Participation of Patients With Limited English Proficiency in Gynecologic Oncology Clinical Trials

Soledad Jorge, MD, MPH[1]; Shatreen Masshoor, BA[2]; Heidi J. Gray, MD[1]; Elizabeth M. Swisher, MD[1]; and Kemi M. Doll, MD, MCSR[1]

ABSTRACT

Background: Significant disparities exist in recruitment of minorities to clinical trials, with much of the prior literature focused on race/ethnicity only. Limited English proficiency (LEP) is a known barrier in healthcare that may also drive disparities in trial enrollment. We sought to determine participation rates in gynecologic oncology trials among patients with LEP and to explore barriers to their participation. **Methods:** In a retrospective cohort study, electronic health record data from >2,700 patients treated over 2 years at one academic gynecologic oncology practice were abstracted and the primary exposure of having LEP was identified. The primary outcome was enrollment in a clinical trial. Demographic, financial, clinical, and healthcare access–related covariates were also abstracted and considered as potential confounders in a multivariable logistic regression model. Age, race, ethnicity, and insurance status were further examined for evidence of effect modification. In addition, a survey was administered to all gynecologic oncology research staff and gynecologic oncology providers (n=25) to assess barriers to research participation among patients with LEP. **Results:** Clinical trial enrollment was 7.5% among fluent English speakers and 2.2% among patients with LEP (risk ratio, 0.29; 95% CI, 0.11–0.78; *P*=.007), and remained significantly lower in patients with LEP after adjusting for the identified confounders of Hispanic ethnicity and insurance payer (odds ratio, 0.34; 95% CI, 0.12–0.97; *P*=.043). There was a trend toward race and LEP interaction: Asian patients were equally likely to participate in research regardless of language fluency, whereas White and Black patients with LEP were less likely to participate than non-LEP patients in both groups (*P*=.07). Providers reported that the most significant barriers to enrollment of patients with LEP in research were unavailability of translated consent forms and increased time needed to enroll patients. **Conclusions:** Patients with LEP were 3.4 times less likely to participate in gynecologic oncology trials than fluent English speakers. De-aggregation of race, ethnicity, and language proficiency yielded important information about enrollment disparities. These findings offer avenues for future interventions to correct disparities.

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Background

Clinical trials are critical to advancing scientific knowledge and medical care. In the case of cancer research, clinical trials also provide participants access to cutting-edge treatments that may improve survival and functional outcomes.[1–5] Ensuring the proportional representation of minority groups in these trials is paramount to increase the generalizability and applicability of trial findings and to promote health equity. This has been considered a national priority in the United States since the NIH Revitalization Act of 1993, which established specific guidelines for the accrual of racial and ethnic minorities in NIH-funded research.[6] However, achieving equitable participation remains an ongoing challenge, with a robust body of literature showing ongoing underrepresentation of various racial and ethnic minorities, as well as of economically disadvantaged, elderly, and rural populations.[5,7–10]

In gynecologic oncology, the fact that minority populations are underrepresented in clinical trials is well documented.[11–13] However, the underlying mechanisms are not fully understood. Limited English proficiency (LEP) is a known barrier in healthcare[14–19] that may drive other disparities in trial enrollment. Individuals with LEP constitute 8.6% of the US population and represent the full spectrum of race and ethnic categories.[20] Recent studies have found that patients with cancer with LEP were significantly less likely to participate in cancer trials.[19,21] To date, the enrollment of patients with LEP in clinical trials of gynecologic malignancies remains underinvestigated.

The objectives of this study were to characterize accrual of patients with LEP in gynecologic oncology clinical trials at an NCI-designated Comprehensive Cancer Center, and to identify gynecologic oncology provider–perceived barriers to research participation of patients with LEP.

Methods

We conducted a retrospective cohort study of outpatients treated by gynecologic oncologists at the University of

See page 99 for related commentary.

Washington Medical Center, identified through EPIC medical software. The exposure of interest was LEP, defined as requiring a language interpreter to interface with the healthcare system. During patient intake, coordinators input patients' primary languages into the electronic medical record, which flags subsequent appointments that require a medical interpreter of the corresponding language. The primary outcome of interest was enrollment at any point during the study period in a clinical research study. This was determined by presence of an "active research study enrollment" indicator on EPIC, which can be tracked per-visit. A minimum sample size of 2,655 patients was calculated based on an alpha of 0.05, power of 0.80, estimated incidence of research participation among unexposed of 10%, and an estimated relative risk of 0.50, based on prior literature.[19,21,22] Based on this sample size and the patient flow at our clinics, a 2-year period was selected, from August 2016 to August 2018, for data collection.

We used univariate and multivariate logistic regression models to examine the association between exposure and outcome. Covariates abstracted through the medical record included demographic (age, race, ethnicity), financial (payer, mean adjusted gross income based on a patient's zip code), clinical (provider; having a cancer vs noncancer diagnosis; organ of origin for disease being treated; whether surgery was performed; whether the disease was newly diagnosed, recurrent, or in remission), and healthcare access–related (number of clinic visits over the 2-year study period, distance between home address and hospital). These were each considered as potential confounders. We calculated crude and Mantel-Haenszel risk ratios adjusted for each of these covariates. If crude and adjusted risk ratios differed by >10%, the covariate was included as a confounder in the multivariate model. We took an empirical rather than theory-based approach to confounder identification because there was a dearth of prior research to inform accurate a priori confounder identification. We also explored the association of LEP and clinical trial participation within subgroups of patients using a forest plot. Age, race, ethnicity, and insurance status were further examined for evidence of effect modification using the Breslow-Day test of homogeneity.

Table 1. Baseline Patient Characteristics

Characteristic	Limited English Proficiency n (%)	Moderate/High English Proficiency n (%)
Total, n	184	2,609
Age, mean [SD], y	57.21 [14.98]	57.06 [14.26]
Race		
White	65 (35.3)	2,101 (80.5)
Asian	46 (25.0)	169 (6.5)
Black	15 (8.2)	80 (3.1)
Unknown/Declined to answer	58 (31.5)	259 (9.9)
Hispanic ethnicity	84 (45.7)	90 (3.4)
Visits during study period, mean [SD]	2.58 [2.23]	2.56 [2.32]
Public insurance	134 (72.8)	1,068 (40.9)
Invasive cancer diagnosis	135 (73.4)	1,954 (74.9)
Disease category[a]		
Vulvar	7 (3.8)	149 (5.7)
Vaginal	17 (9.2)	143 (5.5)
Cervical	49 (26.6)	325 (12.5)
Uterine	83 (45.1)	1,009 (38.7)
Ovarian/Fallopian tube	63 (34.2)	1,064 (40.8)
Surgery	100 (54.3)	1,237 (47.4)
New diagnosis	123 (66.8)	1,536 (58.9)
Recurrent disease	10 (5.4)	135 (5.2)
Disease surveillance	41 (22.3)	754 (28.9)
Distance from hospital, mean [SD], miles	142.03 [617.19]	247.97 [738.16]
Adjusted gross income, mean [SD], USD	$74,610 [$40,470]	$85,730 [$52,330]

[a]Disease categories do not add up to 100%, because patients may have been treated for multiple conditions during the study period.

Additionally, we sent a voluntary, anonymous online survey to gynecologic oncology physicians, advanced practice providers, research nurses, and research coordinators at our institution (n=25). Respondents were asked to choose significant barriers to research participation for patients with LEP from among a list of 9 possibilities, and to note the most important barrier (supplemental eAppendix 1, available with this article at JNCCN.org). They were also asked to select effective interventions from a list of 5 options. For each question, respondents had the option to add unlisted ("other") answers.

This study was approved by the University of Washington Institutional Review Board (STUDY00007787).

Results

We identified 2,793 patients treated over the study period (Table 1). Patients with LEP comprised 6.6% of the total patient population (n=184), with 32 different primary languages spoken. The most commonly spoken languages were Spanish (47.8%), Vietnamese (5.4%), Russian (4.9%), and Mandarin (5.9%). The racial breakdown of patients with LEP was 35.3% White, 25.0% Asian, 8.2% Black, and 31.5% unknown/declined to answer. Hispanic ethnicity patients represented 45.7% of the LEP group.

In total, 7.1.% of patients were enrolled in a clinical trial. Research participation was significantly lower among patients with LEP (2.2%) compared with fluent English speakers (7.5%) (risk ratio, 0.29; 95% CI, 0.11–0.78; *P*=.007). Significant confounders were Hispanic ethnicity and insurance payer, meeting the predetermined criteria of altering the Mantel- Haenszel estimator by at least 10%. In a multivariate model adjusting for ethnicity and insurance payer, research participation remained significantly lower in patients with LEP (odds ratio, 0.34; 95% CI, 0.12–0.97; *P*=.043).

The odds of clinical trial participation were numerically lower for patients with LEP in all subgroups except for Asian race (Figure 1). Results of the Breslow-Day test of heterogeneity suggested a trend toward interaction between English proficiency and race (*P*=.068). Although LEP was associated with reduced probability of research participation in both White (0% vs 8% for no LEP) and Black patients (0% vs

Covariate	Sample Size	Odds Ratio	*P* Value
Age			
<65 y	1,858	0.175	.003
≥65 y	935	0.590	.765
Race			
White	2,166	0.000	.008
Asian	215	0.915	1.000
Black	95	0.000	1.000
Unknown/Other	317	0.677	1.000
Hispanic ethnicity			
Yes	174	0.168	.119
No	2,619	0.381	.114
Public insurance			
Yes	1,202	0.369	.104
No	1,591	0.216	.119
Cancer diagnosis			
Yes	2,089	0.310	.011
No	704	0.000	.389
Surgery performed			
Yes	1,337	0.381	.107
No	1,456	0.148	.026
Distance from hospital			
<100 km	1,584	0.353	.039
≥100 km	1,196	0.000	.073
Adjusted gross income			
<50%	1,363	0.251	.040
≥50%	1,361	0.377	.226

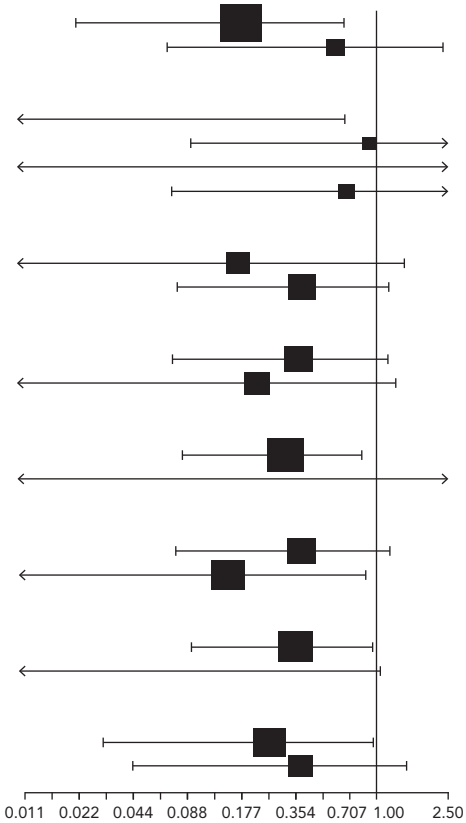

Figure 1. Forest plot of the association between LEP and clinical trial participation by study covariates. Squares represent odds ratios and horizontal lines represent 95% confidence intervals. The vertical line is the line of equal odds. For patients with LEP, the odds of clinical trial participation were numerically lower within all subgroups included in this analysis, except for Asian race.
Abbreviation: LEP, limited English proficiency.

6.2%), the rates of research participation in Asian patients remained relatively stable regardless of language proficiency (4.3% vs 4.7%) (Figure 2).

A total of 19 gynecologic oncology providers responded to the questionnaire (76%). Most respondents (89%) indicated that the lack of translated consent forms was an important barrier to participation of patients with LEP in clinical research, with 32% indicating this was the most important barrier. Increased time needed to consent patients with LEP in research was cited by 74% as an important barrier, with 26% indicating this was the most important barrier. Additionally, 68% of participants responded that study protocols often excluded LEP patients a priori (Figure 3A). Regarding potential interventions, 95% of providers selected improving access to translated consent documents and other study forms. Other responses included developing promotional materials (68%), setting active recruitment or enrollment targets (63%), improving access to interpreters (63%), and increasing appointment length (53%) (Figure 3B).

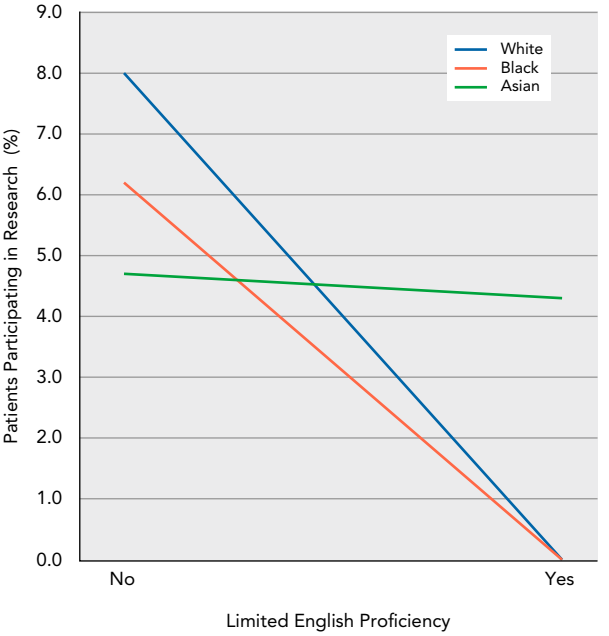

Figure 2. Association between limited English proficiency and research participation, stratified by race.

Discussion

We found that accrual of patients with LEP to gynecologic oncology trials was >3-fold lower than for fluent English speakers, a difference that persisted when adjusting for meaningful confounders. The effect of LEP on trial participation may be modified by race and ethnicity, with LEP being a significant factor in trial participation for Black and Hispanic patients but not Asian patients. Gynecologic oncology providers reported lack of translated informed consent forms, increased time needed to consent patients with LEP, and exclusion of LEP patients based on clinical trial eligibility criteria as the most important accrual barriers, and concomitantly reported the removal of these barriers as potentially effective interventions.

Numerous studies have documented significant health disparities in patients with LEP, including access to care[17–19] and health outcomes in routine practice.[14–16] In the research setting, prior work based in Australia has reported that culturally and linguistically diverse patients (defined as being born in non–English-speaking countries) were less likely to participate in cancer clinical trials than those born in English-speaking countries; additionally, the subgroup of diverse patients whose preferred language was not English were least likely to participate in clinical trials, with an odds ratio of 0.45.[21] Similarly, Roy et al[19] recently reported on various measures of healthcare engagement among LEP patients with breast cancer, among them clinical trial engagement, defined as any documented contact with the clinical trial team (eg, screening), regardless of whether trial enrollment took place. They found that patients whose primary language was not English had lower rates of clinical trial engagement compared with English-speaking patients, with an adjusted odds ratio of 0.29.[19] Conversely, an institutional study of >12,000 cancer cases failed to demonstrate significant differences in trial enrollment rates by most language groups; however, the study used registry-level data and could not account for possible confounding.[22] Our findings are concordant with the former 2 studies and considered demographic, financial, and healthcare access–related variables as potential confounders. Underrepresentation of the LEP population from clinical research not only undermines sound science and trial generalizability but also deprives LEP patients from access to promising new interventions that may improve survival and functional outcomes, further exacerbating disparities in health outcomes.

Although the reasons that racial and ethnic minorities are underrepresented in research are complex and multifactorial, language proficiency may be a significant mediator. Ameliorating clinical trial enrollment disparities for patients with LEP may also help to increase accrual of racial and ethnic minorities into clinical trials more broadly. Indeed, in our cohort, 46% of patients with LEP were Hispanic and 12% were Black, whereas only 3.4% of fluent English speakers were Hispanic and/or Black. Our finding of effect modification by race, though best considered a hypothesis-generating finding given the low absolute number of events, is noteworthy. Exploring the lesser magnitude of impact of LEP in Asian populations may help identify barriers and/or facilitators that can be addressed for the larger population.

In this study, we took an initial step toward understanding the causes of this observed healthy disparity and determining possible solutions. First, most providers noted that often English-language requirements built into clinical trial protocols excluded patients with LEP a priori. In concordance with this observation, a recent study found that close

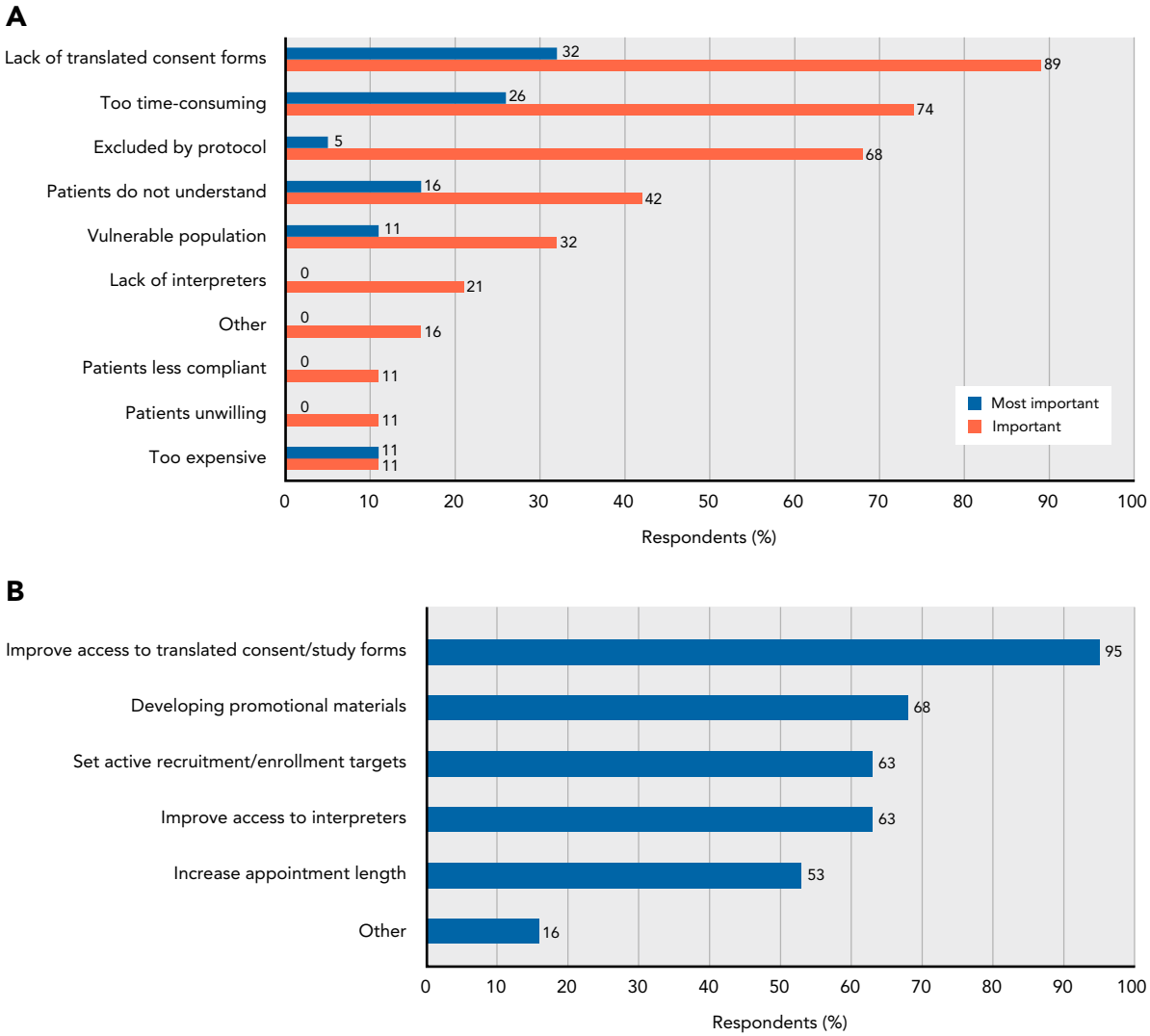

Figure 3. Gynecologic oncology provider–perceived **(A)** barriers to enrolling patients with limited English proficiency in clinical trials, by importance, and **(B)** interventions likely to improve research participation of patients with limited English proficiency.

to 20% of clinical trial protocols published on ClinicalTrials.gov listed English proficiency among their eligibility criteria.[23] Removing such fundamental exclusions, often made without a clear rationale, is a needed and immediately actionable first step. Additionally, difficulty obtaining informed consent was the most cited barrier for enrollment of LEP patients. Perversely, the informed consent process, the very purpose of which is to protect participants, may ultimately harm potential participants with LEP, because protections are designed for English-fluent patients only, and the process may not include translated materials or provide adequate time and resources for interpretation.[24] The provision of adequate funding for translation of study documents and for hiring interpreters and linguistically diverse personnel may help break this barrier and should be incorporated into protocol design.[25,26] Additionally, it is noteworthy that most providers cited time constraints as a significant barrier to enrolling patients with LEP. Allotting extra time per visit, or scheduling more visits, for the purpose of consenting these patients could address this issue. Admittedly, these potential interventions require more effort, time, and/or expense from the part of research teams and funding sources. It is thus important to remember that the underlying principle of health equity is precisely the willingness to allocate resources differentially to achieve equality of healthcare outcome. This not only is an ethical imperative but also ultimately results in better health outcomes for all.[27]

Strengths of this study include the selection of an adequately powered sample of patients derived from a large academic center situated in a diverse urban environment. The exposure of interest—limited English proficiency—is reliably captured in the medical record, given that need for an interpreter is tracked for clinical purposes. Additionally, we were able to consider numerous potential confounders and test them empirically. Nevertheless, some potentially important covariates were not available, which is a

limitation of this retrospective study. For example, we were not able to collect information regarding patient comorbidities, which are known barriers to clinical trial enrollment. Another limitation was the use of the EPIC research indicator functionality to define the outcome of interest, which may have missed participation in nonpharmacologic or noninterventional trials not tracked in the medical records.

Conclusions

This study demonstrated that patients with LEP participate in gynecologic oncology trials at rates approximately 3 times lower than their English-fluent counterparts, and that Black and Hispanic patients with LEP may be disproportionately affected. Preliminary work suggests that logistical factors, such as trial inclusion criteria, unavailability of translated study documents, and time constraints, are important barriers to their enrollment. Research is underway to further elucidate structural, clinical, and attitudinal barriers from both the provider and patient perspective. Ultimately, multilevel interventions are needed to correct these disparities.

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eAppendix 1: Provider Survey: Barriers to Participation of Patients with Limited English Proficiency in Clinical Trials

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1. **What is your role in the research team?**
   a. Principal investigator
   b. Co-investigator
   c. Referring physician
   d. Research/Clinical nurse
   e. Clinical research coordinator/data coordinator
   f. Research assistant
   g. Other (explain): _____

2. **How many years have you been involved in medical research?**
   a. Less than 1 year
   b. 1 to 5 years
   c. 6 to 10 years
   d. More than 10 years

3. **In your opinion, which of the following are significant barriers to participation of patients with limited English proficiency in clinical studies? (*Select all that apply*)**
   ☐ Research protocols and/or IRB policies often exclude patients who cannot understand English.
   ☐ Providers are often hesitant to approach patients with limited English proficiency to participate in research because they consider them a vulnerable population.
   ☐ Translated informed consents and other study-related materials are seldom available.
   ☐ Language interpreters are seldom available.
   ☐ The consent process is too time consuming for patients with limited English proficiency.
   ☐ Involving patients with limited English proficiency in clinical studies is too expensive.
   ☐ Patients with limited English proficiency tend to be unwilling or uninterested in participating in clinical studies.
   ☐ Patients with limited English proficiency often do not understand what the study entails, even with an interpreter.
   ☐ Patients with limited English proficiency are less likely to comply with the study protocol and/or complete the study.
   ☐ Other (explain): _____

4. **Given the same options as above, which do you consider to be *the most important* barrier to participation of patients with limited English proficiency in clinical studies? *(Select one)***
   ☐ Research protocols and/or IRB policies often exclude patients who cannot understand English.
   ☐ Providers are often hesitant to approach patients with limited English proficiency to participate in research because they consider them a vulnerable population.
   ☐ Translated informed consents and other study-related materials are seldom available.
   ☐ Language interpreters are seldom available.
   ☐ The consent process is too time consuming for patients with limited English proficiency.
   ☐ Involving patients with limited English proficiency in clinical studies is too expensive.
   ☐ Patients with limited English proficiency tend to be unwilling or uninterested in participating in clinical studies.
   ☐ Patients with limited English proficiency often do not understand what the study entails, even with an interpreter.
   ☐ Patients with limited English proficiency are less likely to comply with the study protocol and/or complete the study.
   ☐ Other (explain): _____

(continued on next page)

eAppendix 1. Provider Survey: Barriers to Participation of Patients with Limited English Proficiency in Clinical Trials (cont.)

5. **Which of the following do you think would be effective interventions to increase participation of patients with limited English proficiency in clinical studies?** ***(Select all that apply)***
   - ☐ Improve availability of translated informed consents and other study documents
   - ☐ Improve access to interpreters
   - ☐ Increase length of appointments for patients with limited English proficiency
   - ☐ Disseminate promotional material in various languages to encourage patient engagement in research
   - ☐ Set enrollment targets for patients with limited English proficiency (and other underrepresented groups) in clinical studies and actively recruit patients to meet targets (direct outreach)
   - ☐ Other (explain): _____

We invite you to share any other thoughts you have on participation of patients with limited English proficiency in clinical studies:

Thank You for Your Time!