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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  - 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
- Some Questions of Particular Interest
  - Differences in morbidities and risk factors among Hispanic/Latino subgroups
  - Role of acculturation in contrasting patterns of disease

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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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- Ages: 18 -74 years
  - 6,000 ages 18-44 years
  - 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

HCHS - SOL Field Centers

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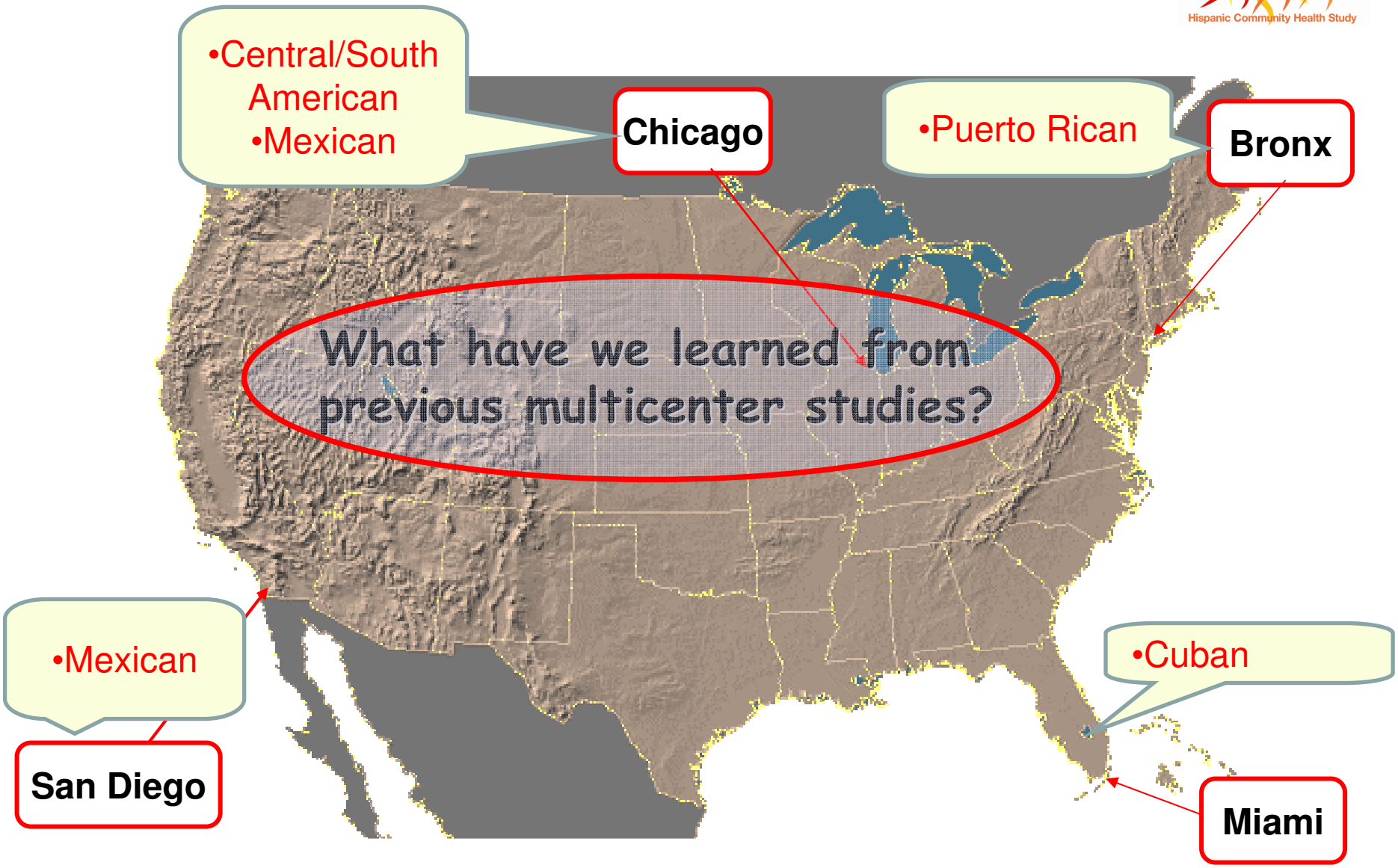

HCHS SOL Field Centers

Sampling targets by country-of-origin

	Central/ South Amer.	Cuban	Mexican	Puerto Rican
Bronx	8%		7%	84%
Chicago	35%		43%	21%
Miami	24%	70%		
San Diego			97%	

Missing cells < 5%

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
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  - 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

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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

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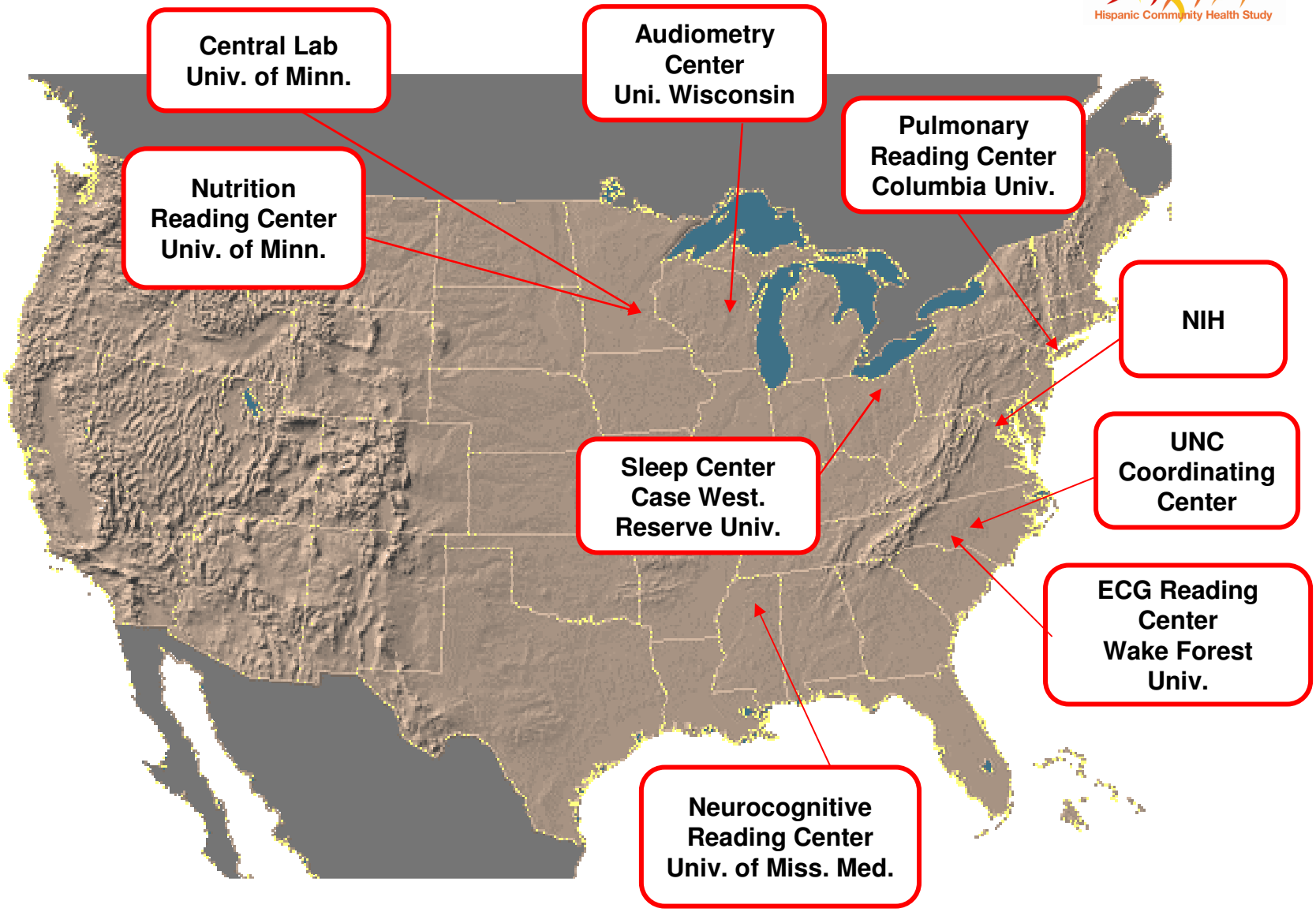
Procedures

- **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



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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- 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.cscc.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:

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