Unpacking Trial Offers and Low Accrual Rates: A Qualitative Analysis of Clinic Visits With Physicians and Patients Potentially Eligible for a Prostate Cancer Clinical Trial

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QUESTION ASKED: What are the circumstances under which patients potentially eligible for a prostate cancer therapeutic clinical trial at a major cancer center are actually offered the chance to participate by their oncologists?

SUMMARY ANSWER: Of the 62 video-recorded interactions with patients potentially eligible for a clinical trial, only 29% actually included an explicit trial offer, and another 12% included a pending offer. In many of the interactions in which a trial was not explicitly offered, the patient learned that his cancer had not progressed, which may explain the lack of a trial offer. However, nearly half of the interactions with patients whose cancer had not progressed did not receive an offer. Findings suggest that current rates of trial accrual, estimated to be approximately 8%, may be misleading, given that most patients are not eligible to participate.

WHAT WE DID: We conducted a qualitative directed content analysis of 62 video-recorded interactions with physicians (n = 13) and patients (n = 43) with intermediate- or high-risk prostate cancer. We observed and coded the interactions in 3 steps: (1) classification of all interactions as explicit offer, offer pending, trial discussed/not offered, or trial not discussed; (2) in interactions with no explicit offer, classification of whether the cancer had progressed; (3) in interactions classified as progression but no trial offered, identification of factors discussed that may explain the lack of an offer.

WHAT WE FOUND: Of the 62 video-recorded interactions observed and coded, 29% were classified

as including an explicit offer, 12% as including a pending offer, 18% as including a trial discussion but no offer, and 39% as having no trial discussion. Of the interactions with no offer, 57% included information suggesting that the cancer had not progressed. In 68% of the remaining interactions with patients whose cancer had progressed but did not receive an offer, reasons for the lack of offer were identified, but in 32%, no explanation was provided.

BIAS, CONFOUNDING FACTORS: This was a secondary analysis, using qualitative methods and a relatively small convenience sample of men with prostate cancer; findings cannot be generalized to other populations. Also, we examined video-recorded patient-oncologist interactions and thus could not consider factors that may have occurred outside of these clinical interactions.

REAL-LIFE IMPLICATIONS: Findings suggest that reports of low accrual rates may be misleading. Most consider accrual rates among all patients with cancer, but this study suggests that considering only patients with the potential to enroll in a cancer clinical trial as the denominator may provide a more accurate picture. This is a more clinically useful approach that may demonstrate that accrual rates are much higher than previously thought. A more accurate assessment of accrual rates would allow investigators to develop appropriately targeted interventions. These interventions could be focused on increasing accrual rates among eligible patients by improving communication about trials and on increasing the denominator, or the number of eligible patients.

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abstract

PURPOSE Cancer clinical trial accrual rates are low, and information about contributing factors is needed. We examined video-recorded clinical interactions to identify circumstances under which patients potentially eligible for a trial at a major cancer center were offered a trial.

METHODS We conducted a qualitative directed content analysis of 62 recorded interactions with physicians (n = 13) and patients with intermediate- or high-risk prostate cancer (n = 43). Patients were screened and potentially eligible for a trial. We observed and coded the interactions in 3 steps: (1) classification of all interactions as explicit offer, offer pending, trial discussed/not offered, or trial not discussed; (2) in interactions with no explicit offer, classification of whether the cancer had progressed; (3) in interactions classified as progression but no trial offered, identification of factors discussed that may explain the lack of an offer.

RESULTS Of the 62 interactions, 29% were classified as explicit offer, 12% as offer pending, 18% as trial discussed/not offered, and 39% as trial not discussed. Of those with no offer, 57% included information that the cancer had not progressed. In 68% of the remaining interactions with patients whose cancer had progressed but did not receive an offer, reasons for the lack of offer were identified, but in 32%, no explanation was provided.

CONCLUSION Even in optimal circumstances, few patients were offered a trial, often because their cancer had not progressed. Findings support professional recommendations to broaden trial inclusion criteria. Findings suggest accrual rates should reflect the proportion of eligible patients who enroll.

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INTRODUCTION

Accruing patients in therapeutic clinical trials is critical to testing the safety and efficacy of new cancer treatments,¹ but only approximately 8% of patients with cancer enroll.^{2,3} Most patients never have the opportunity to enroll in a clinical trial because of the small number of trials available, restrictive eligibility criteria, and/or lack of hospital infrastructure.²⁻⁷ Yet, underenrollment persists, even when patients are eligible for available trials. Some patients, although eligible, are not informed about a trial because their physician or medical facility lacks the interest, ability, or resources to participate in trials.⁸⁻¹⁰ Other patients decline participation because of concerns about costs, logistics, or the trustworthiness of medical institutions or experimental therapies.⁵ The problem of underenrollment is even greater among racial/ethnic minority populations, despite disproportionately higher rates of cancer incidence and mortality in these groups.¹¹⁻¹³

Most interventions to address barriers to trial enrollment are aimed at patient knowledge and attitudes,¹⁴⁻¹⁷ although it is unclear whether these are the greatest barriers, and thus the most effectively placed interventions. One way to identify unknown barriers is by examining clinical interactions with patients in optimal clinical trial circumstances—patients who, through screening, are found to match the eligibility criteria for an available clinical trial and are receiving care at a medical institution with a highly functional clinical trial infrastructure. A previous analysis of video-recorded interactions at 2 National Cancer Institute (NCI)-designated comprehensive cancer centers with a strong focus on trial accrual¹⁸ found that only 20% of 235 patients received an explicit offer to participate in a trial. However, in this study, patients were not screened before interactions; therefore, it was not clear whether the small number of trial offers could be attributed to

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patient ineligibility, a lack of offers on the part of the physicians, or other factors.

We advanced that study by conducting a qualitative directed content analysis of video-/audio-recorded patient-oncologist clinical interactions with patients who were found upon screening to meet the eligibility criteria for an available prostate cancer therapeutic trial available at the participating cancer center where they were being seen. The purpose of this analysis was to identify factors that may contribute to low accrual rates by determining whether and under what circumstances patients who are potentially eligible for a clinical trial are offered the chance to participate in such trials.

Participating patients were receiving care at 1 of 2 NCI-designated comprehensive cancer centers, which, by definition, have highly functional clinical trial infrastructures. Examining these clinical interactions can shed light on clinical trial accrual in several ways. First, this analysis can help determine whether potentially eligible patients are offered the chance to enroll in a trial, and if not, why not. Second, it can provide information to improve the way accrual rates are evaluated. Accrual rates are usually calculated as the proportion of patients who enroll in a trial out of all patients with cancer, rather than out of patients who are eligible for an available trial. Third, findings from this analysis can be used to identify targets of future interventions designed to improve clinical trial enrollment.

METHODS

Participants, Setting, and Procedures

This study was a secondary analysis of data from an ongoing study of patient-physician communication and cancer clinical trials.¹⁹ The purpose of the parent study was to improve rates at which African American and white men with prostate cancer are offered and decide to participate in a clinical trial based on high-quality communication with their physicians. Patient recruitment and data collection for the first phase of the parent study began in November 2016 at Wayne State University/Karmanos Cancer Institute in Detroit, MI, and Johns Hopkins/Sidney Kimmel Comprehensive Cancer Center in Baltimore, MD. All procedures were approved by institutional review boards at each site, and all participants provided informed consent. Study participants included physicians (medical oncologists, urologists, and radiation oncologists) and their patients. Physicians were eligible if they regularly treated patients with prostate cancer at 1 of the 2 research sites. Adult patients of participating physicians were eligible if they had a diagnosis of intermediate- or high-risk prostate cancer (as defined by the National Comprehensive Cancer Network); self-identified as non-Hispanic, black or African American, or white; had been seeing a participating physician for less than a year and expected to see the physician at least once in the upcoming year; was able to read and write in English

well enough to provide consent and complete study materials; and may have been eligible for a therapeutic clinical trial available at the cancer center where they were receiving treatment within 2 years of consent. At the time of consent, patients and physicians were informed they were being invited to participate in a study of communication and asked to complete baseline surveys assessing their demographic and other health-related characteristics. Patients and physicians were not informed about screening or eligibility of any specific patient. Patients were then tracked for up to 2 years to determine whether they met eligibility criteria for an available therapeutic clinical trial at the participating cancer center where they were being seen. If so, they completed surveys before and after the interaction with their physician, were randomly assigned to receive either usual care or a brief communication intervention, and had at least 1 clinical interaction video recorded. Procedures for the parent study are available elsewhere.¹⁹

This study was a qualitative directed content analysis²⁰ of the video/audio recordings from the first phase of data collection in the parent study. These recordings, collected between January 2017 and October 2018, were accompanied by verbatim transcripts and patient self-reported demographic characteristics, and included 13 physicians and 43 patients. Most patients ($n = 28$; 65%) appeared in only 1 recording, 12 (28%) appeared in 2 recordings, 2 (4.7%) appeared in 3 recordings, and 1 (2.3%) appeared in 4 recordings. Patient mean age was 66 years (standard deviation, 8.5 years); 18 patients (41.9%) were African American (Table 1). Among the physicians, 1 physician appeared in 12 interactions and another in 9 interactions. The remaining 11 physicians appeared in ≤ 7 interactions.

Analysis

We conducted a descriptive directed content analysis of verbatim transcripts using Dedoose qualitative analysis software.²¹ Qualitative content analysis is a set of analytical methods that allows researchers to examine language for the purpose of classifying large amounts of text into an efficient number of categories that represent similar meanings.²⁰ For this study, we conducted a directed content analysis, which is often used when prior research exists about a topic but is incomplete and could benefit from further description. In a directed content analysis, researchers use prior research, theory, or framework to help focus their research question and to identify initial coding categories. They then refine categories as appropriate to a specific dataset as a way to extend prior research.

Video/audio coding. Coding involved 3 steps (Fig 1). The first step identified whether physicians explicitly offered or discussed a clinical trial. Members of the research team (S.E., T.F.M., T.L.A., L.M.H.) used an iterative process to identify and define categories of clinical trial offer/no offer based on those identified in Albrecht et al.¹⁸ This step

TABLE 1. Patient Participant Characteristics (n = 43)

Characteristic	Value
Mean age, years (SD)	66 (8.5)
Race	
African American or black	18 (41.8)
Caucasian or white	25 (58.1)
Education	
≤ High school	15 (34.9)
Some or graduated from college	19 (44.2)
Graduate or professional degree	9 (20.9)
Annual household income, %	
< 20,000.00	5 (11.6)
20,000-39,000	3 (7.0)
40,000-59,000	8 (18.6)
60,000-79,000	6 (14.0)
> 80,000	18 (41.9)
Marital status	
Single	6 (14.0)
Married or partnered	27 (62.8)
Divorced or widowed	3 (7.0)

NOTE. Data are No. (%) unless otherwise indicated.
Abbreviation: SD, standard deviation.

involved independently viewing the recordings and reading the transcripts to identify categories,¹⁸ meeting as a team to discuss and refine the categories and their definitions, and then reviewing the recordings and transcripts and discussing until reaching consensus. Final categories and definitions for this step were (1) offer (ie, at least 1 clinical trial was discussed and explicitly offered); (2) offer pending (ie, at least 1 trial was discussed and offered pending tests, such as scans or blood tests); (3) trials discussed but not offered (ie, no specific trial was offered); and (4) trial not discussed (ie, no mention of trials). Then, trained coders observed each interaction to assign it a category; interrater reliability among the 3 coders was very high (intraclass correlation coefficient [ICC], .93; $P < .05$). Observers also identified and abstracted the sections of the transcript where trial discussions occurred. This process determined the number of interactions in each category and provided exemplars of each category.

Recurrent or relapsed disease is generally required for consideration of a change in treatment or clinical trial²²; therefore, the second step, which was applied only to interactions that did not include an offer (ie, categories 2-4), identified patients whose disease was stable on their current treatment. Trained coders observed each interaction and classified it according to whether physicians informed patients their disease had progressed or was stable; interrater reliability was very high (ICC, .93; $P < .01$).

FIG 1. Video/audio coding process and findings.

The third step was applied to the remaining interactions with patients whose cancer had progressed but had *not* received a trial offer. Coders observed each interaction to identify factors likely to explain the lack of an offer during these interactions. Coders had 81% agreement; disagreement was resolved through discussion.

RESULTS

We report the findings of our coding system with the number and proportion of interactions that were included in each category. We also provide quotations to illustrate each of the 4 categories in the first coding step.

Step 1: Coding of 62 Interactions

The definition of the 4 categories of trial offer/no offer, verbatim examples from the transcripts, and number/proportion of interactions that were assigned to each category are provided in the following sections.

Offer (category 1). The physician makes an *explicit offer* to a patient to participate in a trial and includes the opportunity for the patient to make a decision about whether to enroll. Explicit offers occurred in 18 (29.0%) of the recorded interactions.

Example: 1020-2. Physician: Your options are a different standard-of-care pill, but we worry that if you go from that pill to the other pill, we don't get a lot of mileage out of that because it's too similar.

So, this trial is for folks exactly like you, where you've been on the pills for a while, they figured out—the cancer figured out how to get around it. I have a trial with different pills, to try to kill it a different way, and it's specifically targeting the prostate cancer cells, the ones that's figured out how to get around.

Offer pending (category 2). The discussion of a specific trial or trials, with an explicit offer anticipated but not extended, occurred in 9 (14.5%) of the interactions.

Example: 1011-2. Physician: It might be an opportunity to put on a second drug on top of this current drug. So [research nurse] is looking to see. We have about 2 trials to consider. But one of them, I just gotta make sure. The one that I am thinking of, I have to make sure that there is an opening.

Discussion but no offer (category 3). A discussion of trials in general or about prior trials in which the patient has participated, but no offer of a specific trial, occurred in 11 (17.7%) of the interactions.

Example: 1020-1. Physician: And you know I'm happy to always consider stuff experimental but at this moment we don't have one that is exactly like this.

No discussion (category 4). There was no mention of trials in 24 (38.7%) of the recorded interactions.

Example: 1003-2. Physician: Because, obviously, if today's PSA [prostate-specific antigen] keeps going up, we need to look and see what's going on. Okay? And, chances are we are going to have to put you on a medication called _____. These are pills that have a very good chance of working against the cancer, and they will likely shrink the disease and, you know, also lower the PSA, and the good thing is they are likely to work for long periods of time.

Step 2 Coding

Of the 44 interactions that did not include an offer, 25 (56.8%) included information that the patient's cancer had not progressed, which likely explains the lack of an offer.²²

Step 3 Coding

Step 3 coding was applied to the 19 remaining interactions that included patients who did not receive a trial offer but whose cancer had progressed. The reasons for the lack of a trial offer during the interaction were as follows: more tests were needed to determine the extent of progression and/or final eligibility (n = 6); no trial was available (n = 3); the physician was waiting for a study slot (n = 2); the patient was recovering from an unrelated condition before considering a trial (n = 1); and a decision was made to stay the course despite progression (n = 1). In 6 interactions, no reason was provided.

DISCUSSION

To our knowledge, this is the first study to examine recorded clinical interactions using qualitative content analysis to determine whether and under what circumstances patients screened to match eligibility criteria for a therapeutic clinical trial at an NCI-designated comprehensive cancer center are offered the chance to participate. Of the 62 interactions analyzed, only 18 (29.0%) included an explicit offer. This is higher than our earlier observational study, which found that only 20% of the interactions analyzed included an explicit offer.¹⁸ We extended that work by screening patients before the interactions to identify those who initially qualified for an available trial and by qualitatively analyzing the interactions to identify reasons for the lack of offer in the remaining interactions. More than half of these involved patients whose physicians informed them that their cancer had not progressed and therefore no change in treatment was necessary. Another 40%, however, involved patients whose cancer had progressed, but did not receive a trial offer; in 6 of these, no trial was mentioned.

Findings suggest that reports of low accrual rates may be misleading. Most consider accrual rates among all patients with cancer, but this study suggests that considering only patients with the potential to enroll in a cancer clinical trial as the denominator may provide a more accurate picture. This is a more clinically useful approach that may demonstrate that accrual rates are much higher than previously thought. However, this approach will likely require a national registry.

A more accurate assessment of accrual rates would allow investigators to develop appropriately targeted interventions. These interventions could be focused on increasing accrual rates among eligible patients and on increasing the denominator, or the number of eligible patients. The first type should focus on barriers to trial accrual at the level of patients and clinicians, such as their beliefs and attitudes about trials and the way they communicate with each other.¹⁹ For example, we described an interaction with no trial discussion (example 1003-2; coding step 1, category 4), involving a patient whose disease had progressed and was recommended standard of care, rather than a clinical trial. This type of interaction may benefit from a communication intervention to prompt physicians and patients to discuss clinical trials. The second type of intervention could focus on increasing the pool of patients who can participate by, for example, improving the ability of smaller community hospitals to make trials available or by broadening inclusion criteria to make trials more inclusive. Overly restrictive eligibility criteria can slow clinical trial accrual and limit generalizability of findings.^{7,8} The American Society of Clinical Oncology, Food and Drug Administration, and Friends of Cancer Research advocate broadening eligibility criteria to enable more patients to participate in trials.^{7,22}

We identified reasons that emerged during interactions for why patients whose cancer had progressed did not receive an offer. In most cases, there was at least a mention of a trial, suggesting that physicians were aware of and interested in discussing trials, as would be expected at these research institutions. Physicians may have been unaware of available trials for these patients or may have known of patient circumstances that limit a patient's willingness or ability to agree to participate and/or adhere to the protocol, such as comorbidities. In a large study of patients with a diagnosis of breast, lung, colorectal, or prostate cancer,⁸ the presence of at least 1 comorbidity was strongly associated with patient reports of whether they discussed a trial with their physician or received a trial offer. Still, these comorbidities may have unnecessarily precluded a trial discussion or offer. Comorbidities most associated with the lack of an offer were hypertension, prior cancer, and hearing loss, which may have reflected a perception that a patient could not participate, rather than reflecting actual exclusion criteria for a specific trial. Additionally, physicians may refrain from offering trials because of biases and potentially inaccurate perceptions of patients' beliefs or circumstances.²³

Findings from this study, conducted in a racially diverse patient population, are consistent with those from other studies suggesting that patients from minority groups are less likely to receive trial offers than white patients.²⁴ Over a third of the patients in the study sample were African American, but a disproportionately high number of African American patients (56%) had at least 1 interaction categorized as having no mention of a trial, whereas only 20% of white patients had at least 1 interaction with no mention of a trial. Prior research suggests that African American patients are more likely to decline participation because of medical mistrust,^{5,25-27} are more likely to receive care at under-resourced institutions with poorly functioning clinical trial infrastructures, and have a greater number of comorbidities than white patients and therefore do not match the criteria for available trials.⁴ However, these reasons do not seem to explain the apparent racial disparities in our study. Patients were not offered the chance to participate in a clinical trial in these interactions, so they had no opportunity to refuse; they were receiving care at large research centers with available trials, and through screening, they matched eligibility criteria. At the same time, it was beyond the scope of this study to examine the influence of other important exclusion criteria, such as the incidence of comorbidities. Other types of analyses of

communication in clinical interactions with diverse patients are clearly needed.²⁸

This study has several limitations, and conclusions should be interpreted cautiously. First, this was a secondary analysis, and eligibility criteria were established for the parent study that prevented us, for example, from examining interactions with patients with different cancers, from different racial groups, and from different genders or who spoke a language other than English. Second, we used qualitative methods and a relatively small convenience sample of patients with 1 type of cancer. Our inference is implicitly quantitative, but our analytic approach was qualitative. Thus, the frequencies and percentages are provided for descriptive purposes only, and their use as point estimates is very limited. Additional research is needed to determine whether findings are applicable in larger samples and other settings. Third, it was beyond the scope of the study to examine factors not discussed during the interactions that may have affected whether patients received a trial offer. Finally, this study focused on individual interactions, rather than on the trajectory of care a patient may receive; patients may have received an offer in a different visit or via telephone.

There is also the possibility that because some physicians in the study saw several patients, a single physician could have neglected to discuss trials. Also, it is possible that the intervention, a patient-focused brochure designed to improve trial-related communication, may have influenced the number of offers. In fact, however, neither of these were the case; all but 1 of the physicians in the sample were involved in interactions with a trial discussion with a patient whose cancer had progressed, and patients who had been randomly assigned to receive the intervention appeared in both the offer and the no-offer categories.

Finally, this study highlights the need for in-depth study of communication processes that occur between patients and physicians. Additional studies using qualitative methods such as discourse analysis could identify communication processes of patients, family members, and health care providers that occur during interactions that include a trial offer and are associated with patient understanding of trials and willingness to participate. Innovative methods can lead to shifts in thinking that will result in a better understanding of the factors that influence offers, with the goal of identifying interventions to increase the proportion of patients who receive an explicit trial offer and subsequently decide to participate.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST AND DATA AVAILABILITY STATEMENT

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REFERENCES

1. Institute of Medicine: A National Cancer Clinical Trials System for the 21st Century: Reinventing the NCI Cooperative Group Program Institute of Medicine. Washington, DC, National Academies Press 2010.
2. Unger JM, Cook E, Tai E, et al: The role of clinical trial participation in cancer research: Barriers, evidence, and strategies. *Am Soc Clin Oncol Educ Book* 35: 185-198, 2016
3. Unger JM, Vaidya R, Hershman DL, et al: Systematic review and meta-analysis of the magnitude of structural, clinical, and physician and patient barriers to cancer clinical trial participation. *J Natl Cancer Inst* 111:245-255, 2019
4. Hamel LM, Penner LA, Albrecht TL, et al: Barriers to clinical trial enrollment in racial and ethnic minority patients with cancer. *Cancer Contr* 23:327-337, 2016
5. Ford JG, Howerton MW, Lai GY, et al: Barriers to recruiting underrepresented populations to cancer clinical trials: A systematic review. *Cancer* 112:228-242, 2008
6. Diehl KM, Green EM, Weinberg A, et al: Features associated with successful recruitment of diverse patients onto cancer clinical trials: Report from the American College of Surgeons Oncology Group. *Ann Surg Oncol* 18:3544-3550, 2011
7. Kim ES, Bruinooge SS, Roberts S, et al: Broadening eligibility criteria to make clinical trials more representative: American Society of Clinical Oncology and Friends of Cancer Research Joint Research statement. *J Clin Oncol* 35:3737-3744, 2017
8. Unger JM, Hershman DL, Fleury ME, et al: Association of patient comorbid conditions with cancer clinical trial participation. *JAMA Oncol* 5:326-333, 2019
9. Somkin CP, Altschuler A, Ackerson L, et al: Organizational barriers to physician participation in cancer clinical trials. *Am J Manag Care* 11:413-421, 2005
10. Bylund CL, Weiss ES, Michaels M, et al: Primary care physicians' attitudes and beliefs about cancer clinical trials. *Clin Trials* 14:518-525, 2017
11. Siegel RL, Miller KD, Jemal A: Cancer statistics, 2018. *CA Cancer J Clin* 68:7-30, 2018
12. Chen MS Jr, Lara PN, Dang JH, et al: Twenty years post-NIH Revitalization Act: Enhancing minority participation in clinical trials (EMPaCT): Laying the groundwork for improving minority clinical trial accrual: Renewing the case for enhancing minority participation in cancer clinical trials. *Cancer* 120:1091-1096, 2014 (suppl 7)
13. Balakrishnan AS, Zhao S, Cowan JE, et al: Trends and predictors of adjuvant therapy for adverse features following radical prostatectomy: An analysis from Cancer of the Prostate Strategic Urologic Research Endeavor. *Urology* 131:157-165, 2019
14. Meropol NJ, Buzaglo JS, Millard J, et al: Barriers to clinical trial participation as perceived by oncologists and patients. *J Natl Compr Canc Netw* 5:655-664, 2007
15. Jacobsen PB, Wells KJ, Meade CD, et al: Effects of a brief multimedia psychoeducational intervention on the attitudes and interest of patients with cancer regarding clinical trial participation: A multicenter randomized controlled trial. *J Clin Oncol* 30:2516-2521, 2012
16. Langford AT, Hawley ST, Stableford S, et al: Development of a plain language decision support tool for cancer clinical trials: Blending health literacy, academic research, and minority patient perspectives. *J Cancer Educ* [10.1007/s13187-019-1482-5](https://doi.org/10.1007/s13187-019-1482-5) [epub ahead of print on February 9, 2019]
17. Ghebre RG, Jones LA, Wenzel JA, et al: State-of-the-science of patient navigation as a strategy for enhancing minority clinical trial accrual. *Cancer* 120: 1122-1130, 2014 (suppl 7)
18. Albrecht TL, Eggly SS, Gleason ME, et al: Influence of clinical communication on patients' decision making on participation in clinical trials. *J Clin Oncol* 26: 2666-2673, 2008
19. Eggly S, Hamel LM, Heath E, et al: Partnering around cancer clinical trials (PACCT): Study protocol for a randomized trial of a patient and physician communication intervention to increase minority accrual to prostate cancer clinical trials. *BMC Cancer* 17:807, 2017
20. Hsieh HF, Shannon SE: Three approaches to qualitative content analysis. *Qual Health Res* 15:1277-1288, 2005
21. dedoose: W application for managing, analyzing, and presenting qualitative and mixed method research data, (ed Version 8.0.35), SocioCultural Research Consultants, LLC, 2018. <https://www.dedoose.com/userguide/researchbasics/qualitivedatadatadataprocessingandanalysis#QualitativeDataDataProcessingAndAnalysis>
22. Jin S, Pazdur R, Sridhara R: Re-evaluating eligibility criteria for oncology clinical trials: Analysis of investigational new drug applications in 2015. *J Clin Oncol* 35: 3745-3752, 2017
23. Penner LA, Dovidio JF, Gonzalez R, et al: The effects of oncologist implicit racial bias in racially discordant oncology interactions. *J Clin Oncol* 34:2874-2880, 2016
24. Wendler D, Kington R, Madans J, et al: Are racial and ethnic minorities less willing to participate in health research? *PLoS Med* 3:e19, 2006
25. Braunstein JB, Sherber NS, Schulman SP, et al: Race, medical researcher distrust, perceived harm, and willingness to participate in cardiovascular prevention trials. *Medicine (Baltimore)* 87:1-9, 2008
26. Rogers CR, Rovito MJ, Hussein M, et al: Attitudes toward genomic testing and prostate cancer research among black men. *Am J Prev Med* 55S103-S111, 2018 (5, suppl 1)

27. Clark LT, Watkins L, Piña IL, et al: Increasing diversity in clinical trials: Overcoming critical barriers. *Curr Probl Cardiol* 44:148-172, 2019
28. Hamel LM, Moulder R, Albrecht TL, et al: Nonverbal synchrony as a behavioural marker of patient and physician race-related attitudes and a predictor of outcomes in oncology interactions: Protocol for a secondary analysis of video-recorded cancer treatment discussions. *BMJ Open* 8:e023648, 2018

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST**Unpacking Trial Offers and Low Accrual Rates: A Qualitative Analysis of Clinic Visits With Physicians and Patients Potentially Eligible for a Prostate Cancer Clinical Trial**

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Elisabeth I. Heath

Honoraria: Bayer, Dendreon, Sanofi, Seattle Genetics

Consulting or Advisory Role: Agensys

Speakers' Bureau: Sanofi

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Other Relationship: Caris Centers of Excellence

Susan Eggly

Consulting or Advisory Role: United Health Care/Optum, Amgen

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