Jackson Heart Study Protocol

Manual 6

Echocardiography

Visit 1

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FOREWORD

This manual is one of a series of protocols and manuals of operation for the Jackson Heart Study (JHS). The complexity of the JHS requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the JHS Study. Manuals 2 and 10 describe the operation of the Cohort and Surveillance Components of the study. Detailed Manuals of Operation for specific procedures, including those of reading centers and central laboratories, make up Manuals 3 through 9 and 11.

JHS Study Protocols and Manuals of Operation

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1	General Description and Study Management
2	Cohort Component Procedures
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4	Blood Pressure
5	Electrocardiography
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1.0 INTRODUCTION AND GENERAL OBJECTIVES

Participants in the Jackson Heart Study (JHS) will have an echocardiographic examination as a part of their first visit cycle. A number of these individuals also participated in the Atherosclerosis Risk In Communities (ARIC) study, and may have had echocardiography as part of that study during the years 1993 to 1996.

As its general objectives, the echocardiography study will (1) characterize a variety of cardiac structural and functional parameters in a large population-based sample of black men and women, and (2) examine these data for relationships with traditional and nontraditional risk factors for cardiovascular disease, prevalent cardiovascular disease, and cardiovascular disease incidence, adding to similar information collected in other important population-based studies.

The echocardiography protocol will incorporate currently accepted standard echocardiographic techniques to enhance comparison with preceding and future studies. Structural parameters to be studied include left ventricular (LV) wall and chambers dimensions, and LV mass (calculated from dimensions). Cardiac functional data will be derived from measurements of systolic performance such as fractional shortening, regional wall motion, and wall stress, and from Doppler data describing left ventricular diastolic filling.

Responsibility for various procedural aspects of the JHS echo exams will be shared among the JHS Examination Center (EC) with its Echo Reading Center (ERC) component and the JHS Coordinating Center (CC). The Echo Reading Center (ERC) is a component of the JHS EC budget in the early phases (under the CC in final phases). The EC, largely through the ERC, and will be responsible for overall monitoring of the echo procedures, quality control, clinical interpretation, analytical measurement and coding of the echo data, and transmission of the data to the CC. The EC will be responsible for technician training, for exam performance, interpretation, and data entry, and for internal quality control functions. The Coordinating Center will be responsible for developing and maintaining the official analysis file and for official analyses of the data, and will provide support for publications, including primary responsibility for statistical analyses. Some data analysis may be done locally at the EC as well, and its investigators will have primary responsibility for coordinating and producing scientific publications.

The echocardiographic examination will be conducted in the JHS Clinic facilities in Jackson. Two trained cardiac sonographers will perform the echo studies. The EC and ERC staff will train these technicians in the specific protocol for the JHS studies.

Components of the ERC will be at both the JHS clinic site as well as on the main campus of the University of Mississippi Medical Center. Data acquisition, archival, and transmission is described in more detail in a subsequent section, but the design for the echo examination as well as the reading process is based on an integrated digital imaging network with acquisition nodes attached to each echo machine, a server computer with additional hardware for permanent archival, and workstation nodes on the network where images are reviewed and analyzed.

2.0 SCIENTIFIC BACKGROUND AND RATIONALE

Echocardiography Data and Cardiovascular Risk in Population Studies

Left ventricular (LV) hypertrophy detected by electrocardiography is associated with a significant risk of cardiovascular morbidity and mortality (1,2). More recently, echocardiography has provided a more sensitive, more direct tool for measurement of LV mass and detection of prevalent hypertrophy. In addition, echocardiography is quantitative, reproducible, and noninvasive (3-6). Reference values for LV mass and criteria for LV hypertrophy were established in the large study population of the Framingham Heart Study (7). Echocardiography provides an objective means of prospectively studying the relationship between LV mass and cardiovascular events.

The pathophysiology of LV hypertrophy in a population may be rather diverse. The impact of age (8), obesity (9), alcohol intake (10), body size, physical activity, and blood pressure (11) on LV mass have been examined. A small proportion of LV hypertrophy is associated with valvular heart disease, but most is not, and the overall incidence of hypertrophy based on Framingham criteria in their population was about 15-20% (12). Dannenberg (8) concluded that the increase in LV mass associated with aging was prominently related to extracardiac factors (such as obesity and hypertension) that accompany advancing age and "not by virtue of an intrinsic myocardial aging process".

Importantly, several reports have documented an increased risk of cardiovascular events and mortality in subjects with LV hypertrophy and some show the risk to be independent of the other known risk factors for coronary heart disease (12-17). As an example of the magnitude of the risk, one study of 3220 subjects age 40 or over with no clinically apparent cardiovascular disease (12) reported that increased LV mass (indexed to height) was associated with cardiovascular mortality (relative risk 1.73 in men, 2.12 in women) and all-cause mortality (relative risk 1.49 in men, 2.01 in women) over a 4-year follow-up period. There was an incremental increase in relative risk of cardiovascular disease of 1.49 for each 50g per meter increase in indexed LV mass for men and 1.57 for women. This study contributed to the identification of LV hypertrophy as a potent risk factor independent of age, diastolic blood pressure, pulse pressure, obesity, and total cholesterol to HDL ratio.

For African-Americans, there are insufficient data on the distribution of LV mass and its association with cardiovascular risk. As the genetic influence of race is seen on some aspects of essential hypertension, so might the risk associated with LV hypertrophy in blacks vary from that of a general or predominantly white population. The impact of other factors such as age, blood pressure, sodium intake, alcohol consumption and many other factors requires further study.

In essential hypertension, LV hypertrophy may be thought of as one type of end-organ damage often leading to two predominant sequelae, congestive heart failure and cardiac arrhythmias (18) including sudden death. Several animal and human studies point to the multiple hemodynamic, humoral, and structural factors that influence hypertension and the development of LV hypertrophy and of its sequelae. But, as shown in the TOMHS study, lowering high blood pressure by any means tended to allow LV hypertrophy to regress. Data are not yet available from current long-term clinical studies designed to assess the change in cardiovascular risk associated with regression of hypertensive LV hypertrophy.

Despite the paucity of intervention data, some authors already suggest that early detection of hypertrophy (necessarily by echocardiography) and aggressive antihypertensive therapy aimed at its regression should be an important goals of the clinician. Despite complex interactions among the factors that influence it, the presence of LV hypertrophy may be a clinically useful summary of the integrated adverse effects of hemodynamic loads and vascular disease on the heart (19).

In the Atherosclerosis Risk In Communities (ARIC) study, echocardiography of the Jackson field center's African-American cohort was done to obtain data on left ventricular mass and prevalent hypertrophy. Based on Framingham-defined criteria for LVH, prevalence was dramatically higher for ARIC participants in Jackson compared to age-matched Framingham study participants. The ARIC study group is

beginning to look at cardiovascular events that have occurred in the ARIC cohort and has the opportunity to evaluate prevalent LVH and its potential association with these events. This sort of outcome-related data is critical to understanding the importance of the high prevalence of LVH in African-Americans. Is this a part of the answer as to why cardiovascular mortality and morbidity are generally higher in the black population?

Planning groups for the JHS considered a number scientific questions and research opportunities . The echocardiography study has the opportunity to evaluate questions in the areas of left ventricular hypertrophy, congestive heart failure, and coronary artery disease.

I.   Left ventricular hypertrophy

What is the typical pattern of progression and regression of LVH, and how do its development, progression and regression relate to other risk factors and to antihypertensive treatment or other therapy?

What is the pathogenesis of the relation of LVH to adverse outcomes, including arrhythmias and sudden death? What are the risk factors for this progression?

What are the prognostic implications (or predictive value for adverse outcomes), of various patterns of LV geometry and hypertrophy?

Are there identifiable genetic factors related to the development, progression and regression of LVH?

What is the temporal relationship between the development of hypertension and LVH (or of other structural and functional parameters such as diastolic filling properties) ?

What is the association between LVH and other target organ manifestations of hypertension such as renal dysfunction and atherosclerosis measured as the presence and progression of carotid artery disease?

II.   Congestive heart failure

What are the typical patterns of development and progression of LV dysfunction and CHF, and how they relate to traditional and non traditional risk factors and to antihypertensive treatment or other therapy?

What is the pathogenesis of CHF, and how is related to traditional and non traditional risk factors?

What is the contribution of normal systolic heart failure to LV dysfunction and CHF in this population, and what is its pathogenesis and relationship to other risk factors?

What are the diagnostic and treatment patterns of CHF in this population, and how they differ from nationally recognized standards or recommendations, including use of echocardiography, cardiac catheterization, and ACE inhibitors?

What are the secular trends in disability, morbidity and mortality from CHF in this population?

Are there identifiable genetic factors related to development and progression of CHF in this population?

III. Coronary artery disease

What is the typical pattern of development and progression of CHD, and how does it relate to traditional and non traditional risk factors, especially hemostatic and inflammatory factors and endothelial dysfunction?

What are the prognostic implications (or predictive value for adverse outcomes) of exercise tolerance testing, coronary calcium, echocardiography, and other noninvasive measures of CHD?

What are the diagnostic and treatment patterns of CHD in this population, and how they differ from nationally recognized standards or recommendations, including use of exercise testing, cardiac catheterization, thrombolysis, revascularization , and proven secondary predictive strategies such as aspirin and beta blockers?

Echocardiography is a tool which characterizes cardiac structure and function in a way that allows quantitative research into questions that may help us better understand, treat, and prevent cardiovascular disease in African-Americans.

3.0 COLLECTION OF ECHOCARDIOGRAPHIC DATA

3.1 Echocardiography Instrumentation and General Operating Features

An "echo machine" is an multipurpose ultrasound system which incorporates technology for image optimization and quantification of cardiovascular targets. The echo machine produces both digital and analog outputs. Analog video is typical stored on videotape but may be captured into a digital imaging network as the primary means of data storage and archival. Some echo machines may use direct digital connections to an image server to accomplish the same task. The echo machine has built-in capabilities for image manipulation and measurement, but for the purposes of the JHS echo study, the quantitative analyses will be done after the participant examination is complete by means of networked image workstations. On these workstations, the digitally stored images can be reviewed in real-time motion and individual frames may be selected for specific quantitative measurements.

In general terms, the echo machine is comprised of a video monitor for viewing the ultrasound data; a keyboard for entry of study identification and for selection of system options; a panel containing image, Doppler, and recording device controls; ports for connection of the ultrasound transducers; ECG display controls; and recording devices. The JHS systems will contain, at least, a digital image capture interface and may also contain a S-VHS videotape recorder. Details of the operation of the echo systems are found in the vendor-supplied users manuals.

3.2 Echocardiography Instrumentation - Transducers

The echo machine is equipped with phased array ultrasound transducers capable of imaging at various ultrasound frequencies. In general, the studies will be performed with the primary operating frequencies near 2.5 to 3.5 MHz. Steerable 2-D directed M-mode is performed at the same imaging frequency. The transducers also are capable of steerable continuous wave (CW) and pulsed Doppler (including color flow mapping). Two different probes may be connected to the machine and selection between the two is by way of a front panel button.

3.3 Echocardiography Instrumentation - Digital Image Storage

The digital imaging system will have specific controls and procedures for patient identification, image capture/review, and transmission of images to the image server at the completion of the study.

The echo machine intrinsically produces digital images in a 512 by 512 pixel matrix. This matrix size defines the limits of resolution in the ultrasound image. The digital image is converted to a standard 525-line video signal which is made available to the image capture system which is able to retain a high degree of resolution and faithfulness to the original image.   Once in digital format, the image is not subject to degradation by repeated viewing, copying, or deterioration of media with the passage of time.

The echo images are stored in a computer format which is widely accepted in the computer industry. DICOM is the predominant image format used in medical applications. DICOM compliant images are vendor-independent and can be transmitted to other locations and viewed on a variety of compliant workstations. JHS echo studies will be permanently archived on a mass media storage device such as digital linear tape (DLT) media. In addition, compact disk (CD) recording may be used as a universal permanent archive media for individual studies.

3.4 Workstation Instrumentation - Analysis At The Reading Center

The echo studies are available on the image network as soon as the study is completed.   The digital video will be reviewed to provide a basic clinical interpretation of the study, in particular to look for important or unexpected echocardiographic findings (for example, aortic stenosis or insufficiency) which may impact on the participant's health care or which may affect the usefulness of the data for the purposes of the JHS echo study.

In addition to real-time video playback, the echo workstations provide tools to make quantitative measurements based on the echo images, and a database in which to store results, format printed reports, and package data for export to the ERC database (eventually to the Coordinating Center). Details of the operation of the echo workstation software will be found in the vendor's operator's manuals. Use of the workstation specifically in the context of JHS echocardiograms will be developed in a subsequent section of this Manual.

3.5   Reading Center Database for Analysis Results

For the purpose of efficient data management and transmission to the Coordinating Center, the data items and pertinent participant information will be entered into a custom database developed and maintained in the ERC.   Study identification and tracking data as well as qualitative analysis results will be entered by keyboard into the database from the Technician (Appendix 1) and Reader (Appendix 2) Worksheets. Errors in manually entered data will be avoided by range checking of numeric data, by use of pick-lists for discrete data-entry choices, and by other programmed logic in the custom database software which comprises the ERC database. Data generated by the echo workstations may be directly exported into the ERC database to avoid manual data entry errors. Additional data fields in the ERC database will accommodate the manually entered items. Participant and study identification data, critical to proper data tracking, will be imported from the technician's entries into the digital image network data files and will be cross checked from the Technician Worksheet for accuracy during the manual keyboard entry of the additional qualitative study results. This Reading Center Database will provide a versatile means of organizing the data, analyzing it for quality control, and formatting the data for transmission to the Coordinating Center.

4.0 THE ECHOCARDIOGRAPHIC EXAMINATION

This section will give an overview of the instrument preparation, patient preparation, and performance standards for the echo examination. The echo technician will record information on the Echo Technician Worksheet.

4.1   Presets on the Instruments

4.1.1   Echo Machine's Application Presets

The echo machine features programmable "application" presets to allow customization of preferred image and Doppler settings, and to allow efficient selection of alternate settings if needed, for example, in the case of technically difficult imaging studies.   A preset will been defined for the JHS echo study based on typical imaging and Doppler parameters for cardiac ultrasound and on the crucial need for high quality M-mode and 2-D data. This preset is active automatically when the machine is powered up, and it can be re-selected from the keyboard prior to each study. The technician may modify some parameters during the course of a study to optimize data quality but these changes are returned to nominal settings when the JHS "application preset" is selected.

4.1.2   Digital Storage System Protocols

The digital image network will obtain participant name and identification from the technicians' entries on the echo machine itself. There will be no individual settings required on the digital system prior to the echo examination.

4.2   Equipment Preparation Prior to Each Study

4.2.1   Echo Machine Preparation

General care instructions are found in the documentation supplied with the machine. Prior to each study the transducer heads should be wiped clean in accordance with the manufacturer's instructions. Disposable EKG electrodes are snapped onto the three leads of the EKG cable prior to attaching to the participant. If any machine parameters have been altered by the previous study, reactivate the "application preset" for JHS. The technician should be confident that recording device(s) are ready and properly positioned to record a new study. The technician should fill in the study identification information on the screen and double-check the participant identification before beginning echo study.

4.2.2   Digital Storage System Preparation.

Preparation of the digital imaging network may or may not be required depending on how the selected vendor has implemented the interface with the echo machine itself. Once the participant identification is known to both the echo machine and the imaging network, the image acquisition may begin.

4.3   Participant Preparation

The participant should remove all clothing from the waist up and don a clinic gown which will provide access to the chest as needed for imaging.

The technician will measure the participant's blood pressure in a comfortable supine position and record it on the imaging system's information screens.

Position the subject in the left lateral position with the head propped up at a slight angle on pillows and a wedge behind him to help maintain this position comfortably. Attach three EKG electrodes as labeled. The "arm" leads (RA and LA) may be placed on the upper chest near the shoulders, and the "left leg" lead (LL) may be placed on the abdomen. The leads should be draped without tension in a way that they will

not interfere with the subsequent examination. Check that a clear EKG signal is displayed on the echo machine. The EKG size control on the echo machine is generally best left in the "AUTO" position.

4.4   Imaging Views and Information Sought

This section reviews the standard set of acoustic windows to be used and the data sought from each view. In addition, a list of items to be recorded is given. In general, for each imaging view and mode specified below, the technicians will activate the "record" button to capture images for a period of time that will encompass 10-20 heartbeats of relevant data unless otherwise specified. All recordings will be performed at end-expiration, obviating the need for using a respirometer and adding consistency to the measurement processes.

4.4.1   Parasternal Views

These views are usually performed in the left 3rd or 4th intercostal space adjacent to the sternum.

4.4.1.1   Parasternal Long Axis View

The ultrasonographer attempts to line the beam perpendicular to the interventricular septum and posterior left ventricular wall. Initially, the focus is on obtaining a clear 2-D image of the aortic valve, aortic root, left atrium, right ventricle, left ventricle, and mitral valve. Color Doppler interrogation is performed to assess aortic and mitral regurgitation.

Data recorded in the parasternal long-axis view:
- 2-D imaging
- Color Doppler mitral and aortic values

4.4.1.2   Right ventricular inflow view

In a modification of the parasternal long axis view, the transducer is angled to the subject's right, demonstrating the tricuspid valve anatomy

Data recorded in the RV inflow view:
- 2-D imaging
- Color Doppler tricuspid valve

4.4.1.3   Parasternal Short Axis View

From the long axis position, the transducer is rotated clockwise 90-degrees to obtain the short axis view. The exam begins at the left ventricular (papillary muscle) level to demonstrate ventricular anatomy and wall motion.

Images are recorded at the mitral valve level to show valve anatomy and motion.

Images are recorded at the aortic valve level to show valve anatomy and motion. Color Doppler is performed at the pulmonary, aortic, and (if adequately visualized) tricuspid valves.

The technician returns to the aortic valve level to perform M-mode recording of the aortic valve and left atrium. M-mode examination is performed at the papillary level taking care to orient the transducer for a view perpendicular to the long axis of the ventricle (creating a circular, rather than oblong, shape to the tomographic image). The M-mode cursor is positioned through the center of the chamber and gain settings are adjusted to optimize the boundary detection of the walls of the interventricular septum and posterior wall. While optimizing M-mode angle and image quality the echo machine display is a split screen showing both M-mode and a miniaturized 2-D image. When the data are optimal, the M-mode display is changed to full screen. The **FREEZE** button is pressed after a full sweep is displayed in the larger format.

The same procedure is carried out for the images at the aortic valve level, described above.

NOTE: If the technician feels that the image data are technically better from the parasternal long-axis view, then that view will be used for M-mode data, positioning the cursor just beyond the mitral leaflet tips and carefully selecting the image plane to coincide with the long axis of the left ventricle. The M-mode data at the aortic valve level may also be obtained from the parasternal long-axis view if image quality is felt to be significantly better than short axis.

Data recorded in the parasternal short axis views:

- 2-D at aortic, mitral, and pulmonary valves
- Color Doppler of valves at aortic level
- 2-D images of LV at papillary level
- M-Mode of LV at papillary level
- M-Mode of Aortic valve and LA

4.4.2 Apical Views

These views are performed in the interspace where the ventricular apex is felt, usually in the left 5th or 6th interspace in the between the midclavicular and anterior axillary lines.

4.4.2.1 Apical 4 Chamber View

The technician strives to achieve an imaging plane directly over the left ventricular apex, parallel to the interventricular septum, and rotated in a manner to show all 4 chambers and both the mitral and tricuspid valves simultaneously.

For efficiency in the protocol, the technician will perform pulsed wave spectral Doppler examinations first.

For mitral inflow data, the range gate is placed near the tips of the mitral leaflets with small adjustments in angle to obtain maximum flow velocity data with a narrow spectral dispersion. After 2-D directed placement of the range gate cursor using the split screen (Doppler and miniature 2-D) mode, a full screen sweep of spectral Doppler is frozen on the screen. A Doppler range gate is placed in the pulmonary vein just posterior to the left atrium, and spectral Doppler recordings are made in the same manner as mitral inflow recordings.

For aortic outflow data, the transducer is tipped to image slightly anterior from the 4 chamber view to show the aortic valve and outflow tract (the "5 chamber" view). The range gate cursor is placed in the left ventricular outflow tract about 0.5 to 1 cm proximal to the aortic valve, again trying to demonstrate a pattern of narrow spectral dispersion and a well-defined velocity profile. Data are recorded as for mitral above. The Doppler mode is then switched to CW (continuous wave) and the interrogating beam directed through the aortic valve to measure peak velocity.

Next the focus in on clear 2-D images of the 4 chambers and AV valves. This view is recorded with particular attention to definition of LV wall boundaries and wall motion.

Data recorded in the apical 4 chamber view:

- Pulsed Doppler of mitral inflow
- Pulsed Doppler/CW Doppler of aortic outflow ("5 chamber view")
- 2-D images of 4 chamber view
- Color Doppler (mitral, aortic, tricuspid)
- Pulsed Doppler of pulmonary vein flow

4.4.2.2   Apical 2 Chamber And Long Axis Views

From the 4 chamber view, the transducer is rotated along its imaging axis 90 degrees counterclockwise to show the left ventricle and atrium from the apex (the 2 chamber view). This view is recorded and the 2-D images are captured on the digital system with particular attention to definition of LV wall boundaries and wall motion. The transducer is rotated slightly to simultaneously image the mitral and aortic valves (the apical long axis view) and color flow Doppler data is recorded.

Data recorded in the apical 2-chamber and long axis:

- 2-D image of 2-chamber view
- Color Doppler of mitral/aortic in long axis

4.4.3   Supplementary Views

With the important priority of measuring LV wall and chamber dimensions, inability to obtain useable images from other acoustic windows (especially parasternal) should prompt the technician to image from the **subcostal view**. Both a 4 chamber view and a short axis of the LV at the papillary level should be attempted. Recognition by the technician of significant abnormalities should prompt further examination which may require additional views. For example, a suggestion of aortic root dissection should prompt examination from the **suprasternal notch**. Sometimes supplementary Doppler interrogation from standard views is required, such as with the recognition of valvular aortic stenosis where continuous wave Doppler (CW) should be carefully employed to measure peak flow velocity through the valve.

4.5   Completing the Study

4.5.1   Completing Data Storage.

The final procedure for the echo examination is to indicate the completion of the study [by keyboard command on the echo machine] so that the images can be transmitted to the network server and subsequently to the digital archive.

4.5.2   Completing the Participant Encounter

During the file save operation is a convenient time to disconnect the EKG cable and remove the electrode pads. Provide the participant with a towel to remove any residual ultrasound gel while he/she gets dressed.

4.6   Transmittal of Data to the Echo Reading Center

At the completion of the day's studies, any written worksheets and logs are copied and packaged together for pickup by the ERC where the data will be analyzed. It is anticipated that studies will be delivered on a daily basis. The studies will be logged in at the Reading Center using the information on the technician worksheets. The echo study itself is stored on the image server accessible to the ERC over the imaging system's network connections. Each study's progress through the reading and data entry processes will be noted in the logs of the reading center.

5.0 ECHO READING CENTER WORK

5.1   Overview

The reading protocol is designed with consideration for several important factors. Foremost, the data must be accurate and reproducible. The techniques used conform to widely accepted standards, where they exist; where they do not, data is analyzed in an optimal fashion based on technical calculations, validation, and/or recommendations from other laboratories. In contrast to most previous studies, all the quantitative data are computer-driven measurements from digitized images. This method is consistent with the techniques used in the ARIC Study echocardiographic work. The techniques and computer systems used are anticipated to be the most widely applied in both clinical and research echocardiography as most methods of "hard copy" are abandoned. Indeed, routine M-mode echocardiography has been largely discontinued in many clinical laboratories because of its technical difficulty and because of the widespread acceptance of 2-D image measurements in clinical labs. M-mode, however, retains important historical significance and usefulness as a research tool, and care has been taken to record optimal M-mode data and to use standard conventions for analysis. The digital imaging system used for the study represents the state of the art in echocardiography storage and analysis systems as it has evolved with availability of powerful computer systems, massive data storage devices, and fast, scalable networks. Such systems are widely available to clinical echo labs as well. The system has been shown to produce accurate measurements from previous validation studies, and the protocols allow rapid, efficient generation of the study data.

We propose a general approach to the recording and scoring of the M-mode, two-dimensional and Doppler echocardiographic data.

For M-mode echocardiographic, pulsed and continuous wave Doppler parameters, measurements will be made, when possible, from 3 (consecutive) beats. The American Society of Echocardiography Standards will be used for making all M-mode echocardiographic measurements.

For M-mode measurements of the left ventricle, left atrium and aorta, all of which will be derived from a cursor positioned on the two-dimensional image, measurements will not be made from beats recorded with the cursor at a greater than 20 degrees angle to the meridian. In addition, in the two-dimensional parasternal short-axis view, M-mode left ventricular measurements will not be made when, in the absence of wall motion abnormalities, there is an eccentricity index of 1.3 - i.e., when the radius of the left ventricular cavity in one axis is less more than 30% larger than the radius of the cavity in another axis.

The criteria for quality control suggested by Schieken and associates will be used as a gold standard to determine acceptable quality of M-mode echocardiograms of the left ventricle. These criteria are:

1.   generation of a single dominant line representing each interface being imaged

2.   demonstration of continuous interface lines at least 5mm in length at the point of measurement; and

3.   demonstration of interfaces with the motion pattern characteristic of the specific cardiac structure being imaged

For two-dimensional echocardiographic parameters, measurements will be made from a single optimal beat. Criteria for selection of beats will include:

1.   recording the image in the proper plane without producing ovoid images from improper angulation in the short-axis view, or apical foreshortening from improper angulation in the apical views;

2.   recording the most clearly visible endocardial and epicardial interfaces. Left ventricular measurements will not be made from a given view if at least 80% of the endocardium (or epicardium) is not visualized well enough for planimetry. The black-white interface, rather than the leading edge,

will be used to planimeter the endocardium. For purposes of planimetry, the papillary muscles will be included within the left ventricular cavity.

Images will be selected at end-diastole and end-systole for computation of left ventricular diastolic volume and mass, end-systolic volume, and ejection fraction. The video frame closest to end-diastole will be identified by reference to the simultaneously recorded mitral valve: the frame showing initial coaptation of the mitral valve marks end-diastole. The first frame in which QRS complex appears on the EKG channel may also be used to mark end-diastole. End-systole will be determined by locating the frame preceding initial diastolic mitral opening. If the mitral valve is not seen, the smallest visible left ventricular dimension will be selected.

For pulsed Doppler measurements of aortic and mitral peak velocities and flow velocity integrals, spectral curves will be traced using peak velocity conventions. Measurements will not be performed from pulsed Doppler beats demonstrating maximum spectral dispersion greater than 30% of peak velocity.

5.2   Echocardiographic Findings Triggering "Alert" and "Notification" Procedures

Each echocardiographic study will be interpreted clinically by one of the ERC cardiologists within a few days of the examination. If there is any question raised by the echo technicians regarding clinically important abnormalities, the echo study is read immediately following the completion of the study. This approach led to timely detection of the clinically important abnormalities found in the ARIC echo study.

5.2.1   Echo "Alert" (Emergent) Parameters

- Aortic dissection
- Vegetation
- Tumor
- Flail leaflet
- Thrombus
- Suspected pericardial tamponade

Suspected pericardial tamponade will be defined echocardiographically as the presence of a pericardial effusion with right atrial and right ventricular chamber collapse and respiratory variations exceeding 30% in Doppler peak velocities recorded at any cardiac valve site.

"Alert" findings are those echocardiographic conditions (listed above) which will trigger an "urgent" phone call by the reading cardiologist to the EC co-investigator oversight of the JHS participants clinical issues. The ERC cardiologist will contact the participant's physician of record, if so directed by the EC physician, in order to communicate the findings and the relative urgency indicated by the findings.

5.2.2   Echo "Notification" (Urgent, Not Emergent) Parameters

"Notification" conditions are those echocardiographic findings which will be reported promptly, but not emergently to the EC P.I. These findings should trigger a statement commenting on their presence as part of the letter sent to the referring physicians.

- LV ejection fraction less than 30%
- Aortic aneurysm
- LV enlargement: LV end-diastolic dimension greater than 6.5 cm
- Aortic stenosis: Aortic valve area less than 1 cm squared (or peak velocity greater than 4 m/sec).

5.3   Quantitative and Qualitative Data Elements Measured and Recorded

The following sections summarize the technical plan for recording, analyzing, storing and transmitting the echocardiographic data.

5.3.1   Ultrasound Imaging Equipment

Images are acquired using the Agilent (Hewlett Packard) Sonos 4500 imaging system with system setting, software, and transducers optimized for cardiac ultrasound imaging. Two-dimensional and M-mode imaging is at an approximate frequency of 2.5 megahertz (MHz) using current generation phased array transducer. Internally, the image is a digital matrix. Digital and analog video outputs are produced by the echo machine for recording and archival.

5.3.2   Digital Image Acquisition

The Sonos 4500 is modified with a digital image capture module replacing the traditional video tape recorder. Echocardiographic images are stored chronologically into the digital system in a manner exactly like they would be recorded onto videotape. The technician uses a "Tape" button to start and stop recording as the various echo views obtained during the course of the examination. Study identification information and the recorded images are saved onto a central digital image server where they reside on a massive array of hard disk drives. This server is optimized for data storage, fault tolerance, and security. Data are stored on a RAID array (Redundant Array of Inexpensive Disks) to virtually eliminate risk from hardware failure. The digital image server automatically records the study onto permanent archive media ("DLT" or Digital Linear Tape). The echo studies stored on the image server are available on the network for review and analysis by use of image workstations. These workstations may also be used to record a permanent record in DICOM-compliant CD format.

5.3.3   The Reading Workstation

The technician worksheets are delivered to the Echo Reading Center to begin the analysis process. Each echocardiographic study will undergo both a clinical reading as well as quantitative measurement of specific cardiac findings. Together these data comprise the echo data set that will ultimately be forwarded to the JHS CC.   This workstation is a high-end PC-based workstation with specific hardware and software to facilitate the realtime playback of echo studies and to efficiently accomplish the quantitative measurements that are to be made.   Both the images and the computer assisted measurements are stored on the digital image server.

5.3.4   The ERC database

The final common location for all the non-image data generated by the analysis process is a database stored on an network server computer which is located at the Echo Reading Center. The database, written using Microsoft Access, consolidates the various sources of data to facilitate data archival, quality control procedures, data transmission to the Coordinating Center, and data analysis. Keyboard entry is required for data items recorded on the Technician Worksheet and the Reading Worksheet. Quantitative data is imported from the network image server's Oracle database to avoid keyboard entry errors. There is at least one form of backup for each type of data, and the entire consolidated database is backed up by disk mirroring and magnetic tape archives on a daily basis. Finally, cumulative data sets are sent to the Coordinating Center (CC) on a regular basis to form the study's "official" data files. The listing of the ERC database fields represents the data items that will be collected for transmission to the CC (Appendix 3).

5.4   General Guidelines for Measurements

The following sections discuss the ERC analysis guidelines and processes. The echo studies will undergo clinical as well as analytic review. In Section 5.2, the issue of alert notifications was discussed.

5.4.1   Clinical Review

Appropriate sections of the Reading Worksheet are completed by the reader during the video review. The video is viewed on the workstation's monitor by retrieving the participant from a list of available

studies on the image server, and playing the motion video using the playback dial and other controls. This process is much like reviewing a videotape on a VCR.

First, view the parasternal long axis 2-D images for evaluation of chambers sizes (LV, LA, and aortic root), for LV wall thicknesses, for valvular morphology and motion, and for a general clinical review for other abnormalities (right ventricular size, pericardial effusion, vegetation, thrombus, aortic dissection, etc.).

Determine the relative angle between the ultrasound beam in the axial direction and the interventricular septum. When the septum is more 20 degrees from being perpendicular to the axial direction, the subsequent M-mode data will not be useable due to the artifactual effect of this angulation on dimensional measurements.

Evaluate and record regional wall motion. Normal wall motion requires no entry on the wall segment diagram of the Reading Worksheet. Regional segments with abnormal motion or ones which are not interpretable are marked by writing a code letter in that segment of the diagram (H=hypokinetic, A=akinetic, D=dyskinetic, and X=not interpretable). An entire view may be marked as "not useable" by marking the appropriate above that view's diagram. This process will, of course, apply to the interpretation of wall motion in each of the four recorded views of the left ventricle.

Next, view the color flow Doppler data for the parasternal long axis view. A composite interpretation of the color flow data will be recorded later after reading data from the other views.

The parasternal short axis 2-D images are viewed next. Evaluate the technical quality of the study by the presence of a circular shape to the chamber at the papillary muscle level; the ratio of the LV diameter in the axial direction to the perpendicular LV diameter should not exceed 1.3. If it does, M-mode data of the LV derived from the parasternal window will be marked as "Not Useable" (as described in following sections), and 2-D dimensional measurements may not be made from the short axis view but may be obtained from the long axis view.

Regional wall motion is recorded for the short axis view at the papillary muscle level. Examine valve morphology and motion in the short axis view at the aortic valve level. Interpret color flow Doppler data at this level.

M-mode recordings of the LV and aorta/LA are generally next on the recording. Although no clinical interpretation is rendered from the M-mode, it is important to examine the recording for proper M-mode cursor placement just beyond the mitral leaflet tips (for LV), and for reassessment of the (optimally perpendicular) angle between the M-mode cursor (axial) and the septum.

The technician has now switched to the apical window to record pulsed Doppler data of the mitral inflow. Although no interpretation is rendered from the videotape, the study is evaluated for technical features. In the apical 4 chamber view, the pulsed Doppler range gate should have been placed in a position near the mitral leaflet tips during diastole which produces well-defined E and A waves with minimal spectral dispersion. Pulsed Doppler recordings of the left ventricular outflow tract should have been made in the apical 5 chamber view with the Doppler range gate in the outflow tract, well away from the mitral inflow and about 0.5 to 1.0 cm below the aortic valve. The ideal apical window places the ultrasound beam nearly parallel to each of the two flows measured in this section. If more than a 30 degree angle is present, the data should be marked as "not useable".

Next, evaluate the real-time 2-D images of the apical 4 chamber and 2 chambers views. Record regional wall motion abnormalities and interpret the color flow Doppler data. At this point, all color flow data has been viewed, so that an overall interpretation of each valve's data can be recorded. Look for other abnormalities to complete the clinical interpretation. Specifically, record the presence or absence of an LV aneurysm or thrombus.

An abnormal echodense object in or near the apex of the LV is assumed to be thrombus, especially in association with abnormal wall motion in that area. Intracardiac masses located elsewhere in the heart, especially those attached to valves, are not assumed to be thrombus and are recorded in the "Other findings:" section of the Reading Worksheet. These findings are examples of "alert" findings which should elicit prompt notification as described in a Section 5.2.

5.4.2   Categorizing Clinical Findings

The recorded echo study has now been reviewed. Go down the worksheet to record final interpretations of qualitative and semi-quantitative data which may require integration of findings from all four views. The Appendix includes a sample of the Echo Reading Worksheet.

The presence and severity of chamber enlargement is based on a clinical interpretation of the videotaped data an is not assigned or reassigned based on subsequent quantitative measurements of the digital data.

The presence and severity of LV hypertrophy is judged on clinical experience with echo interpretation and is not to be assigned based on subsequent quantitative dimensional or mass measurements.

The LV ejection fraction is a visual estimate of normal, borderline, or abnormal overall systolic function. Assign an overall regional wall motion interpretation as described above.

Mitral and aortic leaflet morphology is assigned as "None or Minimal Sclerosis" when no more than a slight increase in echogenicity of the leaflets is present and valve motion is normal. "Definite sclerosis" is assigned when echogenicity in the leaflets is clearly abnormal and/or there is leaflet thickening with no more than mild restriction to leaflet motion. "Definite stenosis" is assigned when leaflet motion is significantly restricted. The study protocol does not specifically call for continuous wave Doppler data to estimate valve gradient or area, but if obtained by the technician as supplemental data, this may be used for assignment of valve abnormality.

Record the presence and severity of valve regurgitation based on integration of all the color flow data.

5.4.3   Quantitative Measurements

Image workstation software will be used to measure the following parameters.

LV septum thickness - diastole   M-MODE
LV septum thickness - systole   M-MODE
LV diameter - diastole   M-MODE
LV diameter - systole   M-MODE
LV posterior wall thickness - diastole   M-MODE
LV posterior wall thickness - systole   M-MODE
Left atrium diameter M-MODE
Aortic root diameter M-MODE
Percent fractional shortening of LV M-mode diameter (calc)
LV mass from M-MODE data
LV septum thickness - diastole   2-D
LV septum thickness - systole   2-D
LV diameter - diastole   2-D
LV diameter - systole   2-D
Percent fractional shortening of LV 2-D diameter (calc)
LV posterior wall thickness - diastole   2-D
LV posterior wall thickness - systole   2-D
Left atrium diameter   2-D
Aortic root diameter   2-D
LV mass from 2-D data (calc)
Doppler aortic outflow MEAN velocity
Doppler aortic outflow PEAK velocity
Doppler aortic outflow Velocity Time Integral
Heart rate during aortic Doppler study
Systolic ejection time
LV outflow tract cross sectional diameter
LV stroke volume = CSA x VTI (calc from AOVSCSA_V x AOSYSVL_V)
Cardiac output = HR x SV (calc from AOHR_V x AOSTKVL_V)
Cardiac index = C.O. / BSA
Doppler mitral inflow peak velocity of E wave
Doppler mitral inflow peak velocity of A wave
Doppler mitral inflow ratio of peak E to peak A
Doppler mitral inflow VTI of E wave
Doppler mitral inflow VTI of A wave
Doppler mitral inflow VTI of first 1/3 of diastole
Doppler mitral inflow Ratio of E-wave VTI to total diastolic VTI
Doppler mitral inflow Ratio of A-wave VTI to total diastolic VTI
Doppler mitral inflow Ratio of first 1/3 VTI to total diastolic VTI
Heart rate during mitral Doppler study
Diastolic filling time
Total diastolic VTI

[NOTE: The details of the measurement process will be found in the Operator's Manual of the image workstation software. Such a manual is available in preliminary form pending final selection and purchase of the analysis equipment. Further details can be developed in this section or obtained from the Operator's Manual after equipment acquisition.]

Measurements will be made by the cardiologist co-investigators. As technicians gain experience in the JHS study protocol, the echo study investigators may choose to implement a protocol allowing some measurements to be completed by the echo technicians with subsequent review by the cardiologist co-investigators. Such a protocol would be preceded by training of technical personnel, certification of their work in a pilot phase, followed by implementation of technician measurements with appropriate quality monitoring. The goals of the study in obtaining consistent, reproducible, and accurate echo data will be facilitated by limiting analytical measurement work to one or two highly experienced cardiologists, but other large centers such as Framingham have successfully employed technicians to do a significant proportion of the measurement work.

6.0 TECHNICIAN TRAINING, CERTIFICATION, AND QUALITY MONITORING

6.1   Technician Training

The EC will recruit cardiac sonographers in hopes of hiring individuals with strong experience in clinical imaging and/or study protocol imaging. Under direction of the cardiologist co-investigator, two sonographers will undergo training to perform echocardiography examinations per the JHS echo exam protocol. Training will begin with basic didactic sessions on the goals of the echo examinations and the priorities placed on accuracy and consistency throughout the imaging protocol. The echo machine operation and control settings will be taught during actual examinations by the technicians-in-training under cardiologist supervision on JHS staff volunteers. The cardiologist offers guidance, suggestions for improvement, and answers questions as they arise.

6.2   Technician Certification

After the initial training (and in conjunction with the pilot testing procedures), each technician will undergo certification by performing 10 complete echocardiogram examinations (performed during the pilot Phase I). The technician's examination will be scored for each 2-dimensional imaging view, M-mode, and Doppler examination. For imaging modes, grading will be based on proper spatial orientation and definition of good endocardial and epicardial boundaries. For Doppler modes, grading will emphasize proper orientation of the interrogating beam and measurement gate, and of the ability to obtain clear Doppler data demonstrating smooth velocity contours with highest velocity for spectral Doppler, and consistent beat-to-beat data for the Doppler color flow mode.

For each imaging view, 2-D, M-mode, and Doppler exams, a quantitative score of 3 is given for "excellent" data recordings that provide images and/or Doppler data of unequivocal clarity such that quantitative measurements are easily made, a score of 2 is given for "average" quality recordings with data that is confidently measurable, a score of 1 is given for "fair" quality recordings which are marginally acceptable for measurements, and a score of 0 (zero) is given for an exam component which is not usable for the study or not recorded. A simple average of at least 2.0 will be required for the technician to be certified as having adequate skills to perform the study protocol. Any technician failing to meet certification requirements will undergo additional training and re-testing before performing independent examinations on study participants.

While the technicians will be expected to complete the echocardiogram study within 30 minutes, a strict time limit will not be imposed during certification procedures.

In the event that a new technician joins the study staff, the same initial training and certification procedures will be followed as described above.

In addition to these certification procedures, technician training and refinement of techniques will be an ongoing process, facilitated by the fact that the ERC cardiologist staff will be a working closely with each of the technicians throughout the JHS Visit cycle.

6.3   Monitoring

Echocardiographer performance is monitored throughout the examination cycle. The cardiologist co-investigator will record data quality and adherence to the scanning protocol as part of the reading process for each echo study. The appropriateness of spatial orientation, the visualization of the endocardial and epicardial boundaries, and the transducer placement will be evaluated and recorded in the echo study's data record.

Quality is monitored throughout the study. The quality control procedures consist of (a) comparing the results given by the same sonographer for repeat studies performed on randomly selected participants; (b) monthly reports containing statistics of the frequency of successful examinations by sonographer

(grade 2 or 3 on reader evaluation); (c) trending of core data items to evaluate inter-sonographer differences and drift.

6.4   Recertification

Recertification will be performed at 12 month intervals for the all technicians. At the certification anniversary, five randomly selected scans performed by each technician during the prior month are reviewed and evaluated by the cardiology co-investigator. The results of these evaluations, in combination with the monthly quality control reports, are considered for recertification.

A sonographer must complete a minimum of 10 echocardiograms each month to maintain certification. If less than 10 scans are performed for 2 consecutive months (but not more than 2 months), the technician must undergo recertification as follows:

A.   The cardiology co-investigator updates the technician regarding changes in procedures;

B.   The technician scans 10 participants per month;

C.   Routine quality control checks continue;

D.   The sonographer remains on the current annual recertification procedure.

If the sonographer performs no scans for more than two months, the recertification process is as follows:

A.   The cardiology co-investigator updates the technician regarding changes in procedures;

B.   The technician observes a minimum of four scans;

C.   The first four scans performed by the technician are performed under supervision by the cardiology co-investigator;

D.   When four consecutive scans are considered acceptable by the reader (cardiology co-investigator), the technician is recertified.

If a major change in the echocardiography protocol occurs, sonographers will undergo recertification as follows:

A.   The cardiology co-investigator will update the sonographer on the new protocol;

B.   The technicians will observe at least one scan performed by the cardiology co-investigator;

C.   The technicians perform four scans on JHS participants under the supervision of the cardiologist;

D.   When four consecutive scans are considered acceptable by the reader (co-investigator), the sonographer is recertified.

If quality assessment at the reading center indicates significant reduction in a technician's study quality, individualized training and/or recertification examinations may be required.

6.5   Quality Assessment

6.5.1   General

The utility of echocardiographic measures of cardiac anatomy and function has been demonstrated in clinical and population studies. Cardiac abnormalities assessed by this techniques (e.g., left ventricular hypertrophy) have been associated with an increased incidence of cardiovascular morbidity and mortality. Given the greater sensitivity and specificity of echocardiographic measure in comparison to other indirect measures of cardiac abnormalities, the echocardiogram may serve as a surrogate measure of preclinical manifestations of cardiovascular disease and as a prognostic indicator for future clinical events (i.e., hypertension, myocardial infarction, and/or stroke).

Since this is a large scale population study of African-Americans from which a very valuable data set will be generated, quality control is of particular importance. Previous population studies (ARIC, Framingham Heart Study, CARDIA, and CHS) have indicated that considerable training and experience are required to assure optimal echocardiographic data acquisition of sufficient quality. The goals of this strict echocardiography quality control program are to (1) provide quantitative documentation of the reproducibility of the scanning and reading procedures, and (2) assure the comparability of the JHS echo scanning and reading procedures with ARIC and other important echocardiography data sets.

6.5.2   Essential Features of the Quality Control Program

1. To assure adherence to study protocol, supervision of the performance of echocardiographic procedures utilized by technicians will be done by the ERC cardiologist staff, each highly experienced in echo methodology and research.

2. Regular meetings among technicians and reading center physicians will be conducted. At these meetings, the staff will critically review studies to identify opportunities for improvement in data quality and security, and in efficiency and details of protocol. The technicians will better recognize the image quality and techniques necessary to allow the study readers to obtain accurate, reproducible quantitative information. At the same time, the study cardiologists can provide ongoing feedback to improve the technicians' skills, their understanding of ultrasound principles, and their recognition of echocardiographic abnormalities.

3. To identify potential protocol deviations, difficulties, or inefficiencies, consultant experts in the field may periodically visit the EC to assess scanning and reading procedures.

4. Assessment of inter- and intra-technician/reader variability.

6.5.3   Technician Quality Assessment Procedures

6.5.3.1   (Omitted)

6.5.3.2   Assessment of Intra- and Inter-Reader Variability During the Pilot Phase

To provide estimates of intra-reader repeatability, after initial reading of the pilot phase testing/certification, 50% of the scans will be reread by the same reader. The remaining 50% will be read by a second reader. Additional repeat readings will be performed throughout the study.

In addition to the above quality control procedures a random sample of 20 echocardiograms performed during the first three months of the study may be sent to consultants for reading.

6.5.3.3   Assessment of Intra-technician Variability During the Examination Period

Intra-technician variability will be assessed throughout the examination period by the performance of quality control repeat echocardiograms in a 5% random sample of participants. The Coordinating Center

will generate a list of randomly selected JHS IDs for the purpose of QC repeat examinations. After the initial scan on each participant is complete, the technicians will check the QC master list to determine eligibility of the participant for repeat measurements. If the participant's ID matches the QC list, he/she will be asked to volunteer for a repeat echocardiogram.

7.0 OVERVIEW OF DATA HANDLING

The study procedures have been designed with consideration for optimizing completeness, integrity, and safety of the data collected. There is redundancy in data collection and storage, automation and/or range-checking during data entry, use of analog and digital media in industry-standard formats, and appropriate quality monitoring activity.

Technicians record image and Doppler data as digital images which are stored on a digital image server's hard disks. These massive disk arrays are configured with hardware redundancy so that hardware failure will not result in data loss. In addition, the completed studies are automatically archived, as a background task, to permanent storage media. As previously mentioned, the data are stored in DICOM-compliant system to provide the broadest versatility for data exchange and future compatibility.

The Echo Reading Center will maintain a computer database for storage of all the data relevant to the echo studies. Participant identification and qualitative observations made at the examination will be input from written data on the technician worksheets. Qualitative data generated by the reading center's review of the study will also be entered from written worksheets. Quantitative results of measurements on the analysis workstation will be directly imported into the database without keyboard data entry. This process will not only duplicate other written and electronic records of this information but also consolidate data for local analysis and for ease of archiving the study results onto the UMC network servers.

Data on all network servers are backed up on a daily basis by the UMC Department of Information Systems (UMC DIS). Data security and confidentiality are ensured by network and application level login requirements. Access rights are determined by the data "owners" (in this case, the JHS through the EC and ERC) and are implemented by UMC DIS network managers.

All data required for analysis will be transmitted to the Coordinating Center where the official analysis files will be maintained. The ERC will develop an export and transmission process to suit the CC's needs for specific data formats.

8.0 COLLABORATION WITH JHS CENTERS AND COMMITTEES

The ERC will be primarily responsible for development of the echocardiography protocol, training of JHS technicians and other personnel in execution of the protocol, and monitoring of protocol adherence. In these roles, collaboration and coordination of activities with other Examination Center components will be required. The ERC will collaborate with the Coordinating Center in early phases to develop data transmission formats and procedures. The ERC will develop any custom software interfaces or other procedures necessary to format and deliver the JHS echo data to the CC.   The ERC will collaborate with the CC throughout the study to provide and evaluate quality control data, and to respond to CC requests to reassess additional questions that might arise.

9.0 TIMING GOALS

The ERC will have a goal for examination and reporting of echo study data within 2 weeks of the examination. Transfer of data to the CC will occur at a frequency requested by the CC but no more often than monthly. The quality checks and data "cleaning" must occur at the ERC with ample opportunity for detection of measurement and data entry errors prior to committing the data to the CC's database. The clinically relevant reading of the echo study will be done within 24 to 48 hours of the examination. Other requirements of the CC, for example quality control reports, will be generated in a timely manner in collaboration with the ERC.

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APPENDICES

JHS Echocardiography   Technician Worksheet

Name   : _____   ID   : _____   Date   : _____

Age   : _____   BP   : _____ / _____   HR   : _____

Height   : _____ (cm) (in)   Weight : _____ (lb) (kg)

Tech ID: _____   Data storage

Position for study: ☐ 45° left   ☐ OTHER: _____

LV M-mode from   ☐ para. short   ☐ para. long   ☐ unobtainable

Ao/LA M-mode from   ☐ para. short   ☐ para. long   ☐ unobtainable

Comments

2-D or color flow

M-mode

Pulsed Doppler

Other

Alert findings: ☐ Aortic dissection*   ☐ Aortic stenosis
                     ☐ Thrombus*   ☐ Mitral stenosis
                     ☐ Vegetation*   ☐ Mod/Severe _____ regurg
                     ☐ Large pericardial effusion* ☐ Marked LV dysfunction
                     * Called Dr. _____ Date/Time: _____

Study Time: *START:* _____   *STOP:* _____
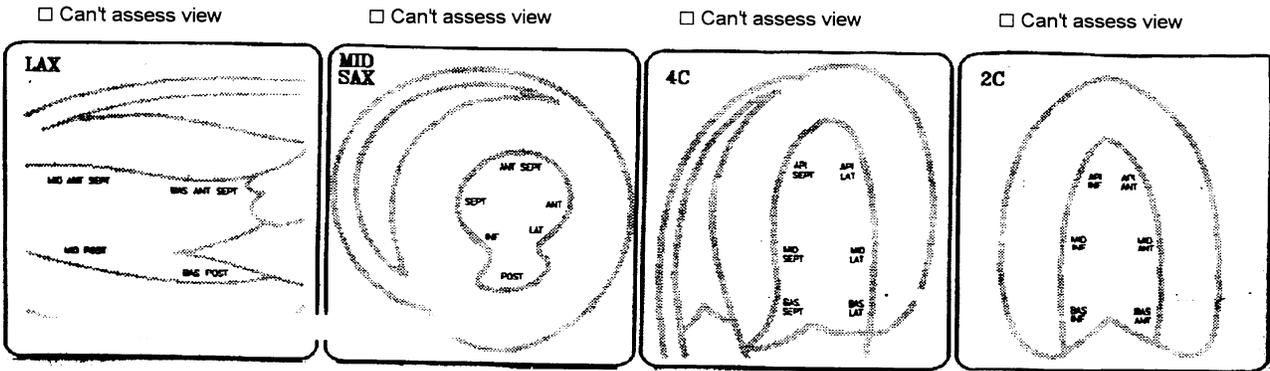
JHS Echocardiography   Reading Worksheet

Reader ID _____   Date: _____ Archive # _____

QUALITATIVE 2-D DATA

LA enlargement	□ None **[0]**	□ Mild **[1]**	□ Mod **[2]**	□ Severe **[3]**	□ Can't assess **[9]**
LV enlargement	□ None	□ Mild	□ Mod	□ Severe	□ Can't assess
Ao root dilation	□ None	□ Mild	□ Mod	□ Severe	□ Can't assess
LV hypertrophy	□ None	□ Mild	□ Mod	□ Severe	□ Can't assess
LV ejection fraction	□ Normal	□ Mild ↓	□ Mod ↓	□ Severe ↓	□ Can't assess
LV regional wall motion	□ Normal **[N]**	□ Borderline **[B]**		□ Definitely abnormal **[A}**	□ Can't assess **[9]**

MARK ABNORMAL SEGMENTS: *H=hypokinetic A=akinetic D=dyskinetic X=can't assess segment*

□ Can't assess view   □ Can't assess view   □ Can't assess view   □ Can't assess view

Aortic leaflets	□ Min or no sclerosis **[0]**	□ Definite sclerosis **[1]**	□ Definite stenosis **[2]**	□ Can't assess **[9]**
Mitral leaflets	□ Min or no sclerosis	□ Definite sclerosis	□ Definite stenosis	□ Can't assess
Mitral Regurgitation	□ None **[0]** □ Trace **[1]**	□ Mild (clearly abnl) **[2]**	□ Mod/Severe **[3]**	□ Can't assess **[9]**
Aortic Regurgitation	□ None □ Trace	□ Mild	□ Mod/Severe	□ Can't assess
Tricuspid Regurgitation	□ None □ Trace	□ Mild	□ Mod/Severe	□ Can't assess
Pulmonary Regurgitation	□ None □ Trace	□ Mild	□ Mod/Severe	□ Can't assess
Mitral anular calcif.	□ None	□ Mild	□ Mod/Severe	□ Can't assess
Mitral prolapse	□ None	□ Mild	□ Mod/Severe	□ Can't assess
Ao Root fibrocalcific chg	□ None	□ Mild	□ Mod/Severe	□ Can't assess
LV aneurysm	□ None **[N]**	□ Ant/apical **[A]**	□ Inf/posterior **[I]**	□ Can't assess **[9]**
LV thrombus	□ No **[N]** □ Yes **[Y]**			□ Can't assess **[9]**

2-D : LV Measured from	□ para. long **[L]**	□ para. short **[S]**	□ Not measured **[9]**
M-mode : LV Measured from	□ para. long **[L]**	□ para. short **[S]**	□ Not measured **[9]**
Septal orientation >30 ?°	□ No □ Yes		

OTHER ECHO FINDINGS:

STUDY QUALITY

	EXCELLENT (3)	GOOD (2)	FAIR (1)	NOT USEABLE (0)	NOT RECORDED (9)
2-D parasternal	□	□	□	□	□
2-D apical view	□	□	□	□	□
M-mode LV	□	□	□	□	□
M-mode Ao/LA	□	□	□	□	□
Doppler - mitral	□	□	□	□	□
Doppler - Ao/LVOT	□	□	□	□	□
Color flow data	□	□	□	□	□

ALERT FINDINGS / ACTION TAKEN : □ none
OTHER COMMENTS ON PROCEDURE OR DATA:

Appendix 3   Echo Reading Center Database Field Definitions

Echo Reading Center Database field definitions

ID	JHS ID
DATE	Study Date
Tech	Technician Initials
Reader	Reader Initials
ReadDate	Reading Date
PTNAME	Participant Name
Archive Disk	Disk/tape for permanent archive
Videotape	Videotape if study is recorded
ReadSeq	Reading order (QC)
Seq	Study scan order (QC)
AGE	Age
HEIGHT	Height
HEIGHT_UNT	units, CM/IN
WEIGHT	Weight
WEIGHT_UNT	units, LBS/KG
BSA	Calculated body surface area
BPREST_S	Systolic BP
BPREST_D	Diastolic BP
qLADil	Left atrial dilation (0=No 1=Mild 2=Mod 3=Sev 9=Can't assess)
qLVDil	Left ventricular dilation
qAODil	Aortic root dilation
qLVH	LV hypertrophy
qLVEF	Degree of LV dysfunction
qLVRWM	Regional wall motion (N=Normal B=Borderline A=Abnl 9=Can't assess)
qAVLEAF	Aortic leaflets (0=Normal 1=Sclerosis 2=Stenosis 9=Can't assess)
qMVLEAF	Mitral leaflets
MR	Mitral regurgitation (0=None 1=Trace 2=Mild 3=Mod/Sev 9= ?)
AR	Aortic regurgitation
TR	Tricuspid regurgitation
PR	Pulmonary regurgitation
MAC	Mitral Anular Calcification (0=None 2=Mild 3=Mod/Sev 9= ?)
MVP	Mitral Valve Prolapse
AoCalcif	Aortic root fibrocalcific change
LVAneurysm	LV Aneurysm present? (N=No A=Ant/apical I=Inf/Posterior 9=?)
LVClot	LV thrombus present ? (N=No Y=Yes 9=can't assess)
OtherFindings	Other echocardiographic interpretation
2DDataView	View used to measure LV on 2D (L=para long S=para short N=Not done)
MMDataView	View used to measure LV on MM (L=para long S=para short N=Not done)
SeptalAngle	Septal angle to echo beam > 30 degrees (N=No Y=Yes)
q2DPara	Quality of 2D parasternal (3=Ex 2=Good 1=Fair 0=not usable 9=not done)
q2DApex	Quality of 2D apical views
qMMLV	Quality of M-mode of LV
qMMAOLA	Quality of M-mode of Aorta and left atrium
qPWMitral	Quality of pulsed Doppler of mitral valve inflow
qPWLVOT	Quality of pulsed Doppler of LV outflow tract
qCOLOR	Quality of color flow Doppler study
qALERT	Presence of "alert" findings (N=No Y=Yes)

Appendix 3 (con't)

COMMENTS	Comments on study, data, or anything other than clinical interp.
LMIVS_DV	LV septum thickness - diastole M-MODE
LMIVS_SV	LV septum thickness - systole M-MODE
LMLVDM_DV	LV diameter - diastole M-MODE
LMLVDM_SV	LV diameter - systole M-MODE
LMLVPW_DV	LV posterior wall thickness - diastole M-MODE
LMLVPW_SV	LV posterior wall thickness - systole M-MODE
LMLADM_V	Left atrium diameter M-MODE
LMAORT_V	Aortic root diameter M-MODE
LMLVDM_PV	Percent fractional shortening of LV M-mode diameter (calc)
LMLVMAS_V	LV mass from M-MODE data
L2IVS_DV	LV septum thickness - diastole 2-D
L2IVS_SV	LV septum thickness - systole 2-D
L2LVDM_DV	LV diameter - diastole 2-D
L2LVDM_SV	LV diameter - systole 2-D
L2LVDM_PV	Percent fractional shortening of LV 2-D diameter (calc)
L2LVPW_DV	LV posterior wall thickness - diastole 2-D
L2LVPW_SV	LV posterior wall thickness - systole 2-D
L2LADM_V	Left atrium diameter 2-D
L2AODM_V	Aortic root diameter 2-D
L2LVMAS_V	LV mass from 2-D data (calc)
AOMVELS_V	Doppler aortic outflow MEAN velocity
AOPKVEL_V	Doppler aortic outflow PEAK velocity
AOSYSVL_V	Doppler aortic outflow Velocity Time Integral
AOHR_V	Heart rate during aortic Doppler study
AOEJCTM_V	Systolic ejection time
AOVSCSA_V	LV outflow tract cross sectional diameter
AOSTKVL_V	LV stroke volume = CSA x VTI (calc from AOVSCSA_V x AOSYSVL_V)
AOCROUT_V	Cardiac output = HR x SV (calc from AOHR_V x AOSTKVL_V)
AOCRIDX_V	Cardiac index = C.O. / BSA
MIPKVLE_V	Doppler mitral inflow peak velocity of E wave
MIPKVLA_V	Doppler mitral inflow peak velocity of A wave
MIPKE_A_V	Doppler mitral inflow ratio of peak E to peak A
MIVTIEW_V	Doppler mitral inflow VTI of E wave
MIVTIAW_V	Doppler mitral inflow VTI of A wave
MIVTI3_V	Doppler mitral inflow VTI of first 1/3 of diastole
MIVTIET_V	Doppler mitral inflow Ratio of E-wave VTI to total diastolic VTI
MIVTIAT_V	Doppler mitral inflow Ratio of A-wave VTI to total diastolic VTI
MIVTI3T_V	Doppler mitral inflow Ratio of first 1/3 VTI to total diastolic VTI
MIHR_V	Heart rate during mitral Doppler study
MIFILTM_V	Diastolic filling time
MIDVTI_V	Total diastolic VTI