THE HISPANIC COMMUNITY HEALTH STUDY/STUDY OF LATINOS SOCIOCULTURAL ANCILLARY STUDY: SAMPLE, DESIGN, AND PROCEDURES

Objectives: The Hispanic Community Health Study/Study of Latinos (HCHS/SOL) Sociocultural Ancillary Study aims to examine associations between sociocultural and psychosocial factors and cardiovascular disease (CVD) and metabolic syndrome prevalence in Hispanics/Latinos. The conceptual framework is based on the Reserve Capacity and Lifespan Biopsychosocial Models, which emphasize multiple risk and protective pathways underlying socioeconomic and ethnic influences in health. This study describes the rationale, participants, and procedures for the HCHS/SOL Sociocultural Ancillary Study.

Design and Setting: The Sociocultural Ancillary Study to the HCHS/SOL is a cross-sectional cohort study with future opportunities for prospective investigation.

Participants: Participants were 5,313 adults, aged 18–74 years, of self-identified Hispanic/Latino descent and representing multiple Hispanic/Latino background groups, recruited from the Bronx, N.Y., Chicago, Ill., Miami, Fla., and San Diego, Calif.

Intervention: Participants completed an interview-administered sociocultural assessment battery within 9 months of their HCHS/SOL clinical baseline exam.

Outcome Measures: The primary outcomes are CVD and metabolic syndrome and its component risk factors.

Results: The Sociocultural Ancillary Study sample is broadly representative of the HCHS/SOL cohort. Weighted demographics are: 55% male, 56% 18–44 years, 44% ≥45 years, and 37% Mexican, 20% Cuban, 16% Puerto Rican, 12% Dominican, 8%

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Central American, and 5% South American descent.

Conclusions: By testing theoretically driven hypotheses concerning sociocultural and psychosocial factors in CVD, the Sociocultural Ancillary Study seeks to inform future prevention and intervention efforts for US Hispanic/Latinos. (*Ethn Dis.* 2014;24[1]:77–83)

Key Words: Cardiovascular Disease, Culture, Hispanic, Latino, Metabolic Syndrome, Psychosocial Factors, Social Factors

Introduction

The Hispanic/Latino population grew by 43% between 2000 and 2010¹ and Hispanics/Latinos are expected to comprise 30% of the United States (US) population by 2050.2 The terms Hispanic or Latino encompass more than 20 national origin groups, with substantial diversity in ancestry, sociodemographic and cultural characteristics, migration, and US geographic distribution. However, many studies have evaluated the Hispanic/Latino population as a unitary entity or have examined individual ethnic groups (eg, Mexican Americans). Therefore, critical knowledge gaps limit progress in effectively addressing the health needs of the Hispanic/Latino population.

To contribute a clearer picture of Hispanic/Latino health, the National Institutes of Health (NIH) and the National

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Heart, Lung and Blood Institute (NHLBI) established the Hispanic Community Health Study/Study of Latinos (HCHS/ SOL).^{3,4} This landmark epidemiologic cohort study included 16,415 Hispanics/ Latinos aged 18-74 years, representing multiple Hispanic/Latino backgrounds, recruited from four US communities. The goals were to describe the prevalence of risk and protective factors of cardiovascular disease (CVD), pulmonary disease, and other chronic diseases, and to quantify all-cause mortality, fatal and non-fatal CVD, and pulmonary disease exacerbation over time. The first study based on the HCHS/SOL cohort reported relatively low rates of self-reported heart disease and stroke, but high rates of CVD risk factors that were comparable or greater to those identified in non-Hispanic Whites in other national studies.5 Prevalence of individual risk factors varied significantly across Hispanic/Latino background groups. Participants who were born in the United States were at greater risk than first-generation immigrants for CVD and multiple risk factors; greater duration in the United States was also associated with higher CVD prevalence. These findings demonstrate the need to look beyond pan-ethnic groupings to examine patterns of CVD and associated risk factors within the diverse US Hispanic/Latino population.

Sociocultural factors are posited to have an important role in Hispanic/Latino health. However, most studies in this area have been limited to proxy indicators of acculturation, such as nativity or language preference. Researchers have called for expanding this

area with studies that examine specific processes that may help explain epidemiological patterns in Hispanic/Latino health. 7,8 Other research suggests that psychosocial factors (eg, depression, social support) predict CVD incidence and progression, with effect magnitudes similar to those of traditional risk factors.9 However, to date only limited research has addressed psychosocial influences in health among Hispanics/Latinos. The HCHS/SOL included brief assessments of select sociocultural factors,3 but did not include well-established measures of psychosocial constructs related to CVD, such as social support, stress, and intrapersonal resources (eg, optimism), or cultural constructs with purported relevance to Hispanic/Latino health, including spirituality, sex roles, and family relationships.

In 2009, the HCHS/SOL Sociocultural Ancillary Study was initiated to expand the focus on socioeconomic, cultural, and psychosocial processes in the HCHS/SOL. The specific aims of the HCHS/SOL Sociocultural Ancillary Study are: 1) to examine associations of sociocultural and psychosocial factors with CVD and metabolic syndrome prevalence¹⁰ and its component risk factors (ie, obesity, diabetes, hypertension, dyslipidemia) among HCHS/SOL participants, and 2) to simultaneously examine the relative contributions of multiple sociocultural and psychosocial determinants of CVD prevalence and metabolic syndrome and its components, using structural equation modeling (SEM). The sociocultural assessment battery was chosen with attention to psychometric considerations and appropriateness for use in Hispanic/Latinos. Nonetheless, one obstacle to examining sociocultural influences in Hispanic/ Latino health is the lack of systematic evidence regarding measurement properties of relevant scales. Thus, a secondary aim of the study was to thoroughly examine the psychometric characteristics of key assessment instruments.

...we expect the results of our study will contribute to the understanding of the complex patterns and determinants of Hispanic/Latino health and will inform future prevention and intervention efforts that will capitalize on areas of resilience while reducing disproportionate risk.

The guiding conceptual framework for the HCHS/SOL Sociocultural Ancillary Study blends elements of the Reserve Capacity Model, which focuses on psychosocial risk and resource factors underlying socioeconomic status (SES)-related health disparities, 8,11 and the Lifespan Biopsychosocial Model, which focuses on multiple psychosocial and biobehavioral pathways that explain how ethnicity/race and SES combine to influence health across the lifespan. 12 Thus, as shown in Figure 1, the framework suggests that SES combined with ethnic/cultural context shapes psychosocial risk and protective factors in several domains. First, aspects of the sociocultural context (eg, low SES, acculturation) may increase exposure to stress and adversity across the lifespan, while reducing positive events. Second, such processes may shape psychosocial risk (eg, negative emotions) and protective factors (eg, social support). The detrimental effects of stress may be compounded by fewer resources with which to manage life's demands, and fewer opportunities to replenish resources as a consequence of ongoing stress exposure. These protective resources have been referred to as Reserve Capacity. 11,12 Limited protective resources may create feedback

loops that perpetuate stress and related negative cognitive-emotional states.

As shown in Figure 1, the model also accounts for culturally driven processes that have been proposed as possible protective or risk factors in Latino health.⁸ Hispanics/Latinos may experience a high burden of stress due to SES disadvantage, immigration experiences, or ethnic discrimination. However, traditional Hispanic/Latino values could bear resources, such as high family interconnectedness and spirituality, that mitigate exposure to or effects of stress.^{8,13} Empirical studies supporting the associations of cultural factors with objective health outcomes are scarce. Thus, our conceptual framework addresses criticisms of the acculturation literature, and its typical emphasis on proxy indicators, 14 by directly examining the explicit beliefs (eg, fatalism), values (eg, family interdependence, sex roles), and behaviors (eg, religiosity, social integration) that may help explain how Hispanic/Latino ethnicity relates to health.

This conceptual model will be used to guide hypothesis-driven studies concerning the main effects, additive impact, and interactive effects of associations among sociocultural and psychosocial constructs and CVD risk factors and prevalence. Further, capitalizing on the large and diverse sample, analyses will examine variability in observed associations according to SES, Hispanic/Latino ethnic background, and acculturation (ie, tests of effect moderation), and the degree to which intermediate psychosocial processes explain differences in risk and health profiles attributable to broad sociocultural factors (eg, SES, nativity). Ultimately, the study aims to contribute to the understanding of the complex patterns and determinants of Hispanic/Latino health, to inform future prevention and intervention efforts that will capitalize on areas of resilience while reducing disproportionate risk.

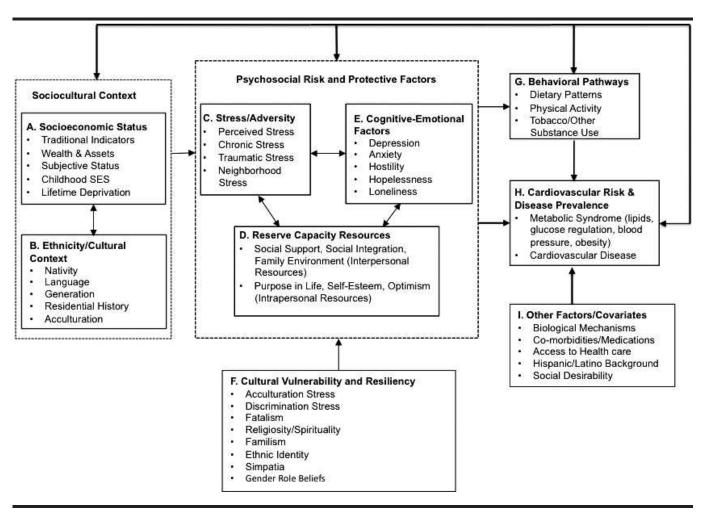


Fig 1. Conceptual model of sociocultural and psychosocial influence on CVD risk and prevalence

METHODS

Overview of the HCHS/SOL

Details concerning the HCHS/SOL have been presented previously.3,4 Briefly, the HCHS/SOL is an observational cohort study of 16,415 Hispanic/Latino persons aged 18-74 years, who were recruited from the Bronx, N.Y., Chicago, Ill., Miami, Fla., and San Diego, Calif., using a two-stage probability sample of household addresses. The selected communities are in diverse regions of the United States and represent 4 of the 10 largest Hispanic/ Latino urban metropolitan areas. The sampling approach was designed to allow comparison of some of the largest US Hispanic/Latino background groups, including Mexican, Puerto Rican, Cuban, Dominican, Central American, and South American. However, all individuals who self-identified as being of Hispanic or Latino descent at the sampling stage, and who were Spanish and/or English speaking, were eligible. The 45-74 year age group was oversampled to allow accurate ascertainment of chronic disease rates. Participants underwent baseline examination (2008-2011) and at least 3 yearly telephone follow-up assessments to identify new CVD and pulmonary events or exacerbations, with adjudication via medical records. The baseline examination included comprehensive physiological, behavioral, and sociodemographic assessments, and limited assessment of sociocultural factors.³ A follow-up clinical exam is planned that will allow ascertainment of incident cardiovascular, metabolic, and other disease outcomes.

HCHS/SOL Sociocultural Ancillary Study

Design

The HCHS/SOL Sociocultural Ancillary Study is a cross-sectional cohort study 15 of associations between sociocultural and psychosocial factors and prevalence of CVD and metabolic syndrome and its component risk factors. Using data from HCHS/SOL annual telephone-based follow-up assessments, and pending completion of a

Table 1. HCHS/SOL Sociocultural Ancillary Study demographic characteristics by field center and overall

Characteristic ^a	Bronx n=1342		Chicago n=1329		Miami n=1315		San Diego n=1327		Overall n=5313	
	n	%	n	%	n	%	n	%	n	%
Age										
18–44	527	58.67	502	65.56	442	44.10	564	62.52	2035	56.46
≥45	815	41.33	827	34.44	873	55.90	763	37.48	3278	43.54
Sex										
Male	505	42.04	522	46.58	530	47.34	457	45.45	2014	45.15
Female	837	57.96	807	53.42	785	52.66	870	54.55	3299	54.85
Hispanic/Latino Background										
Dominican	496	36.31	14	.69	22	1.74	2	.45	534	11.70
Central American	67	4.80	153	8.38	323	16.00	10	.61	553	7.57
Cuban	16	1.05	8	.90	745	67.33	6	.96	775	20.32
Mexican	69	10.90	752	61.38	10	1.04	1249	93.39	2080	36.55
Puerto Rican	570	36.76	253	20.52	40	3.62	17	1.57	880	15.76
South American	67	4.33	116	5.88	149	7.97	18	.94	350	4.79
More than one	56	5.86	32	2.26	24	2.30	25	2.08	137	3.31
Marital Status										
Single	557	46.42	265	28.47	371	29.82	303	27.19	1496	33.98
Married/with partner	491	37.27	784	57.28	627	47.57	746	56.55	2648	48.21
Separated/divorced	230	12.19	218	11.99	268	19.04	219	13.54	935	14.49
Widow(er)	64	4.12	61	2.27	46	3.58	54	2.72	225	3.32
Household annual income										
<\$30K	957	68.46	911	66.80	1004	75.30	768	52.51	3640	66.21
≥\$30K	309	25.80	363	29.23	185	14.13	522	45.23	1379	27.79
Missing	76	5.74	55	3.97	126	10.57	37	2.26	294	6.00
Educational attainment										
<high school<="" td=""><td>523</td><td>39.71</td><td>602</td><td>38.43</td><td>351</td><td>27.67</td><td>422</td><td>26.42</td><td>1898</td><td>32.69</td></high>	523	39.71	602	38.43	351	27.67	422	26.42	1898	32.69
≥High school	792	60.29	701	61.57	939	72.33	876	73.56	3308	67.31
Nativity										
US Mainland	343	28.78	203	24.30	46	4.52	325	32.40	917	21.91
Other	999	71.22	1125	75.70	1268	95.48	1001	67.60	4393	78.09
Language of interview										
Spanish	872	58.93	1063	70.47	1249	93.31	1021	68.74	4205	73.21
English	468	41.07	266	29.53	66	6.69	302	31.26	1102	26.79

^a Statistics are unweighted count (n) and sample design weighted percent (%).

follow-up clinical visit, incident disease outcomes and risk factor progression will also be examined.

Participants and Recruitment

The target sample was 5,280 participants, distributed equally across the four field centers. The Sociocultural Ancillary Study began recruitment following the first wave of parent study enrollment. All participants were eligible if they completed the parent study, consented to being contacted for future research, and were willing to attend a

separate visit within 9 months. Bilingual study recruiters attempted to reach 7,321 HCHS/SOL participants; 6,246 (85.3%) were successfully contacted (1,075 could not be reached), and 5,313 (73% of targeted and 85% of screened participants) participated between February 2010 and June 2011. The majority of participants completed the Sociocultural Assessment within 6 months (88.3%) and most within 4 months (72.6%) of the baseline exam. Because HCHS/SOL sample households were randomly sampled to form

three waves and years of recruitment, eligible participants were representative of the broader parent study.⁴ The Sociocultural Ancillary Study has at least one participant in 550 (82%) of the 670 block groups (ie, statistical divisions of census tracts that typically contain 600 to 3,000 people) that compose the HCHS/SOL recruitment catchment area. The Sociocultural Ancillary Study sample can be considered a representative sub-sample of the HCHS/SOL parent study cohort, with the exception of lower participation in some

higher SES strata. Table 1 displays sample characteristics in the target population overall and by field center. Approximately 62% (n=3,278) of the participants in the Sociocultural Ancillary Study are 45-74 years old, which reflects the HCHS/SOL oversampling in this older age group. Most participants preferred being interviewed in Spanish (ranging from 65% in the Bronx to 93% in Miami). In the target population, 43.54% were $\geq 45, 54.9\%$ were women, 48.2% were married or cohabitating, and 66.2% had annual incomes <\$30K. The Hispanic/Latino background distribution in the Sociocultural Ancillary Study was similar to that of the parent study target population.

Procedures

Institutional Review Board approval was obtained from all study sites for all HCHS/SOL Sociocultural Ancillary Study procedures and materials, and all participants provided written informed consent. Participants attended a 1-2 hour interview, during which trained bilingual research assistants described the study, obtained written informed consent, and administered the assessments. Data were entered directly into a computer data management system, which maximized data accuracy. Participants who expressed significant distress or a desire for psychosocial services received a list of referrals for low or no-cost counseling. Safety protocols were in place to manage urgent scenarios (eg, reported suicidal intent). Participants were compensated \$60 for their time and effort.

Study staff members were centrally trained and certified by principal investigators and coordinating center personnel in all procedures. Study coordinators observed field center interviewers on at least two recruitment calls per month, and promptly corrected any protocol deviations. Assessment interviews were audiotaped and study coordinators reviewed at least one randomly selected

tape per interviewer per month, to ensure protocol fidelity. An external review process was also implemented, with cross-center exchange of two randomly selected audiotapes per interviewer every two months. Data management reports were examined monthly to monitor recruitment progress and data quality.

Assessment Battery

The battery was designed by investigators to assess all major constructs in the proposed conceptual model. Where possible, instruments available in both English and Spanish, and shown to be psychometrically sound and appropriate to Hispanics/Latinos in prior research, were used. Most constructs were represented by multiple indicators to provide a thorough approach and reliability of measurement, and to allow modeling of latent constructs. For measures not previously available in Spanish, bilingual HCHS/SOL staff and investigators translated the measures, using forward and back translation with reconciliation by a committee composed of individuals from diverse Hispanic/Latino backgrounds, to ensure semantic and conceptual equivalence across Hispanic/Latino groups. 16

Study Outcomes

Data from the parent study exam are used to ascertain CVD (coronary heart disease [CHD], stroke, other CVDs) prevalence, metabolic syndrome prevalence, and its component risk factors. Details concerning assessment of physiological factors and health history have been reported elsewhere.³ Coronary heart disease was assessed through a combination of self-reported information (history of a cardiac event or procedure) and electrocardiographic evidence of myocardial infarction observed at baseline. The American Heart Association/NHLBI modified National Cholesterol Education Program criteria¹⁷ were used to determine presence of metabolic syndrome. Additional analyses, as described below, will examine major risk factors that underlie metabolic syndrome and contribute to CVD (ie, obesity, hypertension, diabetes, and dyslipidemia). 18

Statistical Analyses

Logistic regression analyses will be used to identify unique predictors of CVD and metabolic syndrome prevalence and risk factors, as defined by Aim 1. For Aim 2, SEMs will test integrated models of associations among social, psychological, and cultural factors with CVD and metabolic syndrome and its component risk factors, guided by the conceptual framework shown in Figure 1. First, exploratory and confirmative factor analysis will be applied to identify latent variables underlying major theoretical constructs (eg, SES, stress, reserve capacity). Alternative models will be considered, since the boundaries between constructs are quite permeable. Multiple group analyses will be used to test invariance of the measurement models across Hispanic/Latino background groups. 19 In evaluating the fit of all models, multiple indices will be examined (eg, root mean square error of approximation, comparative fit index).²⁰ Analyses will control for demographic variables collected in the parent study baseline exam, including age, sex, Hispanic/Latino background group, and field center. Other demographic and health-related covariates will be selected using theory-guided hypotheses and preliminary analyses. In some reports, demographic variables such as age, sex, nativity, and Hispanic/Latino background group will also be examined as potential effect modifiers.

To evaluate scale measurement properties (secondary aim), analyses will examine internal consistency (ie, Chronbach's alpha) by language, and in each ethnic background group. Confirmatory factor analyses will be conducted to examine if the factor structure established in prior research is replicated in the current study, and multigroup models will test the structural invariance of scales across English and

Spanish versions and Hispanic/Latino groups. Minor modifications may be made to scales to improve psychometric properties. If a scale is shown to lack adequate reliability and validity, the aims of the study will not be compromised given the latent construct approach and the use of multiple indicators for each major theoretical construct assessed.

Statistical Power

The study sought a sample size of 5280, or approximately 1/3 of the parent cohort, which provides adequate statistical power (at least 80%) to detect an association of small-moderate magnitude (OR=1.25-1.50) for a relatively common outcome (30% prevalence), and to detect an effect of moderate magnitude (OR=1.50) for a less frequent outcome (5%), assuming an alpha of .05 and covariates accounting for 25% of variance in a given outcome. The target sample size also ensures adequate power to identify overall model fit and tests of specific model parameters within planned SEMs.²¹

DISCUSSION

The landmark HCHS/SOL will provide critical information regarding

The HCHS/SOL

Sociocultural Ancillary Study will provide important complementary data regarding socioeconomic, cultural, and psychosocial factors that may serve as barriers or facilitators to optimal health among Hispanics/Latinos.

health risk and protective factors and patterns of CVD and other chronic diseases in the US Hispanic/Latino population. The HCHS/SOL Sociocultural Ancillary Study will provide important complementary data regarding socioeconomic, cultural, and psychosocial factors that may serve as barriers or facilitators to optimal health among Hispanics/Latinos. The research is based in a conceptual model that will guide hypothesis testing for numerous studies. The approach addresses several important methodological and conceptual limitations of prior research, including a focus on a limited representation of the Hispanic/Latino population, or alternatively, aggregation across diverse groups, the focus in the acculturation literature on proxy indicators, rather than examining the specific processes that may best explain patterns of health among Hispanics/Latinos, and a lack of theoretical grounding. The study examines CVD, a leading cause of death in Hispanics/Latinos, and related metabolic conditions that disproportionately affect this population. Because all ancillary study data are linked with the parent study, there is vast potential for future research examining associations of sociocultural and psychosocial factors with a range of endpoints, such as health care use patterns, lifestyle factors, and other health conditions.

Limitations of the parent HCHS/ SOL and the Sociocultural Ancillary Study include the focused sampling approach, and the fact that findings cannot be generalized to the entire Hispanic/Latino population. A further limitation is that CVD and stroke prevalence—central outcomes in the Sociocultural Ancillary study—are primarily based on self-report. Other researchers have noted limitations of this approach, in terms of discrepancies relative to medical records information. 22,23 Additional limitations specific to the HCHS/SOL Sociocultural Ancillary Study include data collection conducted within 9 months but not

concurrent with the parent study examination. Adopting a relatively broad time window was important to allow an inclusive sample, since the ancillary study commenced one year after the parent study, however, this may create interpretive difficulties in relation to some research questions. A more general limitation of the Sociocultural Ancillary Study is its cross-sectional design. Telephone follow-up assessments, and a second clinical exam planned for the parent study, will allow ascertainment of sociocultural influences in chronic disease incidence and risk factor progression over time.

Research articles documenting associations of sociocultural and psychosocial factors with CVD and metabolic syndrome prevalence and component risk factors will contribute to the limited existing knowledge base in diverse Hispanic/Latino groups across the United States. Findings may also help guide future efforts aimed at improving health among Hispanics/Latinos, with potential contributions to understanding health and disease models in other ethnic minorities. Until recently, very limited empirical data has documented the contribution of multiple factors in health among Hispanics/Latinos in the United States, particularly in a large sample that is diverse in regard to SES, background, nativity, and acculturation. Therefore, findings from the HCHS/ SOL and the Sociocultural Ancillary Study may help shape policy aimed at augmenting prevention efforts in the largest ethnic minority group in the United States.

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