Recruitment and Retention of Hispanic/Latino Research Subjects

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Study Design: Case Control study
Objective: Determine if maternal atopy is a risk factor for severe bronchiolitis.
Study subjects: Mother-infant dyads; biological mother and full-term infants without significant health problems.
Predictor variables: Atopic predisposition is determined by taking the family history of atopic diseases, allergy skin testing of the infant’s mother, and infant serum IgE level when > 9 months.
Outcomes: Hospitalization, bronchiolitis severity score, and length of hospital stay.
Future: Extend cohort enrollment and follow children until age 5 years and the development of asthma.
Study Recruitment

- Inclusion / Exclusion criteria:
  - Full-term infant (37-42 weeks gestation), birth wt. > 5 lbs. and without any significant medical problems
  - Exclude infants who are at risk for severe bronchiolitis for non-genetic reasons.
  - Biological mother available
- Inpatients must have significant respiratory impairment
- Outpatients must have symptoms consistent with a URI
Nashville is Changing….

- 170% growth from 1990 to 2000!!
- Studies enrolling younger families require Spanish speaking staff.

Hispanic population in the Midstate

Davidson County gained more Hispanic residents from 2000 to 2004 than any other county in the area, and Robertson’s Hispanic population grew the fastest. Here are statistics on several counties in the greater Nashville area, ranked by increase in Hispanic population.

<table>
<thead>
<tr>
<th>County</th>
<th>Hispanic population 2000</th>
<th>Hispanic population 2004*</th>
<th>Increase</th>
<th>Growth rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davidson</td>
<td>26,091</td>
<td>35,889</td>
<td>9,798</td>
<td>37.6%</td>
</tr>
<tr>
<td>Rutherford</td>
<td>5,065</td>
<td>9,019</td>
<td>3,954</td>
<td>78.1%</td>
</tr>
<tr>
<td>Bedford</td>
<td>2,811</td>
<td>4,550</td>
<td>1,739</td>
<td>61.9%</td>
</tr>
<tr>
<td>Williamson</td>
<td>3,197</td>
<td>4,617</td>
<td>1,420</td>
<td>44.4%</td>
</tr>
<tr>
<td>Robertson</td>
<td>1,447</td>
<td>2,826</td>
<td>1,379</td>
<td>95.3%</td>
</tr>
<tr>
<td>Sumner</td>
<td>2,291</td>
<td>3,257</td>
<td>966</td>
<td>42.2%</td>
</tr>
<tr>
<td>Maury</td>
<td>2,264</td>
<td>3,081</td>
<td>817</td>
<td>36.1%</td>
</tr>
<tr>
<td>Wilson</td>
<td>1,127</td>
<td>1,917</td>
<td>790</td>
<td>70.1%</td>
</tr>
<tr>
<td>Marshall</td>
<td>767</td>
<td>970</td>
<td>203</td>
<td>26.5%</td>
</tr>
<tr>
<td>Macon</td>
<td>349</td>
<td>550</td>
<td>201</td>
<td>57.6%</td>
</tr>
<tr>
<td>Cheatham</td>
<td>437</td>
<td>631</td>
<td>194</td>
<td>44.4%</td>
</tr>
<tr>
<td>Dickson</td>
<td>484</td>
<td>667</td>
<td>183</td>
<td>37.8%</td>
</tr>
<tr>
<td>Cannon</td>
<td>157</td>
<td>264</td>
<td>107</td>
<td>68.2%</td>
</tr>
<tr>
<td>Trousdale</td>
<td>110</td>
<td>185</td>
<td>75</td>
<td>68.2%</td>
</tr>
<tr>
<td>Smith</td>
<td>200</td>
<td>261</td>
<td>61</td>
<td>30.5%</td>
</tr>
<tr>
<td>Hickman</td>
<td>222</td>
<td>275</td>
<td>53</td>
<td>23.9%</td>
</tr>
<tr>
<td><strong>Tennessee</strong></td>
<td><strong>123,838</strong></td>
<td><strong>167,025</strong></td>
<td><strong>43,187</strong></td>
<td><strong>34.9%</strong></td>
</tr>
</tbody>
</table>

* Estimated

Tennessean, 8/12/05
## Epidemiologists Like Data

### Davidson County

<table>
<thead>
<tr>
<th>SEX</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 4</td>
<td>2,989</td>
</tr>
<tr>
<td>5 to 9</td>
<td>1,951</td>
</tr>
<tr>
<td>10 to 14</td>
<td>1,402</td>
</tr>
<tr>
<td>15 to 19</td>
<td>2,427</td>
</tr>
<tr>
<td>20 to 24</td>
<td>4,221</td>
</tr>
<tr>
<td>25 to 29</td>
<td>4,084</td>
</tr>
<tr>
<td>30 to 34</td>
<td>2,997</td>
</tr>
<tr>
<td>35 to 39</td>
<td>2,101</td>
</tr>
<tr>
<td>40 to 44</td>
<td>1,386</td>
</tr>
<tr>
<td>45 to 49</td>
<td>949</td>
</tr>
<tr>
<td>50 to 54</td>
<td>643</td>
</tr>
<tr>
<td>55 to 59</td>
<td>358</td>
</tr>
<tr>
<td>60 to 64</td>
<td>226</td>
</tr>
<tr>
<td>65 to 69</td>
<td>131</td>
</tr>
<tr>
<td>70 to 74</td>
<td>106</td>
</tr>
<tr>
<td>75 to 79</td>
<td>87</td>
</tr>
<tr>
<td>80 to 84</td>
<td>38</td>
</tr>
<tr>
<td>85 PLUS</td>
<td>35</td>
</tr>
</tbody>
</table>

| ALL AGES | 26,091 | 27,998 | 30,101 | 32,417 | 34,976 | 37,796 | 39,834 | 42,088 | 44,588 | 47,348 | 50,397 |
## Nashville Study: Infant Demographics

<table>
<thead>
<tr>
<th></th>
<th>Inpatient</th>
<th>Outpatient</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boys</td>
<td>67 (54)</td>
<td>29 (47)</td>
<td>96 (52)</td>
</tr>
<tr>
<td>Girls</td>
<td>56 (45)</td>
<td>33 (53)</td>
<td>89 (48)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>67 (54)</td>
<td>25 (40)</td>
<td>92 (50)</td>
</tr>
<tr>
<td>African American</td>
<td>27 (22)</td>
<td>19 (31)</td>
<td>46 (25)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>28 (23)</td>
<td>16 (36)</td>
<td>44 (24)</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>Median (range)</td>
<td>9 (0-54)</td>
<td>13 (0-56)</td>
</tr>
</tbody>
</table>
Hispanic Subjects

- 50 classified as Hispanic
  - 8 bi-racial
  - \( \approx 34 \) Spanish Speaking
- This year Hispanics are less common (15%). (??)
- Recruitment rates 43 enrolled / 77 eligible (56%)
  - ED: 20%
  - OBS: 50%
  - PACC: 47%
  - VCH: 74%
What do I know about recruitment of Hispanic study subjects?

- Studied German
- Studied Spanish
- Worked in Chicago
- Married Javier
- Research Nurse
  - HIV clinical trials
  - Asthma cohort study
  - RSV allergy study
• Slides from the NIH -

Sex/Gender and Minority Inclusion in NIH Clinical Research

What Investigators Need to Know!
NIH Policy on Inclusion of Women & Minorities in Clinical Research

Why does NIH have this policy?
- Mandated by Congress, 1993 PL 103-43
- Ethical principal of justice and importance of balancing research burdens and benefits
Public Law PL 103-43

- Women and Minorities **must** be included in all clinical research studies
- Women and Minorities **must** be included in Phase III clinical trials & the trial must be designed to permit valid analysis
- Cost is **NOT** allowed as an acceptable reason for exclusion
- NIH to support outreach efforts to recruit and retain women, minorities, and their subpopulations in clinical studies
Instructions in PHS 398

- Section E: Human Subjects Research
  - Inclusion of Women
  - Inclusion of Minorities

- Failure to include = Return Application Prior to Review
Instructions in PHS 398

- Inclusion of Women and Minorities
  Sections **must** include:
    - Subject Selection Criteria & Rationale
    - Rationale for Any Exclusions
    - Enrollment dates (start and end)
    - Outreach Plans for Recruitment
    - Proposed Composition Using New Tables
Funding Decisions

- Applications with Unacceptable Plans cannot be funded – must revise plans!
Requirements for NIH-Defined Phase III Clinical Trial Applications

- Progress Reports need to include
  Both:
  - Enrollment Table
  - Statement in text about progress in data analyses for sex/gender and ethnicity/racial effects.
Update to NIH Policy for Inclusion

- OMB Directive 15 Issued 1997
  - Collecting Data by Self-Report:
  - Two Separate Questions
    - Question 1: Ask about Ethnicity
    - Question 2: Ask about Race WITH OPTION to select more than one racial designation
NIH Policy for Inclusion

- OMB Directive 15 Issued 1997
  - Ethnic Categories:
    - Hispanic or Latino
    - Not Hispanic or Latino
  - Racial Categories:
    - American Indian or Alaska Native
    - Asian
    - Black or African American
    - Native Hawaiian or Other Pacific Islander
    - White
FDA and Inclusion of Minorities

- The FDA agrees with the NIH.
  - However, not that aggressively.
  - FDA does not fund clinical research.
  - NDAs should demonstrate that the testing population is similar to the final market.

- Ethnic targeting of drugs requires data.
  - BiDil

- There isn’t much on the web site.
Many immigrants will consider Hispanic/Latino to be a race.

What’s a mestizo?

Being indigenous (Native American) may not be acknowledged.

Why are you collecting the data?
IRB and Consent

- Consent is a process – not a document.
- Subject needs to understand.
- To understand the process and obtain consent, Spanish language is frequently required.
  - ESL subjects may be consentable in English
  - SSL subject may NOT be consentable in Spanish.
Non-English Consent Forms

- The consent document is special, and it requires IRB approval.
  - Option 1: A translated short form and short study description.
  - Option 2: A fully translated consent form.
- What about the sponsor?
  - They may have a translated consent.
  - Short forms are standard.
- Translation is written
  - The translation must be competent.
  - The translator must document competence by submitting a language ‘resumé’.
Consent is a Process

- The person obtaining consent must be able to communicate with the subject.
  - Spanish or interpreter is required.
  - Interpretation is spoken.
  - The visit will take longer than normal.
- What is a good interpreter?
  - Unbiased and uninterested in the outcome.
  - Not a family member.
  - Trusted community member with ability and respect.
  - You can talk to them for two minutes prior to the visit to clarify the rules.
    - Interpret everything and ask ?s as needed.
    - Clarify barriers in understanding as appropriate.
The Short Form

- We are asking you to participate in a research study.
- Before you give your consent, the investigators must tell you (i) the purpose, the procedures, and the duration of the study, (ii) if the study includes experimental procedures; (iii) any risks, problems, or benefits you can expect due to study participation; (iv) if there are other available treatments that may help you; and (v) how they protect your privacy.
- When necessary, the investigator should tell you (i) if there are available funds to compensate you in case of injury, (ii) if there may be unanticipated risks; (iii) the circumstances in which the investigator may stop your participation; (iv) if the study will cost anything; (v) what will happen if you decided to stop participating in the study; (vi) when they will give you new information that may change your decision to participate; an (vii) how many people will participate in the study.
La Forma Corta

- Le pedimos que participe en una investigación científica.
- Antes de dar su consentimiento, los investigadores tienen que decirle (i) el propósito, los exámenes, y la duración de la investigación; (ii) si la investigación incluye procedimientos experimentales; (iii) cualquier riesgo, problema, ó beneficio que se pueda esperar por participar en la investigación; (iv) si hay otros procedimientos que le puedan ayudar; y (v) cómo le protegen la privacidad.
- Cuando sea necesario, el investigador le debe decir (i) si hay fondos disponibles para compensarle en caso de heridos; (ii) si es posible que surjan riesgos sin anticipación; (iii) las circunstancias en las cuales el investigador puede parar su participación; (iv) si participar en la investigación le costará algo; (v) que le pasará si Usted decide dejar de participar; (vi) cuando le avisan de información nueva que pueda cambiar su decisión de participar; y (vii) cuantos personas participarán en la investigación.
How to find an interpreter

- Look around your research group
  - Non-research staff
  - Friendly colleagues
- Ask patient to bring one along
  - Family members are not encouraged.
  - Community / Religious organizations
- Language Line won’t work typically for research.
A few language bits

- Estudio ≠ Research
  - Unless you speak Spanglish
  - ‘Investigación Científica’
  - An ‘estudio’ is diagnostic or prognostic.
- Proficiency is required
- Fluency may not be
- Regional differences
  - Typically unimportant in the presence of good will.
- Community leaders may have strong opinions on language. This can become an issue.
My Recent Experience as a Medical Interpreter

- Siloam Clinic in Nashville
- Subjects nod a lot, even when they don’t have any idea what’s going on.
- Family members are frequently poor interpreters.
- Interpreters do get better with practice and training.
Retention of Latino Subjects

- After enrollment, you need to follow the subject.
  - Interpreter may change after consent.
  - If you can’t communicate with the subject, then who is your contact person?
  - How much trust is there?
- In my experience, follow up is more difficult than enrollment.
- It may be easiest to say ‘yes’ and then disappear.
- What are the potential adverse effects associated with loss to follow up?
  - Is it worth it?
  - What special steps can be taken to ensure retention?
Nashville’s Hispanic Community

- Young, diverse, mobile community
- Mexico / Central America
- Not a lot of trust between community and hospitals or clinics.
The Challenges of Being Illegal

- Many are here legally. If not…
- Subjects may not want to be found
- Fraud is required for daily life
- The influence of criminal gangs & traffickers is growing.
- Insurance
  - The kids born here qualify for TennCare
  - The kids born there don’t
  - Workers are frequently un-insured
Issues of Trust

- There are not yet a lot of clinics, or institutions that have roots in Nashville’s Latino community.
- How do we start to nurture trust?
  - Meet the needs of the community by providing care and interpreters as needed.
  - Build rapport by seeking common ground.
  - Don’t give up too easily.
- Building trust is a slow process and recruitment and retention do suffer in the current environment.
Names

- Hispanics have two (or more) last names.
- Birth certificates and medical records frequently get confused.
- I'm Rachel Maria Hayes Boeke de Enriquez
- My husband is Javier Enriquez Martinez
- My son is Diego Enriquez Hayes
Some Stories

- Deported Young Mother
  - Kept silent about her family after detention to protect them.
  - Returned to Chicago in 8 weeks.
  - Has not returned to work.
  - Watches children at home now to earn money.
  - Today, I don’t think she’d make it back in 8 weeks.
An Outsider

- Indigenous Mexican woman who came with her husband.
- Her husband ‘left’.
- Found a new man.
- Communication is difficult – her Spanish is limited.
- Consented her in two visits
- Phone use is difficult
- Adherence was excellent.
Wheezing baby in PICU

- Parents were scared.
- Bilingual staff are rare.
- You can help the family.
  - Translate while you’re there.
  - Make them feel welcome
  - Be another voice to reassure them.
- You won’t have a lot of competition to enroll the family.
Medical Migrants

- A woman sponsored her sister’s immigration.
- She wants psychiatric care.
- The sister is very ‘odd’.
- Has never been properly treated or diagnosed.
- Minimal care in the US is superior to what’s available in Mexico.
- The US sister is legal, bilingual, and stable.
On the other hand …

- 80 something woman with diabetes.
- Family wants to use her visit for medical care.
- Will return to Mexico within three months.
- Really – what can we do about diabetes in 3 months?
- There will be NO adequate follow up care.
- Operate on her foot.
- The family understood this.
The Problems of Immigrant Families

- Imagine your stressed American families.
  - Unstable transportation / communication.
  - Shifting priorities.
- Make it worse.
  - No English
  - Lack of trust
  - Undocumented immigrant.
- It takes effort to overcome these barriers.
Why Immigrate?

- Immigrants suffer.
  - Poverty
  - Violence
  - Gangs
  - Travel is difficult.
  - Undocumented immigrants suffer more.
The Bathroom
Medicine and Hispanic Culture

- Traditional beliefs are prevalent
  - Many Latin American physicians discourage discussion of traditional therapies in regular care.
  - Therefore, you’re unlikely to hear about traditional beliefs either.
- Cultural sensitivity is always important.
- In my experience, economics are more important than belief systems.
In summary

- Language is the biggest barrier, and one of the easiest ones to overcome.
- Trust is the second biggest barrier, and harder to overcome.
- Practical problems caused by poverty, which is common among non-English speaking immigrants, are similar to those in other disadvantaged groups.
- Cultural differences, while present, are typically less important.