

INCLUSION OF NON-ENGLISH SPEAKERS IN CLINICAL RESEARCH

**Judith Bernstein, RNC, PhD
Edward Bernstein, MD
BUSM / BUSPH**



Overview

- rationale for inclusion
- study requirements
- barriers to inclusion
- strategies for addressing challenges

The rationale for inclusion....

- extensive health disparities & consequences
 - IOM report, 2003; AHRQ report, 2005
- 18% of U.S. residents age 5+ speak a language other than English at home
- 21 million people (8%) have limited English proficiency or LEP (2000 census)
- 19% have gone without care when sick because of lack of interpreter (RWJ survey, 2002)
- failure to include this population in research
 - impairs generalizeability of research findings

Exclusion of research is discrimination

 The principle of justice requires that both the burdens and benefits of research should be applied uniformly CLAS standards (12/00) and federal OCR guidance define exclusion from research as a form of discrimination related to national origin, governable under Title VI of the Civil Rights Act of 1968

Non-English-speaking (NEP) and Limited English-speaking Persons (LEP) are routinely excluded....

- Survey of researchers (n=172)
- 40% of authors excluded LEP enrollees
- Enrollment rate for LEPs 22%
 - Issue not ever considered
 - translation concerns
 - staffing problems
 - no potential LEP subjects

Frayne SM, et al. Exclusion of non-English speaking persons from research. J Gen Intern Med 1996;11:39-43.

Quality of Research Participation

- enrollment without ensuring complete comprehension

compromises

- autonomy

- safety

- quality of study results

- Hiring an untrained interpreter is no solution

Clinical Consequences of Interpretation Errors

Trained Interpreters vs Ad Hoc or None

- 57 audio-transcript encounters in 2 pediatric EDs
 - 2,367 transcript pages; 61,478 lines of dialogue
- 20 trained interpreters (I); 27 ad hoc (AH); 10 none (NI)
- 1,884 interpreter errors (18% clinically significant)
 - I=12% vs AH=22% vs NI=20%
- omission errors
 - NIs=54% vs AH=47% vs I=42% ($p<.03$)

Study requirements for enrolling participants with LEP



Study design

- Will you need to modify objectives?

- i.e. to include a sub-analysis to test generalizeability

- Inclusion criteria--which languages will you include?

- If you include diverse groups

- problem of collapsing into less than useful 'other' category

- If you limit to the most common language groups

- greater validity, but loss of generalizeability

Recruitment Plan

- PI may lack familiarity with neighborhood info channels
 - media, churches, grocery stores, advocacy groups
 - community leaders, outreach workers, social workers, probation officers
- language barriers often complicated by cultural issues
 - even a study name may resist translation

Consent Generation

- consent: local IRB process
- translation/back-translation of study forms
 - cost
 - accuracy
 - dialect / idioms / country-by-country variation
 - educational level
 - level of acculturation
 - formatting

Form Validation

- validation of forms for each language and population
 - medical literacy
 - Likert scales-- the problem of precise distinctions
 - cultural variation in willingness to disclose
 - variations in expectations affect responses
(Euroquol)
- validation of standardized (normed) instruments
 - e.g: variation across race/ethnicity for CAGE

Measurement Problems

- capturing heterogeneity within minority subgroups

- How do you measure ethnicity?

- What is Hispanic? Latino(a)

- How do you measure nativity?

- What is Puerto Rican?

- How do you define LEP or primary language (criteria)

- How do you measure acculturation?

- What is primary language?

- How long have you been in the US?

Interpretation

- cost must be built into study budget
- interpreter type and availability issues
 - prn interpreter service (with study team)
 - availability, emergencies?
 - training re study procedures?
 - as regular study personnel
 - recruitment issues?
 - proficiency issues?
- enrollee literacy problems
 - oral interview vs enrollee written self-response—apples and oranges?

Challenges to generalizeability— Follow-up rates

■ follow-up begins at intake with

- relationship of respect

- explanation of the study

- valid consent

 - verify through re-statement in own terms

- extensive contact information

■ high follow-up rates are achieved with

- peer researchers trained as trackers

- cultural competence in contacts

- adequate reimbursement

Data analysis challenges— Statistical methods

- adequacy of sample size / power
 - inclusion vs over-sampling & weighting
- sample heterogeneity within racial subgroup
 - nativity, ethnicity, language, acculturation
- control for confounding factors
 - variation of lifestyle behaviors and SES with ethnicity, acculturation, and language

Consent Issues

How to guarantee the spirit of
informed consent, not just the
letter of the law.....



NCIHC Report, 10/01

- Guidance from the Office of Protection from Research Risks accepts oral presentation of consent elements
 - short written statement verifying oral presentation
 - interpreter required to be fluent in both languages
 - consent may be witnessed by the interpreter
 - English consent form must be provided to enrollee to take home

Limitations of Oral Consent

- type and quality of interpreter
- PI may be unable to monitor adherence to consent protocol
- potential for coercion--vulnerable population, especially if undocumented
- sending home materials written in English is not culturally competent—does not provide foundation for family participation in decision making

Barriers to LEP participant recruitment -- enrollee concerns

- insecurity about comprehension
- failure of trust
 - history of substandard care, misinformation
 - consider traumatized refugee status
- fear of social consequences of truth-telling, especially if undocumented
- burdens of participation, especially if low income
- unclear benefits of participation, if no sub-analysis

Can researchers comply?

Yes.....

with difficulty, but IRBs need to
play a more active support role



What guidance do our nation's IRBs offer?

30 websites, including 23 top-ranked research schools

Did the institution.....	
Explain use of short form	60%
Discuss language barriers in research	53%
Provide guidance on use of interpreters	40%
Discuss ethical/legal problems re LEP	20%
Discuss problems related to exclusion	17%
Offer guidance for translating forms	7%
Define 'expected' or 'anticipated' enrollment	0%

Resnik DB, Jones C. Research subjects with limited english proficiency: ethical and legal issues. *Accountability in Research* 2006;13:257-277.

RESOURCE

 Jacobs E, Alvarado-Little, Hardt E. Recommendations for the ethical involvement of limited English speakers in research. National Council on Interpreting in Health Care, 2001. Accessed at <http://www.ncihc.org> 10/3/06.