Limited English Proficiency, Informed Consent, and Clinical Trials

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Abstract

Ample literature acknowledges language barriers in standard care of practice. However, there is an acute shortage of research on communication barriers during the informed consent process in clinical trials. To contribute to the growing need to address Limited English Proficiency (LEP) in health care, a qualitative case study was used to explore communication methods and the understanding of LEP guardians of pediatric patients while participating in the informed consent process during clinical trials. Five principal investigators with diverse medical backgrounds, nine LEP Spanish speaking guardians, and five interpreters from the Language Assistance Program at a North Texas Research Institution (NTRI) participated in the study. Four major themes impacting decision making emerged: (a) the influence of physician and principal investigator as authority figure, (b) communication challenges including emotional involvement and verbal and non-verbal language, (c) cultural awareness and sensitivity including religious or spiritual beliefs and country of origin, and (d) level of education. A significant finding of the study was the importance of the inclusion of LEP participants’ country of origin and recognition of various dialects to mitigate communication barriers; the ability to speak Spanish was not enough. In addition, LEP guardians’ previous knowledge and/or experiences with clinical trials in their country of origin influenced their understanding of participation. The findings of this study support the literature on communication and language barriers in the healthcare system.

Future studies in the areas of communication between principal investigators and phase I oncology patients will address patients understanding about research participation applying social constructivism theory. In addition, a review of the current literature related to clinical trial participation and the informed consent process.

Keywords: informed consent process, clinical trials, communication barriers, Limited English Proficiency, cultural competency, health literacy