Southern Community Cohort Study: Establishing a Cohort to Investigate Health Disparities

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Objectives: To demonstrate the methods of recruitment of a low-income, predominantly African-American study population for the Southern Community Cohort Study (SCCS), a prospective epidemiologic investigation of racial disparities in cancer risk.

Methods: Partnerships with community health centers (CHCs) were formed to reach underserved populations throughout the south. Recruitment of participants (aged 40–79) in CHCs began in March 2002. Participants complete a comprehensive baseline interview and provide a blood or buccal cell sample. Recruitment will expand to the general population of the south to achieve a broad cross-section of socioeconomic status. The final cohort size is expected to be approximately 100,000.

Results: A high level of cooperation and recruitment was achieved in the CHCs. From March 2002 to October 2004, 32,632 participants (80% black, 41% male, 62% with total household income <$15,000, 34% with <12 years schooling) enrolled. Participants reported a high prevalence of medical conditions (21% diabetic, 44% obese) and adverse health behaviors (45% current smokers).

Conclusions: Working in CHCs is successful for recruiting a population that has been difficult to reach in previous studies. The SCCS is a unique cohort that will provide a rich resource for evaluating disparities in cancer and other chronic disease risk as it is followed over time.

Key words: African Americans ■ epidemiology ■ neoplasms ■ prospective studies ■ cardiovascular disease

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U.S. cancer statistics document higher incidence rates of most forms of cancer, including cancers of the oral cavity, pharynx, esophagus, stomach, colon, lung, cervix, kidney, liver and prostate, among African Americans than whites, yet reasons for the racial disparity are poorly understood.[1-3] Blacks also experience poorer survival than whites for nearly all forms of cancer, so that the disparities tend to be even greater for mortality than for incidence.[1-4] Mortality rates for both stroke and heart disease are also higher among blacks than whites in the United States.[5,6]

To date, the limited participation of African Americans in major epidemiologic investigations has made it difficult to identify reasons for these health disparities. Blacks comprise <5% of many prominent follow-up studies[7-11] and intervention studies.[12-14] In the 1990s, two large cohort studies were initiated with higher representation of African Americans: the Multiethnic Cohort Study, drawn from population-based samples in California and Hawaii, has 16% African-American composition (N ~35,000)[15]; and the Black Women's Health Study includes 64,500 black women identified from magazine subscriber lists and professional organizations.[16] Smaller studies of narrower focus have also been launched, such as the Jackson Heart Study, which is following approximately 5,300 African-American men and women in a prospective study of cardiovascular disease in the Jackson, MS area.[17]

Factors associated with low socioeconomic status (SES) (e.g., poor living conditions, limited access to healthcare services, social stresses, poor health habits) should strongly relate to health outcomes, and it is possible that these factors underlie many of the currently documented racial disparities. To understand the role of socioeconomic disadvantage versus race, studies including low-income adults are needed in order that these factors be investigated in tandem. Enrolling participants across a full spectrum of SES (particularly the lower levels) is challenging, however. The ongoing National Longitudinal Mortality Study (NLMS), a large census-based

cohort that through linkage to the National Death Index is examining demographic and socioeconomic differentials in U.S. mortality rates, has the built-in capacity to include all levels of SES but has little or no baseline risk factor or health data.[18,19]

This manuscript describes the design and implementation of the Southern Community Cohort Study (SCCS), a prospective cohort study designed to identify the underlying reasons for racial disparities in cancer and other chronic disease risk, with the ultimate goal of providing possible avenues for effective interventions and/or preventive strategies. The southeastern United States was chosen as the setting for this study because of its: a) high proportion of long-term African-American residents, b) high proportion of long-term rural residents (another under-studied group), and c) distinctive patterns in both disease occurrence and exposure prevalence. We describe our methodology as well as report on the characteristics of this cohort after 2.5 years of recruitment.

MATERIALS AND METHODS

This study was approved by the institutional review boards at Vanderbilt University and Meharry Medical College. All participants provided written informed consent and (since April 14, 2003) a signed Health Insurance Portability and Accountability Act (HIPAA) authorization.

Preliminary Work

Before initiating the SCCS, we carried out pilot studies to test various aspects of the full-scale investigation, including recruitment methods and materials, the survey instrument and biospecimen collection. This pilot work, described elsewhere[20], focused on the feasibility of enrolling subjects from both the general population and from attendees of community health centers (CHCs), which are government-funded healthcare facilities that provide basic health services primarily to low-income individuals.[21] A primary finding of our pilot work was that CHC-based in-person recruitment was highly successful in an African-American and low-income population, a specific target of the SCCS.[20] By the end of the pilot study, we had formed relationships with 15 CHCs across the south who supported the study and were willing to act as recruitment sites. In the pilot study, enrollment of participants through sampling driver's license, voter registration and commercial mailing files was also found to be feasible for broadening the socioeconomic diversity of the cohort.

Significant effort was devoted to developing and refining the baseline questionnaire, which elicits information on demographics; anthropometry; tobacco use; diet; alcohol consumption; physical activity; personal medical history; family medical history; reproductive history (for women); medica-

Table 1. Distribution of initial Southern Community Cohort Study Members by Race, Sex and Age Group (N=32,632), 2002–2004

Race/Ethnicity	Age Group (Years) 40–49 N	%	50–59 N	%	60–69 N	%	70–79 N	%	Total N	%
Males (N=13,360)										
Black/African-American	6,235	(84.0)	3,332	(82.2)	1,110	(74.9)	284	(71.2)	10,961	(82.0)
White	1,002	(13.5)	627	(15.5)	335	(22.6)	104	(26.1)	2,068	(15.5)
Hispanic/Latino	49	(0.7)	14	(0.4)	6	(0.4)	3	(0.8)	72	(0.5)
Asian or Pacific Islander	3	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.0)
American Indian or Alaska Native	12	(0.2)	12	(0.3)	5	(0.3)	2	(0.5)	31	(0.2)
Other racial group	26	(0.4)	20	(0.5)	8	(0.5)	3	(0.8)	57	(0.4)
Mixed race	91	(1.2)	45	(1.1)	16	(1.1)	3	(0.8)	155	(1.2)
Unknown	8	(0.1)	3	(0.1)	2	(0.1)	0	(0.0)	13	(0.1)
Total	7,426	(100.0)	4,053	(100.0)	1,482	(100.0)	399	(100.0)	13,360	(100.0)
Females (N=19,272)										
Black/African-American	7,500	(80.6)	4,720	(76.8)	2,063	(72.4)	710	(73.4)	14,993	(77.8)
White	1,577	(17.0)	1,274	(20.7)	709	(24.9)	231	(23.9)	3,791	(19.7)
Hispanic/Latino	38	(0.4)	21	(0.3)	23	(0.8)	5	(0.5)	87	(0.5)
Asian or Pacific Islander	9	(0.1)	9	(0.2)	2	(0.1)	0	(0.0)	20	(0.1)
American Indian or Alaska Native	19	(0.2)	12	(0.2)	2	(0.1)	1	(0.1)	34	(0.2)
Other racial group	30	(0.3)	15	(0.2)	8	(0.3)	6	(0.6)	59	(0.3)
Mixed race	116	(1.3)	79	(1.3)	33	(1.2)	12	(1.2)	240	(1.3)
Unknown	15	(0.2)	20	(0.3)	10	(0.4)	3	(0.3)	48	(0.3)
Total	9,304	(100.0)	6,150	(100.0)	2,850	(100.0)	968	(100.0)	19,272	(100.0)

tion use; emotional well-being and social support; religion/spirituality; health insurance; use of medical and cancer screening services; occupational history; and miscellaneous factors, such as cell phone use and seat belt use. The largest single portion of the baseline questionnaire concerns the collection of data on usual dietary intake, using an 89-item food frequency questionnaire (FFQ) that was developed specifically for this study population.[20] The questionnaire is comprehensive yet restricted in length to assure a reasonable administration time, both as an in-person interview and paper questionnaire (23 pages in the pilot study). The priorities were to include questions about factors that were: 1) known or suspected to be major contributors to cancer risk (e.g., diet), 2) suspected to play a role in racial disparities (e.g., access to healthcare), or 3) emerging as potentially important risk or protective factors for cancer (e.g., nonsteroidal anti-inflammatory drugs). We also made an effort to utilize many questions (or question groups) used previously in other large epidemiologic studies to facilitate meaningful comparisons in research findings across the different populations. To aid us in refining the final questionnaire, we also conducted two gender- and racially mixed focus groups (one in Nashville, TN, and one in Jacksonville, FL) consisting of 12 and 10 pilot study participants, respectively. The pilot participants provided detailed feedback about the questionnaire, as well as about other printed study materials, recruitment strategies and overall methods.

SCCS Recruitment and Methodology

Study base. The SCCS is seeking to enroll approximately 100,000 male and female participants in the southeastern United States, over two-thirds of whom will be African-American. More than half are expected to be recruited from CHCs and the remainder from stratified random sampling of general population sources. Cohort member enrollment is limited to English speakers between the ages of 40 and 79 who have not been under treatment for cancer (with the exception of nonmelanoma skin cancer) within the past year. Participants are currently being recruited from CHCs in Alabama, Arkansas, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee, Virginia and West Virginia. General population recruitment in these states is slated to begin in 2005. Census statistics indicate that approximately four million blacks aged 40–79 and about five times as many whites reside in these states.[22]

Subject enrollment and data collection—CHCs. Cohort member enrollment commenced at 14 CHCs in March and April 2002. An additional seven CHCs joined as recruitment sites in March 2003, another four joined in October 2003, and seven more joined in October 2004. (See www.southerncommunitystudy.org for a listing of participating CHCs.) CHCs continue to join the study on an ongoing basis, and they are selected to reflect a range of rural and urban areas as well as for the racial makeup of their patient population.

Study interviewers work on-site at each CHC enrolling participants. The interviewers are hired by the CHCs from the local community and are trained by SCCS scientific personnel. To date, 75% of the interviewers have been African-American, in approximate racial concordance with the participating CHCs' patient population. The interviewers approach entrants to the CHC who appear to be age-eligible and assess their interest and eligibility. Potential participants are typically approached in lobbies and other waiting areas and could be patients, persons accompanying patients, persons using the pharmacy, etc. The interviewers utilize promotional materials placed within the CHC (large color posters, color brochures, small flyers on lobby seats) and sometimes placed outside of the CHC (e.g., brochures left in churches) in order to raise awareness of and interest in the study. The interviewers also typically carry a letter of support signed by a prominent physician or administrator within the CHC to reinforce the legitimacy of the study to potential participants.

Consent is obtained by the study interviewers, who review the informed consent form with the participants in a private area in the CHC. The interviewers receive training on the protection of human subjects and the administration of the consent form from the SCCS scientific staff, and complete two online tutorials offered through the National Institutes of Health and the Office for Human Research Protections (DHHS) on this subject. When they encounter participants with low literacy skills, they read the consent form aloud to the participant. All participants are given a copy of their signed consent form.

In-person baseline interviews are conducted in a private office in the CHC using a laptop computer and a specially designed computer-assisted personal interview (CAPI) with substantial logic-checking and skip pattern features built into the instrument. The CAPI also accesses a continuously updated participant roster to ensure that persons do not participate more than once. Handcards are used to facilitate several sections of the interview, allowing the participant to read answer choices off the card. Specific questions within the CAPI are updated as needed on an ongoing basis—for example, to reflect new medications on the market. Interviewers also abstract measured weight, height and blood pressure from the participants' medical records if those meas-

urements were taken on the day of study enrollment.

Data collected from the CAPIs are electronically sent to the SCCS data processing center on a daily basis from each CHC. After the uploading and archiving of the data, it is automatically erased from the laptop. This process helps safeguard the security of the data at the CHC, frees space on the laptops, and enables daily updating and checking of the master SCCS database.

With the exception of those who report infection with HIV or hepatitis (because of shipping restrictions), participants are asked to donate a blood (20 ml) or exfoliated buccal cell sample (if blood was refused) at study enrollment. Except for the rare instance where the study interviewer is a phlebotomist, blood samples are collected in the CHC lab by the on-duty phlebotomist. Participants who agree to donate blood are asked a supplemental set of questions about factors that could affect the interpretation of laboratory results or biomarker data (for example, time of last meal; date of last menstrual period; and recent (within the past 24 hours) use of cigarettes, medications and certain foods). Buccal cell samples are collected by the study interviewer, using the swishing method[23] with Scope® mouthwash. All biospecimens are recorded with the date and time of collection, kept refrigerated and normally shipped on the same day of collection for next-morning delivery to Vanderbilt University. The buccal cells are obtained from the mouth rinse, and the blood is separated into its components (plasma, serum, buffy coat, red blood cells and clot) by centrifugation and aliquotted into storage vials, which are stored at -80°C.

Upon completion of the baseline interview and provision of a biospecimen, the participants are given $10 to acknowledge their time and effort.

Subject enrollment and data collection—general population. In order to recruit participants with more diverse income and education into the cohort, we will use government rosters (i.e., driver's license, Medicare), organizational listings and com-

Table 2. Selected Baseline Characteristics of initial Southern Community Cohort Study Members by Sex and Race (N=32,571), 2002–2004

	Males				Females					
	AA		Non-AA*		AA		Non-AA*		Total	
	N	%	N	%	N	%	N	%	N	%
Education										
<9 years	1,030	(9.4)	275	(11.5)	1,260	(8.4)	406	(9.6)	2,971	(9.1)
9–11 years	2,883	(26.3)	478	(20.0)	3,732	(24.9)	880	(20.8)	7,973	(24.5)
High school/GED	4,002	(36.5)	780	(32.7)	5,049	(33.7)	1,450	(34.3)	11,281	(34.6)
Vocational/technical/business training	583	(5.3)	120	(5.0)	867	(5.8)	250	(5.9)	1,820	(5.6)
Some college or junior college	1,739	(15.9)	487	(20.4)	2,794	(18.6)	832	(19.7)	5,852	(18.0)
Graduated from college	521	(4.8)	166	(7.0)	897	(6.0)	282	(6.7)	1,866	(5.7)
Graduate school	202	(1.8)	79	(3.3)	389	(2.6)	130	(3.1)	800	(2.5)
Unknown	1	(0.0)	1	(0.0)	5	(0.0)	1	(0.0)	8	(0.0)
Total	10,961	(100.0)	2,386	(100.0)	14,993	(100.0)	4,231	(100.0)	32,571	(100.0)
Income										
<$15,000	6,982	(63.7)	1,439	(60.3)	9,314	(62.1)	2,499	(59.1)	20,234	(62.1)
$15,000–$24,999	2,371	(21.6)	534	(22.4)	3,458	(23.1)	846	(20.0)	7,209	(22.1)
$25,000–$49,999	1,146	(10.5)	275	(11.5)	1,551	(10.3)	525	(12.4)	3,497	(10.7)
≥$50,000	344	(3.1)	128	(5.4)	456	(3.0)	305	(7.2)	1,233	(3.8)
Unknown	118	(1.1)	10	(0.4)	214	(1.4)	56	(1.3)	398	(1.2)
Total	10,961	(100.0)	2,386	(100.0)	14,993	(100.0)	4,231	(100.0)	32,571	(100.0)
Selected Conditions										
Obesity†	2,865	(26.2)	752	(31.6)	8,554	(57.7)	2,002	(47.7)	14,173	(43.8)
Hypertension‡	5,245	(47.9)	1,106	(46.4)	9,463	(63.2)	2,112	(50.0)	17,926	(55.1)
Diabetes‡	1,772	(16.2)	464	(19.5)	3,641	(24.3)	872	(20.7)	6,749	(20.8)
High cholesterol‡	2,200	(20.1)	727	(30.5)	4,605	(30.8)	1,653	(39.1)	9,185	(28.2)
Current cigarette smoker	6,730	(61.4)	1,369	(57.4)	4,978	(33.3)	1,671	(39.6)	13,497	(45.3)

AA: African-American; * Non-African-American group comprised of participants who reported being white, Hispanic/Latino, Asian or Pacific Islander, American Indian or Alaska native, other racial group, or mixed race; † Obese defined as body mass index ≥30 kg/m^2, calculated using self-reported weight and height at the time of the baseline interview; ‡ Self-reported using the question: "Has a doctor ever told you that you have had...?"

mercial mailing files covering residents of the study states and randomly select an age-, sex- and race-stratified sample of persons aged 40–79 to contact for potential participation. We will strive to achieve the same relative proportion of African Americans to non-African Americans in this group of participants as in the group recruited at the CHCs.

Financial considerations dictate that we utilize a mailed, self-administered questionnaire for data collection in this phase of the study. This paper questionnaire will mirror the CAPI currently in use in the CHCs. Informed consent will be obtained via a consent form in the questionnaire booklet. When these participants return a completed questionnaire and signed consent form, they will be mailed a buccal cell collection kit (with instructions) and asked to self-collect the sample using the swishing method and mail it back to the lab at Vanderbilt.

Cohort follow-up. Cohort member retention is a primary challenge for all prospective studies but can be particularly difficult in minority and less educated populations.[24-27] To aid us in minimizing loss to follow-up, we collect detailed contact information during the baseline interview, including a home address (and mailing address if different); home, work and cell phone numbers; Social Security number; email address (if available); and the name and phone number of a close friend or relative of the participant. In addition, welcome letters (a simple one-page letter welcoming the new participant to the study) are mailed to participants within two months of their enrollment. Part of the letter confirms their contact information, and a tear-off postcard allows the participant to correct or update their address or phone number as necessary. Newsletters containing information about the study and various health topics are also mailed to participants annually. Participants are also given refrigerator magnets bearing the toll-free number of the study and a reminder to call if their address or phone number changes.

For health outcome ascertainment, we will rely primarily on passive (via registry linkage) follow-up. The major emphasis will be on follow-up for mortality via linkage to the National Death Index and Social Security mortality files, and for cancer incidence via linkage to state cancer registries. In addition, every few years we will attempt to re-contact study subjects and, using a self-administered questionnaire, ask them about interim health outcomes, changes in key exposures originally collected during the baseline interview (for example, health behaviors and insurance status), and new exposures of emerging interest. These methods will allow for the study of both cancer (and other disease) incidence and mortality outcomes.

RESULTS

A high level of participant enrollment was achieved in the CHCs. The calculation of a standard response rate, however, is not possible, due to the recruitment strategies employed by the interviewers. In addition to randomly approaching single individuals, some interviewers found that a successful means of recruitment was to speak to an entire CHC lobby at once, explaining the study and its eligibility requirements, then enrolling the resulting volunteers. Moreover, we found that there were various routes by which potential participants came to the interviewer already prescreened for interest and eligibility: 1) through word-of-mouth referrals from previous participants; 2) through referrals from the CHC receptionists or medical staff; and 3) from volunteers who sought out the interviewer in response to seeing posters, flyers, brochures or even articles and advertisements placed in local newspapers by some CHCs.

As of October 31, 2004, 32,632 participants had enrolled in the SCCS from 25 CHCs. Enrollment figures by sex, race and age are shown in Table 1. Fifty-nine percent of the enrollees were female and 80% were African-American. The vast majority of the non-African Americans were non-Hispanic whites. The mean (SD) age of participants at the time of enrollment was 51.5 (8.7) years. Eighty-six percent of cohort members were born in one of the 11 enrollment states, suggesting that we successfully recruited long-term residents of this area.

Nearly all (99%) of the enrolled participants completed the entire CAPI, and the mean length of an interview was 50 minutes for females (average 273 questions) and 48 minutes for males (average 255 questions). Supplemental data on measured weight, height and blood pressure for 25%, 18% and 24% of participants, respectively, was available for abstraction from medical records. A biologic specimen was donated by 91% of the cohort members. Because 7% self-reported hepatitis or HIV (and thus were not asked for a specimen), 99% of cohort members eligible to do so donated a specimen. More than half of the study participants (51%) donated a blood sample, 42% donated a buccal cell sample, and 1% donated both.

Table 2 shows selected baseline characteristics of the cohort members by race (African-American, non-African-American) and sex. The overall educational level of the participants was low, with about one-third having completed <12 years of schooling, about 40% having a high-school diploma or equivalent (including vocational school), and about one-quarter having had some education beyond high school. The population was also one of very low income, with 62% reporting a total household income of <$15,000.

The prevalence of obesity and serious chronic disease among the cohort members was substantial. Forty-four percent of cohort members overall were obese, defined as a body mass index of 30 kg/m^2 or greater, with the highest prevalence observed among black females (58%). Fifty-five percent of the cohort reported physician-diagnosed hypertension, 28% reported physician-diagnosed high cholesterol, and 21% reported physician-diagnosed diabetes. The prevalence of current smoking in the cohort was high (45% overall), particularly among men (61% for black men and 57% for nonblack men).

DISCUSSION

Despite higher rates of morbidity and mortality from many cancers and nonmalignant chronic diseases, African Americans have been poorly represented in epidemiologic studies. One impediment to inclusion has been the tendency of studies to sample from populations where African Americans have limited representation.[7-9,28,29] Moreover, African Americans have often been reluctant to participate because of mistrust resulting from the historical exploitation of blacks in medical research studies, the belief that medical research is not carried out ethically, and the view that chronic disease prevention is a low priority in the context of more immediate socioeconomic and psychosocial pressures.[24,25,30-35]

We sought various means of overcoming these barriers. First, we identified a geographic area where African Americans are well represented, and within those areas, identified CHCs as a means of gaining access to a portion of that population. Second, we established strong ties between the study team and the CHC network in the south, who could partner with the study and effectively promote it as a credible and worthwhile endeavor. For the study team, this involves visits to CHCs across the south, meetings with and presentations to CHC staff, attendance at regional and national CHC conferences to meet CHC administrators and promote the study, and assigning a study field manager to each CHC to act as a day-to-day liaison. Third, at the CHCs, we recruit subjects face to face, and our study interviewers are not viewed by potential participants as "outsiders" to their community. Interviewers are hired as employees of the CHC, come from the local community, tend to be racially concordant with the patient population and are often motivated by community-driven interests. Some of the study interviewers are long-time employees of the CHC and therefore are already known and trusted figures to the patient population. Finally, our study materials were designed to be culturally sensitive and comfortable for a wide range of educational levels, as well as to impart a clear message about the relevance of this study to the health of southerners—African Americans in particular.

These strategies are very labor-intensive. In particular, enrolling cohort members at CHCs across the south is a complex operation, and the management of a strict scientific protocol at numerous autonomous organizations (many with multiple clinics functioning as recruitment sites) requires a high level of coordination. The recruitment success we have achieved, however, demonstrates the value of the CHC relationships. On a practical level, working within the CHC also facilitates the collection of biologic specimens, particularly blood. Most CHCs have on-site laboratories and phlebotomists, and it is often possible to have the SCCS blood taken jointly with blood already required for physician-ordered tests, increasing donation rates. Being present within CHCs also allows access to medical records, and it facilitates in-person interviewing, which is preferable to phone or self-administered surveys. Another important benefit of this approach is the drawing of CHCs into the research arena, with the potential for this experience to promote a lasting interest and ongoing participation in public health research projects.

Specific challenges associated with CHC-based field work should also be discussed. Our experience indicates that recruitment at an average CHC abates within 12 months due to the depletion of the pool of eligible study participants. Seasonal fluctuations in patient attendance at the CHCs also affect subject enrollment, with low points occurring during the winter holiday season and during the summer months. Some CHCs have sufficiently large patient populations to have recruitment extend for a number of years and to weather slow periods of patient flow, but this is uncommon. The inclusion of CHCs from rural areas is a particular challenge, as they can be very small in size; lack support, such as internet connectivity and conveniently timed Federal Express service for biospecimen shipments; and involve multiple geographically dispersed sites (which makes efficient field work difficult if interviewers need to travel from site to site).

CHC patients are not representative of the general southern population. However, one of our goals was to reach persons of low SES from rural and urban areas in the south who would be extremely difficult to reach by other means. Twenty-two percent of African-American adults in our current enrollment states live below the poverty level.[22] Therefore, while not being broadly representative of southern blacks, CHCs capture a group that makes up a sizeable minority of that population and a group that is at especially high risk for premature morbidity and mortality. Another advantage of this recruitment strategy is the enrollment of white participants

who have similar incomes and educational backgrounds. This helps reduce some of the confounding by socioeconomic status that is present in most studies that attempt to enroll large numbers of blacks and whites. Historically, through investigator-defined study bases and through participant self-selection, prospective cohort study members typically represent a higher SES stratum than the general population, with exposure information corresponding to that stratum. The SCCS has the potential to extend the usefulness of the collective body of cohort data past this boundary by adding information from a different, understudied population.

Starting in 2005, a segment of the SCCS cohort will be drawn from a separate, population-based sample and thus provide additional participants that span middle- and upper-income levels. In total, the SCCS cohort will cover the broad SES spectrum to enhance variability in exposures, distinguish effects of race from economic level and therefore aid in drawing etiologic inferences. Our preliminary data suggest that we already have a more than adequate range of important exposures within the current CHC-enrolled cohort to conduct powerful statistical analyses. It remains to be seen how different the exposures will be between the CHC-enrolled and the population-enrolled portions of the cohort, but all statistical analyses will be stratified by enrollment type.

The use of different modes of data collection (in-person interviews versus self-administered questionnaires) for the CHC-enrolled and general population-enrolled segments of the cohort, respectively, raises the issue of possible systematic differences in reporting answers between the two groups. Steps will be taken to minimize differences between the two surveys. For example, intelligent character recognition technology will allow participants to answer most questions on the paper form the same way they could during an interview (i.e., writing in their numeric answers rather than having to choose from preassigned categories). While there is little published data about the relative performance of these two methods among African Americans specifically, we expect: 1) more missing data from the self-administered questionnaire, but 2) fairly comparable reporting of health indices and health-related behavior.[36-39] Also, as mentioned above, our statistical analyses will be conducted separately for these two groups to examine any effect modification before the groups would be combined.

With regard to follow-up, participant-identifying information obtained at baseline will enable nearly complete mortality follow-up through the National Death Index and other sources, even if participants move from the south. Through state cancer registries, we will also be able to ascertain information on incident cancer diagnoses, although reporting lags will result in over two-year delays in case identification in some states. We anticipate that active follow-up will be especially challenging due to the low education and income levels of many participants.

In summary, the SCCS is an ambitious undertaking, seeking to enroll large numbers of adults from segments of the American population underrepresented in previous epidemiologic research. The success of the study to date derives largely from the utility of the CHC system for the recruitment of African-American and low-income participants. We are assembling a unique cohort of southerners and oversampling African Americans to investigate the racial disparities that are currently seen in cancer risk and other chronic disease outcomes. Biospecimen collection for the SCCS has been exceptionally successful, and the resulting repository will aid us in investigating molecular markers for cancer and other diseases, and in exploring gene-environment and gene-gene interactions. We anticipate that the future results of the SCCS will be valuable for assessing risk factors and for developing prevention measures aimed at cancer and other serious diseases, especially among African Americans.

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