



ITHS

Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

NED 2020

Networking to Enhance Development

A Conference By and For Research Coordinators

iths.org/ned2020

Inclusiveness from Theory to Application: Enrolling Research Subjects with Limited English Proficiency

Kelly J. Shipman, MS, CCRP
Clinical Research Coordinator
Bioethics and Palliative Care Program
Seattle Children's

Disclosures

-No financial disclosures

-I am white, female, have an advanced degree,
and part of a dominant culture

-I am not an expert in this topic, but I have some
lessons to share

ACTIVITY: In no more than 3 words, describe your experience or impression of involving subjects with Limited English Proficiency in research

Learning Objectives

- 1 Identify two ways to address inclusiveness in research from a regulatory perspective
- 2 List two strategies to employ when engaging participants in research who have Limited English Proficiency (LEP)

Background and Rationale

“Have a very good reason for everything you do.”

-Laurence Olivier

Definition

Limited English Proficiency (LEP)

Anyone above the age of 5 who reported speaking English less than “very well” (U.S. Census Bureau)

Background

LEP Population in the U.S.

- ▶ Total population of U.S. (2018): 327 million, 31 million born outside country
- ▶ In 2018, 21.9% of U.S. spoke language other than English at home
- ▶ 4.4% of households were limited English-speaking
- ▶ Spanish most common language spoken at home, other than English (followed by other Indo-European, Asian & PI, other)

The Problem

Despite the millions of people in the U.S. with LEP, there has been historic underrepresentation of subjects with LEP in research





NED 2020

Networking to Enhance Development

ITHS

Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

“Dark and difficult times lie ahead. Soon we must all face the choice between what is right and what is easy.”

-Harry Potter and the Goblet of Fire

ITHS

Institute of **Translational** Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Rationale for Inclusion of LEP subjects

Why this is important - Disparities

- ▶ Disparities exist in quality of healthcare provided to diverse patients and families
 - ▶ LEP and/or low health literacy has been associated with poorer health outcomes among Latinos, Asian Americans, and other ethnic minorities in the U.S. (Sentell and Braun 2012)
 - ▶ Health disparities linked to access to care barriers and other socioeconomic determinants of health (Avilés-Santa 2017)
- ▶ Advances in biomedical research were developed with highly selected patient populations – not representative
 - ▶ Much unknown about variations in disease course and therapy response among diverse individuals

Rationale for Inclusion of LEP subjects

Why this is important - Ethics

- ▶ Make research more generalizable
- ▶ Include all subjects otherwise eligible – principle of justice (Resnik 2006)
- ▶ Subject selection to be equitable, with respect for persons
- ▶ Exclusion would violate Title VI of Civil Rights Act (no discrimination under federally-funded activities)
- ▶ Exclude subjects with LEP only with sound scientific or ethical reason
- ▶ Intention may not to be *exclusive*, but efforts may not be made to be *inclusive*



NED 2020

Networking to Enhance Development

ITHS

Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Questions, Comments?

ITHS

Institute of **Translational** Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Barriers to enrollment of LEP subjects

What stops patients

- ▶ LEP population more likely than others to experience these barriers
 - ▶ Patient mistrust of research due to historical and current discrimination
 - ▶ Limited health literacy
 - ▶ Costs to patients
 - ▶ Physician attitude toward patient adherence to protocol

Barriers to enrollment of LEP subjects

What stops us

- ▶ Study budgets (translation and interpretation costs)
- ▶ Lack of bilingual personnel to assist with recruitment and retention
- ▶ Physician lack of awareness of clinical trials
- ▶ Health care system failing to address patients' informational needs at appropriate language and health literacy levels (Livaudais-Toman 2014)



NED 2020

Networking to Enhance Development

ITHS

Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Questions, Comments?

ITHS

Institute of **Translational** Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

What would you do?

You talked with your team and identified two potentially eligible subjects for your study. Per study eligibility, you are permitted to enroll subjects with LEP. One subject speaks English primarily and the other does not.

What would be different and what would be the same about each approach?

What sort of barriers might you face in your role when it comes to the recruitment of the patient with LEP?

Lessons Learned

“I’ve learned that I still have a lot to learn.”

-Maya Angelou

Translation and Interpretation

- ▶ Study budgets can be limited
- ▶ Budget in translation costs up front - tough to add in later
- ▶ Translation: text, Interpretation: oral
- ▶ Fixed costs based on institutional costs
- ▶ Sponsors can require supporting documents for translation services
- ▶ Payment agreement for interpreters

Translation and Interpretation

- ▶ Example of document translation costs:
 - ▶ 24 pages initially translated into Spanish (consent, door sign, info sheet, assent, survey): \$653.79
 - ▶ 11 pages initially translated into Vietnamese (consent): \$581.72
 - ▶ Minor document revisions in Spanish and Vietnamese: \$460.08
- ▶ Someone on research team may check translations for accuracy, which may require more communication with translation company

Informed Consent

Follow the regulations & guidance

- ▶ Federal regulations and guidance: Consent must be understandable to subject or representative
- ▶ Local policies (i.e., IRB)
- ▶ Short form: placeholder until full consent can be translated
 - ▶ <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/obtaining-and-documenting-informed-consent-non-english-speakers/index.html>
- ▶ Even with a consent in the patient's language, consent forms still difficult to interpret/understand!
- ▶ Someone on team may check translations to ensure clarity

Collaboration

- ▶ Partner with interpreters and patient navigation early on in your study
- ▶ If using in-person interpreter, schedule at least 1 day in advance
- ▶ Meet interpreter outside of room, provide context and explain purpose of conversation
- ▶ State no more than 20 words at a time for interpretation – will increase the odds of understandability, due to fewer interpreter alterations (Sinow 2017)
- ▶ Interpreters should interpret exactly what you say – if elaborating, it is OK to course correct
- ▶ May use video or phone interpreter if allowed per protocol and/or IRB policy



NED 2020

Networking to Enhance Development

ITHS

Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Questions, Comments?

ITHS

Institute of **Translational** Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Approaches

- ▶ Partner with people who have expertise – interpreters, patient navigators
- ▶ Clear and simple communication, respect for people's time
- ▶ Ask if they know what research is
- ▶ Explain what research is and what it isn't
 - ▶ Use example of research on something simple (i.e., Tylenol)
- ▶ Emphasize voluntariness and difference from clinical care
- ▶ Normalize choice to say “Yes” or “No”

Approaches

- ▶ My positionality: White, female, English speaking (monolingual), part of medical community
 - ▶ Why should they trust me?
- ▶ Try to establish rapport, show respect by
 - ▶ Ask permission to be in their lives for a bit
 - ▶ Explaining simply, yet thoroughly, what you are offering
 - ▶ Checking in often to assess understanding
 - ▶ Acknowledge others in room
 - ▶ Make study as easy as possible to participate in
- ▶ Bias is inherent – important to recognize this in ourselves!
 - ▶ How does bias influence our interactions with potential research participants?

Approaches

- ▶ One page sheet of basic study points
- ▶ How to ensure comprehension?
 - ▶ Ask for questions/concerns throughout consent process
 - ▶ Explain study, leave consent, come back for another conversation
 - ▶ LEP approaches have made me think about my English language approaches – what assumptions am I making?
- ▶ Culturally, some LEP patients feel they have to say “Yes” to provider recommendations, including research
 - ▶ How to separate independent decision to participate in research?
 - ▶ Trust in patients’ ability to ask questions, express concerns, and say “No”



NED 2020

Networking to Enhance Development

ITHS

Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Questions, Comments?

ITHS

Institute of **Translational** Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.



NED 2020

Networking to Enhance Development

ITHS

Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

ACTIVITY!

ITHS

Institute of **Translational** Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Simple Approaches

How would you simplify this language?

“You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.”

Simple Approaches

How would you simplify this language?

“You should know that if you are assigned to receive the experimental treatment, we cannot guarantee that it will be as effective as the standard treatment.”

Simple Approaches

How would you simplify this language?

“The scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities.”

Simple Approaches

How would you simplify this language?

“Federal regulations require that all subjects be informed of the availability of medical treatment or financial compensation in the event of physical injury resulting from participation in the research.”

Simple Approaches

How would you simplify this language?

“This research may include the collection of the following biospecimens: blood, saliva. This research includes whole genome sequencing of these biospecimen samples. Whole genome sequencing is the process of determining your complete DNA makeup.”

Simple Approaches

How would you simplify this language?

“Routine Clinical Trial Procedures (these include exams, tests, or procedures that are needed to administer the bevacizumab, monitor the effects of the bevacizumab, and prevent or treat complication):”

Simple Approaches

How would you simplify this language?

“We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.”

Tell us!

What additional suggestions do you have for successful recruitment and enrollment of subjects with LEP?

What will you do?

**What is one thing you can commit to, going forward,
to involve subjects with LEP in your research?**

“It is our choices, Harry, that show what we truly are, far more than our abilities.”

-Harry Potter and the Chamber of Secrets



NED 2020

Networking to Enhance Development

ITHS

Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Thank You

Acknowledgments!

Amy Trowbridge

Jori Bogetz

Arika Patneau and the Seattle Children's Palliative Care team

Juan Kraus, *in memoriam*

Patty Hencz

Emelina Diaz Wiley and the Interpreter Services staff @ SCH

Blanca Fields, Alicia Adiele, and the Patient Navigation staff @ SCH

The staff and faculty @ SCH Bioethics & Palliative Care program

Hanna Schlaack

Laura Sotelo Guerra

Aric Lane and the NED organizers

References

1. Resnik DB and Jones CW. Research Subjects with Limited English Proficiency: Ethical and Legal Issues. *Account Res.* 2006 Apr-Jun; 13(2): 157-177.
2. U.S. Census Bureau, 2018. American community survey 1-year estimates. Available from https://data.census.gov/cedsci/all?q=Language%20Spoken%20at%20Home&intcmp=aff_cedsci_banner&g=&t=Language%20Spoken%20at%20Home&hidePreview=false&table=S1601&tid=ACSST1Y2018.S1601&lastDisplayedRow=14. Accessed Jan 2, 2020
3. Avilés-Santa ML, Heintzman J, Lindberg NL et al. Personalized medicine and Hispanic health: improving health outcomes and reducing health disparities – a National Heart, Lung, and Blood Institute workshop report. *BMC Proceedings* 2017; 11(Suppl 11):11
4. Sentell T and Braun K. Low Health Literacy, Limited English Proficiency, and Health Status in Asians, Latinos, and Other Racial/Ethnic Groups in California. *J Health Comm.* 2012;17(Suppl 3): 82-99.
5. Livaudais-Toman J, Burke NJ, Napoles A, Kaplan CP. Health Literate Organizations: Are Clinical Trial Sites Equipped to Recruit Minority and Limited Health Literacy Patients? *J Health Dispar Res Pract.* 2014; 7(4): 1-13.
6. Sinow CS, Corso I, Lorenzo J, Lawrence KA, Magnus DC, Van Cleave AC. Alterations in Spanish Language Interpretation During Pediatric Critical Care Family Meetings. *Crit Care Med.* 2017 Nov; 45(11); 1915-1921.
7. Fisher-Borne M, Cain J, Martin SL. From Mastery to Accountability: Cultural Humility as an Alternative to Cultural Competence. *Social Work Education* 2015; 34(2): 165-181.



ITHS

Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

NED 2020

Networking to Enhance Development

A Conference By and For Research Coordinators

iths.org/ned2020