BOTANICAL DIETARY SUPPLEMENT USE AMONG HISPANIC/LATINO ADULTS IN THE UNITED STATES: COMPARISON OFA DIET- VS. MEDICATION-BASED SURVEY

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A dissertation submitted to the faculty at the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the Department of Epidemiology in the Gillings School of Global Public Health.

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ABSTRACT

Keturah Ruth Faurot: Botanical Dietary Supplement Use among Hispanic/Latino Adults in the Hispanic Community Health Study/Study of Latinos:
Comparison of a Diet- vs. Medication-based Survey
(Under the direction of Anna Maria Siega-Riz)

Botanical supplement use is common in the United States, but its assessment is difficult among Hispanics/Latinos. This report documents the prevalence of botanical and non-vitamin non-mineral (NVNM) supplement use over a 30-day recall period in a sample of Hispanics/Latinos in the US as measured with two instruments. Dietary supplement assessment in the Hispanic Community Health Study/Study of Latinos included both a medication inventory and a nutrition-based dietary supplement interview, enabling a comparison of instruments across supplement categories. Additional supplements were captured from 24-hour dietary recalls. In addition, characteristics of botanical supplement users and their motivations for use were explored.

The prevalence of dietary supplement use was substantially higher as measured in the dietary supplement interview as compared to the medication inventory: for total dietary supplements (40 vs. 26%, respectively), for NVNM supplements (25 vs. 13%), and botanicals (9 vs. 4%). Concordance between the two measures was fair-moderate by Cohen's Kappa (0.28 – 0.56). Estimates were sensitive to inclusion of botanical teas captured exclusively from 24-hour dietary recalls with increases in botanical supplement prevalence from 7 to 15% with their addition. After vitamins and minerals, the most prevalent supplement ingredients consumed were omega-3 fatty acids (9.7%), lutein (9.6%), and lycopene (10.5%).

The prevalence of botanical supplement use varied across Hispanic/Latino background. Individuals with a self-reported Mexican, Central or South American background were more likely to use botanicals than individuals with a Dominican, Cuban, or Puerto Rican background. Other characteristics associated with botanical supplement use included age, income, and adoption of healthy lifestyle behaviors. The association of education with botanical supplement use was stronger for more rather than less acculturated individuals. Motivations for supplement use included treatment/prevention of health conditions and appearance enhancements.

Botanical use prevalence varied by Hispanic/Latino background, but characteristics of botanical supplement users across backgrounds were similar to those in the general US population as were the types of botanical supplements captured. Results suggest that drivers of commercial botanical supplement consumption may not differ between Hispanics/Latinos and the non-Hispanic white population and indicate an interest in self-improvement. Clearly needed are better dietary supplement assessment strategies and standardization of categorization.

This work is dedicated to my dear husband, Tom Keeler, and to the memory of two individuals whose tenacity and belief in promoting the common good were a constant source of inspiration.

Gloria Ines Suarez

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LIST OF ABBREVIATIONS AND SYMBOLS

AHEI = Alternative Healthy Eating Index

CI = Confidence interval, calculated using binomial method

CAM = Complementary and alternative medicine

N = number of studies, individuals in population

n = individuals in category, sample

NVNM = Non-vitamin, non-mineral

NHANES = National Health and Nutrition Evaluation Survey

NHIS= National Health Interview Survey

PABAK = Prevalence- and bias-adjusted kappa

RDA = Recommended Daily Allowance

SASH = Short Acculturation Scale for Hispanics

US = United States of America

κ = Cohen's Kappa

CHAPTER 1: INTRODUCTION AND SPECIFIC AIMS

Botanical dietary supplement use among Hispanic/Latino Americans is common, particularly among those over the age of 60 where use exceeds that of non-Hispanics/Latinos [1-3]. Although little is known about factors associated with botanical supplement use among these rapidly growing populations, preliminary evidence suggests that, unlike for non-Hispanics/Latinos, acculturation and access to care may play a substantial role, although the direction of the associations is uncertain. Botanical dietary supplement use in older adults is of particular concern given the increased potential for interaction with prescription medications or substitution for appropriate conventional medical care [4]. Despite the risks, more than 65% of Hispanic/Latino botanical users report that their physicians never ask about their botanical supplement use [5] and less than 20% disclose their use [6, 7].

Methodological issues specific to these populations need to be addressed in order to achieve valid prevalence estimates. For example, the way in which botanical supplement use has been assessed in the past may not be valid in a population where many botanical supplements are consumed as teas rather than as capsules or tablets, potentially leading to prevalence underestimates. In the current literature, prevalence estimates are highly variable, ranging from 5 to 94%. Possible selection bias and outcome misclassification hampers interpretation of available estimates. Requirements for accurate botanical supplement use prevalence estimates include: 1) a large sample (N>10,000) of Hispanics/Latinos; 2) sampling of multiple Latino cultural groups; 3) inclusion of recent immigrants; and 4) outcome assessments that include botanical supplement common among Hispanics/Latinos.

The proposed analyses assess botanical supplement use among Hispanics utilizing both the medication inventory (4 week medication and supplement use) and the two 24-hour diet recalls (with a 30-day dietary supplement interview) from the Hispanic Community Health Study/Study of Latinos (HCHS/SOL), a prospective cohort study designed to identify risk factors and disease prevalence among Hispanic/Latino populations within the US. HCHS/SOL has enrolled16,415 individuals (aged 18 to 74) from four communities: Miami, the Bronx, Chicago, and San Diego representing Hispanic/Latino groups from Cuba, Puerto Rico, Mexico, the Dominican Republic, Central and South America. The double assessment (medication inventory plus dietary supplement interview with dietary recalls) could serve as a reference standard for calibrated estimates of botanical supplements and the prevalence of different types of botanical supplements across groups of Hispanic/Latino backgrounds. Correlates of botanical supplement use will be examined, with special attention to factors that are found to differ by Hispanic/Latino background.

Specific Aim 1: Evaluate the prevalence of botanical supplement use in the HCHS/SOL cohort across assessment instruments

a. *Estimate the prevalence of botanical and non-vitamin, non-mineral dietary supplement use among Hispanics/Latinos as assessed at baseline by the:*
   1) Medication inventory;
   2) Dietary supplement interview (with and without dietary recall data); and
   3) Combined medication inventory/dietary supplement interview

b. *Compare dietary supplement prevalence estimates based on the medication inventory with those of the dietary supplement interview (with and without dietary recall data) and the combined assessment across categories of supplements (any dietary supplement, NVNM supplements, any supplement with botanical components, primarily botanical supplements).*

Specific Aim 2: Explore population characteristics associated with botanical supplement use among Hispanics/Latinos with particular attention to:

a. *Hispanic/Latino background, as defined by country of origin (Cuba, Puerto Rico, Dominican Republic, Mexico, Central, and South America);*
b. *Acculturation (Born in US, years in the U.S., Short Acculturation Scale for Hispanics);*
c. *Access to healthcare (insurance status, perceived lack of access);*
d. *Health indicators (medication use and perceived health);*
e. *Health behaviors (non-smoking status, physical activity, adherence to healthy dietary guidelines);*
f. *Demographics (age, gender, education, income);*
g. *Geographic location in the United States.*

Understanding botanical supplement use patterns is essential to protect the public from harm, but these patterns are poorly understood among Hispanics/Latinos, soon to be the largest ethnic minority in the US. The HCHS/SOL cohort provides a unique opportunity to address some of the challenges inherent in measuring botanical supplement intakes among Hispanics/Latinos. The sampling strategy of HCHS/SOL, ensuring representation of all Hispanic/Latino background groups and recent immigrants, provides the basis for estimating patterns of botanical supplement use particular to Hispanics/Latinos. In addition, HCHS/SOL is unique in its double assessments of botanical supplement use (dietary supplement interview with recall and medication inventory).

CHAPTER 2: BACKGROUND

2.1 Potential Risks of Botanical Dietary Supplement Use among Hispanics/Latinos

The Dietary Supplement Health and Education Act of 1994 (DSHEA) defined the dietary supplement.

TABLE 2.1.Definition of a dietary supplement under the Dietary Supplement Health and Education Act

"*A dietary supplement*

- *Is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, **an herb or other botanical**, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.*
  - ***Is intended for ingestion in pill, capsule, tablet, or liquid form**.*
  - *Is not represented for use as a conventional food or as the sole item of a meal or diet.*
  - *Is labeled as a "dietary supplement."*
  - *Includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision)."*

Under DSHEA, botanical products, including teas, alcoholic extracts, capsules, and tablets, are regulated as dietary supplements, resulting in a lower level of government oversight of product safety as compared with pharmaceutical drugs. Although recent amendments to DSHEA require that manufacturers follow current Good Manufacturing Practices and submit serious adverse events to the Food and Drug Administration (FDA), current regulations fall short of full public protection [8]. New research points to increasing reasons for concern about dietary supplement use as a mechanism for interactions with medications and this concern is highest with botanical supplement [9, 10]. Product contamination, either intentional (e.g., addition of undeclared drugs) or accidental (e.g., formulation error or plant misidentification) is problematic [11]. Up to 30% of Mexican Americans have reported that they obtain both their botanical supplements and drugs from Mexico, increasing worries about product safety [6, 12, 13]. In addition, blood lead levels have been found to be higher among women using herbal products [14].

Botanical supplement use among Hispanics/Latinos is popular within the US especially among patient populations. In fact, supplement use is higher among individuals with chronic conditions than those without [15] and individuals with chronic illness are more likely to take prescription medications concomitantly. Concurrent use of supplements and medications approaches 25% in the general population and 75% among those 55-70 years old [16-18].

Medication-botanical interactions are incompletely understood. Of concern are both pharmacokinetic and pharmacodynamic interactions [9]. For example, St. John's Wort induces Cytochrome P450 (CYP450) isoenzymes and reduces blood levels of antiviral medications in HIV, transplant-rejection suppressants, and oral contraceptives [19-21]. Unfortunately, the extent of CYP450 activity of many botanicals is yet unknown [9], especially those common among Hispanics/Latinos [22]. Concomitant use of anticoagulants and/or antiplatelet agents and botanical supplement is especially worrisome, given that multiple botanical agents possess antiplatelet activity [23]. For example, use of *Ginkgo biloba* with aspirin has resulted in cases of intracranial bleeding [20]. Adverse effects associated with many botanical supplement common among Hispanics/Latinos are uncertain. Studies have documented episodes of hypoglycemia possibly associated with a combination of nopal and oral hypoglycemic agents [24]. Other studies identified multiple *potential* medication-supplement interactions [25]. For example, chamomile (manzanilla), a popular botanical in several Hispanic/Latino populations, because of its effects on cytochrome P450 substrates, could interact with multiple commonly-used medications [5]. However, the clinical significance of many of these potential interactions is unknown [25].

In spite of the potential risks, rates of disclosure of botanical supplement use to physicians are low. In the general population, about a third of supplement users report their use to health care providers; among Hispanics/Latinos disclosure rates vary from 7 to 66% with a median of 34.5% [5-7, 26-38]. Seventy-five percent of studies reported disclosure rates less than 50%. Disclosure rates are likely to be even lower among individuals who are marginalized and/or speak little English [39] . Moreover, in a chart review, only 15% of botanical supplement use was documented in the medical record [31]. Substitution for appropriate medical care may also put individuals at risk. Small studies suggest that botanical supplement use is greater among Hispanics/Latinos without insurance and with low incomes [12, 40]. Underutilization of medical care, due to limited access or perceived discrimination [41], could strongly impact choices to use botanical supplements.

2.2 Unique Patterns of Botanical Supplement Use in Hispanic/Latino Populations

Hispanic/Latino populations encompass people from diverse cultural traditions with differences in dialects, primary language, and traditions [22]. In some Hispanic/Latino populations, attitudes and beliefs about the use of botanical medicines are part of a cultural belief system transmitted through female relatives [2, 22, 41-43]. Surveys and interviews with Hispanic/Latino immigrants report a belief that botanical remedies are safer than prescription drugs and consistent with family traditions [43, 44]. Medications are not eschewed, however; herbal teas are often consumed along with medications, especially among diabetics [41, 45]. In fact, conventional medical care and physician's advice may be highly valued [40]. However, herbal remedies may be chosen because they are consistent with cultural practices and are cheaper and easier to obtain; in two studies, annual income was the strongest predictor of alternative medicine use (chiefly botanicals) [40, 45]. In other studies, in areas of the country far from traditional sources of botanicals, botanical supplement use may be less common because it is less available. Hence, use patterns may be consistent with pragmatic self-care behaviors [2, 46-48]. Among Hispanics/Latinos, botanical supplement may be used for treatment of symptoms and minor illnesses, much in the same way other Americans try over-the-counter medications [49].

Unlike in the general population, factors related to botanical supplement use among Hispanics/Latinos are incompletely understood. Education appears either to play a limited role or to vary across categories of acculturation [50, 51]. Moreover, the operational definition of acculturation itself is variable. Studies that utilized acculturation scales disagreed on the importance of unidimensional as opposed to bidimensional theoretical models. Unidimensional acculturation, typically measured with the Short Acculturation Scale for Hispanics/Latinos [52], characterizes orientation toward the new and initial cultures as occurring along a continuum; a person reporting Spanish-language activities and friends would receive a lower acculturation score on a unidimensional scale. Bidimensional acculturation [53], on the other hand, assesses endorsements of aspects of both the US culture and the culture of origin [54, 55]. Most studies including acculturation as a covariate, however, limit its definition to length of residence in the US and/or primary language [56, 57], the latter possibly conflated with employment opportunity and income rather than Hispanic/Latino identity [40].

Some studies report higher botanical supplement prevalence estimates among recent immigrants [5, 29, 58, 59], but others find no association between length of residence and the prevalence of botanical supplement use [33, 40, 56, 60]. Moreover, a closer examination of the studies suggests that overall prevalence may not differ much by acculturation, regardless of its measurement, but by the types of botanicals used. In one study, botanical use patterns among those with higher US acculturation scores were more similar to that of the non-Hispanic white (NHW) sample than to less acculturated Hispanics/Latinos [29]. Similarly, in a small study of middle-aged Mexican American women, those who used botanical supplements common among Hispanics/Latinos scored higher on the Mexican orientation of the bidimensional acculturation scale as compared with women who used botanical supplements popular in the US culture [46]. In another, most participants did not know the English names for the botanical supplements they were using currently [5]. It should also be noted that the Spanish names for these herbs may vary from country to country.

2.3 Overcoming Existing Methodological Barriers

A botanical assessment instrument should have good test-retest reliability, be easy to administer, and, most importantly, contain extensive prompts, known to aid recall of over-the-counter products. In addition, prompts should include questions about botanical supplements meaningful to the target population. In Hispanic/Latino populations, it is particularly important to inquire about herbal teas and those herbs common among Hispanics/Latinos, but uncommon among the general public. Despite its importance, outside of randomized trials, few US studies have assessed botanical supplement use in any population, and even fewer have employed comprehensive strategies. Assessment strategies in studies have varied; most cohort studies have relied on self-completed questionnaires [61-64] or telephone surveys [65], invariably requiring participants to choose from a list of botanical supplement. Personal interviews with examination of products is considered a more comprehensive method and served as a criterion standard for a vitamin supplement validation study [66]. In addition to HCHS/SOL, the Hispanic Established Populations for the Epidemiologic Study of the

Elderly (EPESE) used this method. In EPESE, participants were asked if they "had taken any folk medicine, herbs, or herbal remedy in the 2 weeks prior to the baseline interview" (p M715)[59], a strategy that improves upon the typical assessment.

HCHS/SOL appears to be unique, however, in its double assessment of botanical supplements, requesting information on botanical supplements with both medication and dietary data. Because some botanical dietary supplements are considered treatments, like medications, and others are more like preventatives, like vitamins, different supplements may be captured by alternative methodologies. In addition, different forms of botanical supplements may be captured better by one instrument than the other. For example, in some Hispanic/Latino populations, medicinal plants are prepared as "liquadas" in a blender and many are prepared as teas. Hence, it would be important to assess the value of adding the dietary recall botanical supplement assessment to that of the medication questionnaire. If the overlap between instruments is small and the prevalence of botanical supplement use increases substantially with the double assessment, this strategy could become the new criterion standard, at least in Hispanic/Latino populations.

Unfortunately, despite these careful assessment procedures, HCHS/SOL may yet be underestimating botanical supplement use. Usual assessment of botanical supplements via tablets and capsules limit the ability to accurately characterize botanical supplement use among Hispanics/Latinos because, as a matter of cultural practice, many Hispanics/Latinos consume botanical supplements in food-like forms. It is unclear whether or not participants will include herbal teas with their medications and the question about botanical supplements in the dietary recall targets products more common in the general population than among immigrant Hispanics/Latinos. A systematic review of prevalence of botanical supplement use documents wide variations in prevalence estimates, partially related to the nature of the assessment instruments; those that specifically target Hispanic/Latino populations and include the use of teas result in much higher prevalence estimates.

CHAPTER 3: PRELIMINARY STUDIES

3.1 Systematic Review of Botanical Supplement Prevalence among Hispanics/Latinos

Establishing accurate prevalence estimates are critical: underestimates could misrepresent the public health impact of botanical supplement use. Prevalence estimates of botanical supplement use are often dependent on self-report measures, and, as such, vary by multiple factors.

Methods

To further elucidate factors associated with variations in prevalence among Hispanics/Latinos, a team of researchers (Gardiner, Filippelli, Faurot) conducted a systematic review of the available literature. Our strategy included electronic database searches (CINAHL, EMBASE, Global Health, CAB Abstracts, and Medline) with keywords: *herbal, herb, medicinal plant, botanical*, *and Hispanic or Latino* along with a manual search of retrieved references. Only studies with at least 1% and at least 10 Hispanics/Latinos were included with publication dates of 1998-2011. Information was extracted on study and sample characteristics, and rates of disclosures to clinicians. The following were expected to have an impact on prevalence estimates: 1) the sampling strategy (convenience vs. probability); b) study size, including proportion of Hispanics/Latinos in the sample; c) the time period of the recall (< 30 days vs. 12 months vs. "ever used"); d) characteristics of the population studied (patients vs. general public, older vs. younger adults, proportion of males); and e) region of the country (Mexican border states vs. other states vs. national samples). Other extracted data included variables not available in all of the studies such as measures of acculturation (percent of sample born in the US, years living in the US, and preferred language) and participant health status. In addition, we documented the study definition of a botanical supplement. This varied from all "biologically-based" CAM therapies (including botanical supplements, other dietary supplements and special diets) to non-vitamin non-mineral supplements (AKA herbal and "natural" or "specialty" supplements), botanical supplements limited to commercial products, and botanical supplements inclusive of plus "home remedies" and/or herbal teas). We further identified possible sources of recall, selection, and information bias in the estimates (Appendix 1) based on the study designs.

Results

Study heterogeneity necessitated primarily descriptive analyses. To examine the impact of sample characteristics across studies, we limited our analysis to those studies with unique populations. If the study was based on the 2002 NHIS sample, we used the report with estimates for the entire population rather than estimates for subgroups, such as older adults or patients with diabetes. Fifteen studies used duplicate data and were set aside [2, 16, 61, 67-76]. Of the remaining studies, eighteen were excluded because they were missing prevalence estimates for Hispanics/Latinos [13, 42, 47, 77-90], seven included less than 10 Hispanics/Latinos [91-97], six were qualitative studies [41, 48, 98-101], and four reported the use of BDS for treatment of a specific illness [102-105]. Use of botanical supplements for any indication (rather than for a specific disease) within samples of patients with various illnesses was retained. Of the forty-two studies meeting these criteria, seven described the prevalence of the use of biologically-based therapies or dietary supplements including vitamins and minerals [10, 40, 46, 106-108]. In addition, one study reported of chamomile use [109]. Thirty-four studies had reasonably similar outcomes [3, 5-7, 27-37, 44, 59-61, 73, 110-123]. In these studies, botanical supplements were described as herbal medicines, herbal therapies, herbal products, or herbs for treatment or prevention of illness. Some studies also included "herbal and home remedies" in the estimates. **TABLE 3.1** presents prevalence estimates separately for studies of botanical supplement use and over 1-2 weeks, over 6-12 months, and over 2 years or more.

Of the 34 studies defining botanical supplements as herbal remedies or therapies, study size ranged from 23 to 29,990 with Hispanic/Latino sample sizes of 11 to 4,196. Fifty percent of studies reported less than 500 subjects. Seventy-one percent (n=24) of samples included non-Hispanics, 44% had a minority Hispanic/Latino sample, and 9% included fewer than 50 Hispanics/Latinos. More than half (53%) of the studies were conducted within patient populations. Studies among patients included those with cancer [35, 106, 117], HIV [116, 124], diabetes [31], osteoarthritis [29], menopause [37, 123], surgical patients [7, 26], and pregnancy [27]. Regional studies included those from states along the Mexican border (TX, NM, AZ, CA: 53%) and those in other parts of the country (FL, NY, MA, IL).

Nineteen percent of the studies were representative of the national population. BDS prevalence estimates among Hispanics/Latinos ranged from 4.7% (over 1 week) to 94% (use in past year).

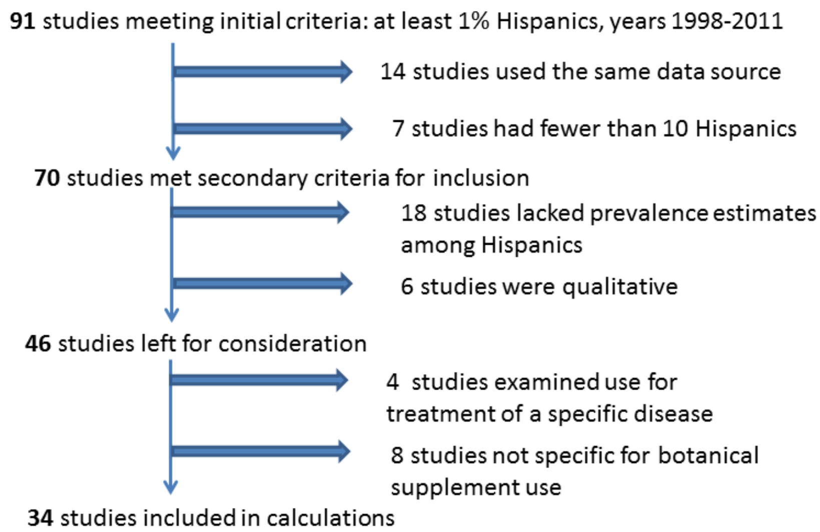


FIGURE 3.1 **Description of studies included in systematic review of botanical dietary supplement use among Hispanics in the US**

In regional samples, potentially biased by the sampling strategy, prevalence estimates were up to three times as high as in nationally-representative population surveys. However, in nationally-representative samples, ethnic minorities, especially recent immigrants, may be under-represented, especially among older age groups [113]. For example, among studies of individuals along the Mexican border over a 12 month period, prevalence estimates of botanical supplement use range from 21 to 94% [3, 6, 7, 28, 32, 34, 36, 60, 111, 118]. In contrast, prevalence estimates among Hispanics/Latinos in nationally-representative samples range over a similar time period range from 7 to 23% [30, 114, 115, 119, 122, 123].

TABLE 3.1. Prevalence of the use of botanical supplements in studies Including Hispanics/Latinos 1998-2011 across characteristics of included studies

	Prevalence of use of botanical supplements				
	n	N	Median	95% CI	P^a
Overall	32	95,523	42	21, 61	
Time period					
Over ≤30 days	5	18,108	12	4.7 , 43	0.02
Over 6-12 months	18	75,050	31	19 , 59	
Over 2+ years	9	5,365	50	37, 75	
Sample type					
Probability	11	82,002	19	8.9, 48	0.02
Convenience	21	14,521	49	35, 63	
Data collection method					
Interview	20	74,401	27	12, 60	0.3
Written	12	22,122	46	21, 63	
Publication type					
CAM journal	7	19, 500	28	12, 51	0.4
General journal	25	77,023	43	19, 62	
Regional vs. national					
Regional	25	16,496	50	35, 62	0.002
National	7	80,027	15	7.7, 22	
Sample population					
General public	16	88,578	20	10, 49	0.01
Patients	16	7,945	50	36, 65	
Target age of population					
Adults ≥65	7	9,147	12	6.3, 50	0.02
Adults <65	25	87,376	47	27, 62	
Gender distribution					
Majority males	8	5,034	51	19, 76	0.2
Majority females	24	91,489	36	18, 61	
Language of instrument					
Spanish & English	19	16,701	47	28, 64	0.02
English only	13	78,822	17	9.1, 50	
Sample proportion of H-L					
Majority H-L	15	8,142	42	29, 67	0.03
Minority H-L	17	88,381	21	12, 50	
Size of H-L sample					
N < 250	17	8,060	52	42, 63	0.03
N ≥ 250	15	88,463	23	15, 37	
Botanicals common among H-L					
No	12	83,087	19	10, 49	0.02
Yes	20	13,436	49	29, 66	

Abbreviations: H-L—Hispanics -Latinos; n= number of studies; N = sum of sample populations; CI = confidence interval, calculated using binomial method; CAM = Complementary and alternative medicine. a. *p* values are based on Kruskal-Wallis (or Mann-Whitney U) rank nonparametric tests. All analyses were conducted in Stata 12.

Not surprisingly, because the language used to describe botanical supplements among Hispanics/Latinos differs from that of the general US public (including plant names, product formulations, and typical use patterns), assessment instruments designed for Hispanic/Latino populations produce higher prevalence estimates than those created for national samples. In some studies, supplement definitions consisted of commercial products only; in others, information on any botanical substance (including herbal teas) used to prevent or treat a disease or illness was solicited. As teas are the most prevalent form of supplements consumed in many Hispanic/Latino populations [125], a botanical assessment instrument that excludes them will result in serious underestimates. Among the 11 studies of botanical supplement use over 12 months with instruments that target herbs common among Hispanics/Latinos, particularly herbal teas, prevalence of use among Hispanics/Latinos ranges from 18 to 94 % (weighted median 28%)[3, 6, 28, 32, 34, 36, 60, 111, 115, 124] while among those that do not target Hispanic/Latino herbs, the range is 7 to 55% (median 12%) [26, 30, 110, 114, 118, 119, 122, 123].

TABLE 3.2. Medicinal plants common among Hispanic/Latino populations in four areas of the US

Texas/New Mexico		Florida	
English	Spanish	English	Spanish
Aloe	Savila	Aloe	Savila
Chamomile	Manzanilla	Chamomile	Manzanilla
Cornsilk	Pelo de Elote	Garlic	Ajo
Damiana	Damiana	Ginger	Jengibre
Diabetil tea	Te Diabetil	Ginseng	Ginseng
Garlic	Ajo	Linden	Tilo
Lime (Linden)	Tilo	Star anise	Anis estrella
Mints	Hierbabuena	Valerian	Valeriana
Osha	Hierba del cochino		
Prickly pear	Nopal		
California		**Illinois**	
English	Spanish	English	Spanish
Aloe	Savila	Aloe	Savila
Cactus	Nopal	Anise	Anis estrella
Cascara	Cascara	Chamomile	Manzanilla
Chamomile	Manzanilla	Cornsilk	Pelo de Elote
Ginseng	Ginseng	Garlic	Ajo
Peppermint	Hierbabuena	Ginseng	Ginseng
Rue	Ruda	Herbal teas	Te hierbas
Wormwood	Ajenjo	Mullein	Gordolobo
Flaxseed	Semillas de lino	St. John's wort	Hierba de San Juan

Herbs in bold were reported in multiple studies. Additional herbs reported among Mexican Americans include Bricklebush (Prodigiosa), Eucalyptus (Eucalipto), Loquat (Nispero), Milkberry (Perllila), Matarique (Matarique), Trumpet tree (Lapacho or Taheebo), Wormwood (Ajenjo), and Yellow Bells (Tronadora).

In the general population (2007 NHIS), of those who used botanical supplements over a period of 12 months, 75% had also used botanical supplements over the past 30 days (primary calculation). Other studies have documented similar patterns of regular use of supplements among users [126]. In contrast, "point prevalence" or prevalence of botanical supplement use over a week or two, across the studies in this sample, averages almost a quarter of the estimates of use over a period of several months. This pattern may be related to the types of herbs most common within Hispanic/Latino populations, particularly among those who identify with traditional Mexican and Central American cultures [28, 29, 40]. In the general population, the most commonly used botanical supplements are those typically taken daily (e.g., glucosamine, ginseng, garlic, ginkgo, St. John's Wort, saw palmetto)[2, 73, 127]. In contrast, among Hispanics/Latinos, the most common herbs are those used for intermittent treatment of symptoms (e.g., manzanilla, tila, hierba buena, savila). Botanical supplements most common among Hispanic/Latino populations in the surveyed literature are listed in Table 2 [6, 7, 22, 40, 43, 113, 125, 128].

Discussion

The sample of studies was not restricted by any definition of study quality; no studies were free of bias, particularly selection bias. Studies based on national probability samples were either hampered by an overall poor response rate [30, 129], did not report a response rate [104, 108, 119], or had a differential, lower response rate for Hispanics/Latinos [115]. In addition, studies utilizing the NHIS, based on the US census with data collection by census staff, may have excluded certain Hispanic/Latino populations, such as recent or undocumented immigrants. Other probability samples used sampling frames biased toward individuals with higher incomes. For example, an otherwise excellent study limited its sample to older women covered by a particular health plan [118] and another limited the sample to seniors with a Medicare supplement [79]. Similarly, studies that utilized telephone surveys exclude those without telephones [88, 107, 114]. Samples based on baseline clinical trial populations [18, 105] may also not have been representative of the target population [130]. Studies using cohort follow-up samples [87, 123] may have suffered from bias due to differential loss to follow up. Many convenience studies were likely to have been biased by differential non-response:

non-users of BDS may have been less likely to respond. Most studies were unable to provide information on non-responders. The two studies that did provide information on responders compared with the target population indicated that responders were more likely to be female and white [81] or better educated [89], characteristics associated with higher rates of botanical supplements use. Some of the best studies with convenience samples, with close to 100% response rates are difficult to compare, due to the difference in their target populations. One study was undertaken in a low-income clinic [60] and another in an ophthalmology specialty clinic [95].

Other potential sources of bias included recall and information bias. The majority of the studies asked participants to recall their use of botanical supplements over a period of several months. It is unclear whether or not participant characteristics, such as poor health [34] or adverse pregnancy outcomes [27] may have resulted in differential recall. Even in studies with a fairly short recall period, outcome misclassification is a real possibility. However, in a study of participants in a clinical trial, kappa statistics comparing questionnaire to a medication interview ranged from 0.49 to 0.87 (fair to excellent) [18].

Outcome misclassification is related not only to poor participant recall, but also to variable botanical supplement definitions. Although we excluded studies of dietary supplements (including vitamins/minerals) and biologically-based therapies (including special diets) from our final analysis, we cannot be certain that questions about "herbal products" (e.g., Rivera, 2007) and "herbal remedies" (e.g., Burge, 2002) are the same. In addition, some studies included non-herbal natural substances in their analysis (e.g., Greenlee, 2009) and others any plant-based product used to treat a symptom or illness (e.g., White, 2009). It is with trepidation that we presented any measures of central tendency, recognizing that we are aggregating outcomes that may be fundamentally different.

In the general public, botanical supplement use is more prevalent among middle-aged persons, women, and those with chronic conditions [122, 127]. National samples have also predicted higher use of botanical supplements among older Hispanics/Latinos as compared with non-Hispanic whites, up to age 70 [131]. However, among Hispanics/Latinos in the selected samples, botanical supplement use in studies targeting older adults is somewhat lower than among younger adults. Use within patient populations is higher, but predominantly female populations do not necessarily have higher prevalence estimates.

The language of the study instrument had an impact on estimates. Not only do studies offered only in English exclude those who are less proficient in English, they also may result in misclassification. In one study, most of the participants did not know the English name for over 90% of the herbal products in the study [5]. Regional studies, even those with probability sampling, reported much higher prevalence estimates than national studies. The differentials are likely to be due to a combination of factors, including non-response bias in the convenience samples, and outcome differences (variations in how the questions are asked), in the national samples.

3.2 Prevalence of Botanical Supplement Use among Hispanics/Latinos in a National Sample

Despite the acknowledged heterogeneity among those categorized as "Hispanic/Latino", little is known about the effect of country of origin on prevalence estimates. Multiple studies reported prevalence estimates among specific US Hispanic/Latino populations (e.g., Mexican Americans in El Paso [50], Mexican and Central/South Americans in California [40, 60], but prevalence by Hispanic/Latino country of origin has not been reported [22]. Curiously, although the 2007 NHIS contains data on Hispanic/Latino country of origin, studies utilizing this data have reported only aggregate Hispanic/Latino estimates.

Based on a review of the literature, the 2007 NHIS instrument was expected to capture the pattern of NVNM supplement use of the general population, rather than the pattern more common among Hispanic/Latino immigrant populations. Hence the following hypotheses were entertained:

1. Higher acculturation (as measured by immigrant status) would be associated with greater use of botanical supplements (including NVNM supplements)
2. Higher education would be associated with greater use of botanical supplements
3. Use of botanical/specialty supplements would be highest for the 45-64 year old age group
4. Female gender would be associated with higher use of NVNM supplements
5. Use of botanical supplements would be associated with greater access to health care as measured by insurance status and usual health care home
6. Hispanics/Latinos with greater incomes would be more likely to use NVNM supplements
7. Hispanics/Latinos would be less likely than individuals of other ethnicities to use NVNM supplements

Methods

In preparation for the current study the prevalence of dietary supplement use among participants in the 2007 National Health Interview Survey (NHIS) was assessed, including Hispanics/Latinos. NHIS is a national multistage probability sample administered annually since 1957 by US Census interviewers to one sample adult per household. Each year, the NHIS includes questions about a broad range of health indicators; every five years since 2002, the alternative health supplement is administered. The NHIS oversamples elderly minorities.

In the 2007 NHIS, according to the interview guide, participants are asked: *"People take herbs and non-vitamin supplements for a variety of reasons.* ***By herbal supplements we mean pills, capsules or tablets that have been labeled as a dietary supplement. This does NOT include drinking herbal or green tea****. Have you EVER taken any herbal supplements listed on this card for yourself?"* Products on the list include the following supplements botanical as well as other non-vitamin, non-mineral (NVNM) dietary supplements: black cohosh, chasteberry, comfrey, cranberry, Echinacea, ephedra, evening primrose, feverfew, flaxseed oil, garlic, ginkgo, ginseng, goldenseal, guarana, grape seed extract, green tea, EGCG, hawthorn, horny goat weed, kava, lecithin, lutein, lycopene, milk thistle, saw palmetto, senna, soy, St. John's Wort, and valerian.

In our preliminary study, prevalence of NVNM (including botanical) supplement use was examined by age, gender, education, acculturation, and access to care variables (insurance) across racial and ethnic categories. To explore the independent influence of these variables for Hispanic/Latino versus non-Hispanic individuals, logistic regression models were constructed with botanical/NVNM supplement use as the outcome. Further, prevalence estimates were examined by Hispanic/Latino country of origin: Mexican, Cuban, Puerto Rican/Dominican and Central/South American. Finally, the prevalence odds ratio was calculated for supplement use by Hispanic/Latino country of origin controlling for demographic factors.

In addition, because many of the studies reported high proportions of Hispanics/Latinos with less than a high school education and education may not have the same effect on botanical supplement use among Hispanics/Latinos, a logistic regression model was constructed stratifying on education. Thus, our initial full model included Hispanic/Latino ethnicity vs. non-Hispanic, four categories of age

(18-24, 25-44, 45-64, 65-85), three categories of education (<high school, high school graduate, at least some college), sex, insurance coverage (none vs. some), healthcare access (usual place for care vs. none) poverty status, and a Hispanic/Latino* education interaction term. All analyses were conducted in Stata 12.1 with application of sampling weights (StataCorps, LLC). Analyses of data for Hispanics/Latinos with different cultural backgrounds are, of necessity, exploratory; no current literature focuses on the differences in BSDS use patterns among American Hispanics/Latinos.

Results

TABLE 3.3 presents the prevalence data across covariates of interest for Hispanics/Latinos as a group, compared with other racial/ethnic groups. Models were examined for effect modification by education, poverty status, and both. The strongest model, both in terms of explanatory power and model fit was the model stratified on poverty status. Controlling for age, sex, education, and insurance/ health care access, and immigrant status Hispanics/Latinos with an income higher than the poverty line were less likely to use BSDS than non-Hispanics/Latinos with a prevalence odds ratio (POR) of 0.73 and 95% confidence interval (CI): 0.63, 0.86. In contrast, Hispanics/Latinos with an income below the poverty line had about half the odds of botanical supplement use: POR 0.55 (0.38, 0.80). Poverty was also associated with a lower likelihood of botanical supplement use among non-Hispanics/Latinos: POR 0.82 (0.72, 0.95).

Those most likely to use botanical supplements had at least some post-high school education; less than a high school education was associated with one-third the likelihood of botanical supplement use [POR 0.33 (0.28, 0.38)] while those with a high school diploma had about half the odds of BSDS use [POR 0.56 (0.51, 0.61)]. Women were slightly more likely to use botanical supplement than men: 1.24 (1.14, 1.35) and older individuals were more likely to use botanical supplement than younger ones. Those without insurance were slightly more likely to use botanical supplement [POR 1.14 (1.00, 1.29)] and those without a usual place of care were slightly less likely to use botanical supplement than those with health care access: POR 0.88 (0.76, 1.00). Individuals born in the US were more likely to use botanical supplements than immigrants [POR 1.36 (1.20, 1.54)]. Self-reported health (good to excellent vs. fair or poor) was not influential and was removed from the models. The model c statistic was only fair at 0.65, suggesting that other factors predictive of botanical supplement use are unaccounted for in the analysis.

TABLE 3.3. Prevalence of botanical and NVNM supplement use in the US population in the 2007 NHIS

		White Non-Hispanic *n = 13,859	African-American *n = 3,612	Hispanic/Latino All races *n = 4,173	Other† *n = 1,654
Variable	n	% (se) †	% (se)	% (se)	% (se)
Overall	23385	21.0 (0.44)	10.1 (0.59)	9.71 (0.51)	18.8 (1.15)
Age					
18 - 24	2,494	16.4 (1.34)	7.19 (1.38)	3.55 (0.87)	15.4 (2.99)
25 - 44	8,538	19.5 (0.68)	10.7 (0.89)	9.75 (0.74)	16.7 (1.54)
45 - 64	7,503	24.3 (0.73)	11.0 (1.03)	13.0 (1.20)	18.7 (2.29)
65 +	4,581	19.7 (0.79)	9.27 (1.37)	10.5 (1.75)	27.9 (3.84)
Gender					
Male	10,373	18.6 (0.60)	10.0 (0.97)	9.86 (0.77)	17.8 (1.59)
Female	13,012	23.0 (0.56)	10.2 (0.70)	9.58 (0.70)	19.6 (1.62)
Education					
< HS	4,223	11.6 (0.88)	3.55 (0.76)	4.43 (0.52)	12.6 (2.79)
HS	6,519	16.7 (0.60)	7.92 (0.97)	8.81 (0.98)	17.0 (2.56)
>HS	12,383	24.9 (0.60)	14.5 (1.02)	16.5 (1.09)	20.7 (1.41)
Insurance					
None	4,043	21.2 (1.0)	9.32 (1.19)	7.31 (0.75)	16.1 (2.40)
Some	19,266	20.0(0.45)	10.4 (0.67)	11.0 (0.71)	19.5 (1.32)
Usual place for healthcare					
Yes	19,425	21.5 (0.42)	10.1 (0.56)	10.1 (0.59)	17.3 (1.32)
No	3,534	22.3 (1.20)	9.55 (1.41)	6.30 (0.77)	19.5 (2.92)
Born in the US					
Yes	18,810	21.0 (0.44)	10.2 (0.62)	13.6 (1.02)	23.6 (2.05)
No	4,557	20.2 (1.68)	10.0 (1.93)	7.12 (0.61)	14.2 (1.22)
Total family income					
<$20K	5,649	18.0 (0.81)	6.16 (0.69)	6.22 (0.76)	16.4 (2.24)
$20-39K	5,797	19.1 (0.81)	10.6 (1.06)	7.10 (0.91)	19.8 (2.56)
$40-59K	4,104	21.7 (0.96)	10.9 (1.58)	11.0 (1.23)	18.6 (2.75)
$60K+	7,835	23.2 (0.68)	15.8 (1.47)	16.8 (1.50)	19.9 (1.71)

*n = sample, but percentages are weighted. †Other race/ethnicities include Asian Americans and American Indians; NVNM= non-vitamin, non-mineral

Among Hispanics/Latinos, individuals reporting a Central/South American background or mixed Hispanic/Latino background were more likely to use BSDS than those reporting a Mexican background (POR 1.48 CI: 1.03, 2.02 and 1.86 CI: 1.41, 2.47) (**Table 3.4**). Botanical supplement use was strongly associated with age; among Hispanics/Latinos, individuals in the 65-74 age groups had more than three times the odds (POR 3.45 CI: 1.91, 6.22) of botanical supplement use as those in the 18-24 age group. Insurance status, US birthplace, and years in the US were not predictive of botanical supplement use and had little effect on estimates by Hispanic/Latino ethnicity.

TABLE 3.4. Prevalence of botanical and NVNM supplement use among Hispanic/Latino populations in the 2007 NHIS

Variable	Mexican American *n = 1,581 % (se) †	Cuban American n = 187 % (se)	Puerto Rican n = 593 % (se)	Central/ South American n = 663 % (se)	Other Hispanic/ Latino‡ n = 1,149 % (se)	Non-Hispanic n = 19,125 % (se)
Overall	6.3 (0.59)	9.6 (1.27)	9.4 (2.67)	10.1 (1.31)	11.5 (0.87)	18.8 (0.33)
Age						
18 - 24	3.0 (1.20)	0	5.0 (2.43)	2.6 (1.83)	4.1 (1.56)	14.4 (0.93)
25 - 44	6.7 (0.86)	11.4 (5.30)	8.9 (1.97)	11.0 (1.98)	12.8 (1.46)	17.0 (0.54)
45 - 64	7.1 (1.44)	11.5 (4.34)	13.7 (2.90)	11.1 (2.62)	14.5 (2.13)	21.5 (0.56)
65 - 85	6.8 (2.46)	6.7 (3.81)	8.4 (2.58)	12.8 (3.81)	12.4 (3.06)	18.9 (0.65)
Gender						
Male	5.3 (0.85)	9.4 (3.83)	14.7 (2.80)	9.4 (2.15)	11.0 (1.40)	17.4 (0.42)
Female	7.2 (0.88)	9.4 (3.27)	6.6 (1.19)	10.6 (1.68)	11.9 (1.28)	20.0 (0.46)
Education						
< HS	5.9 (1.16)	17.8 (6.19)	11.0 (2.07)	10.5 (2.15)	11.9 (1.50)	19.3 (0.60)
HS	7.9 (1.61)	9.5 (5.43)	7.0 (2.47)	3.5 (1.22)	13.8 (2.20)	18.4 (0.70)
>HS	6.1 (1.04)	4.7 (3.19)	8.7 (2.22)	11.8 (2.26)	9.2 (1.64)	18.7 (0.51)
Insurance						
None	6.4 (1.34)	10.0 (5.85)	9.8 (3.04)	5.2 (2.29)	11.5 (2.38)	18.7 (0.72)
Some	6.3 (0.66)	9.5 (2.77)	9.2 (1.27)	11.1 (1.51)	11.4 (1.02)	18.8 (0.36)
Born in US						
Yes	6.1 (0.64)	10.4 (3.15)	9.6 (1.32)	10.6 (1.43)	11.0 (1.00)	18.9 (0.36)
No	7.7 (1.76)	4.4 (4.29)	9.8 (3.80)	5.9 (2.35)	15.1 (3.24)	18.2 (0.76)
Family income						
<$20K	4.5 (1.01)	3.4 (2.70)	4.7 (1.46)	8.2 (1.90)	9.9 (1.96)	15.3 (0.62)
$20-39K	4.3 (0.85)	9.7(6.29)	11.0 (3.02)	4.8 (1.85)	11.1 (2.29)	17.8 (0.69)
$40-59K	10.1 (1.88)	5.3 (3.72)	12.5 (3.14)	15.8 (3.36)	9.32 (2.24)	20.1 (0.85)
$60K+	11.0 (2.32)	26.6 (7.54)	19.3 (4.26)			22.4 (0.64)

*n = number of participants in 2007 sample, not representative sample. †Frequencies are weighted. ‡Other Hispanic/Latino includes those reporting mixed ethnicity.

Discussion

As expected, the results conform to patterns noted in prior nationally-representative studies of botanical and NVNM supplement use among US adults and are consistent with our expectations. As the literature indicates higher use patterns among Hispanics/Latinos with medical conditions [59, 79, 89, 132] and among individuals who visit health care professionals [5], it is not surprising to find higher use among those with a health care home. The literature is mixed with regard to the impact of insurance coverage. Some studies suggest higher use among the insured [30], while other studies suggest the opposite [114, 133]. The current findings support a modest effect of access to care on use of botanical supplements common in the general US public.

In this sample, consistent with prior studies in US populations, educational attainment was associated with greater botanical and NVNM supplement use [2]. Poverty was associated with lower botanical and NVNM supplement use and this effect was magnified for the Hispanics/Latinos in the sample. The association between income and the use of complementary and alternative medicine (CAM) has been documented in prior studies [35, 131, 134], but no study has examined these effects stratified by ethnicity. NVNM supplement use, as assessed, was less common among individuals born outside the US, a finding consistent with prior studies of botanical and NVNM supplement use in national samples [135]. In regional samples, however, even those with probability samples, the CAM use (including botanical and NVNM supplement use) is often higher among immigrants [34].

It should be noted that the "*herbal supplements listed on this card*" in the NHIS botanical and NVNM supplement use assessment did not include most of the botanical supplements usual in Hispanic/Latino populations. In addition, because both common botanical supplements among Hispanics/Latinos and herbal teas are specifically excluded from collection, the prevalence of NVNM use among Hispanics/Latinos in the NHIS analysis is likely to be substantially underestimated. The 2002 NHIS Complementary and Alternative supplement included herbal teas (although did not specify most botanical supplements common among Hispanics/Latinos). This may be the reason why the prevalence of botanical and NVNM use over 12 months among Hispanics/Latinos appears to have declined substantially, from about 18 % [30] in 2002 to less than 9% in 2007.

3.3 Summary and Implications

Understanding NVNM and botanical supplement use patterns is essential to protect the public from harm, but these patterns are poorly understood among Hispanics/Latinos, soon to be the largest ethnic minority in the US. The HCHS/SOL cohort provides a unique opportunity to address some of the challenges inherent in measuring NVNM and botanical supplement intakes among Hispanics/Latinos. The sampling strategy of HCHS/SOL, ensuring representation of Hispanic/Latino background groups and thorough assessment of both acculturation and access to care, provides the basis for estimating patterns of NVNM and botanical supplement use particular to Hispanics/Latinos. In addition, HCHS/SOL is unique in its double assessments of dietary supplement use.

To our knowledge, this is the first study in a large representative sample to estimate the effects of Hispanic/Latino country of origin on the prevalence of botanical supplement use among Hispanics/Latinos. In addition, because the assessment of Hispanic/Latino background is captured in HCHS/SOL, I will be the first to be able to assess the impact of varying Hispanic/Latino background groups. Study measurements also enable us to examine not only the impact of country of origin and acculturation, but also income, education, and access to healthcare, all covariates that have been incompletely accounted for in previous work. Hence, the study will yield data of value to public health professionals in planning botanical supplement guidelines and education.

CHAPTER 4: RESEARCH DESIGN AND METHODS

4.1 Overview of Study Design

The proposed study of botanical supplement use and patterns of use among Hispanics/Latinos utilized the baseline data of the Hispanic Community Health Study/Study of Latinos (HCHS/SOL), a prospective cohort study designed to identify risk factors and disease prevalence among Hispanic/Latino populations within four communities in the United States (Miami, Bronx, Chicago, and San Diego) representing immigrants from Cuba, Mexico, Puerto Rico, and Central/South America. HCHS/SOL has completed enrollment of a representative sample of 16,000 Hispanics/Latinos; including 10,000 individuals aged 45-74. Baseline data collection included a medical history and physical exam as well as assessments of acculturation, health behaviors, family structure, health care access, nutrition, and physical activity. The HCHS/SOL cohort is the first to enroll an adequate sample of Hispanics/Latinos of different backgrounds to make possible a robust assessment of the prevalence of NVNM and botanical supplement use and its correlates in these populations.

Eligibility

All participants in the HCHS/SOL cohort were eligible to participate in the primary analysis. The HCHS/SOL sample was a stratified two-stage probability sample of 16,414 from the communities included; ensuring unbiased inferences [136].

HCHS/SOL cohort sample selection, recruitment, and enrollment

The source population for HCHS/SOL is that of non-institutionalized adults aged 18-74, either gender, of Hispanic or Latino origin residing in specific census tracts in the city of Chicago, Miami-Dade County, San Diego County, and the Bronx, NY. HCHS/SOL investigators chose these communities to achieve a balanced recruitment of Hispanics/Latinos from across the US and countries of origin [137].

Within the communities, they selected census tracts based on their proximity to the field center clinic (one in each of the four cities) and to achieve a broad demographic representation, additionally cross-stratifying by high vs. low concentration of Hispanic/Latino residents and high vs. low SES [136]. To recruit individuals, a letter is sent to the selected household, individuals within the household are contacted and screened for eligibility (living in the household, age 18-74, able to attend a clinic visit, and not planning to move within 6 months)[136]. Screened individuals then attend a study visit at the field center clinic where they review/sign the consent documents and participate in study assessments.

External validity

The HCHS/SOL sampling strategy ensured generalizability to Hispanics/Latinos in the selected communities. However, because HCHS/SOL recruits only from urban areas and their surrounding counties, generalizability does not extend to all Hispanics/Latinos in the US.

HCHS/SOL cohort quality control procedures

The HCHS/SOL cohort staff consists of a central Coordinating Center and four Field Centers. Overall data collection procedures are presented in the Field Center Procedures Manual. Procedures include steps for the following: 1) sampling and recruitment, 2) safety screening 3) scheduling study visits, 4) obtaining informed consent, 5) participant flow, and 6) administration of each element of data collection and management. All HCHS/SOL field center technicians were fully trained and certified in the procedures, passing a training exercise with a score of at least 80%. In addition, with the approval of the study participant, interviews were audio-recorded and randomly selected for reviewed by Field Center supervisors and Central Coordinating Center monitors. Discrepancies were brought to the attention of the Quality Control Committee for corrective action.

Medication inventory

For the medication use inventory, participants in HCHS/SOL were asked to bring in all medications they had taken in the past four weeks, including herbal remedies, to their study appointment. Upon their arrival at the appointment, a staff member captured product information with a barcode scanner. The staff member copied down information for any product that did not successfully scan, including the UPC/NDC code, name and strength. Data was entered into a Medispan MDDB database with Micromedex and Lexicomp products in Spanish added. Coding success was close to 100% for single-ingredient products and many botanical supplements are listed in the database. If individuals did not bring their medications, staff attempted to obtain the medication information by telephone.

Medications and other medicinal products were classified by their indication and drug classes. Misclassification could occur if the individual is taking a product for a different indication. Botanical supplements not in the MDDB database were to have been recorded on the data form verbatim, usually in Spanish. These supplements required review and coding by trained healthcare professionals (physicians, pharmacists, physician assistants).

Dietary Supplement Interview and Dietary Recall

A second assessment of botanical supplements occurs with the dietary supplement interview. At the time of the visit to the field center clinic, clinic technicians interviewed participants about botanical supplements use over the 24 hours and 30 days prior to the study visit. Dietary interviewers were to have had access to the medication inventory, but data sharing was said to be uncommon. With or without the medication inventory, dietary interviewers asked the interview questions about botanical use. After dietary interviewers obtained the dietary information, through a 24-hour recall, they asked individuals ten questions about dietary supplement use, including one question about botanical supplements: “Did you take any products containing one or more herbal or botanical ingredients like Echinacea, ginseng, ginkgo or St. John’s Wort?” Next, they reviewed label information for any supplements brought to the interview. Interviewers also asked participants how much of the product they took, how long they had taken it, and why they took the product. The dietary interviewers inquired about use of herbal teas during the dietary recall, although this inquiry covered a 24 hour period only. A second dietary recall was conducted by telephone within 45 days of the first assessment. During the second dietary recall, only supplement use over the past 24 hours was assessed.

Dietary interviewers entered data directly into the Dietary Supplement Assessment Module (DSAM) Nutrition Data System for Research database (NDSR). Botanical supplements that did not match in the DSAM, were captured with information from the product label, listed as "Missing Dietary Supplement Products" and saved as DSAM User Products to be validated against outside resources.

4.2 Categorization of Dietary Supplements

Supplements reported in the medication inventory and the dietary supplement interviews were examined in detail. The first step was to categorize supplements as botanical products, botanical-containing products, or other non-vitamin, non-mineral dietary supplements in both the medication inventory and the dietary recall. For this work, it was necessary to obtain label information for the dietary supplement products in both files.

To categorize the dietary supplements, the Langual categorization system for dietary supplements as proposed by Saldanha, Dwyer et al. (2011) was adapted [138]. Coded product facets included product type (Facet A), physical form (Facet E, with collapsed categories), and ingredients (Facet H) (**TABLE 4.1**). Coding using the Langual system moves from the broad to the specific. Hence, product types were coded with three levels. The first identified the product as a prescription medication, dietary supplement, over-the-counter medication, or other (topical products). The second level identified the dietary supplement products in 10 different categories: vitamin, mineral, botanical, amino acid or protein, other supplement type, metabolite, combination product, unknown, homeopathic, or other. The third level identifies the supplement components more specifically.

Individual ingredients common in the dataset and of potential value to the goals of the Hispanic Community Health Study/Study of Latinos (HCHS/SOL) were captured. Specifically, because HCHS/SOL focuses on tracking cardiovascular and metabolic outcomes, products containing supplements marketed for these outcomes (e.g., Coenzyme Q-10, Omega-3 fatty acids) or with reported concerns about adverse reactions (e.g., Glucosamine) were identified (**TABLE 4.2**).

TABLE 4.1. Product characteristics coded in the medication inventory and dietary supplement interview data from HCHS/SOL

Prod_type1	Prod_type2	Prod_type3	Phys_Form
1 medication			1. Tablet/caplet /capsule/soft gel/gummies
2 DS			2. Liquid (alcohol-based (tincture, tonic)
3 OTC	1. Vitamin		3. Liquid (water-based (syrup, liquadas)
4 other		1. single	4. Tea bags
		2. multiple vitamins	5. Other raw herb
	2. Mineral		6. Other (Powders or Bars, etc.)
		1 single	7. Unknown
		2 multiple	8. other
	3. Herbal/botanical or herbal extract		
		1 yeast	
		2 algae	
		3 fungus	
		4 single botanical (added)	
		5 multi-botanical (added)	
	4. Amino acid/protein		
		1 single or multiple	
	5. Other dietary substance to supplement the diet		
		1. fiber	
		2. enzymes	
		3. probiotic bacteria	
		4. other	
	6. Metabolite, constituent, extract, isolate, or combination of any of these		
		1. hormone precursors	
		2. steroid precursors	
		3. 7-dehydrocholesterol, phospholipids	
		4. lutein, lycopene and similar (carotenoids)	
		5. omega-3 fatty acids (fish oil, flax oil)	
		6 omega 6 fatty acids	
		7. Omega 3 & 6 fatty acids	
		8. Co-Q10	
		9. Glucosamine, Chondroitin, MSM (including Hyaluronic acid)	
		10. other metabolite	
	7. Combination of any of the above ingredients listed in 1– 6 above		
		1. MVM x	
		2. Mineral(s) & botanical	
		3. MVM & amino acids	
		4. MVM & botanical	
		5. MVM & fatty acids	
		6. Vitamin(s) & botanical	
		7. Vitamin(s) & fatty acids	
		8. Other not listed above	
	8. Unknown		
		88 unknown	88 unknown
	9. Homeopathic		
		99 homeopathic	
	111 other	111 other	111 other

Abbreviations: Prod_type1 codes the broad product type: medication (prescription), dietary supplement (DS), non-prescription medications, and other: primarily topical products (by definition, excluded as dietary supplements. Prod_type2 narrows the description as per Saldanha (2012) and Prod_type3 provides an additional level of detail. MVM=Multivitamins with minerals

TABLE 4.2. Ingredients coded from product name data in the medication inventory and dietary supplement interview files

Product Ingredients	Product Ingredients
Alpha-lipoic acid	Mineral
Amino acids	Minerals
Bioflavonoids (citrus bioflavonoids, soy isoflavones, quercetin, rutin)	MSM
Botanicals	Multi-botanical
Chondroitin	Multi-vitamin
Cod liver oil (coded as an omega-3)	Omega-3
Coenzyme Q-10	Omega-6
Collagen (coded as a protein when separate)	Omega-3-6-9
Fiber	Phospholipid
Fungus	Phytosterols
Glucosamine	Probiotic
Homeopathic (regardless of constituents)	Propolis (bee pollen, propolis, royal jelly)
Hormone precursor	Protein
Lipotropic	Vitamin
Lutein	
Lycopene	
Metabolite-other	

4.3 Outcome Definitions: Dietary Supplement Variables

The proposed descriptive analysis reported botanical supplement prevalence estimates as assessed by the medication history and by the dietary recall assessment, both separately and as an aggregate and with the inclusion of botanical teas (from the 24-hour dietary recall).

Analyses were based on multiple definitions of botanical supplement use: 1) dietary supplement products alone, as captured in the dietary supplement interview, dietary products (with a few additional bulk botanicals) as captured in the medication inventory, and products from the dietary supplement interview plus dietary botanical teas and nopal as captured in the dietary recall. The latter definition was inclusive of herbal teas and other herbal food-based products, such as liquadas, Herbalife-brand liquid supplements with botanicals, but excluded botanicals included in “energy drinks” (difficult to identify in this dataset). The rationale for this added step was that some herbal teas (e.g., chamomile, estafiate) and herbal liquadas (e.g., aloe, nopal) have documented biologic activity, may have toxic properties, and may interact with medications [5, 83, 139].

TABLE 4.3. Primary dietary supplement variables

Variable name	Description	Operalization
rxwbot_any dywbot_any eiwbot_any dywbot24_any eiwbot24_any dywbotf_any eiwbotf_any	Use of any product with a plant-based substance reportedly used for the prevention of disease or the treatment of symptoms, interim illnesses, or diseases. Use by this definition was derived from the medication inventory (rx), dietary supplement interview (dy) following the recall, the dietary supplement interview plus 24-hour (bot24) dietary recall data and combined medication inventory and dietary supplement interview data (ei). An additional variable assigned all fiber products to botanicals (botf).	Any use (1) vs. no use (0)
rxpbot_any dypbot_any eipbot_any	Many products contain a mixture of ingredients. Definitions were also created to capture products that were primarily botanicals with < 50% of the recommended daily allowance (RDA) for any listed vitamin or mineral. Use by this definition was derived from the medication inventory (rx), the dietary supplement interview (dy), and either (ei).	Any use (1) vs. no use (0)
rxwnvnm_any dywnvnm_any eiwnvnm_any dywnvnm24_any eiwnvnm24_any	Use of any non-vitamin, non-mineral dietary supplement, including botanicals. Use by this definition was derived from the medication inventory (rx), dietary supplement interview (dy) following the recall, the dietary supplement interview plus 24-hour (xxxx24) dietary recall data and combined medication inventory and dietary supplement interview data (ei).	Any use (1) vs. no use (0)
rxwpvnm_any dypnvnm_any eipnvnm_any	Use of any dietary supplement that is primarily non-vitamin, non-mineral (with < 50% RDA of a vitamin or mineral). Use by this definition was derived from the medication inventory (rx), dietary supplement interview (dy) following the recall, the dietary supplement interview plus 24-hour (nvnm24) dietary recall data and combined medication inventory and dietary supplement interview data (ei).	Any use (1) vs. no use (0)
rxds_user dyds_user eids_user	Identifies users of any dietary supplement, whether vitamin, mineral, botanical, or other NVNM.	Any use (1) vs. no use (0)
ingxxx variables	Specific botanical and NVNM ingredients were captured from the DSAM, based on the dietary data alone.	Any use (1) vs. no use (0)
ffxxx variables	Specific botanical ingredients (botanical teas, nopal) were captured from the 24-hour recalls	Any use (1) vs. no use (0)

DSAM=Dietary supplement assessment module of the NDSR

Because standard definitions are lacking, prevalence estimates were calculated for all of the classifications of botanical supplements delineated in Table 4.3. These include estimates based on both broad and narrow definitions of botanical supplement use: 1) including botanical teas; 2) including all fiber products; 3) including all NVNM products; 4) limiting to commercially-available botanical supplement products alone. Distinctions were also made between products that contained a botanical or NVNM ingredient (such as a multivitamin, multi-mineral with ginseng or lutein) and products that were primarily botanicals or NVNM that had incidental vitamin or mineral ingredients. Overall dietary supplement use was also captured.

TABLE 4.4. Additional dietary supplement variables

Variable Name	Description	Operalization
rxwbot_2plus dywbot_2plus eiwbot_2plus rxwbot24_2plus dywbot24_2plus eiwbot24_2plus eiwbotf_2plus	Variables identify users of 2 or more products with botanical ingredients. Use by this definition was derived from the medication inventory (rx), dietary supplement interview (dy) following the recall, the dietary supplement interview plus 24-hour (bot24) dietary recall data and combined medication inventory and dietary supplement interview data (ei). An additional variable assigned all fiber products to botanicals (botf).	Any use (1) vs. no use (0)
rxwnvnm_2plus dywnvnm_2plus eiwnvnm_2plus dywnvnm24_2plus eiwnvnm24_2plus	Variables identify users of 2 or more products with botanical or other NVNM ingredients. Use by this definition was derived from the medication inventory (rx), dietary supplement interview (dy) following the recall, the dietary supplement interview plus 24-hour (nvnm24) dietary recall data and combined medication inventory and dietary supplement interview data (ei).	Any use (1) vs. no use (0)
rxds_3plus dyds_3plus eids_3plus	Identifies users of 3 or more dietary supplements of any type, whether vitamin, mineral, botanical, or other NVNM.	Any use (1) vs. no use (0)
rxpowds_user dypowds_user eipowds_user	Identifies users of powdered (or wafer) dietary supplements by the medication inventory, the dietary supplement interview, or both.	Any use (1) vs. no use (0)
rxliqds_user dyliqds_user eiliqds_user	Identifies users of liquid (or teabag) dietary supplements by the medication inventory, the dietary supplement interview, or both.	Any use (1) vs. no use (0)
rxcaptabds_user dytabds_user eitabds_user	Identifies users of tablet (or capsule) dietary supplements by the medication inventory, the dietary supplement interview, or both. Any encapsulated product was classified in this category.	Any use (1) vs. no use (0)

Users of multiple botanical or NVNM supplements may constitute a different population than the occasional or casual user [86]. Hence, additional analyses assessed the prevalence of the multiple supplement user, defined as use of 3 or more dietary supplements and by 2 or more botanical or NVNM supplements. To further characterize supplements, the physical form of the supplement was captured (tablet or capsule, liquids or teas, powders or wafers). For all supplement types, a variable was created that identified the number of supplements each individual takes.

Individual botanicals were extracted from the ingredient files associated with the dietary supplement interview. Hence, a person was classified as a user of the particular botanical if any of the products consumed contained that botanical.

Motivations for botanical supplement use

In the dietary supplement interview, individuals were asked why they were taking a particular supplement. These reasons for use of supplements were extracted from the dietary supplement interview files and categorized into reported use for 19 different conditions (anemia, allergy, low appetite, cancer, diabetes, eye health, indigestion, gynecological conditions, heart health, kidney disease, joint health, liver health, lipid abnormality, lung disease, pain, prostate problems, sexual problems, thyroid health, mental stress), to supplement the diet, for prevention of health problems (bone health, immune system, healthy aging, general health, bowel health/digestion, mental clarity), and for nonspecific reasons. In addition, some participants indicated that the supplement had been recommended by a healthcare provider or by a family member or friend.

4.4 Covariate Assessments

Hispanic/Latino background

The primary variable of interest is Hispanic/Latino background. The literature reports very little data on any variation by background group. The variable is assessed in the Personal Information Questionnaire. In addition to inquiries about their place of birth, participants were asked, "*Which of the following best describes your Hispanic/Latino heritage?"* Response choices include both citizen of country or heritage, e.g., Dominican or Dominican descent. The proposed analysis variable will examine patterns of botanical supplement use by cultural background (Puerto Rican, Dominican, Cuban, Mexican, Central or South American or other Hispanic/Latino).

Acculturation

A key variable is acculturation, assessed as in the HCHS/SOL Sociocultural Questionnaire. The first 6 questions assess use of Spanish vs. English language, the second four address preferences for spending time with Hispanics/Latinos vs. non-Hispanics, and the third two items assess ethnic identity. The HCHS/SOL Sociocultural Questionnaire is based on the Short Acculturation Scale for Hispanics (SASH)[140], a 12-item scale validated with multiple Hispanic/Latino groups in California, Florida, and Wisconsin. Three factors in the scale, Language Use, Media, and Ethnic Social Relations achieved internal consistencies (Cronbach's α) of 0.90, 0.86, and 0.78. The scale discriminated first and second generation immigrants and was highly correlated with both length of residence in the US and subjective evaluation of acculturation (ρ = 0.70, 0.76). This variable is usually dichotomized at ≤2.99 (less acculturated), >2.99 (more acculturated) as per scoring instructions[141]. However, because HCHS/SOL altered the scale, per study guidelines, it was used as a continuous variable with a range from 1 to 4. Additional acculturation variables included years of US residence and birthplace within the US.

Access to healthcare

Current insurance status formed one variable: any vs. no insurance. A second variable will identify perceived lack of care access in the Health Care Use questionnaire, based on the question: "*Have you been unable to get healthcare when you needed it*? "

Medication use

Medication use was captured from the participant derived files. This included any use of medications for target conditions: cardiovascular disease, metabolic disease, lung disease and kidney disease. For this analysis, use of medication was dichotomized to any use of target medications and no target medication use.

Chronic disease

The HCHS/SOL Medical History captured chronic medical illness, including hypertension, heart disease, diabetes, lung disease, and kidney disease, among others. In botanical supplement literature, association or predictive models usually include a measure of chronic disease, most often the number of chronic conditions reported, (either as a continuous or a categorical variable) [2, 34, 126, 142]. The association between conditions captured in HCHS/SOL and botanical supplement use was explored. A simple index was created assigning a value of 1 to any of the conditions captured in the participant-derived files, except end-stage kidney disease. Following the Charlson Index, this condition was given a value of 2 [143]. Associations with the derived index were based on a score of 0, 1 or 2.

Perceived health

In other studies of botanical supplement use, individuals with poor perceived health are more likely to consume botanical supplements than those who perceive their health as good [15]. It is unknown whether or not these patterns apply to Hispanic/Latino populations. In HCHS/SOL, perceived health is measured with the Medical Outcomes Study 12-item Short Form (SF-12), a common measure in health research validated in numerous populations [144]. To maintain consistency with other studies, the first question of the scale was used ("Compared with a year ago, how would you rate your current health" –excellent, very good, good, fair, poor). It was categorized as very good to excellent, good, and fair to poor).

Demographics, income, and education

The HCHS/SOL cohort protocol included a thorough assessment of demographics and health behaviors. Demographics variables and their derivation and potential categories are listed in **TABLE4.3**. Prior studies have documented a consistent association between age and botanical supplements use with prevalence peaking in the 45-64 age groups, but the peak has been found to be later among Hispanics/Latinos [145]. Because the relationship between age and botanical supplement use was non-linear, it was categorized according to age groups defined in NHANES.

Education and income have been consistently associated with supplement use in the general population [122, 146], but the associations within Hispanic populations have been less consistent. Education was derived from reported years of schooling and categorized as less than a high school graduate, high school graduate or equivalent, and post-secondary education.

Income was derived from the midpoint of the reported family income categories, expressed as a percent of the published poverty threshold based on the family size and year of the field center clinic visit. Because supplement use is known to vary by geographic location within the US [122], field center location was also be examined.

Health behaviors

Positive health behaviors have been associated with dietary supplement use, including abstaining from cigarette smoking, getting physical activity, and adopting healthy dietary patterns [147, 148]. In addition, botanical supplement users are less likely to smoke than those not using botanicals [119]. In HCHS/SOL, cigarette smoking was ascertained via self-report. Participants were asked, *"Have you ever smoked at least 100 cigarettes in your entire life?"* If they answered yes, they were asked if they are current smokers. The variable is categorized as current smokers, former smokers, and never smokers. For most analyses, current nonsmokers were identified.

Physical activity assessment was based on variables from the global physical activity questionnaire as developed by the World Health Organization. Participants were asked how often and how long they engage in moderate and vigorous physical activity at work, for transportation (e.g., cycling, walking), and recreational activity. For the purposes of this analysis, physical activity was dichotomized as meeting or not meeting the 2008 physical activity recommendations of the Centers for Disease Control and Prevention [149]. The guidelines call for 150 minutes of moderate physical activity and/or 75 minutes of vigorous physical activity per week.

Eating patterns were summarized with the Alternative Healthy Eating Index-2010 (AHEI-2010). The AHEI was developed to update prior healthy eating indices based on US Dietary Guidelines with recommendations derived from scientific studies of diet and health outcomes [150, 151]. The AHEI assigns values for consumption of vegetables, fruit, whole grains, sugar-sweetened beverages, nuts/legumes, red/processed meats, trans fat, long-chain n-3 fatty acids, total polyunsaturated fatty acids, sodium, and alcohol intake with a maximum value of 110 [151]. In the Women's Health Initiative, the mean AHEI was 38.2; the mean for Hispanics was slightly lower at 34.5 [152]. In contrast, the mean AHEI in the Nurses' Health Study was 50.6.

TABLE 4.5. Additional variables

Covariate	HCHS/SOL questionnaire	Item	Potential categories
Gender	Personal Information	Gender	Male, Female
Geographic area		Field Center location	Miami, Bronx, Chicago, San Diego
Season of the year	Exploratory	Date of visit	Spring, summer, fall, winter

4.5 Analysis Procedures for Specific Aim 1

After construction of the dietary supplement data files, they were examined for frequencies, missing data, and uncoded responses. Uncoded responses were classified as delineated above. Just over 100 products required additional identification by José Rivera, PharmD, an expert in botanical medicine among Hispanics/Latinos. Twenty-nine products from the medication inventory could not be identified; 57 from the dietary supplement inventory.

Once all potential botanical supplements were identified, they were classified as belonging or not belonging to the dietary supplement classifications: botanical dietary supplement by each definition and by each assessment instrument (medication inventory, dietary supplement interview with and without dietary recall data, either the medication inventory or the dietary supplement interview). Each HCHS/SOL participant was classified as a botanical supplement user, based on his or her use of any botanical supplement over the past 30 days by the various definitions (**TABLE 4.3**). Prevalence estimates were calculated separately for dietary supplement and botanical supplement use under each definition and by each assessment instrument. All prevalence estimates were adjusted with HCHS/SOL-provided sample and nonresponse weights and standardized to the age distribution of the 2010 US Census.

Compare prevalence estimates of botanical supplement use between the medication inventory and the dietary supplement interview across categories of supplements

An important assumption was required for the analysis. Despite the fact that the dietary supplement interviewers had access to the medication inventory data, we presumed that, as per protocol, the dietary recall interviewers asked each participant about their supplement use, regardless of any botanical supplements reported with the medication inventory, and that they refrained from prompting if negative responses are contradicted by the medication inventory. This enabled us to compare the medication inventory prevalence estimates with the dietary recall estimates and assess the concordance of the two with a Cohen's kappa statistic. Please see Chapter 6 for analysis details.

4.6 Analysis of Specific Aim 2: Estimate population characteristics and use patterns associated with botanical supplement use among Hispanics/Latinos with particular attention to:

a. *Hispanic/Latino background, as defined by country of origin (Cuba, Puerto Rico/Dominican Republic, Mexico, Central/South America;*
b. *Acculturation (language preference, years in US, born in US);*
c. *Access to healthcare (insurance status, perceived lack of access);*
d. *Health indicators (medication use and perceived health):*
e. *Health behaviors(smoking, physical activity, healthy eating pattern);*
f. *Demographics (age, gender, education, income, geographic area):*
g. *Season of the year and area of the US*

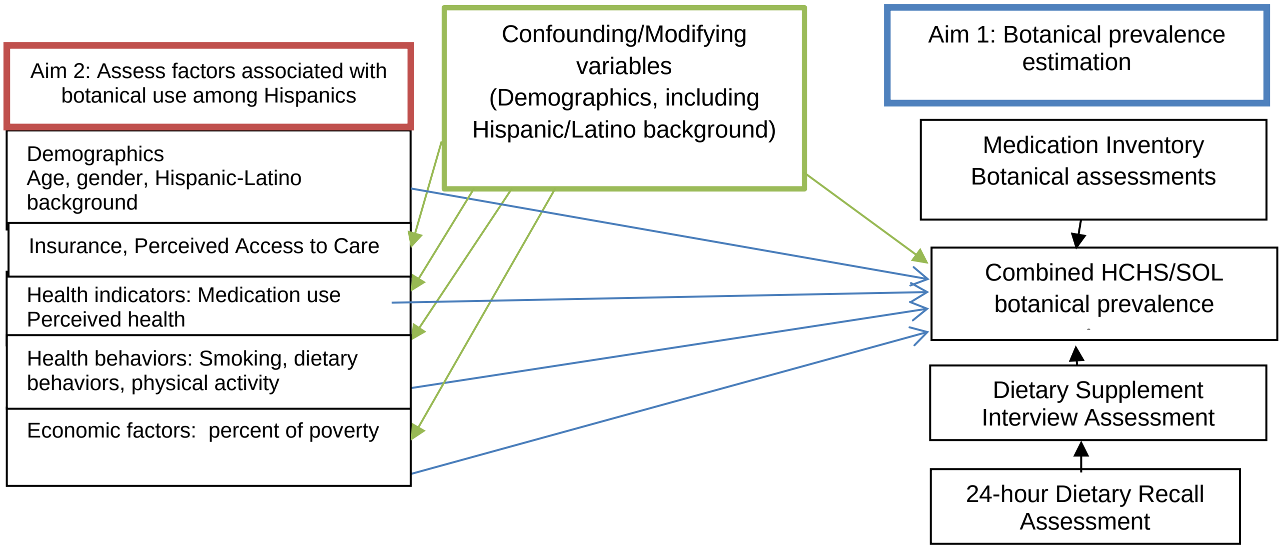


FIGURE 4.1. Schematic of research plan for Aim 2

4.6 Analysis Procedures for Specific Aim 2

The goal of the analysis was to characterize botanical supplement users across definitions (botanical supplement product use, botanical supplement products with teas, and botanical supplement products with other NVNM supplements) with particular attention to Hispanic/Latino background. Other than the 2007 NHIS report for the use of "biologically-based Complementary and Alternative Medicine" [122], distributions of botanical supplement use across Hispanic/Latino background groups has not been reported. No published manuscripts have examined the distributions of characteristics of botanical supplement users across Hispanic/Latino background.

For this analysis, all variables were examined for distributions across Hispanic/Latino background. Stratification of variables by age, gender, acculturation, and Hispanic/Latino background was investigated to examine the potential for effect modification. Based on these exploratory analyses along with examination of the impact of interaction terms in the models, decisions were made regarding including the need to present stratified analyses. Sample size considerations necessitated collapsing categories and presenting non-stratified results. All analyses were conducted in Stata 13 (*StataCorp, LP, College Station, TX)* with survey analysis commands applying sample and non-response weights. Additionally, bivariate distribution analyses were standardized to the age distribution of the US 2010 Census.

Multivariate binomial regression

After examining relationships among the variables, binomial regression analyses were used to examine the characteristics of botanical supplement users in HCHS/SOL. Definitions of botanical supplement use included botanical products (including fiber products), botanical products plus botanical teas, and all NVNM supplements. Each of these definitions relied on defining a supplement user as one who reported use either by the medication inventory or the dietary supplement interview. The sample was restricted to individuals with complete data for all variables of interest (see Chapter 7) utilizing Stata survey subpopulation commands to ensure appropriate adjustment of standard errors.

Two types of models were constructed. The first employed logistic regression to identify variables independently associated with botanical supplement use across the three definitions. Models including age, Hispanic/Latino background and gender were examined for odds ratio modification by including interaction terms. Interaction terms were dropped from the model if they were jointly not significant at the p=0.05 level using a partial F test. Additional stratified models were then examined, but only those that had an impact on the interpretation were retained. Otherwise, only summary models were reported. After interactions between age, gender, and background were assessed, all other variables were added to the model. Variables that did not contribute significantly to the model (partial F test) were dropped. Because field center location was expected to be an influential variable and was too collinear with Hispanic/Latino background to include in models, the variable cross-classifying field center and Hispanic/Latino background was substituted into models.

Most model evaluations employed survey procedures. However, because survey procedures do not support model comparison statistics, goodness of fit (Hosmer-Lemeshow) and discrimination (area under the receiver operating curve) statistics were checked without the survey commands.

The second modeling strategy was designed to examine the relationship between each of the sample characteristics and botanical supplement use. Here, log binomial models were created adjusting only for those variables identified as confounders in a directed acyclic graph. Non-confounders, e.g. variables within the causal pathway between the variable of interest and botanical supplement use, were not included in models [153]. For example, models for this Hispanic/Latino background were controlled for age and gender. Each model was examined for prevalence ratio modification through the inclusion of interaction terms of all other variables in the model with the primary exposure term for the model. The significance of these terms was tested jointly with a partial F test. Retained interaction terms followed the same strategy as reported for the logistic models.

Model adjustment strategies

Minimally-sufficient adjustment sets were determined for the variables of interest. Particularly of interest was Hispanic/Latino background. Based on published literature, the following assumptions were made in drawing up a directed acyclic graph (DAG)[154] (**FIGURE 4.2**):

1) Hispanic/Latino background varies by age and gender;
2) Age varies by gender;
3) Geographic location in the US is a function of Hispanic/Latino background and age;
4) Acculturation, defined by the SASH scale, US birthplace and years in the US, is a function of age, gender, and field center location.
5) Education is a function of Hispanic/Latino background (e.g., Cuban populations have greater education than Mexican) and is also influenced by age (older individuals acquired less education), gender, and acculturation (born in the US);
6) Perceived health is a function of age, gender, and education;
7) Positive health behaviors (non-smoking, healthy eating habits, physical activity) have been associated with increasing age, female gender, higher education, higher income, better perceived health, lower acculturation, and area of the country (western US)[147];
8) Income is a function of age, gender, education, and area of the US. It may also be a function of Hispanic/Latino background, but that is likely to be secondary to differences in education, age, and area of the US [155];
9) Insurance coverage is a function of age, income, and area of the US [155];
10) Perceived access to care is a function of age, insurance coverage, and area of the US;
11) Medication use is a function of age, insurance coverage, and area of the US.

Given assumptions about the relationships of the variables, the web-based graphical tool, DAGitty, version 2.0, was used to verify minimally-sufficient adjustment sets (**TABLE 4.6**)[156]. Where multiple adjustment sets were possible, the set without both Field Center and Hispanic/Latino background (highly collinear) was chosen.

Table 4.6. Minimally-sufficient adjustment set for key variables

Exposure variables	Minimally-sufficient Adjustment Sets
Hispanic/Latino background	Age, gender
Age	Hispanic/Latino background, Gender
Health Behaviors	Age, Gender, panic/Latino Background, Income, Insurance, Medication Use, Perceived Access to Care
Perceived Health	Acculturation, Age, Education, Gender
Acculturation	Field Center, age, Gender
Education	Acculturation, Age, Gender, Hispanic/Latino Background
Field Center	Age, Hispanic/Latino Background
Income	Age, Education, Field Center, Gender
Insurance coverage	Acculturation, Age, Field Center, Income
Perceived healthcare access	Acculturation, Age, Education, Gender, Hispanic/Latino Background, Income, Insurance, Medication Use (or Field Center, Insurance)
Medication Use	Age, Gender, Health Behavior, Hispanic/Latino Background, Income, Insurance, Perceived Access to Care

Power estimation

The HCHS/SOL cohort enrolled 16,414 participants, 16,060 of whom could be included in the analysis of Aim1 and 13,786 in Aim 2. With an expected prevalence of botanical supplements use between 0.15 and 0.25, a 2-sided alpha of 0.05 and a complete case analysis, power was estimated to be adequate for the planned analyses (**TABLE 4.6**).

TABLE 4.7. Power estimates for analysis of characteristics of botanical supplement users

Variable	N total	Measurement	Ref. level	Baseline	Difference	POR	Power
Background group	7680	Discrete groups	Mexican	0.06 to 0.30	0.03-0.20	1.15 - 4.16	89-99+%
Acculturation	7680	Quartiles	More acculturated	0.1 to 0.25	0.025-0.15	1.14 - 3.00	89-99+%
Insurance status	15360	None, any	insurance	0.1 to 0.20	0.03 – 0.20	1.34 – 3.86	79-99+%
Medication use	7680	0, 1+	No meds	0.10 to 0.20	0.03 – 0.30	1.34 – 6.00	79-99+%
Perceived Health	15360	Excellent/good vs. fair/poor	Good to excellent	0.15 to 0.25	0.03 - 0.15	1.24 – 2.43	71-99+%

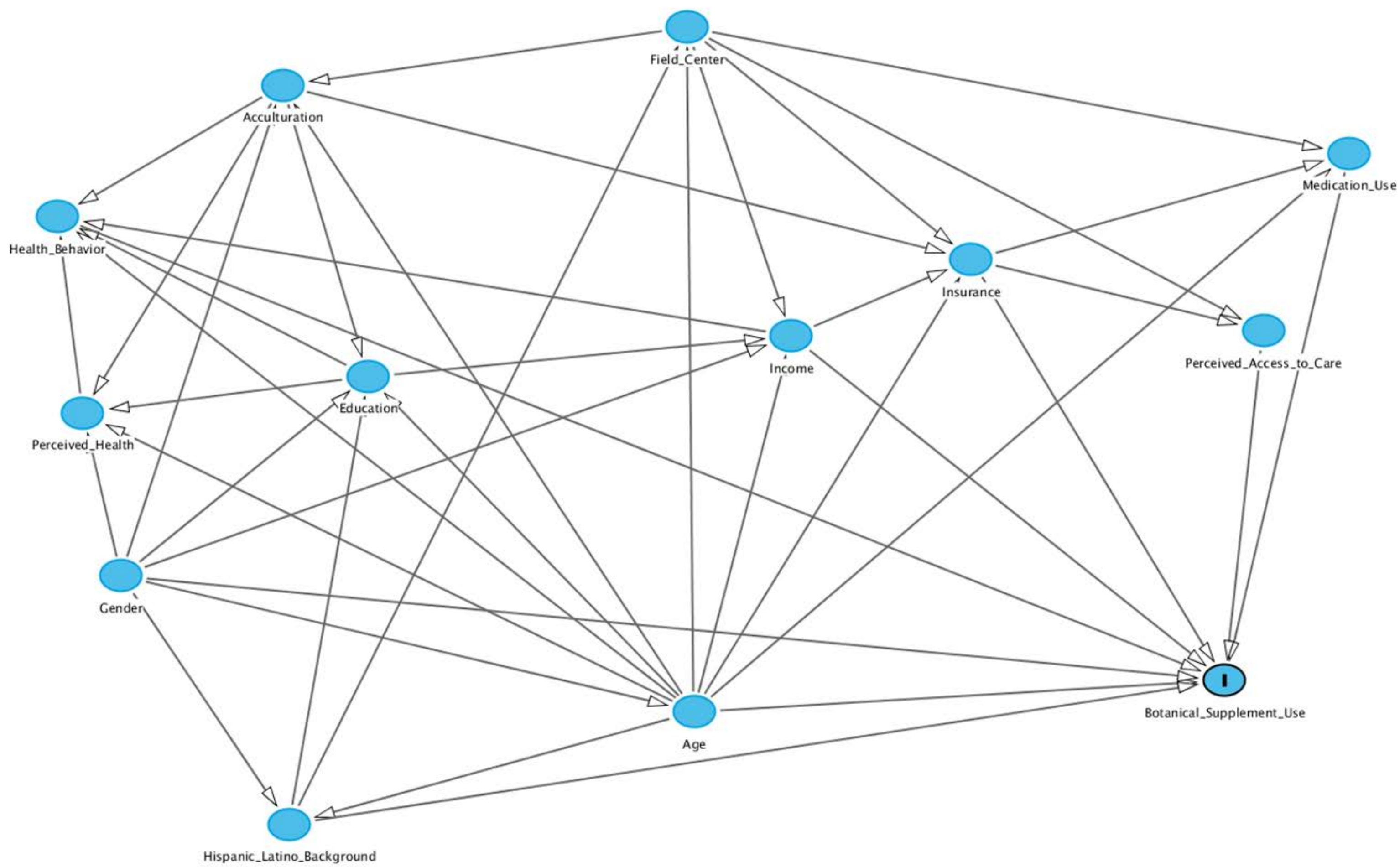


FIGURE 4.2 Directed Acyclic Graph depicting variable relationships associated with botanical supplement use in HCHS/SOL

CHAPTER 5: EXPLORATORY AND SENSITIVITY ANALYSES

5.1 Exploration of the Medication Inventory and Dietary Supplement Interview Data

Medication inventory data

The medication inventory data, first to be available for coding, utilized a database developed for medications—both prescription and over-the-counter—that categorizes substances by their primary indication. Vitamins, minerals, and fatty acids were largely recorded as nutritional products, but botanical supplements showed up in several categories including nutritional products, bulk chemicals, gastrointestinal agents, lipid-lowering agents, alternative medicines, and miscellaneous natural products. Identifying the botanicals required review of all of these files. Approximately 1500 substances were not identified by the medications database; many of these were found to be dietary supplement products (with and without botanicals). Of the 1500, twenty-nine could not be identified. An additional 1640 products could not be coded due to insufficient information (entered as "Nutritional Supplement" or "Misc. Natural Product" or "unknown") resulting in an unknown status for <400 individuals. Because the medications database mixed botanicals into several classification categories, it was not possible to ascertain if these products contained botanicals.

Ultimately, a dataset comprised of >10,000 entries was merged with the dietary supplement interview data and the file with derived variables. Frequencies were calculated for total dietary supplement use by participant along with prevalence of use of multiple supplements, non-vitamin, non-mineral supplements (including botanicals), and botanical products.

Dietary supplement interview data

A similar process was employed for the dietary data, released in December 2012. The dietary supplements from the 30-day supplement interview were recorded in the dietary supplements module (DSAM) of the NDSR. Released data included detailed supplement product names and/or descriptions, allowing for refined product coding using the Langual-based coding scheme. Although the goal of this project is distinguishing botanicals from non-botanicals, additional data on product constituents from the DSAM were considered potentially useful. The coding scheme was reviewed and revised based on newly available data with increased granularity. All but 57 of the78 unknown products were identified by Dr. Rivera resulting in an unknown status for 18 individuals. The medication data was reexamined to ensure that the coding and product identification was consistent across the datasets.

We found that the dietary supplement interview files did not record botanical teas. Because we saw botanical teas in the medication inventory data, we requested the opportunity to review the food level files from the 24-hour recall data. After gaining access to these files in June, we extracted multiple variables, including botanical teas (chamomile, hibiscus, herbal) and liquid dietary supplement products containing protein supplements, aloe, or nopal. Individuals were counted as a supplement user if they consumed one of the products on either day. We created datasets including and excluding green tea (*Camilla sinensis*) and nopal (whole fruit) as botanicals for this analysis. Liquid supplement products with nopal were included in both datasets.

The dietary data contains approximately 2,700 different products representing > 15,000 entries. We estimated the prevalence of use of any dietary supplement, 3 or more dietary supplements, non-vitamin, non-mineral supplements, and botanical supplements based on the 30-day supplement files alone. We repeated the analysis including botanical teas and other liquid supplements as captured from the food file data. All estimates were adjusted with sample and nonresponse weights to reflect the Hispanic/Latino population in the four target areas, namely the Bronx, Miami, Chicago, and San Diego. Prevalence estimates across different assumptions on what is counted and not counted as a dietary supplement, a non-vitamin, non-mineral supplement, and a botanical supplement were calculated (**TABLE 5.3**).

Ingredient files

Ingredient files for the dietary supplement data also became available in June 2013. The file contained 41, 096 entries for individual ingredients of reported dietary supplement products and classified them with the same schema used in NHANES (vitamins, minerals, botanicals, amino acids, and other). There were differences in classification as compared with the Langual-based scheme (and, possibly some misclassification). However, it was useful for classifying individuals as users of supplements with various ingredients to identify the prevalence of specific botanical and other NVNM ingredients. Because it was not possible to identify the components of the medication inventory data with the same level of granularity, the Langual-based categorization scheme was used for comparison of the medication inventory and dietary supplement interview.

5.2 Comparison of Prevalence across Botanical Supplement Definitions

Preliminary exploratory analyses compared prevalence estimates across supplement definitions. These preliminary comparisons were not restricted to individuals with data for both the medication inventory and the dietary supplement interview, nor were they standardized to the age distribution of the US population **(TABLE 5.1).** This resulted in some differences as compared with tables in the following chapters.

The medication inventory alone captured fewer dietary supplements of any kind—about 25% compared with a prevalence of 38% from the dietary supplement interview. Combining the two, i.e., counting as supplement users anyone who reported taking a supplement by either method, increased the prevalence of any supplement to about 42%. Larger proportional increases were noted in other supplement categories. For example, supplements with NVNM components by the dietary supplement interview were nearly double that of the medication inventory. Adding botanical teas and other liquid supplements from the 24-hour dietary recalls (food files) tripled the estimates for botanical supplement use. Similar patterns were present with comparisons of the users of 3 or more dietary supplements and 2 or more NVNM or botanical products. More multi-supplement users were identified in the dietary supplement interview and these increased slightly with identification of a user by either instrument. Not surprisingly, because the dietary recalls capture food-based supplements, not captured well by the other assessments, the prevalence of multi-botanical users increases more than 4-fold with the addition of botanical teas. Interestingly, there were fewer liquid supplements reported with the dietary supplement interview than with the medication inventory. Many of these types of products were seen with the dietary recall files. Contrary to expectation, very few raw botanicals (e.g., bulk herbs) were captured in either the dietary supplement interview or the medication inventory. Only scanning the food files for nopal increased those estimates.

TABLE 5.1 Prevalence of non-vitamin, non-mineral and botanical supplement use in the HCHS/SOL Cohort across datasets

Variable	Medication Inventory	Dietary Supplement Interview (no teas)	Dietary Supplement Interview With Dietary Recall data (excluding nopal/green tea)	Dietary Supplement Interview With Dietary Recall data (with teas- including nopal/green tea)	Medication Inventory or Dietary Supplement Interview	Medication Inventory or Dietary Supplement Interview plus Dietary Recall (with herbal teas, no nopal)	Medication Inventory or Dietary Supplement Interview plus Dietary Recall (with nopal & herbal/green tea)
	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
Any dietary supplement (DS)	24.7 (23.5, 26.0)	38.5 (37.1, 39.9)	42.3 (40.8, 43.8)	44.3 (42.8, 45.8)	42.5 (41.1, 43.9)	45.7 (44.2, 47.2)	47.4 (45.9, 48.9)
DS with any NVNM component	12.2 (11.5, 13.0)	23.7 (22.4, 30.0)	29.0 (27.6, 30.4)	31.8 (30.4, 33.3)	26.7 (25.4, 27.9)	31.6 (30.2, 33.0)	34.1 (32.7, 35.9)
DS primarily NVNM	10.6 (10.0, 11.4)	18.3 (17.2, 19.4)	24.3 (23.0, 25.6)	27.5 (26.1, 28.9)	20.9 (19.8, 22.1)	26.5 (25.2, 27.8)	29.5 (28.1, 31.0)
DS with any botanical component	4.3 (3.9, 4.7)	8.9 (8.2, 9.7)	15.1 (14.1, 16.2)	19.1 (17.9, 20.4)	11.1 (10.3, 11.9)	17.0 (15.9, 18.1)	20.8 (19.6, 22.1)
Primarily botanical products	3.3 (3.0, 3.6)	5.6 (5.1, 6.2)	12.2 (11.3, 13.1)	16.6 (15.5, 17.7)	7.3 (6.7, 7.9)	13.6 (12.7, 14.6)	17.9 (16.8, 19.1)
Use of 3+ DS	6.2 (5.6,6.8)	9.4 (8.7, 10.2)	8.8 (8.7, 11.1)	12.1 (11.3, 13.1)	10.9 (10.2, 11.8)	8.7 (8.6, 8.8)	13.4 (12.5, 14.3)
Use of 2+ NVNM	3.1 (2.8, 3.5)	5.1 (4.6, 5.8)	9.1 (8.3, 9.9)	9.8 (9.0, 10.7	6.3 (5.7, 6.9)	9.9 (9.1, 10.7)	10.6 (9.8, 11.5)
Use of 2+ DS with botanicals	0.9 (0.8, 1.1)	2.1 (1.9, 2.4)	5.1 (4.6, 5.7)	5.6 (5.0, 6.2)	2.6 (2.3, 2.9)	5.5 (5.0, 6.1)	6.0 (5.4, 6.6)
Use of 2+ botanical products	0.7 (0.6, 0.8)	1.2 (1.0, 1.4)	4.1 (3.6, 4.5)	4.2 (3.7, 4.7)	1.6 (1.4, 1.8)	4.4 (4.0, 4.9)	4.5 (4.1, 5.0)
Liquids/Teas*	3.4 (2.7, 4.2)	1.1 (0.7, 1.7)	19.1 (17.6, 20.6)	24.6 (23.1, 26.2)	2.9 (2.4, 3.6)	19.0 (17.6, 20.4)	24.1 (22.7, 25.6)
Powders*	25.7 (26.7, 27.8)	30.7 (28.9, 32.6)	31.0 (29.8, 33.2)	30.8 (29.2, 32.6)	33.0 (31.2 , 34.8)	33.6 (31.9, 35.3)	33.0 (31.3, 34.7)
Tablets, capsules*	88.5 (86.7, 89.9)	89.9 (88.7, 91.1)	82.4 (81.0, 83.7)	78.8 (77.4, 80.3)	90.4 (89.2, 91.5)	84.5 (83.2, 85.7)	81.5 (80.1, 82.7)
Other form (e.g., raw herb)	1.4 (0.9, 2.2)	0.1 (0.04, 0.3)	0.1 (0.05, 0.3)	5.6 (4.8, 6.7)	0.9 (0.6, 1.4)	0.9 (0.6, 1.3)	6.0 (5.1, 7.0)

Abbreviations:: DS—dietary supplements; NVNM—non-vitamin, non-mineral products, including botanicals.
[†]Proportions are adjusted by sample and nonresponse weights. * reflects proportion of supplement users who reported us e of at least one product in this category.
Note: estimates in this table were not corrected with new information and were not restricted to comparisons of individuals who had data for both measures.

5.3 Sensitivity Analyses: Assignment of Unclassifiable Supplements to NVNM and botanical categories

Incomplete product identification in the medication inventory data limited the ability to make the datasets entirely comparable. To assess the impact of products that could not be compared (set to missing in all but total dietary supplement analysis), additional analyses were completed assigning random samples of those products to supplements with NVNM and botanical ingredients.

Statistical analysis

First, the 1640 uncoded products were identified. Second, the proportion of the total supplements belonging to each category of NVNM and botanical supplement was defined. Third, a random sample corresponding to 33% of those uncoded supplements was assigned to the category of products with NVNM ingredients. Correspondingly, 25% of supplements were assigned to the category of a primarily NVNM supplement, 17% were assigned to a category of supplements containing a botanical ingredient, and 12.5% were assigned to the category of a primarily botanical supplement. Additional samples increased the percentages of supplements assigned to each category as follows: 1) 67-100% was assigned as products containing a NVNM; 2) 50-75% of products were assigned as a primarily NVNM product; 3) 17-50% of products were assigned as containing a botanical; and 4) 12.5-37.5% of products were assigned as primarily botanical products. The dataset was then restructured to identify supplement users rather than individual supplements. Prevalence and kappa statistics were recalculated for each of the new datasets. This process was repeated with 5 additional random samples. All comparisons were restricted to participants who had data for both the medication inventory and the dietary supplement interview.

Results and interpretation

Assignment of random samples of those supplements that could not be coded to botanical reduced the discrepancy between the prevalence as assessed by the dietary supplement interview and that of the medication history. For example, if half of the uncoded supplements actually had a botanical ingredient, the prevalence of supplements with a botanical as ascertained by the medication inventory increased to 7.0-7.5% as compared with 9.4% by the dietary supplement interview (**TABLE 5.2**). If 37.5% of those supplements were actually primarily botanical products, their prevalence in the medication inventory might exceed their prevalence in the dietary supplement interview (5.9-6.4 vs. 5.9%). Similar reductions in the discrepancies were seen for supplements with NVNM ingredients and primarily NVNM supplements. The discrepancy between the two assessments remained fairly large (16% vs. 25%), even if all of the uncoded supplements were assigned to the category of supplements with NVNM ingredients. Interestingly, concordance statistics improved slightly, but remained in the fair to moderate range (κ: 0.34-0.59). Results suggest that the unclassifiable supplements did not have a major influence on the interpretation of the comparison between the medication inventory and dietary recall.

TABLE 5.2. Sensitivity Analysis: Comparison of 30-day NVNM and botanical assessments through the medication history and dietary supplement questionnaire in the HCHS/SOL Cohort*

	Medication Inventory	Dietary Supplement Interview	Kappa
Variable	% (95% CI)	% (95% CI)	(95% CI)
DS with any NVNM component	12.9	24.6	0.50
33% of missing set to NVNM	14.2 – 14.3		0.42 - 0.45
67% of missing set to NVNM	15.1 – 15.3		0.46 – 0.47
100% of missing set to NVNM	16.0		0.47
DS primarily NVNM	11.3	19.0	0.49
25% of missing set to NVNM	12.3 – 12.4		0.50
50% of missing set to NVNM	13.7 - 13.8		0.50 -0.51
75% of missing set to NVNM	13.7 – 14.5		0.51
DS with any botanical component	4.4	9.4	0.30
17% of missing set to botanical	5.5 – 5.7		0.32 – 0.34
33% of missing set to botanical	6.4 – 6.6		0.34 – 0.36
50% of missing set to botanical	7.0 – 7.5		0.35 – 0.37
Primarily botanical products	3.5	5.9	0.32
13% of missing set to botanical	4.1 - 4.4		0.34 – 0.37
25% of missing set to botanical	4.8 – 5.1		0.37 – 0.39
38% of missing set to botanical	5.9 – 6.4		0.38 – 0.40

Abbreviations: DS—dietary supplements; NVNM—non-vitamin, non-mineral products, including botanicals; MH—medication history; DS—dietary recall

†Proportions are adjusted by sample and nonresponse weights and are age-standardized to the 2010 Census distribution for Hispanics/Latinos

*Analysis is restricted to subjects with data for both the medication inventory and the dietary supplement interview. Estimates are based the range across six random samples. Ideally, 1000 samples would be examined.

5.4 Bivariate Analyses

Defining supplement users by their reported use in either the medication inventory or the dietary supplement interview, bivariable patterns were explored across a number of variables associated with dietary supplement use as reported in the literature. These included demographic (Hispanic/Latino background, age, gender, education), acculturation (years of US residence, immigrant generation (born in US), language preference), economic (income), access to health care (insurance, perceived lack of access), health indicators (medication use, chronic illness, perceived health), and health behaviors (smoking, physical activity, healthy eating pattern). Also examined were patterns of supplement use by marital status, season and location of the field center. Prevalence estimates were calculated for use of any dietary supplement, for use of a primarily NVNM supplement (includes botanicals) and for use of a primarily botanical supplement (without fiber products) (**TABLE 4.3**). Sample and nonresponse weights were applied; analysis was restricted to participants with data for both the medication inventory and dietary supplement interview.

For this analysis, the study population consisted of 15,772 participants who provided summary medication inventory data and the dietary supplement interview (**TABLE 5.3**) Adjusting for sampling probabilities and nonresponse, 26% of the population was seen in the Bronx, 16% in Chicago, 30% in Miami, and 27% in San Diego. Individuals with a Mexican background were the most numerous (38%), followed by Cubans (21%), Puerto Ricans (15%), Dominicans (9%), Central Americans (7%), South Americans (5%), and Other (mixed heritage)(4%). Forty-eight percent of the participants were less than forty, with a mean age of 41. Forty-eight percent were male. Participants had lived in the US for a mean of 20 years and 72% had lived in the US ≥10 years. Only 22% of the population was born in the US and only 25% preferred to use English rather than Spanish for communication. Thirty-two percent of the population had less than a high school education and 39% had post-secondary education. About 64% reported family incomes at 200% of the poverty threshold or less; 65% had an income of < $30,000 per year. About half were uninsured and half were living with a partner. With regard to health behaviors, 79% were nonsmokers and 66% met the CDC 2008 physical activity guidelines: 75 minutes of vigorous or 150 minutes of moderate physical activity per week through work, transportation, or leisure activities.

The mean score for the 2010 Alternative Healthy Eating Index, based on US Dietary Guidelines and scientific studies of diet and health outcomes [150, 151], was 47.5.

In unadjusted analyses, differences in total supplement use across Hispanic/Latino background were relatively small. Larger differences were seen when comparing botanical supplement use. Mexicans, Central, and South Americans reported greater use than other groups. Females reported more use than males and use of all supplement types increased with age. Prevalence of use of any dietary supplement, NVNM supplements, and botanical supplements increased with age.

Small differences were seen across acculturation variables; considering botanicals, greater prevalence (8 vs. 5%) was present for those who prefer to speak Spanish and with first generation (born outside the US) vs. second generation (born in the US) immigrants, but use increased with length of residence in the US (not adjusted for age). Prevalence also increased with a post-secondary education and with an income of at least $30,000 per year. Income adjusted for family size (poverty status) also indicates greater prevalence with greater family income. NVNM supplement use varied substantially by field center location; participants in San Diego (27%) and Miami (24%) reported greater use than Chicago (17%) and the Bronx (15%).

Dietary supplement use was associated with positive health behaviors. Prevalence of use of any dietary supplement, NVNM supplements, and botanicals increased with greater adherence to a healthy eating pattern, as measured with the 2010 AHEI. For example, the highest quintile of the AHEI, corresponding to a mean value of 60.0 (95% CI: 59.8, 60.2), was associated with a prevalence of botanical supplement use of 14% whereas the lowest quintile (mean 38.7; 95% CI: 38.5, 38.8) was associated with a prevalence of 4%. Prevalence of dietary supplement use (any, NVNM, or botanical) was about the same for those who adhered to physical activity guidelines as those who did not. Smokers were much less likely to take supplements of any kind. For example, prevalence of NVNM use among smokers was 14% and increased to 23% among nonsmokers.

TABLE 5.3 Prevalence of dietary supplement use over 30 days defined by either the medication inventory or dietary supplement interview

		Use of any dietary supplements		Use of any primarily NVNM supplements		Use of any primarily botanical supplements	
	N*	n*	*% (95% CI)* †	n	*% (95% CI)*	n	*% (95% CI)*
Overall	15,722	7455	42.8 (41.3, 44.3)	3,854	21.2 (20.1, 22.4)	1,449	7.6 (6.9, 8.2)
Hispanic/Latino background							
Dominican	1,469	617	41.0 (36.9, 45.1)	255	15.2(12.8, 17.6)	70	4.5 (3.0, 6.0)
Central Amer.	1,151	805	43.3 (39.8, 46.9)	451	23.5 (20.8, 26.2)	170	9.6 (7.7, 11.6)
Cuban	3,240	1,005	42.1(39.2, 45.1)	573	23.4 (21.2, 25.6)	141	6.2 (4.9, 7.4)
Mexican	6,006	3,176	44.5 (41.9, 47.0)	1,705	22.4 (20.4, 24.3)	773	9.8 (8.7, 10.8)
Puerto Rican	2,383	1,112	40.5 (37.5, 43.6)	452	17.4 (14.7, 20.0)	131	4.5 (3.5, 5.6)
South Amer.	796	534	48.3 (44.0, 52.6)	307	25.1 (21.5, 28.9)	124	9.0 (6.9, 11.0)
Other Hisp.‡	669	206	36.2 (29.8, 42.7)	111	18.4 (13.2, 23.5)	40	6.7 (3.9, 9.5)
Gender							
Male	6,258	2,537	38.1 (36.3, 40.0)	1,277	18.5 (17.0, 20.0)	446	6.0 (5.2, 6.7)
Female	9,415	4,918	47.1 (45.3, 48.9)	2,577	23.7 (22.2, 25.1)	1,003	9.0 (8.2, 9.9)
Age							
18 - 29	4,295	676	26.9 (24.5, 29.4)	146	8.9 (7.2, 10.7)	110	4.4 (3.3, 5.5)
30 - 39	3,302	879	38.0 (35.0, 41.0)	313	14.7 (12.7, 16.8)	205	8.1 (6.6, 9.5)
40 - 49	3,444	1,913	46.6 (44.3, 48.9)	612	20.5 (18.3, 22.8)	400	8.0 (6.9, 9.1)
50 - 59	2,511	2,336	54.6 (52.6, 57.0)	1,331	26.2 (24.3, 28.0)	449	9.7 (8.4, 11.0)
60 - 69	1,655	1,317	59.4 (56.1, 62.7)	1,142	30.5 (28.2, 33.0)	233	9.4 (7.5, 11.3)
70 - 74	509	330	70.4 (65.3, 75.5)	443	35.3 (31.0, 39.6)	52	11.6 (7.7, 15.6)
Education							
< HS	4,946	2,670	40.0 (38.1, 42.0)	1,282	17.9 (16.5, 19.4)	469	5.9 (5.2, 6.7)
HS graduate	4,409	1,713	37.9 (35.4, 40.3)	826	17.2 (15.5, 18.8)	311	5.8 (4.9, 6.7)
Some college	6,071	2,908	48.4 (46.0, 50.8)	1,653	26.4 (24.4, 28.3)	635	10.0 (8.8, 11.2)
Marital status							
Single	5,376	1,662	34.1 (31.9, 36.2)	738	14.6 (13.0, 16.1)	255	4.9 (40.1, 5.8)
Partnered	7,737	3,993	45.6 (43.5, 47.7)	2,170	23.6 (22.0, 25.2)	862	9.0 (8.1, 9.9)
Widowed or divorced	2,582	1,787	52.9 (50.1, 55.6)	939	27.8 (25.5, 30.1)	329	8.7 (7.4, 10.0)
Language preference							
Spanish	11,841	6,398	44.3 (42.6, 46.0)	3,263	22.3 (21.0, 23.5)	1,234	7.9 (7.2, 8.6))
English	3,881	1,048	38.4 (35.4, 41.4)	591	17.9 (15.6, 20.2)	215	6.6 (5.3, 7.9)
Born in US							
No	12,179	6,493	45.1 (43.5, 46.6)	3,370	22.8 (21.6, 24.1)	1,279	8.2 (7.5, 9.0)
Yes	3,532	1,244	35.9 (33.0, 38.9)	479	15.5 (13.5, 17.6)	167	5.2 (4.0, 6.3)
Years in US							
< 5	2,168	722	36.5 (33.5, 39.5)	361	17.0 (14.6, 19.4)	130	5.2 (4.0, 6.3)
5 -9	2,233	848	39.1 (36.0, 42.2)	446	20.6 (20.9, 23.5)	168	7.8 (6.1, 9.5)
10+	11,262	5,858	44.8 (43.2, 46.5)	3,037	22.2 (20.9, 23.5)	1,147	8.0 (7.3, 8.7)
Insurance status							
None	7,776	3,467	39.6 (37.7, 41.4)	1,881	20.9 (19.5, 22.3)	772	8.1 (7.2, 8.9)
Any	7,655	3,885	46.2 (44.3, 48.2)	1,930	21.8 (20.1, 23.4)	664	7.1 (6.2, 8.1)
Income (income_c2)**							
< $30,000	9,259	4,546	41.6 (40.0, 43.2)	2,289	19.7 (18.5, 21.0)	840	6.8 (6.2, 7.5)
$30,000+	5,030	2,342	47.4 (45.0, 49.8)	1,310	25.4 (23.1, 27.7)	519	9.5 (8.2, 10.7)
Percent of poverty							
<100%	5,639	2,584	39.2 (37.2, 41.2)	1,231	17.5 (16.1, 19.0)	439	6.0 (5.2, 6.8)
100-<200%	5,010	2,577	43.7 (41.6, 45.8)	1,398	22.0 (20.4, 23.7)	551	8.4 (7.5, 9.4)
200-<300%	1,986	977	46.9 (43.0, 50.8)	538	24.8 (21.6, 28.1)	207	8.0 (6.5, 9.5)
300% or more	1,646	745	54.6 (50.2, 59.0)	430	31.5 (27.7, 35.3)	160	11.5 (9.1, 13.9)

Prevalence estimates include medication history estimates updated by the dietary assessment. *N = overall frequencies are adjusted, but n=raw sample frequencies. Percentages reflect sample and nonresponse weights. All estimates are standardized to the age distribution of the 2010 census †Percent of use with 95% confidence interval s based on sample and nonresponse weights. ‡Other Hispanic/Latino includes those reporting mixed backgrounds. **Missing 9.1% of data for the income variable

TABLE 5.4 Prevalence of dietary supplement use over 30 days defined by either the medication inventory or dietary supplement interview across additional covariates

		Use of any dietary supplements		Use of any NVNM supplements		Use of any botanical supplements	
	N*	n*	*% (95% CI)* †	n	*% (95% CI)*	n	*% (95% CI)*
Alternative Healthy Eating Index Quintiles							
Q1: mean 39	3,929	1,098	33.0 (30.3, 35.6)	487	13.8 (12.0, 15.5)	149	4.3 (3.3, 5.3)
Q2: mean 44	3,534	1,336	39.4 (37.0, 41.9)	645	18.7 (16.7, 20.8)	223	5.7 (4.7, 6.7)
Q3: mean 49	3,150	1,482	43.6 (41.0, 46.1)	763	20.5 (18.7, 22.3)	268	7.3 (6.0, 8.6)
Q4: mean 53	2,688	1,617	49.0 (46.0, 52.0)	879	26.5 (23.8, 29.2)	351	9.9 (8.3, 11.5)
Q5: mean 60	2,277	1,875	57.4 (54.2, 60.6)	1,064	33.1 (29.5, 36.6)	452	13.8 (12.1, 15.6)
Meets 2008 Physical Activity Guidelines							
Yes	10,469	4,717	42.6 (40.7, 44.5)	2,472	21.3 (19.9, 22.8)	949	7.6 (6.8, 8.3)
No	5,170	2,714	43.3 (41.3, 45.3)	1,373	21.1 (19.5, 22.7)	497	7.6 (6.8, 8.4)
Cigarette use							
Never smoked	9,617	4,685	44.0 (42.3, 45.8)	2,409	21.7 (20.5, 23.0)	926	7.8 (7.0, 8.5)
Former Smoker	2,726	1,662	50.1 (47.4, 52.9)	941	27.8 (25.5, 30.1)	360	11.0 (9.5, 12.4)
Current smoker	3,339	1,094	33.2 (30.5, 35.8)	500	14.3 (12.3, 16.3)	120	4.3 (3.2, 5.4)
Chronic medication use†							
Yes	4,977	3,493	53.8 (51.6, 56.0)	1,864	29.1 (27.5, 30.8)	638	9.3 (8.3, 10.4)
No	10,746	3,962	37.8 (36.0, 39.5)	1,990	17.5 (27.5, 30.8)	811	6.7 (6.0, 7.5)
Chronic illness score‡							
0	4,249	1,385	36.0 (33.5, 38.6)	664	15.9 (14.2, 17.6)	299	7.0 (5.9, 8.2)
1	5,322	2,319	40.1 (38.0, 42.1)	1,200	19.0 (17.4, 20.6)	468	7.0 (6.0, 7.9)
2 or more	6,151	3,751	49.9 (47.9, 52.0)	1,990	26.7 (25.0, 28.5)	682	8.4 (7.5, 9.4)
Perceived Health							
Very good to excellent	4,437	1,728	41.8 (39.2, 44.3)	933	21.2 (19.0, 23.4)	352	7.5 (6.3, 8.7)
Good	7,238	3,394	41.8 (39.9, 43.7)	1,758	20.7 (19.3, 22.2)	683	7.7 (6.8, 8.5)
Fair to poor	4,615	2,314	46.1 (43.6, 48.6)	1,156	22.2 (20.5, 24.0)	410	7.4 (6.4, 8.5)
Season							
Winter	3,339	1,539	42.7 (39.9, 45.5)	793	21.4(19.0, 23.8)	597	7.5 (6.1, 8.8)
Spring	4,262	2,225	45.9 (43.1, 48.6)	1,194	23.8 (21.8, 25.9)	836	8.1 (6.8, 9.4)
Summer	4,296	1,911	41.0 (38.5, 43.4)	923	18.0 (16.1, 19.8)	617	6.3 (5.4, 7.2)
Fall	3,825	1,780	41.6 (38.7, 44.5)	944	21.7 (19.7, 23.7)	630	8.4 (7.0, 9.7)
Field center location							
Bronx	4,180	1,574	38.7 (36.2, 41.2)	613	14.6 (12.9, 16.3)	162	4.0 (3.1, 4.8)
Chicago	2,565	1,770	36.6 (34.4, 38.7)	862	17.0 (15.2, 18.7)	365	7.3 (6.0, 8.5)
Miami	4,766	1,847	43.4 (40.9, 46.0)	1,069	24.0 (22.2, 25.9)	343	7.6 (6.5, 8.7)
San Diego	4,212	2,264	50.2 (46.7, 53.7)	1,310	27.1 (24.2, 30.0)	579	11.3 (9.8, 12.7)

Prevalence estimates include medication history estimates updated by the dietary assessment. *N = overall frequencies are adjusted, but n=raw sample frequencies. Percentages reflect sample and nonresponse weights. All estimates are standardized to the age distribution of the 2010 census †Percent of use with 95% confidence interval s based on sample and nonresponse weights. †Medication use was based on use of any of the following classes of medications: anti-anginal, anti-arrhythmic, anticoagulant, anti-platelet, anti-diabetic, antihypertensive, cardiac glycoside, chemotherapy, lipid-lowering agent, or non-steroidal anti-inflammatory. Variable does not include use of oral contraceptives, fertility agents, or hormone replacement therapy. ‡Exploratory variable--Chronic illness score assigns one point each to asthma, COPD, diabetes, dyslipidemia, hypertension, stroke, cerebrovascular disease, and chronic kidney disease. End stage renal disease is given a score of 2.

Both use of chronic medications and presence of a chronic health condition was associated a higher prevalence of botanical and NVNM use. For example, the prevalence of NVNM use was 27% among those with 2 or more conditions compared with 16% among participants with no chronic conditions. Of the two variables, the medication use variable was more strongly related to supplement use and thus was chosen for inclusion in models.

CHAPTER 6:

COMPARISON OF A MEDICATION INVENTORY AND A DIETARY SUPPLEMENT INTERVIEW IN ASSESSING DIETARY SUPPLEMENT USE IN THE HISPANIC COMMUNITY HEALTH STUDY/STUDY OF LATINOS (HCHS/SOL)

6.1 Introduction

Growth in the number of dietary supplements on the market has been marked, increasing from 4,000 products in 1994 to 55, 000 in 2009 [157]. Dietary supplements result in > $20 billion in sales each year with growth of about 6% per year [158] and prevalence of dietary supplement use is common in the United States (US) general public [122, 147]. In national studies, among Hispanics/Latinos, the reported prevalence of any dietary supplement use (34%) in the past 30 days was lower as compared with Non-Hispanic whites (59%) [147]. National studies of botanical and non-vitamin, nonmineral supplement use in the prior year also report lower prevalence among Hispanics/Latinos, 12% compared with 23% [122], but other studies conducted within Hispanic/Latino populations have resulted in much higher estimates: >60% in past twelve months [50, 113], leading to questions about the comparability of study designs.

Assessment of supplement use is challenging in any population, but is particularly difficult among ethnic minorities and with regard to botanical and other non-vitamin, non-mineral (NVNM) supplements. Most observational studies rely on self-completed questionnaires [61-64] or telephone surveys [65] to collect dietary supplement data, asking participants to choose from a list of supplements that may or may not be consistent with cultural traditions. Product examination is considered a criterion standard for supplement assessment [66], but, if not assessed in the home, could miss supplements individuals forget to bring in to the study visit. A more systematic approach to supplement assessment is clearly indicated.

The current study utilizes the baseline data of the Hispanic Community Health Study/Study of Latinos (HCHS/SOL). HCHS/SOL is unique in its supplement assessments in two ways. The study collected supplement data in a sample of US Hispanics/Latinos using both a dietary interview method and medication-based (product examination inventory) method to assess supplement use over 30 days. In addition, dietary supplement use was also captured in the 24-hour recall data, reflecting immediate use. This analysis measured the prevalence of dietary supplement use among Hispanics/Latinos of diverse Hispanic backgrounds by a medication inventory and a dietary supplement interview and compared the two with concordance statistics. Prevalence selected supplement ingredients was also calculated.

6.2 Methods

Data source

The HCHS/SOL is a prospective cohort study designed to identify risk factors and disease prevalence among Hispanic/Latino residents of four communities in the United States (Miami, Bronx, Chicago, and San Diego). To achieve a representative sample of the target population, a two-stage area household probability design was employed [136, 137]. HCHS/SOL investigators chose communities to achieve a balanced recruitment of Hispanics/Latinos from across countries of origin and geographic areas of the US [137]. Within communities, census tracts were selected based on their proximity to the field center clinics and demographics; study plans called for cross-stratifying by high vs. low concentration of Hispanic/Latino residents and high vs. low SES [136]. This report is based on cross-sectional data from the baseline data collection, 2008-2011.

Study population

The study enrolled 16,415 non-institutionalized adults who self-identified their background as Cuban, Dominican, Puerto Rican, Mexican, Central American, South American or other Hispanic/Latino. Individuals within sampled households were screened for eligibility (living in the household, age 18-74, able to attend a clinic visit, and not planning to move within 6 months) [136]. Enrolled individuals attended a comprehensive examination visit at the study field center where they reviewed/signed consent documents and participated in study assessments, including demographic, medical, nutrition, and physical activity assessments. Study procedures were approved by the institutional review boards at the participating institutions. The current analysis, based on de-identified data, was exempted.

Categorization of outcome data

Dietary supplement use was captured from product name files within the medication inventory, the dietary supplement interview, and the two 24-hour dietary recalls. Dietary supplement products were categorized using an adapted form of the Langual categorization system for dietary supplements proposed by Saldanha, Dwyer et al. (2012) [138]. The Langual system involves coding multiple facets of a product, from the general, to the specific. For this study, coded facets included product type (Facet A), physical form (Facet E, with collapsed categories), and ingredients (Facet H).

Medication inventory

Participants in the HCHS/SOL were asked to bring all medications, dietary supplements, and herbal remedies taken in the 4 weeks prior to their baseline visit. The medication inventory was designed to therapeutically classify all prescription and over-the-counter medications and supplements, including vitamins, minerals, herbals, and supplements used by participants during the four weeks preceding examination. The inventory involved scanning any Universal Product Code (UPC) bar code symbols on medication packaging, pill imprint searches using Facts & Comparisons® Drug Identifier and Ident-A-Drug Reference© when necessary, and automated therapeutic classification of > 99% of products based on their generic/brand name using a Master Drug Data Base (Medispan MDDB®) supplemented with Spanish-language brand and generic name equivalents from Lexi-Comp Online™ and OVID© Martindale. For the remaining 1% of products, manual coding was performed by healthcare professionals with expertise in medication and supplement identification. Approximately 10,000 products were identified as dietary supplements. Over 1,600 products could not be coded beyond identification as a dietary supplement due to insufficient information, resulting in missing NVNM data for 630 individuals (4%).

Dietary supplement interview

At the time of the field center clinic visit, immediately following the 24-hour dietary recall, technicians interviewed participants extensively (in Spanish or English, according to their preference) about their recalled dietary supplement use in the 30 days prior to the study visit. The dietary supplements from the 30-day supplement interview were recorded in the Dietary Supplement

Assessment Module (DSAM) of the Nutrition Data System for Research database (NDSR). Information for supplements that did not match in the DSAM were updated from the product label (obtained from the manufacturer when possible) and validated against outside resources. DSAM-based product name files were recorded with greater detail than the medication inventory files, enabling refined product coding, a process that was extended to the medication data to ensure that the coding and product identification was consistent across the datasets. The dietary supplement interview data consisted of approximately 2,700 different products representing ~15,000 entries. Calculations of the prevalence of individual botanicals within dietary supplement products depended on the DSAM ingredient-level dataset. Botanical supplement reports were limited to those most common—those with a prevalence of at least 0.2%.

Dietary recall

The 30-day dietary supplement interview files recorded few botanical teas. However, botanical teas were documented in the two 24-hour dietary recalls, along with other liquid dietary supplement products containing protein supplements, aloe, or nopal. Three additional estimates were calculated: 1) estimates of supplement use including botanical teas without green or black tea (*Camellia sinensis*) and nopal (whole fruit); 2) estimates including green tea and nopal; and 3) estimates considering all fiber products as botanical (otherwise coded as NVNM products to supplement the diet).

Statistical analysis

The distribution of key variables was examined across dietary supplement users, NVNM supplement users, and botanical supplement users, including demographics (age, gender, education, percent of poverty for family size and year), healthcare access (percent of poverty, insurance status, self-reported lack of access to care), health behaviors (cigarette smoking, diet quality, physical activity), and acculturation measures (language preference, years of residence in the US, born in US). All variables were examined for univariate distributions and missing data; analyses were based on 16,060 individuals who had data for both the medication inventory and dietary supplement interview. Prevalence estimates defined supplement users across multiple supplement types: 1) users of any dietary supplements; 2) users of supplements containing any NVNM (including botanicals); 3) users of supplements consisting of primarily NVNM ingredients (including botanicals); 4) users of supplements containing any botanical ingredients; 5) users of supplements primarily botanical; 6) users of 3 or more supplements; 7) users of 2 or more NVNM supplements; 8) users of 2 or more botanical supplements; 9) users of liquid (including teas) vs. tablet/capsule vs. powdered supplement products. Definitions of dietary supplements have not yet been standardized. Based on the available product information, combination products that contained ≥50% of the recommended daily allowance (RDA) of a vitamin or mineral, but also contained a botanical or other non-vitamin, non-mineral (NVNM) ingredient were classified as a dietary supplement with NVNM. Those that contained <50% RDA of a vitamin or mineral were classified as a primarily NVNM product. Botanicals were similarly classified. NVNM products included botanicals, but botanical products excluded other NVNM (e.g., glucosamine, co-enzyme Q10, omega-3 and omega-6 fatty acids, fiber products, enzymes, probiotics, amino acids, and protein supplements) (**FIGURE 6.1**).

Because neither the dietary supplement interview nor the medication inventory could be considered a gold standard measure, comparison of the two was limited to calculation of Cohen's Kappa statistics with positive and negative agreements [159, 160] and prevalence and bias-corrected kappa (PABAK) [161]. Kappa statistics were interpreted following established criteria [162]. In addition, to look at the sensitivity of dietary supplement prevalence estimates to various assumptions, estimates were calculated based on: 1) the dietary supplement interview updated with botanical teas from the dietary recall; 2) the dietary supplement interview with 24-hour recall data including nopal and green tea; and 3) the combined dietary supplement interview, medication inventory, and dietary recall.

6.3 Results

Characteristics of the study population

Distributions of key characteristics of the study population are presented, classifying participants as users of any dietary supplement (n= 7,658), users of NVNM supplements (including botanicals) (n=3,916), users of botanical supplements (n=1,433), and users of no supplements (n=8,402) based on their reported use in either the dietary supplement interview or the medication inventory (**TABLE 6.1**). Supplement use categories are nested (**FIGURE 6.1**). Users of supplements that included NVNM ingredients were older (mean age of 47 vs. 38 years among non-users), had lived in the US longer (21.0 vs. 18.6 years), and were more likely to be living in Miami. Users of botanical supplements only had a higher education and greater adherence to a higher quality diet as measured by the 2010 Alternative Healthy Eating Index. They were more likely to be of Mexican background and living in San Diego; they were less likely to have insurance or to have been born in the US.

Concordance of the medication inventory and dietary supplement interview

Prevalence of supplement use as measured by the dietary supplement interview was higher than that for the medication inventory, even for overall dietary supplement use (39.6% vs. 26.0%) (**TABLE 6.2**). The absolute differences were smaller, but the proportional difference was greater for NVNM or botanical products. Prevalence estimates of products with any NVNM or any botanical components in the dietary supplement interview were about twice that of the medication inventory. Positive agreement and overall Kappa statistics were consistent with moderate agreement for most comparisons (κ: 0.44-0.57). Kappa for botanical products was only fair (κ: 0.28-0.33), but negative agreement was high, as was prevalence and bias-adjusted kappa (PABAK: 0.79-0.86). Kappa statistics for liquid or powdered products (κ: 0.11-0.13) were low, but negative agreement for these products were high at 0.96-0.98 (PABAK: 0.85-0.95). Over 90% of products were described as tablets or capsules (including chew tablets) or powders. Concordance for tablet products was also moderate (0.52). Negative agreement was high across all categories of supplements (κ: 0.82-0.99). In sensitivity analyses, categorizing products likely to be NVNM or botanical supplements, based on their similarity to products that were definitely classified as such, reduced the disparity between the two assessments (**TABLE 6.2**).

Sensitivity of the prevalence estimates to ascertainment strategy

NVNM and botanical prevalence estimates were sensitive to inclusion of botanical teas and other liquid supplements captured in the dietary recalls (**FIGURE 6.2**). Estimates were also sensitive to inclusion of dietary fiber as a botanical (otherwise coded as a non-botanical NVNM). The use of botanical teas (excluding green tea) was relatively common: 6.6% (95% CI: 5.9, 7.3) reported drinking a botanical tea on either of the recall visits. The prevalence of use of any nopal was 3.2% (95% CI: 2.7, 3.6) and the prevalence of the use of dietary green tea was 3.6% (95% CI: 3.1, 4.1). If teas, liquid nopal, and other liquid supplements were included in the estimates as primarily botanical supplements, prevalence increased by 131% in women and 105% in men. Additionally counting brewed green tea and nopal as botanical supplements increased the prevalence of botanical supplements substantially, by 32% in women and 34% in men. Additionally, counting all fiber products as botanicals increased the prevalence of botanical use by another 9% in women and 11% in men to 22.5% and 14.7%, respectively. The combined dietary and medication information resulted in a prevalence of 43.8% (95% CI: 42.4, 45.2) for any dietary supplement, 27.7% (95% CI: 26.4, 28.9) for supplements with NVNM, and 11.7% (95% CI: 10.9, 12.5) for supplements with botanical components.

Individual supplement ingredients

NVNM ingredients included fish oil, glucosamine or related products, lutein-containing products; prevalence of these substances and individual botanical ingredients were calculated from the ingredient files (**TABLE 6.3**). Among the NVNM supplements, omega-3 fatty acids, lutein, and lycopene were the most common, occurring with a prevalence of about 10%. Omega-3 fatty acids were most often consumed as single supplements, while lutein and lycopene were often added to multivitamin products. Other common combination products included those containing glucosamine (3.5%) and lipotropic agents (primarily lecithin and inositol—3.4%). These, too, were most often consumed as combination products.

Many combination products containing vegetable or fruit extracts were counted as botanicals. Over 2 percent of study participants consumed a supplement with at least one vegetable extract and over 4% consumed a product containing a fruit extract. Culinary herbs, such as parsley, sage, and oregano were occasional constituents of combination products.

Ginkgo and ginseng were the most commonly reported botanicals (2.6%), followed by green tea extracts and garlic (1.7%). Licorice was also a component of botanical products among about 1% of participants. Chamomile at 0.23% and nopal at 0.13% were less common constituents of dietary supplement products—almost 2% of participants reported consuming chamomile tea in the dietary recall (1.9%; 95% CI: 1.6, 2.3).

6.4 Discussion

Depending on the assessment (medication inventory and/or dietary supplement interview +/- dietary recall data), HCHS/SOL estimated that 4.5-21.6% of participants reported taking botanical supplements and 12.5-35.2% reported use of NVNM supplements, including botanicals. Results of this study demonstrate the challenges of accurate dietary supplement assessments, particularly with regard to the botanical and other NVNM products. Estimates based on the medication inventory alone differed substantially from those based on the dietary supplement interview and neither assessment appears to have captured use completely. Some products were reported only with the medication inventory and others only with the dietary supplement interview. Botanical estimates in particular were markedly sensitive to varying assumptions about what constitutes a botanical product—including all fiber products as botanicals, a reasonable, but not universal assumption, substantially increased estimates, as did the inclusion of botanical teas and other liquid dietary supplements ascertained in the 24-hour dietary recall files.

The importance of accurate measurement of dietary supplement use cannot be overstated. Although dietary supplements have biologic activity with the potential for adverse reactions and interactions with drugs [10, 163], dietary supplements are not regulated with the same level of scrutiny as drugs [10]. The limited regulation also precludes adequate surveillance of use—estimates of interactions and harmful reactions rely on adverse event reporting from individual users and their health care providers, many of which will go unrecognized [157, 164]. Unlike prescription drugs, tracking use via pharmacy charges is not possible, and supplement recording via medical records is poor, particularly among ethnic minorities [39].

Comparability of assessment comparisons with other studies

The most accurate self-report measure of dietary supplement use is considered to be a detailed interview with label capture and transcriptions, conducted in the home [66]. Other studies have used a label capture system conducted in the clinic for supplement assessment, similar to the medication inventory in HCHS/SOL [165, 166]. In these studies, participants completed a dietary supplement questionnaire at home prior to the in-person interview, perhaps prompting improved supplement recall.

Kappa statistics in studies comparing questionnaires with label capture have been variable, ranging from 0.46 to 0.92 [66, 166]. Agreement of supplement use as measured by a telephone interview compared to a label capture was somewhat lower—with a kappa as low as 0.14 [165]. A fourth study compared vitamin and mineral supplement assessment via a self-completed health questionnaire and two types of dietary assessments, a food frequency questionnaire and a 7-day food diary [167]. Agreement in these studies comparing the three instruments was substantial (κ: 0.72 – 0.81).

In contrast, our agreement statistics are somewhat lower, especially for botanical products. Although every effort was made to classify dietary supplement products in the two datasets, some misclassification was likely, given the amount of missing information in the medication inventory data that prevented complete product characterization. In addition, a kappa statistic is less reliable in a setting of low prevalence, as seen with botanical supplements [168] and with imbalances in the marginal totals as was seen in both the botanical and NVNM data [160]. However, moderate agreement was seen with the comparisons of overall dietary supplement use and with comparisons of NVNM supplements and negative agreement statistics were uniformly high. Unfortunately, more sophisticated techniques for correcting misclassification were not possible, given the absence of a gold standard or a validation sample.

Low agreement was not surprising, given the very different databases employed for the medication inventory as compared with the dietary supplement interview. In the former, supplements were added to a database designed for medications—many NVNM supplements were recorded with insufficient detail to completely assess their ingredients. In contrast, the dietary supplement interview used the Dietary Supplement Assessment Module (DSAM), a database designed specifically for capture of dietary supplement data. The DSAM data was much more detailed, in most cases listing full product names and ingredients.

In addition to the superiority of the DSAM, a clinic-based review of medications may be more likely to underestimate dietary supplement use. In clinical situations, accurate capture of dietary supplement use is uncommon: 33% of individuals with chronic disease reported that they disclosed supplement use to their conventional health care provider and disclosure rates were lower among Hispanics (22%) [39]. When asked why they did not disclose their supplement use, patients reported that they did not think that it was important for their providers to know [169]. A similar mechanism may be driving the lower prevalence in the medication inventory data in this study.

Some concern has been expressed about the independence of the medication inventory and dietary supplement interview data—original plans called for dietary interviewers to have access to the medication inventory files. However, the data was usually entered electronically and, because the two assessment systems were incompatible, electronic data was not shared. Study staff for both the medication inventory and dietary supplement interview may have had access to either the bag of products brought in for analysis or to a list of the products, but the dietary supplement interview protocol called for asking each participant a series of questions about dietary supplement use. Assessments were completed on the same day in a flexible manner and it is likely that the dietary recall was more often completed second. Improved recall for supplements may have occurred when participants were asked a second time. In addition, the supplement interview followed a 24-hour recall; possibly bringing to mind supplements not previously remembered or brought in to the field center clinic.

Comparability of HCHS/SOL dietary supplement prevalence estimates

HCHS/SOL estimates are consistent with comparable studies (probability sample, capturing supplement use in ≤ 30 days) of botanical dietary supplement use among Hispanic/Latinos with prevalence estimates for botanicals ranging from 4 to 9%, depending on the instrument, increasing to 15% with the addition of data from the dietary recall (botanical teas and other liquid supplements also consumed as foods). Commonly-reported supplements are consistent with patterns in the general US public, rather than those reportedly common among Hispanics/Latinos such as mint, chamomile, and linden [170].

Comparable studies were limited to four; most targeted an older population. In a home-based interview of dietary supplement use in the past 2 weeks with label capture among individuals 77 or older in Texas, about 38% of Hispanics reported using vitamin or mineral supplements and 5% reported using botanicals, most commonly garlic, ginkgo, and saw palmetto [171]. Another study employed a similar strategy (home-based interviews, use in past 2 weeks) among Mexican Americans ≥65 across the US-Mexican Border States and reported botanical medicine use was about 10% [59]. In this study, investigators specifically inquired about the use of herbal teas. Most common botanical supplements were consistent with previously reported favorites among Hispanics/Latinos: chamomile, mint, and aloe [59]. In a telephone interview of supplement and medication use in the past 7 days [73] in the general US public, the prevalence of NVNM use was 12% among Hispanics; the most common supplements were lutein, ginkgo, garlic, and glucosamine [73], similar to those reported in HCHS/SOL. Another telephone interview (subjects ≥ 52), reported Hispanic/Latino use of any supplement at 45% and botanicals at 12%.

Limitations and Strengths

All participants were recruited from urban centers; the dietary supplement habits of Hispanics/Latinos in rural areas may be very different. However, although the target population is limited to the four cities, HCHS/SOL's design, using probability sampling within diverse regions, is superior to the convenience samples typical of many dietary supplement studies in these populations.

Dietary supplement assessment suffers from the same limitations as other data largely dependent on self-report or inventory methods conducted outside the home. It is unclear whether or not either the medication inventory or the dietary supplement interview adequately captured supplement use. Limitations of the medication inventory are enumerated above. In addition, because supplements were spread across the files, instead of receiving a designation as a supplement, some supplements could have been missed, artificially reducing the prevalence estimates resulting from these data. The dietary supplement interview assessment was limited by the use of prompts for supplements common in the general population (Echinacea, ginseng, ginkgo, St. John's Wort), rather than those common among Hispanics/Latinos (e.g., chamomile, mint, and aloe). However, the dietary supplement interview data, using the DSAM, achieved much greater detail than has been reported in prior studies and the ability to add botanical teas from the 24-hour recall data filled in some of the missing information from the dietary supplement interview alone.

Areas for future research

The reported prevalence of types of dietary supplements (botanical, NVNM) has been variable among Hispanics/Latinos. Some of this variability is related to sampling design (probability vs. convenience), but, based on the findings in this report, it is likely that some of the variability reflects the non-standardized definitions of what constitutes a botanical or even a dietary supplement. Studies that include only purchased dietary supplement products are not counting home remedies such as botanical teas. Because raw botanicals and teas are part of the health practices of many ethnic minority populations, including Hispanics/Latinos, excluding them from estimates may lead to measurement error.

Accurate measurement depends on many factors, only some of which are under the control of the investigator. If, in the planning stages of a study, the investigator includes prompts for dietary supplements consistent with cultural use patterns, under-measurement of those supplements is less likely. Measurement will be enhanced by utilizing a study database specific for dietary supplements, such as the DSAM along with a detailed interview process and a supplement inventory with label capture. Because rules for classifying supplements as botanical or NVNM are not yet universal, reporting results of sensitivity analyses will improve understanding of how the estimates were obtained. Similarly, greater detail in reporting product classifications will enable improved comparisons of results across studies.

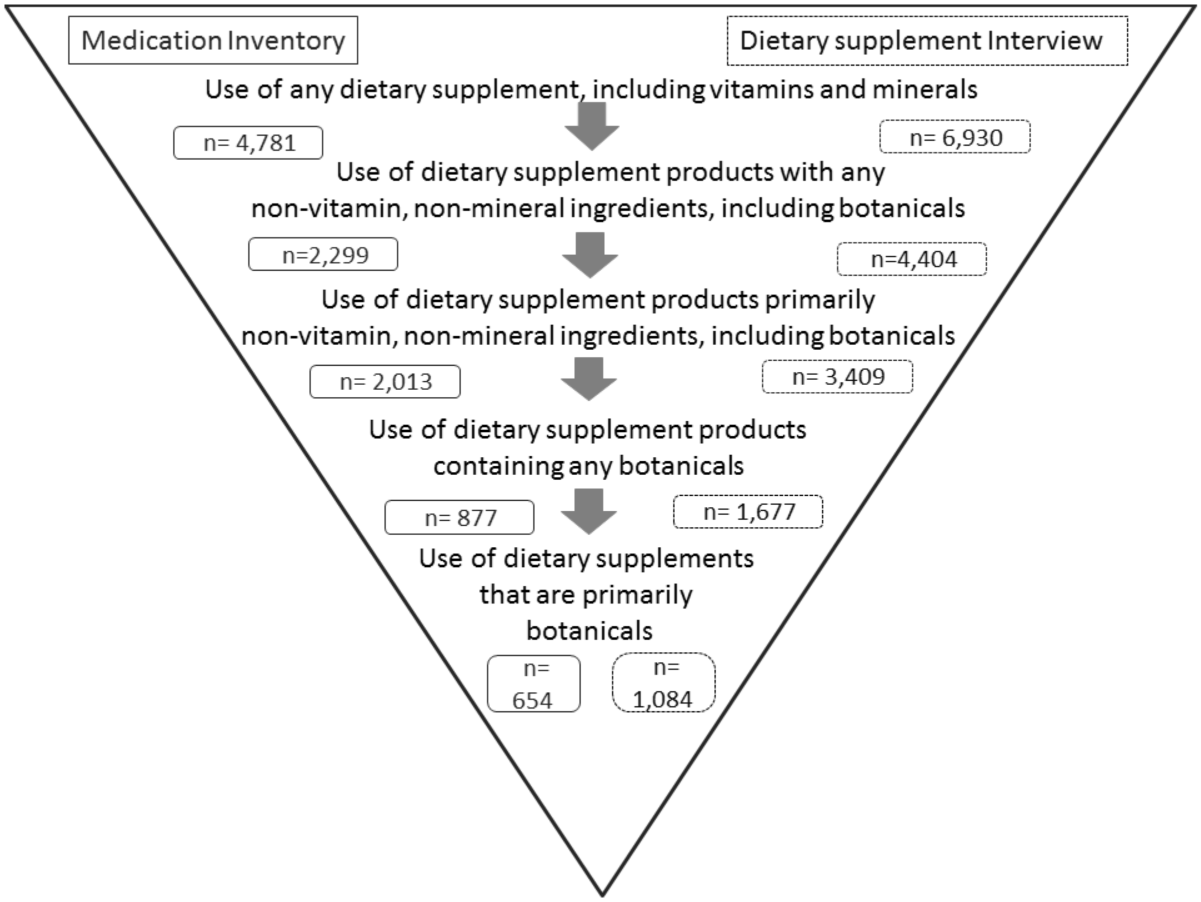


FIGURE 6.1. Dietary supplement assessment protocol schematic. Sample is restricted to participants with data for both the medication inventory and the dietary supplement interview.

TABLE 6.1. Distribution of sample population characteristics by use of supplement types[a] in HCHS/SOL

	N[b]	Users of any supplements N=7,658 Mean or % (95% CI) [c]	Users of any NVNM supplements N= 3,916 Mean or % (95% CI) [c]	Users of any botanical supplements N=1,433 Mean or % (95% CI) [c]	Nonusers of dietary supplements N=8,402 Mean or % (95% CI) [c]
Mean age	16, 060	45.5 (44.8, 46.1)	47.0 (46.2, 47.8)	45.0 (43.7, 46.3)	37.7 (37.1, 38.2)
% Female	9,643	56.6 (54.8, 58.4)	56.9 (54.4, 59.5)	62.5(58.5, 66.4)	48.3 (46.8, 49.8)
Mean % poverty threshold	14,669	169 (160, 178)	186 (173, 199)	181 (166, 196)	142 (137, 147)
Hispanic/Latino Background (%)					
Dominican	1,443	9.8 (8.3, 11.7)	7.7 (6.2, 8.1)	6.0 (4.3, 8.4)	9.8 (8.4, 11.3)
Central American	1,693	7.6 (6.5, 9.0)	8.4 (7.0, 10.2)	9.5 (7.4, 12.1)	7.0 (6.0, 8.2)
Cuban	2,305	18.6 (16.0, 21.7)	20.4 (17.4, 23.9)	16.6 (13.3, 20.4)	22.8 (19.2, 26.9)
Mexican	6,397	40.0 (36.5, 43.6)	41.1 (37.1, 44.3)	49.6 (44.9, 54.4)	35.0 (31.7, 38.4)
Puerto Rican	2,646	14.6 (13.0, 16.4)	12.4 (10.4, 14.7)	8.7 (6.7, 11.3)	16.8(15.0, 18.7)
South American	1,063	5.6 (4.8, 6.6)	5.9 (4.8, 7.1)	5.6 (4.2, 7.4)	4.6 (4.0, 5.3)
Other	513	3.7 (3.0, 4.6)	4.0 (2.9, 5.5)	3.9 (2.5, 6.0)	4.1 (3.5, 4.8)
Preference for Spanish	16,060	74.8 (72.6, 76.8)	74.8 (72.6, 76.8)	74.6 (71.8, 77.2)	76.8 (74.6, 78.9)
Born in US (%)	2,863	21.5 (19.6, 23.5)	21.2 (19.1, 23.5)	18.1 (15.0, 21.7)	21.2 (19.7, 22.9)
Mean years in US	15,994	21.2 (20.5, 22.0)	21.0 (20.2, 21.9)	21.1 (20.1, 22.1)	19.9 (19.0, 20.7)
Education (%)					
< HS	5,988	28.4 (26.4, 30.5)	25.2 (22.6, 27.9)	24.7 (21.0, 28.8)	36.2 (34.5, 38.1)
HS graduate	4,076	26.4 (24.7, 28.2)	25.0 (22.5, 27.7)	23.0 (19.8, 26.6)	29.2 (27.8, 30.6)
At least some college	5,674	45.2 (42.8, 47.7)	49.9 (46.5, 53.2)	52.3 (47.5, 57.1)	34.6 (32.9, 36.3)
% with no insurance	7,814	47.2 (44.8, 49.6)	51.5 (49.3, 53.0)	55.2 (50.6, 59.8)	50.8 (48.7, 52.9)
% unable to get needed healthcare	2,665	15.1 (13.7, 16.6)	15.8 (13.8, 17.9)	17.0 (14.3, 20.0)	15.6 (14.4, 16.8)
% Meeting physical activity guidelines[d]	10,198	68.7 (66.9, 70.5)	70.4 (67.8, 72.9)	68.2 (63.7, 72.3)	64.5 (62.9, 66.0)
Mean AHEI[e]	16,060	48.3 (47.9, 48.7)	49.0 (48.4, 49.5)	50.0 (49.3, 50.8)	47.1 (46.7, 47.5)
Cigarette use (%)					
Never smoked	9,760	64.6 (62.8, 66.4)	64.8 (62.2, 67.4)	64.5 (60.4, 68.3)	57.8 (56.1, 59.7)
Former Smoker	3,180	18.7 (17.3, 20.1)	20.1 (18.3, 22.0)	23.4 (20.3, 26.8)	17.6 (16.6, 18.8)
Current smoker	3,090	16.7 (15.1, 18.5)	15.1 (12.9, 17.5)	12.1(9.6, 15.2)	24.5(23.1, 26.0)
Self-reported health (%)					
Fair-poor	4,750	25.5 (23.6, 27.4)	23.7 (21.6, 26.1)	29.8 (26.1, 28.6)	26.3 (24.9, 27.8)
Good	7,405	45.0 (43.0, 47.0)	44.5 (41.7, 47.4)	46.6 (42.6, 50.6)	47.1 (45.5, 48.7)
Very good - excellent	3,852	29.5 (27.6, 31.5)	31.7 (28.8, 34.8)	28.2 (24.6, 32.0)	26.6 (25.2, 28.1)
Geographic area (US) (%)					
Bronx	3,969	25.8 (22.9, 29.0)	20.4 (17.6, 23.5)	15.0 (12.0, 18.6)	29.6 (26.5, 33.0)
Chicago	4,075	14.2 (12.3, 16.4)	13.6 (11.3, 16.2)	16.2 (13.0, 20.0)	17.0 (14.9, 19.3)
Miami	3,997	28.8 (24.9, 32.9)	31.6 (27.3, 36.2)	29.6 (24.8, 34.8)	31.5 (27.0, 36.4)
San Diego	4,019	31.2(27.0, 35.6)	34.5 (29.4, 39.9)	39.2 (33.2, 45.5)	21.9 (18.9, 25.2)

Abbreviations: AHEI = alternative healthy eating index. a. Supplement users were defined as users by either the medication inventory or the dietary supplement interview. Categories presented for comparison of distributions include only users of any dietary supplement, users of primarily NVNM products (including botanicals) and users of botanical supplements. b. N = number of participants in sample, rather than the representative population. c. Means and percents reflect sample weights. d. Physical activity data was summarized as meeting or not meeting CDC 2008 guidelines for physical activity. e. Nutritional data was summarized with the Alternative Healthy Eating Index-2010 (AHEI-2010). The AHEI was developed to update prior healthy eating indices based on US Dietary Guidelines with recommendations derived from scientific studies of diet and health outcomes [150, 151]. The AHEI assigns values for consumption of vegetables, fruit, whole grains, sugar-sweetened beverages, nuts/legumes, red/processed meats, trans fat, long-chain n-3 fatty acids, total polyunsaturated fatty acids, sodium, and alcohol intake with a maximum value of 110 [151]. Healthy individuals aged 55-80 in the Nurses' Health Study had a mean AHEI-2010 of 53.2 [150].

TABLE 6.2. Comparison of 30-day dietary supplement use assessed through the medication inventory and dietary supplement interview in HCHS/SOL[a]

	Medication Inventory (MV)	Dietary Supplement Interview (DI)	MV+ DI+	MV+ DI-	MV- DI+	MV– DI-	Positive agreement	Negative agreement	Cohen's Kappa	Prevalence- and Bias-Adjusted Kappa[c]
Variable	% (95% CI)[b]	% (95% CI)[b]	n	n	n	n	(95% CI)	(95% CI)	(95% CI)	
Any dietary supplement (DS)	26.0 (24.7, 27.3)	39.6 (38.3, 41.0)	4053	728	2877	8402	0.69 (0.68, 0.70)	0.82 (0.82, 0.83)	0.52 (0.51, 0.54)	0.55
DS with any NVNM component	12.5 (11.7, 13.3)	24.6 (23.4, 25.9)	1733	560	2285	10,843	0.55 (0.53, 0.56)	0.88 (0.88, 0.89)	0.44 (0.43, 0.46)	0.63
DS primarily NVNM	10.9 (10.2, 11.6)	19.0 (17.9, 20.1)	1465	529	1594	11,833	0.58 (0.56, 0.60)	0.92 (0.91, 0.92)	0.50 (0.48, 0.52)	0.72
DS with any botanical	4.5 (4.1, 4.9)	9.3 (8.5, 10.1)	417	458	1205	13,544	0.33 (0.31, 0.36)	0.94 (0.94, 0.94)	0.28 (0.26, 0.31)	0.79
Primarily botanical products	3.3 (3.0, 3.7)	5.8 (5.2, 6.3)	327	548	563	13,983	0.37 (0.34, 0.40)	0.96 (0.96, 0.96)	0.33 (0.30, 0.36)	0.86
Use of 3+ DS	6.7 (6.1, 7.4)	9.9 (9.2. 10.7)	912	335	863	13,950	0.60 (0.58, 0.62)	0.96 (0.96, 0.96)	0.56 (0.54, 0.59)	0.85
Use of 2+ primarily NVNM products	3.2 (2.8, 3.7)	5.4 (4.7, 6.0)	363	221	480	14,357	0.52 (0.48, 0.55)	0.98 (0.98, 0.98)	0.49 (0.46, 0.53)	0.91
Use of 2+ primarily botanical products	0.7 (0.6, 0.9)	1.2 (1.0, 1.4)	71	145	124	15,081	0.35 (0.29, 0.40)	0.99 (0.99, 0.99)	0.34 (0.28, 0.40)	0.97
Liquids/Teas	1.7 (1.4, 2.0)	0.9 (0.7, 1.1)	34	260	138	15,590	0.15 (0.10, 0.19)	0.98 (0.98, 0.98)	0.13 (0.09, 0.18)	0.95
Powders	5.6 (5.0, 6.2)	2.7 (2.3, 3.2)	102	885	337	14,698	0.15 (0.12, 0.17)	0.96 (0.96, 0.96)	0.11 (0.09, 0.14)	0.85
Tablets, capsules	23.9 (22.7, 25.1)	38.3 (37.0, 39.6)	3765	633	2932	8692	0.68 (0.67, 0.69)	0.83 (0.82, 0.84)	0.52 (0.51, 0.53)	0.56
Sensitivity Analysis										
DS with NVNM[d]	15.5 (14.4, 16.5)	24.7 (23.5, 25.9)	2133	778	2248	10,817	0.58 (0.57, 0.60)	0.88 (0.87, 0.88)	0.47 (0.45, 0.48)	0.62
DS with botanical[d]	5.1 (4.6, 5.6)	9.4 (8.6, 10.2)	486	525	993	13,520	0.39 (0.37, 0.41)	0.95 (0.94, 0.95)	0.34 (0.31, 0.36)	0.80

Abbreviations: DS—dietary supplements; NVNM—non-vitamin, non-mineral products, including botanicals; MV—medication inventory; DS—dietary supplement interview. Agreement statistics were calculated with DAG_Stat, an Excel-based program for calculation of agreement statistics [172]. a. Analysis is restricted to subjects with data for both the medication inventory and the dietary supplement interview (n = 16,060). An additional 639 (4%) of participants took only supplements for which insufficient detail was available for coding. b. Proportions are adjusted by sample and nonresponse weights and are age-standardized to the 2010 Census distribution for Hispanics/Latinos. c. The prevalence and bias-adjusted Kappa (PABAK) adjusts not only for the prevalence effect (the difference between the positive and negative agreements), but also for differences in the marginal probability of supplement use between the assessments. d. Sensitivity analysis reflects coding supplements with insufficient information, but likely to be NVNM and botanical (based on similar or nearby products).

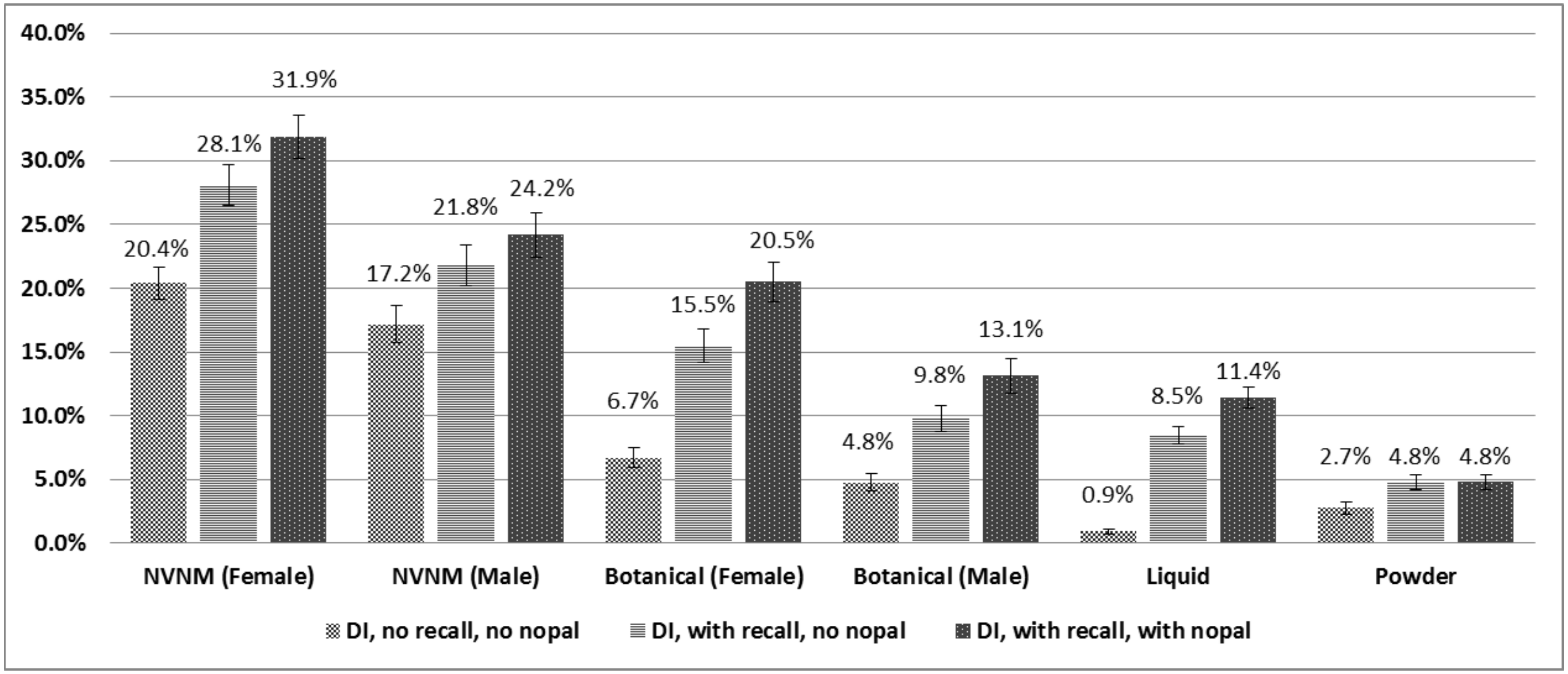


FIGURE 6.2. Prevalence of non-vitamin, non-mineral supplements considering the addition of supplements captured in the dietary recalls.

Prevalence estimates are standardized to the 2010 US Census and weighted with sample and non-response weights and stratified by gender
DI no recall no nopal references the dietary supplement interview data without dietary recall data
DI with recall no nopal references the dietary supplement interview data with addition of dietary recall data, but excluding raw nopal and green tea
DI with recall with nopal references the dietary supplement interview data with dietary recall data including raw/cooked nopal and green tea
Only nopal ingested outside recipes was included in these estimates.

TABLE 6.3. Prevalence of Selected Supplement Ingredients in the 30-Day Dietary Supplement Interview

Supplement ingredient	N	Prevalence	Supplement ingredient	N	Prevalence
Vitamins	5,763	32.8 (31.6, 34.1)	Botanicals		
Minerals	5,577	31.8 (30.5, 33.1)	Garlic	336	1.7 (1.4, 2.1)
NVNM			Ginger	111	0.66 (0.47, 0.85)
Amino acids	568	3.2 (2.8, 3.6)	Ginkgo	461	2.6 (2.2, 3.0)
Chondroitin	356	2.0 (1.6, 2.3)	Ginseng	442	2.6 (2.2, 3.0)
Coenzyme Q10	173	1.0 (0.72, 1.3)	Grain[e]	273	1.5 (1.2, 1.8)
Collagen	181	0.91 (0.70, 1.1)	Grape seed	180	0.94 (0.72, 1.1)
Enzyme	55	0.26 (0.16, 0.35)	Green tea	280	1.7 (1.4, 2.0)
Fiber	249	4.2 (3.7, 4.7)	Guarana	54	0.30 (0.19, 0.40)
Glucosamine	672	3.5 (3.0, 4.0)	Hawthorn	43	0.21 (0.11, 0.32)
Lipotropic[a]	677	3.5 (3.1, 3.8)	Holy basil	30	0.22 (0.09, 0.35)
Lutein	1,606	9.6 (8.8, 10.4)	Horseradish	54	0.38 (0.21, 0.55)
Lycopene	1,688	10.5 (9.7, 11.4)	Horsetail	163	0.72 (0.54, 0.90)
MSM	273	1.4 (1.1, 1.7)	Licorice	236	0.96 (0.77, 1.2)
Omega-3 [b]	1,794	9.7 (8.9, 10.4)	Milk thistle	72	0.52 (0.25, 0.79)
Omega-6[c]	193	1.1 (0.81, 1.5)	Mint	54	0.27 (0.17, 0.36)
Omega-9 [d]	146	0.89 (0.58, 1.2)	Mushroom	102	0.44 (0.28, 0.61)
Probiotics	121	0.57 (0.41, 0.73)	Nettle	45	0.35 (014, 0.57)
Protein	362	2.2 (1.8, 2.6)	Olive leaf	40	0.21(0.11, 0.30)
Botanicals			Parsley	155	0.89 (0.67, 1.1)
Aloe	128	0.60 (0.43, 0.76)	Pepper (black)	43	0.24 (0.11, 0.37)
Astragalus	48	0.30 (0.16, 0.45)	Pine bark	93	0.41 (0.28, 0.53)
Bioflavonoids	37	0.29 (0.15, 0.44)	Pumpkin seed	59	0.47 (0.27, 0.67)
Black cohosh	80	0.31 (0.22, 0.39)	Rhodiola	89	0.42 (0.28, 0.55)
Boswellia	82	0.28 (0.19, 0.37)	Rose hips	76	0.30 (0.21, 0.40)
Cascara/ Senna	96	0.41 (0.31, 0.55)	Rosemary	95	0.59 (0.41, 0.77)
Cayenne	96	0.42 (0.30, 0.54)	Sage	39	0.24 (0.12, 0.36)
Cinnamon	103	0.52 (0.37, 0.67)	Saw palmetto	107	0.86 (0.61, 1.1)
Chamomile	55	0.24 (0.16, 0.32)	Schisandra	59	0.36 (0.23, 0.49)
Dandelion	76	0.39 (0.26, 0.52)	Seaweed	216	1.0 (0.80, 1.3)
Dong quai	54	0.25 (0.15, 0.35)	Soy	103	0.50 (0.36, 0.64)
Echinacea	101	0.69 (0.49, 0.89)	Spirulina	158	0.87 (0.66, 1.1)
Elderberry	53	0.34 (0.18, 0.49)	Turmeric	80	0.38 (0.24, 0.52)
Eleuthero	105	0.57 (0.35, 0.79)	Uva Ursi	45	0.20 (0.12, 0.28)
Fennel	54	0.29 (0.19, 0.40)	Valerian	46	0.22 (0.14, 0.31)
Fo-ti	58	0.22 (0.14, 0.30)	Vegetable extract	438	2.3 (2.0, 2.7)
Fruit extracts	810	4.2 (3.7, 4.6)	Yerba Mate	42	0.26 (0.16, 0.36)

a. Lipotropic: lecithin, inositol.
b. Omega-3: fish oils, flaxseed oil;
c. Omega-6: linoleic acid, borage, evening primrose oils;
d. Omega-9: olive oil, oleic acid;
e. Grain: oats, wheat, corn, quinoa, alfalfa;
Note: Chamomile, Green tea, and Nopal are also commonly consumed as foods—no included in these estimates

CHAPTER 7:
CHARACTERISTICS OF BOTANICAL SUPPLEMENT USERS IN THE HISPANIC COMMUNITY HEALTH STUDY/STUDY OF LATINOS

7.1 Introduction

Hispanics/Latinos are the largest minority groups in United States (US). Currently, Mexicans make up the majority of the Hispanics living in the US, but the number of immigrants from other countries is growing rapidly [173]. Hispanics/Latinos increasingly encompass individuals from varied cultural traditions with differences in dialects, primary language, and traditions [22] as well as different experiences within the US. Shared health belief have been posited [174], but the extent to which these belief systems influence commonalities across Hispanic/Latino background groups in the use of botanical supplements is less clear. Studies that have reported botanical supplement use patterns among Hispanics/Latinos largely have largely focused on a single region (e.g., Mexican Americans in Texas and/or southwestern US)[50, 59] making comparisons of the unique characteristics across subgroups more challenging and potentially leading to stereotypes and misconceptions about the use of botanical supplements among different groups of Spanish-speaking patients. In addition, characteristics of botanical supplement users across Hispanic/Latino subgroups have been poorly characterized due to the lack of a large enough sample of Hispanics/Latinos of different backgrounds.

Unlike in the general population, factors related to botanical supplement use among Hispanics/Latinos are incompletely understood. Education appears either to play a limited role or to vary across categories of acculturation [50, 51]. Moreover, the operational definition of acculturation itself is variable Most studies including acculturation as a covariate limit its definition to length of residence in the US and/or primary language [57, 135], the latter possibly conflated with employment opportunity and income rather than Hispanic/Latino identity [40]. Other studies include acculturation scales, such as the Short Acculturation Scale for Hispanics/Latinos [140], to assess the degree to which individuals are oriented to the new vs. the initial culture. Some studies report higher botanical supplement prevalence estimates among recent immigrants [5, 29, 59, 175], but others find no association between length of residence and the prevalence of botanical supplement use [33, 40, 60, 135]. Moreover, a closer examination of the studies suggests that overall prevalence may not differ much by acculturation, regardless of its measurement, but by the types of botanicals used. In one study, botanical use patterns among those with higher US acculturation scores were more similar to that of the non-Hispanic white (NHW) sample than to less acculturated Hispanics/Latinos [29]. Similarly, in a small study of middle-aged Mexican American women, those who used botanical supplements common among Hispanics/Latinos scored higher on the Mexican orientation of an acculturation scale as compared with women who used botanical supplements popular in the US population [46].

Because the definition of botanical supplements varies across studies, comparisons of patterns of use across studies are challenging. Some studies of botanical supplement use may count teas, extracts, tinctures and raw botanicals with or without non-botanical components [6, 59] while others may be limited to commercially-available products [122]. Often, botanical supplements are categorized with other non-vitamin, non-mineral (NVNM) supplement products, such as glucosamine and probiotics [78, 108].

The Hispanic Community Health Study/Study of Latinos (HCHS/SOL) provides a unique opportunity to address some of the challenges inherent in measuring botanical supplement intakes among diverse groups of Hispanics/Latinos. The sampling strategy of HCHS/SOL, ensuring representation of all Hispanic/Latino background groups, provides the basis for estimating patterns of use particular to Hispanics/Latinos. This report examines botanical usage patterns by Hispanic/Latino background across different botanical supplement definitions and explores reported reasons for use.

7.2 Methods

Study Population

HCHS/SOL, a prospective cohort study, examines prevalence of disease among Hispanic/Latino residents in four US communities: Miami, Bronx, Chicago, and San Diego. The study employed a two-stage area household probability design utilizing census tracts [136, 137] to achieve a balanced recruitment of Hispanics/Latinos from across countries of origin, income diversity, and neighborhood Hispanic/Latino concentration [137]. Sampled individuals within households were screened for eligibility (living in the household, age 18-74, ability to attend a clinic visit)[136]. From 2008-2011, enrolled subjects attended a comprehensive baseline visit at the study field center including demographic, medical, nutrition, and physical activity assessments. This report utilizes baseline cross-sectional data from 13,789 individuals with complete data for all variables of interest of the 16,415 non-institutionalized adults, self-identified as Hispanic/Latino.

Botanical supplement assessments and definitions

Botanical supplement use was assessed via a past 4-week medication inventory and a detailed past 30-day dietary supplement interview. Consumption of other botanicals was derived from two 24-hour dietary recalls, assessing intakes of foods as well as botanical teas, traditional medicinal foods, and other dietary supplements. Outcomes in this report are based on defining a supplement user as a person reporting use by either the medication inventory or dietary supplement interview with or without the addition of botanical supplements captured in the 24-hour food recall. This study employed three overlapping definitions of botanical supplements: 1) products with botanical ingredients; 2) products with botanical ingredients plus other NVNM ingredients, such as probiotics and glucosamine; and 3) products with botanical ingredients plus raw plants (dried or fresh) often used as medicinal substances according to available literature (e.g., botanical teas, nopal, aloe)[170].

Reasons for botanical use

In the dietary supplement interview, participants reported reasons for taking each supplement and these were recorded verbatim. Text files were reviewed and grouped into categories. Because multiple reasons were given for use of some supplements, categories are not mutually exclusive.

Population characteristics of interest

Self-reported Hispanic/Latino background was of interest. Background groups included: Dominican, Cuban, Puerto Rican, Mexican, Central American, South American, and “other Hispanic/Latino”. The latter classification included individuals reporting more than one background group. Variables associated with botanical supplement use in other population-based studies were also of interest. These included: 1) age (18-24, 25-34, 35-44, 45-54, 55-64, 65-76); 2) gender; 3) education (< high school, high school graduate, post high school; 4) wealth (percent of poverty for household size in the intake year as defined by the US Census in 4 categories: ≤100% , 101-200%, 201-300%, and >300%)); 5) insurance status (no insurance vs. any); 6) perceived lack of access to care ("*Were you unable to get healthcare when you needed it?"*--no lack of access) 7) cigarette smoking (nonsmoker vs. smoker); 8) physical activity—adequate activity as defined by 2008 guidelines from the Center for Disease Control and Prevention; 9) use of prescription medications (vs. no medication use)); 11) perceived health as measured by the Rand short form, ("Compared with a year ago, how would you rate your current health", categorized as very good to excellent, good),and fair to poor; and 12) location of the HCHS/SOL field center (Bronx). In addition, acculturation was measured via the Short Acculturation Scale for Hispanics (SASH)[141]. SASH measures orientation to Spanish language and preferences for Hispanic/Latino media and social interactions [52]. Finally, dietary patterns as defined by the Alternative Healthy Eating Index (AHEI) based on US Dietary Guidelines and scientific studies of diet and health outcomes [150, 151]. A maximum value of 110 is related to consumption of red/processed meats, sugar-sweetened beverages, trans fat, vegetables, fruit, whole grains, nuts/legumes, long-chain n-3 fatty acids, total polyunsaturated fatty acids, sodium, and alcohol [151].

Statistical analysis

All variables were examined for distributions and missing data—only the income variable was missing more than 5% of values (8%). Because of the complex sampling design, sampling and nonresponse weights were applied, completed with Stata 13 (*StataCorp LP*, *College Station, TX*) survey commands. Sample characteristics were estimated across Hispanic/Latino background, standardized to the age distribution of the 2010 US census.

Logistic models were constructed to identify the set of variables independently associated with botanical supplement use. Backward elimination strategies defined significant associations. Log binomial models—reporting prevalence ratios and predicted prevalence—were constructed to assess the association between variables of interest and botanical use, controlling for potential confounding variables. Confounding variables were determined through a graphical process, a directed acyclic graph, that enables definition of a minimally-sufficient adjustment set of confounders for each exposure-outcome association.[156] Each model was examined for prevalence ratio modification. Partial F tests including all potential interactions with the variable of interest tested statistical significance of potential modifiers. Summary prevalence ratios are reported; modifiers with consistent impacts on the estimates are discussed.

7.3 Results

Differences in variables reportedly associated with botanical use were noted across Hispanic/Latino background (**TABLE 7.1**). Notably, Cubans tended to be better educated and incomes were higher among Puerto Ricans, who were also more likely to have lived in the US 10 years or longer. Central and South Americans were least likely to have been born in the US.

Independent associations

The following variables were independently associated with botanical supplement use: Hispanic/Latino background, age, female gender, wealth, education, having no insurance, healthy dietary pattern, physical activity, nonsmoking, medication use. Perceived health and perceived lack of healthcare access and acculturation were not independently associated with botanical supplement. Model discrimination was 0.66. Field center location was too collinear with Hispanic/Latino background to include both in most models. When it was entered instead of Hispanic/Latino background, field center location was significantly associated with botanical supplement use.

Because of the increased prevalence when NVNM supplements were added to the botanicals, cross-classification of site and background could be included in the model. Models of NVNM supplement use were independently associated with field center by Hispanic/Latino background, age, gender, wealth, education, and positive lifestyle behaviors, but not insurance. Botanical teas and nopal (prickly pear cactus fruit) added to botanical supplements were independently associated with the same variables. There was a suggestion of heterogeneity by acculturation, which was explored in detail in additional models.

Patterns of botanical supplement use by population characteristics

Controlling for age and gender, the prevalence of botanical use varied substantially across Hispanic/Latino background **(TABLE 7.2**, **FIGURE 7.1**). Mexicans reported the greatest prevalence of botanical products at 17% (95% CI: 15-19%); prevalence estimates for Central and South Americans were similar (14 and 16%, respectively). Individuals with a Puerto Rican, Cuban, or Dominican background reported taking products with botanical ingredients with almost half the prevalence as did individuals with Mexican backgrounds **(TABLE 7.2)**.

Variations across botanical supplement definitions were less marked. Adding other NVNM products to botanicals attenuated the differences among background groups. Conversely, adding botanical teas from the 24-hour dietary food recalls to the definition of a botanical supplement tended to exaggerate the differences among background groups with prevalence ratios ≤0.50 for individuals from Puerto Rico or Cuba compared with those from Mexico.

Botanical use increased with age, income, and education across all definitions, though with evidence of heterogeneity (**FIGURE 7.2**). With high acculturation (SASH score = 4), individuals with a post-secondary education were 2.7 times as likely to use botanical supplements (with teas) as those with less than a high school education. With low acculturation (SASH score = 1), individuals with high acculturation were only 1.1 times as likely to take botanical supplements.

Women were more likely to take botanical supplements than men, but differences were small at higher incomes (38% for both genders at an income 301% of the poverty threshold or more, compared with 24 vs. 20 % at <100% of the poverty threshold). Increases in use with age was more evident for NVNM products—compared with individuals 18-24 years old, those 65-76 were 3 1/2 times as likely to take NVNM products.

Across all definitions, botanical use increased with positive health behaviors (healthy dietary pattern, physical activity, non-smoking). For example, for each 5 point increase in the AHEI, the probability of supplement use increased by 12-20%. Active individuals were about 1.2 times as likely to be botanical users as inactive ones. Again, some heterogeneity was noted: nonsmokers from Caribbean backgrounds were 1.5 times as likely to take NVNM supplements as smokers, but non-smokers from continental Latin America were not significantly more likely to take NVNM supplements. Individuals who considered themselves in very good to excellent health were more likely to report botanical use than those who reported fair to poor health. Prescription medication use was more common among botanical supplement users.

Substantial differences were present in prevalence by HCHS/SOL field center location. Individuals in San Diego were more than twice as likely to consume botanical products as individuals in the Bronx (PR 2.20; 95% CI 1.82, 2.68). Prevalence of NVNM supplement use in San Diego and Miami was similar (31% and 33%, respectively), bur lower in Chicago (24%) and the Bronx (21%). Compared with Dominicans in the Bronx, continental Latin Americans, and Puerto Ricans were about as likely to take botanical supplements. However, in Chicago, continental Latin Americans were more likely to take botanical supplements than Puerto Ricans (**TABLE 7.3**).

Motivations for botanical supplement use

Individuals reported taking botanical and other NVNM supplements for a number of reasons (**FIGURE 7.3**) , including for: 1) physical health conditions (e.g., anemia, cancer, diabetes, eye health, heart or lung disease, kidney disease, lipid control, pain, prostate care, poor appetite); 2) mental health (stress, mental clarity); 3) illness prevention (general health, detoxification, immunity, bone health); 4) digestion/ bowel health; 5) to improve training and energy; and 6) to improve appearance (hair, skin, nails, weight loss). Another 34% of botanical users reported taking the product to supplement or compensate for an inadequate diet. Almost 10% of botanical users gave nonspecific reasons for use or were not sure why they were taking supplements. Ten percent reported that their botanical supplement had been recommended by their health care provider while 5.7% reported that a friend or family member had recommended the product. Reasons given for botanical use varied less across Hispanic/Latino background (**TABLE 7.4**). A statistically significant difference emerged in the use of botanicals to increase energy, particularly for NVNM: controlling for age, Cuban and South Americans reported that they used 15% of supplements for energy, compared to about 20 % of Mexicans, Dominicans and Central Americans, and 33% of Other Hispanics/Latinos. Puerto Ricans and Dominicans were less than half as likely to report botanical supplement use for pain as Cubans and Mexicans.

7.4 Discussion

Differences in the prevalence of botanical supplement use in Hispanic/Latino background groups were marked. Individuals with a self-reported Dominican, Cuban, or Puerto Rican background were much less likely to report taking botanical supplements than individuals with a Mexican, Central or South American background. Differences were greater with the addition of botanical teas and were less evident when including other NVNM supplements.

In general, in HCHS/SOL, patterns of supplement use were similar across Hispanic/Latino background groups and these patterns were similar to those reported in the general US public. Botanical supplement use increased with age, female gender, education, income, and adherence to healthy lifestyle behaviors. However, some heterogeneity was noted across education categories: more educated individuals were markedly more likely to take botanical supplements with increasing acculturation, but this pattern was not present among less educated individuals, especially when botanical teas were added.

In the 2007 NHIS, prevalence of botanical supplements (including NVNM and special diets) was greatest among Puerto Ricans and differences across Hispanic/Latino background were small [122]. Otherwise, characteristics of supplement users in the overall US population were similar to those described in HCHS/SOL: increasing prevalence with age (to age 69), education, and income [122]. In multivariate logistic regression models in the 2002 NHIS, botanical supplement use was associated with female gender, living in the northeast or west, having no medical insurance, perceived poor to fair health, and taking medication [176]. In contrast, in HCHS/SOL, botanical use was least common in the northeast (Bronx) and health perceived as very good or excellent was associated with greater use. In both the 2002 NHIS and the 1998 MEPS survey, individuals with perceived lack of access to healthcare were more likely to use botanical supplements [177, 178]; in HCHS/SOL, neither having insurance nor perceived access to care appeared to be strongly associated with botanical use. In the Vitamins and Lifestyle study, botanical use was associated with a healthier lifestyle, including greater physical activity, non-smoking, and greater intakes of fruits/vegetables [127]. Similar patterns were seen in HCHS/SOL: nonsmokers had about 1.4 times the probability of botanical use compared with smokers. The association of botanical use with healthy dietary patterns (AHEI 2010) was particularly strong: prevalence of botanical use was 18 % (95% CI: 16, 21) in the top quintile of AHEI compared with 8% (95% CI: 8, 10) in the lowest quintile.

In previous studies among Hispanics/Latinos, patterns have been more mixed, particularly with regard to acculturation variables. In a study of patients in New Mexico (2000-2001), low acculturation as measured with the SASH scale, was associated with greater use of botanicals [29]. In contrast, in the 2002 NHIS, acculturation, defined as nativity plus years of residence in the US, was not predictive of botanical use [56]. In HCHS/SOL, greater acculturation (SASH scale) was associated with a higher probability of botanical and NVNM product use, but did not predict the use of botanical supplements when botanical teas were included—in fact the trend was in the opposite direction. Two studies have reported that more acculturated Hispanics/Latinos use botanical supplements similar to the general US public and the less acculturated use botanical home remedies [29, 50].

Motivations for botanical supplement use closely corresponded to those reported in the 2007-2010 NHANES, with slightly greater emphasis in HCHS/SOL on supplements for weight loss, energy, and mental health.

Limitations

This study was limited in that specific prompts for supplements historically prominent in some Hispanic/Latino populations were not included in assessments [170]. However, addition of botanical teas and other traditional products from the food-based dietary recall mitigated that deficiency. In addition, the current analysis defined botanical supplement use broadly to lessen any impacts of under-assessment.

The necessity of excluding individuals with data missing for any of the variables possibly resulted in selection bias. Although both sampling and nonresponse weights were applied, the extent of the missing data could have had an impact on the results, especially in that the analysis dataset was enriched with individuals more likely to take botanical supplements. A sensitivity analysis based on multiple imputation is underway, but imputation itself is sensitive to model misspecification and may be less reliable in complex survey data [179].

Importance for prevention

In this study, botanical supplement use was strongly associated with positive lifestyle behaviors. Moreover, reasons for supplement use indicated interest in self-care and prevention.

Unfortunately, although individuals are choosing to take botanical supplements to improve their health, the potential for harm associated with their use is real. Botanical supplements are often taken with medications, increasing concerns botanical-medication interactions [9, 180]. Product contamination, either intentional (e.g., addition of undeclared drugs)[181] or accidental (e.g., plant misidentification) is problematic [163] and may be more common in imported products [14]. Up to 30% of Mexican Americans obtain botanical supplements from Mexico [6, 12, 13], increasing worries about product safety. In spite of the potential risks, rates of disclosure of botanical supplement use to physicians are low; only about a third of supplement users report their use to healthcare providers and rates are often lower among Hispanics/Latinos [7, 31, 39]. In both provider-patient interactions and public health messaging, culturally-sensitive and respectful communication is in order, encouraging disclosure by asking about and honoring what individuals choose to improve their health and sharing what is known about the safety and effectiveness of botanical supplements. Urgently needed is more research in botanical safety and effectiveness, better education of healthcare providers (including pharmacists, physicians, extenders, and nurses), and better surveillance of supplement use and products.

Conclusions

Botanical supplement use in HCHS/SOL varied greatly by Hispanic/Latino background, but overall, characteristics of botanical supplement users and motivations for use indicate an interest in health improvement. Improving botanical supplement disclosure will require considerate, culturally-sensitive communication.

TABLE 7.1 HCHS/SOL Study population characteristics by Hispanic/Latino background and botanical supplement use

		Dominican N = 1,206		Central American N=1,427		Cuban N=1,890		Mexican N=5,642		Puerto Rican N=2,273		South American N = 930	
		mean or % (se)[a]	mean or % (se)	mean or % (se)	mean or % (se)	mean or % (se)	mean or % (se)	mean or % (se)	mean or % (se)	mean or % (se)	mean or % (se)	mean or % (se)	mean or % (se)
		Non-users	Users	Non-users	Users	Non-users	Users	Non-users	Users	Non-users	Users	Non-users	Users
Mean age	N[b]	39 (0.8)	43 (1.8)	39 (0.5)	44 (1.3)	47 (0.5)	49 (1.5)	38 (0.4)	42 (0.7)	43 (0.6)	44 (1.5)	43 (0.8)	43 (1.8)
% Female	13,789	60 (2)	69 (5)	51 (2)	55 (5)	44 (1)	52 (4)	51 (1)	61 (3)	49 (2)	52 (5)	54 (2)	61 (6)
Mean SASH score	11,020	39 (0.8)	43 (2)	39 (0.5)	44 (1)	47 (0.5)	49 (2)	38 (0.4)	42 (0.7)	43 (0.6)	44 (1)	43 (0.8)	43 (2)
% in US 10+ years	10,732	76 (2)	80 (4)	67 (2)	66 (5)	51 (2)	64 (5)	78 (1)	78 (2)	93 (1)	93 (3)	58 (3)	69 (4)
Education (%)													
< HS	5,038	38 (2)	27 (5)	39 (2)	30 (4)	19 (1)	12 (2)	40 (2)	30 (2)	35 (2)	19 (3)	23 (2)	19 (3)
HS graduate	3,595	24 (2)	21 (4)	28 (2)	19 (4)	32 (2)	33 (5)	29 (1)	23 (2)	29 (2)	14 (3)	29 (2)	14 (3)
Post-secondary	5,156	38 (2)	53 (5)	33 (2)	51 (5)	50 (5)	55 (5)	32 (2)	47 (3)	36 (2)	56 (5)	48 (3)	67 (5)
Percent of poverty threshold (%)													
0 – 100%	5,623	49 (2)	40 (5)	50 (2)	32 (3)	39 (2)	27 (4)	40 (2)	31 (2)	38 (2)	28 (4)	38 (3)	27 (4)
101 – 200%	5,002	35 (2)	36 (5)	34 (2)	39 (4)	37 (1)	44 (5)	35 (1)	39 (2)	30 (2)	29 (4)	39 (2)	42 (5)
201 – 300%	1,834	11 (1)	8 (3)	11 (1)	13 (3)	13 (1)	19 (4)	13 (1)	14 (1)	16 (2)	18 (4)	13 (2)	13 (3)
300% or more	1,330	5 (1)	16 (5)	5 (1)	16 (4)	10 (1)	10 (3)	11 (1)	16 (3)	16 (1)	25 (4)	11 (2)	19 (3)
% with insurance	7,012	71 (2)	76 (4)	34 (2)	34 (4)	39 (2)	35 (5)	45 (1)	45 (3)	79 (1)	69 (4)	43 (3)	40 (5)
% lacking HC access	2,323	14 (1)	17 (4)	20 (2)	24 (4)	19 (1)	23 (4)	12 (1)	13 (2)	15 (1)	15 (4)	18 (2)	17 (4)
% physically active [d]	8,874	66 (2)	67 (5)	69 (2)	77 (3)	57 (2)	62 (4)	68 (1)	74 (2)	68 (2)	76 (3)	68 (2)	80 (3)
Mean AHEI	13,789	49 (0.2)	50 (0.5)	48 (0.2)	48 (0.4)	43 (0.1)	44 (0.4)	53 (0.2)	54 (0.3)	41 (0.2)	42 (0.5)	46 (0.3)	47 (0.6)
% Nonsmokers	9,516	88 (2)	92 (2)	86 (1)	86 (3)	72 (2)	87 (3)	82 (1)	86 (2)	66 (2)	78 (4)	88 (1)	88 (4)
% taking medication[e]	7,291	35 (2)	40 (4)	31 (2)	40 (4)	37 (1)	39 (4)	34 (1)	39 (2)	36 (1)	44 (4)	28 (2)	29 (2)
Perceived health (%)													
Fair to poor	4,022	26 (2)	34 (5)	29 (2)	30 (5)	31 (2)	35 (5)	27 (1)	29 (3)	27 (2)	32 (50	31 (2)	38 (5)
Good	6,434	39 (2)	37 (5)	46 (2)	50 (5)	46 (2)	40 (4)	51 (1)	50 (2)	41 (2)	39 (5)	51 (2)	44 (5)
Very good - excellent	3,333	35 (2)	30 (4)	24 (2)	21 (3)	23 (1)	25 (3)	22 (1)	21 (2)	32 (2)	29 (4)	19 (2)	18 (3)

Abbreviations: SASH= Short Acculturation Score for Hispanics; HS = high school; HC = health care; AHEI = alternative healthy eating index. a. All estimates (except age) are standardized to the age distribution of the US 2010 census with application of sampling and non-response weights. b N = number of respondents in sample, not representative sample. c. Percents reflect sample weights. d. Physical activity data was summarized as meeting or not meeting CDC 2008 guidelines for physical activity. e. category counts prescription medication

TABLE 7.2 Adjusted prevalence ratios of botanical supplement use in HCHS/SOL

		Users of products with NVNM ingredients N= 4,873	Users of products with botanical ingredients N=2,246	Users of botanical supplements including teas N=3,479
	N	Prevalence Ratio (95% CI) [c]	Prevalence Ratio (95% CI) [c]	Prevalence Ratio (95% CI) [c]
Hispanic/Latino background				
Dominican	1,206	0.72 (0.62, 0.84)	0.54 (0.43, 0.69)	0.57 (0.49, 0.67)
Central American	1,432	1.05 (0.93, 0.1.18)	0.94 (0.78, 1.12)	0.71 (0.62, 0.82)
Cuban	1,890	0.87 (0.78, 0.98)	0.62 (0.51, 0.75)	0.47 (0.40, 0.54)
Mexican	5,642	1	1	1
Puerto Rican	2,273	0.75 (0.66, 0.85)	0.58 (0.47, 0.70)	0.45 (0.38, 0.54)
South American	932	1.07 (0.94, 1.23)	0.85 (0.67, 1.07)	0.99 (0.86, 1.14)
Other	414	0.99 (0.79, 1.25)	0.73 (0.51, 1.04)	0.68 (0.50, 0.93)
Age (18-24 referent)	1,254	1	1	1
25-34	1,788	1.56 (1.25, 1.94)	1.73 (1.30, 2.31)	1.51 (1.20, 1.90)
35-44	2,593	2.14 (1.75, 2.63)	1.87 (1.41, 2.46)	1.90 (1.53, 2.35)
45-54	4,232	2.71 (2.24, 3.28)	2.02 (1.55, 2.64)	2.00 (1.62, 2.45)
55-64	2,894	2.99 (2.43, 3.67)	1.93 (1.45, 2.57)	2.00 (1.60, 2.50)
65-76	2,894	3.56 (2.87, 4.40)	2.12 (1.53, 2.95)	2.14 (1.67, 2.74)
Female gender (male ref.)	8,158	1.16 (1.07, 1.26)	1.30 (1.14, 1.47)	1.46 (1.32, 1.62)
SASH scale (per 1 point increase)	2,408	1.13 (1.07, 1.19)	1.13 (1.05, 1.22)	0.96 (0.90, 1.02)
Education (< HS , < 10 years in US)	5,038	1	1	1
HS graduate, < 10 years in US	3,595	1.04 (0.84, 1.30)	0.92 (0.69, 1.23)	0.93 (0.75, 1.15)
>HS, < 10 years in US	5,156	1.39 (1.12, 1.71)	1.25 (0.93, 1.66)	0.98 (0.79, 1.22)
HS graduate, 10+ years in US		1.18 (1.06, 1.31)	1.20 (1.01, 1.42)	1.13 (0.99, 1.28)
>HS, 10+ years in US		1.68 (1.54, 1.85)	2.04 (1.76, 2.36)	1.59 (1.42, 1.77)
Percent of poverty (0 – 100% ref.)	5,623	1	1	1
101 – 200%	5,002	1.21 (1.11, 1.31)	1.35 (1.18, 1.53)	1.20 (1.09, 1.33)
201 – 300%	1,834	1.37 (1.22, 1.54)	1.47 (1.02, 1.46)	1.23 (1.04, 1.45)
300% or more	1,330	1.50 (1.35, 1.68)	1.65 (1.37, 1.98)	1.38 (1.20, 1.59)
Insurance (uninsured ref.)	7,012	0.99 (0.91, 1.08)	0.89 (0.79, 1.03)	0.96 (0.86, 1.06)
Lacking healthcare access	2,323	1.02 (0.93, 1.12)	1.12 (0.96, 1.30)	1.08 (0.95, 1.23)
Physical activity (low activity ref.)	8,874	1.21 (1.12, 1.29)	1.36 (1.17, 1.59)	1.11 (1.02, 1.22)
AHEI (per 5 points)	13,789	1.12 (1.08, 1.15)	1.17 (1.11, 1.22)	1.20 (1.16, 1.23)
Nonsmoker (smoker ref.)*	9,516	1.38 (1.24, 1.55)	1.31 (1.08, 1.58)	1.47 (1.28, 1.68)
Prescription Medication use	7,291	1.18 (1.09, 1.28)	1.21 (1.07, 1.36)	1.09 (0.95, 1.25)
Perceived health (fair to poor ref.)	4,022	1	1	1
Good	6,434	1.01 (0.93, 1.10)	1.07 (0.92, 1.24)	1.11 (0.99, 1.25)
Very good to excellent	3,333	1.16 (1.05, 1.28)	1.21 (1.03, 1.43)	1.21 (1.07, 1.37)

Abbreviations: AHEI = alternative healthy eating index. a. Supplement users were defined as users by either the medication history or the dietary supplement interview +/- data from the dietary recalls. All estimates (except age) are standardized to the age distribution of the US 2010 census. Models presented here are summary models. Control variables in models are as follows: Hispanic/Latino background – age and gender; age –gender ; education—acculturation variables, age, gender, and Hispanic/Latino background; poverty—age , gender, education, field center location; insurance—acculturation, age, field center location, percent of poverty; perceived healthcare access—acculturation, age, gender, Hispanic/Latino background, percent of poverty, insurance, medication use; acculturation—age, gender, field center location; health behaviors—age, gender, Hispanic/Latino background, percent of poverty, insurance coverage, perceived access to care; perceived health—age, gender, education, acculturation.. *indicates statistically significant prevalence ratio modification: See Supplemental Table 1.

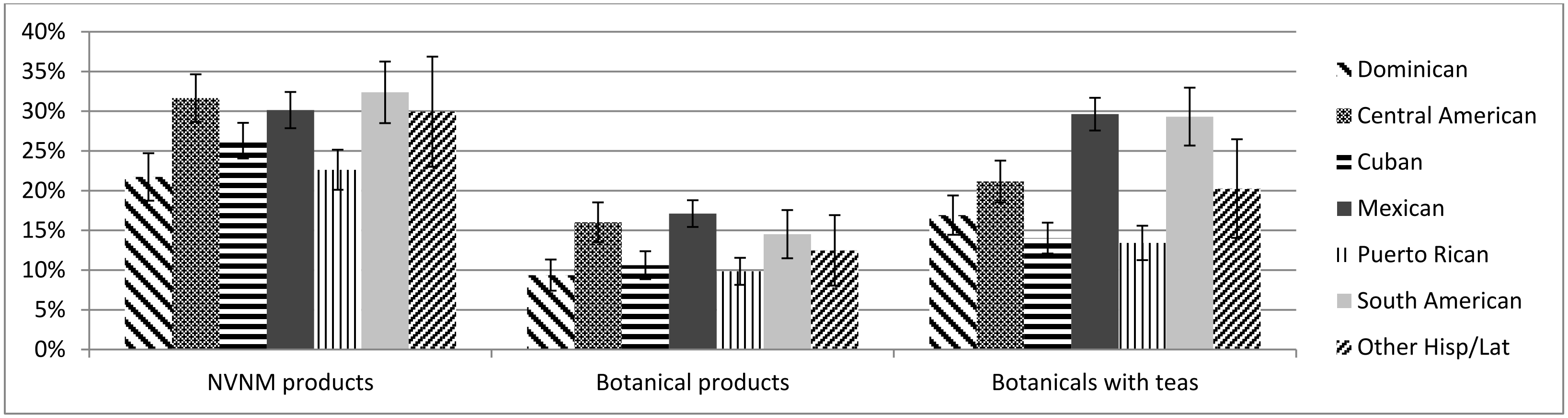


FIGURE 7.1. Comparison of model-predicted prevalence of use of botanicals in the past 30 days by various definitions across Hispanic/Latino background

Estimates are based on model-predicted marginal means with 95% confidence intervals. Botanicals include any product with a botanical ingredient, botanicals with teas also include botanical teas from the 24-hour dietary recall files, NVNM products include botanicals and other non-vitamin, non-mineral ingredients (e.g., fish oil, glucosamine). All estimates are weighted (sample, non-response).

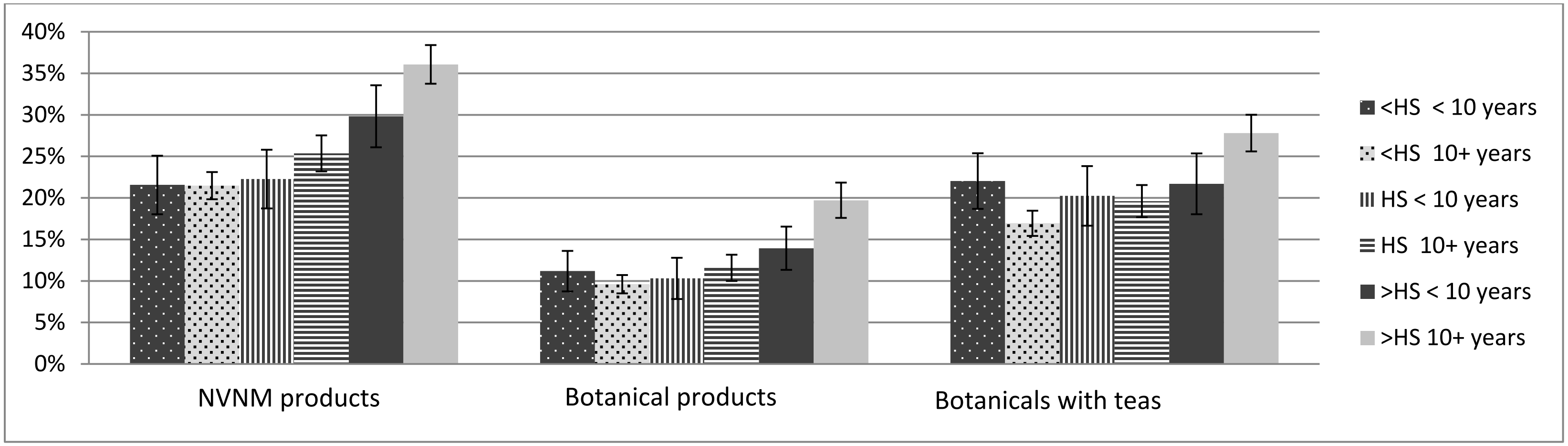


FIGURE 7.2. Heterogeneity in the association of education and years of residence in the US with botanical supplement use

Estimates are based on model-predicted marginal means with 95% confidence intervals. Botanical products include any product with a botanical ingredient, botanicals with teas also include botanical teas from the 24-hour dietary recall files, NVNM products include botanicals and other non-vitamin, non-mineral ingredients (e.g., fish oil, glucosamine).<Hs = less than high school education, HS = high school graduate , >HS =post-secondary education. <10 and 10+ years indicates years of residence in the US. All estimates are ghted (sample, non-response).

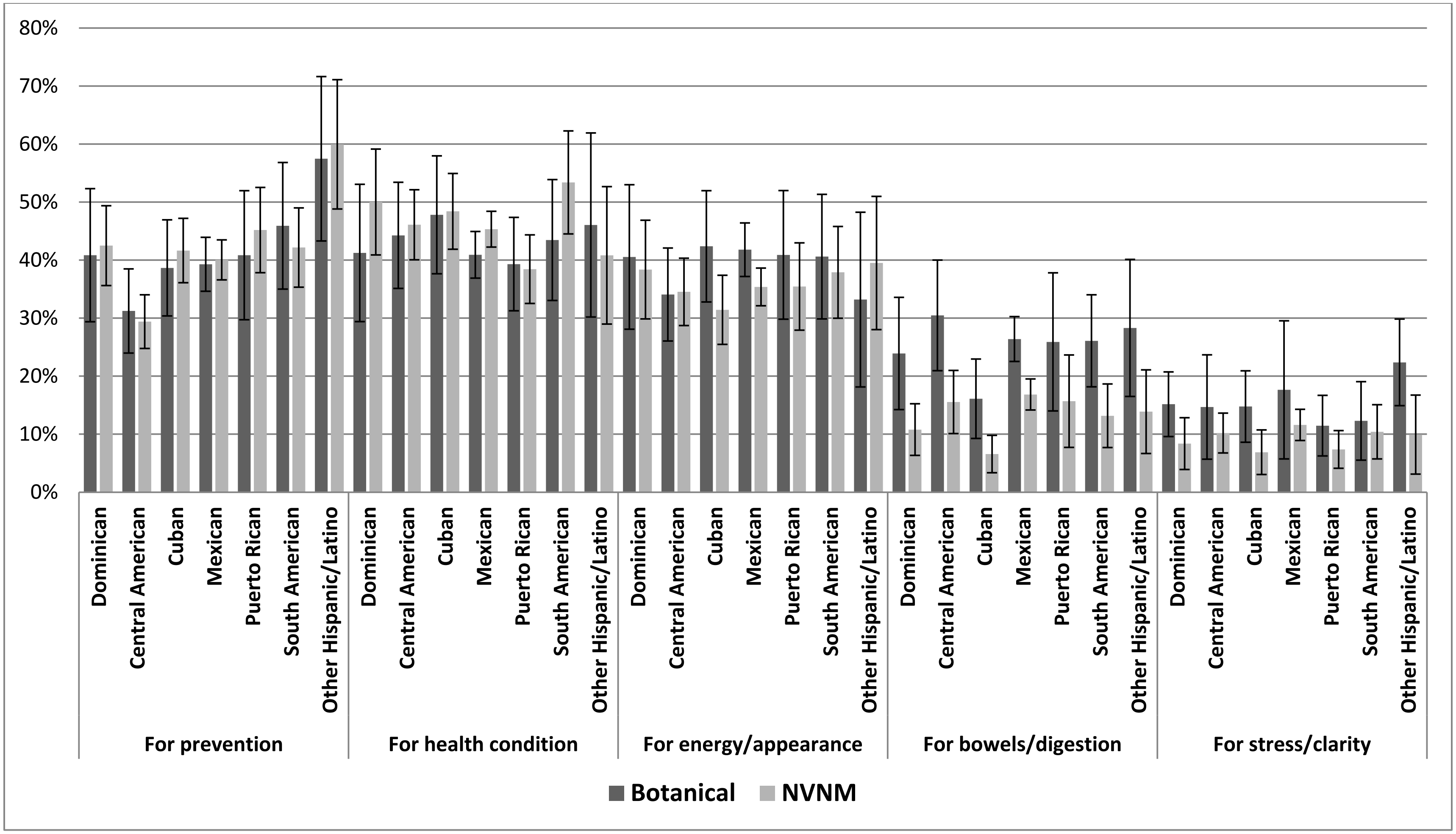


FIGURE 7.3. Comparison of selected reasons for use of botanicals and NVNM across Hispanic/Latino background

Individuals reported reasons for use of each supplement in the 30-day dietary supplement interview. Percentage is reported with sample and non-response weights yielding 95% confidence intervals. Botanicals are commercial supplements with botanical ingredients; NVNM are supplements with botanical and other non-vitamin, non-mineral ingredients (e.g., glucosamine, fish oil).

TABLE 7.3. Botanical supplement use across Background and Site in the Hispanic Community Health Study/Study of Latinos

			Users of products with NVNM ingredients N= 4,873		Users of products with botanical ingredients N=2,246		Users of botanical supplements including teas N=4,108	
Background	Site	N	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Dominican	Bronx	1,221	289	20.2 (17.5, 23.2)	116	8.7 (6.8, 10.9)	222	16.2 (13.9, 18.8)
Central American	Bronx	171	51	26.1 (19.4, 34.1)	16	10.5 (5.9, 18.0)	30	16.2 (10.8, 23.6)
Mexican	Bronx	190	34	17.4 (11.7, 25.1)	20	9.5 (5.6, 15.8)	39	19.4 (13.2, 27.6)
Puerto Rican	Bronx	1,538	354	20.4 (17.6, 23.5)	118	7.2 (5.8, 9.0)	203	12.8 (10.4, 15.7)
South American	Bronx	165	39	20.6 (14.8, 27.9)	20	11.5 (6.9, 18.5)	44	28.0 (20.3, 37.2)
Other	Bronx	222	44	28.4 (22.0, 35.7)	16	7.7 (3.9, 14.8)	34	13.3 (8.1, 20.8)
Central American	Chicago	411	140	31.4 (26.5, 36.7)	60	10.4 (7.6, 14.3)	128	28.3 (23.0, 34.2)
Mexican	Chicago	2,384	634	24.4 (22.0, 27.0)	329	12.9 (10.9, 15.1)	721	27.2 (25.0, 29.6)
Puerto Rican	Chicago	761	218	23.1 (19.6, 27.1)	84	9.7 (7.2, 12.8)	126	15.7 (12.8, 19.2)
South American	Chicago	371	127	29.0 (22.4, 36.7)	70	15.1 (10.9, 20.5)	127	28.5 (23.0, 34.8)
Other	Chicago	150	39	27.8 (14.9, 45.7)	21	14.4 (8.6, 23.1)	33	24.1 (16.1, 34.6)
Central American	Miami	1,023	349	31.8 (28.7, 35.1)	166	16.4 (13.9, 19.2)	239	22.1 (19.4, 25.0)
Cuban	Miami	2,248	665	25.4 (23.3, 27.6)	234	9.7 (8.2, 11.5)	353	15.1 (13.0, 17.5)
South American	Miami	464	195	37.8 (32.9 (42.9)	85	15.6 (12.1, 19.9)	162	33.5 (28.5, 39.0)
Other	Miami	295	105	32.6 (26.6, 39.1)	52	17.9 (13.1, 24.1)	78	26.8 (21.0, 33.6)
Mexican	San Diego	3,781	1,480	34.8 (32.0, 37.7)	789	17.9 (16.1, 19.9)	1,477	35.0 (32.4, 37.8)
Other	San Diego	243	102	39.7 (30.6, 49.6)	47	17.2 (11.3, 25.2)	85	36.5 (27.9, 46.0)

TABLE 7.4. Reasons for botanical /NVNM supplement use in HCHS/SOL

		Overall % (n)*	Dominican % (n)	Central American % (n)	Cuban % (n)	Mexican % (n)	Puerto Rican % (n)	South American % (n)	Other Hispanic-Latino % (n)
Conditions	Anemia	3.4 (150)	5.2 (17)	2.7 (14)	2.5 (15)	2.7 (52)	5.0 (31)	3.7 (13)	6.5 (8)
	Increase appetite	0.9 (38)	1.8 (6)	1.5 (8)	1.2 (7)	0.3 (6)	1.4 (9)	0.3 (1)	0.8 (1)
	Cancer	1.0 (45)	1.5 (5)	1.0 (5)	1.2 (7)	1.0 (19)	0.3 (2)	1.4 (5)	1.6 (2)
	Diabetes	1.6 (70)	0.6 (2)	0.8 (4)	1.2 (7)	2.2 (42)	1.0 (6)	1.7 (6)	2.4 (3)
	Eye/Ear health	2.7 (119)	2.1 (7)	2.5 (13)	2.0 (12)	2.9 (56)	2.6 (16)	3.4 (12)	2.4 (3)
	Indigestion	1.3 (56)	0.6 (2)	0.8 (4)	0.3 (2)	1.7 (33)	1.1 (7)	1.4 (5)	2.4 (3)
	Gynecological	5.0 (221)	7.0 (23)	4.4 (23)	4.1 (24)	5.5 (105)	3.6 (22)	5.4 (19)	4.1 (5)
	Heart/Lipid health	12.8 (568)	18.5 (61)	11.4 (59)	9.7 (57)	11.0 (210)	18.4 (113)	13.1 (46)	17.9 (22)
	Kidney disease	0.8 (36)	1.2 (4)	0.4 (2)	0.7 (4)	1.0 (18)	0.3 (2)	1.1 (4)	1.6 (2)
	Joint health	13.0 (716)	5.5 (18)	15.2 (79)	14.0 (82)	19.6 (374)	11.7 (72)	21.4 (75)	13.0 (16)
	Liver health	1.5 (65)	0.6 (2)	2.1 (11)	1.5 (9)	1.3 (24)	1.9 (12)	1.4 (5)	1.6 (2)
	Lung disease	1.6 (70)	3.3 (11)	2.1 (11)	2.0 (12)	0.9 (18)	2.3 (14)	1.1 (4)	0
	Pain	10.7 (474)	7.3 (24)	10.6 (55)	11.1 (65)	11.6 (221)	7.6 (47)	14.3 (50)	9.8 (12)
	Prostate/ Sexual	1.9 (86)	1.5 (5)	1.7 (9)	3.6 (21)	1.6 (30)	1.8 (9)	2.0 (7)	2.4 (3)
	Other conditions	1.2 (55)	0.9 (3)	0.6 (3)	1.5 (9)	1.3 (24)	1.6 (1.6)	1.4 (5)	0.8 (1)
Nutrition	Supplement diet	28.6 (1,268)	20.4 (67)	26.8 (139)	24.3 (143)	31.0 (593)	30.4 (187)	27.4 (96)	35.0 (43)
Prevention	Healthy aging	2.1 (95)	2.4 (8)	1.9 (10)	0.7 (4)	2.5 (47)	2.4 (15)	2.9 (10)	0.8 (1)
	Bone health	22.8 (1,013)	27.7 (91)	21.4 (111)	11.9 (70)	23.7 (454)	27.3 (168)	25.7 (90)	23.6 (29)
	Immune system	12.6 (561)	11.6 (38)	9.6 (50)	23.8 (140)	9.0 (173)	12.7 (78)	17.1 (60)	17.9(22)
	General health	20.7 (68)	20.7 (68)	12.5 (65)	14.5 (85)	20.1 (384)	20.0 (123)	16.6 (58)	26.8 (33)
Bowel	Bowel health	9.9 (440)	10.0 (33)	11.0 (57)	5.9 (35)	11.4 (218)	8.3 (51)	7.4 (26)	16.3 (20)
	Digestion	4.1 (182)	3.7 (12)	3.3 (17)	0.7 (4)	5.6 (107)	2.8 (17)	5.1 (18)	5.7 (7)
Mental	Stress	5.0 (223)	2.7 (9)	3.3 (17)	1.7 (10)	7.2 (138)	3.3 (20)	5.4 (19)	8.1 (10)
	Mental clarity	6.4 (282)	5.5 (18)	7.9 (41)	3.9 (23)	6.9 (131)	5.8 (36)	6.9 (24)	7.3 (9)
Appearance	Increase energy	19.1 (847)	20.7 (68)	22.2 (115)	13.4 (79)	21.0 (401)	17.2 (106)	13.4 (47)	25.2 (31)
	Improve sport	3.0 (135)	4.0 (13)	1.7 (9)	1.4 (8)	3.0 (58)	4.4 (27)	3.7 (13)	5.7 (7)
	Lose weight	6.6 (293)	5.5 (18)	4.8 (25)	4.6 (27)	8.3 (159)	4.4 (27)	7.7 (27)	8.1 (10)
	Hair, skin, nails	9.7 (432)	10.6 (35)	11.9 (62)	8.7 (51)	7.8 (149)	11.2 (69)	15.4 (54)	9.8 (12)
Other	Nonspecific	3.4 (150)	2.1 (7)	1.7 (9)	3.4 (20)	4.0 (76)	2.8 (17)	4.9 (17)	3.3 (4)
	Unknown	5.0 (223)	2.7 (9)	3.5 (18)	3.9 (23)	6.7 (128)	4.6 (28)	4.0 (4)	2.4 (3)
Recommended	Clinician	14.7 (654)	14.0 (46)	13.1 (68)	16.5 (97)	14.5 (277)	15.7 (97)	15.7 (55)	11.4 (14)
	Friend/family	5.7 (251)	4.0 (13)	4.2 (22)	4.1 (24)	6.9 (132)	5.2 (32)	5.7 (20)	6.5 (8)
	General	3.6 (156)	3.6 (12)	2.3 (12)	3.2 (19)	4.3 (83)	3.6 (22)	1.7 (6)	3.2 (4)

CHAPTER 8: DISCUSSION AND CONCLUSIONS

8.1 Key Study Findings

Prevalence of botanical supplement use

This study documents that the prevalence of botanical and other NVNM supplements among Hispanics/Latinos depends on the methodology of data collection and definition used First, differences in the method of ascertainment influenced results. The prevalence of supplements consumed in the past 30 days containing a botanical was 4.4% as ascertained by the medication inventory and was 9.4% as ascertained in the dietary supplement interview, increasing to 11.6 % if defined by either the medication inventory or the dietary supplement interview. Second, different definitions of botanical supplements greatly influenced prevalence estimates. If all fiber products were considered botanicals, the prevalence of products with botanicals increased to 12.3% and if botanical teas from the dietary recall were added, the prevalence was 22.8%. Many studies conflate botanical and other so-called "specialty supplements" (here labeled NVNM ingredients). Prevalence of supplements with NVNM ingredients was 12.9% by the medication inventory, 24.6% by the dietary supplement interview, and 27% when defined by either measurement instrument.

Due to differences in the assessment period and differences in the target population, no prior studies are entirely comparable to HCHS/SOL. The expected prevalence of botanical supplement use was calculated prior to the analysis. Based on median estimates from a systematic review of botanical supplement use among Hispanics/Latinos, the prevalence of botanical supplement use among Hispanics/Latinos, including botanical teas, in the past 12 months was between 30 and 45%. Estimated use in the past 30 days, based on the 2007 NHIS data would be 70-75% of that in the past 12 months. Because many botanical supplements are consumed episodically, one would expect an additional reduction in the prevalence, perhaps by another 25%. Hence, the expected prevalence of botanical supplements with teas was between 15 and 25%. Applying the same logic to estimate the prevalence of botanical supplement products only (without teas), the expected prevalence was 5-10%. Study findings are consistent with these expectations.

The prevalence of individual supplement ingredients from the dietary supplement interview was also calculated. Among dietary supplement users (about 40% of the population), 25% were taking a supplement with an essential fatty acid and almost 30% were taking a supplement with lutein or lycopene. Another 11% were taking a supplement with an ingredient usually used for arthritis (glucosamine, MSM, chondroitin, collagen) and 10% reported taking a supplement for joint health. Popular botanicals among supplement users included ginkgo (6.5%), ginseng (6.7%), and garlic (4.4%). Licorice was also a relatively common ingredient (2.4%). Aloe and chamomile were infrequent ingredients in dietary supplement products captured in the dietary supplement interview, but were seen more often in the 24-hour dietary recalls.

Patterns of botanical supplement use among Hispanics/Latinos

Characteristics of botanical supplement users in HCHS/SOL were similar to those seen in the general US population [122, 147]. Defining botanical and NVNM supplement users by their reported use in either the medication inventory or the dietary supplement interview, users were more likely to be better educated and have a higher income. They were also more likely to be physically active, non-smokers, with greater adherence to healthy diet recommendations. HCHS/SOL participants who considered themselves in good health were more likely to use botanical supplements, but they were also more likely to take at least one chronic prescription medication.

In general, Hispanics/Latinos of Cuban, Dominican and Puerto Rican descent were less likely to take botanical supplements than individuals of Mexican, Central or South American descent. Individuals reporting a mixed Hispanic/Latino heritage were more likely than others to report use of botanicals. However, this pattern did not hold across all study sites and all definitions of botanical supplement use. For example, in the Bronx, with relatively more Puerto Ricans (n=1,538) and Dominicans (n=1,221), the prevalence of NVNM supplements in those groups (about 20%) exceeded the prevalence for Mexicans (17%). In contrast, the prevalence of NVNM supplements among Mexicans in San Diego (n=3,781) was almost 35%. For data including botanical teas, prevalence among Mexicans was consistently higher than Puerto Ricans, Dominicans, and Cubans, but remained higher for Mexicans in San Diego (35%) as compared with Mexicans in Chicago (27%) and the Bronx (19%).

Motivations for supplement use among Hispanics/Latinos

Individuals in HCHS/SOL reported a variety of reasons for taking supplements. Among those who were taking supplements with NVNM ingredients, 21% (age-standardized) reported taking supplements for their general health and 13% were taking NVNM supplements for cardiovascular health (heart, blood pressure, lipid abnormalities). Ten percent of NVNM users were taking supplements for stress or anxiety. About 8% of NVNM users gave nonspecific reasons for use: they had heard it was a good product or they were not sure why they were taking it.

Despite the fact that the dietary supplements reported in HCHS/SOL were similar to those reported in the general population, reported motivations for use (of any dietary supplement) were somewhat dissimilar. For example, in HCHS/SOL, the reported use of supplements for weight loss was 6% compared with 3% in NHANES 2007-2010 [147]. HCHS/SOL participants were also more likely to report taking supplements for energy (18 vs. 11%), mental health (7 vs. 4%), and bowel health (6 vs. 5%) and to supplement the diet (29 vs. 22 %). HCHS/SOL participants were less likely to report supplement use for heart health (14 vs. 15%), joint health (9 vs. 12%) or bone health (15 vs. 25%), but 7% also reported taking supplements to treat pain conditions. Motivation patterns are consistent with those previously reported: use of supplements to treat self-limited or minor conditions [49] and to improve health [182].

8.2 Study Limitations

Possible inconsistent coding

Identifying and coding supplements as botanicals and other NVNM in HCHS/SOL was a difficult process. Although guidance was sought from and given by the Office of Dietary Supplements, the author was unable to ensure that coding procedures were entirely consistent with other studies. The investigator chose the Langual-based process, because it was more specific than the NHANES-based supplement coding process. The latter was appropriate for and applied to the categorization of individual supplement ingredients in the dietary supplement data. Because much of the medication-based data could not be coded at the ingredient level, ingredient-level coding was not appropriate for these data. The Langual-based coding scheme was easily adapted to product-level data and enabled the capture of many individual ingredients and the assignment of supplements to both broad and narrow categories.

Every effort was made to ensure consistent coding across the datasets and repeated data checks were performed. However, inconsistencies undoubtedly occurred. The medication-based and dietary-based data were very different in character. The medication-based data encoded much product information in a numeric variable saved as a string, but this information did not include specific ingredients. Where sufficient detail was available for the products, ingredients were obtained from online product labels and saved in an Excel spreadsheet, but only the most common ingredients were encoded, usually as classes of products such as protein, fiber or lipotropic agents. Particularly common individual ingredients were coded separately, e.g., omega-3 and omega-6, glucosamine with related chondroitin, MSM, and collagen, and lipotropic agents. Inconsistencies in coding could have influenced negatively the concordance statistics and resulted in biased estimates. An additional review of the coding of both the medication inventory and dietary supplement interview data would be desirable.

Possible additional measurement error

Lower overall estimates in the Bronx are of some concern. It is unclear whether botanical supplement use is just not as popular in the Bronx, or if there a systematic measurement error affecting those estimates. However, in previous studies, the prevalence of NVNM therapies in the northeast (18%) was lower than that seen in the west (24%) [122].

No standardization for botanical supplement assessments

A standard procedure for botanical supplement capture and assessing prevalence does not exist. Some methods restrict prevalence estimates to supplements that are consumed at least once per week and others count any use. Some studies ask about supplement use in the past week [73, 107] or two weeks [59, 171], others collect data on supplement use in the past year, e.g., [115, 119] or supplement use at any time in the participant's life, e.g., [5, 183]. Some studies ask about use of supplements for a particular indication. For example, studies request information about the use of supplements for diabetes [102] or arthritis [184]. Others ask about supplement use by individuals with certain conditions (e.g., menopause [37]) or individuals who are taking medications [16]. These differences in study design can make a large difference in prevalence estimates.

No studies have presented methods for correction for measurement error in dietary supplement studies. As noted above, all prior studies have compared duplicate instruments across supplements with kappa and intra-class correlation statistics. Calibration of botanical supplement use is hampered by the lack of a "gold standard", an instrument with 100% sensitivity and specificity for defining the variable.

In the nutritional epidemiology literature, a literature with similar measurement error challenges, several methods have been considered, all of which presume continuous exposure variables and utilize linear regression models. The goal of these models is to approximate the "true" value of a dietary value given available measures. They include: 1) validation with an instrument considered error-free (the "gold standard" or "criterion" measure) in a subsample with application of a correction to the entire sample [66, 165]; 2) repeated assessments in the same population with the same instrument[185]; and/or 3) assessments with one or more additional, but error-prone instruments with utilization of statistical methods to come closer to the "true" measure [186]. The latter approach is hampered by non-identifiability when multiple variables are unknown. Non-identifiability can be solved by either making assumptions about the actual value of one of the variables and examining the sensitivity of the analysis to variations in the value [187] or by utilizing a Bayesian approach, making assumptions about the range and the shape of the distribution of unknown variables, based on prior literature and analyses [186, 188]. Other model-based procedures, e.g. regression calibration, correct measurement error in one variable by regressing it on an outcome, preferably one with little error. In regression calibration, analysts substitute the expected value of a variable, based on one or more values measured with error. The procedure requires setting one measure as the criterion, but uses all available information in setting up the equation.

In the current study, neither of the assessment instruments could be considered a gold standard. The medication inventory, if done in the home, could have been a criterion measure. But an inventory completed at a study visit could miss supplements participants fail to bring to the visit [189]. Alternatively, the dietary supplement interview, following the 24-hour dietary recall as it does, may be a better criterion measure, making the assumption that the dietary supplement interview is more sensitive than the medication inventory for the outcome. In the current study, it may be possible to define a calibration coefficient for adjusting the probability of botanical supplement use as assessed by the medication inventory by regressing it on the probability of use as determined by the dietary supplement interview including probability of being a botanical user given covariates as assessed in Aim 2. However, attempts to run this calculation resulted in improbably large correction estimates. Additional work in this area is needed.

It could be possible to estimate the "true botanical supplement prevalence" based on the imperfectly measured medication-based and dietary-based estimates using a structural equation modeling approach [190]. Structural equation modeling (SEM) is an attractive method for situations in which observed variables, measured with error, are expressions of a latent variable. In future, consultation with an expert in SEM may make the desired calculation possible.

Missing data

Very little data was missing for the dietary supplement interview or for the medication inventory. Moreover, even though more than 1600 products in the medication inventory could not be coded, because many individuals took multiple supplements, less than 4% of individuals were affected. Sensitivity analyses changed the interpretation of the comparisons between methods very little.

More data was missing for the analysis of characteristics of botanical supplement users. The analysis was restricted to individuals with complete data for all of the variables included in models. Data was missing for the medication inventory or dietary recall (355), education (386), physical activity (246), dietary quality (243), cigarette smoking (93), perceived health (238), birthplace (73), years of US residence (120), insurance status (323), and income (1488), resulting in a reduction in the analysis population from 16,415 to 13,735(16%). Individuals included in the analysis differed from those excluded by: 1) background group (fewer Cubans, more Mexicans); 2) gender (fewer females); 3) education (fewer less educated, more highly educated); 3) physical activity (more active); 4) smoking (fewer smokers); 5) AHEI score (slightly higher in analysis dataset); and 6) acculturation (slightly higher SASH score). Hence the analysis dataset was enriched by individuals more likely to be supplement users. In addition, modeling missing variable status revealed several variables predicted missing value status with regard to percent of poverty. Attempts to correct for missing data with multiple imputation programs were unsuccessful due to the need to include survey design characteristics in the model.

Lack of generalizability of study findings

Although HCHS/SOL recruits Hispanics/Latinos from across the United States and across background groups, by design, all of the target areas/field centers are in urban areas. Hence, the results of this study will not be generalizable to rural Hispanic/Latino populations, such as immigrants to small towns or migrant farmworkers.

8.3 Importance to Public Health and Clinical Medicine

Prevalence estimates use botanical supplements use in Hispanic/Latino populations are currently uncertain, partially due to differences in use botanical supplement definitions in the literature. This effort examined botanical and NVNM supplement use by multiple definitions, some intentionally very broad (all NVNM products or any botanical, including fiber products and food-like botanical remedies captured from the 24-hour dietary recalls) and some very narrow (botanical products captured in the dietary supplement interview). The many different prevalence estimates sheds light on how and why the differences have occurred across studies and may lead to a better understanding of botanical supplement use in Hispanic/Latino populations. Moreover, this study estimated population characteristics of botanical supplements users using multiple definitions, yielding a greater capacity for comparisons across studies in the literature.

Understanding characteristics of supplement users is important to defining the likely supplement user. In addition, understanding drivers of botanical and NVNM supplement use are essential to communication with patients about their use. Botanical supplements have biologic activity and may interact with medications. For example, ginkgo, a relatively popular botanical supplement in HCHS/SOL, may result in serious bleeding including intracerebral hemorrhage [191] and bleeding risk may be more prominent with the concomitant administration of aspirin [192]. Individuals who take medications are more likely to take botanical supplements than those who do not and this finding was confirmed within HCHS/SOL. However, as seen in the US general public, botanical supplement users in HCHS/SOL were also more likely to exhibit evidence of health-seeking behaviors, such as healthy dietary patterns and avoidance of smoking. Increasingly, healthcare professionals are recognizing the desirability of empowering patients to take an active interest in maintaining good health. Honest communication with patients is critical, particularly with patients who choose dietary supplements [193]. Adherence to both healthy lifestyle choices and medication recommendations has been associated with positive health outcomes [194]. Adherence depends on a mutually respectful relationship between the healthcare professional and the patient as well as recognition of outcomes important to patients [194]. Botanical supplement use, serving as a marker for other health-seeking behaviors, should be part of the conversation with patients.

A respectful conversation about botanical supplement use is doubly important with patients who are members of a minority group. Hispanics/Latinos are less likely than non-Hispanic whites to disclose their supplement use to their healthcare professionals [134]. Patients, who encounter other barriers to health care due to language challenges, structural barriers, and discrimination, may be even less likely to bring up botanical supplement use spontaneously. In addition, based on the results of this study, unless patients are asked specifically about taking various types of supplements, such as botanical teas or liquid aloe supplements, they may not even think about them. Healthcare professionals find that they must inquire about botanical supplement use in several different ways to achieve a complete sense of what a patient is taking (Gardiner, personal communication).

Overall, dietary supplement use is captured poorly in the US and this is especially true for botanical supplements. Botanical supplements may have both positive and negative long term effects, but these effects are inadequately studied. Thousands of supplement products are introduced to the marketplace each year [158]. Despite good manufacturing process rules, many botanical supplement products currently do not contain label-stated ingredients and may contain misidentified plants and intentional adulteration with pharmaceuticals [39, 195]. Some of the weight loss botanical products identified in HCHS/SOL were known to contain undeclared medications (e.g., Fruta Planta) that had been recalled by the US FDA. Other identified products from Latin America contained a mixture of prescription and OTC medications, vitamins, and NVNM ingredients (e.g., Reumofan Plus).

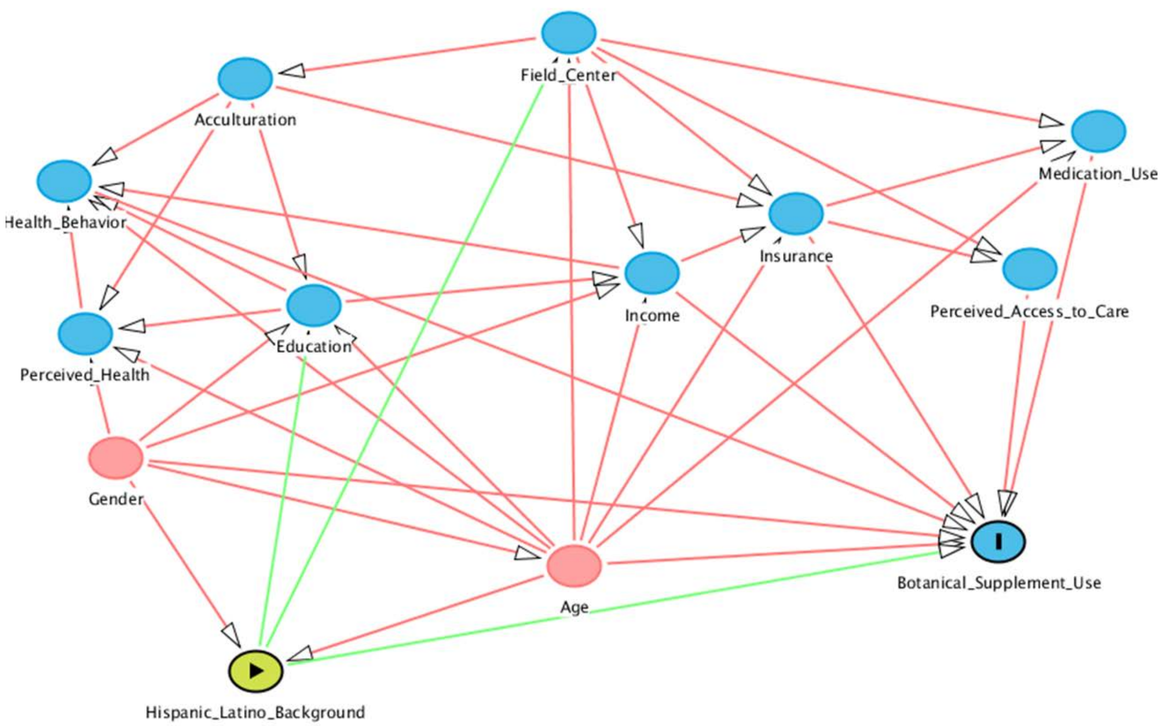
8.4 Future directions

Multiple opportunities exist for the improvement of botanical supplement capture. Based on experience with HCHS/SOL, further collaboration with the Office of Dietary Supplements could refine the derived Langual-based coding scheme to make it broadly applicable to dietary supplement coding in other settings. Capture of all dietary supplement ingredients, such as is possible through the DSAM, is clearly superior, but may not be possible in smaller studies with fewer resources or to clinicians, unless, the DSAM were broadly and freely available to both researchers and clinicians.

Improving botanical supplement capture within Hispanic/Latino populations depends on a thorough understanding of the patterns of botanical supplement use within Hispanic/Latino populations, including understanding differences among background groups. In this study, differences were suggested by the increased disparity in botanical supplement prevalence between Mexicans and Dominicans with the addition of botanical teas. In prior studies, botanical teas comprised a substantial component of supplement use among Mexican Americans [38, 59, 69]. That HCHS/SOL captured few botanical teas outside the dietary recall assessments raises questions about the adequacy of botanical supplement ascertainment strategies in the study. A validation study would be indicated for these populations, involving home-based dietary supplement inventories with prompts for capture of raw botanical product use, either in product form (e.g., commercial teas) or in other raw forms (home-grown herbs, nopal). This type of study could also inform a dietary supplement questionnaire for future follow-up.

Improving botanical supplement capture in general depends not only on better communication with healthcare professionals, but also on improved surveillance techniques. Currently, even if a conversation takes place between clinicians and patients about botanical supplement use, the medical chart often does not reflect it [169, 196]. Adverse event reporting depends on spontaneous reports to poison control centers, supplement manufacturers, or the FDA adverse event reporting system. It is estimated that <1% of dietary supplement adverse events are reported [197]. A better system would capture supplement use routinely for storage in a national database. This would require a partnership between dietary supplement vendors, community pharmacies, clinicians, and patients as well as database programmers. With voluntary routine capture of dietary supplement use, a better understanding of both the value and perils or supplement use can be assessed.

APPENDIX. EXAMPLE OF DIRECTED ACYCLIC GRAPH WITH EXPOSURE HIGHLIGHTED



Daggity software, through its color-coding (exposure antecedents in pink, green lines indicating variables in causal pathway), enables the identification of antecedents of a variable in its relationship with a designated outcome. Adjustment sets are easily constructed.

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