, and 'don't know.' We combined the no and 'don't know' options to capture lack of access. For descriptive purposes, a separate item in the survey asked how many providers of each specialty, including urology, were available at the practice group's site specifically. We use both the absolute number (a count variable) to describe urologist capacity and that item's non-zero response (a binary variable) to denote urologists located at the practice group site.

The primary independent variable of interest is NCORP practice group *ownership status.* We collapsed survey responses indicating ownership status to create four categories:1) *Independently owned*, 2) *Payor-provider owned*, meaning the owner served as payor and provider, and included HMO/Payor-owned groups, groups part of military hospitals or the Veterans Administration, and groups owned by a health system which also had a health plan; 3) *Health-system or University owned*; and 4) *Publicly owned,* referring to ownership by state or local governments.

Measures of self-reported health system, practice group, and NCORP characteristics also were examined to control for known clinical trial accrual mediators (e.g., organization size, measured as total number of providers of all cancer-related specialties, a proxy for physician supply; and multi-specialty group status, an indicator for the likelihood of multidisciplinary cancer care, and measured as the presence of at least one other cancer specialist (surgical, radiation, gynecological, or pediatric oncologist, or urologist). Health system covariates included whether the practice group had a hospital outpatient clinic (yes/no); was designated a critical access hospital (yes/no); or was designated a safety-net hospital (yes/no). Outpatient clinics provide ambulatory care but are financially and clinically integrated with a hospital under Centers for Medicare and Medicaid Services' (CMS) billing rules. Critical access hospitals are designated by CMS and provide special funding to maintain emergency services in rural areas without other hospital services. [44] Fewer than half of critical access hospitals provide urological services. [45] Although not a federal designation, safety net hospitals are typically identified as public hospitals or private hospitals with a mission to provide care to vulnerable populations, and are found to, and sometimes defined as, having disproportionate Medicaid caseload. [46,47]

Other covariates included Minority and Underserved NCORP (MU-NCORP) designation, and the practice group's geographic region, per the US Census Bureau, [48] to control for urological demand. We included Puerto Rico as a separate region because urological supply for the territory is not documented in publicly available datasets.

2.1. Statistical analyses

We characterized the sample using descriptive statistics (proportions, medians, and interquartile ranges). We examined associations between the outcome and each practice group characteristic using chi-squared tests for categorical variables and non-parametric k-sample equality of medians test for median comparisons. We used multivariable logistic regression to assess independent associations of practice group with the outcome. We tested the significance of categorical constructs in the multivariable model using Wald chi-squared tests. We also computed average-adjusted predicted probabilities for significant, categorical predictors to standardize the estimates across the practices groups and increase understanding of their impact. All analyses were conducted in Stata. [49] All available factors theorized to contribute to the urology participation were included in the model.

Practice groups with missing outcome data were excluded. We supplemented missing data for safety-net hospitals and critical access hospitals using publicly available records; [50,51] practice groups were classified as not belonging to these categories if they were not listed in the source data. We supplemented missing information on being a multi-specialty practice group based on the provider roster on the websites of the practice groups. We imputed missing data for total number of providers using the mean number of providers in our analytic sample. We checked assumptions *post hoc* by replacing missing values with the most frequently occurring value in the data and compared results. [52] To further assess sensitivity of our findings to 1) imputation, 2) missing data on urologist supply; and 3) assumptions about the influence of large practice groups, we compared results of: 1) imputed covariates assumed to be missing at random to complete case analysis; 2) full results adjusted by region to results excluding Puerto Rico; and 3) full results to results including fewer than 6 and fewer than 4 practice groups.

3. Results

The survey provided data for 504 of 943 CTEP institutions (53% representation rate), self-grouped into 227 practice groups by survey respondents. Of the 227 practice groups, one had missing data on the primary outcome. Seventeen practice groups were primarily pediatric facilities. Thus, 209 practice groups were included in the analysis.

Of the 209 practice groups, 97 (47.5%) reported having urologists at their site; 133 (63.6%) reported having a urology practice available for care delivery research participation(Table 1). Among 204 practice groups who provided the absolute number of urologists, the number ranged from 0 to 128. The median number of urologists was 0 with an interquartile range of 3 across the network.

The most common type of NCORP practice group ownership was a payor-provider system (38.8%; n = 81), while 14 practice groups (6.7%) reported public ownership (Table 1). Median organization size was 12 physicians (interquartile range = 23) of any oncology-related specialty; 183 practice groups (88.4%) reported having providers from multiple specialties. Most practice groups had a hospital-based outpatient clinic (81.3%; n = 170), 21.4% had critical access status, and 23.2% identified as safety-net hospitals (n = 48). Sixteen percent of practice groups were part of a MU-NCORP (n = 34). Over half were located in the Midwest (n = 111) region. Six practice groups (2.9%) were from Puerto Rico.

In bivariate analyses (Table 2), group ownership was statistically significantly associated with access to urologists for research (p = 0.016). In addition, oncology practice groups were more likely to have access to urologists if the practice groups had a hospital outpatient clinic (p < 0.001,. identified as a safety-net hospital (p = 0.04), or were a multi-specialty practice group (p = 0.002).

After controlling for other covariates, group ownership was not statistically significantly associated with access to urologists (Table 3) A Wald test to identify the joint significance of the construct was not significant (p = 0.4). Instead, practice groups with a hospital outpatient clinic were three times more likely (OR 3.09, CI 1.28–7.47) and those identifying as a safety-net hospital were two and half times more likely (OR 2.41, CI 1.04–5.59) to have access to urologists for participation in research. The average predicted probability of having access to urologists was 24% points higher among practice groups with hospital outpatient clinics. The average predicted probability of having access to urologists was 16% points higher among oncology practice groups identifying as safety net hospitals.

In the sensitivity analyses, interpretation of findings was relatively unchanged when we: used complete case analysis rather than imputed values for missing data; excluded the measure of urologist supply in a subsample of the data; or assessed the influence of large practice groups in multivariable analyses excluding practice groups with fewer than 6 and fewer than 4 practice groups; thus we considered the model robust to these specifications.

Table 1
Sample characteristics for 209 non-pediatric NCI community oncology research program (NCORP) practice groups participating in 2017 NCORP landscape survey.

Covariate	N (Percent) or Median (IQR)
Urologists available for research	
Yes	133 (63.6%)
No	76 (36.4%)
Missing	0
Urologists on site	
Yes	97 (47.5%)
No	107 (52.5%)
Missing	5
Number of urologists overall	0 (0–3)
Missing	5
Group ownership	
Independently owned	75 (35.9%)
Payer-provider owned	81 (38.8%)
Health-system Owned	39 (18.6%)
Publicly owned	14 (6.7%)
Missing	0
Organization size[a]	12 (7–30)
Missing	2
Multi-specialty practice group	
Yes	183 (88.4%)
No	24 (11.6%)
Missing	2
Has hospital-based outpatient clinic	
Yes	170 (81.3%)
No	39 (18.7%)
Missing	0
Affiliated with critical access hospital	
Yes	44 (21.4%)
No	162 (78.6%)
Missing	3
Identifies as safety net hospital	
Yes	48 (23.2%)
No	159 (76.8%)
Missing	2
Region	
Northeast	13 (6.2%)
Midwest	111 (53.1%)
South	36 (17.2%)
West	43 (20.8%)
Puerto Rico	6 (2.9%)
Minority/Underserved NCORP site	
Yes	34 (16.3%)
No	175 (83.7%)
Missing	0

IQR=Interquartile Range.
[a] Number of all oncology specialty providers.

4. Discussion

We examined the structural capacity of a well-established community oncology research network to engage urologists in cancer research. Practice group respondents were distributed across the U.S. and

Table 2
Bivariate analysis of access to urologists for cancer care delivery research participation by levels of independent variables for 209 non-pediatric NCI community oncology research program (NCORP) practice groups.

	Access to Urologists		
	Yes (N=133)	**No (N=76)**	**p-value**[a]
	N (Percent) or Median (IQR)		
Group ownership			0.016
Independently owned	39 (52%)	36 (48%)	
Payer-provider owned	55 (67.9%)	26 (32.1%)	
Health-system Owned	26 (66.7%)	13 (33.3%)	
Publicly owned	13 (92.9%)	1 (7.1%)	
Organization Size[b]	15 (25)	10 (16.5)	0.02
Multi-specialty practice group			0.001
Yes	123 (67.2%)	60 (32.8%)	
No	8 (33.3%)	16 (66.7%)	
Has hospital-based outpatient clinic			<0.001
Yes	119 (70%)	51 (30%)	
No	14 (35.9%)	25 (64.1%)	
Affiliated with critical access hospital			0.945
Yes	28 (63.6%)	16 (36.4%)	
No	104 (64.2%)	58 (35.8%)	
Identifies as safety net hospital			0.014
Yes	38 (79.2%)	10 (20.8%)	
No	95 (59.7%)	64 (40.3%)	
Region			0.655
Northeast	7 (53.8%)	6 (46.2%)	
Midwest	75 (67.6%)	36 (32.4%)	
South	23 (63.9%)	13 (36.1%)	
West	24 (55.8%)	19 (44.2%)	
Puerto Rico	4 (66.7%)	2 (33.3%)	
Minority/Underserved NCORP site			0.524
Yes	20 (58.8%)	14 (41.2%)	
No	113 (64.6%)	62 (35.4%)	

[a] P-value calculated from bivariate Chi-squared test for categorical variables or non-parametric k-sample equality of medians test for median comparisons.
[b] Number of all oncology specialty providers.

represented NCORP types in similar proportions to practices within the NCORP as a whole (e.g., 17% of NCORP practices are MU-Underserved and the majority are concentrated in the Midwest, [40] similar to our respondents.) Among this sample, 64% had access to urologists for research participation within their network. An earlier study of the potential capacity of NCORP practice groups to conduct research with non-oncologists demonstrated that 85% of oncology practice groups had affiliated radiologists or radiology practices available for research (69% participate in research) and 79% had access to primary care for research (31% participated in research). [36] Although NCORP may have more studies amenable to multi-disciplinary specialty cancer care research than primary care research, oncology practice groups have less access to urologists than other provider types. More than a third of NCORP practice groups do not have access to urologists. Moreover, urologists in the network are concentrated in a small number of practices, suggesting only a small proportion of practice groups could open trials requiring urologists. These findings suggest that low accrual to federally funded urologic oncology trials may be related to the limited access to urology groups in community cancer research networks.

We hypothesized oncology practice group ownership would be associated with access to urologists for research participation. Ownership was significantly associated with urology practice access in univariate analysis, but it was not significantly associated with urology practice access after controlling for other practice, organizational and geographic characteristics. Our findings differ from other analyses assessing radiologists and primary care providers. [36] Differences may result from underlying differences in the organization of oncology and urology practices. Oncology practices are increasingly incorporated into hospital-owned practices. [38,39] However, private practice remains the dominant ownership type in urology, [41] despite declines in the number of urologists in private practice over the last decade. Moreover, the urology workforce is distributed differently than other specialties, with greater rural representation than oncologists and more solo providers than other specialities. [53,54] Alternatively, differences may reflect differences in data and analytic choices The radiology analysis was completed on data from a different year, controlled for a different mix of covariates, and defined ownership differently, grouping public ownership with integrated delivery systems and university-owned practices. Our choice to separate the effect of public ownership increased the effect size of public ownership while decreasing the effect size of payor-owned practices. The wide confidence interval may also suggest that the effect is driven by an outlier in the small group of publicly owned practice groups. Statistical power and observational study design limitations (e.g., differential distribution of unmeasured confounders) could also potentially restrict our ability to detect relationships. The odds of publicly owned group practices having urology practice availability compared to privately owned group practices was

Table 3
Multivariable Logistic Regression Modeling Results of Access to Urologists for Cancer Care Delivery Research Participation among non-Pediatric NCORP Practice Groups (N = 209).

	Odds Ratio (95% CI)	*P-value*[b]	*P-value*[a]	*Average Predicted Probability*		
	(n = 209)			Yes	No	Difference
NCORP Practice Group Ownership			0.40			
Independently owned	Reference					
Payer-provider owned	1.24 (0.56–2.79)	0.60				
Health-system Owned (not including health plan)	1.29 (0.52–3.19)	0.60				
Publicly owned	6.33 (0.74–54.17)	0.09				
Size[c] **(1 oncology provider)**	1.01 (0.99–1.02)	0.28				
Multi-specialty practice group	2.01 (0.71–5.68)	0.19				
Has hospital-based outpatient clinic	**3.09 (1.28–7.47)**	**0.01**		0.68 (0.61–0.75)	0.44 (0.27–0.61)	0.24
Affiliated with critical access hospital	0.84 (0.39–1.81)	0.66				
Identifies as safety net hospital	**2.41 (1.04–5.59)**	**0.04**		0.76 (0.64–0.89)	0.60 (0.53–0.67)	0.16
Minority/Underserved NCORP site	0.48 (0.16–1.43)	0.19				
Region			0.69			
North-East	Reference					
Midwest	1.45 (0.4–5.18)	0.57				
South	1.76 (0.4–7.83)	0.46				
West	1.19 (0.3–4.72)	0.81				
Puerto Rico	5.36 (0.46–62.69)	0.18				

[a] Calculated with Wald Chi-squared test for Joint test of Significance.
[b] Based on pair-wise comparisons.
[c] Number of all oncology providers.

substantial (6.33) and marginally significant (p = 0.09). Thus, suboptimal power to detect differences may explain the study's failure to reject the null hypothesis.

Our results on access to urologists for research participation within a community-based research network differ in other ways from research on access to other types of providers. Oncology group size was not associated with access to urologists, contrary to other studies. [36,37] Practice size is associated with access to primary care providers and to radiologists' participation in research. [36]' For urologists, characteristics of the hospital connected to the practice group were associated with access to urologists: having an outpatient department on a hospital campus and self-identifying as a safety net hospital. The implications of these factors independently impacting access to urologists for research remain unclear but hospital rather than oncology program characteristics may be a better indicator of access to urologists.

Outpatient status was associated with access to both urologists and to radiologists for participation in research, but was not associated with access to primary care providers. [36]' Safety net status was associated with access to urologists, but was not associated with access to radiologist or primary care provider for research participation. Outpatient clinic designation indicates a higher level of financial and clinical integration, possibly confounding some types of ownership, but may also precipitate the need for specialists. Safety net clinics may provide a more comprehensive array of services as part of their core mission to serve all.

Regardless of the structural characteristics that may hinder access to urology practices, a large proportion of practice groups may need support to engage urology practices in research. Thirty-six percent of oncology practice groups had no access to urologists for research, but even among those reporting access, the majority were not co-located with the urologists, which could present additional barriers to research engagement. Research bases or investigators may need to support the time and resources required to build relationships and work across departments and institutions. Further, action may be overdue; 14 years ago, Swanson et al., suggested expansion of what was then the CCOP program to urologists, as urologists cited barriers to access rather than lack of interest in having their patients participate in clinical trials. [11] Some progress is evident, as implementation scientists have created promising models to increase urologists' referral to clinical trial eligibility screening. [35,54,55] Rather than asking community urologists to establish research programs within their practices, this research suggests it may be more effective to create referral channels for clinical trial eligibility screening at designated cancer programs. Further, organizations may need to include other surgical specialists, such as gastroenterologists, and general surgeons who provide much cancer care to rural patients. As the field increases its understanding of cancer care delivery, [53] opportunities to include other cancer care providers we may revealed. Future research may also need to better characterize the specialty needs trials require. Most research on trial characteristics associated with accrual failure focuses on trial size, sponsor type, and methodological characteristics, rather than implementation-related factors, such as personnel necessary for trial conduct. Such, innovative approaches are needed to increase cancer clinical trial accrual to achieve goals set forth in the nation's Cancer Moon Shot and to help community urologists adhere to national cancer guidelines calling for the treatment of cancer patients in the context of clinical trials when appropriate. More than 20% of the US cancer burden is urologic. [56] Increasing the reach of cancer clinical trials to all cancer providers by intentionally including them could increase the pool of potentially eligible cancer patients screened for trials.

4.1. Limitations

Our study was conducted within a single cancer research network; thus findings may not be generalizable to other research networks, particularly those focused on urological research. [27] Additionally, not all practice groups participated in the survey. Although respondents do not seemingly differ on select fundamental network characteristics, findings may not reflect the population of NCORP practice groups. The survey asked about a subset of clinical research, CCDR, which is a novel network undertaking sometimes requiring use of unfamiliar data collection processes and study design methods, and which some network participants may perceive as less germane to patient care than treatment trials. CCDR is shown to have lower uptake than clinical trials among NCORP practices. [40] Therefore, if respondents interpreted the item as differentiating access for CCDR versus treatment trials, our analysis may underestimate the access to urologists for participation in clinical trials. Finally, outcomes, practice group, and health system characteristics were self-reported. Ten percent of survey participants reported that they did not know whether they had access to urologists, opening the possibility of measurement error. Whether there is systematic bias in that error, affecting the results is unknown.

5. Conclusions

Sixty four percent of NCORP practice groups have access to urology practices for CCDR. Detailed documentation of the available specialties at each practice group in research networks may help investigators plan trials. Research groups may require directed support to increase their capacity to engage non-oncology cancer care providers.

Disclosures/competing interests

None.

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Abbreviation key

CCDR	Cancer Care Delivery Research
CMS	Centers for Medicare and Medicaid Services
CTEP	Cancer Therapy Evaluation Program
HMO	Health Maintenance Organization
MU-NCORP	Minority and Underserved NCORP
NCI	National Cancer Institute
NCORP	NCI Community Oncology Research Program

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