The Hispanic Community Health Study (HCHS) / Study of Latinos (SOL)

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The Hispanic Community Health Study (HCHS) – Study of Latinos (SOL)

- **Goals**
  - Quantify the prevalence of cardiovascular disease and other chronic conditions in U.S. Hispanic/Latino populations
  - Quantify the frequency and distributional patterns of their risk factors
  - Examine the temporal change in risk factors, the incidence of selected chronic diseases, and the factors associated with the risk of these conditions in U.S. Hispanic/Latino populations
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- **Some Questions of Particular Interest**
  - Differences in morbidities and risk factors among Hispanic/Latino subgroups
  - Role of acculturation in contrasting patterns of disease
Why a cohort study in U.S. Latinos?
Why at this time?
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- The largest minority group in the U.S.
  - Underserved
  - Understudied
- Multiple health and socioeconomic issues
Why a study in Hispanics/Latinos
Why at this time?

- The largest minority group in the U.S.
  - Underserved
  - Understudied
- Multiple health and socioeconomic issues
- The “Hispanic Paradox”
  - Adverse economic circumstances and some elevated risk factors in Hispanics
  - Apparent lower CVD and all cause mortality
  - Does it merely reflect bias (undercounting, out-migration….)?
  - Is this the case in every Hispanic/Latino group?
Why a Cohort Study?

- Probability sampling would best support inference to the target population, e.g., baseline prevalence.
- Longitudinal cohort study would best support inferences on relationships among risk factors and outcomes and measure change in attributes.
- Practical considerations restrict either choice of study design (e.g., long term residence in the study area, socio-economic instability).
Sampling and Recruitment

Hybrid design selected

- Each field center purposively selected the target geographic area based on
  - Concentration of Hispanic/Latino persons
  - Proximity to field center
  - Diversity of socio-economic characteristics
- Probability sampling used to select census blocks and households within the target area
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- Probability sampling used to select census blocks and households within the target area
- Difficult concept to understand by some in the target population. Added to which:
  - Immigrants
  - Low SES & Literacy
- Intensive community engagement efforts used to enable recruitment and retention of selected household
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Target populations in four different geographic locations

- Sample size: 16,000 persons who self-identify as Hispanic/Latino
- Ages: 18 - 74 years
  - 6,000 ages 18-44 years
  - 10,000 ages 45-74 years
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- Sample size: 16,000 persons who self-identify as Hispanic/Latino
- Ages: 18 - 74 years
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  - 10,000 ages 45-74 years
- Approximately 4,000 persons who self-identify with any of the following Hispanic/Latino subgroups:
  - Mexican
  - Puerto Rican
  - Cuban
  - Central/South American
HCHS - SOL Field Centers

- Chicago
  - Central/South American
  - Mexican
- Bronx
  - Puerto Rican
- San Diego
  - Mexican
- Miami
  - Cuban
What have we learned from previous multicenter studies?
HCHS SOL Field Centers

- Central/South American
- Mexican
- Puerto Rican

- Puerto Rican
- Central/South American

- Mexican

- Cuban
- Central/South American

San Diego

Chicago

Bronx

Miami
## Sampling targets by country-of-origin

<table>
<thead>
<tr>
<th>Location</th>
<th>Central/ South Amer.</th>
<th>Cuban</th>
<th>Mexican</th>
<th>Puerto Rican</th>
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<tr>
<td>Bronx</td>
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<td>7%</td>
<td>84%</td>
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<tr>
<td>Chicago</td>
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<td>70%</td>
<td>43%</td>
<td>21%</td>
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<tr>
<td>Miami</td>
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<td>97%</td>
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<tr>
<td>San Diego</td>
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Probability Sampling Design

- Each member of the study population has a known, non-zero probability of being selected
- Stratification is used to facilitate coverage of important segments of the local population
  - Low versus high SES
  - Low vs. high concentration of Hispanic households
Probability Sampling Design

- Each member of the study population has a known, non-zero probability of being selected.
- Stratification is used to facilitate coverage of important segments of the local population:
  - Low versus high SES
  - Low vs. high concentration of Hispanic households
- Cluster sampling for cost-effectiveness
- Two-stage design selected for efficiency:
  - Census block groups selected at the 1st stage
  - Households within block groups selected at the 2nd stage
Interviews

- Personal and Contact Information
- Personal and Family Medical History
- Nutrition
- Lifestyle and Habits
- Wellness, Depression/Anxiety Scales
- Dental History
- Occupational, hearing, respiratory history and environmental exposure
- Cognitive Function
- Acculturation and Socioeconomic characterization
Procedures

- Anthropometry
- Seated Blood Pressure
- Ankle-Brachial Pressures
- Electrocardiogram
- Pulmonary function testing
- Spirometry
  - Inhaled bronchodilators and Nitric Oxide measurement - COPD and BA
- Oral Glucose Tolerance Test
  - Normal and Impaired Glucose Tolerance
  - 2 Hour OGTT
Procedures

- Ear Exam and Audiometry
- Dental Exam
  - Periodontal disease and cavities
- Physical Activity Assessment
  - History and 7-day physical activity recording using accelerometers
- Portable Sleep Monitor - Sleep Apnea
- Blood assays
Procedures

- **Blood tests**
  - CBC
  - Fasting and 2-hr plasma glucose
  - Fasting Insulin
  - Leptin (adiponectin)
  - hsCRP
  - HbA1c
  - Lipids (total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides)
  - Serum creatinine
  - Albumin
  - Urine microalbumin/creatinine ratio
  - Hepatic enzymes (ALT, AST)
  - Hepatitis A, B and C serologies
  - Iron, transferrin
  - DNA extraction
HCHS SOL Central Agencies

Central Lab
Univ. of Minn.

Audiometry
Center
Uni. Wisconsin

Pulmonary
Reading Center
Columbia Univ.

Nutrition
Reading Center
Univ. of Minn.

Sleep Center
Case West. Reserve Univ.

NIH

UNC
Coordinating
Center

ECG Reading
Center
Wake Forest
Univ.

Neurocognitive
Reading Center
Univ. of Miss. Med.
Reporting of Study Results

- **Results of Established Value in Medical Practice**
  - Initial report at conclusion of exam visit
  - Measurements and assays at central laboratories transferred to the coordinating center
  - Reports retrieved by field centers from study website

- **Emergent/urgent Reports**
  - Measurements in “alert” ranges are reported on an expedited schedule
Disease Endpoints

Event Ascertainment

- Annual follow-up by telephone
- COPD and asthma exacerbations
- Investigation of hospitalized events
- Non-fatal and fatal cardiovascular events
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Event classification

- Review of hospital and EMS records
- Decedent’s next of kin, coroner’s report and primary physician
- Review by panel and standardized classification of events
Why an effort-intensive, “classic” cohort study?

- New/unusual populations, processes and phenotypes
- The breadth of unanswered questions and interdisciplinary interests
- A baseline to assess change in traits of understudied populations and the risk of events in such populations
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- New/unusual populations, processes and phenotypes
- The breadth of unanswered questions and interdisciplinary interests
- A baseline to assess change in traits of understudied populations and the risk of events in such populations
- A resource to support research by the scientific community at large, U.S.-based and international
- The above increase the need for rigor in data acquisition, documentation, interdisciplinary collaboration, transparency, and readiness to share data
Quality assurance/control

- **Detailed protocol development**
  - A clear description of the study design, training, certification, and the various data collection activities form the blueprint for the study.
  - Each protocol is a written reference for staff and researchers for the routine, as well as the exceptional.
  - Those protocols constitute the HCHS Manuals of Operation ([http://www.cscce.unc.edu/hchs/](http://www.cscce.unc.edu/hchs/)).
Quality assurance/control

- **Staff Certification**
  - Criteria to define the adequacy of an individual's training have been established
  - Certification indicates that an acceptable performance standard has been mastered
  - The Coordinating Center (CC) monitors the data acquisition to ensure that the research staff performs only those functions for which they are certified
Quality assurance/control

- Observation monitoring
  - Over-the-shoulder observations of staff by supervisors are made to identify techniques that need improvement and points where the protocol is not being followed.
  - Also, periodic monitoring visits by CC or Reading Center staff are made to observe clinic activities.
  - Immediate feedback is given on issues related to protocol adherence, and recommendations are given to the field center Principal Investigator for action.
Quality assurance/control

- **Quantitative monitoring**
  - Repeat measurements taken by the same and different technicians are used as quality control tools.
  - Random repeat within-visit measurements for anthropometry and blinded duplicate blood and urine samples collected to determine reliability of measurements.
Quality assurance/control

- **Quantitative monitoring**
  - Mean and standard deviations of study variables, by technician, are monitored for differences among technicians and trends over time
  - Digit preference in anthropometry and blood pressure are monitored
  - The entire clinic visit repeated on volunteers (n=60) to quantify day to day repeatability.
Chronology

- **Time line**
  - Year 1: planning
  - Years 2-4: recruitment
  - Years 4-7: follow-up and data analysis

- Recruitment and baseline examination (3 years)

- Yearly telephone contact for changes in health status, behaviors, and adverse events

- Future examination

- Ancillary studies by investigators not affiliated with HCHS/SOL are being received and approved
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Our website:

http://www.cscc.unc.edu/hchs/