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Design and Implementation of the Hispanic Community Health Study/Study of Latinos

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PURPOSE: The Hispanic Community Health Study (HCHS)/Study of Latinos (SOL) is a comprehensive multicenter community based cohort study of Hispanics/Latinos in the United States.
METHODS: The Study rationale, objectives, design, and implementation are described in this report.
RESULTS: The HCHS/SOL will recruit 16,000 men and women who self-identify as Hispanic or Latino, 18 to 74 years of age, from a random sample of households in defined communities in the Bronx, Chicago, Miami, and San Diego. The sites were selected so that the overall sample would consist of at least 2000 persons in each of the following origin designations: Mexican, Puerto Rican and Dominican, Cuban, and Central and South American. The study includes research in the prevalence of and risk factors for heart, lung, blood and sleep disorders, kidney and liver function, diabetes, cognitive function, dental conditions, and hearing disorders.
CONCLUSIONS: The HCHS/SOL will (1) characterize the health status and disease burden in the largest minority population in the United States; (2) describe the positive and negative consequences of immigration and acculturation of Hispanics/Latinos to the mainstream United States life-styles, environment and health care opportunities; and (3) identify likely causal factors of many diseases in a population with diverse environmental exposures, genetic backgrounds, and early life experiences.
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INTRODUCTION

The rapid growth of the Hispanic/Latino population in the United States has underscored the need for a thorough evaluation of the health risks and disease burden in Hispanics, the impact of immigration and acculturation on health, and the causes of disease, including genetic and environmental, in a population with diverse life styles, behaviors, exposures, ethnicity and places of origin. The terms Hispanic or Latino are used interchangeably in this study to refer to populations who self-identify in this manner. The Hispanic/Latino population grew from 22.4 to 35.3 million persons from 1990 to 2000, became the largest minority in the United States in 2003, and is expected to triple by 2050 (1, 2). Despite increasing obesity and diabetes, and a generally lower socioeconomic status, cardiovascular mortality is often observed to be lower in Hispanics/Latinos, a pattern often referred to as the Hispanic Paradox (3–6). Data show that the longer Hispanic/Latino immigrants live in the United States, the worse some cardiovascular risk factors become (7). The diversity by country of origin may influence disease risk by varying degrees, as suggested by the differing levels of some risk factors and some morbidities observed in Hispanics/Latinos of different countries of origin (8–10).

In response to a working group in 2003 titled "Epidemiologic Research in Hispanic Populations; Opportunities, Barriers and Solutions" (11), the National Heart, Lung and Blood Institute (NHLBI) initiated in 2006 the Hispanic Community Health Study/Study of Latinos (HCHS/SOL). To maximize productivity and scientific opportunities that

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Selected Abbreviations and Acronyms

ALT = alanine transaminase
AHA/ACC = American Heart Association/American College of Cardiology
AHI = apnea-hypopnea index
AST = aspartate aminotransferase
ARES = apnea risk evaluation system
CBC = complete blood count
CRP = c-reactive protein
DNA = deoxyribonucleic acid
ECG = electrocardiogram
ED = emergency department
FEV1 = forced expiratory volume in one second
FPQ = food propensity questionnaire
FVC = forced vital capacity
HCHS/SOL = Hispanic Community Health Study/Study of Latinos
HCV = hepatitis C virus
HDL = high density lipoprotein
HEE = hearing examination (questionnaire)
HX = history
NHANES = National Health and Nutrition Examination Survey
NHLBI = National Heart, Lung, and Blood Institute
NINDS = National Institute of Neurological Diseases and Stroke
OGTT = oral glucose tolerance test
RNA = ribonucleic acid
SBP = systolic blood pressure
SF-12 = standard form 12 items
TOAST = trial of ORG10172 in acute stroke treatment
UIBC = unsaturated iron binding capacity
WAIS-R = Wechsler Adult intelligence Scale-Revised

could be realized within the HCHS/SOL, scientific direction and financial resources were also obtained from six other Institutes or Centers within the National Institutes of Health (National Center on Minority Health and Health Disparities, the National Institute of Deafness and Other Communications Disorders, the National Institute of Dental and Craniofacial Research, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Neurological Disorders and Stroke, and the Office of Dietary Supplements). This study describes the objectives, design, content, and implementation of this landmark study that addresses cardiovascular disease, stroke, asthma, chronic obstructive lung disease, sleep disorders, dental caries and periodontal disease, hearing impairment and tinnitus, diabetes, kidney and liver disease, and cognitive impairment. The protocol and manuals of operation are found in the study web site (12).

MATERIALS AND METHODS

The HCHS/SOL has the following specific operational objectives:

1. To identify, sample and recruit up to 4000 persons who self identify as Hispanics or Latinos, 18 to 74 years of age, from each of four communities in the United States with a stable population and strong community structure (a total of up to 16,000 persons) with participants from each of the following origins: Mexican, Cuban, Puerto Rican and Dominican, and Central and South American;
2. To conduct a detailed and standard characterization of these study participants including questionnaires and procedures to characterize chronic conditions and their putative antecedent factors;
3. To conduct an annual follow-up telephone contact of study participants;
4. To identify new coronary heart disease, stroke, heart failure, and chronic obstructive lung disease events that require hospitalization after the initial examination; to identify acute exacerbations of asthma or chronic obstructive pulmonary disease requiring emergency department care or hospitalization; to identify deaths; to review and adjudicate medical information from hospital, physician, and other records;
5. To develop innovative hypotheses, carry out data analysis, and disseminate findings through publications from this study;
6. To provide community education and feedback based on the study findings that will improve the health of the communities;
7. To provide opportunities for collaboration with the wider community of scientists and publicize the potential for such opportunities; and
8. To provide opportunities for career development and research experience for minority investigators.

The HCHS/SOL is a prospective, population-based, cohort study consisting of a baseline examination lasting approximately 7 hours, a follow-up telephone call within 6 weeks with a second 24-hour dietary recall, and annual follow-up telephone calls to ascertain any hospitalizations and other significant clinical events and to update participants' contact information. The first annual call also includes a food propensity interview to assess dietary patterns. Health events that occur during the follow-up are identified, relevant medical records obtained, and clinical events reviewed and evaluated according to predefined criteria. Recruitment and examination of study participants will last approximately three years, and follow-up and identification of clinical events will continue for an average of 3 years in this contract period. Institutional review board approval has been obtained institutions at each field center and the coordinating center.

Community Description and Involvement

The four communities included in the HCHS/SOL are located in the Bronx, NY; Chicago, IL; Miami, FL; and San Diego, CA. These field centers were selected based on the peer review of study proposals and with consideration

of geographical balance and place of origin. A more detailed description of the sites and maps of their location can be found in the manual of operations (12). The population numbers presented below are estimates based on the 2005–2007 American Community Survey (13).

The Bronx is home to about 700,000 Hispanic/Latino individuals, representing 51% of the approximately 1.4 million Bronx residents (13). Puerto Ricans are the most represented Hispanic/Latino subgroup in the Bronx constituting 46% of Hispanic/Latinos, followed by Dominicans at 31%, Mexicans at 9%, and the remaining groups combined at 14%. Recruitment is conducted throughout the Bronx in census tracts that were selected based on the goal of socioeconomic diversity and accessibility to the HCHS/SOL clinical center.

The city of Chicago has over 700,000 individuals of Hispanic/Latino origin, representing nearly 30% of the estimated 2.7 million residents (13). Persons of Mexican origin constitute the majority of Hispanics/Latinos (73%), followed by Puerto Ricans (14%), and the remaining groups combined at 13%. The targeted area for recruitment in Chicago is composed of ethnically diverse neighborhoods including several that have been majority Hispanic/Latino for decades and others with more recent Hispanic/Latino in-migration.

Miami-Dade County, Florida has about 2.4 million residents of which 1.5 million are of Hispanic/Latino origin (13). Persons of Cuban origin represent 52% of Hispanics, followed by South American (16%), Central American (14%), and the remaining groups combined at 18%. Recruitment is being conducted in the southwest section of Miami-Dade County and in Hialeah.

San Diego County has a population of about 3 million with 30% of Hispanic/Latino origin (13). The vast majority (88%) are of Mexican origin with 12% in the remaining groups combined. The combined region of South Suburban (54% Hispanic/Latino) and South Central (38% Hispanic/Latino) San Diego County, commonly referred to as the "South Bay" is the target community.

The HCHS/SOL was developed recognizing the importance of community participatory research requiring community involvement throughout the study (14). Each field center has a community advisory board that meets on a regular basis to provide advice on a wide range of community issues related to the study. Community members have provided input and advice on the informed consent, questionnaire development, Spanish translation, and issues related to community sensitivities and values.

Participant Sampling and Recruitment

The sampling design was established to support two analytical objectives: first to estimate the prevalence, mean values and distribution of risk factors, with sufficient sample size to stratify by place of origin and other relevant demographic characteristics; and second to evaluate relationships among baseline risk factors, and relationships of baseline risk factors with disease outcomes. Representative samples of participants are drawn from census tracts in these defined communities and are recruited from households using strategies that maximize participation rates, minimize nonresponse, and minimize attrition during follow-up. The study was conceptualized with recognition that community involvement was essential for its success, thus a community-defined sample was needed rather than a sample drawn from very wide geographical areas. Recruitment involves intensive community publicity and direct contract from recruiters. A bilingual study web site is available for the public and participants (www.saludsol.net) individualized to each field center. The detailed sampling design and recruitment strategies are described by LaVange et al. (15).

Examination Overview

Each field center has a specialized examination site accessible to the sampled community. All sites are convenient to public transportation and provide a van service or taxi service to assist participant attendance. Participants are reimbursed for expenses involved in attending the examination. Persons are excluded from the study if they have plans to move from the region within 6 months, are unable to travel to the field center, or are unable to complete the study questionnaires in English or Spanish. Women who are pregnant are rescheduled for a visit approximately 3 months postpartum. All staff are bilingual allowing the use of Spanish or English at the preference of the participant. All forms and questionnaires are in both languages.

The baseline examination averages 7 hours in length, with variation associated with the age and health condition of the participant. Because a fasting blood draw is required, examinations begin in the morning. At the reception, participants are welcomed, and informed consent is obtained. Participants are asked to bring medications to the study center where these are recorded.

Table 1 details the standardized examination content and its typical flow and duration, although the sequence may vary by field center. The examination includes a series of fixed and flexible components that are organized to accommodate first the collection of informed consent before any data collection, followed by the collection of measurements that must be obtained in the fasting state, followed by a glucose screening test to determine eligibility for a glucose load. The fast is broken by a snack at the appropriate time in the examination. Participant safety is paramount and some procedures are not carried out if contraindicated (e.g., glucose tolerance test, albuterol challenge during pulmonary testing, and a periodontal examination). Neurocognitive testing and the ankle-brachial blood

TABLE 1. Example of HCHS/SOL baseline interview and procedure blocks

Content	Estimated time (minutes)
Fasting block	66
Reception, informed consent, change clothes, urine collection	30
Anthropometry	08
Phlebotomy, glucose load	16
2-Hour glucose load, snack	12
Procedures, flexible sequence	107
ECG	15
Ankle brachial SBP (persons 45–74 years of age)	17
Seated blood pressure	11
Audiometry + HEE questionnaire	22
Lung function	15
Oral examination + verification of screening status	20
Change clothes	07
Blocks of interviews, flexible sequence: A	45
24-Hour dietary recall, supplements	45
Blocks of interviews, flexible sequence: B	28
Alcohol	02
Dietary behavior	03
Economic background	02
Health care use	04
Hearing Hx	04
Medical Hx	07
Medication and supplement use	06
Blocks of interviews, flexible sequence: C	44
Neurocognitive (persons 45–74 years of age)	16
Occupation	07
Oral health	05
Personal identifiers	07
Personal information	09
Blocks of interviews, flexible sequence: D	43
Physical activity	05
Respiratory Hx	09
SF-12 health status	05
Sleep Hx	02
Sociocultural	07
Tobacco use	02
Well being	04
Visit exit	20
Exit interview	10
Sleep and activity monitoring instructions and tracking	10
Total clinic attendance time	353

ECG = electrocardiogram; SBP = systolic blood pressure; HEE = hearing examination; Hx = history; SF = standard form.

pressure measures are not carried out in those less than 45 years of age. Complete documentation of the examination content, questionnaires, forms, and a manual of procedures are available at the study web site (16).

Questionnaire Content

The questionnaires and a brief description of their content can be found in Table 2. Questionnaires are interviewer-administered and collect participant identification, location and contact information; health and medical history including cardiovascular and pulmonary diseases, sleep habits and disorders, hearing loss or tinnitus, use of hearing aids, noise exposure, and oral/dental health; social and behavioral factors and support including family structure and community involvement, association with religious and other social organizations, education, and traditional and/or Hispanic/Latino values; occupational history including occupational risk factors potentially related to cardiovascular and lung diseases, cancer, and hearing loss; disability; access to health care and use of health care facilities; smoking history and passive smoke exposure; alcohol consumption, and current physical activity. Dietary intake is ascertained using a 24-hour dietary recall at the initial examination and again 6 weeks later. A food propensity questionnaire developed to include Hispanic/Latino foods is administered during the first year annual follow-up call. If not previously translated through a well-described and standard process, questionnaires were newly translated into Spanish, certified by an independent translator, and tested by focus groups at each field center to identify relevant differences in word usage by nationality or region of origin.

Examination Procedures

The baseline examinations are outlined in Table 2. Weight, height, and abdominal and hip girth are measured with participants wearing light clothing, as is an efficient measure of bio-impedance to estimate body fat composition. Standard resting brachial blood pressure is measured three times in the seated position with a tested, automated sphygmomanometer (Omron model HEM-907 XL [Omron Healthcare Inc, Bannockburn, IL]). To obtain the ankle and brachial blood pressure index, blood pressure is assessed bilaterally in the brachial, dorsalis pedis, and posterior tibial arteries with a Doppler probe. Digitized records of a standard digital 12-lead ECG and a 2-minute rhythm strip are obtained and results processed at a central electrocardiogram (ECG) reading center. Standard digitized spirometric measurements of timed pulmonary function (forced vital capacity or FVC, the forced expiration volume in 1 second or FEV1, and the ratio between these two values, FEV1/FVC) are obtained using the SensorMedics model 1022 (SensorMedics/Viasys, Yorba Linda, CA) dry-rolling seal volume spirometer. Participants whose first spirometric test indicates impaired lung function undergo repeated spirometry testing after inhaling a bronchodilator to determine if the airway obstruction is reversible. An oral examination is conducted to measure periodontal disease and other dental conditions. The hearing examination includes otoscopy and assessment of hearing loss using measures of

TABLE 2. Components of the examination

	Description
Initial procedures	
Personal information	List all household members, age, origin, years in US, social security number for mortality follow-up, household location for geocoding.
Contact information	Collect names, addresses, and telephone numbers of two other persons who would know participant's location.
Informed consent	Obtain signed informed consent that complies with all required standards.
Medical release form	Allows the study to obtain access to participant's medical records.
Questionnaire	
Health and medical history	General health status, cardiovascular and lung illnesses, asthma, diabetes and kidney diseases, cancer, sleep disorders, and hearing loss or tinnitus.
Family history	All conditions under the study such as cardiovascular disease, diabetes, hearing loss, kidney disease, and cancer.
Acculturation	Assessment of residence history, country of origin, ancestry, and degree of adaptation to new physical, cultural, social, and economic environment.
Social and behavioral	Family structure, community engagement, affiliation and association with other social structures such as church and social organizations, formal education and training, traditional and/or Hispanic/Latino values and behaviors, and risk factor behaviors.
Occupational	Specific occupation(s) and aspects of occupation potentially related to lung and cardiovascular diseases, cancer, and hearing loss.
Health care	Health insurance, use of health care facilities, barriers to health care and utilization access.
24-Hour dietary recall	Questions on dietary habits over past 24 hours, plus a food propensity questionnaire (FPQ) developed to include Hispanic/Latino foods. The 24-hour recall is obtained during initial examination and again within 6 weeks of examination. Includes information on dietary supplements and botanicals, both standard and alternative. The FPQ is administered in the 1-year follow-up telephone call.
Smoking	Past and current cigarette use, ever use of cigars and pipes, cessation attempts including use of medications to assist without quitting, and use of modified harm-reduction tobacco products, exposure to second hand smoke.
Alcohol consumption	Usual intake and drinking patterns.
Physical activity	Current physical activity including work, household, leisure, and sport-related activity.
Disability	SF-12 instrument.
Weight loss/gain	History of weight gain or loss.
Sleep	Sleep disordered breathing, apnea, restless leg syndrome, number of hours slept, sleeping during the day.
Medication	Prescription and nonprescription use, vitamin/dietary supplements and alternative medications taken in past month. Participants are instructed to bring all these medications to the examination site for direct recording.
Oral/dental health	Access and barriers to care, oral cancer, oral health-related quality of life.
Hearing	Hearing ability, hearing aid use, tinnitus, noise exposure, hearing protector use, pressure equalization tube use, recent cold/sinus/earache, recent loud noise/music exposure and self-assessment of hearing symmetry.
Exam procedures	
Blood pressure	Standard epidemiology procedures (5 minute rest, 3 measures), and using an automated blood pressure device. Separately, measure ankle and arm blood pressure using standardized Doppler procedures.
Pulmonary function	Obtain digitized spirometric measurements of timed pulmonary function (FVC, FEV1). After first spirometric test, participants with impaired function will inhale a bronchodilator followed by a second spirometry test.
Sleep assessment	Overnight sleep disordered breathing, particularly to assess sleep interruption due to sleep apnea.
ECG	Standard digital 12-lead ECG and 2-minute rhythm strip.
Anthropometry	Weight, standing height, abdominal, and bioelectrical impedence.
Physical activity	Measure activity using activity monitors worn by participants.
Dental	Medical exclusion, tooth count, functional occlusion/occlusion pairs, coronal caries, restorative materials, root caries, periodontal disease, and recommendations for dental health care.
Audiometry	Otoscopy, acoustic immittance, and pure tone audiometry.
Cognitive function	Six-item screener, the Spanish English Verbal Learning Test, the Word Fluency Test of the Multilingual Aphasia Examination, and the Digit Symbol Substitution Test of the Wechsler Adult Intelligence Scale-Revised (WAIS-R). These measures tap five cognitive domains: global mental status, verbal learning and memory, word fluency, and psychomotor speed, respectively.

FPQ = food propensity questionnaire; SF-12 = standard form 12 items; FVC = forced vital capacity; FEV1 = forced expiratory volume in one second; ECG = electrocardiogram; WAIS-R = wechsler adult intelligence scale-revised.

acoustic immittance and pure tone audiometry. Testing is conducted in a sound-treated booth using earphones (TDH-50 Telephonics Corporation, Framingdale, NY) and a clinical audiometer in a manner consistent with the guidelines of the American Speech-Language-Hearing Association. Testing protocols for the dental and hearing components are comparable to those used in the National Health and Nutrition Examination Survey (NHANES).

Cognitive performance measures include a six-item screener, the Spanish English Verbal Learning Test, the

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Word Fluency Test of the Multilingual Aphasia Examination, and the Digit Symbol Substitution Test of the Wechsler Adult Intelligence Scale-Revised (WAIS-R). These measures tap five cognitive domains: global mental status, verbal learning and memory, word fluency, and psychomotor speed, respectively.

After the visit to the study examination center, participants are requested to wear a portable motion sensor (Actical accelerometer, model 198-0200-03; Minimiter Respironics, Bend, OR) to measure actual physical activity for a period of 7 days. The Actical device measures the occurrence and intensity of motion in all directions and sums and stores the signals as "activity counts." To assess any sleep disturbances participants wear an Apnea Risk Evaluation System (ARES [Advanced Brain Imaging, Carlsbad, CA]) Unicorder for 1 night. This device uses a novel pulse oximeter measuring oxygen saturation and heart rate, and sensors that measure airflow, snoring sounds (by microphone), and head movement and body position (by accelerometry) and enables computation of the apnea hypopnea index (AHI).

Blood and urine specimens are collected at each site according to the standardized protocol. Daily fresh and frozen specimens are shipped to the central laboratory for measurements outlined in Table 3. A urine sample is collected from participants preferably at the beginning of the exam for measurement of albumin and creatinine. Fasting blood is collected soon after arrival, and a second collection is done after a 2 hour glucose tolerance test. After the postload venipuncture, participants are provided with a snack.

TABLE 3. Components of the blood, urine, and laboratory measurements

Measure	Description
Venipuncture	Obtain fasting blood samples for laboratory analytes above. Whole blood, serum, plasma, and leukocytes, DNA, and paxgene tubes are stored for future analyses.
Glucose tolerance	2-Hour oral glucose tolerance test.
Spot urine	Collect early on arrival at examination site.
Additional blood	Collect additional tubes of blood to use for 5% blind replicate samples.
Lab Measurements from blood	Total cholesterol, HDL cholesterol, triglycerides, glucose (pre- and post-OGTT), insulin, glycosylated hemoglobin, iron, creatinine, ALT, AST, UIBC, CBC with differential, platelets, serology for Hepatitis A, B, and C, and HCV RNA (on the subset hepatitis C positive), CRP.
Lab measurements from urine	Albumin, creatinine

DNA = deoxyribonucleic acid; HDL = high density lipoprotein; OGTT = oral glucose tolerance test; ALT = alanine transaminase; AST = aspartate aminotransferase; UIBC = unsaturated iron binding capacity; CBC = complete blood count; HCV = hepatitis C virus; RNA = ribonucleic acid; CRP = C-reactive protein.

Approximately 80 mL of blood are collected. A repository of plasma, serum, genomic DNA, RNA, and urine is established at the central laboratory for future analysis. Details on the laboratory collection, processing and analysis can be found in the laboratory manual (17).

Data Collection, Management, and Quality Assurance

All data are collected using a direct computer-based data entry system developed and programmed by the Coordinating Center. Intermediate paper forms are not used with the exception of field center routing and scheduling forms, neurocognitive tests that are not designed for computer based administration, and back-up forms to allow for computer or internet malfunctions. Online editing takes place at the time of data entry so that queries can be made of participants and errors corrected immediately.

Quality assurance includes central training of all staff; standardized certification of the staff inclusive of recruiters; direct observational monitoring of the recruitment, examination procedures, administration of the interview, and equipment calibration schedules; within visit repeat measurements of both laboratory and procedures to determine measurement variability; and analysis of all collected data to identify errors in measurement or questionnaire administration.

Central Laboratory and Reading Centers

To standardize the examination and measurement process across study sites, a central laboratory and central reading centers serve as foci for protocol development, training and certification of staff, centralized measurements or readings, and quality assessment and control. The Central Laboratory established the uniform blood processing and shipping procedures, conducts all laboratory assays, implements blind replicate measurements for a 5% sample, conducts measurements of blinded samples from standardized samples, provides technical support to the field centers and transfers the study results to the coordinating center. Equivalent training, standardization, reading, and quality control functions are also conducted by the Pulmonary Function Testing Reading Center, the Central Electrocardiogram Reading Center, the Sleep Reading Center (for the overnight sleep monitors), the Audiometry Reading Center, the Nutrition Reading Center (for the 24-hour dietary recall and food propensity questionnaires), and a Neurocognitive Center (for the neurocognitive performance tests).

Participant Follow-Up

After the examination and completion of laboratory tests, participants are provided with a summary of their study results of established medical value. Interpretation of the

results per current guidelines and pertinent recommendations are provided. Working with its community advisory committee the study assists participants who do not have a health care provider in obtaining a medical referral. Each field center has a network of free or sliding fee scale providers to assist those without medical insurance.

Participants are contacted by telephone approximately 6 weeks after the baseline visit to obtain a second 24-hour dietary recall. One year after the baseline visit, participants are again contacted by telephone to obtain information on any change in personal contact information, as well as doctor visits, emergency care, or hospitalization since baseline. After the NHANES procedures, a food propensity questionnaire is also administered (similar to a food frequency questionnaire, but without information on the portion size consumed) to elicit information on consumption of certain foods during the previous year (18).

Endpoint Ascertainment and Classification

During the annual follow-up phone call, deaths, hospitalizations, and emergency department visits of participants that occur from the baseline examination through the end of the follow-up period are identified. Information relevant to the classification of study outcomes are abstracted from the medical records by trained personnel. Events are classified according to study protocol (19) as a combination of computer-based algorithms and an overview of the medical records by a panel of clinical specialists trained in the HCHS/SOL classification criteria. The HCHS/SOL event classification criteria were selected for comparability to those of other pertinent epidemiologic studies. The cardiovascular endpoints include myocardial infarction, fatal coronary heart disease, heart failure, and stroke. Additionally, the study will ascertain exacerbations of asthma that result in an emergency department or hospital visit, and hospitalizations and emergency department visits for chronic obstructive pulmonary disease. Deaths are identified from reports by next-of-kin, obituary searches, and matches to the National Death Index. A summary of the criteria for these endpoints are shown in Table 4.

Study Governance and Oversight

A Steering Committee (consisting of the principal investigators of each field center, the principal investigator of the coordinating center, and the project officer of the NHLBI) provides the scientific and procedural direction for the HCHS/SOL. Reporting to the Steering Committee are the following committees: Ancillary Studies, Publications, Community Relations, Endpoints, Operation/Examination, Retention/Follow-up, Sampling/Recruitment, Translation/Validation, Quality Control, Questionnaires, and Career Development.

The HCHS/SOL is conducted under the oversight of each institutional review board at the field centers and coordinating center institutions. The study has an Observational Studies Monitoring Board that serves as advisory to the NHLBI and provides oversight on participant burden, safety, study progress and reviews all ancillary studies. As a study funded by Federal contracts the data collection forms received clearance from the Office of Management and

TABLE 4. Endpoint events and criteria

Endpoint	Information source	Criteria summary*
Acute myocardial infarction	Hospital, ED	AHA/ACC criteria
Heart failure	Hospital, ED, self-report	Physician diagnosis, patient receiving treatment for heart failure, pulmonary edema by x-ray, poor left ventricular function
Atrial fibrillation	Hospital, ED, self-report	Evidence of physician diagnosis, review of ECG findings
Peripheral arterial disease	Hospital, ED, self-report	Evidence of symptomatic disease with a diagnostic procedure or therapeutic intervention
Resuscitated cardiac arrest	Hospital, ED	Evidence from review of medical records
Angina pectoris	Hospital, ED	Evidence of physician diagnosis, revascularization procedure, findings from ECG and angiography
Cardiac revascularization	Hospital, ED	Review of medical records
Venous thromboemobolism	Hospital, ED, self-report	Physician review of positive duplex ultrasound or venogram, Doppler ultrasound or impedance plethysmography, and results of ventilation/perfusion scans or angiography
Stroke	Hospital, ED	Modified TOAST criteria
Transient ischemic attack	Hospital, ED	NINDS criteria
Chronic obstructive	Hospital, ED, self-report	Modification from other studies; see Pulmonary Disease Manual of Operations*
Asthma	Hospital, ED, self-report	Modification from other studies, see Manual of Operations*

ED = emergency department; AHA/ACC = American Heart Association/American College of Cardiology; ECG = electrocardiogram; TOAST = Trial of ORG10172 in Acute Stroke Treatment; NINDS = National Institute of Neurological Diseases and Stroke.
*Specific references and details of criteria for event definitions can be found in the manual of operations (19).

Budget. The table in the appendix describes each institution and staff involved in the HCHS.

DISCUSSION

Although the HCHS/SOL is the most comprehensive study of Hispanics/Latinos in the United States to date, limitations exist. First, whereas the community-based sampling design will permit inferences to the larger population from which it is drawn, inferences cannot be made regarding prevalence of risk factors or disease to the larger Hispanic Community across the United States. Because many of the procedures have also been conducted by the NHANES and other studies, the HCHS/SOL will conduct analysis to compare to these other studies. Second, although the study aims to investigate the "Hispanic Paradox," this requires comparison to non-Hispanic populations. However, a non-Hispanic cohort was not included in this study. Consequently, comparisons to non-Hispanic populations will be based on the use of common protocols with other studies, principally the Multi-Ethnic Study of Atherosclerosis and other NHLBI epidemiology cohorts. For research components missing from the core study, there is an ancillary study process to encourage additional grant support. Ancillary study procedures and policies can be found on the HCHS web site (20).

The HCHS/SOL is designed to inform health care providers, the public health community, and the Hispanic/Latino population on the frequency of impaired health in Hispanics/Latinos, the likely causes associated with these conditions and the measures needed to promote the health of the Hispanic/Latino population in the United States. Although not a national sample, it will provide comprehensive information on risk factors and burden of disease outcomes of significant breadth. Knowledge from this study will also provide understanding of the consequences of major changes in life-style and health care due to immigration. The resulting information will not only improve the health of Hispanics or Latinos, but can lead to measures resulting in improved health for the United States population at large.

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APPENDIX

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