The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard Bioethics Collaborative

Tuesday, June 29, 2021 | 2:00PM-4:00PM ET
Virtual Meeting

Limited English Proficiency and Translation of Study Materials
Meeting Summary

Introduction

Limited English proficiency (LEP) refers to a limited ability to read, speak, write, and/or understand English. Approximately 60 million individuals in the United States (US) do not speak English, and an additional 25 million people may be defined as LEP.[1]

The MRCT Center recently executed a systematic review of the language requirements in the eligibility criteria of clinical trials in ClinicalTrials.gov. Of all interventional clinical trials for adults with at least one site in the US and registered between 1/1/2019 and 12/1/2020, approximately 19% required the ability to read, write, and/or speak English or be a native English speaker. Some English language requirements may be scientifically justified, such as when a study uses an outcome measure that is only validated in English, but most trials requiring proficiency in English fail to justify the eligibility criterion. As such, exclusion in the absence of justification raises ethical issues.

Individuals who are excluded from research on the basis of language are unfairly prevented from having the opportunity to participate in research and accessing the potential benefits of research participation. Importantly, the exclusion of individuals with LEP may limit the generalizability and applicability of the research and contribute to health inequities. Eliminating English language requirements, however, would necessitate other safeguards (e.g., translation and interpreter services) to ensure informed and voluntary consent and maintain participant safety, and these safeguards may delay and add to the expense of research. Bioethics Collaborative attendees convened to discuss how research stakeholders should balance ethical responsibilities (i.e., ensuring fair access to research and scientific generalizability) and practical constraints (i.e., the expense and delay of safeguards to ensure informed consent and maintain participant safety) to overcome the exclusion of individuals with LEP from research.

Issues of Justice

A principle of justice is the equitable selection of participants who should have the opportunity to choose whether or not to volunteer, to potentially benefit from access to interventions not available elsewhere, to access other potential benefits (e.g., ancillary medical care), and to

contribute to their community and society. As a principle of autonomy, individuals should be able to decide for themselves whether to participate in research.

Since English language is not a biological variable, some skepticism exists as to whether exclusion will inhibit generalizability of the research. The countervailing argument is that language proficiency is a social determinant of health and may be a poor surrogate for other variables. Further, responses to behavioral interventions may correlate with cultural factors and thus with language.

Regulatory Perspectives

The Common Rule[2] and FDA regulations[3] require that Institutional Review Boards (IRBs) review research to ensure the equitable selection of study participants. Neither set of regulations, however, explicitly address language requirements as influencing equitable selection of study participants. Here we distinguish people whose preferred language is other than English from people who communicate in English but who have difficulty understanding, reading, or writing the language. For discussions of translation, we focus on the former.

The Common Rule[2] allows the use of a "short form" written consent document as an alternative consent process, and FDA guidance[3] associates use of the short form with the accommodation of individuals with LEP in research. When an individual with LEP is unexpectedly encountered during the enrollment process, the individual may be enrolled in research as long as the elements of informed consent are presented orally in a language understood by the individual and the individual signs the short form written consent document, a document in their preferred language, that attests that the elements of informed consent were presented orally.[2,3] However, the Common Rule and FDA guidance do not specify the situations in which it is appropriate to obtain consent for research using the short form. In particular, the regulations place no restrictions on short form usage on the basis of risk; short forms may be used to obtain consent for any type of research, including high-risk interventional studies. Attendees questioned whether it would be more appropriate to titrate short form use to research risk and/or to the sporadic participant who speaks a different language for whom there is no time to translate the long form consent.

Once an individual consents using the short form, the Common Rule[2] requires that researchers provide the individual with a written summary of the information that was presented to them orally. Guidance from the Office for Human Research Protections (OHRP) states that "the IRB-approved English language informed consent document may serve as the summary."[4] How this is accomplished in languages other than English in the absence of translation, or whether the English language informed consent document is considered sufficient for someone who does not speak English, is not clear.

Beyond the short form requirements, regulatory documents lack clear direction on translation of informed consent materials for research. One attendee suggested that codifying a requirement to translate informed consent materials for research would provide FDA and OHRP with an enforceable standard and minimize the variability in institutional and IRB policies regarding translation. Regulatory text could require translation of the informed consent materials in situations in which individuals who do not understand English are anticipated to enroll in the research but carve out certain situations in which translation is less or not necessary (e.g., a one-time skin biopsy with no participant follow-up) and in which a translated written consent document would not add meaningfully to the protection of participants.

IRB Perspectives

Since the IRB always reviews and approves the English versions of the study materials first, the translation and approval of study materials in other languages lags behind the English version. Some research ethics boards in Canada require members to possess some level of proficiency in both English and French, and some provinces require dual versions of the study materials. Attendees considered the idea that IRBs in the US, and perhaps members of the wider medical community generally (such as medical students and physicians), should possess some level of proficiency with English *and* Spanish given the prevalence of Spanish in the US population. The bilingual capacity may be harder to implement in the US, a country with no designated federal language, and impossible to require other than through the law. Nevertheless, IRBs in the US may be able to learn from the processes employed by Canadian research ethics boards to develop and maintain multi-lingual capacity.

The discussion on the (lack of) linguistic capabilities of IRBs in the US highlighted another issue raised by IRB review of translated materials. IRB members often lack the ability to understand and review translated materials; submitting these materials for IRB review often delays the accommodation of individuals with LEP without adding meaningfully to the protection of research participants. To make the review process more efficient, IRBs could provide investigators with a list of certified translation services and simply receive a copy of the certified translated documents without an expectation to review and approve. While there is room to improve the efficiency of IRB review of translated materials, it was clear to attendees that IRBs cannot abrogate their duty to ensure the accurate translation of study materials. Without an appropriate policy, investigators may rely on free online translation services that produce unreliable and inaccurate translations.

Developing and instituting policies to expedite the review of translated materials will take time. IRBs can improve immediately, however, by carefully reviewing eligibility criteria for language requirements and interrogating the basis of exclusionary language requirements. Ideally, IRBs would have access to data on the languages used in a community and the languages used in a research population as well as guidance on how to analyze language requirements in light of these data.

The Importance of Proactive Planning for Sponsors and Sites

Proactive planning is important to the accommodation of individuals with LEP in research. Constraints on the timeline for a research study make it challenging to translate study materials in a timely manner once a study has started enrolling participants.

Attendees offered recommendations for proactive planning to accommodate individuals with LEP in research. Sponsors could use a linguistic map to obtain a baseline understanding of the languages used in an area, and they should ask clinical trial sites about the languages used by the population at the site. Sponsors should ask sites about their capacity to accommodate all languages, including Spanish, and consider how the study timeline affects the accommodation of individuals with LEP. When selecting sites, vendors (e.g., companies that coordinate participant travel, provide mobile technologies for research, and recruit participants), and outcome measures, sponsors should consider the diversity of languages offered.

Despite proactive planning, there is always the potential that an individual who is proficient in an unanticipated non-English language will seek enrollment in a research study, and it remains unclear how to balance ethical responsibilities and practical constraints in this situation. The decision to translate materials to an uncommon language often depends on how close the study is to completing enrollment, the expected scientific value added by including the individual in research, and the variable practices and institutional cultures at study sites.

Conclusion

Providing equitable access to research is a responsibility shared by sponsors, sites, CROs, IRBs, investigators and others. Attendees identified a set of expectations to which various parties in research can hold themselves and others accountable to increase research access for individuals with LEP.

- Expectations of sites
    - Collect community and disease-specific data on the languages used by the population at a site
    - Have available interpreters or interpreter services who are familiar with research
- Expectations of vendors
    - Provide products and services in a diverse range of non-English languages
- Expectations of IRBs
    - Review language requirements in eligibility criteria
- Expectations of sponsors
    - Translate study materials if a site requests it
    - Provide study materials in Spanish unless it can be reasonably assumed that individuals who are proficient in Spanish will not enroll in a study

These expectations primarily focus on the translation of study materials. While important, the translation of study materials is only one measure to accommodate individuals with LEP in research. The Bioethics Collaborative concluded with recognition of the fact that additional action is needed to provide individuals with LEP with fair access to research and a positive and safe experience once enrolled in research, such as making language-concordant study staff or interpreter services available during the informed consent process and during an individual's research participation.

Potential Future Work

- Summarize:
  - The lack of clarity in the regulations on the use of the short form;
  - The situations in which it is appropriate and inappropriate to consent an individual to research using the short form; and
  - Provide guidance on use of the short form
- Contact research ethics boards in Canada and elsewhere (e.g., South Africa, the European Union) to gauge best practices for developing the capacity to review study materials in multiple languages.
- Draft a list of recommendations to encourage the accommodation of individuals with LEP in research

Reference List

1. Betancourt JR, Renfrew MR, Green AR, et al. Improving patient safety systems for patients with limited English proficiency: a guide for hospitals. (Prepared by the Disparities Solutions Center, Mongan Institute for Health Policy at Massachusetts General Hospital and Abt Associates, Cambridge, MA, under Contract No. HHSA290200600011I). Rockville, MD: Agency for Healthcare Research and Quality; July 2012. AHRQ Publication No. 12-0041. September 2012.

2. Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R § 46 (2020).

3. A Guide to Informed Consent. U.S. Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guide-informed-consent. Published January 21, 2020. Accessed July 15, 2021.

4. Lin M. Informed Consent of Subjects Who Do Not Speak English. HHS.gov. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/obtaining-and-documenting-infomed-consent-non-english-speakers/index.html. Accessed August 3, 2021.