VIEWPOINT

Inclusion of Non–English-Speaking Participants in Studies of Parkinson's Disease: A Call to Action

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Our current understanding of Parkinson's disease (PD) is informed almost entirely by research on people of European ancestry.[1,2] Failure to include a diversity of persons with PD in clinical trials denies certain groups the opportunity to share in the benefits and burdens of research, and risks an understanding of pathophysiology and treatment that may limit generalizability. In addition, research exclusively on a homogeneous population eliminates opportunities for discoveries that may benefit everyone. For example, the LRRK2 mutation was first discovered in the Basque population in Northern Spain and also found to be very prevalent in North African Berbers—but is now known to be a vital genetic risk factor across *all* PD populations.[3,4]

Recently, there has been a call to action to increase inclusion of diverse populations in PD clinical research.[2] Some trials for people with PD have specifically recruited underrepresented groups.[5-8] The Study in Parkinson's Disease of Exercise Phase 3 (SPARX3) clinical trial explicitly prioritized diverse recruitment. Three years into the trial we have encountered multiple barriers specific to the recruitment of non–English-speaking participants in the United States that are important for the PD community to address.

Although we are committed to understanding the many barriers that make the enrollment of a diverse population a challenge, we focus in this article specifically on language. There has been a call to increase inclusion of individuals with limited English proficiency in *all* phase 3 clinical trials,[9] yet this remains an elusive goal even for Parkinson's trials specifically focused on fostering inclusion of underrepresented populations in Parkinson's research.[8] Speaking a language other than that in which the trial has been designed raises several complex and unique challenges that may not be fully appreciated by scientists in study design. These challenges can raise complex Institutional Review Board (IRB) issues that are not encountered in the inclusion of other underrepresented groups and need to be understood early in study design. For example, there is no requirement for any change to a consent form based on race or ethnicity. Yet, incorporation of multiple spoken languages and/or literacy levels can require fundamental changes to trial forms and protocol, as well as determination of which languages to target and why.

In this Viewpoint, we focus exclusively on language (we do not address literacy). We summarize the confluence of factors that made inclusion of non–English-speaking participants a major challenge in SPARX3. We call for systems change (not just "trying harder") to facilitate consideration of inclusion of non–English-speaking participants from the earliest stages of trial design.

SPARX3 Experience

SPARX3 tests whether high-intensity endurance exercise slows progression in persons with PD who have not yet initiated medication for PD. The study team explicitly prioritized diverse recruitment and continues to do so. We engaged a consultant who previously studied recruitment of underrepresented groups in PD clinical trials.[6,7,10,11] Under her guidance, three hours at the kick-off meeting were devoted to rationale,

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strategies, and techniques for recruiting a diverse population. Techniques included use of quality improvement tools to identify site-specific barriers and solutions to recruitment of diverse participants. Focus was placed on the use of SPARX3 neurologists to facilitate recruitment by developing trusting relationships with local minority-serving physicians who treat patients with PD. In addition, each site was required to attend four webinar modules in coordination with ongoing individual site-specific follow-up meetings to encourage and assist recruiting.

Individuals with a first language other than English were one type of diverse participant considered for inclusion in the trial, especially because this group represents a growing percentage of the U.S. population. About 21.6% of people older than 5 years living in the United States do not speak English at home, and 8.6% are not proficient at English.[12] Considering the population most likely to suffer from PD, as of 2016, 55.6% of foreign-born individuals and 1.5% of native-born individuals aged 65 years and older spoke English less than "very well."[13] The study team planned to include non–English-speaking participants by following Health and Human Services Office for Human Research Protections (HHS-OHRP) Guidelines for National Institutes of Health (NIH)-funded clinical trials that specify the need for translation and back-translation (to verify accuracy) of the informed consent document into the participant's language.[14] Subsequent study interactions were planned to take place via an interpreter or bilingual medical staff. Unfortunately, these preparations were insufficient for several reasons, starting with the complexities encountered in differing IRB regulations.

SPARX3 is enrolling at 26 US locations via 30 IRBs and two Canadian sites. There are more IRBs than locations because some U.S. sites host one study location across multiple institutions. The local IRBs are all in reliance agreements with one central IRB. Canadian sites work with their own Research Ethics Board, each of which is independent. Initially we planned to translate and back-translate the Informed Consent Form (ICF) into Spanish for every single site and into other languages as requested by sites. However, given the $1400–$3300 per site cost of translation and the reality that some sites may not recruit any Spanish-speaking participants, the decision was made to translate the ICF only when requested by a site.

A central process was followed to coordinate and track which sites would be enrolling non–English-speaking participants. Once the English version of each site's ICF was approved by the central IRB, the SPARX3 Regulatory Specialist reached out to see if that site was planning on recruiting non–English-speaking participants. If the site indicated they were planning to recruit non–English-speaking participants, and the site's local context form (that was previously submitted) did not reflect that they would be recruiting non–English-speaking participants, the Regulatory Specialist requested the form be revised to provide these details. Early in the trial, two sites expressed interest, and two ICFs were translated into Spanish and one into Mandarin.

Additional sites planned to submit forms for translation as well. As one of these sites was preparing to screen a non–English-speaking participant, additional issues were discovered. When sites revised their local context form to state they would recruit non–English-speaking participants, they had to specify if there were local IRB guidelines and state laws governing translation. If sites had no local guidelines or laws, then they deferred to the central IRB's policy regarding recruitment of non–English-speaking participants.[15] It was then discovered that the central IRB's policy stipulated that all study materials had to be translated into the participant's language, not just the ICF. This was not foreseen by the principal investigator because the central IRB's policy differs from the HHS-OHRP Guidelines[14] and from many other IRBs. Policies for inclusion of non–English-speaking participants in clinical trials vary widely between IRBs. Federal guidance on enrollment of non–English-speaking participants in research is limited to the short HHS-OHRP guidelines, which focus exclusively on ICF requirements and govern only NIH-funded clinical trials.[14] There is no federal policy specifying how study interactions subsequent to informed consent should take place,[16] thus resulting in differing IRB policies across the United States.

Because sites following their local IRB's policies may not have had to translate all study documents, but sites deferring to central IRB policy would need to, the SPARX3 study team further investigated translation of all study materials into participant language on an as-needed basis. Unfortunately, translation of the android and iPhone special-purpose app used to interface with the Zephyr Monitor was not trivial. The Zephyr Monitor is used by participants to track heart rate, electrocardiogram data, and cadence. This would have required extensive revalidation of underlying code to ensure accurate data collection and participant security (these apps can securely upload the data to the cloud—a feature many other apps do not have). Thus, although multiple heart rate apps exist, this particular app—which does not currently exist in languages other than English—is necessary as part of the SPARX3 trial design as originally conceived and funded. The inability to translate this app represented a hard stop in enrolling non–English-speaking participants as long as there was a requirement in place that all study materials must be fully translated.

The study team is still exploring whether certain sites may be able to recruit non–English-speaking participants through differing site-specific local IRB policies

(and Research Ethics Board policies for Canadian sites), but to date, SPARX3 has not been able to include a single non–English-speaking participant. Thus, although diversity of recruitment was prioritized from inception of the trial, the inclusion of non–English-speaking participants was not considered in enough detail early enough in design to allow successful execution. By the time it became clear that the central IRB had a regulation in place requiring full study translation, it was not possible to translate the Zephyr Monitor app—an essential monitoring tool of the trial—without significant coding changes.

In retrospect, both regulatory and Zephyr Monitor app issues could have been anticipated with more careful deliberation before the start of the trial. However, the complexity that these regulatory issues put on the trial have highlighted fundamental issues pertaining to inclusivity in clinical trials that we bring to the attention of the movement disorders community. Because spoken language affects the very design of the trial in a way other identities do not, it must be considered separately and in detail during trial conception and design. In addition, there are several inherent trade-offs that must be considered and justified in the decision to include or not include non–English-speaking participants.

The Trade-Offs

There are at least two inherent trade-offs when considering inclusion of non–English-speaking participants in clinical trials in the United States. The first is between two of the ethical principles laid out in the Belmont Report:[17] respect for persons and justice. The principle of respect for persons requires that participants enter into and participate in research "voluntarily and with adequate information."[17] The principle of justice requires that the benefits and burdens of research with human participants should be shared equitably.[17] In other words, the risks of research should not be borne exclusively by one segment of society (e.g. Black men in the Tuskegee Syphilis Study[18]), and the benefits of research should not be available to just one segment of society either (e.g. an experimental potentially curative cancer drug offered in a trial that ultimately recruits almost entirely highly educated, upper-middle-class, White individuals).

Maximizing respect for persons would mean providing equitable access to all research information regardless of spoken language. In the best-case scenario, not only would all study documents be fully translated into participant language, but the entire study team would also be fluent in that participant's language. Short of that, use of an interpreter or trial staff member fluent in the participant's language for every study interaction may be adequate. This methodology has been utilized in prior trials, such as RECRUIT,[6,7] and it was the method we planned to use in SPARX3. RECRUIT was a cluster-randomized trial designed to assess approaches to recruitment of underrepresented groups into specialty clinical trials. It was layered on top of four traditional NIH-funded parent trials in cardiology (CABANA, PACES), oncology (BMT CTN), and neurology (STEADY-PD III) and took place at 50 sites across the four trials. Although the RECRUIT trial encountered significant issues regarding language and IRBs,[6] a small number of sites in posttrial qualitative interviews cited use of interpreters as a strategy to recruit and retain participants who did not speak English.[19]

The original plan to translate ICF alone (as specified by HHS-OHRP guidelines[14]) and have subsequent study interactions through an interpreter or bilingual medical staff member does not fully maximize respect for persons. However, we initially chose this approach to try and simultaneously maximize justice. With more than 7000 spoken languages in the world,[20] full translation of a research study into every language is not possible. If we picked only the most common languages and offered the study in, for example, English and Spanish, we would be maximizing respect for individuals who speak those languages, but we would be excluding everyone who does not speak one of those two languages. We chose instead to try and accommodate all spoken languages that might present, thereby maximizing both respect for persons and justice to the extent possible when considering both principles together.

There is also another trade-off that must be considered in conjunction with the first: the trade-off between justice and scientific complexity. SPARX3 was designed such that it was close to the maximum of participant burden when executed in English. It takes longer to complete a clinical visit via interpreter,[21] and thus non–English-speaking research visits also presumably take longer. If this represents undue burden on participants (e.g., 12- instead of 8-hour study visit), the protocol of the study would have to be reduced in scope. In addition, if there are scenarios in which translation and interpretation are inadequate means to convey the information needed to fulfill respect for persons and to ensure scientific validity, the protocol or even scientific question may need to be revised. For example, through one of our Canadian sites we learned that the Plains Cree language spoken by the Saddle Lake Cree Nation and Samson Cree Nation does not contain a word for Parkinson's disease. The word that best captures the disease is nanamispêciwin, which means "cannot quit shaking" or "shaking forever."[22] Conducting a study in languages that do not even have a word for Parkinson's disease raises important questions and concerns about the ability to correctly capture all of the outcome measures and may warrant revision of study protocol.

Balancing the Trade-Offs: A Hypothetical Example

Realizing that the very definition of a trade-off is that both principles cannot be maximized, we have considered ways in which we might have designed SPARX3 differently from the beginning. One option would have been to run a much simpler study: fewer outcome measures (perhaps just the primary outcome measure, which is the key measure in a phase 3 clinical trial), less participant burden, and less complexity in translation. This would possibly have allowed a study run across 28 locations to maximize justice through accommodating any language that presented, so long as the IRB regulations allowed for our original plan to translate ICF accompanied by interpreters or bilingual medical staff for every study interaction.

However, if we wanted to keep the current level of scientific complexity, this solution would not work. Rather, perhaps we could have had certain sites in areas with a high concentration of a language other than English designated to offer the study entirely in that language (full translation of study materials and study staff fluent in the language). Such a paradigm has been implemented in Parkinson's Study Group–approved trials.[5,23] Such specialization would maximize respect for persons who speak *that* language in *that* location, but it would not help with making the benefits and burdens of this study available to all possible participants throughout the United States.

To help maximize justice in this scenario, perhaps we could have additionally designated one or two sites able to accommodate any language. These sites would need to have been located at an IRB that allows translation of ICF alone because full translation of the study into multiple languages that present themselves over the course of recruitment is logistically not possible. Participants who presented at a site that was neither fluent in their language nor able to accommodate any language could have been given the option to be transported to one of the specialized sites that could have accommodated any language.

Proposed Solutions to Increase Inclusion of Non–English-Speaking Participants in Research

Beyond this hypothetical example of how SPARX3 could have been designed differently to prioritize non–English-speaking participants, we suggest the following four systemic changes for United States-based trials that would help avoid the situation in which we found ourselves: unable to enroll a Spanish-speaking participant despite having every intention of doing so.

1. **Earliest possible opportunity to consider justice:** Although the IRB application will ask an investigator whether they plan to enroll non–English-speaking participants, this prompt is too late in the study design process to affect true inclusion of non–English-speaking participants. Most investigators in the United States obtain IRB approval postfunding and in the case of large-scale clinical trials, this can take well over a year. As such, unless explicitly identified in funding announcements, consideration of spoken language can easily escape even the most diligent investigator. This becomes crucially important because recruiting non–English-speaking participants requires specific budgetary considerations that need to be considered a priori.
   Rather, we must create a system that embeds consideration of justice—of making the burdens and benefits of research available to all—into the earliest phases of trial design. Especially because the decision to include more than one spoken language may alter the very design and science of the trial, this is the phase at which it must be considered. This could be supported by NIH planning grants that emphasize consideration of justice. Grant agencies could offer consultation services similar to those offered by the Community Access, Recruitment and Engagement Center at Massachusetts General Hospital[2] to assist investigators in planning the details of recruitment of underrepresented groups. Such resources would inform local principal investigators of the myriad issues involved, mitigate the need to reinvent the wheel across the United States, and begin to build the skills needed for recruitment of non–English-speaking participants in the next generation of investigators.
2. **Weigh trade-offs explicitly:** As we have hopefully demonstrated, it is easy to say one wants to enroll non–English-speaking participants and much harder to accomplish this in reality. We need to create a culture in which we can honestly and openly weigh trade-offs between ethical and scientific principles. Only a handful of Parkinson's trials list language as an inclusion or exclusion requirement.[24,25] Trials should a priori plan for whether they will (a) specifically seek to enroll these participants, (b) accommodate them if they present, (c) make site-dependent decisions, or (d) exclude them. The trade-offs we have laid out should be explicitly explored and justified in study protocols. Only by exploring this in each future study will we move closer to a consensus on scenarios in which it might be prudent to exclude non–English-speaking participants and scenarios in which it is societally and scientifically essential to include such participants.
3. **Regulatory consistency:** Currently, multisite trials remain caught between variation in local and central

IRB policy. We suggest creation of a national policy that extends beyond the current minimal HHS-OHRP guidelines.[14] We suggest this policy specify translation of ICF at minimum and mandate use of interpreters or bilingual medical staff for all study interactions. Such a policy might also define a formal rubric for balancing the trade-offs we have identified. This would ensure all IRBs would issue the same guidance regarding enrollment of non–English-speaking participants. Going one step further, use of a central IRB that is followed by all sites would minimize the regulatory burdens in attempting to enroll non–English-speaking participants across multiple sites, as well as simplify many other aspects of multicenter trials.

4. **Funding:** Recruitment of non–English-speaking participants into clinical trials takes more administrative acumen, time, and funding than recruiting English-speaking participants. Grant agencies must fund the extra expenses. Entities holding copyright on research assessment tools could be incentivized to provide these tools in multiple languages. In addition, recruitment of non–English-speaking participants may also require reduction in scientific complexity. Grant review panels must value the benefits of more simply designed trials that prioritize justice over scientific complexity. This may require a reconsideration of what it means for a study to be innovative, one of the major criteria for review of NIH grants.

Call for Systemic Change

Despite federal law protecting the legal right to culturally and linguistically appropriate medical services for individuals with limited English proficiency,[26,27] studies have shown medical interpreters are underused in clinical settings.[28] Given federal guidance on inclusion of non–English-speaking participants in clinical trials is even sparser,[14] it has become clear that measures are not routinely being taken to include participants with limited English proficiency in clinical trials.[9] By including individuals who speak different languages in clinical research, we include individuals of different identities and ancestries. Yet, language presents a unique consideration among other identities. This is because inclusion of individuals who speak languages other than that in which a trial was designed requires fundamental alterations in trial design at the level of the study protocol, not just in recruitment strategy.

After discovering the complexities of recruiting non–English-speaking participants into a trial examining a potentially disease-modifying[29,30] therapy for PD, we have proposed four systemic changes that would facilitate the inclusion of non–English-speaking participants into clinical trials. First, inclusion of non–English-speaking participants in service of maximizing justice must be considered from the very earliest phases of trial design. Second, the inherent trade-offs between respect for persons versus justice and between scientific complexity versus justice must be weighed explicitly. Third, a national policy that goes beyond the existing HHS-OHRP regulation[14] to facilitate inclusion of non–English-speaking participants into research studies along with centralization of IRB duties is needed. Finally, we suggest that the work needed to include diverse individuals into research studies must become part of research machinery and funding if it is ever to be accomplished. To borrow a quote from the quality improvement literature: "Every system is perfectly designed to get the results it gets."[31] If we want to increase enrollment of diverse participants, we have to change the system. ■

Data Sharing

Data sharing is not applicable to this article because no datasets were generated or analyzed during the study.

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References

1. Gilbert RM, Standaert DG. Bridging the gaps: more inclusive research needed to fully understand Parkinson's disease. Mov Disord 2020;35(2):231–234. https://doi.org/10.1002/mds.27906
2. Siddiqi B, Koemeter-Cox A. A call to action: promoting diversity, equity, and inclusion in Parkinson's research and Care. J Parkinsons Dis 2021;11(3):905–908. https://doi.org/10.3233/jpd-212593
3. Healy DG, Falchi M, O'Sullivan SS, et al. Phenotype, genotype, and worldwide genetic penetrance of LRRK2-associated Parkinson's disease: a case-control study. Lancet Neurol 2008;7(7):583–590. https://doi.org/10.1016/s1474-4422(08)70117-0
4. López de Munain A, Martí Massó JF, Pérez TJ. The discovery of the Dardarin gene 15 years later: a globalized local history. Mov Disord 2020;35(4):708. https://doi.org/10.1002/mds.27969
5. Pramipexole in levodopa-treated Parkinson disease patients of African. Asian, and Hispanic heritage. Clin Neuropharmacol 2007; 30(2):72–85. https://doi.org/10.1097/01.wnf.0000240943.59617.4c
6. Tilley BC, Mainous AG 3rd, Amorrortu RP, et al. Using increased trust in medical researchers to increase minority recruitment: the RECRUIT cluster randomized clinical trial. Contemp Clin Trials 2021;109:106519. https://doi.org/10.1016/j.cct.2021.106519
7. Tilley BC, Mainous AG 3rd, Smith DW, et al. Design of a cluster-randomized minority recruitment trial: RECRUIT. Clin Trials 2017; 14(3):286–298. https://doi.org/10.1177/1740774517690146

8. Sanchez AV, Ison JM, Hemley H, et al. Designing the fostering inclusivity in research engagement for underrepresented populations in Parkinson's disease study. Contemp Clin Trials 2022;115:106713. https://doi.org/10.1016/j.cct.2022.106713
9. Alhalel J, Francone N, Post S, O'Brian CA, Simon MA. How should representation of subjects with LEP become more Equitable in Clinical Trials? AMA J Ethics 2022;24(4):E319–E325. https://doi.org/10.1001/amajethics.2022.319
10. Amorrortu RP, Arevalo M, Vernon SW, et al. Recruitment of racial and ethnic minorities to clinical trials conducted within specialty clinics: an intervention mapping approach. Trials 2018;19(1):115. https://doi.org/10.1186/s13063-018-2507-9
11. Tilley BC, Mainous AG 3rd, Elm JJ, et al. A randomized recruitment intervention trial in Parkinson's disease to increase participant diversity: early stopping for lack of efficacy. Clin Trials 2012;9(2):188–197. https://doi.org/10.1177/1740774512436881
12. US Census Data. Detailed Languages Spoken at Home and Ability to Speak English for the Population 5 Years and over: 2009-2013. Updated Nov 30, 2021. Accessed December 20, 2021. https://www.census.gov/data/tables/2013/demo/2009-2013-lang-tables.html
13. Roberts A, Ogunwole S, Blakeslee L, Rabe M. The Population 65 Years and Older in the United States: 2016. United States Census Bureau. https://www.census.gov/content/dam/Census/library/publications/2018/acs/ACS-38.pdf
14. Office for Human Research Protections. Informed Consent of Subjects Who Do Not Speak English. Updated 1995. Accessed December 20, 2021. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/obtaining-and-documenting-infomed-consent-non-english-speakers/index.html
15. Human Research Protection Office. University of Pittsburgh. Non-English Speaking Participants Updated April 2021;26. https://www.hrpo.pitt.edu/non-english-speaking-participants
16. Chadwick GM, Lisa. CITI MODULE: Consent with Subjects Who Do Not Speak English 2016; Updated Jan 2018.
17. Commission T. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. 1978.
18. The U.S. Public Health Service syphilis study at Tuskegee. Centers for Disease Control and Prevention. Updated April 22 June 16, 2022;2021. https://www.cdc.gov/tuskegee/index.html
19. Investigators R. Unpublished Communication Regarding Manuscript in Progress. 2022.
20. Ethnologue: Languages of the World. Twenty-fifth edition. SIL International. http://www.ethnologue.com
21. Fagan MJ, Diaz JA, Reinert SE, Sciamanna CN, Fagan DM. Impact of interpretation method on clinic visit length. J Gen Intern Med 2003;18(8):634–638. https://doi.org/10.1046/j.1525-1497.2003.20701.x
22. Personal E-mail Communication between Dr. Daniel Corcos and Dr Kelvin Jones 2022.
23. Schwarzschild MA, Ascherio A, Casaceli C, et al. Effect of urate-elevating inosine on early Parkinson disease progression: the SURE-PD3 randomized clinical trial. JAMA 2021;326(10):926–939. https://doi.org/10.1001/jama.2021.10207
24. Pahor M. Molecular Tranducers of Physical Activity Consortium (MoTrPAC) - Adult Updated Apr 18, 2019.
25. Tanner CM, Cummings SR, Schwarzschild MA, et al. The TOPAZ study: a home-based trial of zoledronic acid to prevent fractures in neurodegenerative parkinsonism. NPJ Parkinsons Dis 2021;7(1):16. https://doi.org/10.1038/s41531-021-00162-1
26. Executive Order 13166--improving access to services for persons with limited English proficiency. Fed Regist2000; 65(159):50121–50122.
27. Title VI, 42 USC §2000d et seq (2016).
28. Hsieh E. Not just "getting by": factors influencing providers' choice of interpreters. J Gen Intern Med 2015;30(1):75–82. https://doi.org/10.1007/s11606-014-3066-8
29. Ahlskog JE. Does vigorous exercise have a neuroprotective effect in Parkinson disease? Neurology 2011;77(3):288–294. https://doi.org/10.1212/WNL.0b013e318225ab66
30. Schenkman M, Moore CG, Kohrt WM, et al. Effect of high-intensity treadmill exercise on motor symptoms in patients with De novo Parkinson disease: a phase 2 randomized clinical trial. JAMA Neurol 2018;75(2):219–226. https://doi.org/10.1001/jamaneurol.2017.3517
31. IHI Multimedia Team. Like Magic? ("Every system is perfectly designed…"). 2021.

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