

Health Care Poor Underserved. Author manuscript: available in PMC 2010 September 16.

Published in final edited form as:

J Health Care Poor Underserved. 2010 February 1; 21(1): 26–37. doi:10.1353/hpu.0.0245.

The Southern Community Cohort Study: Investigating Health Disparities

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Summary

Over 73,700 adults age 40–79, nearly 70% African American, were recruited at community health centers across 12 southeastern states; individual characteristics were recorded and biologic specimens collected at baseline for later follow-up. The Southern Community Cohort Study is a unique national resource for assessing determinants of racial/ethnic differentials in diseases.

Keywords

Cancer; cohort study; African Americans; health disparities; community health studies

The incidence of and mortality from several cancers, cardiovascular disease, stroke, diabetes, and many other chronic illnesses tend to be greater among African Americans than among other population groups in the United States. ^{1,2} The Meharry-Vanderbilt Alliance, described in this issue of the *Journal*, has stimulated research addressing this national problem. One such major initiative launched by investigators at Vanderbilt, Meharry, the International Epidemiology Institute, and Community Health Centers throughout the Southeast is the Southern Community Cohort Study (SCCS). ³ The goal of the SCCS is to elucidate and discover the sources of higher rates of cancer and other diseases among African Americans in comparison with Whites in this region. The SCCS protocols are reviewed and approved by Institutional Review Boards at Vanderbilt University and Meharry Medical College.

Here, we describe the partnership between scientific investigators and local health centers that has enabled the recruitment of large numbers of adults into the SCCS. The study methods are outlined, characteristics of the cohort are presented, and unique opportunities for research in the coming years are outlined.

Recruitment of study subjects. Recruitment of participants into the SCCS across a 12-state area of the Southeast (Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia) (Figure 1) began in March 2002 and was completed in September 2009. Some participants entered the study by completing questionnaires mailed to random samples of adults, but most (approximately 85%) of the participants were enrolled at community health centers (CHCs), institutions offering basic health and preventative services mainly to the medically uninsured. We focus on the CHC component of the SCCS in this paper. The 71 CHCs working together with the SCCS,

which are listed in Box 1, have provided a venue through which some of the barriers to recruitment of minorities and the poor into health research could be overcome. Paramount was the established relationship between the centers and the local community. The CHCs were a welcoming and familiar place where essential health and community services were routinely obtained by community residents; thus, when CHC interviewers approached people coming to the centers* and asked if they might be willing to join in a health study to assess the causes of cancer, many agreed and took the time to provide informed consent and complete the study interview. Prior to the SCCS, few CHCs had participated in large-scale epidemiologic studies and few existing cohorts had sizeable percentages of minority, poor, rural, or medically underserved participants. Thus the SCCS fills a gap in population coverage and provides a unique assembly of adults, nearly two-thirds African American, at elevated risk of cancer and several other chronic diseases.

Study questionnaire. After signing the informed consent document describing the study's rationale, risks, and benefits, the participants completed the baseline 45–60 minute in-person interview. The interview was administered by CHC personnel specially trained in computer-assisted interviewing techniques. The laptop computers housed the structured study questionnaire, as well as prompts and skips induced by certain responses, which aided in the flow of the interview and the standardization of the information collected. The questionnaire delved into various aspects of the participant's characteristics, behaviors, and health status. Sections included demographic characteristics (education, income, residence); tobacco use; medical history; family history of cancer, heart disease, and diabetes; medication use; physical activity; emotional well-being and spirituality; health services utilization; home environment; occupation; and (via a food frequency questionnaire [FFQ]) diet and nutrition.

Biologic specimens. The SCCS also sought and obtained biologic specimen donations from many of the participants. At the CHCs participants were asked to donate a 20-ml blood sample and, beginning in the third year of the study, a urine specimen, but a buccal cell or saliva specimen was accepted if the subject did not wish to donate blood.

Validation studies. Although many of the questions in the SCCS questionnaire were adapted from questionnaires used and validated in other settings, a series of validation studies were also carried out to assess the reliability of the questionnaires within the SCCS. Selecting samples of approximately 150 to 800 SCCS participants (size depending on the needs of the particular validation study), we sought to validate FFQ information via 24-hour dietary recalls and/or nutrient biomarkers, physical activity patterns via repeat interviews and use of accelerometers, tobacco use status via measurement of serum cotinine, and disease occurrence for self-reported diabetes via confirmation in medical records and by measurement of HbAlc. Self-reported height and weight were compared with contemporaneous clinic recorded measurements for over 20% of the participants. We also collected and banked repeat blood samples from over 650 participants and repeat urine samples from over 240 participants for future comparability assays to check for concordance of biomarker levels over time periods spanning one to three years.

Follow-up of participants. Active follow-up has begun for approximately 30,000 of the early (March 2002–August 2004) entrants into the SCCS. A four-page follow-up questionnaire (one for males, one for females) was mailed, with second and third mailings to non-responders succeeded by telephone calling. Subsequent mailings/telephone calls to the remainder of the cohort participants will be conducted in batches in an attempt to have the first follow-up

^{*}The large majority of participants were enrolled at the CHC facility itself, although some were recruited through outreach efforts in the surrounding community

questionnaire completed approximately five years after entry into the SCCS, and additional follow-up questionnaires completed every five years thereafter.

The roster of participants enrolled in the SCCS was recently submitted to the Social Security Administration (SSA) for determination of current vital status. Cohort member information for those known through SSA to have died (or whose current status is unknown to SSA) will be sent to the National Death Index (NDI) to ascertain cause (or fact and cause) of death. The SSA and NDI submissions will then be updated annually.

The process of linkage with cancer registries has also begun in the 12 states in which recruitment has taken place. These searches will be the primary means of identification of incident cancer diagnoses. Although reporting lags of one to two years are common, the registries provide nearly complete and unbiased ascertainment of cancers diagnosed among the participants after their entry into the SCCS. Once sufficient numbers of cancer cases have been identified, a series of case-control studies nested within the SCCS will be launched to test specific hypotheses about etiologic factors for specific cancers and other diseases and the sources of racial disparities. The major cancers (those occurring in the lung, breast, prostate and colon/rectum) will be evaluated in the next several years, followed by cancers with less frequent occurrence thereafter.

Overview of initial findings. A total of approximately 73,700 men and women age 40–79 have been enrolled in the SCCS at the CHCs shown in Box 1. The composition of the cohort reflects the composition of persons in the study age range seen at the CHCs, with nearly 70% being African American and the remainder mainly non-Hispanic White, and 60% being female (Table 1). The median age at entry was approximately 51 years.

Table 2 shows that the majority of these SCCS participants reported low household incomes, and that nearly one-third had not completed high school. Table 2 also shows selected characteristics of the participants which place them at elevated risk for future adverse health outcomes. Notable are the high prevalences of (1) current cigarette smokers (reaching nearly 60% among Black men), (2) obesity (reaching 57% among Black women), and (3) diabetes (affecting nearly one-fifth of the cohort members).

As shown in Table 3, biologic specimens have been donated by 90% (54% blood, 39% buccal cell, with 2% donating both) and have been shipped and placed in long-term frozen storage in our facilities at Vanderbilt. Since we began to collect urine specimens, nearly 60% of the CHC participants have provided the supplemental urine specimen. With blood separated into 14 vials, buccal cells into one vial, and urine into eight vials, the SCCS biospecimen repository now contains over 750,000 aliquots.

Questionnaire validation efforts are nearing completion. Results to date show correlations between self-reported and clinic recorded height and weight exceeding 0.95, and we have validated 96% of self-reported diabetes diagnoses from confirmatory medical records or elevated HbAlc measurements. Ongoing analyses show much lower correlations between multiple nutrient and physical activity indices derived from the questionnaire responses vs. from the special validation surveys, but the associations were significant and generally in line with those reported in other cohorts.

With the establishment of the cohort completed and the systematic follow-up now identifying cases of death and illness among study participants, opportunities abound for the utilization of the SCCS resource to help identify the causes of cancer and other chronic diseases and contributors to the higher incidence and/or mortality rates among African Americans than among Whites. To date, most SCCS studies have been cross-sectional, using the baseline

questionnaire data and stored biologic specimens, but incidence-based prospective analyses will be feasible in the coming years.

Highlights of some of the recent cross-sectional analyses include findings that: (1) While national studies show up to two-fold excesses of diabetes in Blacks compared with Whites, in the SCCS, where socioeconomic differences are minimal, the crude prevalence of diabetes was only 34% higher among African American than White women, with the excess cut in half when body mass index and other factors were adjusted for, and there was little racial differential among men;5 (2) African Americans in the South had markedly lower levels of serum vitamin D (25(OH)D) than Whites, with nearly half the SCCS Black population having levels below 15 ng/ml, and that even among those with supposed adequate dietary vitamin D intakes, nearly one-third had insufficient levels; 6 (3) colonoscopy screening was only half as common among Black as among White participants, even among those with family histories of colorectal cancer;7.8 (4) high (>3 mg/1) C-reactive protein levels were four times more common among the obese than those with BMI <25 kg/m², significantly increased by 60 to 80% among smokers and women, and after adjustment for these factors 40% more common among Blacks than Whites; 9 (5) benign prostatic hyperplasia (BPH) was reported only half as often by Black (4.4%) than White (9.9%) male SCCS participants, although among those with BPH, Blacks more often than Whites underwent surgical intervention for treatment of the condition; ¹⁰ and (6) development of a nutrient database taking gender, race and geographic region into account provided improvements, compared with using overall national food composition data, in food frequency questionnaire scoring for most micro- and macro-nutrients.11

Discussion

The SCCS is now established as a national resource for research into the causes of chronic diseases among African Americans and into differentials in risk factors and outcomes between Blacks and Whites. The data collected on each individual are extensive, and cover a wide range of behavioral, environmental, medical, and other attributes. All observational epidemiologic studies are subject to some misclassification of information, and pure gold standards to assess the true status of reported exposures or conditions are often not available. However, the validation efforts completed thus far indicate that the survey questionnaire used in the SCCS yields information that can be considered as generally reliable and repeatable, with concordances between study questionnaire data and that from the validation sub-studies typically similar to those reported in other cohorts. The biospecimen repository is a particular strength of the SCCS, with DNA available for 90% and stored blood and urine samples for large subsets of the cohort.

The cohort was assembled through the cooperation of a network of community health centers throughout the South, enabling important access to a vulnerable segment of the American population often not included in health research. The characteristics of the enrollees, particularly the high rates of smoking and of obesity, are such that the cohort is likely to experience elevated incidences of cancer, cardiovascular disease, kidney disease, and other chronic illnesses in the years to come. We hope that the knowledge gained from the research enabled by the SCCS will provide needed information to develop effective strategies aimed at primary cancer and other disease prevention (identifying the determinants of an illness so that steps can be taken to avoid its occurrence), secondary prevention (identifying the process of disease development at a preclinical or an early enough stage when it is more amenable to treatment), and tertiary prevention or control (minimizing the adverse impacts of the disease once it occurs). Such strategies can then be tested for effectiveness within the SCCS population itself, or within the CHC patient population generally.

The SCCS has strong community ties and adheres to many of the principles of community-based participatory research (CBPR), although some elements of CBPR are not incorporated, primarily due to the extended geographical area and large size and scope of this project. The study investigators and CHC partners have clearly engaged underserved communities to specific action around health issues of concern to them. Although the entire community could not be part of the research design process, directors and staff of the CHCs had significant impact on early design choices, selection of recruitment methods and questionnaire design, and also allowed the piloting of design options to occur within the CHCs. The SCCS has also increased community capacity in carrying out research, as many CHCs now have the expertise necessary to take part in or oversee other research activities. De-identified data are also available to the CHCs. However, the community does not share full control in data analysis or interpretation and formal community advisory boards do not guide the direction of the research, although CHC leaders are consulted in a number of topic areas.

The SCCS resource is being utilized by faculty at Vanderbilt and Meharry, and the Meharry-Vanderbilt Alliance, but is available to scientific researchers globally. Plans are underway for the routine computation by the SCCS study team of rates among cohort members classified by race, gender, and various baseline characteristics of the following health outcomes: overall mortality; cause-specific mortality; cause-specific cancer incidence; and, pending governmental approvals, cause-specific rates of hospitalization for cardiovascular and cerebrovascular disease, diabetes, end-stage renal disease, and other conditions. We will also continue direct follow-up of the cohort via mail and telephone survey. As cancer cases accrue from the cohort follow up, nested case-control studies can begin, first testing hypotheses related to the determinants among African Americans of lung, breast, prostate, and colorectal cancer and of common non-malignant diseases, and assessing the underlying reasons for cancer and other health disparities.

Additional research opportunities utilizing the SCCS abound. The cohort provides a unique resource for new investigations studying determinants of the higher rates and poorer outcomes not just of cancer but also of various other chronic diseases among African Americans, and for determining contributors to health disparities.

In addition to cancer investigations, a few of the possibilities for additional research include studies involving: (1) linkage of the cohort with Medicare and Medicaid files maintained by the CMS to ascertain diagnoses and compute rates of cardiovascular, cerebrovascular, neurologic and other diseases, as well as data on physician encounters, medications, and costs associated with these illnesses; (2) assessment of the natural history of chronic renal disease, including characterizing serum creatinine levels and linkage of the cohort with the national end-stage renal disease registry; (3) prospective studies of the characteristics and outcomes among the over 15,000 diabetics in the SCCS and evaluations of HbAlc and other markers for characterization of the prevalence and determinants of undetected diabetes; (4) evaluations of the correlates and determinants of obesity and the interrelationships of obesity with other morbidities; (5) barriers to access and utilization of health services experienced by the medically uninsured or underinsured; (6) assessment of serum 25(OH)D and other measures of Vitamin D and their relations to cardiovascular and other diseases; (7) assessment of blood and/or urinary biomarkers and exposure to various environmental agents and how they are associated with chronic disease outcomes; (8) quality of life, function, and other attributes of survivors of chronic illnesses; (9) depression as a risk and prognostic factor for various disease outcomes; and (10) utilization of the SCCS DNA repository for genetic studies, including genome-wide association studies, for a large variety of diseases.

These are just a few of the many types of investigations that could be initiated within the SCCS at a fraction of the cost of *de novo* studies. The SCCS study team at Vanderbilt University,

Meharry Medical College, and the International Epidemiology Institute welcomes inquiries and interests in collaborations to help fully make use of this national resource. Interested scientists can find instructions for gaining access to study materials by visiting the SCCS web site (www.southerncommunitystudy.org).

Notes

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Figure 1. Locations of community health center enrollment sites.

Table 1

NUMBERS OF PARTICIPANTS ENROLLED IN THE SOUTHERN COMMUNITY COHORT STUDY AT COMMUNITY HEALTH CENTERS ACCORDING TO SEX, RACE, AND AGE

Sex	Race	Age at Entry (years)	N^a
Male	African American	40–49	11,200
		50-59	7,000
		60–79	2,900
		Total	21,100
	Other b	40–49	3,700
		50–59	2,600
		60–79	1,700
		Total	8,000
Female	African American	40–49	14,300
		50-59	9,700
		60–79	5,500
		Total	29,500
	Other b	40–49	6,100
		50–59	5,100
		60–79	3,800
		Total	15,100
Total	Total	Total	73,700

^aRounded to nearest 100.

b Among males, "Other" race is comprised of Caucasians (83 7%), Hispanic (2.3%), Asian or Pacific Islander (0 3%), American Indian or Alaska Native (1.3%), Other racial group (1.6%), Mixed racial group (6.5%), or unknown/missing racial group (4.4%). Among females, "Other" race is comprised of Caucasians (83.0%), Hispanic (2.2%), Asian or Pacific Islander (0.4%), American Indian or Alaska Native (1.3%), Other racial group (1.4%), Mixed racial group (6.2%), or unknown/missing racial group (5.6%).

Table 2

SELECTED CHARACTERISTICS OF SOUTHERN COMMUNITY COHORT STUDY PARTICIPANTS ENROLLED AT COMMUNITY HEALTH CENTERS^a

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Indicator Level (n=21,100)b (n=8,000)b Education (years) <12 35 30 Education (years) <12 37 35 Income (\$ 1000s) <15 64 58 Body Mass <25 15 21 Body Mass <25 38 30 Index (kg/m²) <25-29 35 35 Index (kg/m²) <25-29 35 50 Smoker <4 6 Smoker <24 6 Former <25 35 Diabetes <27 Smoker <27 <27 Former <28 <27 Smoker <28 <27 Former <28			Males	les	Fem	Females
Level (n=21,100)b (n=8,000 <12 35 12 37 >12 37 <15 64 15-25 22 <25 15 <25 38 25-29 35 30-34 17 >40 4 Nover 21 Former 19 Yes 18			African American	$\mathrm{Other}^{\mathcal{C}}$	African American	$Other^{\mathcal{C}}$
 <12 35 12 37 >>12 >>12 27 64 15-25 22 >>2 >25 38 25-29 38 25-29 38 25-29 38 30-34 17 30-34 17 35-39 7 >>40 4 Never 21 Former 60 Yes 18 	Indicator	Level	$(n=21,100)^b$	$q^{(000,8=\mathrm{u})}$	q(005,600)	$^{\rm (n=15,100)}b$
12 37 >12 27 >13 27 <15 64 15-25 22 >22 <25-29 38 25-29 35 30-34 17 35-39 7 >40 4 Never 21 Former 60 Yes 18	Education (years)	<12	35	30	32	28
>12 27 15–25 64 15–25 15 <25 38 25–29 35 30–34 17 >40 Never 21 Former 60 Yes 18		12	37	35	34	34
15–25 64 15–25 22 22 22 25–29 35 35–39 7 21 21 21 21 21 21 21		>12	27	35	34	38
15–25 22 >25 15 <25	Income (\$ 1000s)	<15	64	28	62	56
>25 15 25 25 28 25-29 35 30-34 17 35-39 7 7 240 8 4 Never 21 Former 60 Yes 18		15–25	22	21	23	20
 <25 38 25-29 35 30-34 17 35-39 7 >40 4 Never Eomer Former Current 60 Yes 18 		>25	15	21	15	23
25–29 35 30–34 17 35–39 7 >40 4 Never 21 Former 19 Current 60	Body Mass	<25	38	30	17	25
30–34 17 35–39 7 >40 4 Never 21 Former 19 Current 60	Index (kg/m ²)	25–29	35	35	25	26
35–39 7 >40 4 Never 21 Former 19 Current 60 Yes 18		30–34	17	20	25	22
>40 4 Never 21 Former 19 Current 60 Yes 18		35–39	7	6	17	13
Never 21 Former 19 Current 60 Yes 18		×40	4	9	16	14
Former 19 Current 60 Yes 18	Smoker	Never	21	20	47	37
Current 60 Yes 18		Former	19	27	19	24
Yes 18		Current	09	53	34	39
	Diabetes	Yes	18	20	25	22

 $^{^{}a}$ Numbers in the body of the table are percentages.

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 $^{^{}b}$ Rounded to nearest 100

^cAmong males, "Other" race is comprised of Caucasians (83.7%), Hispanic (2.3%), Asian or Pacific Islander (0.3%), American Indian or Alaska Native (1.3%), Other racial group (1.6%), Mixed racial group (65%), or unknown/missing racial group (4.4%) Among females, "Other" race is comprised of Caucasians (83.0%), Hispanic (2.2%), Asian or Pacific Islander (0.4%), American Indian or Alaska Native (1.3%), Other racial group (1.4%), Mixed racial group (6.2%), or unknown/missing racial group (5.6%).

 Table 3

 SOUTHERN COMMUNITY COHORT STUDY BIOSPECIMEN DONATIONS AT COMMUNITY HEALTH CENTERS

		Blood	Buccal	Urine
Sex	Race	N^a	N^a	N^a
Male	African American	11,500	7,600	5,900
	Other b	4,600	2,400	3,100
Female	African American	15,000	13,400	8,600
	Other b	8,600	5,300	6,100
Total	Total	39,700	28,700	23,700

^aRounded to nearest 100.

b Among males, "Other" race is comprised of Caucasians (83.7%), Hispanic (2 3%), Asian or Pacific Islander (0.3%), American Indian or Alaska Native (1.3%), Other racial group (1 6%), Mixed racial group (6.5%), or unknown/missing racial group (4.4%). Among females, "Other" race is comprised of Caucasians (83 0%), Hispanic (2.2%), Asian or Pacific Islander (0 4%), American Indian or Alaska Native (1.3%), Other racial group (1.4%), Mixed racial group (6 2%), or unknown/missing racial group (5.6%).

 $$\operatorname{Box} 1$$ COMMUNITY HEALTH CENTERS PARTICIPATING IN THE SCCS (SOUTHERN COMMUNITY COHORT STUDY)

Clinic Name	Main City	State
Birmingham Health Care, Inc.	Birmingham	AL
Central Alabama Comprehensive Health, Inc.	Tuskegee	AL
Central North Alabama Health Services, Inc.	Huntsville	AL
Family-Oriented Primary Health Care Clinic, Inc.	Mobile	AL
Franklin Primary Health Center, Inc.	Mobile	AL
Health Services, Inc.	Montgomery	AL
Mostellar Medical Center	Bayou La Batre	AL
Quality of Life Health Services, Inc.	Gadsden	AL
Rural Health Medical Program, Inc.	Selma	AL
Southern Rural Health Care Consortium	Russellville	AL
Tri-County Medical Center, Inc.	Evergreen	AL
Whatley Health Services, Inc.	Tuscaloosa	AL
Boston Mountain Rural Health Center	Marshall	AR
CABUN Rural Health Services, Inc.	Hampton	AR
Corning Area Healthcare, Inc.	Corning	AR
East Arkansas Family Health Center, Inc.	West Memphis	AR
Jefferson Comprehensive Care System, Inc.	Pine Bluff	AR
Lee County Cooperative Clinic, Inc.	Marianna	AR
White River Rural Health Center, Inc.	Augusta	AR
Bond Community Health Center	Tallahassee	FL
Family Medical and Dental Centers	Palatka	FL
Florida Community Health Centers, Inc.	W Palm Beach	FL
Jacksonville Community Health Center, Inc.	Jacksonville	FL
Manatee County Rural Health Services, Inc.	Parrish	FL
Albany Area Primary Health Care, Inc.	Albany	GA
Southside Medical Center, Inc.	Atlanta	GA
Stewart Webster Rural Health, Inc.	Richland	GA
West End Medical Centers, Inc.	Atlanta	GA
Westside-Urban Health Center	Savannah	GA
Family Health Centers, Inc.	Louisville	KY
Lexington-Fayette County Health Department	Lexington	KY
Park DuValle Community Health Center	Louisville	KY
White House Clinics	Richmond	KY
Catahoula Parish Hospital Service District No. 2	Sicily Island	LA
Iberia Comprehensive Community Health Center	New Iberia	LA
Southwest Louisiana Center for Health Services	Lake Charles	LA
Teche Action Clinic	Franklin	LA
Aaron E. Henry Community Health Services Center, Inc.	Clarksdale	MS
Central Mississippi Health Services, Inc.	Jackson	MS

Clinic Name	Main City	State
Coastal Family Health Center, Inc.	Biloxi	MS
Delta Health Center, Inc.	Mound Bayou	MS
Dr. Arenia C. Mallory Community Health Center, Inc.	Lexington	MS
Family Health Care Clinic, Inc.	Pearl	MS
Family Health Center, Inc.	Laurel	MS
G.A. Carmichael Family Health Center	Canton	MS
Greater Meridian Health Clinic, Inc.	Meridian	MS
Jackson-Hinds Comprehensive Health Center	Jackson	MS
Jefferson Comprehensive Health Center, Inc.	Fayette	MS
Northeast Mississippi Health Care, Inc.	Byhalia	MS
Gaston Family Health Services, Inc.	Gastonia	NC
Lincoln Community Health Center, Inc.	Durham	NC
Beaufort-Jasper-Hampton Comprehensive Health Services, Inc	Ridgeland	SC
Eau Claire Cooperative Health Centers	Columbia	SC
Family Health Centers, Inc.	Orangeburg	SC
Franklin C. Fetter Family Health Center	Charleston	SC
Little River Medical Center, Inc.	Little River	SC
Margaret J. Weston Medical Center	Clearwater	SC
Matthew Walker Comprehensive Health Center, Inc.	Nashville	TN
Memphis Health Center, Inc.	Memphis	TN
Rural Health Services Consortium, Inc.	Rogersville	TN
Southside & Dodson Avenue Community Health Centers	Chattanooga	TN
United Neighborhood Health Services, Inc.	Nashville	TN
Central Virginia Community Health Center	New Canton	VA
New Horizons Healthcare	Roanoke	VA
Peninsula Institute for Community Health	Newport News	VA
Portsmouth Community Health Center	Portsmouth	VA
St. Charles Health Council, Inc.	Pennington Gap	VA
Vernon J. Harris Medical Center	Richmond	VA
Shenandoah Valley Medical System	Martinsburg	WV
Valley Health Systems, Inc.	Huntington	WV
WomenCare, Inc.	Scott Depot	WV