# Toward Resolution of Cardiovascular Health Disparities in African Americans: Design and Methods of the Jackson Heart Study

**Objective:** The design, overall methods, and major phenotypes for the all-African- American Jackson Heart Study (JHS) are detailed.

**Methods:** Participants were enrolled from the three counties that make up the Jackson, Mississippi metropolitan area. Relatives of selected participants were recruited to develop a large, nested family cohort. Participants provided extensive medical and social history, had an array of physical and biochemical measurements and diagnostic procedures, and provided genomic DNA.

**Results:** Data and biologic materials have been collected from 5302 adult African Americans, including 1499 members of 291 families. Participants have a high prevalence of diabetes, hypertension, obesity, and related disorders.

**Discussion:** The JHS dataset and biologic materials (serum, DNA, and cryopreserved cells) offer a valuable resource for the study of diseases that are of particular importance to African Americans. (*Ethn Dis*. 2005;15[suppl 6]:S6-4–S6-17)

**Key Words:** African Americans, Cardiovascular Disease, Jackson Heart Study, Longitudinal Study, Methods

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## INTRODUCTION

Ethnic and regional disparities in cardiovascular disease (CVD) morbidity and mortality are broad based, well documented, and substantial in size.[1–4] Table 1 presents recent (2002) age-adjusted CVD mortality by cause, sex, and ethnicity for the United States (US) and Mississippi.[5] Mortality rates by sex were higher among African Americans than European Americans in almost every disease category, both nationally and in Mississippi. Further, overall CVD mortality in African-American men and women in Mississippi was 12% and 22% higher, respectively, than in the rest of the nation.

In the Atherosclerosis Risk in Communities (ARIC) Study, a four-center, population-based study including 3728 African Americans from Jackson, Miss, incident coronary heart disease was associated with traditional risk factors in African Americans, as in other populations, with hypertension being a particularly potent predictor.[6] African Americans with myocardial infarction (MI) were more likely to die before hospital admission, less likely to have cardiac procedures, and more likely to die during long-term followup than European Americans (≥29 days after MI; median followup 3.3 and 3.7 years, respectively).[7,8] The latter finding was significantly attenuated by adjustment for the use of cardiac procedures, which argues that ethnic disparities in care contributed to the observed differences in mortality. Among ARIC participants who died more than a month after MI, African Americans were much more likely to have diabetes, hypertension,

a low educational level, low income, and lower mean levels of physical activity than European Americans.[8] In the ARIC study, 87.4% of all African Americans were from the Jackson, Miss, cohort, whereas European Americans were from other sites; thus some of the observed "ethnic" differences may actually have had a regional basis. Mississippi's rates of CVD are high, irrespective of ethnicity (Table 1).

The extraordinarily high prevalence of CVD among African Americans in Mississippi led to the initiation of the Jackson Heart Study (JHS), which builds on the Jackson ARIC cohort. The primary objective of the JHS is to investigate the causes of CVD in African Americans to learn how best to prevent this group of diseases in the future. Data from the study are expected to increase understanding of the current epidemic of CVD in the United States and to provide a basis for efforts to end the ethnic disparities that characterize it. Data addressing both traditional and nontraditional risk factors for CVD have been collected. These data include extensive personal and family medical history, information on diet and physical activity, assessment of an array of physical measures and biomarkers, and noninvasive clinical studies of heart and lung function. They further include measures of psychological, social, and cultural factors, including racism and discrimination, stress, religious practices, and other non-biologic variables that may have implications for CVD. Finally, because humans lived in Africa for thousands of generations before small numbers of them left to populate all other regions, the genetic complexity

**Table 1.  Age-adjusted CVD mortality rates[*] per 100,000 population (2002)**

|  | Overall | Black Males | White Males | Black Females | White Females |
|---|---|---|---|---|---|
| **A. United States** | | | | | |
| Overall CVD | 319.0 | 490.6 | 372.2 | 366.4 | 264.3 |
| Coronary heart disease | 170.8 | 250.6 | 220.5 | 169.7 | 131.2 |
| Stroke | 56.2 | 81.7 | 54.2 | 71.8 | 53.4 |
| Heart failure | 19.5 | 23.3 | 20.5 | 20.5 | 18.6 |
| Hypertension | 17.1 | 49.6 | 14.4 | 40.5 | 13.7 |
| End-stage renal disease | 3.1 | 11.7 | 2.9 | 9.7 | 1.9 |
| **B. Mississippi** | | | | | |
| Overall CVD | 420.7 | 600.8 | 458.0 | 440.9 | 366.7 |
| Coronary heart disease | 192.3 | 274.3 | 232.5 | 175.9 | 145.0 |
| Stroke | 69.6 | 97.7 | 64.7 | 79.2 | 60.9 |
| Heart failure | 46.8 | 53.3 | 51.4 | 49.9 | 41.3 |
| Hypertension | 32.8 | 66.1 | 20.7 | 51.9 | 24.1 |
| End-stage renal disease | 5.4 | 12.0 | 3.8 | 11.2 | 2.9 |

* ICD10 definitions used to analyze mortality rates: overall CVD, I00-I99; coronary heart disease, I20-I25; stroke, I60-I69; heart failure, I50; hypertension, I10-I13; end-stage renal disease, N18.0.

CVD=cardiovascular disease.

of modern African and African-derived populations is much greater than that of other populations,[9,10] and many physiologically important genetic polymorphisms may be of uniquely African origin. Thus the JHS includes a large Family Study that is nested within the overall cohort, and genomic DNA has been prepared from all consenting JHS participants.

The JHS seeks not only to study disparities in CVD health and health care but also to address these disparities. In 2002, >36% of Mississippi's population but <7% of its physicians were African American.[11] Thus the goals of the JHS include attracting minorities to careers in medicine, public health, epidemiology, and biostatistics, as well as building research capacity at minority institutions. A documented, pervasive need exists in African-American communities for increased knowledge about CVD prevention and CVD health promotion.[12,13] Accordingly, the JHS supports an active community outreach program and has developed a network of community health advisors who work through churches and civic organizations to promote health awareness and provide accurate health information. Overall, the JHS has become invested in its community in ways that strengthen its scientific enterprise while repaying the community in some measure for its trust and generosity.

In aggregate, the JHS is an ambitious, multifaceted effort to study and assist a historically disadvantaged community that has a tremendous burden of CVD and related disorders. This effort will depend on the involvement and energy of medical and public health scientists locally, nationally, and internationally. The JHS should become a valuable resource to this scientific community while protecting and serving the interests of JHS participants and the population that they represent. This article describes the methods by which these ends will be pursued. Readers are encouraged to visit the JHS website (ccaix.jsums.edu) for greater detail.

## ENVIRONMENT AND ORGANIZATIONAL STRUCTURE

The JHS is a large, community-based, observational study whose participants were recruited from urban and rural areas of the three counties (Hinds, Madison, and Rankin) that make up the Jackson, Miss, metropolitan statistical area (MSA). Jackson is the capital of Mississippi, the state with the largest percentage (36.3%) of African Americans in the United States. The JHS is a collaboration among three Jackson-area institutions, two of which, Jackson State University and Tougaloo College, are historically Black colleges and universities (HBCUs). The study is divided operationally into three centers, each with specific responsibilities and a distinct institutional affiliation.

The JHS principal investigator (HAT) directs the combined operations of the three centers and holds academic appointments at each of the three JHS academic institutions. The JHS Coordinating Center is operated by Jackson State University and is responsible for cohort definition (eg, randomization, demographic tracking), data management, and community outreach. The Examination Center, operated by the University of Mississippi Medical Center, is responsible for recruitment and data collection. The Undergraduate Training Center is headquartered at Tougaloo College and has an explicit mission to increase the number of African Americans pursuing careers in the health sciences, particularly epidemiology and public health. The Undergraduate Training Center is thus a novel component of the study and is discussed in some detail both in this paper and in a separate article.[14]

The JHS offices and clinic are located in the Jackson Medical Mall (JMM), which is situated in the heart of the African-American community of Jackson and near the geographic center of the Jackson MSA. The JMM was formerly a large, enclosed shopping mall that was remodeled to support a variety of health-related and human services enterprises. In addition to the JHS, the JMM houses, among other things, the outpatient teaching clinics of the University of Mississippi Medical Center and Jackson State University's new

School of Public Health. Thus, it is a primary portal to full-service medical care and a rising center of epidemiologic scholarship.

## COMMUNITY OUTREACH

Public health scientists have increasingly recognized the value of community participation in defining key questions, carrying out protocols, and interpreting and responding to research findings.[15,16] Participatory research has become especially important in epidemiologic studies as communities seek to work with researchers to address health problems that concern them both.

Personal experience of healthcare disparities and a history of abuse in projects like the Tuskegee Study[17,18] have led many African Americans to mistrust the medical community, particularly medical investigators. Thus, an active community outreach program was developed well before the start of JHS recruitment. This program is intended to build an atmosphere of trust and support in the community but also to better understand sociocultural factors that might influence the success and findings of the study and to address the documented need for increased knowledge of CVD prevention among African Americans.[12,13] The initial goal of the outreach program was to produce broad-based awareness of the JHS among the 120,780 African-American adults living in the 2361-square mile Jackson MSA (an area >20% larger than the state of Delaware). A critical long-term goal is to build a collaborative trust that will grow over the life of the JHS, particularly as new research findings emerge.

Members of the African-American community have been incorporated throughout the JHS structure, beginning with the Council of Elders, a group of respected community members who were ARIC participants and who have provided advice on broad aspects of the study's planning and function since its earliest phases. Additional community members are included on most operating committees. The JHS public relations efforts have used television and print advertisements that feature local sports figures and other luminaries, and presentations have been made at sporting events and local gatherings. The Partnership for Community Awareness and Health Education (PCAHE) involves still other community members in a committee structure that initiates health outreach efforts and events, including educational seminars and community celebrations. The PCAHE has implemented a cardiovascular Community Health Advisers Network in which interested residents from across the Jackson MSA are trained to provide counseling on heart-healthy diet and lifestyle changes, improved medications adherence and monitoring, and access to healthcare resources. For more information regarding the Community Health Advisers Network, see www.usm.edu/csho/.

Community outreach efforts have been based on an awareness of the central role of churches in African-American communities. Many area churches have willingly embraced the JHS. Other contacts have been made through schools, beauty shops, and civic organizations. The involvement of local students in Undergraduate Training Center activities has created valuable incidental interactions with their friends and relatives. Scheduled meetings between members of the JHS staff and community have included a series of luncheons in the JMM convention center, an annual JHS family reunion, and JHS birthday celebrations in which participants are invited back for project updates, educational presentations, food, and entertainment in a relaxed and welcoming setting. Finally, JHS participants receive a quarterly newsletter updating them on recent developments. In the future, this newsletter will inform participants of study findings that may be relevant to their health and communicate potential follow-up actions they might choose. Such actions could include requesting their own investigational results and, when appropriate, pursuing clinical testing and management. The JHS community outreach efforts will be described in detail in a future paper.

## METHODS

### The Jackson Heart Study Recruitment

In prior studies, recruitment and retention of African Americans has been challenging,[19,20] suggesting a need for new approaches if research in this population is to succeed.[21–25] Strategies that have been helpful in the past include community involvement in planning and initiating research, raising research awareness through churches, community organizations, and trusted healthcare providers, and the use of culturally relevant publicity campaigns.[26,27] These approaches correspond closely to the community outreach components of the JHS. Before starting the JHS, community-driven strategies for effective recruiting were further explored through a participant recruitment and retention study. Findings of this study emphasized, among other things: 1) the need to integrate scientific data gathering with serving community and family aspirations; 2) the importance of continuous involvement in the community, rather than sporadic involvement primarily serving investigator priorities; 3) the importance of community involvement in selecting and training recruiters and clinic staff and in defining clinic procedures; and 4) the value of community members in helping to define the language and description of the study and in seeking community assent to proceed. Results of this study are published elsewhere.[28]
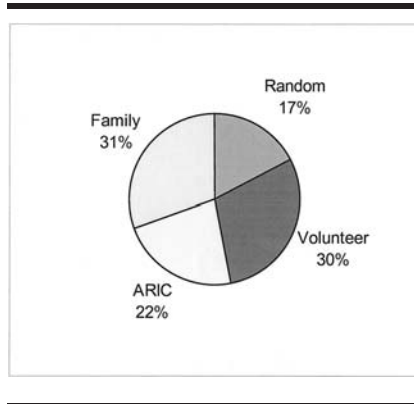
**Fig 1. Sources of JHS participants. The diagram shows the proportion of the JHS cohort that was enrolled from each of the four recruitment pools. The proportion for the Family Cohort includes secondary family members only; index family participants were attributed to their original cohort type. Participants recruited through the Family Cohort who were not, in the end, biologic family members (eg, spouses who did not share participating children with a family member) were excluded from the final Family Cohort that will be used for genetic analysis (*n*=1,499); such participants will be included among unrelated JHS participants in the overall cohort**

*The Jackson Heart Study Sample*

Figure 1 shows the components of the JHS cohort, sampled from among the noninstitutionalized African-American adults in the Jackson MSA. Recruitment was limited to persons 35–84 years old except in the family cohort, where those ≥21 years old were eligible. The original target of 6500 participants was reduced to 5500 after the first year of recruitment. The final cohort of 5302 participants includes 6.59% of all African-American Jackson MSA residents aged 35–84 (*N*=76,426, US Census 2000)[29] plus, in the Family Study, 252 participants aged 21–34 and 14 participants ≥85 years old. This cohort is predicted to have sufficient power to detect relationships within study data.

Jackson was one of the four clinic sites of the ARIC study, established in 1987.[30] As the only exclusively African-

American component, it became the foundation of the JHS. The original JHS study design included only the Jackson ARIC, random, and family components (Figure 1). To reach overall recruitment goals and address community concerns regarding broad participation, however, a structured volunteer sample was added later, in which demographic cells for recruitment were designed to mirror the eligible population. Details of this strategy are published separately.[31] For all four sample sources, sampling began by identifying an eligible householder, defined as a self-identified African American between 35 and 84 years old residing in the sampling area. If an eligible householder from the Accudata America commercial listing (described below) was living in the household or was survived by a spouse living in the household, all age- and race-eligible members of the household were eligible for recruitment.[31]

Former ARIC participants had originally been recruited through random selection from a drivers' license registry. Similarly, potential new JHS participants were chosen randomly from the Accudata America commercial listing, which provides householder name, address, zip code, phone number (if available), and age group in decades. Race was ascertained by home visit for persons living in neighborhoods that were >80% African-American according to the 1990 census. Those living in other neighborhoods were prescreened for race eligibility by a telephone call. Random sample lists were generated every three to six months, and each list was exhausted before a new list was generated. Initial contact with eligible householders was made by home visit. After at least three unsuccessful visits, additional contact efforts were made by telephone. A selected housing unit was only considered a non-contact after at least five unsuccessful contact attempts had been made in specified time windows.

The JHS family cohort[32] was nested within the overall cohort by recruiting families from among the relatives of JHS participants (index participants) who reported having at least two siblings and four other first-degree relatives, all ≥21 years old and living in the tri-county area. Each index participant was asked to provide pedigree data, family contact information, and permission to contact listed relatives. Recruiters were trained to extend pedigrees in the field. To increase the number of large pedigrees, the lower age limit for the family cohort was set at 21 years, with no upper age limit. Family Study participants completed the same tests and measures as all other JHS participants.

*Recruiter Preparation and Training*

The JHS Council of Elders participated in recruiter hiring and training. An eight-week training program that included practical field experience was focused on knowledge of the JHS rationale and methods, effective communication with prospective participants, and command of JHS recruitment procedures. The JHS investigators gave lectures on epidemiologic study design, sampling methods, and research ethics and procedures, among other topics. Recruiters were introduced to the structured survey instruments to be used during the home induction interview and to all components of the clinical examination, including a detailed rationale and description of each JHS measure. Each recruiter underwent a complete home induction interview and baseline clinical examination to gain first-hand experience of the requirements and demands on study participants. The recruiters were of varying ages and had different educational backgrounds. Two of the eleven recruiters were male, and all were African-American. The number of active recruiters varied during different phases of the recruitment effort, as detailed elsewhere.[31]

## BASELINE INDUCTION AND EXAMINATION

Table 2 lists the components of the JHS baseline induction and examination. These items were completed during the home induction interview, initial clinic visit, or 24-hour follow-up home visit or will be completed by annual telephone interviews or routine surveillance of cohort hospitalizations and deaths. Questionnaires used to collect sociocultural data are described elsewhere in greater detail.[33]

Verbal consent was obtained before conducting the home induction interview. An informed consent document was completed and signed before starting the clinic examination. All methods were approved by the institutional review boards of Jackson State University, Tougaloo College, and the University of Mississippi Medical Center.

### Home Induction Interview

Enrollment of each participant was started by the home induction interview, which lasted 30–45 minutes, during which the interviewer and participant completed a set of paper forms. The interview established each respondent's eligibility, enumerated other eligible household members, collected a variety of health and sociocultural data, and ended by scheduling the JHS clinic appointment. Family structure data gathered during the interview were used to determine potential eligibility for the JHS Family Study. All JHS forms are available by contacting the Coordinating Center (jsums.edu/~jhs/).

### Forms Completed During the Home Induction Interview

#### Household Enumeration

This form confirms the address and ethnicity (self-identified) of the sample individual and gathers information on all household members, including their name, date of birth, ethnicity, sex, and marital status. All household residents

in the 35- to 84-year age range who self-identified as African Americans were eligible to participate in the JHS.

#### Eligibility

The eligibility form confirmed that each sample person and household member met the JHS eligibility criteria and recorded the number of first-degree relatives ≥21 years old living in the JHS tri-county area to assess eligibility for the Family Study. In addition, it determined the respondent's level of awareness of the JHS and identified factors affecting willingness to participate.

#### Personal and Family Health History

This form, adapted from the ARIC personal history form, gathers baseline information on the respondent, her/his parents, and all full siblings and biological children. Questions addressed self-perceived health status (excellent, good, fair, poor), hospitalizations, CVD risk factors (blood pressure, cholesterol), heart attack, stroke, diabetes, renal disease, circulation problems, cancer, chronic lung disease, and asthma.

#### Physical Activity

Thirty items were assessed in four areas, including: 1) active living (routine daily activities); 2) occupational activity; 3) home, yard, and garden activities; and 4) sports and exercise. Questions were modified from the Kaiser Physical Activity Survey, which was based on ARIC methods and has recently been validated in a multiethnic sample of women.[34,35] A few items were changed slightly to adapt them for use with male respondents in the JHS.

#### Tobacco Use

Questions addressed all types of tobacco (cigarettes, pipes, cigars, chewing tobacco, dip/snuff) and include assessments of environmental tobacco smoke exposure and, for cigarette smokers, nicotine dependence (Fagerström Test for Nicotine Dependence, items 4–9).[36]

#### Healthcare Access and Use

This form was based on items from the Detroit Area Study (www.tcaup.umich.edu), the National Survey of Black Americans (http://webapp.icpsr.umich.edu),[37] and other standardized questionnaires that measure the availability, accommodation, acceptability, and affordability of healthcare services. Questions assessed whether the respondent had insurance and a usual source of care, extent of use of preventive services during the past year (dental, primary health care), barriers to care (transportation, getting an appointment, getting time off work), and level of trust and satisfaction with health services.

#### Global Stress

The global stress form was developed for the JHS and is an eight- item, self-report measure that assesses global perceptions of chronic stress rather than discrete occurrences of stressful events. It provided a subjective score of stress during the prior 12 months with respect to job pressures, relationships with others, neighborhood conditions, caregiving responsibilities, legal problems, medical problems, racism and discrimination, and difficulties meeting basic needs (housing, food, bills, etc).

#### Social Support

The social support form was based in part on the Berkman Social Network Index[38] and questions from the East Side Village Health Worker Partnership (www.sph.umich.edu)[39–41] and assessed both structural support components (type and frequency of contacts) and negative aspects of support.

#### Personal Data and Socioeconomic Status

Data were obtained regarding place of birth, marital status, education, income, employment or retirement status, first full-time job, spousal education and occupation, and house-

**Table 2. Major components in the JHS Exam 1**

| Medical History | Physical Examination | Blood/Urine Analytes | Interview/Questionnaire Constructs |
|---|---|---|---|
| **Health Behavior**<br>• Tobacco use<br>• Alcohol / drug consumption<br>• Physical activity<br>• Nutrition<br><br>**Medication Survey**<br>• Prescription medication<br>• Non-prescription medication<br>• Vitamin survey<br>• Folk/herb medication<br>• Medication-taking behaviors<br><br>**Reproductive History**<br>• Menopausal status<br>• Gynecological surgery<br>• Hormone replacement<br><br>**Symptoms/Procedures**<br>• Chest pain<br>• Respiratory symptoms<br>• Stroke symptoms<br>• CVD procedures | **Anthropometry**<br>• Standing height<br>• Neck girth<br>• Waist girth<br>• Weight<br><br>**Blood Pressure**<br>• Sitting<br>• Standing<br>• Ankle<br>• Ambulatory<br><br>**CVD Evaluation**<br>• Electrocardiography<br>• Echocardiogram<br>• Carotid ultrasound<br>• Respiratory function | **Blood/Plasma/Serum**<br>• Aldosterone<br>• C-reactive protein<br>• Chlamydia antibody<br>• Chloride<br>• Total Cholesterol<br>• HDL Cholesterol<br>• Complete blood count<br>• Cortisol<br>• Creatinine<br>• Endothelin<br>• Glucose<br>• HBA1C<br>• Homocysteine<br>• Insulin<br>• LDL Cholesterol<br>• Leptin<br>• Lp(a)<br>• Plasma renin<br>• Potassium<br>• Sodium<br>• Triglycerides<br>• Uric Acid<br><br>**Urine**<br>• Albumin<br>• Chloride<br>• Creatinine<br>• Potassium<br>• Sodium | **Coping / Spirituality**<br>• Coping strategies<br>• Religious involvement<br>• Daily spiritual experience<br>• Interpersonal support<br>• John Henryism<br>• Optimism<br><br>**Negative Emotions**<br>• Depression<br>• Anger<br>• Hostility<br><br>**Racism / Discrimination**<br>• Daily/chronic discrimination<br>• Response to discrimination<br>• Perceived racism<br>• Residential segregation<br><br>**Access to Health Care**<br>• Primary care<br>• Insurance/medication<br>• Trust/satisfaction<br><br>**Socioeconomic Position**<br>• Personal/spousal/parental<br>• Household wealth<br>• Job strain<br>• Class mobility<br>• Neighborhood SES<br><br>**Stress**<br>• Major life events<br>• Minor stressors<br>• Chronic stress |

hold wealth. Subjective data addressed job latitudinal satisfaction[42] and measures of thwarted aspirations and relative deprivation.[43] During annual followup, questions on childhood, parental, and neighborhood socioeconomic status (SES) provided complementary data to allow tracking of the participant's socioeconomic status at different stages of life. All data will be geo-referenced with the US Census to allow contextual analyses of community SES factors.

*Contact*

Multiple ways to contact each participant were recorded, and contact information for a healthcare provider was obtained, if available.

*Interviewer Observations*

Immediately after the interview, the recruiter noted observations that may help with JHS retention of the participant.

*Approach to Life Forms A, B, and C*

These are self-administered forms that were returned by the participant at the clinic visit, or if needed, were completed with the assistance of the interviewer. Form A is a 16-item version of the Interpersonal Support Evaluation List.[44] It assessed emotional support, interactive relationships, material support, and self-esteem. Form B, a 16-item version of the much longer (85-item) Coping Strategies Inventory,[45] addressed problem-focused versus emo-

tion-focused coping, as well as approach versus avoidance coping styles. Form C assessed religion, spirituality, and religious coping and is based on standardized measures that were included in the General Social Survey (webapp. icpsr.umich.edu).[46]

## CLINIC EXAMINATION

Participants arrived fasting for the clinic examination, which took ≈4.5 hours and began with a discussion of all interviews and procedures. Participants then completed the informed consent document, with staff assistance as needed. Explanatory audio- and videotapes were also offered, followed by anthro-

pometry, blood pressure measurement, 12-lead electrocardiogram, echocardiography, B-mode carotid ultrasonography, venipuncture, and pulmonary function testing (see Table 2).[47] Ankle-brachial systolic blood pressure measurements were obtained during the ultrasonography procedure. After a brief rest and a snack, participants completed additional interviews, including a medication survey, medical history, stroke symptoms survey, reproductive history, diet-food frequency questionnaire, and for family study participants, a family structure/family address book and parental identification form (full name and age of both biologic parents). Sociocultural interviews in the clinic addressed perceived discrimination and alcohol and drug use. Each participant had an exit interview to ascertain completeness of the exam, review abnormal results, and provide instructions on 24-hour studies (urine collection, ambulatory blood pressure, physical activity measurements) and any substudies (see below). Take-home questionnaires included a hassles and mood inventory, and when needed, a form to record additional family contact information. These were collected during the 24-hour follow-up home visit.

## Informed Consent

The complexity of the JHS protocol led to the use of a "layered" informed consent document through which participants could, to a limited extent, tailor their participation in the study. Separate consent responses regulated the management of participants' personal medical records and study results, specified participation or non-participation in genetic research, defined whether research was to be limited to JHS "focus diseases" only, and stipulated the level of data and sample access by non-JHS investigators. Future analyses will include only data and samples for which valid consent applies.

## Physical Measures Completed During the Clinic Visit

### Anthropometry

Weight was recorded to the nearest kilogram by using a balance scale. Height was measured with the heels and back of the head touching a vertical centimeter ruler and with the lower margin of the bony orbit level with the supratragal notch of the ear (Frankfort horizontal plane). Abdominal girth and neck circumference were measured in the horizontal plane at the umbilicus and cricothyroid membrane, respectively. Linear measurements were to the nearest centimeter.

### Blood Pressure

Sitting blood pressure was determined in the resting state by recording two measurements with a Hawksley random zero sphygmomanometer equipped with one of four cuff sizes selected by measured arm circumference.[48] Ankle-brachial systolic blood pressure ratio was measured for each leg with appropriately sized (to measure) arm and ankle blood pressure cuffs and an 8-MHz Doppler pen probe with built-in speakers.

## Electrocardiogram

A supine 12-lead digital electrocardiogram (ECG) was recorded with the Marquette MAC/PC digital ECG recorder (Marquette Electronics, Milwaukee, Wis), and with electrode placement that duplicated that of the ARIC study.[47,49] The ECGs are analyzed in accordance with the Minnesota Code Classification system,[50] via an extensively validated computer algorithm that was developed specifically for epidemiologic studies.[51–53] In-hospital surveillance ECGs were read visually according to the Minnesota Code Classification system.

### Echocardiography

Echocardiography was performed by a certified, experienced cardiac ultrasonography technician with a

Sono 4500 echocardiograph donated anonymously to the JHS (Philips Medical Systems).[47] Digital images were stored in a Digital Imaging and Communications in Medicine (DICOM) format. The procedure was a prioritized 30-minute two-dimensional (2D) and M-mode examination resembling typical clinical echocardiography with parasternal, apical, and subcostal windows. All four chambers were imaged for assessment of valvular shape and function and left ventricular (LV) filling and outflow, with particular emphasis on LV dimensions and systolic function to allow calculation of LV mass. Doppler data included peak and mean velocities for LV outflow and peak velocities of tricuspid regurgitation (if present), mitral inflow (with velocity-time integrals for mitral inflow E- and A-wave), and pulmonary vein inflow components (S, D, and A waves). Ventricular wall motion characteristics were assessed qualitatively.

### Ultrasonography

Carotid ultrasonography was based on the method of Pignoli et al[54] as modified for the ARIC study,[55,56] and took approximately 30 minutes. Instrumentation was the same as for echocardiography except that a 7.5-MHz rectangular array transducer was used to interrogate relatively shallow carotid arteries. After an initial scan to identify landmarks and survey for any stenotic lesions, the protocol scan was conducted in the longitudinal view to assess three key segments of the right and left carotid arteries: the distal straight 1-cm portion of the common carotid artery; the 1-cm portion of the bifurcation distal to the tip of the flow divider; and the 1-cm portion of the internal carotid artery immediately proximal to the tip of the flow divider. All images were recorded to videocassettes and shipped to the Ultrasound Reading Center for interpretation.[47]

## Venipuncture

Participants were in a supine position for 20 minutes prior to venipuncture, and blood was collected within a designated one-hour time window for all participants. Blood was collected into bar-coded containers in accordance with recommendations of the National Committee for Clinical Laboratory Standards.[57,58] The participant was instructed not to make a fist, and the tourniquet was applied for no longer than two minutes. Plasma and serum were prepared from selected samples by sedimentation in a refrigerated centrifuge within two hours of blood collection. Laboratory methods are described in a separate publication.[47]

## Pulmonary Function

Spirometry was performed as recommended by the American Thoracic Society,[59] with a dry rolling seal spirometer (Occupational Marketing, Houston, Tex). Measurements included forced vital capacity (FVC), forced expiratory volume at 1 second ($FEV_1$), 3 seconds, and 6 seconds, and peak flow as well as flows at 25%, 50%, and 75% of total volume. Both calculated data and raw wave-form data were stored for each forced exhalation performed, and quality scores for the test were developed and attached to each participant's data.

## Forms Completed During the Clinic Visit

### Medication Survey

This survey recorded prescribed and over-the-counter medications, vitamins, mineral supplements, and herbal or home remedies used within two weeks prior to the participant's interview, as well as current and regular use of aspirin and nonsteroidal anti-inflammatory drugs. The survey also queried usual medication-taking practices (not limited by the two-week window) as well as use of folk or herbal remedies.

## Medical History

This form recorded symptoms of chest pain, intermittent claudication, congestive heart failure, sleep apnea or other sleep disturbances, history of procedures to diagnose or treat cardiovascular disease, and history of renal dialysis (current or past). Chest pain was characterized as angina and/or myocardial infarction by London School of Hygiene criteria (Rose Questionnaire).[60]

## Respiratory Symptoms

The respiratory symptoms form was adapted from the Adult Respiratory Symptoms Questionnaire[61] and reviewed symptoms of cough, wheezing, breathlessness, and asthma. It was a condensed version of the questions on respiratory symptoms in the respiratory symptoms/physical activity form of ARIC visit 1.

## Stroke Symptoms

The stroke symptoms form, initially used in ARIC visit 1, collected extensive data regarding prior diagnosis of a stroke or transient ischemic attack or a history of neurologic symptoms, including their onset, duration, and anatomic localization and effects on speech, movement, vision, sensory function, consciousness, and subjective sensations.

## Reproductive History

Data were recorded regarding menarche, pregnancies, live births, menopausal symptoms and menopause, gynecologic surgery, and use of oral contraceptives and hormone therapy, including specific product(s) used, dose, duration, and route of administration.

## Diet-Food Frequency

The Delta Nutrition Intervention Research Initiative (NIRI) Food Frequency Questionnaire was developed by the Lower Mississippi NIRI Food Frequency Working Group[62] and is being validated in the Mississippi Delta region. It was shortened by the Working Group for JHS use so that it could be completed within 20 minutes. It was designed to measure usual dietary intake over a six-month period among southeastern, African-American respondents, based on food lists and portion sizes obtained from pilot telephone-administered 24-hour recalls of adults in this population.

## Family Address Book and Parental Identification Form

The family address book recorded the name, age, birth date, and contact information of participants' spouse(s), children, parents, paternal and maternal grandparents, whole- and half-siblings, grandchildren, nieces, nephews, and spouses' parents, grandparents, and siblings. An initial pedigree based on data in the address book was refined during family recruitment. The parental identification form recorded the full names (including maiden name) and birth dates of the biological parents of Family Study participants and identifies relatives who are already participants in the JHS or ARIC.

## Discrimination

The discrimination form was adapted from the Discrimination Scale,[63] the Everyday Racial Discrimination Questionnaire,[64] and the Perceived Racism Scale[65] and records the participant's attributions, day-to-day experiences, major life events, and coping/responses to racial discrimination.

## Alcohol and Drugs

This form used questions from ARIC and from the third National Health and Nutrition Examination Survey (NHANES III).[66] Participants were classified as lifetime alcohol abstainers, ever users, and users during the past 12 months, and characterized regarding preferred beverage, history of heavy use, and quantity/frequency of use during the past 12 months. Other questions identified lifetime abstainers or ever users of cocaine or other drugs and queried estimated total number of cocaine uses.

*24-hour Follow-up Data Collection*

Participants completing the baseline clinic visit were provided with materials and instructions for a 24-hour urine collection, ambulatory blood pressure monitoring (ABPM), physical activity monitoring (PAM), and forms A–D of the Hassles and Mood Inventory (see below). The ABPM equipment (Medifacts International, Rockville, Md) included a laptop computer and modem, a Spacelabs 90207 Oscillometric ABPM device and supporting equipment, and one of four sizes of blood pressure cuff fitted by measure to the participant's nondominant arm. The PAM equipment included a CSA (Computer Science Applications, Shalimar, Fla) accelerometer and a digiwalker step counter affixed to the waist. After the 24-hour monitoring period, ABPM and PAM equipment and the collected urine were either returned to the Examination Center or retrieved by a JHS representative.

*Hassles and Mood Inventory*

These take-home forms were given to all participants or, when needed, were completed with the assistance of clinic staff. Form A, the weekly stress inventory,[67] is an 87-item checklist of minor stressors. Participants recorded whether each stressor occurred during the past week and rated their subjective responses on a seven-point Likert-type scale (1=not stressful; 7=extremely stressful), producing summary scores for: 1) the number of stressful events and 2) the sum of subjective ratings. Form B, the Center for Epidemiologic Studies Depression Scale, is a 20-item questionnaire developed by the National Institute of Mental Health[68] to measure the frequency of depressive symptoms during the past week (rarely or none of the time to most or all of the time). Form C is a 27-item, true-false questionnaire that assessed experiential hostility (cynicism, suspiciousness, mistrust, resentful feelings toward others) to produce a composite hostility score

(CHO).[69] Form D, the Spielberger Anger Expression Inventory,[70] is a 16-item checklist that assessed participants' reactions to anger, recording on a four-point Likert-type scale (1=never; 4=almost always) how often the participant reacts in the manner described by each item.

## Diet and Physical Activity Substudy

Five hundred male and female JHS participants of varying ages, socioeconomic levels, and physical activity levels were selected to participate in the diet and physical activity substudy to assess the validity of JHS's food frequency questionnaire (FFQ; the shortened form of the Delta NIRI FFQ) and physical activity form.[71,72] Substudy participants provided 24-hour diet recalls at each of four return clinic visits and during a fifth visit completed the long Delta NIRI FFQ. A step counter was worn during the week before each visit. Both the full and shortened Delta NIRI FFQs will be analyzed and validated by comparing the nutrient intakes calculated from them with the average intakes of four 24-hour diet recalls per participant. Recorded step counts, coupled with data from concurrent ambulatory blood pressure monitoring and 24-hour physical activity monitoring will be compared with responses on the physical activity form to assess this form's validity.

## ANNUAL FOLLOWUP AND SURVEILLANCE

At twelve-month intervals after the baseline clinic visit, participants are contacted by telephone to: update contact information; confirm vital status; document interim medical events, hospitalizations, and functional status; and obtain additional sociocultural information.[73] Questions about medical events, symptoms of CVD, and functional status are repeated annually,

whereas different sociocultural information is collected each year to complement data from the baseline visit. Ongoing cohort surveillance includes abstraction of medical records and death certificates for relevant International Classification of Diseases (ICD) codes, and adjudication of nonfatal events and deaths.[73] ICD-9 codes that are screened to detect possible hospitalized myocardial infarction include hypertensive heart disease (402), acute myocardial infarction (410), other acute and subacute ischemic heart disease (IHD) (411), old myocardial infarction (412), angina pectoris (413), other chronic IHD (414), cardiac dysrhythmias (427), heart failure (428), and acute pulmonary edema (518.4). ICD10 codes screened to identify deaths possibly due to CHD include diabetes mellitus (E10–14), essential hypertension (I10), hypertensive heart disease (I11), unstable angina, angina pectoris (I20), acute myocardial infarction (I21–23), other acute IHD (I24), chronic IHD (including old MI) (I25), cardiac arrest (I46), paroxysmal tachycardia (I47), atrial fibrillation (I48), other cardiac arrhythmias (I49), heart failure (I50), ill-defined heart disease (I51), atherosclerosis (I70), postprocedural disorder of circulatory system (I97) (not I97.2), pulmonary edema (J81), respiratory failure (J96), other sudden death (R96), unattended death (R98), and other ill-defined cause (R99). Hospitalizations or deaths related to congestive heart failure or stroke are identified by similar methods; the ICD codes reviewed to detect these events are detailed elsewhere.[73]

## RESULTS REPORTING AND ASSISTANCE WITH HEALTH CARE

Data of known clinical value were routinely released to participants and their healthcare providers as stipulated by each participant's consent document. An

extensive protocol defines the urgency of reporting and recommended medical followup as emergent (transport to emergency facility), urgent (one day followup), immediate (one week followup), or routine. A social worker is on site to assist participants with obtaining needed health care. The JHS results that are considered to be of research value only are not routinely reported to participants, though they may be released on an ad hoc basis in response to a written request from the participant, at the discretion of the principal investigator.

## DATA MANAGEMENT

The JHS Coordinating Center performs all JHS data management and quality control and manages interactions with the two laboratories (University of Mississippi Medical Center, University of Minnesota) and the five specialized reading centers (electrocardiography, echocardiography, carotid ultrasound, pulmonary function, ambulatory blood pressure monitoring) that support the JHS.[47] In collaboration with the advisory coordinating center at the University of North Carolina, the JHS Coordinating Center developed a computer-assisted data management system (DMS) based on the Clintrial 4.3 software system. The DMS supports data entry from paper forms, direct electronic data capture, and transfer and management of data from the JHS laboratories and reading centers. Detailed JHS laboratory, reading center, and data management methods have been published previously.[47]

## INITIAL CHARACTERIZATION OF THE JHS COHORT

Figure 1 shows the proportions of the JHS cohort that were recruited from each target group. Former ARIC participants
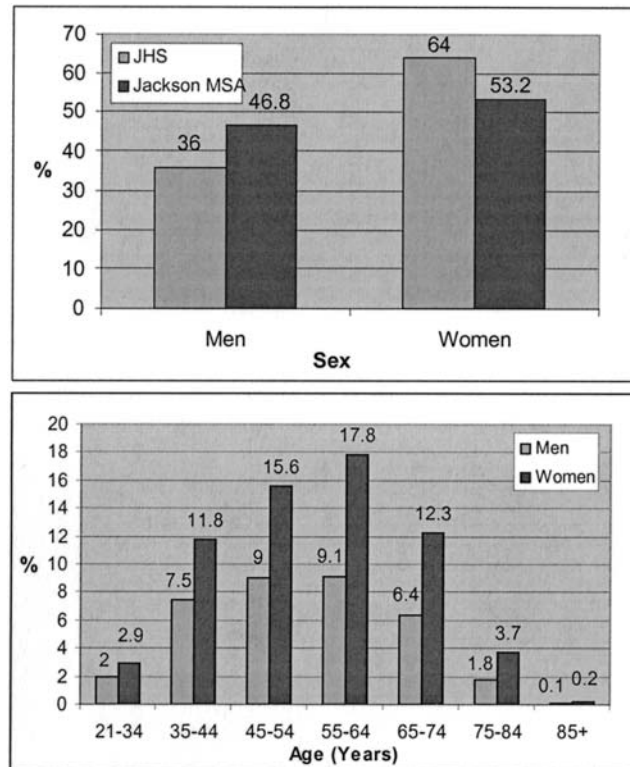


**Fig 2. Age and sex of JHS participants. The first panel compares the sex distribution of JHS participants with that of all Jackson MSA residents aged 35–84. The second panel shows the age distribution of JHS participants by sex**

and randomly selected individuals each make up approximately a fifth of the cohort. Remaining participants were enrolled through the Family Study or in a constrained volunteer sample[31] in approximately equal proportions. A comparison of sex in the JHS cohort and the tri-county recruitment area (Figure 2a; 2000 Census) shows a relative excess of women in the target area, which is accentuated in the JHS cohort. A large proportion of JHS participants are between 45 and 64 years old (Figure 2b), a range that may be expected to have a high incidence and prevalence of the JHS focus diseases. An analysis of selected baseline characteristics of the cohort (Table 3) shows that obesity and hypertension are strikingly prevalent, with a larger proportion of women affected than men. Almost a fifth of participants have diabetes according to American Diabetes Association crite-

ria,[74] and another 14.4% have pre-diabetes.

## THE UNDERGRADUATE TRAINING CENTER

Tougaloo College, the site of the Undergraduate Training Center, has a long history of preparing undergraduate students for advanced studies in the health professions. In the late 1960s, the first African-American students to attend the University of Mississippi's Medical School were Tougaloo graduates, and a large proportion of the African-American physicians, dentists, and other health professionals now practicing in Mississippi are former Tougaloo students. The preparation of Tougaloo students for health-related graduate studies has been strengthened by the development of an array of

**Table 3. Selected Baseline Clinical and Demographic Characteristics**

| Phenotype | Mean (SD) | | |
|---|---|---|---|
| | Male *n*=1907 | Female *n*=3395 | All *N*=5302 |
| Age (years) | 54.1 (13.0) | 55.3 (12.7) | 54.9 (12.9) |
| Weight (kg) | 94.6 (22.6) | 88.6 (21.7) | 90.8 (22.2) |
| Height (cm) | 177.4 (7.2) | 164.1 (6.5) | 168.9 (9.3) |
| Body mass index (kg/m$^2$) | 30.0 (6.8) | 32.9 (7.8) | 31.9 (7.6) |
| Systolic BP (mm Hg) | 127.9 (18.0) | 126.5 (18.7) | 127.0 (18.4) |
| Diastolic BP (mm Hg) | 81.4 (10.7) | 77.3 (10.2) | 78.0 (10.6) |
| Overweight (%)* | 27.5% | 39.9% | 32.0% |
| Obese (%)* | 41.4% | 59.9% | 53.3% |
| Pre-hypertension (%)* | 25.2% | 17.5% | 20.2% |
| Hypertension (%)* | 59.7% | 63.4% | 62.1 |
| Pre-diabetes (%)* | 16.5% | 13.1% | 14.4% |
| Diabetes (%)* | 17.2% | 19.8% | 18.8% |

\* Defined in accordance with NHLBI and American Diabetes Association guidelines. Overweight: BMI=25–29.9; Obese: BMI=30+.[74–76]

programs, several of which have extramural funding, including a summer science program, the pre-medical/dental program, and the Minority Access to Research Careers (MARC) and Minority Biomedical Research Support (MBRS) programs. The JHS Undergraduate Training Center seeks to leverage these programs to increase the number of African Americans entering public health and related fields by providing added educational and research opportunities across a range of academic levels. Its activities include the Science Language Arts and Mathematics (SLAM) program with emphasis in epidemiology for high school students, the JHS Scholars Program for undergraduate students, and a postgraduate course in epidemiology for more advanced students and health professionals. Detailed descriptions and preliminary results of these programs are provided in a separate manuscript.[14]

## High School Outreach Programs SLAM I, II, and III

These three four-week summer workshops emphasize language, quantitative, and science skills and expose students to issues of public health and epidemiology. A team of college and high school teachers develops challenging sessions that link mathematics and natural science with articulate expression to cultivate critical thinking. Instruction is overseen by curriculum coordinators in each of the three skill areas. Additional input is gained from JHS Scholars who serve as tutors and from the high school students themselves. The SLAM workshops are advertised by distributing fliers to all area high schools, by notices on the Jackson Public School website, and by visits to most high schools by the Undergraduate Training Center staff. SLAM workshops I, II, and III are attended by 9th, 10th, and 11th graders, respectively. Placement in SLAM II or SLAM III is contingent on completion of specific high school science and math classes as well as the prior SLAM workshop level. A student may attend all three SLAM workshops during the high school years.

## JHS Scholar Program

The JHS Scholar Program provides stipends and research opportunities to selected students both during the academic year and the summer. Twelve scholars are selected during the spring semester of their freshman year based on a minimal grade point average (GPA) of 3.0, an ACT score ≥20 (or its SAT equivalent), a personal statement of the student's professional goals, professors' letters of recommendation, fall semester grades, and an interview with the selection committee. Once selected, scholars who perform well may stay in the program through all four years at Tougaloo College. Scholars must take the four JHS-supported courses (Introduction to Public Health and Epidemiology; Biostatistics; Ethics, Medicine, and Technology; and Research Methods in Public Health and Epidemiology), attend colloquia, participate in assigned JHS scientific activities, and attend scientific and public health-related conferences that are required by their course work. Freshman students are introduced to concepts of public health, CVD, and health disparities through a weekly seminar series. After the freshman year, a two-hour per week professional development obligation at the JHS Coordinating Center, Examination Center, or in community outreach is required of all scholars. Scholars are matched with professionals in their area of interest and are strongly encouraged to participate in research activities. Their performance and progress are evaluated twice a year by the Undergraduate Training Center staff. To continue as scholars they must maintain a minimum GPA of 3.0 overall and exhibit appropriate attitude and behavior. Scholars entering the junior and senior year must participate in health-related research at liaison or other national or international institutions during the summer months. Summer research progress is monitored, and students present their findings and experiences in regularly scheduled seminars at the JHS and Tougaloo.

As of the 2004–2005 academic year, 43 students were active JHS Scholars (12 freshman, 11 sophomores, 10 juniors, 10 seniors), and this number will be expanded to 48 by 2007. Twenty-four scholars have completed the program (five in 2003, ten in 2004, nine in 2005). Of these 24 scholars, six are now in medical or dental school, 11 are in graduate professional school, and seven are employed in health-related areas. Students have done summer work at >20 distinguished universities and

institutions, including Harvard, Brown, and Cornell Universities, Decode International (Iceland), and the National Institutes of Health.

## Six-Day Introductory Epidemiology Course

Each year since 1997, the Undergraduate Training Center has conducted an intensive introductory epidemiology course for health professionals, graduate students in biomedical or behavioral sciences, and advanced undergraduate students. The course is directed by Moyses Szklo, MD, DPH, professor of epidemiology at Johns Hopkins School of Hygiene and Public Health, and is taught by Dr. Szklo and two other instructors during six full days in the summer. Enrollment is limited to 30 participants. To date, 44 health professionals, 22 graduate students, 45 undergraduates, and 22 others from seven states have completed the course.

## SUMMARY

The JHS is designed to address healthcare disparities affecting African Americans by combining a large observational study of common diseases with a program of community health activism and academic infrastructure building. It is a collaboration involving two distinguished HBCUs and Mississippi's only academic medical center and is supported by the National Heart, Lung, and Blood Institute (NHLBI) and the National Center for Minority Health and Health Disparities of the National Institutes of Health. The NHLBI has on-site staff to help promote the health education and community outreach objectives of the study and to ensure continued sensitivity to community concerns. The JHS is housed at a spacious medical mall that is located in the heart of Jackson's African-American community and is a central access point to full-service medical care, as well as a center of scholarly activity in public

health. The JHS research component combines baseline data regarding economic, sociocultural, behavioral, dietary, and physical activity measures, and an array of physical, biochemical, and genetic attributes to produce a dataset of uncommon richness. A cohort of 5302 participants has been enrolled, including a large, nested family cohort. The prevalence of diabetes, hypertension, and obesity is striking among JHS participants, whose age range is likely to be associated with a continued high incidence of these and related disorders. A second examination began in September 2005 and a third is scheduled for 2008. The data and materials produced by the JHS are intended as a resource to the scientific community and will be accessed by many scientists through mechanisms that protect and serve the interests of the metropolitan Jackson African-American community. The careful and robust use of this resource may provide substantial benefits to the latter community and may ultimately help to relieve longstanding and pervasive CVD health disparities.

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