INCLUSION OF NON-ENGLISH SPEAKERS IN CLINICAL RESEARCH

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Overview

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

- LEP → extensive health disparities & consequences
  - IOM report, 2003; AHRQ report, 2005
- 18% of U.S. residents aged 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%
  - Language issue not ever considered
  - Translation concerns
  - Staffing problems
  - No potential LEP subjects

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

decisions, decisions, decisions…
Study design

Will you need to modify objectives?
  i.e. to include a sub-analysis to test generalizability

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 generalizability
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.....
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
Limited to Spanish speakers, because of lack of availability of ASI in Haitian or Cape Verdean and lack of interpreters for the intervention.

Spanish speaking staff available at all times for assessment and intervention.

24% of enrollees were Spanish speaking.

4% of enrollees were of Haitian background and 4% were Cape Verdean, but they needed to be competent in English to enroll.

19% of enrollees were foreign born.
In RAP I...

- Pilot: $5,000 to translate every form into Haitian, Cape Verdean and Spanish, buying services from a Cambridge company.
- We had Spanish speaking, Haitian Creole speaking and Cape Verdean staff, but most patients were not literate in any language.
- Despite available funds and a pre-agreement, the interpreter service was not able to provide translation in a timely fashion.
- The title of the study did not translate cross culturally.
In RAP II...

We had a Spanish-speaking staff, who updated translated forms when there were changes. The consent was reviewed vigorously, but over time the forms became corrupted with Spanglish and online internet service translations.

The consent form, which had been front and back translated, remained accurate.

It was very difficult to provide quality control (adherence monitoring) of interventions that were conducted in Spanish and Haitian Creole.
In SAFE...

- Staff speak Spanish and Haitian creole, but not on all shifts.
- Opportunities have been lost for enrollment, when they are not on duty.
- We have decided not to enroll when comprehension does not meet the standard of being able to repeat the key elements of the study.
- The consent form is translated and back-translated, but other forms are not because of $
What guidance do our nation’s IRBs offer?

30 websites, including 23 top-ranked research schools

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