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Succinct Cancer Clinical Trial Consent Forms in Rural Patients With Cancer: A Secondary Analysis of a Randomized, Double-Blinded study

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Abstract

Rural patients are often underrepresented in cancer clinical trials. This is a secondary analysis of a study that tested short (2000 word) versus long (6000 word) consent forms with a focus on rurality. Among 240 patients, 89 (37%) were rural. Seventy-one (80%) rural and 117 (77%) nonrural patients signed a consent form of any length ($P = .68$). Forty-one of 47 (87%) rural patients signed a short consent form; in contrast, 30 of 42 (71%) signed a long form. These trends suggest rural patients are more likely to sign short consent forms. Further study is indicated.

Keywords

short consent forms, clinical trials, brevity, succinct, educational

Introduction

Rural disparities in cancer care are well-documented. Compared to nonrural patients, those in rural areas are more likely to be diagnosed with advanced-stage cancer, receive cancer therapy discordant with national guidelines, and manifest inferior survival (1–3). Of incidental note, for purposes here, the term rural uses the United States' government definitions of sparsely populated areas and specifically relies on government databases to distinguish rural from nonrural patients.

Less well documented—but fundamentally important—are disparities in the enrollment of rural patients in cancer clinical trials. Indeed, access and enrollment to cancer clinical trials and high-quality cancer care are closely linked: the former typically provide state-of-the-art cancer care in accordance with national practice guidelines but, at the same time, strive to further improve the standard of care. Despite the importance of clinical trials in rural communities, the data are mixed on the recruitment of rural patients. Unger and others reported that 20% of patients enrolled in clinical trials are rural—a rate commensurate with rates of rurality in the general United States population (4). In contrast, Levit and others have described how poor access to cancer care among rural residents translates into poor access to cancer clinical trials (5). Most agree that for complex, groundbreaking cancer clinical trials which test highly novel drugs, complicated surgical interventions, or radiation-based therapies, patients from rural areas are underrepresented (3).

Recently, our group conducted a randomized, double-blinded study that suggested succinct clinical trial consent forms are associated with a greater patient-reported willingness to enroll in a cancer clinical trial (6). The impetus for this earlier study was the observation that clinical trial consent forms have consistently become more verbose over time—with reports of doubling in length—and the concern that this verbosity detracts from clinical trial accrual (7). This concern for verbosity seems particularly relevant to patients in rural communities; Friedman and others reported

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that time constraints are a major barrier that rural patients cite to explain their reluctance to enroll in a clinical trial (8,9). In this context, it is important to further explore succinct consent forms, which give rise to shorter reading times, and to explore whether a simple intervention of shortening a consent form might prompt rural patients to be more willing to enroll in a complex cancer clinical trial.

Methods

Overview. This is a secondary analysis of a previously reported single-institution, double-blinded randomized study that suggested short consent forms lead to a greater willingness of patients to sign up for a complex cancer clinical trial. The parent trial had been conducted at the Mayo Clinic in Rochester, Minnesota, which serves both rural and nonrural patients.

The parent study had attempted to replicate the recruitment of patients to a clinical trial by directly approaching them, asking them to read a "mock" consent form for a clinical trial, and learning whether they would be willing to sign.

Parent Study. The parent study tested "mock" consent forms of different word counts in adult cancer patients recruited from a chemotherapy unit. "Mock" consent forms were shortened by elimination of superfluous words and were derived from an actual complex clinical trial consent form. The parent study on consent form length employed a Phase 2/3 study design, which used a pre-specified analysis to select between the 2000 and 4000 word consent form at the end of the Phase 2 component, and then pursued the final larger Phase 3 component to test the 2000- and 6000-word (standard) consent forms (10). The current report focuses only on patients who were given the 2000- and 6000-word consent forms.

Blinding had occurred during randomization via an I-Pad® and thereby enabled the patient and study team to access a consent form without knowing whether the assigned form was the short or long version. Patients showed a willingness to sign up for the "mock" trial by either directly signing their assigned consent form on an I-Pad® or by completing a questionnaire to state their willingness to do so (these options were integrated as one response in this paper).

Acquisition of Data on Rurality. For the current study, each patient's medical record was reviewed to acquire information on primary residence and zip code. The Health Resources and Services Administration website (https://www.hrsa.gov/rural-health/about-us/definition/datafiles.html) was used to determine whether a patient's residence was rural. Patients were categorized as rural versus nonrural. A deliberate decision was made to use this binary designation because of the limited sample size and the exploratory nature of this study.

Analyses. Patient demographics and other baseline factors were summarized. Univariable logistic regression models were constructed to assess the impact of relevant factors (rurality status, patient age, gender, whether patients reported previous research participation, assigned word count arm in the parent trial, marital status) on the outcome of whether the patient signed the consent form. These factors were chosen based on clinical relevance as well as evident differences based on whether patients were rural versus nonrural.

Factors that were significant at the 0.20 level in the univariable models were included in a multivariable logistic regression model with age and gender. In another model, factors that were significant at the 0.20 level in the univariable models were included in a multivariable logistic regression model with rurality status included. Odds ratios (ORs) and 95% confidence intervals (CIs) are reported. Data on the percentage of rural patients who signed the consent forms are presented descriptively; because of previously reported direct associations between rurality and older age, the data on the percentage of older patients who signed the consent forms are also presented. All statistical tests were conducted at the two-sided significance level of 0.05. Data were analyzed with SAS statistical software, version 9.4.

Results

Demographics. Among the 240 included patients, 89 (37%) lived in a rural setting. Demographic and other relevant characteristics appear in Table 1. A greater percentage of rural as opposed to nonrural patients, were 65 years of age or older: 51% versus 39%.

Factors Associated with Signing a Consent Form. Seventy-one (80%) of rural patients, and 117 (77%) of nonrural patients signed a consent form of any length, yielding a univariable logistic model odds ratio of 1.146 (95% confidence interval: 0.60, 2.18); $P = .68$.

Factors that were statistically significantly associated with signing a consent form appear in Table 2 and include previous participation in research, cancer type, and consent form length. The short consent form was associated with a greater willingness to sign with an OR of 1.90 (95% CI: 1.01, 3.56); $P = .046$. However, in the multivariable model, none of these factors continued to manifest a statistically significant association with signing a consent form.

Exploring a Short Consent Form in Rural and Older Patients. In looking at the short, 2000-word consent form among rural patients, we observed 41 of 47 (87%) signed. Forty of 47 (85%) who were 65 years or older also signed the short consent form. Among patients who were both rural and older, 20 of 22 (91%) patients signed the short consent form.

In contrast with the long, 6000-word consent form, 30 of 42 (71%) rural patients signed, and, among older patients, 42 of 57 (74%) signed. Finally, among patients who were both rural and older, 16 of 23 (70%) signed the long consent form.

Of parenthetical note, among nonrural patients, 61 of 75 (81%) signed the 2000-word consent form, and 56 of 76 (73%) signed the 6000-word consent form.

Discussion

This descriptive study found that patients from rural communities appear just as willing to sign a consent form that

Table 1. Demographics and Outcome Data.

	Rural N = 89	Nonrural N = 151
Median age, years (range)	65 (23-82)	62 (23-88)
Age 65 + , n (%)		
Yes	45 (51)	59 (39)
No	44 (49)	92 (61)
Gender, n (%)		
Male	40 (45)	68 (45)
Female	49 (55)	83 (55)
Relationship Status, n (%)		
Single	14 (16)	23 (15)
Other	75 (84)	128 (85)
Previous research participation? n (%)		
Yes	62 (70)	107 (71)
No	27 (30)	44 (29)
High school graduate? (%)		
Yes	86 (97)	151 (100)
No	3 (3)	0 (0)
Cancer type (%)		
Lung	11 (12)	19 (13)
Gastrointestinal	10 (11)	15 (10)
Hematologic	28 (32)	29 (19)
Other	40 (45)	88 (58)
Active cancer? n (%)		
Yes	77 (87)	123 (82)
No	12 (13)	28 (18)
Had previously seen a consent form? n (%)		
Yes	74 (83)	126 (83)
No	15 (17)	25 (17)
Assigned Consent Form, n (%)		
6000 Words (control)	42 (47)	76 (50)
2000 Words	47 (53)	75 (50)
Signed/expressed a willingness to sign consent form? n (%)		
Yes	71 (80)	117 (73)
No	18 (20)	34 (23)

describeda complex clinical trial as those from nonrural communities. We previously reported that short consent forms prompt a greater willingness to sign. Now, these secondary analyses show trends to suggest that rural patients might also benefit from short consent forms: among rural patients, 87% were willing to sign the short consent form in contrast to 71% for the long consent form. Further, among older, rural patients, rates of signing were 91% and 70% for the short and long consent forms, respectively. Although this exploratory study suffers from limited power and therefore cannot provide definitive conclusions, it appears that short consent forms are associated with a greater willingness to sign a cancer clinical trial consent form among rural patients.

Although this study focused on rurality and therefore pertains to only a subsegment of the United States' population, rural patients merit attention. Sixty million people live in rural locations. Rurality is associated with disparities in cancer care as well as barriers to insurance coverage and other factors that can negatively impact cancer care (1–3). Recruitment to clinical trials is only one aspect of a much larger set of issues; the provision of succinct information might also be applicable, for example, to concise educational tools that might further help mitigate rural inequities in cancer care.

Limitations

Finally, the current study has limitations that include the fact that it was a secondary analysis and therefore inadequately powered to draw firm conclusions; that we explored only a willingness to sign and not the depth of understanding of consent form content; and that recruitment to the parent trial had occurred from a quaternary medical center. This last point suggests that, in this study, the rural patients might be unrepresentative of rural patients who are unable to travel to a large medical center, less educated, and with less exposure to medical research. Nonetheless, the preliminary findings described here—coupled with the idea that the increasing verbosity of cancer clinical trial consent forms appears to serve no well-stated purpose—underscore the need to consider the use of concise consent forms for

Table 2. Univariable and Multivariable Logistic Regression Models for Signing a Consent Form.[a]

	Univariable model			Multivariable model			Exploratory multivariable model with rurality		
	Odds ratio (95% CI)	*P*-value	Type 3 overall *P*	Odds ratios (95% CI)	*P*-value	Type 3 overall *P*	Odds ratios (95% CI)	*P*-value	Type 3 overall *P*
Participated in previous research study (vs no)	2.08 (1.10-3.94)	.03	.03	1.81 (0.90-3.63)	.10	.10	1.79 (0.89-3.30)	.10	.10
Female (vs male)	0.64 (0.34-1.21)	.17	.17	0.70 (0.35-1.39)	.31	.31	0.68 (0.34-1.35)	.27	.27
Age 65 + (vs < 65)	1.06 (0.57-1.96)	.87	.87	0.83 (0.42-1.62)	.58	.58			
Single (vs other)	1.93 (0.71-5.23)	.20	.20	1.97 (0.69-5.61)	.20	.20	1.90 (0.67-5.39)	.23	.23
Cancer type (vs other)			.03			.13			.13
gastrointestinal	0.38 (0.15-0.95)	.04		0.75 (0.29-1.95)	.55		0.39 (0.15-1.00)	.05	
hematologic	1.82 (0.74-4.48)	.19		0.39 (0.15-0.995)	.05		1.46 (0.55-3.86)	.44	
lung	0.60 (0.24-1.45)	.25		1.47 (0.56-3.84)	.44		0.78 (0.30-2.00)	.60	
Active cancer (vs no)	1.06 (0.47-2.40)	.89	.89						
Previously seen a consent form (vs no)	1.25 (0.57-2.77)	.58	.58						
2000 word (vs 6000 word)	1.90 (1.01-3.56)	.05	.046	1.75 (0.91-3.39)	.09	.09	1.72 (0.89-3.30)	.10	.10
Rural (vs not)	1.146 (0.60-2.18)	.68	.68				1.13 (0.57-2.21)	.73	.73

[a]Education as a variable of interest was unable to be assessed due to low numbers in the "did not graduate from high school" category.

rural patients. At the very least, succinct consent forms merit further study in rural settings.

Author Contributions

All the authors contributed equally to the study. All contributed to interpreting the data, writing/editing the paper, and opportunity to review the final version of the paper. Drs Mandrekar and Jatoi share senior authorship on this paper.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical Approval

The parent study had been approved by the Institutional Review Board; this approval was applied to the current study.

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Informed Consent

Patients had provided informed consent for the parent trial, and this consent was applied to the current study.

Data Availability

The data will be made available on a case-by-case basis to ensure patient confidentiality.

Statement of Human and Animal Rights

All procedures in this study were conducted in accordance with the Mayo Clinic Institutional Review Board (#20-007236).

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