FRAMINGHAM HEART STUDY
OFFSPRING/EXAM 6
ECHOCARDIOGRAPHY MANUAL

Birgitta Lehman, RDCS
Emelia J. Benjamin, MD, ScM

1995-1998

TABLE OF CONTENTS **PAGE**

Introduction to Performing Echocardiography in Offspring Exam 6

Echocardiography is the investigation of choice for the noninvasive assessment of cardiac structure and function. It provides important knowledge of the prevalence, predictors, and prognosis of cardiac disease.

The echocardiography scanning time is approximately 25 minutes. Participant enters the Echo testing room, is set up with electrodes, and is placed on his side on the bed before the scanning starts.

Equipment

One Scanning Room containing the following:

- Treatment Table
- Height adjustable sonographer chair
- Hewlett Packard Sonos 1000 Ultrasound System, Andover, MA
- Hewlett Packard Sonos 1000 Monitor
- 2.5 MHz transducer
- Sony SVHS VCR system
- Foot pedal for capturing images on TomTec system

Two TomTec Echo Reading Stations, each containing the following:

- PC Work Station
- PC Monitor
- Standard Keyboard
- HP Laser Jet Printer
- Sony SVHS HiFi Videocassette Recorder
- Sony Optical Disk Unit
- Panasonic VCR Remote Control Unit
- TomTec Imaging Systems, Inc. Software for Echo measurements, Serial number 6941701
  Date: 06-17-1994

Supplies

- Transducer gel
- ECG electrodes
- S-VHS Video Cassette Tapes

- Sony M.O.D. Magnetic Optical Disks, 128 MB, for storing M-mode and Doppler frames of Echo images.

Examination & Data Cleaning Documentation Materials

- Participant and Sonographer Worksheets
- Participant ID tape labels
- Log book
- Log-In sheets

Miscellaneous

- Standard pillow - for participant
- Blanket – for participant
- Towels – for wiping gel off participant
- Latex Exam Gloves – for sonographer, optional (If participant is allergic to latex, sonographer will scan without gloves.)

Performing the Echocardiography Test

A succinct **Echocardiography Scanning protocol** is provided in the appendix. Below we will give a brief description of performing the Echocardiography test in a standard fashion at the Framingham Heart Study Clinic.

Initial Test Set Up

- In the waiting room the participant reads a set of **instructions about the Echocardiography Test** (see appendix) and signs an informed consent form before arriving at the noninvasive cardiovascular testing station. If not, have the participant read the instructions and sign the consent form before proceeding.
- The sonographer fills out the **FHS Echocardiography Sonographer worksheet** (see appendix). The reverse side of this form is used after the test for qualitative and quantitative interpretation of the echocardiography test (see appendix).

Acquisition

- Enter participant ID# and name and sonographer ID# on the Hewlett Packard Sonos 1000 Ultrasound System (in text below referred to as "HP Sonos 1000").
- Enter participant ID# and name on TomTec system.

Labeling storage media & log in sheet

- The sonographer should also enter exam date, sonographer ID#, SVHS #, CD #, and miscellaneous information for data management, on the **FHS Offspring Exam 6 Echo Log Book Sheet** (see appendix).
- Put participant ID# and name label on the SVHS cassette tape jacket.

Participant Set-up

- Place 4 electrodes on participant's chest.
  1. White - below right clavicle
  2. Green - right rib cage
  3. Black - below left clavicle
  4. Red - left rib cage
- Ask the participant to lie on his/her left side with left arm on the pillow.
- Start echo test and follow directions described in The Ultrasound Scan, see below. (See also Scanning Protocol "at a glance" on page 10).

The Ultrasound Scan

The following standard Echocardiography directions should be followed for the standard Echocardiography test. Before proceeding with the scanning, briefly explain to the participant that he will not be able to watch his heart during the test. However, at the end of the test, he will be shown his heart in motion on the monitor, if he so desires.

Parasternal Long Axis [PLA] View

- Cover transducer's matching layer with ultrasound gel and place transducer on the third or fourth intercostal space left from the sternum so that the orientation point of transducer is directed toward right shoulder and ultrasound beam is parallel to the imaginary line connecting right shoulder with the left flank.
- Start taping on HP Sonos 1000 at depth 20 cm 2-D optimal long axis of LV, so the anterior septum is not at an angle and all cardiac structures in this view are clearly visible.
- Decrease depth, get the biggest possible image without loosing LV posterior wall and continue to record. Clear definition of RV, Aortic Root, AV, LA, MV and LV.
- Narrow the sector, press color Doppler and tape flow trough MV and AV paying attention to regurgitation.

RV Inflow

- Move transducer left from the sternum as far as possible and tilt inferomedially so a long axis of the RV and RA is obtained. Show anterior and posterior leaflets of TV and tape.
- Tape color flow across TV, paying attention to any regurgitant jet.

Parasternal Short Axis [SAX] View

- Rotate transducer about 90 degrees from PLAX so ultrasound beam is perpendicular to long axis of LV and obtain short axis in 2-D.
- Start from the base of the heart showing in 2-D: Aortic root, 3 aortic valve cusps- right, left and non, LA with clear posterior wall definition (be aware of sidelobing simulating false posterior wall.
- Tape color flow on HP Sonos 1000 of AV, MV, and TV.
- Acquire 2 M-Mode full screens of Aortic Root, AV and LA on HP Sonos 1000 as well as TomTec OD. Emphasize box-like opening of aortic valve cusps.
- Tape 2-D sweep from the base of the heart to the apex showing LV wall motion and thickening.
- On your sweep back from the apex to the base, stop at MV and acquire one M-mode frame of MV on TomTec OD and tape on HP Sonos 1000.
- Tilt the transducer inferiorly and obtain cross section in 2-D of the LV at the papillary muscle level. Zoom on the LV and tape with clear boundaries of endocardium and epicardium.

- Place M-mode cursor across LV and acquire 4 frames on TomTec OD with 3 beats each, still in the Zoom mode. Also tape on HP Sonos 1000.

Apical 4-Chamber [A4C] View

- Move the transducer to the apical position in fourth intercostal space and obtain 4-chamber view.
- Start taping at depth 20 cm. Decrease depth to get biggest image possible and tape on HP Sonos 1000.
- Decrease depth, narrow the sector and obtain long axis of the LV from the apex to the mitral valve annulus. Tape on HP Sonos 1000.
- Tape color Doppler flow across MV. Confirm regurgitation.
- Place PW at MV leaflet tips and obtain highest E and A wave velocities of MV inflow. Acquire 2 frames on Tom Tec OD, 1 fast speed and 1 slow speed, as well as tape on HP Sonos 1000.
- Tape color Doppler flow across TV. Confirm regurgitation. If TR present, investigate with CW Doppler and tape on HP Sonos 1000.

Apical 5-Chamber [A5C] View

- Angle transducer anteriorly to visualize LVOT, Aortic root and aortic valve in widest excursion. LV endocardium should be clearly visible.
- Place PW Doppler sample volume in LVOT approx. 0.5 cm from the aortic valve. Aquire 2 screens of PW Doppler LVOT on TomTec OD, 1 at slow speed, and 1 at fast speed.
- Record flow on HP Sonos 1000 as well.
- Place CW Doppler sample volume in LVOT close to aortic valve and aquire highest CW speed possible.
- Also, tape color Doppler flow across aortic valve, confirming aortic regurgitation.
- Ask the participant if they are comfortable. If not readjust transducer.

Apical 2-Chamber [A2C] View

- Rotate transducer from apical 4-chamber to apical 2-chamber view, about 90 degrees counterclockwise or until right sided cardiac structures disappear.
- Narrow sector and acquire several beats in 2-D on different depths showing wall motion and endocardial thickening of LV.
- Tape color Doppler across MV, confirming any regurgitation seen in previous views.
- Decrease the depth showing anterior and posterior walls of LV from the apex to the MV annulus. Record on HP Sonos 1000.

Apical 3-Chamber [A3C] View (Also called Apical Long Axis view [ALA])

- Rotate transducer even more counterclockwise until you see AV and ascending aorta, LA, MV and LV. Narrow sector and acquire several beats in 2-D on HP Sonos 1000 on different depths showing wall motion and endocardial thickening of LV
- Tape color Doppler across MV, confirming any regurgitation seen in previous views.
- Wipe gel off the participant's chest. Ask him/her to lie supine for the last images from the subcostal region.

Subcostal View

- Begin subcostal examination by placing the transducer in the midline or slightly to the participant's right side. Direct ultrasound beam superiorly and leftward toward left clavicle. Tape subcostal 4-chamber view on HP Sonos 1000, with special emphasis on RV free wall.
- Rotate transducer to subcostal short axis. Tape a few beats showing IVC and short axis of LV from the base to the apex.

Finish the echo test, wiping the gel off the participant. Thank the participant for participation, patience and cooperation.
Before proceeding to the next testing station, briefly show the participant the images on the loops on the screen and explain in simple words the different views.

Policy regarding how "hard to press" to obtain measurable ultrasound images

Our policy on 'pressing hard' with the ultrasound transducer on the participant's chest, particularly the obese, states that we will tolerate worse images and will not press to the point of discomfort, if a participant complains during the test.

Policy regarding the length of time of the scan

Since we are limited by a time constraint in the Clinic, we have also made it a policy not to spend more than 25-30 minutes of scanning time on each participant, even if it is difficult to perform the echocardiography test on the participant, due to obesity, heavy smoking history, COPD, prior chest surgery, etc.
In the event that a participant has an abnormal echocardiogram [e.g. aortic or mitral stenosis], that requires more scanning time, the sonographer should inquire with the clinic staff if they may take an extra 5 and maximum of 10 additional minutes. If the clinic staff is concerned about work flow, and requests that the test not be extended, the sonographer may add additional images at the end of clinic, if the participant is willing to wait.

A. *Overview of Echocardiography Laboratory Quality Assurance Measures*

- **Protocol development phase**
  - 6-8 month pilot phase at the end of cycle 5, beginning of cycle 6
  - Site visit by Dr. John Gottdiener (CHS) 12/94 to aid in protocol development, and to facilitate comparability between the two studies
  - Review of the CHS echocardiography manual
  - Review of ARIC echocardiography protocol to facilitate data exchange
  - Development of new 2 page coding sheets to focus our interpretations to key variables of research interest
  - Development of following protocols & written manuals including:
    - Scanning protocol
    - Computer protocol, & interpretation sequence
    - Interpretation guidelines
    - Posted guidelines for what studies require MD over reading & what inconsistencies will trigger data cleaning
    - Data cleaning protocol
    - Reproducibility manual

- ***Laboratory meetings***
  - Weekly or bi-weekly meetings occur to review:
    - Status of readings (reviewing echocardiography log book)
    - Results of reproducibility studies
    - Interpretation issues
    - One abnormal study together to prevent readers from drifting apart

- ***Data entry***
  - Performed by one individual. The individual is instructed to return to the interpreter any echocardiography interpretation forms that are incompletely filled out.

- ***Data cleaning***
  - Cleaning of key identifying data.
  - Logic and consistency checks to make sure interpretations are correct.
  - Data cleaning is occurring on an ongoing basis, to give timely feedback to readers.

- ***Reproducibility***
  - Assessment of intra- and inter-observer reproducibility of echocardiographic measurements and interpretation 2-3 times per year 20 studies each time.
  - Requirement that personnel meet acceptable reproducibility standards before they are certified to read independently
  - Assessment of secular drift of inter-observer reproducibility of echocardiographic measurements and interpretation, by reading a calibration set annually.
  - Assessment of scanning reproducibility by scanning 20 subjects twice.

FHS ECHO PROTOCOL

Set up	***Connect ECG, verify R-beeper & tall R wave; Enter Study ID on HP; Enter pt ID Tomtec; Protocol - MM/Dop***				
VIEW	**DATA SOUGHT**	**DISPLAY**	**RECORD**	**PRI.**	**EMPHASIS**
PLA	2-D	HP	Tape	High	chamber size & function
	Color flow: AV/MV	HP	"	Med	
RV inflow	2-D	HP	Tape	Med	
	Color flow TV; if TR present cw	HP	Tape	Med	
PSA	2-D of AV, MV, TV, LA	HP	Tape	High	AV opening & # leaflets
	Color flow: AV, MV, TV	HP	Tape	Med	If TR present & cw inadequate RVI, repeat cw
	2 M-mode full screen of AV/LA	**Tomtec**	**OD**/tape	**High**	clear boundaries
	2-D sweep: LV(pap to apex)	HP	Tape	High	LV wall motion
	1 M-mode full screen of MV	**Tomtec**	**OD**/tape	Med	clear boundaries
	4 M-mode LV - magnify	**Tomtec**	**OD**/tape/chart	**HIGH**	clear boundaries
Apical 4	2-D all 4 chambers (↓ sector /depth)	HP	Tape	High	chamber size & function
	Color flow: MV	HP	Tape	Med	
	2 PW MV inflow: 1fast 1slow frame	**Tomtec**	**OD**/tape	High	position cursor @ leaflet tips (max velocity) 5 beats
Apical 5	2-D LV	HP	Tape	Med	
	2 PW LVOT: fast 1slow frame	**Tomtec**	**OD**/tape	High	position cursor in LVOT ~ .5 cm from AV; 5 beats
	Color flow AI & cw AV	HP	Tape	Med	If ?AS or AV unknown, focus on cw AV
Apical 4	Color flow TV, if TR present cw	HP	Tape	Med	
Apical 2	2-D (↓ sector & depth)	HP	Tape	High	LV wall motion, endocardial definition
	Color flow: MV	HP	Tape	Med	
Ap. long	2-D (narrow sector & depth)	HP	Tape	Med	LV wall motion, endocardial definition
	Color flow: MV	HP	Tape	Med	
Subcostal	2-D (valves/chambers/IVC/RV wt)	HP	Tape	Low	focus if other parts of study TLS; RV wall thickness
	Review & Lock M-mode/Doppler loop, note option to add additional frames of M-mode				
	Preferred; Check that desired images are "locked"on Tomtec. File and Save.				

COMPUTER PROTOCOL & INTERPRETATION SEQUENCE

1. **Turn on machine** & let machine boot up
   Click on Measure
   Echo Report; File; Retrieve; Select patient

2. **While retrieving video images** cue SVH & reset tape counter
   & fill in information header section of back of coding sheet.

3. **If no video optical disk**, measure MM off SVHS analogue M-mode
- On coding form Video OD # = tech#-000
- Select New patient and enter all the identifying data

4. **Choose patient from roster**
- Check that patient name, patient ID, study date, tape ID, height, US# are correct.
- ***IF ANY OF THE KEY IDENTIFYING DATA IS INCORRECT***
  Select new pt and fill in new roster
- Enter interpreter-study _ _ _-_ _
- Enter interpretation date __/__/__, (2 digits each)
- Accept
- A studies are exam ID 8, omni's are exam ID 7

5. After video images are retrieved
- Pop out video optical disk
- Select left heart & review video images using side arrows
- Code technical quality of MV & LV Doppler
- ***Write down calibrations*** *of LA/AV/MV & LV*
- Tentatively select which LA, AV, MV & LV frame you are going to choose & note it. For LV think of both systole & diastole, septum & posterior wall
- Make a mental note of tricky lines & any questions you have about 2-D

6. Perform **qualitative reading** off the analogue tape
- Note abnormalities in left margin as one reads
- Make quick rough hand-held caliper measurements of LA, AV & LV WT & ID
  These measurements are for guidance & to pick up cal errors
  LVWT you can measure in PLA or PSA. LVID in PSA only
- **Verify that MModes are appropriate*:***
  LV is not too eggy, & not too apical; LA is contained on frame, MV not too eggy, etc.
- After the entire analogue tape has been reviewed
  Code qualitative abnormalities;
  Put ☐ on left margin for sections to be coded after measurements are made
- **Don't forget to check LV wall motion in each view**
- Don't forget to code right heart abnormalities
- Don't forget to code CW of AV & TV

- Code technical quality of 2D, color Doppler, & cw
- Don't make on-line 2D measurements except for:
  RVH, RVE, MV thickness, if necessary or
  If MM of a structure is unmeasurable and you need guidance for coding sheet

7. **Measure video disk**

- Select the measurement you are going to make;
  try to make measurements in the order that they appear on the menu
- **CALIBRATE!!! CHECK CALIBRATION EACH IMAGE!!!**
- Measure MM, 3 beats if possible.
- Measure with blue cursor (hit h for hue thrice)
- If wall is very dark, then measure w/ white cursor
- Code which frame your 2-D & Mmode LV measurements are made from.
- Don't click on:
  mean if you have no more beats to measure, *accept* if you want to mean

8. Finish measurements & **REVIEW REPORT**

- Do the numbers make sense? If they don't make sense *delete* the measurements
- Is the % change wall thickness from sys-dias <50%?
- Have relevant abnormalities been coded if :
  Ao cusp ≤ 1.5, Fractional shortening ≤ .30, Septal wt:post wt > 1.3

9. If you are satisfied with your measurements,
   Measure; Unlock images, Shift F9; Clear images, Shift F5, (screen should go blank)

- Return to report
- Put in your personal OD #a. Wait for yellow light to flash.
  Hit save/print.

Save (in file manager) - Make sure that screen flashes saving correct pt & adds 1 pt.
Write the pt# in the upper right corner of coding sheet, to ensure saving to both ODs
DO NOT TOUCH OD WHILE SYSTEM IS SAVING REPORT, nor while escaping
After saved, pop out OD. Put in back up OD #b wait for yellow light. Hit save. Escape

10. Examine print out

- Add septal + posterior WT end-diastole together
- Check all measurements against height & gender specific chart
- Code LA, aortic root & LV structure on qualitative sheet

11. Finish coding the interpretation section

12. *Check that coding is complete on both front & back of form*

TOMTEC TRICKS

- **RECALIBRATE/OR CHECK CALIBRATION EVERY FRAME**
- Do NOT click on mean or escape if you do not have any new beats to measure
- Do NOT hit accept if you want to mean/measure more beats
- When retrieving video image, if one receives a message that memory is full,
  go off bypass & clear roster of all but one pt.
- Try not to change brightness and contrast
  - If someone has messed with image: go off bypass, video, adjust contrast and brightness by moving the arrow on the horizontal bar, (presently set at 49 for contrast and 0 for brightness);
  - hit Alt-S (setup is then saved).
- To change the number of frames in a protocol,
  go to DOS by hitting Alt- Q.
  c:\FMSVID;
  Type in c:\FMSVID> edit vgcuskey**.**inp (space after edit is important);
  Enter ; put off "Caps Lock" and "Num Lock" if they are on ;
  A blue menu appears. Hit "Page Down" 13 times till you can see the item "frame number". Move the arrow key on the keyboard to move cursor to below the number 12 or 16 and make the appropriate change.
  Hit Alt key; click on Exit;
  c:\FMSVID> mc (note the computer counts 100% twice)
  Setup has been saved.
- To reset computer, hit *center* of reset key
  or hit Alt Q ; c:\FMSVID appears; and then type cvos thus: c:\FMSVID>cvos; Enter.
- Do not click on user fields that we do not intend to use.

MEASUREMENT & INTERPRETATION GUIDELINES

***Calibrate* before measuring any frame**

• **How many beats?**

- Measure at least 3 beats if they are technically adequate, and the inter-beat differences are due to biologic (e.g. respiratory variation)
- If third beat is technically inferior and the given frame is the best available one (see below), measure only two beats. It is better to have two good accurate measurements than to have the results skewed by a third unreliable estimate.
- All 3 beats should be from the same frame
- If rhythm is atrial fibrillation/flutter, measure at least 4 complexes; you may need to measure more than one frame; try to measure adjacent complexes;

• **Extra**-systoles? Look at cardiac rhythm on screen. Avoid measuring premature beats or beat immediately following a premature beat.

• **Which frame?**

- Choose the frame that best defines the leading edges of the structure being measured
- Scan the M-mode frames prior to reading 2-D study, focusing specifically on clarity of leading edges. Make a note on the possible frames you would select for measurement. Make a mental note of presence of multiple linear structures that could represent the leading edge.
- Clarity of leading edges for LV diastolic measurements is a more important consideration compared to clarity of the systolic phase of the cardiac cycle.
- Try to measure aortic root and aortic cusp separation on the same frame
- If two frames are identical in terms of quality, select the first frame as a convention

• **Measuring, general**

- Did you **CALIBRATE?**
- *Which order are cardiac structures measured in?* Begin with LA in systole, Ao Root, Ao cusp separation, E-point to septal separation, and lastly LV dimensions.
- *Which order of* beats: Of three beats on the chosen frame, measure the best looking one first. If all three beats look alike, start measurements of beats from left to right
- *"leading edge to leading edge"* for LA/Ao Root & LV
- *inner to inner* for E-point septal separation (EPSS) and aortic cusp separation.
- Make sure that each ***M-mode measurement reflects reality***. Is it close to your 2-D impression of the cardiac structure (based on either eye balling or on online measurement of the screen with an external caliper)?
- Think about reproducibility...If you are guessing don't measure.

• **Cursor placement?**

- *What if the leading edge is thickened?* (e.g.. calcified aortic root), the measurement cursor is "buried" into the leading edge
- While reading the 2-D study, keep in mind the importance of assessing which of the possible linear structures most likely represents the leading edge of the structure that will be

measured on M-Mode. This judgement is based on excluding the possibility of ventricular trabeculae, chordae tendineae, "side-lobe artifacts," posterior effusions, and other miscellaneous structures that could obscure/mimic the leading edge.

- Look carefully at the M-mode for incomplete or partial *dropout* in lines that may well represent the true leading edge.
- It is permissible to *extrapolate* and drop the measurement cursor to an imaginary leading edge which corresponds in position to an adjacent beat if no leading edge is discernible in a particular beat @ the appropriate time of placement and the beat is otherwise technically adequate for measurement (e.g. isolated dropout in the leading edge of LVPW in one beat alone)
- Remember to *bracket* your cursor placement - place the cursor above, below then exactly where you want to place it.

• **Measuring the LV**

- Check for the presence of an "egg" appearance in the 2-D short axis-view of the ventricle (from which the M-mode is derived). If the ratio of length/ breadth of the ventricle is >1.3, do not make LVID measurements. You can still code the left ID & WT as normal or abnormal depending on the 2-D impression.
- Check that the cursor placement is at the tips of the papillary muscles, i.e. that the cursor is not too apical & that the RV is still present as more than a sliver.
- Check that you are not measuring RV moderator band, papillary muscle or pericardial effusion.
- If you skip measurements make sure the Tomtec hasn't borrowed numbers from elsewhere.

• **Measuring LA, EPSS, aorta**

- Beware of side lobes creating false posterior *LA* walls
- If *Ao* heavily calcified bury leading LA edge
- *EPSS* Place cursor on the same side of the E-point of the mitral tracing as the peak downward excursion of the septum; an 'inner to inner edge technique is used. We extrapolate to point of maximum downward excursion of the septum.
- Measure the *aortic root cusp* separation in early systole using an "inner edge to inner edge" technique (i.e. trailing edge to leading edge)

• **Qualitative coding**

- Try to confirm presence of mild or borderline findings in more than one view e.g. MAC, aortic calcification or trivial regurgitation in more than one view
- If you aren't sure about MAC, aortic calcification, MV thickening, etc. code it as probably normal
- If you really don't know if something is normal or not, code it as unknown
- Look @ specific definitions on posted coding sheet.

• **Coding quality**

- For cw AoV code it as fair if only imaging cw used, &/or only from one view; code good quality if pedoff & > 1 view are recorded & are of adequate quality
- *Good* means highly accurate (reflects reality) & excellent reproducibility

- *Fair* means basic questions are answered correctly, reproducibility reasonable
- *Poor* means reproducibility poor, some ability to comment on questions
- *Inadequate* means accuracy and reproducibility unacceptable

FHS ECHO SPECIFIC READING GUIDELINES 10/95

LA enlargement*	☐ no	☐ borderline	☐ mild	☐ moderate	☐ severe
Mitral Valve					
MV thickening	☐ no **<0.5 cm**		☐ mild **0.5-0.7 cm**		☐ mod/severe **≥ 0.8 cm**
Mitral stenosis	☐ no	☐ possible **2.5-3.9 cm^2**	☐ likely **<2.5 cm^2**		
MAC	☐ no		☐ mild **M-mode < 3 mm** **2-D focal**	☐ moderate **MM 3-5** **2-D >1/3 ring**	☐severe **MM >5 mm** **2D ≥½ circumference**
MVP	☐ no	☐ min. sup. displac. **≤2mm behind annulus**	☐ mild **>2 to <4 mm**		☐ mod/severe **≥ 4 mm**
AorticValve/Root					
AV thickening	☐ no		☐ mild **focal/limited**	☐ moderate **diffuse, some thin leaflet echos appreciable**	☐ severe **diffuse, 'white-out' AV**
Aortic cusp excursion (Use MM+2-D sense)	☐ no **≥1.5 cm**		☐ mild **1.-1.4 cm**	☐ moderate **0.5-0.9 cm**	☐ severe **<0.5 cm**
Aortic root dilation	☐ no		☐present_**≥3.6 _≥3.8cm**		
Aortic root calcium	☐ no		☐ mild **focal ↑, ≤½ ring**	☐ moderate **>½ ring**	☐ severe **entire ring**
LV Structure*					
LV enlargement	☐ no	☐ borderline	☐ mild	☐ moderate	☐ severe
↑ LVWT,	☐ no	☐ borderline	☐ mild	☐ moderate	☐ severe
↑ LVWT, other	☐ no		☐ ASH **sw:pw >1.3** **& sw≥1.3**	☐ ISH **not ASH &** **sw ≥ 1.2 cm_ 1.1_** **pw ≤ 1.2 cm_ 1.1_**	☐ DUSK **discrete upper septal knuckle (visual)**
LV Systolic Function					
LV ejection fraction	☐ normal **≥ 55%**	☐ borderline **50-54%**	☐ mild ↓ **40-49%**	☐ moderate ↓ **30-39%**	☐ severe ↓ **≤29%**

***NOTE:** **For LA/LVwt/LVID check height & sex specific nomograms; delete MM measure if off-axis &/or doesn't make sense.**
For LA consider both parasternal & apical views;
For LVID if eccentric (short/long axis dimension >1.3 don't measure MM), overrule if dilated in apical views

RA/RV/TV/peric.[§]					
RA enlargement	☐ LA nl **RA<LA**		☐ mild **grade cf. w/ LA**		☐ mod/severe **grade cf. W/ LA**
RV enlargement	☐ no **0.9-2.6 cm**		☐ mild **>2.7 PLA**		☐ mod/severe **RV ≥LV** (LV nl)
RV hypertrophy	☐ no **≤0.6 cm**		☐ mild **0.7-0.9 cm**		☐ mod/severe **≥1.0 cm**
Pericardial fluid	☐ no/sys.		☐ mild **localized**		☐ med/large **surrounds ♥ > .5 cm**

[§]**Note R ♥** morphology is subjective & should take into account height, sex & relation to L ♥ size

Valve Regurgitation·					
Mitral {Helmke}	☐ none	☐ trace **w/in 1 cm valve**	☐ mild **RJA/LAA ≤19%**	☐ moderate **20-40%**	☐ severe **≥41%**
Aortic {Perry}	☐ none	☐ trace	☐ mild **JH/LVOH 10-24%**	☐ moderate **JH/LVOH 25-49%**	☐ severe **JH/LVOH ≥50%**
Tricuspid	☐ none	☐ trace **w/in 1 cm valve**	☐ mild **RJA/RAA ≤19%**	☐ moderate **20-40%**	☐ severe **≥41%**
Mitral Stenosis·	☐ none **4-6 cm^2**	☐ trace **2.5-3.9 cm^2**	☐ mild **1.5-2.5 cm^2**	☐ moderate **1.0-1.5 cm^2**	☐ severe **< 1 cm^2**
Aortic Stenosis·	☐ none **3-5 cm^2**	☐ trace **2-3 cm^2** **g10-15 mm Hg**	☐ mild **1.1-2 cm^2;** **g16-29 mmHg**	☐ moderate. **.75-1.1cm^2;** **g30-49 mm Hg**	☐ severe **≤0.75 cm^2;** **g≥50 mm Hg**

·NOTE: Assessment of valvular regurgitation is based on subjective impressions of jet area.
NOTE: Assessment of valvular stenosis should consider LV function and body size.

DESCRIPTION OF WHAT STUDIES REQUIRE MD OVERREAD AND WHAT STATEMENTS WILL FLAG DATA CLEANING ERRORS

Variable	*If value > ___, is variable coded abnormal?*		*If variable size coded abnormal (at least borderline) is variable > ___?*		*MD over read*	
	_	_	_	_	_	_
Left atrium	***≥ 44***	***≥ 48***	***≥ 37.2***	***≥ 42.8***	***≥ 50 all sev.***	***≥ 54 all sev.***
Aortic root	***≥ 36***	***≥ 39***	***≥ 36***	***≥ 38***	***≥ 40***	***≥ 42***
LV enlargement	***≥ 53***	***≥ 59***	***≥ 48.1***	***≥ 53.5***	***≥ 54 ≥ mod.***	***≥ 58 ≥ mod.***
LV wall thickness (septum+posterior)	***≥ 22***	***≥ 24***	***≥ 17.2***	***≥ 19.6***	***≥ 25 ≥ mod.***	***≥ 26 ≥ mod.***

QUALITY CONTROL ASSESSMENT

A. *Data quality on routine interpretations*

1. Tabulations and plots are made to display quality control information for the echocardiographic studies will be performed semi-annually. We are analyzing the % of unmeasurable studies (by variable), and the means & standard deviations for continuous variables including LA, AoR, Ao cusp, EPSS, septal WT diastole, posterior WT diastole, LVID diastole, & fractional shortening. Statistics will be displayed by sonographer & by interpreter. For continuous variables comparisons of mean values will use general linear models to account for sex & height of subjects.
2. Because the studies are measured on line with digital calipers to multiple decimal points, and stored to optical disk, on cycle 6 digit preference has not been a problem.
3. Data entry personnel are instructed to return improperly coded charts to the interpreter prior to entry. Particularly if variables are left blank.

B. *Data cleaning*:

See also p. 18 for data cleaning guidelines &
Appendix 3 for feedback sheet & programming.

We are running data cleaning programs on an ongoing basis to get prompt feedback to interpreters & data entry personnel about problems. The data cleaning program is divided into 2 parts. Initially the demographic data is cleaned. The demographic cleaning ensures that the appropriate subject was interpreted by checking that the ID matches the exam date, etc.

Subsequently the measurement data is cleaned against the qualitative interpretations. This helps detect calibration, coding or keying errors. Essentially the measurements are checked that they are in range and that the qualitative and quantitative data are consistent. (E.g. is the LV internal dimension in systole < diastole; If LV wall thickness is > 24 _ & 22 _, has LV internal dimension been coded dilated, etc.).

C. *Reproducibility*

See also appendix 4 for exam 6 statistics.

1.Objective

- Assessing reproducibility will ensure consistent, high quality of all aspects of the performance, measurement and interpretation of cardiac ultrasounds.
- Assessing reproducibility is essential to ensure the ability to publish manuscripts.

2.Sources of variability

Four distinct sources of differences, or variability can be identified in our echocardiographic studies, namely I) true subject to subject variation, ii) differences generated by different sonographers imaging, iii) differences among different readers, and iv) measurement error within reader. Preliminary analyses of several variables (LV mass, fractional shortening, LA dimension and aortic root size) show that the component of variance attributed to subjects is very much larger than the component due to measurement error; also differences among readers exceed those between sonographers. A fifth source of variability, temporal drift, also

could arise. We will examine the magnitudes of these effects by undertaking two separate reproducibility experiments; one is based on a calibration sample to be reread every year (winter), the other is based on random samples to be read every summer.

3.Timing

- *Pilot phase & advent of new interpreters*: Interpreters will not be allowed to read independently until such time as they demonstrate adequate reproducibility.
- *Implementation phase*. Reproducibility will be assessed on a semiannual basis to ensure that there is no temporal drift in the performance & interpretation of studies.

4.Ultrasonographer imaging reproducibility

- We are currently assessing ultrasonographer imaging acquisition reproducibility.
- The ultrasonographer performing the initial study is not informed about the subject selection until after the initial echocardiogram has been performed.
- The head nurse chooses the subjects to maintain clinic flow and to avoid selection bias of the ultrasonographer unconsciously selecting echogenic subjects. The nurse selects subjects trying to maintain a reasonable age & sex distribution. [We will verify the distribution by analysis later]. After selection, the nurse or ultrasonographer approaches the subject and explains the intent of the protocol and asks them if they are willing to have a second cardiac ultrasound performed.
- If a subject refuses, he/she will not be pressured to cooperate. If the subject agrees, the other ultrasonographer will then perform the second study.
- To ensure clinic flow we will avoid the following:
    - Days when Spanish speaking subjects are being examined
    - Omni participants
    - Unusually heavy days (at the discretion of the head nurse)

5.Measurement reproducibility

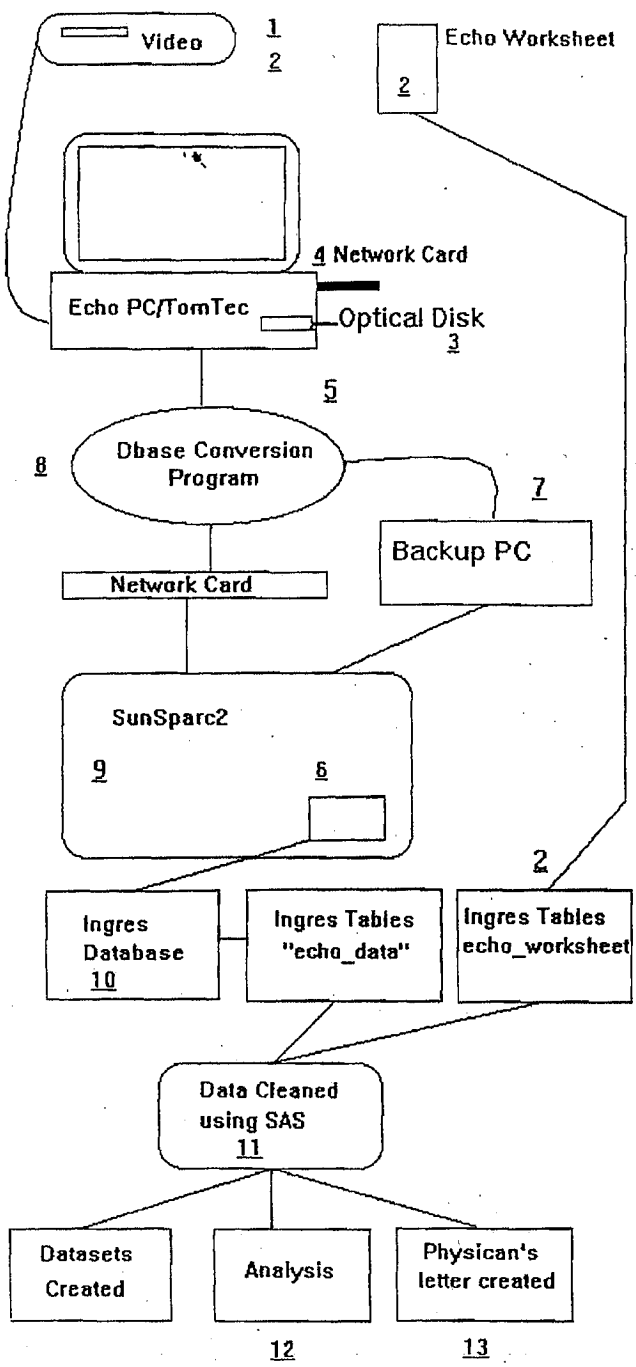
- For the first two reproducibility runs the studies were measured and interpreted twice, on different days. To increase the feasibility of checking reproducibility we will only measure interobserver reproducibility for most of the future runs.
- During the implementation phase 20 studies were measured by 2 cardiologists and 2 ultrasonographers. After the studies were analyzed 3 of the interpreters were certified to read independently. The majority of the studies were reviewed to clarify difficult areas, need for improvement etc.
- The second reproducibility run involved a calibration set of 20 fair quality studies that will be measured annually to detect secular drift in interpretations. After this reproducibility run all four observers were certified to read independently. In addition, one parameter was dropped from the measurement protocol because of inadequate reproducibility (LA at end-diastole), and because scientifically it was not justifiable.
- The crux of the analyses will focus on measurement reproducibility. However, assessment of interpretation variability will also be done to enhance the consistency of our interpretations.

6.Intraobserver & interobserver variability - tests

a. Correlation coefficients
b. Systematic differences will be assessed by bias & % bias
c. Random bias will be assessed by precision & % precision
d. Mean across subjects
e. Estimated variance for a single reading chosen at random
f. Estimated standard deviation for true subject-to-subject variation
g. Estimated standard deviation for errors due to different readings
h. Estimated standard deviation for errors due to different readings
i. Relative error

Appendix 1

Echo laboratory flow sheet



1) A FHS patient comes in for an exam. Echo information is recorded on video tape.

2) Video tape is read to a PC using propriety Software made by TomTec and measurements are made. The data is hand written to an echo worksheet, where it will be data entered into the "echo_worksheet" table within ingres.

3) Measurements are saved to an Optical Disk (D drive)

4) A 3Com network card has been installed in the Echo PC. This card provides a direct link from the TomTec PC to the SunSparc2 workstation. The card is driven by PCNFS (Software written by Sun Computers)

5) Dbase software and Conversion software was installed on Echo PC on third floor and a backup was installed on the first floor. There is no network card on the first floor Echo PC. Dbase is the software format which TomTec propriety software uses. A Dbase program has been created (eroutput.prg) to delimit each field with a "%". eroutput.prg will look for the files er000000.gti and vd000000.gti within the gtistudy directory on the optical disk. These two files contain all the information needed for the ingres tables.

6) The Dbase program creates a file. The conversion program then sends it to the SunSparc2 and places it in an echo directory as an Unix flat file. A time stamp is placed electronically on the optical disk to prevent accidentally transferring records. This will eliminate multiple records from transferring over to ingres. After a dump is done with this set of data, the time stamp will be updated.

7) An option to convert data to 3.5" diskette drive is available. This will make data more portable. If one Echo PC is down, then a conversion is still possible on the other Echo machine. If necessary software can be loaded onto a third machine with an Optical disk and Dos 6.0 or higher.

8) The program will prompt the operator to type in tape id, reader id and current date before the file transfer. This will prevent any over writing or duplicate reading of data.

9) Flat Dos file is converted to an Unix flat file with an "%" delimiting each field via PCNFS. An Unix directory is created with the current transfer date. The file name of the current transfer is given the tape_id-reader_id.dat.

10) The raw data are then transferred into the Ingres tables via the copydb command. An executable file(loaddata*) in the echo/data/bin directory is then run. All data are loaded into "echo_data" table. The order of data coming from Echo PC is in a set format. The order is the same order as the Ingres tables. If a field contain no data then a default of "-1" is used.

11) There are two fields reserved for cleaning the data(checked and cleaned). A "n" or "y" flag will be used. The cleaning process will utilize SAS. Many logical comparisons and if statements will help clean this data.

12) The data is ready to be analyzed.

13) A physicians letter is produced using cleaned data from echo_data and echo worksheet

Appendix 2

Cut points for defining borderline, mild, moderate and severe cardiac chamber enlargement/thickening

Echo Variable	Height (inches)	Refer. 95%ile	Broad 95%ile	Broad 98%ile	Broad 99%ile
LAD	60	42.4	47.7	51.7	53.9
LAD	61	42.5	47.9	51.9	54.1
LAD	62	42.7	48.1	52.1	54.3
LAD	63	42.8	48.3	52.3	54.5
LAD	64	43.0	48.4	52.5	54.7
LAD	65	43.1	48.6	52.6	54.9
LAD	66	43.3	48.8	52.8	55.1
LAD	67	43.4	48.9	53.0	55.3
LAD	68	43.6	49.1	53.2	55.5
LAD	69	43.7	49.3	53.4	55.6
LAD	70	43.9	49.4	53.5	55.8
LAD	71	44.0	49.6	53.7	56.0
LAD	72	44.2	49.7	53.9	56.2
LAD	73	44.3	49.9	54.0	56.4
LAD	74	44.4	50.0	54.2	56.5
LAD	75	44.6	50.2	54.4	56.7
LAD	76	44.7	50.3	54.5	56.9
LAD	77	44.8	50.5	54.7	57.0
LAD	78	45.0	50.6	54.8	57.2

CUTPOINTS

ABNORMAL RANGE

MEN

Echo Variable	Height (inches)	Refer. 95%ile	Broad 95%ile	Broad 98%ile	Broad 99%ile
LVDD	60	52.1	54.2	56.6	60.1
LVDD	61	52.6	54.7	57.1	60.7
LVDD	62	53.0	55.2	57.7	61.2
LVDD	63	53.5	55.8	58.2	61.8
LVDD	64	54.0	56.3	58.7	62.3
LVDD	65	54.5	56.8	59.3	62.9
LVDD	66	55.0	57.3	59.8	63.5
LVDD	67	55.5	57.8	60.3	64.0
LVDD	68	55.9	58.2	60.8	64.5
LVDD	69	56.4	58.7	61.3	65.1
LVDD	70	56.9	59.2	61.8	65.6
LVDD	71	57.3	59.7	62.3	66.2
LVDD	72	57.8	60.2	62.8	66.7
LVDD	73	58.2	60.7	63.3	67.2
LVDD	74	58.7	61.1	63.8	67.7
LVDD	75	59.2	61.6	64.3	68.3
LVDD	76	59.6	62.1	64.8	68.8
LVDD	77	60.0	62.5	65.3	69.3
LVDD	78	60.5	63.0	65.8	69.8

Echo Variable	Height (inches)	Refer. 95%ile	Broad 95%ile	Broad 98%ile	Broad 99%ile
LVWT	60	18.8	22.9	25.2	27.0
LVWT	61	19.1	23.2	25.6	27.4
LVWT	62	19.3	23.5	25.9	27.8
LVWT	63	19.6	23.8	26.3	28.1
LVWT	64	19.8	24.1	26.6	28.5
LVWT	65	20.1	24.4	27.0	28.9
LVWT	66	20.4	24.8	27.3	29.3
LVWT	67	20.6	25.1	27.7	29.6
LVWT	68	20.9	25.4	28.0	30.0
LVWT	69	21.1	25.7	28.3	30.4
LVWT	70	21.4	26.0	28.7	30.7
LVWT	71	21.6	26.3	29.0	31.1
LVWT	72	21.9	26.6	29.4	31.5
LVWT	73	22.2	26.9	29.7	31.8
LVWT	74	22.4	27.2	30.1	32.2
LVWT	75	22.7	27.5	30.4	32.6
LVWT	76	22.9	27.8	30.7	32.9
LVWT	77	23.2	28.2	31.1	33.3

Variable	Height (inches)	95%ile	95%ile	98%ile	99%ile
LAD	54	36.6	43.0	47.2	49.6
LAD	55	36.8	43.3	47.5	49.9
LAD	56	37.0	43.5	47.7	50.2
LAD	57	37.2	43.7	48.0	50.4
LAD	58	37.4	44.0	48.2	50.7
LAD	59	37.6	44.2	48.5	51.0
LAD	60	37.8	44.4	48.8	51.2
LAD	61	38.0	44.7	49.0	51.5
LAD	62	38.1	44.9	49.2	51.8
LAD	63	38.3	45.1	49.5	52.0
LAD	64	38.5	45.3	49.7	52.3
LAD	65	38.7	45.5	50.0	52.5
LAD	66	38.9	45.8	50.2	52.8
LAD	67	39.1	46.0	50.4	53.0
LAD	68	39.2	46.2	50.7	53.2
LAD	69	39.4	46.4	50.9	53.5
LAD	70	39.6	46.6	51.1	53.7
LAD	71	39.8	46.8	51.3	53.9
LAD	72	39.9	47.0	51.6	54.2

CUTPOINTS

ABNORMAL RANGE

WOMEN

Echo Variable	Height (inches)	Refer. 95%ile	Broad 95%ile	Broad 98%ile	Broad 99%ile
LVDD	54	46.8	47.9	50.0	52.1
LVDD	55	47.3	48.3	50.4	52.6
LVDD	56	47.7	48.7	50.9	53.0
LVDD	57	48.1	49.2	51.4	53.5
LVDD	58	48.5	49.6	51.8	54.0
LVDD	59	49.0	50.0	52.2	54.4
LVDD	60	49.4	50.4	52.7	54.9
LVDD	61	49.8	50.8	53.1	55.3
LVDD	62	50.2	51.2	53.5	55.8
LVDD	63	50.6	51.7	54.0	56.2
LVDD	64	51.0	52.1	54.4	56.7
LVDD	65	51.4	52.5	54.8	57.1
LVDD	66	51.8	52.9	55.2	57.5
LVDD	67	52.1	53.3	55.6	58.0
LVDD	68	52.5	53.6	56.1	58.4
LVDD	69	52.9	54.0	56.5	58.8
LVDD	70	53.3	54.4	56.9	59.2
LVDD	71	53.7	54.8	57.3	59.7
LVDD	72	54.0	55.2	57.7	60.1

Echo Variable	Height (inches)	Refer. 95%ile	Broad 95%ile	Broad 98%ile	Broad 99%ile
LVWT	54	16.9	21.4	24.7	27.4
LVWT	55	17.0	21.6	24.9	27.6
LVWT	56	17.1	21.8	25.1	27.8
LVWT	57	17.2	21.9	25.3	28.0
LVWT	58	17.4	22.1	25.5	28.2
LVWT	59	17.5	22.2	25.6	28.4
LVWT	60	17.6	22.4	25.8	28.6
LVWT	61	17.7	22.5	26.0	28.8
LVWT	62	17.8	22.7	26.2	29.0
LVWT	63	18.0	22.8	26.3	29.2
LVWT	64	18.1	23.0	26.5	29.4
LVWT	65	18.2	23.1	26.7	29.6
LVWT	66	18.3	23.3	26.9	29.8
LVWT	67	18.4	23.4	27.0	29.9
LVWT	68	18.5	23.6	27.2	30.1
LVWT	69	18.6	23.7	27.4	30.3
LVWT	70	18.8	23.9	27.5	30.5
LVWT	71	18.9	24.0	27.7	30.7

Appendix 3

Data cleaning materials

tatements used to check data after its entered: (3/96)

or echo measurements:
there is an error if...)

1. Id type not equal to 1,7,8
2. Study date greater than interp date
3. Study date blank
4. Interp date blank
5. Exam # not equal to 6
6. Sonographer # not equal to 28,30
7. Interp not equal to 28,30,86,153
8. Data OD#1 not equal to interp
9. Data OD#1 not equal to 28,30,86,153
10. Data OD#2 is blank
11. SVHS# (tape id) is blank
12. Sonographer # = 28 and SVHS# is even
13. Sonographer # = 30 and SVHS# is odd

or echo worksheet:
there is an error if...)

1. Id type not equal to 1,7,8
2. Exam # not equal to 6
3. Study type not equal to 0,1,2
4. Data entry date blank
5. Keyer space blank
6. Study date blank
7. Study date greater than interp date
8. Study date greater than data entry date
9. Interp date great[6~er than data entry date
10. Sonographer # not equal to 28,30
11. Height less than or equal to 0
12. Height greater than or equal to 80
13. Weight less than or equal to 0 (not used for now)
14. Weight greater than or equal to 500
15. Sex not equal to 1,2
16. Video OD#1 not equal to 28,30
17. Video OD#1 = 30 and sonographer # not equal 30
18. Video OD#1 = 28 and sonographer # not equal 28
19. Video OD#2 is blank
20. Data OD#1 is blank
21. Data OD#2 is blank
22. Data OD#1 not equal to interp
23. SVHS# (tape id) is blank
24. Sonographer # = 28 and SVHS# is even
25. Sonographer # = 30 and SVHS# is odd
26. SVHS location is blank
27. Study quality comment: OD m-mode Ao/LA is blank
28. Study quality comment: OD m-mode LV is blank
29. Study quality comment: OD PW mitral inflow is blank
30. Study quality comment: OD PW LVOT is blank
31. Study quality comment: SVHS 2d study is blank
32. Study quality comment: SVHS CW TR is blank
33. Study quality comment: CW AV is blank
34. Study quality comment: Color doppler is blank
35. Overal study quality comment is blank
36. Interp not equal to 28,30,86,153
37. Reading not equal to 1,2
38. Interp date is blank
39. Data OD#1 is not equal to 28,30,86,153

To: _____ Date: ___/___/___

From: Kathy Lewis

Re: Echo measurement/worksheet error or out of range value

==========

STUDY DATE ___/___/___

ID: ___ - ___ ___ ___ ___ INTERP DATE ___/___/___

DATA OD# ____ - _____ (disk_id1 - disk_id2) SVHS# _____ (tape_id)

==========

Measurements:

_____la diameter (lmladm_v) _____inter vent sept sys (lmivs_sv)

_____aortic root (lmaort_v) _____left post wall dia (lmlvp_dv)

_____aortic cusp sep (lmaocu_v) _____LV sys (lmlvd_sv)

_____inter vent sept dia (lmivs_dv) _____LV dia (lmlvd_dv)

==========

LEFT ATRIUM:

m: if LA >= 4.4 then LA abn if LA abn then LA >= 3.72

f: if LA >= 4.8 then LA abn if LA abn then LA >= 4.28

if LA < 2.1 or > 6.5 then LA out of range

AORTIC ROOT:

m: if AOR >= 3.6 then AOR abn if AOR abn then AOR >= 3.6

f: if AOR >= 3.9 then AOR abn if AOR abn then AOR >= 3.8

if AOR < 2.0 or > 5.0 then AOR out of range

AORTIC VALVE:

if AO Cusp Sep < 1.1 then AO Cusp abn

if AOR <= AO Cusp Separation then there is a problem

if LA <= AO Cusp Separation then there is a problem

if AO cusp sep < 0.5 or > 2.7 then out of range

LEFT VENTRICLE (enlargement):

m: if LV >= 5.3 then LV abn if LV abn then LV >= 4.81

f: if LV >= 5.9 then LV abn if LV abn then LV >= 5.35

if LV diastole < 0.7 or > 2.2 then LV out of range

LEFT VENTRICLE (wall thickness):

m: if IVSS+IVPD >=2.2 then LVWT abn if LVWT abn then IVSS+IVPD >=1.72

f: if IVSS+IVPD >=2.4 then LVWT abn if LVWT abn then IVSS+IVPD >=1.96

if **********then LV out of range

LEFT VENTRICLE (diameter):

if LVD Systole >= LVD Diastole then there is a problem

if LVD Systole < 1.8 or > 6.0 then LVD systole out of range

LEFT VENTRICLE (fractional shortening)

if LVFS < 0.2 : then LV ejection fracation should be normal

Appendix 4

Quality control data

Exam 5
1. Overall
2. Echo data by time period
3. Echo data: Reliability report

Exam 6
1. Overall
2. Echo data by time period
3. Echo data: Reliability report

1. Overall

During Examination Cycle 5, echocardiograms were performed on 3737 subjects (98.4%); left atrial size was measured on 3636 (95.7%) and left ventricular dimensions were complete on 2807 (73.9%) -- the latter comprising intra-ventricular septal wall thickness, posterior wall thickness, plus left ventricular dimensions in systole and at end diastole.

Summary statistics for these data are shown below.

Variable	N	Mean	Std Dev	Minimum	Maximum
EXAMINED	3799	1.0000000	0	1.0000000	1.0000000
ECHO	3799	0.9836799	0.1267200	0	1.0000000
L_ATRIUM	3799	0.9570940	0.2026719	0	1.0000000
L_VENTRI	3799	0.7388787	0.4393038	0	1.0000000
LA	3636	3.7832481	0.5457259	2.2000000	6.5000000
IVSD	2909	0.9579924	0.1374841	0.6000000	2.2000000
LVPD	2889	0.9452752	0.1253499	0.4000000	1.9000000
LVDS	2822	3.0041460	0.4455386	1.8000000	5.8000000
LVDD	2860	4.7590559	0.4502673	0.9000000	7.0000000
FS	2820	36.9138385	6.6845178	0	59.1836735
LVM	2843	199.9172703	50.3086461	80.4384000	522.5839500

2. Echocardiographic Data by Time Period

Data on completeness and magnitudes of measurements of echocardiographic variables are shown on several following pages. Between 98% and 100% of available subjects had the echocardiogram performed, depending on time period, with the exception of the last two periods when several subjects were examined off site. Measurement of left atrial size was available on 95% to 98% of subjects, and of major left-ventricular dimensions on 71% to 83% of subjects, across time periods (excepting the last two half-year periods). Means and variances of most echocardiographic variables were quite consistent across time periods.

Echocardiography (procedures)

HALFYEAR	N	MEAN	STD	MIN	MAX
91.0	349	1.00000	0.00000	1	1
91.5	476	0.98529	0.12050	0	1
92.0	617	0.99190	0.08973	0	1
92.5	577	0.99480	0.07198	0	1
93.0	581	0.98107	0.13641	0	1
93.5	617	0.98541	0.11999	0	1
94.0	473	0.98943	0.10238	0	1
94.5	88	0.93182	0.25350	0	1
95.0	21	0.23810	0.43644	0	1

Left Atrial Size (completeness)

HALFYEAR	N	MEAN	STD	MIN	MAX
91.0	349	0.97708	0.14987	0	1
91.5	476	0.95798	0.20084	0	1
92.0	617	0.97083	0.16843	0	1
92.5	577	0.96880	0.17400	0	1
93.0	581	0.95525	0.20693	0	1
93.5	617	0.94976	0.21862	0	1
94.0	473	0.96406	0.18634	0	1
94.5	88	0.89773	0.30474	0	1
95.0	21	0.23810	0.43644	0	1

Wall Thicknesses and Left Ventricular Dimensions (completeness- aggregate)

HALFYEAR	N	MEAN	STD	MIN	MAX
91.0	349	0.82235	0.38277	0	1
91.5	476	0.75420	0.43101	0	1
92.0	617	0.74392	0.43682	0	1
92.5	577	0.76256	0.42588	0	1
93.0	581	0.74010	0.43896	0	1
93.5	617	0.68233	0.46595	0	1
94.0	473	0.71247	0.45309	0	1
94.5	88	0.80682	0.39706	0	1
95.0	21	0.14286	0.35857	0	1

Statistics for Left Atrial Size

HALFYEAR	N	MEAN	STD	MIN	MAX
91.0	341	3.79472	0.50716	2.2	6.0
91.5	456	3.80877	0.53470	2.4	5.5
92.0	599	3.79649	0.53029	2.4	6.5
92.5	559	3.79016	0.53339	2.4	5.8
93.0	555	3.72629	0.55760	2.2	5.4
93.5	586	3.76399	0.57568	2.3	5.8
94.0	456	3.81162	0.53462	2.2	5.5
94.5	79	3.80759	0.69610	2.5	6.0
95.0	5	3.92000	0.53572	3.4	4.8

Statistics for Intra-Ventricular Septal Thickness

HALFYEAR	N	MEAN	STD	MIN	MAX
91.0	290	0.93690	0.13094	0.6	1.4
91.5	378	0.98519	0.14083	0.6	1.9
92.0	473	0.96173	0.15471	0.6	2.2
92.5	452	0.95442	0.13286	0.7	1.6
93.0	448	0.94888	0.12496	0.6	1.6
93.5	439	0.96241	0.14020	0.6	1.5
94.0	353	0.95496	0.12696	0.6	1.7
94.5	73	0.94795	0.14153	0.7	1.4
95.0	3	0.83333	0.15275	0.7	1.0

Statistics for Left Ventricular Posterior Wall Thickness

HALFYEAR	N	MEAN	STD	MIN	MAX
91.0	290	0.93034	0.12188	0.6	1.3
91.5	374	0.96417	0.12534	0.6	1.5
92.0	470	0.94979	0.13490	0.6	1.9
92.5	451	0.94191	0.12054	0.6	1.4
93.0	443	0.93770	0.11748	0.6	1.5
93.5	437	0.94805	0.13350	0.4	1.5
94.0	348	0.94569	0.11766	0.6	1.3
94.5	73	0.93014	0.12437	0.7	1.2
95.0	3	0.86667	0.20817	0.7	1.1

HALFYEAR	N	MEAN	STD	MIN	MAX
91.0	287	3.03275	0.44160	1.9	4.5
91.5	364	2.95137	0.46012	1.8	5.4
92.0	461	3.02430	0.41788	2.0	5.0
92.5	444	2.97793	0.45374	1.9	5.8
93.0	433	3.02055	0.44583	2.0	5.2
93.5	421	2.97007	0.45398	1.8	5.4
94.0	338	3.07012	0.44545	2.0	5.1
94.5	71	2.95775	0.40591	2.1	4.0
95.0	3	3.53333	0.30551	3.2	3.8

Statistics for Left Ventricular Dimension (Diastole)

HALFYEAR	N	MEAN	STD	MIN	MAX
91.0	290	4.80966	0.43455	3.7	6.1
91.5	370	4.75216	0.46353	3.3	7.0
92.0	463	4.78272	0.44698	3.5	6.4
92.5	450	4.78356	0.44845	3.5	7.0
93.0	439	4.73235	0.43300	3.3	7.0
93.5	432	4.70509	0.47618	0.9	6.6
94.0	342	4.77368	0.43600	3.6	6.8
94.5	71	4.68310	0.45229	3.5	5.8
95.0	3	5.20000	0.36056	4.8	5.5

Statistics for Fractional Shortening

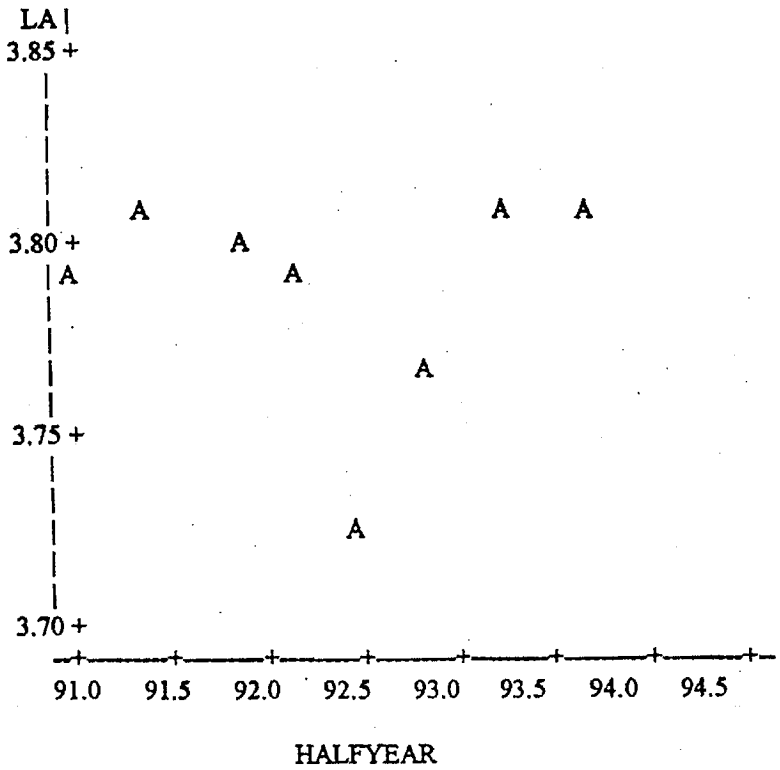
HALFYEAR	N	MEAN	STD	MIN	MAX
91.0	287	37.0410	6.39116	21.4286	57.1429
91.5	364	37.9294	6.61011	15.5556	59.1837
92.0	460	36.7951	6.10038	12.0000	52.1739
92.5	444	37.7946	6.87523	2.0000	57.4468
93.0	432	36.1723	6.80611	13.5593	55.5556
93.5	421	37.0039	6.72376	12.1951	56.5217
94.0	338	35.6073	7.15878	0.0000	51.1111
94.5	71	36.8664	5.90174	22.2222	50.9804
95.0	3	31.8439	7.35601	25.0000	39.6226

HALFYEAR	N	MEAN	STD	MIN	MAX
91.0	290	198.796	49.2995	90.023	350.641
91.5	365	205.066	48.2861	106.604	405.300
92.0	462	202.886	55.7812	80.438	522.584
92.5	445	200.594	48.6025	82.261	374.069
93.0	437	195.948	50.8825	87.545	452.738
93.5	430	197.521	48.3960	90.023	365.988
94.0	340	200.008	49.2434	98.137	410.375
94.5	71	192.857	48.3881	102.327	304.666
95.0	3	202.989	77.0663	134.123	286.231

EXAM 5 -- Statistical Summaries by Time Period

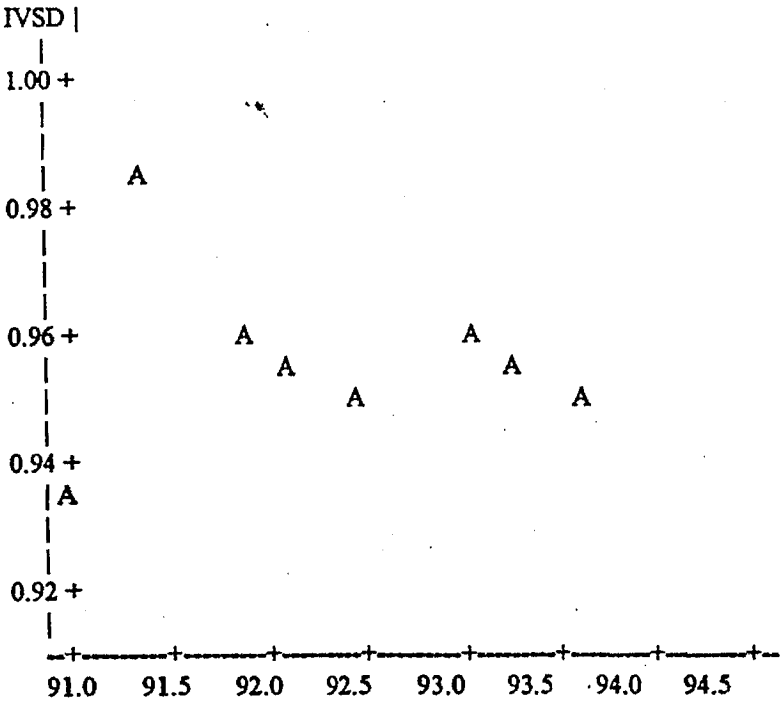
Statistics for Left Atrial Size

Plot of LA*HALFYEAR. Legend: A = 1 obs, B = 2 obs, etc.



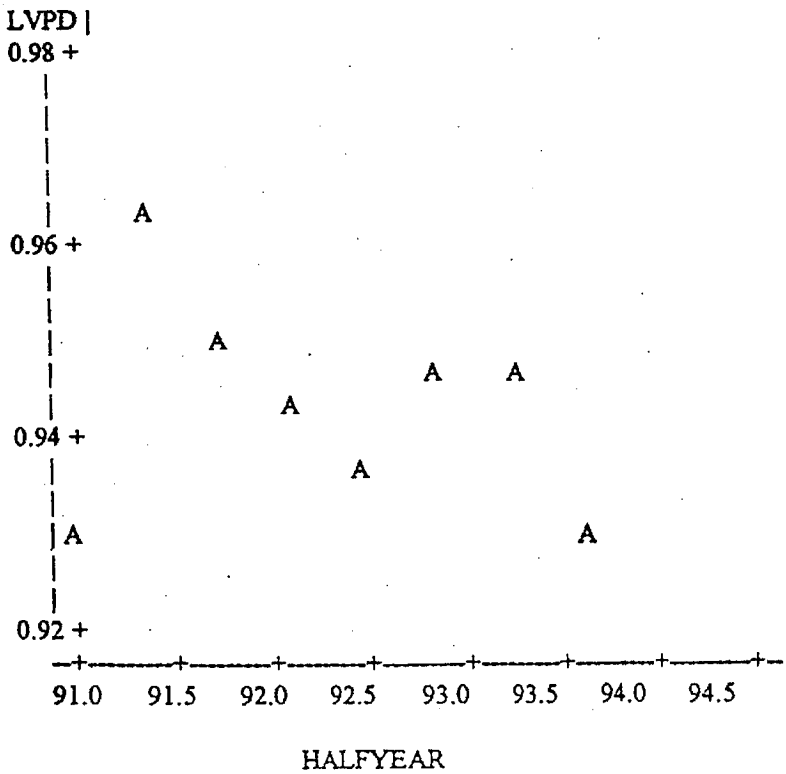
Statistics for Intraventricular Septal Wall Thickness

Plot of IVSD*HALFYEAR. Legend: A = 1 obs, B = 2 obs, etc.



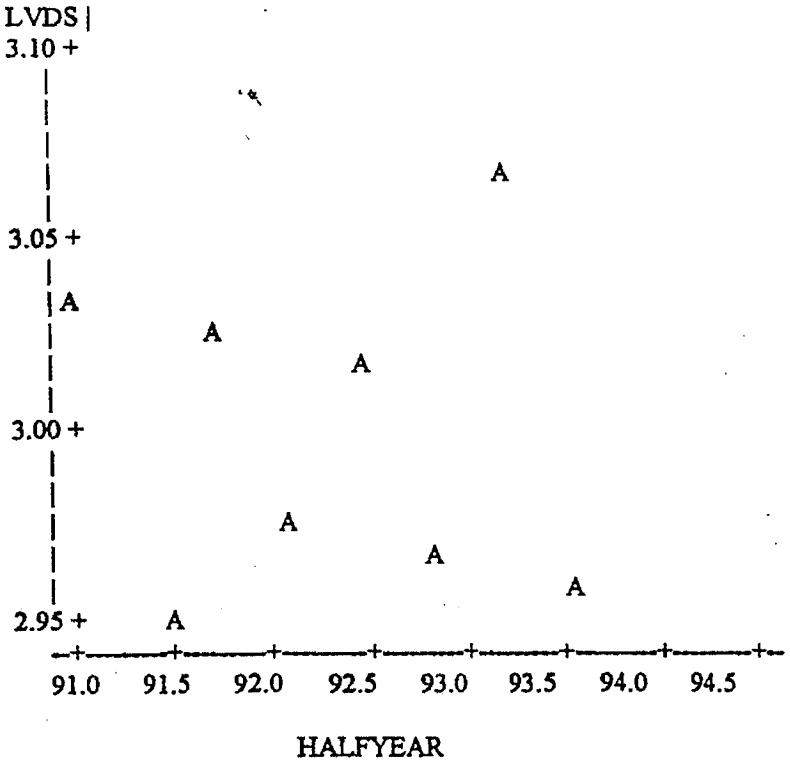
Statistics for Posterior Wall Thickness

Plot of LVPD*HALFYEAR. Legend: A = 1 obs, B = 2 obs, etc.



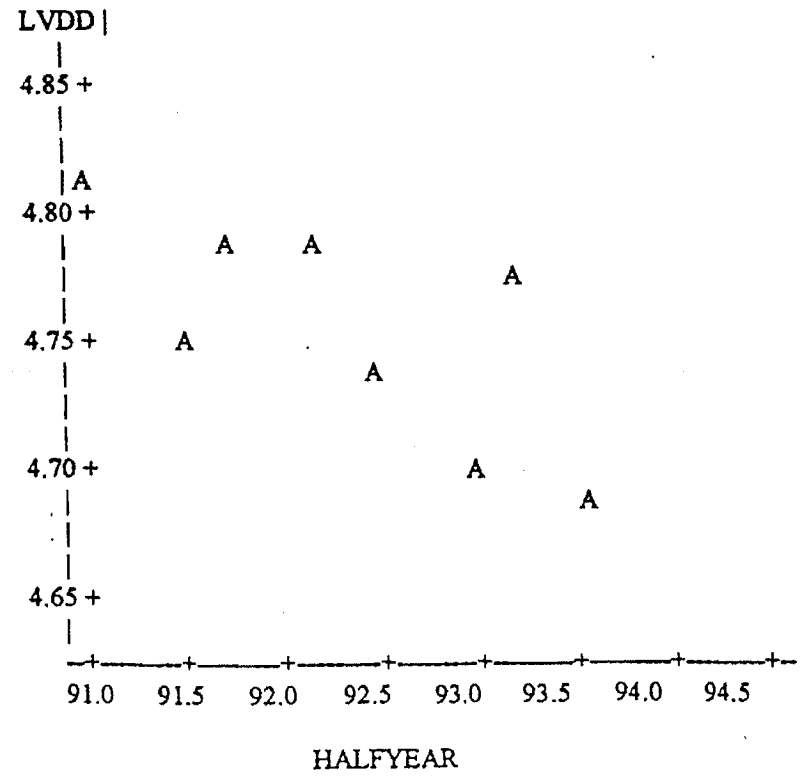
Statistics for Left Ventricular Dimension (Systole)

Plot of LVDS*HALFYEAR. Legend: A = 1 obs, B = 2 obs, etc.



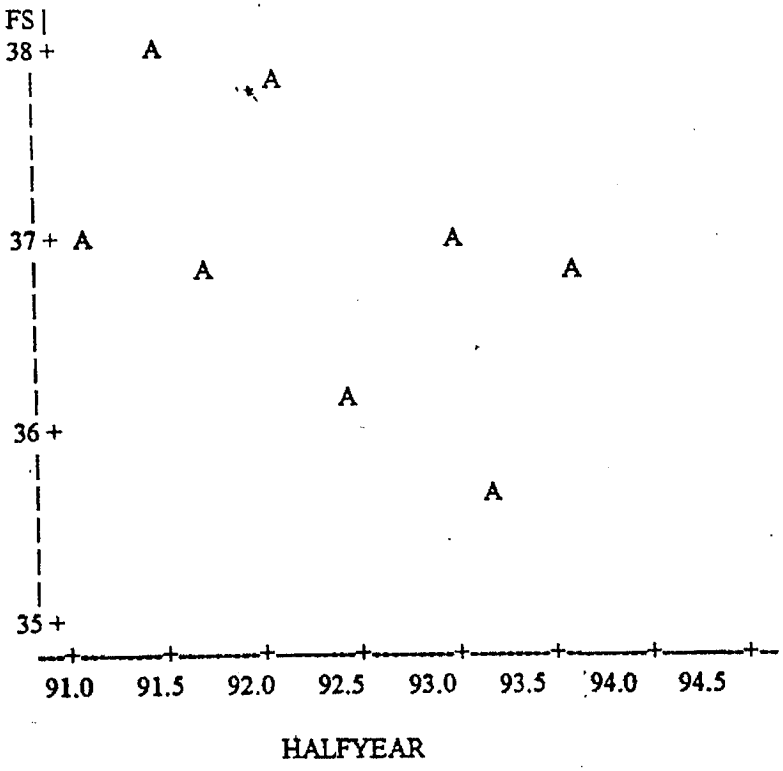
Statistics for Left Ventricular Dimension (Diastole)

Plot of LVDD*HALFYEAR. Legend: A = 1 obs, B = 2 obs, etc.



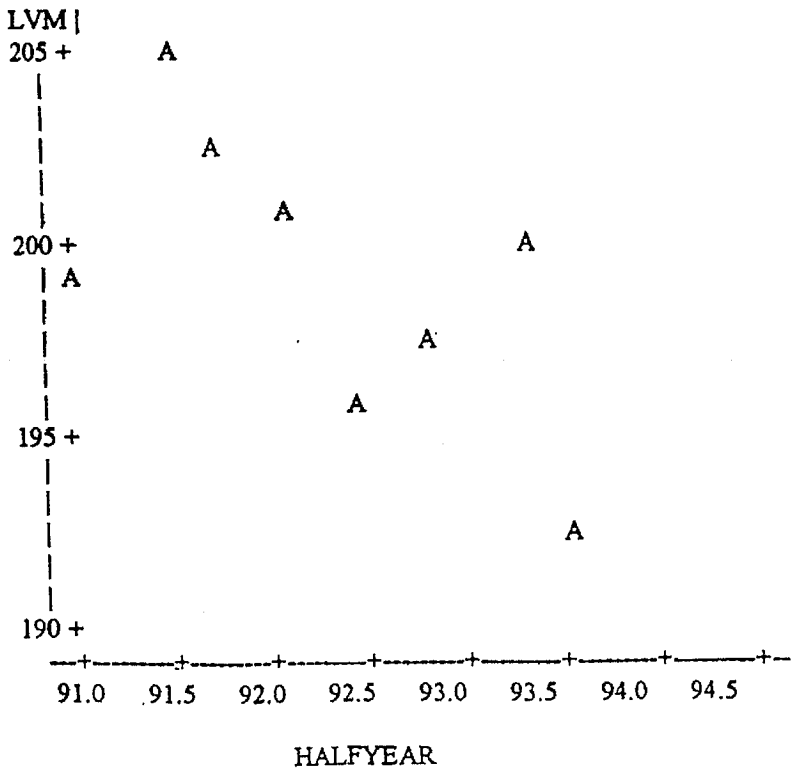
Statistics for Fractional Shortening

Plot of FS*HALFYEAR. Legend: A = 1 obs, B = 2 obs, etc.



Statistics for Left Ventricular Mass

Plot of LVM*HALFYEAR. Legend: A = 1 obs, B = 2 obs, etc.



Twenty echocardiography studies performed during March 1995 were chosen for an experiment to assess intra- and inter-reader reliability. Each study was "read" by four readers (physicians and echo technicians) with replicate readings done about one month later. This report presents statistics for intra-reader and inter-reader comparisons on four separate variables: left ventricular internal dimension measured in diastole, left ventricular mass, fractional shortening, and left atrial internal dimension in diastole.

The template for analysis and reporting was the same for each variable. Within-reader analyses were done first. Included were the mean of all pairs of readings on the same subject (PAIRMEAN), and bias between first and second readings (REL_BIAS) as a percentage of PAIRMEAN. Additionally, variance-components models were used to estimate the standard deviation for each reader of between-subject variability (STD_SUBJ) and of within-subject variability (STD_ERR). Correlations of 1st and 2nd readings by the same reader were estimated from this model, as was the relative error relating STD_ERR to the overall MEAN for each reader. Between-reader analyses were done last, in which simple Pearson correlations were computed using the first reading by each reader for each subject.

A general summary of the analyses is as follows. There was not much bias between first and second readings, providing support for the use of variance-components models. All readers had similar mean values, when compared on the same echocardiographic variable, but there was one notable exception: for left ventricular mass, Reader #4 had a lower mean than the other readers. This appeared to result from lower wall-thickness means for Reader #4 (data not shown). Reader #4 also had higher relative error statistics, reflecting greater intra-subject error than the others. A secondary effect was that inter-reader correlations tended to be lower for pairs including Reader #4 than for other pairs. Excellent inter-reader correlations were seen for left ventricular mass and internal dimension, they were usually high for left atrial dimension, but were lower for fractional shortening.

X1,X2 1st and 2nd readings by a reader on a subject

PAIRMEAN Mean across subjects of (X1 + X2)/2

REL_BIAS 100 * MEAN OF (X1-X2) / MEAN OF [(X1+X2) / 2]

SIG_SUBJ estimated st dev for true subject-to-subject variation

SIG_ERR estimated st dev for errors due to different readings

CORR estimated correlation for X1 and X2 based on variance-components model [SIG_SUBJ / (SIG_SUBJ + SIG_ERR)]^2

REL_ERR relative error, 100 * SIG_ERR / MEAN

Between Pairs Pearson correlations between readers from first readings

Left Ventricular Mass (g)

ITEM	READER_1	READER_2	READER_3	READER_4
PAIRMEAN	192.51380	192.22653	198.03552	167.06867
REL_BIAS	-3.39083	1.83851	-1.92783	-0.52871
SIG_SUBJ	60.40420	58.35254	59.75913	51.07047
SIG_ERR	11.18053	12.43543	8.29167	31.43102
REL_ERR	5.80765	6.47188	4.18696	18.81324
R(X1,X2)	0.96687	0.95656	0.98111	0.72528

Correlations Between Pairs of Readers

READER_1	1.00000	0.90366	0.92533	0.80351
READER_2	0.90366	1.00000	0.95818	0.81776
READER_3	0.92533	0.95818	1.00000	0.86726
READER_4	0.80351	0.81776	0.86726	1.00000

Fractional Shortening (%)

ITEM	READER_1	READER_2	READER_3	READER_4
PAIRMEAN	0.37447	0.35452	0.40302	0.38211
REL_BIAS	-2.06632	3.10199	-1.14892	-4.12015
SIG_SUBJ	0.03692	0.04051	0.06580	0.03786
SIG_ERR	0.02107	0.02746	0.01620	0.04245
R(X1,X2)	0.75430	0.68516	0.94286	0.44299
REL_ERR	5.62744	7.80960	4.01949	11.10969

Correlations Between Pairs of Readers

READER_1	1.00000	0.66420	0.61501	0.33982
READER_2	0.66420	1.00000	0.65759	0.61906
READER_3	0.61501	0.65759	1.00000	0.57150
READER_4	0.33982	0.61906	0.57150	1.00000

Left Ventricular Internal Dimension (Diastole)

ITEM	READER_1	READER_2	READER_3	READER_4
PAIRMEAN	4.93630	4.88800	5.02608	5.02887
REL_BIAS	-0.35857	-0.17013	-0.27556	0.01151
SIG_SUBJ	0.58686	0.54963	0.54681	0.61581
SIG_ERR	0.06939	0.07530	0.07248	0.25446
R(X1,X2)	0.98621	0.98158	0.98273	0.85416
REL_ERR	1.40576	1.54206	1.44209	5.05991

Correlations Between Pairs of Readers

READER_1	1.00000	0.95609	0.94099	0.86642
READER_2	0.95609	1.00000	0.93160	0.87032
READER_3	0.94099	0.93160	1.00000	0.85979
READER_4	0.86642	0.87032	0.85979	1.00000

ITEM	READER_1	READER_2	READER_3	READER_4
PAIRMEAN	3.09840	2.90324	2.99165	2.95705
REL_BIAS	0.42603	0.94813	1.05962	-4.68372
SIG_SUBJ	0.43970	0.35850	0.50347	0.40752
SIG_ERR	0.06820	0.10041	0.13039	0.20494
R(X1,X2)	0.97651	0.92726	0.93715	0.79815
REL_ERR	2.20100	3.47932	4.35837	6.93043
Correlations Between Pairs of Readers				
READER_1	1.00000	0.81879	0.94795	0.78659
READER_2	0.81879	1.00000	0.77857	0.58470
READER_3	0.94795	0.77857	1.00000	0.77131
READER_4	0.78659	0.58470	0.77131	1.00000

1. Overall

Echocardiographic data were available on 340 of 528 participants from examination cycle 6. Summary statistics are shown below. There were valid measurements for 337 (99.1%) subjects for left atrial size, 292 (85.9%) for wall thicknesses, and 290 (85.3%) subjects for left ventricular internal dimensions, fractional shortening and LV mass.

Echocardiography Data

Variable	N	Mean	Std Dev	Minimum	Maximum
LAD	337	4.0268593	0.5879019	2.3697400	6.1624600
IVSD	293	0.9528225	0.1661289	0.6050400	1.9578100
LVPD	292	0.9219233	0.1487276	0.6214700	1.8396600
LVDD	290	4.8858944	0.5481752	3.6680600	7.4599300
LVDS	290	3.1906074	0.5376747	2.0781000	6.3291200
FS	290	0.3487957	0.0584186	0.1050123	0.5076324
LVM	290	165.5691972	51.2693908	78.8291912	410.3400230

2. Echocardiographic Data by Time Period

Statistical summaries are presented by half-year time period for 1995 and the first half of 1996. At first glance, there appears to be a tendency towards increasing dimensions and decreasing fractional shortening across time periods.

HALFYEAR=95.0

Variable	N	Mean	Std Dev	Minimum	Maximum
LAD	58	3.9110033	0.6286057	2.8983100	6.1624600
IVSD	54	0.9248500	0.1520879	0.6050400	1.3277300
LVPD	53	0.8746089	0.1490483	0.6214700	1.1932800
LVDD	53	4.9357528	0.5191181	3.7693400	6.2184700
LVDS	53	3.1388128	0.5759421	2.2184800	4.8813100
FS	53	0.3671334	0.0658846	0.2022165	0.4912581
LVM	53	159.3774949	45.1285972	81.8396761	239.0033034

Variable	N	Mean	Std Dev	Minimum	Maximum
LAD	80	4.0040130	0.5534428	2.6329200	5.4852400
IVSD	69	0.9514516	0.1795598	0.6413500	1.5443100
LVPD	69	0.9234919	0.1485233	0.6610100	1.5021100
LVDD	68	4.8618334	0.6451047	3.8014200	7.4599300
LVDS	68	3.1820666	0.6836033	2.1702100	6.3291200
FS	68	0.3495361	0.0598818	0.1050123	0.4512987
LVM	68	163.1175049	50.2283103	78.8291912	395.3028266

HALFYEAR=96.0

Variable	N	Mean	Std Dev	Minimum	Maximum
LAD	198	4.0696475	0.5884760	2.3697400	5.6974800
IVSD	169	0.9632245	0.1646871	0.6610100	1.9578100
LVPD	169	0.9368425	0.1465957	0.7032300	1.8396600
LVDD	168	4.8780346	0.5171740	3.6680600	6.5042000
LVDS	168	3.2121341	0.4557015	2.0781000	4.8403400
FS	168	0.3421542	0.0539625	0.1968098	0.5076324
LVM	168	168.6277229	53.6312350	83.2065343	410.3400230

Comparisons of means for LAD, LVDD, FS and LVM were made between periods after adjusting for participant's sex, age and height. These adjutest means are shown below. There was a difference in LAD means ($P = 0.005$) across time periods, but not in other variables ($P > 0.08$ for each).

General Linear Models: Least Squares Means

HALFYEAR	LVM	FS	LVDD	LAD
95.0	153.101640	0.36249236	4.82315094	3.72078664
95.5	156.430383	0.35400771	4.79140559	3.94075823
96.0	169.456739	0.33931768	4.90334787	4.07019096

Twenty echocardiography studies performed from March 1995 through September 1995 were selected as a "validation set" for assessing intra- and inter-reader reliability as well as sonographer effects. Ten studies (subjects) were chosen for each of 2 sonographers for a total of twenty subjects. Each subject's study was read twice by each of four readers (2 physicians, 2 echo technicians), with the replicate readings done about one month after the initial reading.

Here, statistics for intra-reader and inter-reader comparisons are reported for four variables: left ventricular mass, fractional shortening, and left atrial internal left ventricular internal dimension measured in diastole, and left atrial internal dimension in diastole.

Overall analyses (not stratified by sonographer) were done first for within-reader and between-reader statistics. As was done for cycle 5, variance-components models were used to estimate the standard deviation for each reader of between-subject variability (STD_SUBJ) and of within-subject variability (STD_ERR). Correlations of 1st and 2nd readings by the same reader were estimated from this model, as was the relative error relating STD_ERR to the overall MEAN for each reader. Between-reader analyses consisted of Pearson correlations between pairs of readers using the first reading by each reader for each subject.

To incorporate different sonographers, the data were reanalyzed using a mixed-model analysis of variance technique: subjects within sonographers had random effects, sonographers and readers had fixed effects. An interaction between reader and sonographer also was investigated.

Mean LV Mass differed among readers, varying from 182.2 to 191.5 grams. Bias and Relative Bias were small for each reader. Furthermore, there was excellent correlation among 1st and 2nd readings within reader (r = 0.917 to r=0.983) reflected in Relative Error values from 2.7% to 6.6%. First readings of different readers also were highly correlated (r=0.901 to r=0.967).

In the mixed-model analysis of variance that included sonographer, Reader was important (P=0.004), but not Sonographer nor the interaction.

Statistics Overall

ITEM	READER_1	READER_2	READER_3	READER_4
PAIRMEAN	185.17795	191.46397	188.12657	182.18563
BIAS	-1.71537	1.56915	2.98449	1.83018
REL_BIAS	-0.92634	0.81955	1.58643	1.00457
SIG_SUBJ	40.52379	42.25433	38.88336	40.31461
SIG_ERR	12.20065	10.78634	5.12465	11.32221
r(X1,X2)	0.91689	0.93882	0.98293	0.92689
REL_ERR	6.58861	5.63361	2.72404	6.21465

Correlations Between Readers on 1st Readings

READER_1	1.00000	0.91205	0.90140	0.92623
READER_2	0.91205	1.00000	0.96362	0.96713
READER_3	0.90140	0.96362	1.00000	0.94527
READER_4	0.92623	0.96713	0.94527	1.00000

Statistics for Sonographer = 28

ITEM	READER_1	READER_2	READER_3	READER_4
PAIRMEAN	178.04799	186.74026	185.13225	174.10279
SIG_SUBJ	38.28223	41.47286	35.20987	39.48326
SIG_ERR	9.30083	9.06821	6.05330	7.06147
r(X1,X2)	0.94426	0.95437	0.97129	0.96901
REL_ERR	5.22378	4.85605	3.26972	4.05592

Statistics for Sonographer = 30

ITEM	READER_1	READER_2	READER_3	READER_4
PAIRMEAN	192.30791	196.18768	191.12088	190.26847
SIG_SUBJ	43.54987	44.78971	43.97297	41.64291
SIG_ERR	14.53294	12.26613	3.98518	14.37082
r(X1,X2)	0.89980	0.93023	0.99185	0.89358
REL_ERR	7.55712	6.25224	2.08516	7.55292

Differences in mean PS existed among readers (Reader #1 had the lowest mean, 34.8% whereas Reader #3 had the highest, 38.5%). But, Bias and Relative Bias were small for all readers (Rel. Bias was under 1.7%). Correlations of 1st and 2nd readings within reader were high (r=0.901 to r=0.944), with Rel. Error values from 4.2% to 6.0%. Correlations of first readings of different readers were good (r=0.729 to r=0.865).

In the mixed-model analysis of variance that included sonographer, Reader was important ($P < 0.0001$), but not Sonographer; the interaction was nominally significant ($P = 0.02$).

Statistics Overall

ITEM	READER_1	READER_2	READER_3	READER_4
PAIRMEAN	0.36397	0.37155	0.38522	0.34786
BIAS	-0.00542	-0.00058	-0.00205	0.00586
REL_BIAS	-1.48854	-0.15608	-0.53296	1.68552
SIG_SUBJ	0.06293	0.07335	0.06316	0.06295
SIG_ERR	0.01971	0.01779	0.01631	0.02090
r(X1,X2)	0.91069	0.94447	0.93747	0.90071
REL_ERR	5.41454	4.78692	4.23423	6.00800

Correlations Between Readers on 1st Readings

READER_1	1.00000	0.86534	0.82954	0.74001
READER_2	0.86534	1.00000	0.86496	0.72945
READER_3	0.82954	0.86496	1.00000	0.85003
READER_4	0.74001	0.72945	0.85003	1.00000

Statistics for Sonographer = 28

ITEM	READER_1	READER_2	READER_3	READER_4
PAIRMEAN	0.37210	0.39265	0.39219	0.35263
SIG_SUBJ	0.07435	0.07867	0.06600	0.07358
SIG_ERR	0.01149	0.02038	0.01833	0.01623
r(X1,X2)	0.97668	0.93713	0.92839	0.95362
REL_ERR	3.08748	5.18921	4.67382	4.60180

ITEM	READER_1	READER_2	READER_3	READER_4
PAIRMEAN	0.35585	0.35046	0.37825	0.34309
BIAS	-0.01344	-0.00423	-0.00659	0.01630
REL_BIAS	-3.77561	-1.20834	-1.74177	4.75022
SIG_SUBJ	0.05204	0.06480	0.06302	0.05408
SIG_ERR	0.02539	0.01475	0.01400	0.02470
r(X1,X2)	0.80768	0.95075	0.95295	0.82738
REL_ERR	7.13584	4.20842	3.70226	7.20019

Relative Bias was about 1% for all readers, but mean values differed among readers once again (4.90 to 5.00 cm). Correlations between 1st and 2nd readings within reader were outstanding (r=0.976 to r=0.990), and Relative Errors were 1.0% to 1.7%. Furthermore, 1st readings by different readers were very highly correlated (r > 0.96).

Using the mixed-model analysis of variance, the Reader effect was found to be important (P < 0.0001), but Sonographer nor the interaction.

Statistics Overall

ITEM	READER_1	READER_2	READER_3	READER_4
PAIRMEAN	4.94413	4.89963	4.95130	5.00058
BIAS	-0.05315	0.00595	-0.01510	-0.04865
REL_BIAS	-1.07501	0.12144	-0.30497	-0.97289
SIG_SUBJ	0.51136	0.52357	0.51272	0.54464
SIG_ERR	0.06492	0.07133	0.05108	0.08405
r(X1,X2)	0.98414	0.98178	0.99017	0.97674
REL_ERR	1.31312	1.45589	1.03174	1.68080

Correlations Between Readers on 1st Readings

READER_1	1.00000	0.98741	0.97848	0.96536
READER_2	0.98741	1.00000	0.98669	0.96447
READER_3	0.97848	0.98669	1.00000	0.96012
READER_4	0.96536	0.96447	0.96012	1.00000

Statistics for Sonographer = 28

PAIRMEAN	4.89670	4.84855	4.91240	4.96915
SIG_SUBJ	0.43517	0.43613	0.42810	0.43349
SIG_ERR	0.08372	0.08544	0.05775	0.06449
r(X1,X2)	0.96431	0.96304	0.98213	0.97835
REL_ERR	1.70977	1.76216	1.17550	1.29777

Statistics for Sonographer = 30

ITEM	READER_1	READER_2	READER_3	READER_4
PAIRMEAN	4.99155	4.95070	4.99020	5.03200
SIG_SUBJ	0.59823	0.61886	0.60703	0.66069
SIG_ERR	0.03769	0.05364	0.04341	0.09985
r(X1,X2)	0.99605	0.99254	0.99491	0.97767
REL_ERR	0.75505	1.08344	0.86999	1.98429

were small (up to 2.7% Rel. Bias). Three Readers had excellent correlations of 1st and 2nd LAD readings (r's above 0.959), whereas the Reader #4 had lower correlation (r=0.739). Rel. Error values were from 2.0% to 8.7%. Correlations between 1st readings of different readers were moderate to high (r=0.617 to r=0.877).

In the mixed-model analysis of variance that included sonographer, Reader was nominally important (P = 0.02), and the Reader * Sonographer interaction (P = 0.01), but not Sonographer per se.

Statistics Overall

ITEM	READER_1	READER_2	READER_3	READER_4
PAIRMEAN	3.11745	2.86936	3.07463	3.08953
BIAS	-0.02805	0.03800	-0.00735	-0.08275
REL_BIAS	-0.89986	1.32434	-0.23905	-2.67841
SIG_SUBJ	0.44380	0.46157	0.41075	0.45155
SIG_ERR	0.09208	0.07964	0.06002	0.26854
r(X1,X2)	0.95873	0.97109	0.97909	0.73874
REL_ERR				

Appendix 5

FHS ECHO Worksheet

Name_____ **ID**___-___ ___ ___ ___ **EXAM** __ __

Study date___/___/___ **Study type** 0 1 2 (0=exam, 1=repeat study, 2=other)

Data entry date___/___/___ **Data entry ID** __ __

Tech ID __ __ **Height (inches)** ___ ___.___ ___ **Weight (pounds)**___ __ __ **Sex M F**

Video OD #_____-_____ **DATA OD #**_____-_____ **SVHS #**_____ **SVHS location**_____

STUDY QUALITY

OD	Good	Fair	Poor	Inadequate
M-mode Ao/LA	☐ =1	☐ =2	☐ =3	☐ =4
M-mode LV	☐ =1	☐ =2	☐ =3	☐ =4
PW mitral inflow	☐ =1	☐ =2	☐ =3	☐ =4
PW LVOT	☐ =1	☐ =2	☐ =3	☐ =4
SVHS				
2-D study	☐ =1	☐ =2	☐ =3	☐ =4
CW TR	☐ =1	☐ =2	☐ =3	☐ =4
CW AV	☐ =1	☐ =2	☐ =3	☐ =4
Color Doppler	☐ =1	☐ =2	☐ =3	☐ =4
Overall study quality	☐ =1	☐ =2	☐ =3	☐ =4

Comments:_____

☐ Priority MD overread:

☐ Severe AS ☐ Severe MS ☐ Mod-severe _____regurgitation
☐ Thrombus ☐ Vegetation ☐ Mass
☐ Large pericardial effusion ☐ Significant LV dysfunction
☐ Other_____
Called Dr._____ Date/time:_____

☐ MD overread, other:

☐ > Mild LAE ☐ > Mild AoR dil. ☐ RA/RV abnormality
☐ Any LVH ☐ Any LVE ☐ LV WMA ☐ ↓ LVEF
☐ MS ☐ > Mild MAC ☐ Any MVP
☐ AS ☐ Bicuspid AV ☐ Valve prosthesis
☐ > Mild _____regurgitation
☐ Other_____

☐ Requested by:

☐_____ ☐ For Dr._____ Date: _____

ver10/25/95

Name_____ID __-_____Reader__ __ __ Reading 1 2 I. Date __/__/__

LA enlargement	☐ **0=no**	☐ **1=borderline**	☐ **2=mild**	☐ **3=mod.**	☐ **4=severe**	☐ **9=unknown**

*Other LA comment*_____

Mitral Valve	☐ **0=normal**	☐ **1=prob nl**	☐ **2=abnl**		☐ **4=prosth.**	☐ **9=unknown**
MV thickening	☐ 0=no		☐ 2=mild		☐ 4=mod/sev	☐ 9=unknown
MS	☐ 0=normal	☐ 1=possible	☐ 2=likely			☐ 9=unknown
MAC	☐ 0=no		☐ 2=mild	☐ 3=moderate	☐ 4=severe	☐ 9=unknown
MVP	☐ 0=no	☐ 1=min.sup.displace	☐ 2=mild		☐ 4=mod/sev	☐ 9=unknown

*Other MV comment*_____

AorticValve	☐ **0=normal**	☐ **1=prob nl**	☐ **2=abnl**		☐ **4=prosth.**	☐ **9=unknown**
AV thickening	☐ 0=no		☐ 2=mild	☐ 3=moderate	☐ 4=severe	☐ 9=unknown
AV cusp excursion	☐ 0=normal		☐ 2=mild ↓	☐ 3=mod. ↓	☐ 4=severe ↓	☐ 9=unknown
Aortic Root	☐ **0=normal**	☐ **1=prob nl**	☐ **2=abnl**			☐ **9=unknown**
Aortic root dilation	☐ 0=no		☐ 2=present			☐ 9=unknown
Aortic root calcium	☐ 0=no		☐ 2=mild	☐ 3=moderate	☐ 4=severe	☐ 9=unknown

*Other AV/Aor comment*_____

LV Structure	☐ **0=normal**	☐ **1=prob nl**	☐ **2=abnl**			☐ **9=unknown**
LV enlargement	☐ 0=no	☐ 1=borderline	☐ 2=mild	☐ 3=mod.	☐ 4=severe	☐ 9=unknown
↑LVWT, concentric	☐ 0=no	☐ 1=borderline	☐ 2=mild	☐ 3=mod.	☐ 4=severe	☐ 9=unknown
↑LVWT, other	☐ 0=no	☐ 1=DUSK	☐ 2=ASH	☐ 3=ISH	☐ 4=oth_____	☐ 9=unknown
LV Regional WMA	☐ **0=normal**	☐ **1=prob nl**	☐ **2=abnl**			☐ **9=unknown**
Septum	☐ 0=normal	☐ 1=paradox.	☐ 2=hypok.	☐ 3=akinetic	☐ 4=dysk.	☐ 9=unknown
Anterior/Anterolateral	☐ 0=normal		☐ 2=hypok.	☐ 3=akinetic	☐ 4=dysk.	☐ 9=unknown
Posterior	☐ 0=normal		☐ 2=hypok.	☐ 3=akinetic	☐ 4=dysk.	☐ 9=unknown
Inferior	☐ 0=normal		☐ 2=hypok.	☐ 3=akinetic	☐ 4=dysk.	☐ 9=unknown
Apex	☐ 0=normal		☐ 2=hypok.	☐ 3=akinetic	☐ 4=dysk.	☐ 9=unknown
LV Systolic Function	☐ **0=normal**	☐ **1=prob nl**	☐ **2=regional↓**		☐ **4=global↓**	☐ **9=unknown**
LV ejection fraction	☐ 0=normal	☐ 1=borderline	☐ 2=mild ↓	☐ 3=mod. ↓	☐ 4=severe ↓	☐ 9=unknown

*Other LV comment*_____ *LVEF__ __%*

Right Heart/Pericardium	☐ **0=normal**	☐ **1= prob nl**	☐ **2=abnl**			☐ **9=unknown**
RA enlargement	☐ 0=no		☐ 2=mild		☐ 4=mod/sev.	☐ 9=unknown
RV enlargement	☐ 0=no		☐ 2=mild		☐ 4=mod/sev.	☐ 9=unknown
RV hypertrophy	☐ 0=no		☐ 2=mild		☐ 4=mod/sev.	☐ 9=unknown
Pericardial fluid	☐ 0=no/sys.		☐ 2=small		☐ 4=med/lge	☐ 9=unknown

*Other right ♡/pericardium*_____

Valve Regurgitation	☐ **0=none**		☐ **2=present**			☐ **9=unknown**
Mitral	☐ 0=none	☐ 1=trace	☐ 2=mild	☐ 3=moderate	☐ 4=severe	☐ 9=unknown
Aortic	☐ 0=none	☐ 1=trace	☐ 2=mild	☐ 3=moderate	☐ 4=severe	☐ 9=unknown
Tricuspid	☐ 0=none	☐ 1=trace	☐ 2=mild	☐ 3=moderate	☐ 4=severe	☐ 9=unknown
If TR present, velocity	☐ 0=(<2)	☐ 1=(2-2.4)	☐ 2=(2.5-2.9)	☐ 3=(3.0-3.6)	☐ 4=(>3.6)	☐ 9=unknown
Mitral Stenosis	☐ **0=none**	☐ **1=trivial**	☐ **2=mild**	☐ **3=mod.**	☐ **4=severe**	☐ **9=unknown**
Aortic Stenosis	☐ **0=none**	☐ **1=trivial**	☐ **2=mild**	☐ **3=mod.**	☐ **4=severe**	☐ **9=unknown**

*Other Doppler comment*_____

Comments:_____

Clinical correlation suggested ☐ **0=not applicable** ☐ **2=yes**

ver 6/21/96

Appendix 6

Framingham Heart Study
Bibliography Related to Echocardiography

FRAMINGHAM HEART STUDY: BIBLIOGRAPHY RELATED TO ECHOCARDIOGRAPHY

1. D. D. Savage, R. J. Garrison, W. P. Castelli, P. M. McNamara, S. J. Anderson, W. B. Kannel, and M. Feinleib. Prevalence of submitral (anular) calcium and its correlates in a general population-based sample (the Framingham Study). *Am.J.Cardiol.* 51:1375-1378, 1983.
2. D. D. Savage, W. P. Castelli, R. D. Abbott, R. J. Garrison, S. J. Anderson, W. B. Kannel, and M. Feinleib. Hypertrophic cardiomyopathy and its markers in the general population: The great masquerader revisited: the Framingham Study. *J.Cardiovasc.Ultrasonography* 2(1):41-47, 1983.
3. D. D. Savage, R. J. Garrison, F. N. Brand, S. J. Anderson, W. P. Castelli, W. B. Kannel, and M. Feinleib. Prevalence and correlates of posterior extra echocardiographic spaces in a free-living population based sample (the Framingham Study). *Am.J.Cardiol.* 51:1207-1212, 1983.
4. D. D. Savage, D. Levy, R. J. Garrison, W. P. Castelli, P. Kligfield, R. B. Devereux, S. J. Anderson, W. B. Kannel, and M. Feinleib. Mitral valve prolapse in the general population. 3. Dysrhythmias: the Framingham Study. *Am.Heart J.* 106:582-586, 1983.
5. D. D. Savage, R. B. Devereux, R. J. Garrison, W. P. Castelli, S. J. Anderson, D. Levy, H. E. Thomas, W. B. Kannel, and M. Feinleib. Mitral valve prolapse in the general population. 2. Clinical features: the Framingham Study. *Am.Heart J.* 106:577-581, 1983.
6. D. D. Savage, W. P. Castelli, S. J. Anderson, and W. B. Kannel. Sudden unexpected death during ambulatory electrocardiographic monitoring. The Framingham Study. *Am.J.Med.* 74:148-152, 1983.
7. D. D. Savage, R. J. Garrison, R. B. Devereux, W. P. Castelli, S. J. Anderson, D. Levy, P. M. McNamara, J. I. Stokes, W. B. Kannel, and M. Feinleib. Mitral valve prolapse in the general population. 1. Epidemiologic features: the Framingham Study. *Am.Heart J.* 106:571-576, 1983.
8. Levy D, Anderson KM, Plehn JF, Savage DD, Christiansen JC, Castelli WP: Echocardiographically determined left ventricular structural and functional correlates of complex or frequent ventricular arrhythmias on one-hour ambulatory electrocardiographic monitoring. Am.J.Cardiol. 1987;59:836-830.
9. Levy D, Savage DD: Prevalence and clinical features of mitral valve prolapse. Am.Heart J. 1987;113:1281-1290.
10. Levy D, Savage DD, Garrison RJ, Anderson KM, Kannel WB, Castelli WP: Echocardiographic criteria for left ventricular hypertrophy: the Framingham Heart Study. Am.J.Cardiol. 1987;59:956-960.
11. Levy D, Anderson KM, Savage DD, Balkus SA, Kannel WB, Castelli WP: Risk of ventricular arrhythmias in left ventricular hypertrophy: the Framingham Heart Study. Am.J.Cardiol. 1987;60:560-565.
12. Savage DD, Brand FN, Kannel WB: Does posterior extra-echocardiographic space always mean disease? Primary Cardiol. 1987;12-18.
13. Savage DD, Garrison RJ, Kannel WB, et al: The spectrum of left ventricular hypertrophy in a general population sample: the Framingham Study. Circulation 1987;75(Suppl I):I-26
14. Savage DD, Garrison RJ, Kannel WB, Anderson SJ, Feinleib M, Castelli WP: Considerations in the use of echocardiography in epidemiology. The Framingham Study. Hypertension 1987;9(Suppl II):II40-II44
15. Levy D, Anderson KM, Savage DD, Kannel WB, Christiansen JC, Castelli WP: Echocardiographically detected left ventricular hypertrophy: prevalence and risk factors. The Framingham Heart Study. Ann.Intern.Med. 1988;108:7-13.
16. Levy D: Left ventricular hypertrophy. Epidemiological insights from the Framingham Study. Drugs 1988;(Suppl 5):1-5.
17. Dannenberg AL, Levy D, Garrison RJ: Impact of age on echocardiographic left ventricular mass in a healthy population (the Framingham Study). Am.J.Cardiol. 1989;64:1066-1068.

18. Levy D, Garrison RJ, Savage DD, Kannel WB, Castelli WP: Left ventricular mass and incidence of coronary heart disease in an elderly cohort. The Framingham Heart Study. Ann.Intern.Med. 1989;110:101-107.
19. Levy D, Garrison RJ, Savage DD, Kannel WB, Castelli WP: Prognostic implications of echocardiographically determined left ventricular mass in the Framingham Heart Study. N.Engl.J.Med. 1990;322:1561-1566.
20. Savage DD, Levy D, Dannenberg AL, Garrison RJ, Castelli WP: Association of echocardiographic left ventricular mass with body size, blood pressure and physical activity (the Framingham Study). Am.J.Cardiol. 1990;65:371-376.
21. Galderisi M, Anderson KM, Wilson PWF, Levy D: Echocardiographic evidence for the existence of a distinct diabetic cardiomyopathy (the Framingham Heart Study). Am.J.Cardiol. 1991;68:85-89.
22. Lauer MS, Anderson KM, Levy D: Influence of contemporary versus 30-year blood pressure levels on left ventricular mass and geometry: the Framingham Heart Study [see comments]. JACC 1991;18:1287-1296.
23. Lauer MS, Anderson KM, Kannel WB, Levy D: The impact of obesity on left ventricular mass and geometry. JAMA 1991;266:231-236.
24. Levy D: Clinical significance of left ventricular hypertrophy: insights from the Framingham Study. J.Cardiovasc.Pharmacol. 1991;17 Suppl 2:S1-S6
25. Manolio TA, Levy D, Garrison RJ, Castelli WP, Kannel WB: Relation of alcohol intake to left ventricular mass: the Framingham Study. JACC 1991;17:717-721.
26. Benjamin EJ, Plehn JF, D'Agostino RB, et al: Mitral annular calcification and the risk of stroke in an elderly cohort. N.Engl.J.Med. 1992;327:374-379.
27. Benjamin EJ, Levy D, Anderson KM, et al: Determinates of Doppler indexes of left ventricular diastolic function in normal subjects (the Framingham Heart Study). Am.J.Cardiol. 1992;70:508-515.
28. Devereux RB, Diodati JG, Levy D: Cardiac hypertrophy: practice implications. Patient Care 1992;88-122.
29. Galderisi M, Benjamin EJ, Evans JC, et al: Intra- and interobserver reproducibility of Doppler-assessed indexes of left ventricular diastolic function in a population- based study (the Framingham Heart Study). Am J Cardiol 1992;70:1341-1346.
30. Galderisi M, Lauer MS, Levy D: Echocardiographic determinants of clinical outcome in subjects with coronary artery disease (the Framingham Heart Study). Am J Cardiol 1992;70:971-976.
31. Lauer MS, Evans JC, Levy D: Prognostic implications of subclinical left ventricular dilation and systolic dysfunction in men free of overt cardiovascular disease (the Framingham Heart Study). Am J Cardiol 1992;70:1180-1184.
32. Lauer MS, Levy D: Left ventricular hypertrophy: risk, clinical correlates, and therapeutic implications. Focus on Hypertension 1992;5-10.
33. Lauer MS, Anderson KM, Levy D: Separate and joint influences of obesity and mild hypertension on left ventricular mass and geometry: the Framingham Heart Study. JACC 1992;19:130-134.
34. Lauer MS, Levy D, Anderson KM, Plehn JF: Is there a relationship between exercise systolic blood pressure response and left ventricular mass? The Framingham Heart Study. Ann.Intern.Med. 1992;116:203-210.
35. Levy D, Murabito JM, Anderson KM, Christiansen JC, Castelli WP: Echocardiographic left ventricular hypertrophy: clinical characteristics. The Framingham Heart Study. Clin Exp Hypertens [A] 1992;14:85-97.
36. Galderisi M, Benjamin EJ, Evans JC, et al: Impact of heart rate and PR interval on Doppler indexes of left ventricular diastolic filling in an elderly cohort (the Framingham Heart Study). Am J Cardiol 1993;72:1183-1187.
37. Krumholz HM, Larson M, Levy D: Sex differences in cardiac adaptation to isolated systolic hypertension. Am J Cardiol 1993;72:310-313.

38. Norman JE, Levy D, Campbell G, Bailey JJ: Improved detection of echocardiographic left ventricular hypertrophy using a new electrocardiographic algorithm. J Am Coll Cardiol 1993;21:1680-1686.
39. Sagie A, Benjamin EJ, Galderisi M, et al: Echocardiographic assessment of left ventricular structure and diastolic filling in elderly subjects with borderline isolated systolic hypertension (the Framingham Heart Study). Am J Cardiol 1993;72:662-665.
40. Sagie A, Benjamin EJ, Galderisi M, et al: Reference values for doppler indexes of left ventricular diastolic filling in the elderly. J Am Soc Echocardiogr 1993;6:570-576.
41. Bikkina M, Levy D, Evans JC, et al: Left ventricular mass and risk of stroke in an elderly cohort. JAMA1994;272:33-36.
42. Lauer MS, Anderson KM, Larson MG, Levy D: A new method for indexing left ventricular mass for differences in body size. Am J Cardiol 1994;74:487-491.
43. Post WS, Larson MG, Levy D: Impact of left ventricular structure on the incidence of hypertension: the Framingham Heart Study. Circulation 1994;90:179-185.
44. Post WS, Larson MG, Levy D: Hemodynamic predictors of incident hypertension: the Framingham Heart Study. Hypertension 1994;24:585-590.
45. Post WS, Levy D: New developments in the epidemiology of left ventricular hypertrophy. Current Opinion in Cardiology 1994;9:534-541.
46. Vaziri SM, Larson MG, Benjamin EJ, Levy D: Echocardiographic predictors of nonrheumatic atrial fibrillation. The Framingham Heart Study. Circulation 1994;89:724-730.
47. Benjamin EJ, D'Agostino RB, Belanger AJ, Wolf PA: Left atrial size and the risk of stroke and death. The Framingham Heart Study. Circulation 1995;92:835-841.
48. Vasan RS, Larson MG, Levy D: Determinants of echocardiographic aortic root size. The Framingham Heart Study. Circulation 1995;91:734-740.
49. Vasan RS, Larson MG, Benjamin EJ, Levy D: Echocardiographic reference values for aortic root size: The Framingham Heart Study. J Am Soc Echocardiogr 1995;8:793-800.
50. Vasan RS, Benjamin EJ, Levy D: Prevalence, clinical features and prognosis of diastolic heart failure: An epidemiologic perspective. J Am Coll Cardiol 1995;26:1565-1574.
51. Vaziri SM, Larson MG, Lauer MS, Benjamin EJ, Levy D: Influence of blood pressure on left atrial size. The Framingham Heart Study. Hypertension 1995;25:1155-1160.
52. Chen L, Benjamin EJ, Larson MG, Evans JC, Levy D: Doppler diastolic filling indexes in relation to disease states. Hypertension 1996;131:519-524.
53. Lauer MS, Larson MG, Levy D: Gender-specific reference M-mode values in adults: population-derived values with consideration of the impact of height. J Am Coll Cardiol 1996;26:1039-1046.
54. Levy D, Lauer MS: Left ventricular hypertrophy: echocardiographic assessment and prognostic implications, in Sutton MGStJ, Oldershaw PJ, Kotler MN (eds): Textbook of Echocardiography and Doppler in Adults and Children. Cambridge,MA, Blackwell Science; 1996:342-352.
55. Lindpaintner K, Lee ML, Larson MG, et al: Absence of association or genetic linkage between the angiotensin-converting-enzyme gene and left ventricular mass. N Engl J Med 1996;334:1023-1028.
56. Norman JE, Levy D: Improved electrocardiographic detection of echocardiographic left ventricular hypertrophy: results of a correlated data base approach. J Am Coll Cardiol 1996;26:1022-1029.
57. Vasan RS, Levy D: The role of hypertension in the pathogenesis of heart failure: a clinical mechanistic overview. Arch.Intern.Med. 1996;156:1789-1796.
58. Post WS, Larson MG, Myers RH, Galderisi M, Levy D: Heritability of left venticular mass:the Framingham Heart Study. Hypertension 1997;30:1025-1028.
59. Vasan RS, Larson MG, Benjamin EJ, Evans J, Levy D: Left venticular dilation and the risk of congestive heart failure in people without myocardial infraction. N Engl J Med 1997;336:1350-1355.
60. Vasan RS, Levy D: The progression from hypertension to heart failure:an overview of pathogenetic mechanisms, in Coats A (ed): Controversies in the Management of Heart Failure. New York, Churchill Livingstone; 1997:1-10.

61. Vasan RS, Larson MG, Levy D, Evans JC, Benjamin EJ: Distribution and categorization of echocardiographic measurements in relation to reference limits: The Framingham Heart Study:formulation of a height-and sex-specific classification and its prospective validation. Circulation 1997;96:1863-1873.
62. Lauer MS, Larson MG, Evans JC, Levy D. Assciation of left ventricular dilation and hypertrophy with chronotropic incompetence in the Framingham Heart Study. Am Heart J 1999; 137:903-909.
63. Haider AW, Larson MG, Benjamin EJ, Levy D. Increased left ventricular mass and hypertrophy are associated with increased risk for sudden death. J Am Coll Cardiol 1998;32:1454-9.
64. Benjamin EJ, Levy D. Why is left ventricular hypertrophy so predictive of morbidity and mortality? Am J Med Sci 1999;317:168-75.
65. Singh JP, Evans JC, Levy D, Larson MG, Freed LA, Fuller DL, Lehman B, Benjamin EJ. Prevalence and clinical determinants of mitral, tricuspid, and aortic regurgitation (the Framingham Heart Study). Am J Cardiol 1999;83:897-902.
66. Vasan RS, Larson MG, Benjamin EJ, Evans JC, Reiss CK, Levy D. Congestive heart failure in subjects with normal versus reduced left ventricular ejection fraction: prevalence and mortality in a population-based cohort. J Am Coll Cardiol 1999;33:1948-55.
67. Freed LA, Levy D, Levine RA, Larson MG, Evans JC, Fuller DL, Lehman B, Benjamin EJ. Prevalence and clinical outcome of mitral-valve prolapse. N Engl J Med 1999;341:1-7.
68. Vasan RS, Levy D, Larson MG, Benjamin EJ. Interpretation of echocardiographic measurements: a call for standardization. Am Heart J 2000;139:412-22.