6.1 Overview of Blood Pressure Measurement

In the AASK Study, sitting and standing blood pressure is measured at every visit in a resting state, using three sitting measurements and one standing measurement with a random-zero sphygmomanometer. The random-zero device has an important advantage over the conventional fixed zero manometer: it prevents the AASK blood pressure observer from knowing the actual blood pressure value and therefore removes judgments about blood pressure levels for readings close to critical values such as a diastolic of 90 mm Hg.

Correct measurement of blood pressure is of the utmost importance to the success of this study since the study proposes to explore both the specific antihypertensives and the different levels of blood pressure control that might slow the rate of decline of renal function in hypertensive African Americans. It is essential that the procedures described below for measuring blood pressure be followed exactly. Precision is essential for valid comparisons of blood pressures between treatment groups and in individuals across time.

6.2 Background

Experience in providing training support for blood pressure observers, to help them achieve and maintain a high standard of measurement performance, has been a potentially valuable by-product of the nation-wide Hypertension Detection and Follow-up Program (HDFP)[1] and the Systolic Hypertension in the Elderly Program (SHEP)[2]. This training activity was necessarily an integral aspect of HDFP and SHEP. However, the measurement problems addressed in the Programs were not unique, and the solutions formulated by the investigators of these trials may therefore be helpful to others who encounter some of the same problems in planning detection and/or follow-up procedures for high blood pressure.

In this spirit, we present to the AASK investigators the essential components of the HDFP/SHEP training and certification programs for blood pressure observers. These components include the step-by-step procedures for use of the random-zero sphygmomanometer; brief lecture/slide presentations for initial orientation of trainees; and the training/certification procedure developed for the HDFP, adapted for the SHEP, and now adapted for use in the AASK Study including a videotape test for the quantitative assessment of individual observers' measurement performance. The actual scoring for this videotape test and its procedures will be conducted by the Data Coordinating Center.

It should be noted that other reference materials are available which blood pressure observers would be well advised to consult. Foremost is the American Heart Association booklet, "Recommendations for Human Blood Pressure Determination by Sphygmomanometers" (the latest edition is by Frolich, et al 1987)[3] (a copy is attached) which has long been regarded as a standard reference on the subject. In addition, a 1978 publication by Prineas (Blood Pressure Sounds: Their Measurement and Meaning - A Training Manual)[4] provides a comprehensive discussion of the problems in blood pressure

measurement as well as an extensive bibliography.

6.3 Training and Certification

High quality blood pressure readings are fundamental to any sound program measuring and controlling blood pressure levels.[6-8] Yet many factors, including influences of the subject, the observer, the equipment, and the circumstances of measurement, work against the attainment of this basic objective. Thus, good results cannot be taken for granted and special attention must be focused on blood pressure measurement procedures.

Before the actual initiation of standardized measurements, a program of training and certification must be provided so that all staff responsible for recording blood pressure readings will be certified as having met a stipulated level of performance. Recertification will be required at annual intervals for the duration of an observer's service in AASK.

The AASK certification process includes training and the successful completion of:

* a written test
* a live evaluation
* a videotape test.

The training strategy adopted by AASK is a two-stage program. Before the program begins, each Clinical Center will identify one specific Training Supervisor for that clinic. The Training Supervisor must have at least 6 months prior experience in taking blood pressures. These Training Supervisors from each Clinical Center (and other blood pressure observers for the general session, if the Centers desire) will meet centrally each year in the first stage of training. The supervisors and observers who pass the program will be certified as Blood Pressure Observers. The Supervisors can, in turn, train additional observers in the Clinical Centers. This is the second stage of training. To this end, each Center will be provided with the full set of training materials needed to reproduce the same program for their field and clinic staff. In this second stage, the Data Coordinating Center will receive documentation of each observer's training performance from the Training Supervisors in the Clinical Centers (including the successful completion of the written test and the live evaluation). However, scoring of the video test will be done by the Data Coordinating Center, WHICH IS RESPONSIBLE FOR IDENTIFYING WHO IS A CERTIFIED AASK BLOOD PRESSURE OBSERVER. Results of the certification tests will be telephoned to a Clinical Center within three (3) working days of receipt of the test data from that clinic. Through this scheme, training will be the responsibility of both the Clinical Centers and the Data Coordinating Center. The Data Coordinating Center will, in addition, remain responsible for overall monitoring and quality control (as will be described in Section 6.7).

6.4Blood Pressure Measurement Step By Step

6.4.1 Overview

In this chapter, the step-by-step procedures for blood pressure measurement in AASK are

presented. It should be emphasized that the steps outlined here can satisfactorily be followed for the vast majority of adult subjects participating in ambulatory screening and follow-up. Exceptional situations do arise, with sometimes serious obstacles to successful blood pressure measurement. The training program for a particular setting must include guidelines for handling such exceptions. Only a few will be noted. It will be the responsibility of the Training Supervisors in the Clinical Centers and in the Data Coordinating Center to encourage observers to note exceptional circumstances and to seek consultation with the Blood Pressure Consultant at the DCC when they arise so that participants will be appropriately evaluated.

The Hawksley MKII random-zero (R-Z) sphygmomanometers are used for blood pressure measurement for all AASK clinic visits and for the determination of peak inflation levels. This manual will concentrate on this device. Because the conventional Baum sphygmomanometer may be used in screening, this device will also be described to a lesser extent, but the procedures are identical (except, of course, for resetting and recording the random-zero level).

It should be noted also that the procedures listed here are illustrated in the third lecture/slide presentation, "Procedures in Blood Pressure Recording" (Section 6.5.7).

6.4.2 Preparation for Blood Pressure Measurement

Some of the many extraneous factors influencing blood pressure are controlled by standardizing the measurement technique and the environment in which the measurement is made. Uncontrolled factors (time of day, identity of the observer) are recorded, so that they can be taken into account during analysis.

AASK patients must abstain from caffeine, smoking, and exercise at least one half hour prior to and until completion of the blood pressure measurement. Current drug intake, including medications affecting blood pressure and non-prescription drugs, is recorded on the day of the examination.

Try to keep the blood pressure measurement as pleasant as possible. Patients should be given full explanation and instructions about the preparation for the blood pressure examination and an opportunity for brief questions. The setting in which blood pressure measurements are made will be standardized, and should take place in a separate, quiet room where no other activity is taking place, and where temperature fluctuations are minimal. Scheduling procedures should try to establish consistent appointment times to minimize as much as possible the impact of daily blood pressure variation. Equipment (including study forms, sphygmomanometer, etc.) should be checked and waiting for the participant.

Allow five minutes of rest in this quiet room after arm measurement and calculation of corrected peak inflation level but before pulse is measured which occurs prior to taking the blood pressure. Explain to the participant that the five minute rest period will provide for more valid blood pressure measurements. Preferably, at this time, the observer should leave the

room. The participant should be relaxed, seated with legs uncrossed and feet comfortably flat on the floor, not dangling.

6.4.3 Blood Pressure Measurement Procedures

The sitting arm blood pressure is measured three times at each clinic visit. It takes approximately 10 to 15 minutes to make three blood pressure measurements including the initial five minute rest. The blood pressure measurements should be done early in the clinic visit but blood pressure measurements are not to be done while a GFR or any other procedure is being performed.

Blood pressure equipment should be checked prior to seeing the patient. Once a participant is given instructions and explanations blood pressure measurement begins. The following steps must be followed precisely. The procedure is described here employing the AASK Blood Pressure Form 10.

All blood pressure measurements conducted by AASK Study Personnel on AASK patients must be recorded in the data base, regardless of the clinical condition of the patient at the time of the measurement. This includes blood pressure measurements taken on days of GFR visits, and at both protocol and interim visits.

If more than one RZ blood pressure measurement is obtained on the same patient the same day, then:

1)Form 10s must be completed for each RZ blood pressure measurement that is taken

2)The Form 10 for the FIRST RZ blood pressure must be keyed by the center into the AASK data base

3)Form 10s for all additional RZ blood pressure measurements recorded on the same day should be faxed to the DCC

4)The complete AASK protocol for blood pressure measurements must be followed for each measurement

All blood pressure measurements taken by AASK personnel should be done by the random zero sphygmomanometer if at all possible. If blood pressure measurements are taken by AASK personnel on AASK patients using non-RZ devices at any time, these measurements must now be recorded on the Form 9 Non-RZ blood pressure form.

Blood pressure measurements conducted by AASK study personnel on AASK patients should be conducted at the AASK clinic or a satellite office if at all possible. This applies both to protocol and interim visits.

Details:

A. In exceptional circumstances blood pressure measurements may be conducted outside the AASK clinic or satellite office (e.g. at the patient's home or work), but the frequency of such measurements should be kept as small as possible.

B. A new item on Form 11 will now capture the location of all visits, so that for some analyses in-home blood pressure measurements can be assessed separately from measurement conducted in the AASK clinics.

6.4.4 Stethoscope

A standard Littman stethoscope (or other comparable stethoscope) with a bell is used. Korotkoff sounds are best heard with the bell because of their low pitch. Stethoscope tubing should be about 10 to 12 inches from the bell piece to "Y" branching. This length provides optimal acoustical properties and allows the observer to read the sphygmomanometer at eye level and in a comfortable position. Earpieces should fit comfortably and snugly in the ears. Four points should be observed in using the stethoscope.

1. The ear pieces should be directed forwards into the external ear canal.
2. The ear pieces should be tight enough to exclude outside sound but not so tight that they cause discomfort.
3. The valve between the bell and the diaphragm should be turned in the direction of the bell.
4. The bell of the stethoscope should be placed lightly on the skin overlying the brachial artery - immediately below, but not touching, the cuff. The brachial artery is usually found above the crease of the arm, slightly towards the body. Light pressure accentuates low-pitched sound and avoids compression murmurs. Pressing too heavily with the stethoscope over the brachial artery causes turbulent flow in the artery and a murmur can be heard which may prolong the apparent duration of fourth-phase Korotkoff sounds.

6.4.5 Arm Measurement and Cuff Sizes

The proper cuff size must be used to avoid under- or over-estimating the correct blood pressure. Baum Calibrated V-Lok cuff sizes are used in the AASK Study. To determine the proper cuff size, the observer must measure the arm circumference at the midpoint of the arm at each visit. This measurement is taken on the right arm that has been bared from the shoulder. With the participant standing, holding the forearm horizontal, the arm length is measured from the acromion (or boney extremity of the shoulder girdle) to the olecranon (or tip of the elbow) with a plastic coated metric tape. The midpoint is marked on the dorsal surface. The participant should then relax the arm along the side of the body. The arm circumference is measured by drawing the tape snugly around the arm at the level of the midpoint marking. Care must be taken to keep the tape horizontal. Also, the tape should not indent the skin. The chart of arm circumference measurements and corresponding cuff sizes (shown below) is consulted, and the indicated cuff size is checked on the study form and used. Do not use the cuff itself as a measurement device because the ranges marked on

the cuff may not correspond with the table. A copy of this chart can be found on Form 10. This chart should be consulted for each arm measurement. The markings found on most blood pressure cuffs should not be used for reference because they may be incorrect.

Determination of Cuff Size Based on Arm Circumference

Arm Circumference	**Cuff Size (cm)**
< 24 cm	Child, Pediatric, Small Adult
24 to < 33 cm	Adult, Regular
33 to 41 cm	Large Adult
> 41 cm	Thigh, Extra Large

6.4.6 Application of the Blood Pressure Cuff

Next, the appropriate cuff (as determined in the arm measurement procedure) is placed around the upper right arm so that the midpoint of the length of the bladder lies over the brachial artery and the mid-height of the cuff is at heart level. The lower edge of the cuff, with its tubing connections, should be placed about 1 inch above the natural crease across the inner aspect of the elbow. The cuff is wrapped snugly about the arm, with the palm of the participant's hand turned upward. The wrapped cuff should be secured firmly by applying pressure to the locking fabric fastener over the area where it is applied to the cuff.

6.4.7 Determining the Peak Inflation Level

For each participant it is necessary to determine the pressure level to which the cuff is to be inflated for accurate measurement of the systolic pressure. This is because the pressure at the start of the reading should always exceed the systolic pressure, otherwise the first of the Korotkoff sounds will be missed (see Lecture #1). This starting pressure is called the Peak Inflation Pressure and is determined as follows. First, the cuff tubing should be attached to the random-zero sphygmomanometer. With the control valve in the OPEN position, the cuff should be inflated while the radial pulse is palpated and the mercury column watched closely. When sufficient pressure has been applied, the pulse will no longer be felt. The cuff should continue to be inflated until it reaches a level of 160 mm Hg. At 160 mm Hg, the control valve is turned to the CLOSE position. Feel for the pulse. If the pulse is still felt, the cuff pressure should be increased until the pulse disappears. Either the first or the second of these procedures will identify the Observed Pulse Obliteration Pressure. When this has been detected, the cuff is quickly and completely deflated. The Observed Pulse Obliteration Pressure and the zero-value are recorded in the spaces provided on the study form and the Corrected Pulse Obliteration Pressure is calculated. To the corrected value, add the R-Z maximum zero number for this device (found next to the mercury column) plus 20 mm Hg. This summed value is the Peak Inflation Level. The cuff is to be inflated to this level or to 160 mm Hg, whichever is greater, for all readings at this examination.

NOTE: All readings on the sphygmomanometer are made to the nearest even digit. Any reading that appears to fall exactly between markings on the column should be read to the next marking immediately above, i.e., 2, 4, 6, 8, or 0. All readings are to be made at the top of the meniscus, or rounded surface of the mercury column. Be careful: when the pressure is released quickly from a high level, a vacuum is formed above the mercury and the meniscus is distorted. A few moments should be allowed for it to reappear before the manometer is read.

6.4.8 Pulse Measurement

Part of the blood pressure measurement procedure is the measurement of the pulse, as observed by palpation of the radial artery at the wrist. For simplicity, the right arm is to be used consistently for measurement of both pulse and blood pressure. This measurement serves two purposes: (1) to document the resting heart rate at the time of examination, and (2) to permit detection of gross irregularities of heart rhythm which may affect the interpretation of the blood pressure readings.

A good stop watch should be used for the 5 minute waiting period prior to pulse measurement, 30 second pulse measurement, and 30 second intervals between blood pressure readings. The Cronus Stop Watch, Model 3-S, is an interval timer and is a preferred timing device. Of the various options, it seems to be the simplest and easiest to read and is generally available at a local sporting goods store. The address of the manufacturer is:

Cronus Precision Products, Inc.
2895 Northwestern Parkway
Santa Clara, California 95051

The measurement of pulse is performed only after the participant has been seated quietly, with feet flat on the floor, in an erect but comfortable posture, for at least five minutes. The patient should refrain from caffeine, smoking, and exercise at least one half hour prior to and until completion of blood pressure measurement. The elbow and forearm should rest comfortably on the table. With the palm of the hand turned upward, the radial pulse is palpated and counted for 30 seconds exactly. The number of beats in 30 seconds is recorded, multiplied by 2, and the product recorded as the heart rate. Any marked irregularity observed during this period should be called to the attention of the Principal Investigator and the Blood Pressure Training Supervisor.

6.4.9 Blood Pressure Readings

Next, the observer should proceed to carry out the first blood pressure reading. Detailed instructions are given below for measuring blood pressure with both a conventional and a random-zero sphygmomanometer.

6.4.10 The Random-Zero Mercury Sphygmomanometer

The design and operation of a conventional sphygmomanometer are based upon the combined principles of compression of the brachial artery under an elastic inflatable cuff, direct auscultation of the Korotkoff sounds through a standard stethoscope, and direct registration of pressure levels by a mercury manometer. The observer inflates the cuff, listens for the first- (systolic) and fifth- (diastolic) phase Korotkoff sounds, reads the mercury level in the column, deflates the cuff, and records the readings.

The Hawksley MKII random-zero sphygmomanometer is also a mercury sphygmomanometer, with the same basic principles of operation. The essential distinction is a mechanism designed to produce a variable level of mercury in the manometer column when the actual pressure in the cuff is zero. This is accomplished through an adjustable-volume chamber which is interconnected with the mercury reservoir at one end and the manometer column at the other end. The adjustment is made by the observer by spinning an external wheel which contacts and rotates an internal, bevelled cam. The position where the cam comes to rest after spinning determines where the bevelled edge will meet the sliding wall of the mercury chamber. When air pressure is applied through the cuff, the wall is displaced until it rests against the cam and only the mercury remaining after filling this new volume of the chamber is displaced into the manometer column. A valve controlled by the observer locks the chamber system after the maximum inflation pressure desired has been applied so that at the end of the reading, and only at the end, the mercury comes to rest at its "randomly" determined zero-pressure level. When this value is subtracted from the recorded readings, the corrected readings give the corresponding actual pressure levels. Thus, by the addition of this mechanism for varying the "zero" level of mercury to the conventional device, the random-zero device obscures the true levels of pressure observed until after the uncorrected blood pressure is recorded and the "zero" level is read and subtracted. In this way, some of the recognized difficulties in observer performance are substantially reduced, primarily interference by observer bias when readings fall near critical levels of blood pressure.

6.4.11 Measuring Blood Pressure with a Random-Zero Device

The steps for readings with the random-zero device are described below.

(1)Wait at least 30 seconds after complete deflation of the cuff following any preceding inflation.

(2)Connect the cuff to the random-zero device.

(3)Ensure that the mercury reservoir lever is in the operating position by turning the control valve on the face of the device to the right to the position marked OPEN.

(4)Using downstrokes only, gently turn the wheel at the right side of the device by stroking it a few times with the extended fingertips of the right hand. (Do not try to spin it wildly!)

(5)Place the ear pieces of the stethoscope into the ears, with the tips turned forward.

(6)Apply the bell of the stethoscope over the brachial artery, just below but not touching the cuff or tubing. The brachial artery is usually found at the crease of the arm, slightly toward the body.

(7)Using the previously determined peak inflation level, inflate to this level or to 160 mm Hg, whichever is greater. The eyes of the observer should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.

(8)Close the thumb valve and turn the control valve to the left, to the position marked CLOSE.

(9)By opening the thumb valve slightly and maintaining a constant rate of deflation at approximately 2 mm Hg per second, allow the cuff to deflate, listening throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the first regular sound is heard), until 10 mm Hg below the level of the diastolic reading (that is, 10 mm Hg below the level where the last regular sound is heard).

(10)Open the thumb valve fully and disconnect the tubing from the cuff allowing the mercury to fall to its "zero" level for this reading. Remove the stethoscope earpieces from the ears.

(11)Record the uncorrected systolic and diastolic readings.

(12)Read the "zero" level for this reading and record it in the space provided on the study form, beneath the uncorrected systolic and diastolic readings.

(13)By subtraction, calculate and record the actual systolic and diastolic readings in the spaces provided. These are the First Random-Zero Blood Pressure Values.

(14)Repeat steps 3 through 13 two more times, waiting at least 30 seconds after complete deflation of the cuff following any preceding inflation. These are the Second and Third Random-Zero Blood Pressure Values.

6.4.12 Criteria for Systolic and Diastolic Blood Pressure

To correctly identify the 1st-phase (systolic) and 5th-phase (diastolic) Korotkoff values, the observer must listen carefully via the stethoscope while reading and interpreting the mercury column. The systolic value can be identified as the pressure level where the first of 2 or more sounds are heard in appropriate rhythm. The diastolic value can be identified as the pressure level where the last of these rhythmic sounds is heard (that is the last audible rhythmic sound not the first point where sound is not heard). The mercury should be made to drop at 2 mm Hg per second, from the maximum pressure until 10 mm Hg below that of the last regular sound heard. The control of the deflation rate is essential for accurate readings and depends on handling of the bulb and its control valve.

PLEASE NOTE: A single sound heard in isolation (i.e., not in rhythmic sequence) before the first of the rhythmic sounds (systolic) or following the last of the rhythmic sounds (diastolic) does not alter the interpretation of the blood pressure.

6.4.13 Blood Pressure Calculations

Blood pressure calculations are made with the mean of the last two readings documented as the clinic visit measurement. When the form is entered into Oracle, the zero value will be subtracted from the readings to get the actual (corrected) systolic and diastolic blood pressure measurements. All arithmetic will be done within Oracle, although you may hand calculate values for patient care using a calculator. MAP is manually calculated by:

$$\frac{SBP-DBP}{3} + DBP$$

If for any reason the observer is unable or has forgotten to complete any portion of the exam, and the participant is gone, leave the items blank on the paper form. If a blood pressure value is missed or forgotten, completely deflate the cuff and start over with a replacement reading after the proper interval. Do not reinflate the blood pressure cuff during a reading. However, under no other circumstances may a replacement reading be obtained. Do not redo a reading that looks unusual to you.

6.4.14 Reporting the Blood Pressure Results to the Participant

The patient may wish to know his or her results before the form is entered into Oracle. If so, average the second and third corrected random-zero readings and give the results to the participant. State clearly the systolic and diastolic pressures and offer to write down these values for the participant.

6.5 Training Materials

6.5.1 Overview of Training Materials

Trainees are first oriented to the subject of blood pressure measurement with a series of lecture-slide presentations. A brief description of each is given here.

1.Blood Pressure Measurement - Problems and Solutions (lecture)

A general discussion of blood pressure, the history of its measurement, and some of the problems and solutions inherent in its measurement. (Section 6.5.4)

2.The Random-Zero Device (lecture and slides)

An explanation of the mechanics and the principles of the operation of this device. (Section 6.5.5)

3.Procedures in Blood Pressure Recording (lecture and slides)

Step-by-step instructions on how to measure blood pressure using the random-zero sphygmomanometer. (Sections 6.5.7 - 6.5.16)

4.Local Blood Pressure Equipment Maintenance and MercuryToxicity Safety Responsibility

(notes)

Step-by-step instructions on how to perform routine maintenance duties on both the random-zero and conventional sphygmomanometers. (Sections 6.5.17 - 6.5.19)

5. Training Observers in the Clinical Center (lecture)

Instructions for the Training Supervisor in local training. (Sections 6.5.21 - 6.6.3)

6.5.2 General Plan

After the first three presentations, the trainee may be given a written examination that tests his or her comprehension of the methods used in measuring blood pressure.

When the supervisor feels that the trainee has reached a satisfactory level of proficiency in determining the systolic and diastolic blood pressure levels, the trainee should be given The Live Blood Pressure Reading Performance Evaluation. The observer must demonstrate to the training supervisor one or more complete and correct blood pressure determination procedures for 1) cuff selection by correct arm measurement, 2) determination of pulse, 3) determination of peak inflation level using the random-zero or conventional sphygmomanometer, as appropriate and 4) correct blood pressure measurement following the protocol. The final test to certify an observer will be a videotape test, originally produced by the HDFP specifically for this purpose. The test involves watching a mercury column on a sphygmomanometer and listening to the simultaneous Korotkoff sounds during blood pressure measurements, then recording the systolic and diastolic levels for each on the videotape test sheet. The sheet is then sent to the Data Coordinating Center. The systolic and diastolic readings are entered into a computer and scored.

6.5.3 Lecture/Slide Presentations

Five lectures (two with slides) are offered in this section to acquaint the trainee with the subject of blood pressure and its measurement.

The training of potential blood pressure observers should begin with a general discussion of blood pressure and some of the history of blood pressure measurement. The first lecture, "Blood Pressure Measurement - Problems and Solutions," addresses these topics and also reviews some of the problems and solutions in blood pressure measurement. This presentation is quite limited with respect to the physiology of blood pressure regulation and the hemodynamics leading to production of the Korotkoff sounds. The objective instead is to provide sufficient information for any trainee of high school graduate level or beyond, without prior clinical training, to appreciate the significance of the auscultatory signals for blood pressure reading and to recognize those factors of greatest importance for the quality of the readings.

The second lecture, "The Random-Zero Device," is accompanied by a slide series that aids in the

explanation of the mechanics and the proper use of this device.

The third lecture, also accompanied by slides, is entitled, "Procedures in Blood Pressure Recording." This presentation gives instructions in the blood pressure measurement technique adopted by the HDFP, SHEP, and now AASK. Procedures for using both the conventional and the random-zero devices are given.

The fourth and fifth lectures will give the local Training Supervisors a broad overview of the maintenance of the blood pressure equipment with special emphasis on mercury safety and tips/requirements for local blood pressure training.

6.5.4 Lecture #1

Blood Pressure Measurement - Problems and Solutions

What is blood pressure? This question can be answered in many ways - for example, in terms of physiologic and sometimes pathologic processes which contribute to blood pressure regulation. Or, blood pressure can be described in terms of the striking excess in risk of death and disease which accompany high blood pressure levels. For our immediate purposes a more useful and more appropriate answer is, simply: Blood pressure is what is recorded when the measurement methods learned through this training program are carried out.

If we are defining blood pressure in terms of the means of measuring it, the nature of this measurement must be understood. A brief historical sketch is helpful. Measurement of blood pressure by means of the usual mercury manometer, cuff and stethoscope is a method less than 100 years old, although Hales described experimental direct arterial pressure measurements over 200 years ago and Harvey described the circulation of the blood more than 300 years ago.

The start of this century was the period when current, indirect methods were introduced. These were more practical than the lethal method of Hales and qualify as what we would term today a "non-invasive" technique. This indirect method, now almost universally employed, combines the work of Riva-Rocci, an Italian physician who developed the inflatable cuff, and Korotkoff, the Russian physician who described his auscultatory findings, heard through a stethoscope placed over the brachial artery, as an improvement over mere palpation of the radial pulse, a technique limited to detecting systolic pressure alone.

The report of Korotkoff's first observations is an informative summary of the specific sounds he described:

On the basis of his observations, the speaker has come to the conclusion that the completely compressed artery under normal circumstances does not produce any sounds. Utilizing this phenomenon, he proposes the auditory method of determining the blood pressure in man. The cuff of Riva-Rocci is placed on the middle third of the upper arm, the pressure within

the cuff is quickly raised up to the complete cessation of circulation below the cuff. Then, letting the mercury of the manometer fall, one listens to the artery just below the cuff with a children's stethoscope. At first, no sounds are heard. With the falling of the mercury in the manometer, down to a certain height, the first short tones appear; their appearance indicates the passage of part of the pulse wave under the cuff. It follows that the manometric figure at which the first tone appears corresponds to the maximal pressure. With the further fall of the mercury in the manometer, the systolic compression murmurs are heard, which pass again into tones (second). Finally, all sounds disappear. The time of the cessation of sounds indicates the free passage of the pulse wave; in other words, at the moment of the disappearance of the sounds, the minimal blood pressure within the artery preponderates over the pressure in the cuff. Consequently, the manometric figures at this time correspond to the minimal blood pressure. Experiments on animals gave confirmative results. The first sound-tones appear (10 to 12 mm) earlier than the pulse, for the palpation of which (e.g., in the radial artery) the inrush of the greater part of the pulse wave is required. [Quoted from Ruskin, A. Classics in Arterial Hypertension, Charles C. Thomas, Springfield, 1956 (pp. 127-128).]

With further refinement in criteria by which changes in sound quality are to be judged, we arrive very nearly, but not quite, at the level of technological advance applicable to the conventional mercury sphygmomanometer today. In summary then, we may define blood pressure as the phenomenon measured when the cuff, mercury manometer and stethoscope are used in the standard manner by a trained observer to assess the cardiovascular status of a subject.

Discussion of blood pressure in these terms would be seriously incomplete, however, if we did not take account of the fact that important problems of measurement exist. It is imperative that these problems be recognized and, as far as possible, overcome. What are they?

An excellent review by Evans and Rose[7] distinguishes first random variation within each subject, and second, systematic variation which they subclassify as follows: "(i) alarmingly large differences in estimation between observers, sometimes as large as 15 mm Hg..., (ii) effects of the circumstances of measurement, both emotional and physical (especially recent physical activity or change of position), (iii) seasonal changes, and (iv) relatively small errors due to overestimation of pressures in fat arms...."

If these are the major categories of problems, what can be done to deal with them? With respect to random individual variation for each person, we obtain multiple readings on each occasion of observation and use as our estimate of blood pressure an average of two readings, always excluding the first inflation of the cuff (used only to estimate the peak inflation level).

What about the systematic biases? Taking those listed in reverse order, we may say the following. The fat arm should be wrapped in a cuff of appropriate size - either the large arm cuff, or if necessary, the thigh cuff - to exclude the effect of a single cuff size in giving falsely high readings for participants with excessive arm girth. Effects of circumstances, especially activity and posture, can be dealt with by requiring that all readings be taken in the sitting

position, only after a minimum period of 5 minutes seated at rest, according to carefully prescribed procedures. As to differences between observers, a systematic difference as large as 15 mm Hg would indeed be alarming, and in fact unacceptable. However, a difference of $\pm$ 4 mm Hg is acceptable. In still another publication dealing with measurement of blood pressure, Rose presented in greater detail some components of the remaining major problem, observer differences in blood pressure readings. These components are considered as of two types, one type affecting chiefly the mean of a series of measurements, the other type chiefly distorting the reported frequency distribution of readings. This latter type includes terminal digit preference, which is the unconscious tendency to choose one digit over others in assigning the value of a reading and the prejudice against certain values. Factors affecting mean differences between observers include mental concentration or reaction time, hearing acuity, confusion of auditory or visual cues, interpretation of sounds, rates of inflation and deflation of the cuff, and reading of the moving column of mercury.

Are there answers to these problems? Regarding hearing acuity, deficiencies can be excluded by satisfactory performance on the videotape test. Regarding the effects of prejudicial reading, a device can be used that is designed primarily to overcome this tendency, the Random-Zero device. For all the remaining problems, we have a single answer: TRAINING. We will talk shortly about the random-zero device and about the standard procedures to control the circumstances of measurement. Training will occupy the rest of our attention to blood pressure measurement, for a good number of hours. The method of training and its specific objectives are therefore worth brief discussion now.

Training in blood pressure measurement will take three forms. First, there will be lecture and slide presentations to acquaint you with the proper procedures for measuring blood pressure and also to familiarize you with the random-zero device. Second, you will take actual live blood pressure readings. The objective of live reading practice is to become thoroughly familiar with the details of standard procedure so that their performance becomes a matter of habit. Proficiency in this aspect of training will be assessed under observation by the training supervisor. And third, your ability to measure blood pressure accurately as a result of this training will be tested using a videotape to simulate the fall of mercury with accompanying Korotkoff sounds during an actual blood pressure measurement. You will be required to determine the systolic and diastolic levels for each subject in the film, within predetermined limits.

Our responsibility, in supervision of this training program, is to offer all possible assistance to each of you, individually, in meeting these requirements and in completing each step necessary for your certification as a qualified blood pressure observer. We trust that you will take every opportunity to raise questions and indicate to us any problems you may have in working with these materials and completing the program satisfactorily. Accurate blood pressure measurement is critical, and there are methods available to substantially reduce the systematic errors that we have recognized. Your participation in this program will take advantage of these methods to assure a highly qualified group of observers.

6.5.5 Lecture #2

The Random-Zero Device

The random-zero device is essentially a mercury sphygmomanometer like the conventional device in common use. It differs in the important respect that a mechanical addition allows the mercury level in the column to be varied for each reading and concealed from the observer until the systolic and diastolic readings have been completed. This arrangement thus avoids the observer bias which is often at play when the observer knows the actual pressure level as the reading is carried out.

How this device is operated and how its mechanical features fulfill the objectives of its design can best be appreciated by inspecting the device, by practicing its use, and by preliminary inside view. We will take this preliminary view first, through a series of slides, and later practice with it.

6.5.6 Slide

Number	**Script For Slide**
1.	As we have already discussed, the random-zero device and the conventional mercury sphygmomanometer are essentially very similar. This can be seen in comparing the two devices side by side. The random-zero device is unique, however, as the following slides will show.
2.	The crucial distinction is the wheel on the right-hand side of the random-zero casing. To get a little closer to the workings of the device, we may remove the front of the casing, to find
3.	the manometer column, the cuff and its connections, and one notable feature: a lever controlling the reservoir outlet. This lever is always closed for carrying the device (i.e., turned to the left) and opened (i.e., turned to the right) for operating it. You might notice also that the mercury rests at a level above 0 mm, even though the cuff is not inflated. Let's take a close look at the mechanism that accomplishes this to see how simple it really is.
4.	To remove the rear portion of the casing (which should be done only by the Training Supervisor or other authorized staff member, and only when necessary for adjustment or standardization) one needs only to remove two screws from the upper face of the device, and two from the lower rear.
5.	Now we can get a better look at the inside. You will notice right away that the wheel you spin from outside is larger in diameter than you might have guessed, and it occupies a central position in the internal mechanism of the device. The movable rear wall of the chamber is the large round disc up above, which is ringed with its rubber seal.
6.	From directly behind you can see the wheel in relation to the chamber wall, and also the black rubber air hose connecting the cuff with the top of the mercury-filled plastic hose which connects the bottom of the reservoir with the chamber.

7.In this view you can see the control knob which the observer operates to open and close the connection between chamber and reservoir. Also, nearly the whole movable chamber wall can be seen. What gets in the way is a small aluminum cylinder cam which we will want to focus on in a moment. From the side we can see the three key elements that give this device its special value: the rubber-edged wheel which is spun (from the outside) before each reading; the cylindrical aluminum cam which contacts the rubber rim of the wheel and spins at the same time (and its bevelled forward end which extends forward in varying degrees depending where it comes to rest); and finally the movable rear wall of the chamber, which will be arrested in its backward movement when pressure is applied as soon as it contacts the cam. When the cuff is inflated, pressure on the reservoir will force mercury into the chamber until the wall reaches the cam and stops. The amount of mercury in the chamber at this point will determine the "zero" reading for this one time, aiding the observer to make objective readings unaffected by knowledge of the true reading.

6.5.7 Lecture #3

Procedures In Blood Pressure Recording

These procedures for blood pressure recording were developed after extensive consideration and discussion of numerous approaches to measurement techniques. In addition to the selection of instruments and specification of criteria for measurement, we specify methods for the entire sequence of steps in blood pressure recording. For all observers, whether inexperienced in blood pressure measurement or accustomed to different procedures, it will be important to become intimately familiar with these procedures and to carry them out, as early as possible, as a matter of habit. As an introduction, the following series of slides is presented to demonstrate the steps involved for the recording of blood pressure. The sequence presented here illustrates use of both the random-zero and the conventional sphygmomanometers.

6.5.8 Slide

Number **Script For Slide**

Equipment and Supplies

1.The equipment needed by each observer includes a random-zero sphygmomanometer in good condition,
2.or a conventional sphygmomanometer (for optional use during AASK screening)
3.Access is needed to the full set of Baum Calibrated V-Lok cuff sizes for this population. These are commonly referred to as the child (or pediatric) or small adult, adult (or regular), large and thigh (or extra large) cuffs, respectively.
4.The inflation bulb should operate smoothly and should perhaps be individualized to each

observer.

5. The stethoscope, in good condition, should be switched for use of the bell in listening to the Korotkoff sounds.

6. A watch with a sweep second hand or with a digital second display, or a stop watch, is needed for measurement of the pulse rate and for timing certain other steps until they become a matter of habit.

7. A plastic coated measuring tape in metric units is required for determination of the correct cuff size for each participant.

8. A ball point pen should be used for all data recording, preferably with medium or larger point, and black ink.

9. Requirements for furniture are simple but must provide for a comfortable resting position of the arm with mid-cuff at heart level.

--A Mayo stand (or other similar device) should be available for use in the annual standing blood pressures. (Note: No Slide.)

--A 6-7 inch high box large enough to place the RZ on so that the RZ can be read at eye level. (Note: No Slide.)

10. The appropriate study form must be in place before measurement begins.

6.5.9 Arm Measurement

11. Measurement of the arm is required for selection of the proper cuff. For this measurement, the arm should be bare.

12. The measurements are taken on the right arm, with the participant standing, holding the forearm horizontal.

13. Arm length is measured from the acromion or bony extremity of the shoulder girdle,

14. to the olecranon, or tip of the elbow.

15. The full arm length from acromion to olecranon is measured, and

16. the midpoint is marked on the dorsal surface of the arm.

17. With the participant's arm relaxed at the side, the arm circumference is measured by drawing the tape snugly (without indenting the skin) around the arm at the level of the midpoint marking. Care must be taken to keep the tape horizontal.

18. The chart of arm circumference measurements and corresponding cuff sizes is consulted, and

19. the proper cuff size is checked. Indicate this cuff size on the form.

6.5.10 Preparation for Actual Readings

20. The participant should then be seated with the elbow and forearm resting comfortably on a table with the palm of the hand turned upward. The area to which the cuff is to be applied must be bare.

21. The brachial artery is located by palpation and marked,

22. as is the midpoint of the rubber bladder within the cuff. Often this point is marked on the cuff itself.

23. The cuff is then wrapped about the arm so that the midpoint of the bladder lies over the brachial artery, and the mid-height of the cuff is at heart level.

24.The random-zero sphygmomanometer is then connected with the cuff.
25.The manometer is positioned so that the midpoint of the column is at the observer's eye level when in position to carry out the measurement of blood pressure.
26.The radial pulse is located, and
27.with the valve in the OPEN position, the cuff is inflated quickly to 160 mm Hg.
28.The pressure is maintained at 160 mm Hg and the valve then turned to the CLOSE position. A pulse measurement is taken. If the pulse is still detected, the cuff is inflated slowly until the pulse disappears. Either the first or the second of these procedures identifies the Observed Pulse Obliteration Pressure.
29.The cuff is quickly and completely deflated.
30.The observed value and the "zero" value are used to calculate (by subtraction) the Corrected Pulse Obliteration Pressure. All three are recorded on the form.
31.The sum of the "maximum zero" level for this Random-Zero (found next to mercury column) plus 20 mm Hg plus the Corrected Obliteration Pressure equals the Peak Inflation Level.

6.5.11 Pulse

32.After the period of 5 minutes at rest has been completed, the radial pulse is counted for a timed interval of exactly 30 seconds.
33.The 30-second count is recorded and multiplied by 2 to give the full number of beats per minute.

6.5.12First Blood Pressure Reading

34.To perform the measurement of blood pressure itself, the brachial artery is again palpated. Note that the arm remains bare.
35.The wheel of the random-zero is gently spun several times with the valve in the OPEN position.
36.The stethoscope earpieces are put in place with the earpieces positioned forward, and
37.the bell of the stethoscope is placed carefully and without excessive pressure over the brachial artery, just between the elbow crease and lower edge of the cuff.
38.With the valve still in the OPEN position, the cuff is inflated quickly and smoothly to the peak inflation level or to 160 mm Hg, whichever is higher.
39.The valve is then turned to the CLOSE position.
40.The cuff is then deflated very steadily at 2 mm Hg per second,
41.to a level 10 mm Hg lower than the level of the last Korotkoff sound heard.
42.The mercury level is now dropped quickly to the "zero" level for this reading.
43.The cuff is then disconnected and the stethoscope removed.
44.The observed values for the SBP, DBP, and "zero" values are recorded.
45.The "zero" value is subtracted to give the corrected SBP and DBP. This completes the first actual reading.

6.5.13Between Readings

46.If the cuff is uncomfortable for the participant you may remove it, and

47.the observer will raise the participant's arm overhead for 15 seconds without the participant's assistance.
48.The arm is then lowered gently,
49.if the cuff was removed it should be replaced, and
50.the random-zero sphygmomanometer is reconnected.

6.5.14Second Blood Pressure Reading

51.The second reading is carried out exactly as the first, following several gentle spins of the wheel on the random-zero with the valve in the OPEN position.
52.The observed SBP, DBP, and "zero" values are recorded,
53.The corrected values are calculated by subtraction of the "zero" value.

6.5.15Between Readings/Third Blood Pressure Reading

---The cuff may be removed once again and the entire sequence is repeated from having the observer raise the participant's arm overhead for 15 seconds to taking a third Blood Pressure Reading. (Note: No Slide.)
---As before, the observed SBP, DBP, and "zero" values are recorded. (Note: No Slide.)
---The MAP (Mean Arterial Pressure) for the visit will be the average of the second and third MAPS. (Note: No Slide.) This will be calculated within Oracle. The blood pressure observer may supply the participant with the corrected blood pressure values if requested.

6.5.16Standing Blood Pressure Readings

After completing these sitting blood pressure readings, the observer spins the wheel a few times. The adjusted arm support (Mayo stand, or a patient bedside adjustable tray holder) should be situated at the participant's immediate right so that unnecessary movement or walking will not occur when the participant is asked to stand.

The participant is asked to stand quietly for 2 minutes. After the 2 minutes, the observer should raise the participant's arm for 15 seconds. The arm is then placed on the Mayo stand. Immediately, the pulse should be taken for 30 seconds and multiplied by 2 to give the full number of beats per minute. The time lapse from standing is now two minutes and forty-five seconds and the cuff is inflated for standing blood pressure. The cuff is inflated to the peak inflation level and the value on the random zero is moved to the closed position. The pressure is deflated at 2 mm Hg. It is deflated at 2 mm Hg per second until 10 mm Hg below the last Korotkoff sound heard and then deflated quickly and completely. Record your results, including the zero value. The arm is lowered to the side for 15 seconds. During the 15 seconds that the arm is at the participant's side, the observed and the corrected SBP, DBP and "zero" levels are recorded.

The cuff is removed. The participant is then asked to be seated. Any subtraction and multiplication unfinished because of the timing requirements during the standing blood

pressure measurement should be completed. The blood pressure measurement phase of the interview is now completed.

6.5.17Lecture #4

Local Blood Pressure Equipment Maintenance And Mercury Toxicity Safety Responsibility

The condition of the instruments for blood pressure measurement is too often ignored in common practice and should be a special responsibility of the blood pressure observer. This person should be acquainted with mercury toxicity safety procedures as well as construction and function of all the blood pressure equipment. The cuffs and stethoscope, cleanliness and general working order can usually be determined by simple inspection. For either the conventional or random-zero sphygmomanometer, handling of breakable parts and of mercury and oxidized waste requires more careful attention. Guidelines for suggested maintenance procedures for the manometers are outlined here.

6.5.18General Guidelines

1.The objective of maintenance of all sphygmomanometers is to ensure their accuracy for blood pressure measurement. The manometer column must be clean and the system free of mercury leakage. The zero level for the conventional device should be accurately read as 0 mm Hg at the top of the mercury meniscus. The "zero" levels for the random-zero device should have a range of approximately 20 mm Hg between the maximum and the minimum "zero" levels. The minimum "zero" level should be 0, 2 or 4 mm Hg and the maximum "zero" level should be 24 mm Hg or less. These values should remain constant for a given instrument, and the maximum "zero" for each instrument should be indicated by a label on the front of the machine itself for use in the calculation of Peak Inflation Levels for each reading taken with the device.

2.These devices should be cleaned and checked thoroughly on a quarterly basis (approximately every three months). More frequent inspections should be made to ensure there has been no mercury spillage or leakage and no obvious malfunction of the device. Instruments used in clinics should be inspected weekly. Those inspections should include a check of zero levels, mercury leakage, operation of valves, manometer columns for dirt or mercury oxide deposit, and condition of all tubing and fittings.

3.Procedures for inspecting the random-zero manometer are outlined below in Section 6.5.19. The manometer portions of both instruments are produced by W. A. Baum Company (Copiague, New York 11726) so that maintenance for this portion of the two devices is the same, as is the case for cuffs, bulbs, and air control valves. More detailed instructions covering these parts are provided in the Baumanometer Service Manual which is available from the W. A. Baum Company.

6.5.19Common Problems with -- and Solutions for -- the Manometer

1.Problem: Dirty manometer column.

Solution:

a.This is due to dirty or oxidized mercury and is usually evident near the zero. Oxide and dirt near random-zero machines "zeros" can result in too high "zero" readings because mercury sticks on the column wall above its equilibrium level. This does not affect conventional manometer readings, but it is hard to see the meniscus, and hence to check the actual zero.

b.Remove the glass manometer column. See Baum instructions for removal of column from conventional manometers.

c.Clean the glass column from its top towards its zero, with the "super" pipe cleaners available from Baum. Hold the column over a container to catch mercury as the cleaner is pushed through and brush the soiled end of the cleaner into the container.

2.Problem: Leaked mercury.

Solution:

This can be due to any of the following:

a.Loose or leaky screw cap at top of manometer

b.Manometer column cracked or chipped, or improperly seated

c.Leaky manometer column gaskets

d.Tilting the random-zero manometer with the mercury reservoir valve OPEN.

e.Loose or leaking random-zero manometer bellows on bleed screw cap.

3.Problem: The mercury level will not remain constant when the bulb valve is closed.

Solution:

a.Connect the manometer to a cuff which is around a one pound coffee can. Pump up the cuff and begin to pinch the tubing closed, starting at the manometer tubing.

b.By a process of pinching the tubing at 1 to 2 inch intervals up to the cuff and then down to the bulb, you will locate an air leak.

c.If an air leak is found in the cuff bladder or in the tubing other than the connections, the bladder may need to be replaced.

d.If the air leak is found in the connections or in the bulb valve, a little silicone spray may alleviate the problem.

6.5.20 Inspection of the Random-Zero Manometer

Unless obviously damaged due to dropping or other accident, the random-zero sphygmomanometer is expected to operate without disturbance of its measurement performance. Periodic checking should be done, however, to ensure against undetectable internal leakage or malfunction of the "randomizing" mechanism.

1. Place device in usual operating position, with reservoir valve OPEN (to side).
2. Remove mounting screws from the front and rear of the wooden or plastic casing and remove the casing keeping the instrument upright at all times.
3. Inspect the base and moving parts for any evidence of mercury leakage.
4. Bleed the air out of the system and check for mercury leaks. Using a 30 ml or larger syringe and a length of tubing, apply greater than 160 mm Hg pressure to the mercury column. (A syringe gives faster and better control than a cuff and a bulb for this purpose, but the observer must be careful not to pull negative pressure. If a cuff is used, it can be wrapped around a one pound coffee can.) Watch the rise of mercury in the chamber and maintain or increase the pressure until the mercury rises into the narrow vertical stem at the top of the chamber. If mercury does not enter the stem despite prolonged high pressure, deflate the cuff and repeat, after slightly opening the thumbscrew at the top of the stem. This will permit escape of any trapped air. When the mercury has entered the stem, close the thumbscrew firmly (but not excessively tight), and deflate the cuff.
5. Verify the maximum "zero" obtainable.

a. The bellows valve should be in the OPEN position and no pressure should be in the cuff. The cam should rotate freely.
b. Set the cam manually in such a position that the level on the end of the cam will contact the moving wall of the chamber after the shortest possible displacement of this wall toward the cam. This position draws the least mercury into the reservoir and produces the highest "zero" level for the amount of mercury in the device at this time.
c. Inflate the cuff above 160 mm Hg and maintain it at this pressure until the chamber wall has come to rest against the bevel of the cam.
d. Turn the valve to CLOSE and deflate and disconnect the cuff.
e. Record the zero level. It should compare closely (within 2 mm Hg) with the value on the label on the face of the manometer.

6. Verify the minimum "zero" level obtainable.

a. Repeat exactly as for (5) above, except to set the cam so that the moving wall of the reservoir will move its maximum distance before contacting the cam. This position draws the most mercury into the reservoir and produces the lowest "zero" level for the amount of mercury in the device at this time.
b. Ensure that full pressure in the cuff is maintained until the wall of the chamber comes to rest against the bevel of the cam. This may take several seconds.
c. Turn the bellows valve to CLOSE and deflate and disconnect the cuff.
d. Record this "zero" level. It should compare closely (within 2 mm Hg) with the value determined when the machine was calibrated.

7. Adjustment of zero levels.

Changes of zero levels are due either to loss of mercury or to air leakage at the bellows air bleed screw. Accuracy of readings is not affected. To adjust zero levels, however, mercury must be added to or removed from the system.

CAUTION: Mercury vapor is very toxic. Tiny droplets vaporize more rapidly than bulk. All loose mercury must be collected and inactivated. One effective and convenient product for mercury vapor reduction is "HgX", a powder produced by Acton Associates, 1180 Raymond Blvd., Newark, NJ 07102. It is recommended that all work be done in a container such as a plastic dish pan when mercury is to be transferred.

a.If the zero levels are too low:

(1)Open the bellows control valve and the valve at the top of the mercury reservoir, unscrew and remove the knurled cap at the top of the manometer column, and remove the air bleed screw at the top of the bellows chamber.

(2)Pour clean mercury into the top of the manometer tube, using a hypodermic syringe barrel or tight paper cone as a funnel. (As Baum writes, mercury can be cleaned of floating dirt and oxides by pouring it through a rolled cone of ordinary scratch paper with pinhole at its apex. Note that some mercury will stick on and in the paper, so handle with care). About 400 grams (or 14 ounces) of mercury are needed to fill an instrument for a zero range of near 10 to 30 mm.

(3)Firmly screw the knurled cap onto the top of the manometer column and apply pressure to the mercury reservoir until the mercury rises into the vertical air column at the top of the bellows chamber. Tighten the air bleed screw quickly and firmly while the mercury is a short distance into the vertical air column.

(4)Apply enough additional pressure to raise the mercury to near the top of the manometer column if it is not already that high. Then release the pressure, thus to collect mercury droplets and clear the column of air bubbles. There are likely to be air bubbles trapped on the walls of the plastic tube at the bottom rear. These can sometimes be removed by tapping the tube sharply, but they are, at any rate, of no consequence.

(5)Determine zero range and adjust as needed (see above).

b.If the zero levels are too high: Unscrew and remove the knurled cap from the top of the manometer column. Using a syringe with a small tube, such as a catheter, remove the mercury from the manometer. (Or, if these are unavailable, pour surplus mercury from the open manometer column. See Baum instructions. Be sure that the mercury reservoir valve is closed before inverting the manometer to pour the mercury out.)

8. Check whether the spin wheel and cam spin freely.

a.Turn the bellows valve on the front of the manometer to OPEN and allow the wall of the chamber to move back to its resting position.

b.Spin several times the rubber-rimmed wheel used in setting the "zero" level for each reading. Note whether the cam spins freely and whether it is excessively loose.

c.Adjust the spin by slightly loosening or tightening the mounting screw at the end of the cam.

d.After any such adjustment, recheck the spinning wheel repeatedly to ensure against excessive tightness or looseness of the cam. If spin wheel and cam are stuck (with bellows control cock open and all pressure released) or the rise of the mercury column is jerky as pressure is raised, there is usually binding or friction between the bellows plate center boss and the centering pin. Accuracy of readings has not been affected. A drop of good, light machine oil takes care of most such problems.

9.To remove the manometer column for cleaning or for inspection of it and of gaskets:

a.Set the cylindrical cam for maximum bellows volume and open the bellows control valve.

b.Raise the reservoir pressure to about 280.

c.Close the bellows valve and release pressure on the reservoir.

d.Tilt the sphygmomanometer to the right (reservoir on down side) until all mercury has disappeared below the manometer column. Close the reservoir valve (handle to front). Rest the device on its right side with the spin wheel above the table surface.

e.The manometer column may now be removed.

10.Maintenance requirements are minimal, but essential.

a.A very occasional drop of light machine oil is recommended on moving parts including the bellows plate centering pin.

b.Do not, however, oil either the bellows control valve stem or the mercury reservoir valve.

c.Ensure that moving parts are free without too much slack.

6.5.21 Lecture #5

Training Observers In The Clinical Center

There are three distinct sections involved in the responsibility of the local Training Supervisors. First is the preparation for the training session. Second is the time scheduling of the sessions. And third is the documentation of certification to the Data Coordinating Center.

6.5.22 Preparation for Training Observers

A.Gather all the blood pressure equipment.

1.Both the conventional and random-zero manometers

2.All four basic sizes of blood pressure cuffs with bulbs

3.A bell stethoscope

Familiarize yourself with all the blood pressure equipment. Prepare for mercury safety procedures and prepare an equipment maintenance schedule. Check all random-zero sphygmomanometers for maximum and minimum zero levels. The standard sphygmomanometers should be checked so that the top of the mercury meniscus is at the zero marking. The stethoscopes should be clean and turned to the bell. The cuffs and air valve should be checked for air leaks.

B.Gather all the Training Materials.

1.This training manual

2.The appropriate forms and paper

3.2 X 2 slide projector and carousel
4.videotape machine
5.Black ball-point pen

You should carefully familiarize yourself with all the training materials. Only you know how much practice will be needed for you to present the lectures to your trainees. Be sure you have plenty of photocopies of all the forms (the Written Examination, the Live Blood Pressure Performance Evaluation Sheet, and the Videotape Test Sheet). Familiarize yourself with the operation of the slide projector and videotape machine.

6.5.23 Training Tips

A. Schedule the training sessions over a period of days. An unhurried schedule gives the trainee a chance to absorb and demonstrate the procedures and knowledge with more confidence. Remember, you may be training someone who needs to unlearn previously learned blood pressure procedures. Also remember the stethoscope can cause ear discomfort when used for several hours at one time.

B. Try to keep the group size workable. The lectures may work for a large group, but consider the waiting/noise factor when scheduling the written test, blood pressure practice/evaluation and the videotape viewing.

C. The certification of the trainee and duties as an observer should not be planned for the same day. The trainee cannot complete the certification and begin taking participant blood pressures that same day. Plan time to allow for the return of all the documentation to the Data Coordinating Center, and return of the notice of certification. If scheduling requires, it may be possible to confirm certification of observers by telephone once all materials have been received. We realize that infrequently a crisis will arise. The videotape test values may be called in by telephone and scored that day, with the written documentation following in the mail, but this should be a rare occasion.

6.5.24 Documentation of Certification

A. Each person in the Clinical Center that will be filling out any part of a blood pressure form will need certification ID. This includes the blood pressure observers.

B. The Written Examination should be taken by the trainee and graded by the supervisor. If there are any differences in responses, it should be discussed and clarified. The supervisor should indicate those responses that were discussed by initialing them.

C. The Live Blood Pressure Reading Performance Evaluation should be carefully followed to ascertain that the trainee has a clear understanding of the procedures. This evaluation should be completed by the supervisor as a passive observer. Avoid prompting the trainee. The trainee should complete one or more complete and uninterrupted exercises of the full procedure. Errors of procedure should be reviewed, discussed and corrected. When carried out without procedural errors, this record should be completed, signed and included with the certification packet of the trainee.

D.The practice videotape should be employed to familiarize the trainee with the process of the videotape. Do not overexpose the trainee to the actual videotape test. When the videotape test is taken, remind the trainee to insert leading 0's where necessary and to complete the entire form. The test will be graded upon arrival at the Data Coordinating Center. If a systematic problem is discovered via computer scoring, the Data Coordinating Center will instruct you as to the type of problem discovered. The specific problem should not be identified to the trainee, as this may artificially bias the trainee's responses. Retraining, possibly by Y-tube readings, may help to identify and correct the problem. If the problem is not corrected within several retrainings, the problem is probably auditory and the trainee would need to be excluded from taking blood pressures. The Data Coordinating Center will need to have complete documentation of the certification before the trainee can be employed as a blood pressure observer. We suggest the supervisor keep the originals and send photocopies to the Coordinating Center. The Coordinating Center will instruct the Training Supervisor when recertifications should be scheduled, on an annual basis.

6.6Certification Procedures And Criteria

6.6.1 Three Steps Needed For Certification

In order to standardize the previously described methods of blood pressure measurement and to ensure that a high level of performance is attained, a three part training session has been developed. After successful completion, an observer is certified to take blood pressures in the study program. The three steps needed for certification are enumerated below.

1.The first step of blood pressure training is the completion of the Written Examination after lectures 1 - 3 have been presented. This is a short examination consisting of questions that test the blood pressure observer's knowledge and understanding of the measurement technique detailed in the training course.

2.The second step is the successful completion of The Live Blood Pressure Reading Performance Evaluation. The training supervisor is to verify the correct procedure for blood pressure measurement by observing the trainee in one or more complete and uninterrupted exercises of the full procedure. When carried out without procedural errors, this record should be completed, signed and included with the certification packet for the trainee. Errors of procedure should be reviewed, discussed and corrected, until one completed determination is accomplished without error.

3.The third step is a series of blood pressure readings presented on a videotape to test the observer's identification of the systolic and diastolic Korotkoff sounds. This tape mimics the actual blood pressure measurement setting by providing a series of blood pressure readings which consist of both the visible falling of the mercury in a sphygmomanometer and the audible Korotkoff sounds. An observer is certified if the criteria of the scoring procedure are successfully met. The criteria of the scoring procedure are not available to the Clinical Center or to the observers. The scoring will be done via computer at the Data Coordinating Center upon receipt of

observer's test sheets.

As a means of maintaining a high level of quality and standardization over time, blood pressure observers will be recertified annually. This recertification will involve, at a minimum, repeated testing by viewing the videotape and submitting a completed test sheet, as well as live measurement performance evaluation. The Data Coordinating Center will notify the Clinical Centers as to the schedule and requirements of the recertification. A further description is in Section 6.7.2.

6.6.2 Instructions for Taking the Video Test

Viewing of the videotape, "Measuring Blood Pressure," may be done in a group or individually. The videotape consists of practice readings followed by twelve systolic and diastolic sequences. After each sequence, the observer should record, on the recording sheet provided, the systolic and diastolic reading for that sequence. All entries should be completely legible and written in black ink. Leading 0's should be entered if appropriate. The manometer in the videotape is read exactly as one would be read in actual practice. Each blood pressure should be read to the nearest even digit.

6.6.3 Three Study Forms Required For Certification Procedures

The three study forms required for certification include:

1. The Written Examination (and its key);
2. The Evaluation Sheet for The Live Blood Pressure Reading Performance Evaluation; and
3. The Videotape Test Sheet.

These three forms may be found under separate cover.

6.7 Blood Pressure Measurement Quality Control

6.7.1 Overview

There are two primary methods for monitoring the performance of trained observers in the measurement of blood pressures during the course of a clinical trial. The first is the completion of an Annual Recertification set of procedures. The second is the three times per year monitoring by the Data Coordinating Center of all observers for digit preference.

In addition to these, AASK has adopted and instituted a comprehensive program to insure the collection of high quality blood pressure measurements. Factors contributing to this include:

1. Recruitment of the most qualified personnel.
2. Standardized training and certification.
3. Retraining of observers having difficulties with standardized measurements.
4. Bimonthly (every other month) observations by the Training Supervisors of data collection techniques of the Blood Pressure Observers on either a patient or AASK personnel, using the checklist at the end of this chapter. One checklist is used for each blood pressure observer. The original should be kept on file and will be reviewed at site visits.
5. Bimonthly (every other month) simultaneous Y-Tube observations of each Observer by the blood pressure Training Supervisor on either a patient or AASK personnel (described in Section 6.7.4).
6. Frequent staff meetings to provide feedback.
7. Continuous editing and analysis of data by the Data Coordinating Center.
8. Presentation of data analyses to the Clinical Centers by the Data Coordinating Center to provide feedback three times per year.
9. Equipment maintenance program (described in Section 6.5.16, Lecture #4).
10. Documentation of the Bimonthly Checklist, Y-tube stethoscope observations, and the dates of the Random-Zero Sphygmomanometer weekly inspections will be sent to the DCC every 4 months.

6.7.2 Annual Recertification and Retraining

As with the initial certification process this recertification process includes the successful completion of:

* a written test
* a live evaluation
* a videotape test.

Training Supervisors will be retrained centrally every spring. Recertifications for the other Blood Pressure Observers will also be annual, but after the recertification of the Supervisors (unless an Observer is centrally recertified).

The recertification procedures for the Blood Pressure Observers will be conducted at the Clinical Centers. However, scoring of the video tests will be done by the Data Coordinating Center, WHICH IS RESPONSIBLE FOR IDENTIFYING WHO IS A CERTIFIED BLOOD PRESSURE OBSERVER. Results of the recertification tests will be telephoned (and subsequently mailed) to a Clinical Center within three (3) working days of receipt of the test data from the clinic. A report based upon the results of these tests may be presented to the Steering Committee and the Policy Board. This report would describe how well the observers are measuring blood pressure levels under standardized conditions, and how many observers had difficulty being recertified.

Of course, the results of the tests may indicate that an observer may need to be retrained in some or all aspects of blood pressure measurement. If this is required, this person will discontinue the measurement of blood pressure levels for the trial until he or she is successfully recertified by the Coordinating Center. Central retraining may be required.

Also, if an observer misses a recertification cycle, he or she must repeat the training program.

6.7.3 Monitoring for Digit Preference

It is well documented in other large blood pressure studies that even well trained observers have the capability to lapse into an unconscious digit preference over time. Digit preference is defined as a predilection to record the terminal digit of a blood pressure measurement as either a "0", or a "2", or a "4", or a "6", or a "8", rather than the actual value. For example, an observer with a "0" digit preference may record an 82 mm Hg DPB (or a 78 mm Hg) as 80 mm Hg.

NO OBSERVER SHOULD EVER HAVE A DIGIT PREFERENCE.

The recertification process should dampen, on an annual basis, any incipient digit preference, but three times per year monitoring and presentation of actual blood pressure measurements by the Data Coordinating Center will identify problems more immediately. If a problem is identified, the blood pressure consultant to the AASK (or his designee) will be notified and corrective procedures implemented. Possible re-training and recertification may be necessary before the regularly scheduled certification.

6.7.4 Bimonthly Y-Tube Stethoscope Observations

Y-Tube stethoscope observations are made for bimonthly quality control. The Training Supervisor has each Observer go through the entire blood pressure measurement procedure using a quality control checklist. The Observer and Supervisor listen with the Y-tube and record the values on separate sheets. Two measurements on one subject are obtained and will be kept on file and reviewed at site visits.

It should be emphasized again that some difference between supervisor and trainee is to be expected (a difference of $\pm$ 4 mm Hg is allowed), and that exact correspondence should not be expected nor taken even implicitly as a criterion of accurate performance by the trainee. Rather, this process is intended to formalize the "live reading," to provide a written record of the results, and to identify gross problems that could be detected only by the Supervisor's close involvement with the Blood Pressure Observer. Any problems identified by the Supervisor or raised by the Observer should be discussed and, as far as possible, resolved.

6.7.5 Responsibilities of the Data Coordinating Center and The Training Supervisors

It is the responsibility of the Data Coordinating Center to centrally train and certify the Training Supervisors. Whereas it is primarily the responsibility of the Training Supervisors to return to the Clinical Centers and train other observers. However, only the Data Coordinating Center is able to certify an observer, as described above.

If, between recertifications, the Data Coordinating Center and/or a Training Supervisor have evidence that an observer is not performing well, the three parties will meet to discuss the matter. It may be necessary for the Data Coordinating Center to temporarily rescind a certification and retrain the observer. In this case, until the observer is recertified, he or she may not take blood pressure measurements for AASK.

It is also the responsibility of the Data Coordinating Center to monitor the specific activities of the Training Supervisors. In addition to the continuous monitoring of all incoming blood pressure data (eg., for digit preference or bad values), the files of the bimonthly blood pressure checklists and Y-tube observations will be reviewed at each site visit for completeness and accuracy. Also at these site visits, the Training Supervisors themselves will undergo checklist monitoring and Y-tube observation. Finally, the Training Supervisors themselves will be recertified centrally every Spring, before the annual recertification of the other Blood Pressure Observers.

6.7.6 Bimonthly Checklist for Monitoring AASK Blood Pressure Observers
(Original to be kept on file at the Clinical Center, send a copy to the DCC for QC)

Performing AASK Technician Name _____
Observer AASK Technician Name _____
Date Observed __ __/__ __/__ __ (Month/Day/Year)

Instructions: Check if procedure step is carried out correctly.

Procedure		Comments
1. ____	Measures arm for correct cuff size	_____
2. ____	Palpates brachial artery	_____
3. ____	Marks brachial artery point	_____
4. ____	Checks center of bladder and wrap cuff correctly	_____
5. ____	Wraps cuff center of bladder over brachial pulse	_____
6. ____	Calculates peak inflation	_____
7. ____	Finds pulse obliteration point using R-Z manometer	_____
8. ____	Calculates peak inflation using R-Z manometer	_____
9. ____	Leaves subject for 5 min. rest, instructs on posture, smoking, talking	_____
10. ____	Takes radial pulse	_____
11. ____	Opens bellows valve, waits for mercury to settle	_____
12. ____	Turns thumb wheel gently	_____
13. ____	Places stethoscope in ears	_____
14. ____	Palpates brachial artery, position's bell of stethoscope on brachial artery	_____
15. ____	Inflates rapidly to R-Z peak	_____
16. ____	Closes bellows knob	_____
17. ____	Deflates cuff 2 mm Hg per second	_____
18. ____	Deflates cuff after 10 mm Hg, after last two consecutive sounds are heard	_____
19. ____	Records readings	_____
20. ____	Reads zero value	_____
21. ____	Observer holds arm vertical for full 15 seconds	_____
22. ____	Begins steps for next readings	_____

Certification Observer may discontinue monitoring at this point unless problems with a procedure is noted. If problems are noted, repeat monitoring beginning with Step 12.

Y-tube Stethoscope Observations: ____ /____ Initials ____
____ /____

____/ ____ Initials ____
____/ ____

Dates that the Random-Zero Sphygmomanometer was inspected (use back of sheet or attach log):

6.8 Acknowledgment of Adaption

AASK

Blood Pressure Measurement

Training and Quality Control

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Adapted from the Procedures

of the Systolic Hypertension in the Elderly Program (SHEP)

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by Darwin R. Labarthe and Melanie Palmer

which were

Based on the Procedures
of the Hypertension Detection and Follow-up Program (HDFP)

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Some text adapted from the ARIC Protocol 11:

"Sitting Blood Pressure and Postural Changes" (4/16/87)

6.9 References

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AASK
BLOOD PRESSURE MEASUREMENT
TRAINING AND QUALITY CONTROL

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