17. BLOOD PRESSURE ASSESSMENT 4

Summary of Edits

Summary of changes between Version 1.0 and 1.1:

- Deleted references to participant blinding to blood pressure measurements
- Added that master trainers are recertified centrally every 6 months
- Arm circumference is also measured at FU 6 and 18 at the first BP of the cluster

Summary of changes between Version 1.1 and 1.2:

- Minor edits and corrections to forms numbers and names
- Required length of stethoscope tubing changed from 10-12" to 18" or less
- If minimum or maximum zero level on RZ devices exceeds determined levels, notify the coordinating center.
- If the mercury column "bounces", read systolic BP at highest level, and diastolic BP at lowest level. (need to verify with AHA)
- Standard and RZ manometers and cuffs are inspected quarterly rather than bimonthly
- Observation is required if technicians take fewer than 4 readings in any 3-month interval.

Summary of changes between Version 1.2 and 1.3:

- Added instructions for obtaining blood pressure measurements when unable to hear initial reading.
- Updated master trainer certification requirements to show that once screening is completed, unblinded master trainers will recertify by using the Y-tubing procedure quarterly, since they will not be able to take follow-up blood pressure measurements on participants.
- If an anaeroid sphygmomanometer is used (at home visits only, instead of RZ or standard), quarterly inspection and annual cleaning are required of the anaeroid devices.

17. Blood Pressure Assessment

Overview

Correct measurement of blood pressure (BP) is of the utmost importance to the success of PREMIER. It is essential that the procedures described in this chapter for measuring BP be followed exactly. Precision is essential for valid comparisons of blood pressure between groups of people and in individuals on different occasions.

In PREMIER, sitting BP is measured using two readings with a random zero (RZ) sphygmomanometer. The essential distinction between the RZ and standard devices is a mechanism designed to produce a variable level of mercury in the mercury tube when the actual pressure in the cuff is zero. This is accomplished through an adjustable bellows chamber that is interconnected with the mercury reservoir at one end and the mercury tube at the other. The adjustment is made by the technician, who spins an external thumbwheel that contacts and rotates an internal, beveled cam; the position at which the cam comes to rest after spinning determines where the beveled edge will meet the movable diaphragm of the mercury chamber. When air pressure is applied through the cuff with the bellows cock in the open position, the diaphragm is displaced until it rests against the cam, and the mercury not accommodated by the new volume of the chamber is displaced into the mercury tube. The bellows cock, or valve, is controlled by the technician and 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 true pressure levels. Thus, by adding this mechanism for varying the zero level of mercury, the RZ device obscures to the technician the true levels of pressure observed until after they have been read and the zero level subtracted. In this way, some of the recognized difficulties in technician performance are substantially reduced, particularly technician bias when readings fall near critical BP levels.

The procedures described herein are based on those used in the Dietary Approaches to Stop Hypertension (DASH) and the Trials of Hypertension Prevention (TOHP) studies.

Equipment Required

Stethoscope

A standard, good quality stethoscope (e.g., Littman, HP) with a bell is used. Korotkoff sounds **are best heard with the bell** because of their low pitch frequency. Stethoscope tubing should be 18 inches or less from the bell piece to the Y branching. This length provides optimal acoustic properties and allows the technician to read the sphygmomanometer at eye level in a comfortable position. Ear pieces should fit comfortably and snugly in the ears.

1. The ear pieces should be directed downward and forward into the external ear canal.

2. The ear pieces should fit tightly enough to exclude outside sound but not so tightly that they cause discomfort.
3. The valve between the bell and the diaphragm should be turned in the correct direction.
4. The bell of the stethoscope should be placed lightly on the skin overlying the brachial artery. 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 results in a murmur which may prolong the apparent duration of phase 4.

Sphygmomanometers

Standard Hawksley RZ instruments are used to collect all study BPs. Standard Baum manometers are used to determine peak inflation level.

The standard mercury manometer consists of a screw cap, a face with numbers, a lined glass column, a reservoir containing mercury, rubber tubing, and a metal case. The rubber tubing from the mercury manometer connects to rubber tubing from the inflatable rubber bladder of the cuff. As the bladder is inflated, the air pressure in the bladder travels through the connecting rubber tubing and pushes the mercury out of the reservoir and into the lined glass column. The number for each line is read when the rounded top of the mercury, the meniscus, is level with it. If the meniscus is exactly between the lines, the reading is made from the line immediately above, i.e., **rounded up to the nearest even number**.

If the mercury column "bounces" with the particpant's pulse, read the systolic bp at the highest level, and read diastolic bp at the lowest level which the mercury reaches on the "bounce". The RZ manometer has all the parts of the standard mercury device. In addition, it has a device built into the box-shaped back that changes the level of mercury in the calibrated glass tube. This device includes a second mercury reservoir area, the size of which can be changed to hold a larger or smaller amount of the mercury, thus allowing different amounts of mercury to remain in the calibrated glass tube and outside reservoir. The size of the second, inner reservoir is changed by turning a wheel on the side of the box. The second reservoir opens and closes with a bellows control valve on the face of the manometer.

All sphygmomanometers used in PREMIER should be sent in for an overhaul prior to screening if they have not been used on a regular basis in the past year or if they have not been overhauled in the past 5 years.

Cuffs

Proper cuff size is essential for accurate BP measurement. Clinical centers must have four standard cuffs available: small adult, regular adult, large adult, and thigh cuff. The cuffs used must be Baumanometer calibrated V-Lok cuffs with Baum brand bladders. The range markings on

these and all commercial cuffs will overlap with the ranges PREMIER uses and do not offer a precise guideline. Therefore, all Baum cuffs used in PREMIER must be clearly marked on the inside surfaces with new range markings which correspond to the arm circumference ranges shown below for each cuff size.

Arm Circumference	Cuff Size
<24 cm	Small adult
24-32 cm	Regular Adult
33-41 cm	Large Adult
42-52 cm	Thigh

The correctly determined cuff size used to record SV1 blood pressure should be the same cuff size used to record all of a participant's blood pressure measurements during screening. The arm circumference is measured to determine cuff size. For 6 and 18 month follow-up, this is measured at the first BP of that cluster only. Round all fractions up to the next whole number (i.e. 32.1 should be coded as 33). The rounded arm circumference is recorded on the SV1 Blood Pressure Form (#02). Because of the potential change in weight or body composition between screening and follow-up, the arm circumference is measured again at FU3, FU12, and for FU6 and FU18 at first BP of cluster only, and recorded on the blood pressure form for the appropriate visit. This allows the staff to determine the correct cuff size to be used during run-in and intervention. If either SV1 cuff size was incorrectly recorded, or cuff size has simply changed between visits, alert the Coordinating Center. All blood pressure measurements should be taken with appropriate cuff size. If necessary, the Coordinating Center will adjust the data entry application to allow this.

Preparation for Blood Pressure Measurement

In relating to the PREMIER participants, remember that participation in the study is voluntary. Participants should be given a full explanation and instructions about the steps involved in BP measurement, as well as an opportunity to ask questions. Participants should be told in advance that their blood pressure readings will be available at each screening visit and at the 6 month follow-up and 18 month visits. However, they will be informed if their blood pressure exceeds the acceptable range at other visits. If a participant insists, a staff member may obtain an additional reading with a standard sphygmomanometer and inform him or her of the results. At the 3 and 12-month visits, this option should not be disclosed to participants in advance, and should be used only if they insist on knowing their blood pressure.

The setting at which BP readings are taken must be a separate, quiet room where no other activity is taking place and where temperature fluctuations are minimal. It is recommended that the room temperature be 65-75^{o} F. Clinic scheduling procedures should also establish consistent appointment times to minimize, insofar as possible, the impact of daily BP variations.

Participants should be told not to engage in vigorous exercise, ingest food or caffeine, or smoke

within a half hour of BP measurements. If a half hour has not elapsed, the BP measurements must be delayed until a half hour has passed.

Measurement Procedures

In PREMIER, BP will be measured 2 times during each designated visit. It will take approximately 15 minutes to take the readings, including an initial five-minute rest period. The BP measurements are obtained during the visit and prior to the group or individual intervention session (if one is scheduled on that same day).

Once the participant has had the procedures explained and the equipment has been checked, BP measurement begins. The following steps must be followed precisely.

The right arm should always be used for the measurements. If the participant indicates that there is a medical reason for not having BP measured on his or her right arm (such as surgery, or if the right arm is missing), reverse chairs and proceed with the left arm. Write a note on the BP form indicating that the left arm has been used. If the participant seems particularly apprehensive about the procedure, delay wrapping the cuff until after the five-minute wait. At SV1, 3 months, 6 months (cluster visit 1), 12 months, and 18 months (cluster visit 1), measure the arm circumference using the following procedure. At other visits through randomization, select the same cuff size as that used at SV1, and check for correct cuff size by using the PREMIER markings on the Baum cuff. If the index line falls on the maximum range markings, proceed to measure the arm circumference: Have participant stand erect holding the forearm horizontal at a 90^{o} angle. Arm length is measured using a measuring tape in metric units, measuring from the acromion or bony extremity of the shoulder girdle to the olecranon or tip of elbow. The midpoint is marked on the dorsal surface of the arm. Have participant relax their arm. With the participant's arm relaxed at their side, measure the arm circumference at the midpoint.

Seat the participant with the right arm on the table. The bend at the elbow (antecubital fossa) should be at heart level. Legs should be uncrossed and feet comfortably flat on the floor. If necessary, place a book, footstool, or other flat object beneath the participant's feet so that they do not dangle.

Palpate the brachial artery (just medial to and above the antecubital fossa) and mark this location for placement of the center of the bladder and stethoscope placement. Place the cuff on the right arm in the proper position. If the brachial artery is occluded by the cuff, as might happen with a very large but short arm, the participant is excluded from participating. Indicate on the appropriate form that you were unable to obtain a valid reading and note the reason.

Allow a five-minute wait before taking the BP. Conversation should be limited during this period. However, a brief explanation of the procedure can be repeated at this time, if necessary.

After five minutes, take a 30-second pulse (radial artery) and record. Then connect the cuff to a

standard mercury manometer to establish the pulse obliteration pressure. Palpate the radial pulse. Rapidly inflate the cuff to 80 mmHg and then slowly inflate it 10 mmHg at a time until the radial pulse can no longer be felt. Deflate and disconnect the cuff. Record the pulse obliteration pressure (POP).

Calculate and record the peak inflation level (pulse obliteration pressure + 60). The peak inflation level used for each BP measurement must be a minimum of 180. If the POP + 60 is not > 180, use 180 mmHg during the actual measurements and record 180 in item 1.e. on the form.

If for any reason, you are unable to get a valid reading of the blood pressure on the participant, she is to be excluded. Indicate on the SV1 Blood Pressure Form (#2) that you were not able to obtain a valid reading and note the reason.

Measurement # 1

Connect the cuff to the RZ manometer. Place ear pieces of the stethoscope in the ears with the tips down and forward. Open the bellows control valve and wait until the mercury settles. Using downstrokes only, turn the thumbwheel two or three times. NOTE: Do not spin the thumbwheel. Inflate rapidly but smoothly to the RZ peak inflation level. The eyes of the technician should be level with the mid-range of the manometer scale. Holding the pressure constant for five seconds with the bulb, close the bellows and control valve. Place the bell of the stethoscope on the brachial artery just below and not touching the cuff or tubing, and slowly deflate the cuff (2 mm per second) while listening.

Record the first and fifth phases, reading the pressure in mmHg and rounding up to the nearest even number. The first sound heard in a series of at least two sounds is recorded for systolic BP (phase 1). For diastolic BP (phase 5), record the first silence in a series of at least two silences, NOT the last sound heard. After noting the DBP, continue to deflate at 2 mmHg per second until 10 mmHg below DBP, then rapidly deflate the cuff by opening the thumb valve. If there is an absent 5th phase (sounds heard to 00 mmHg), the beginning of the 4th phase should be used. Make a note if there is an absent 5th phase. If the participant coughs or sneezes during the measurement and the phases can not be heard clearly, abort the measurement, wait 30 seconds and re-measure blood pressure.

Remove the stethoscope ear pieces. Disconnect the cuff and record the BP reading and the zero reading. **DO NOT SUBTRACT THE ZERO READING UNTIL BOTH MEASUREMENTS ARE COMPLETED.**

Measurement #2

After waiting 30 seconds with the participant's arm passively elevated for 5 seconds and on the table for 25 seconds, repeat as in measurement #1. After both readings are completed, the bellows control valve should be left in the OPEN position. If four identical consecutive zero read-

ings are obtained, the maximum and minimum zeros should be checked before the device is used with another participant. If the maximum and minimum are confirmed, the device should be sent out for service.

When finished recording the two RZ BP measurements, subtract the zero value from the reading to get the actual (corrected) systolic and diastolic values. Because of the importance of BP data in PREMIER, all arithmetic must be done with a calculator after two readings have been completed.

If unable to hear, discontinue the measurement and wait 30 seconds. Then inflate the cuff to the maximum inflation level. Leaving the cuff inflated, have the participant rapidly open and close his or her fist six to eight times, and then proceed with the measurement.

Missing BP Information

If for any reason the technician is unable, or has forgotten, to complete any portion of this protocol and the participant has left this area, draw two horizontal lines through the relevant spaces on the data collection form. This is the correct way to indicate the missed information. If an entire reading is missed or is technically invalid and the participant is still in the clinic, a replacement reading should be obtained. Be sure to completely deflate the cuff and start over with a complete replacement reading. **Under NO other circumstances, however, may a replacement reading be obtained simply because the results seem unusual.** Always wait at least 30 seconds between readings.

Changing the Peak Inflation Level

Occasionally, the Korotkoff sounds may be heard as soon as one places the stethoscope over the brachial pulse. If this happens, the peak inflation level used was too low. Immediately deflate the cuff by releasing the thumbscrew and disconnecting the cuff tube. The participant should then hold the cuff-wrapped arm above the head level for five seconds. Draw a line through the previously recorded pulse obliteration pressure and peak inflation level. Increase each number by 10 and write the new number above the original one, as shown below.

	130
Pulse Obliteration Pressure	~~120~~
	+60
	190
RZ Peak Inflation Level	~~180~~

Proceed with BP measurement, starting at the new peak inflation level.

Overview of Training and Certification

Personnel

All persons obtaining PREMIER RZ blood pressure measurements are required to undergo training and certification in RZ BP measurement technique by a certified trainer. Each clinical site designates two site-specific trainers, one of whom must be trained and re-certified by the study-wide trainers. Each site will also designate an unlimited number of technicians, who must be trained and certified by either the site-specific trainers or the study-wide trainers.

Training and Certification

Study-wide trainers train and certify the site-specific trainers, who in turn train the technicians and another trainer at their sites. The Coordinating Center, on receipt of all necessary documentation of successful training, certifies all technicians. At least one trainer from each site is recertified by the study-wide trainers. These trainers then recertify the technicians and (if necessary) the other trainer at their sites. All BP staff, including trainers and technicians, are recertified between cohorts (approximately every six months). All study-wide master trainers are recertified centrally every 6 months. Certification is verified by the Coordinating Center.

Introduction

In order to standardize the previously described methods of blood pressure measurement and to ensure that a high level of performance is attained a two-stage training program has been developed. 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. At least one coordinator will be recertified centrally for blood pressures at an annual training session.

The training strategy adopted by PREMIER is a two-stage blood pressure program. Before the program begins, each clinical center will identify two specific trainers for that clinic. One trainer from each clinical center will meet centrally in June 1999 for the first stage of training. The full training program will be presented at this time. The trainers who pass the program will be certified as Blood Pressure Trainers. The trainers can, in turn, train additional technicians in the clinical centers and another designated trainer. 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 Coordinating Center will receive documentation of each technician's training performance from the trainers in the clinical centers (including the successful completion of the written test [Form #303] and the Blood Pressure Certification Form [Form #304]). The sites will enter the technician's answers to the video exam (Form #319) into the BP certification module in the data entry/management application. The video test will immediately be scored and if the technician passed the exam, the rest of their

certification results can be entered. If the technician does not pass the video test, they must re-take the test until they pass. After completion of data entry of the certification forms, the original exams should be copied and sent to the Coordinating Center for QC checks (attn:Mike Allison). Various reports are available in the certification system. These reports can be generated at any time to identify who needs to be re-certified and when (see the Certification User's Manual for more details).

Through this scheme, training will be the responsibility of both the clinical centers and the Coordinating Center. The CC will, in addition, remain responsible for overall monitoring and quality control.

Staff will be recertified according to the following schedule:

- All blood pressure master trainers are re-certified centrally every 6 months
- All blood pressure trainers will recertified every 6 months during the face-to-face Steering Committee or at a special training site.
- All blood pressure technicians are recertified by their local trainers during the breaks between cohorts (approximately every six months).
- All blood pressure technicians are required to meet these recertification deadlines unless they have been specially certified (e.g., new hires) during the three months prior to the start of the recertification window. If they have been certified for less than three months prior to this time they may wait for the following certification window before being recertified.

Steps Needed for Certification and Recertification

- First Step

Before starting the certification/recertification process, technicians should read/review Chapter 17, pages 17-1 through 17-9, of the PREMIER Clinical MOP.

- Second Step

All staff taking PREMIER blood pressure outcome measurements must attend a PREMIER training session, or receive training from a certified PREMIER blood pressure trainer.

- Third Step

The third step is a series of blood pressure readings presented on a videotape to test the technician's identification of the systolic and diastolic Korotkoff sounds. The 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. A technician 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 technicians. The scoring will occur after the entry of the technician's test sheets (Forms #303, 304, 305, 319) into the certification application (on the workstation) is complete. The certification application will alert the data entry technician if the BP technician does not pass the video test (see the Certification User's Manual for more details).

- *Instructions for Taking the Videotest*. Viewing of the videotape, "Measuring Blood Pressure," may be done in a group or individually. The videotape consists of one practice reading followed by twelve systolic and diastolic sequences. After each sequence, the technician should record, on the recording sheet provided (Form #319), the systolic and diastolic reading for that sequence. All entries should be complete, legible, and written in black ink. The manometer in the videotape is read exactly as one would read in actual practice. Each blood pressure should be read rounded up to the nearest even digit. Each BP reading should agree within ±4 mmHg on any reading (systolic or diastolic).

▸ Fourth Step

The fourth step of blood pressure certification is the completion of the Blood Pressure Written Examination (Form # 303) after lectures have been presented. This is a short examination consisting of questions that test the blood pressure technician's knowledge and understanding of the measurement technique detailed in the training course. Technicians must score 100% on this exam. Scoring of the exam should be completed by the master trainer.

▸ Fifth Step

The fifth step is the successful completion of Form #305. The trainer is to verify the correct procedure for blood pressure measurement by observing the technician in one or more complete and uninterrupted exercises of the full procedure (Form #305).

- *Y-Tube Stethoscope Observations.* Y-tube stethoscope observations are made for certification and recertification. The technician and trainer listen with the Y-tube and record the values on separate sheets (see Blood Pressure Certification Form #304). Two measurements on each of three subjects should be obtained. Readings by the trainer and technician should agree within ±4 mmHg on any reading (systolic or diastolic), and averages should agree within ±3 mmHg.

▸ Sixth Step

The sixth step is the successful completion of Form #304. The trainer is to verify the correct

procedure for blood pressure measurement by observing the technician in three y-tubed readings, with the trainer and technician simultaneously recording blood pressure on three different individuals (Form #304).

- *Observation of BP Measurement Procedures and Techniques*. All BP technicians must be checked to ensure that they are following procedures correctly and utilizing proper measurement techniques. This is necessary for both certification and re-certification. If these measurements are made on a study subject, the observed blood pressure measurements for training may not be used for data. The trainer uses the BP Observation Checklist (Form #305) to grade the technician while he or she follows the entire BP protocol to obtain two readings on a non-study or study individual, using a regular stethoscope. The trainer should be outside the immediate work area of the technician and should not make any comments during measurement. This part of the certification process should be done separately from the Y-tube certification. When carried out without procedural errors, this record (Form #304) should be completed, signed, and included with the certification packet for the technician. Errors of procedure should be reviewed, discussed, and corrected until one completed determination is accomplished without error.

After successfully completing the certification/re-certification, the completed forms are entered into the Certification System (see the Certification User's Manual for details). As a means of maintaining a high level of quality and standardization over time, blood pressure technicians will be re-certified between cohorts (approximately every six months). The Coordinating Center will notify the clinical centers as to the schedule and requirements of the re-certification. A further description is in the section called Annual Recertification and Retraining.

Summary of Requirements for Blood Pressure Certification and Recertification

<u>Certification</u>

1. Read Blood Pressure Assessment (Chapter 17, pg. 17-1 through 17-9 of the MOP).
2. Attend PREMIER training session, or receive training from a certified PREMIER blood pressure trainer.
3. Successfully complete all blood pressure examples on Videotape Test Sheet (Form #319) (100% correct).
4. Successfully complete the Blood Pressure Written Exam (Form #303) (100% correct).
5. Successfully complete blood pressure measurement technique and procedure. Record and submit results on Blood Pressure Observation Checklist Form (Form #305).
6. Successfully complete three Y-tube stethoscope readings (average of three readings <u>+</u>4 of trainer measurements), using three different people, with PREMIER BP Trainer. Record and submit results on the Blood Pressure Certification Form (Form #304).

Recertification

1. Required every six months for clinic staff and for Blood Pressure Trainers. At least one trainer at each site must be recertified centrally every six months.
2. Successfully complete blood pressure measurement technique and procedure. Record and submit results on Blood Pressure Observation Checklist Form (Form #305).
3 Successfully complete three Y-tube stethoscope and dual readings using three different subjects. Record and submit results on Blood Pressure Certification form (Form #304).
4. Successfully complete the Blood Pressure Written Exam (Form #303) on blood pressure measurement (100% correct).
5. Successfully complete all blood pressure examples on Videotape Test Sheet (Form #319) (100% correct).
6. Must be actively taking blood pressure measurements using a random zero sphygmomanometer (at least 4 measurements per month). More than one violation of this criteria in any consecutive three month interval results in a lapse of certification.

Study Forms Required for Certification Procedures

Four study forms are required for certification.

1. Blood Pressure Written Examination (Form #303) and its key.
2. PREMIER Blood Pressure Observation Checklist Form (Form #305).
3. PREMIER Blood Pressure Certification Form (Form #304).
4. The Videotape Test Sheet (Form #319).

These four forms may be found in the Quality Control section of the PREMIER Forms Manual.

Blood Pressure Measurement Quality Control

Overview

Two primary methods exist for monitoring the performance of trained technicians in the measurement of blood pressures during the course of a clinical trial. The first is the completion of a biannual recertification. The second is the regular monitoring by the Coordinating Center of all technicians for digit preference.

In addition to these, PREMIER 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 technicians having difficulties with standardized measurements.

4. Observations once every three months by the Blood Pressure Trainer of BP measurement techniques of the blood pressure technicians on either a participant or nonparticipant, using the Quarterly Checklist for Monitoring Blood Pressure Observers (Form #302). One checklist is used for each blood pressure technician. These should be kept on file and will be reviewed at site visits.
5. Biannual (every six months) simultaneous Y-tube observations of each technician by the blood pressure Trainer on either a participant or nonparticipant (described in Bi-Annual Y-Tube Stethoscope Observations).
6. Frequent staff meetings to provide feedback.
7. Continuous editing and analysis of data by the Coordinating Center.
8. Presentation of data analysis to the clinical centers by the Coordinating Center to provide feedback three times per year.
9. Equipment maintenance program (described in Local Blood Pressure Equipment Maintenance and Mercury Toxicity Safety Responsibility).

Monitoring for Digit Preference

It is well documented in other large blood pressure studies that even well trained technicians 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 an "8", rather than the actual value. For example, a technician with a "0" digit preference may record an 82 mmHg DPB (or a 78 mmHg) as 80 mmHg.

NO TECHNICIAN SHOULD EVER HAVE A DIGIT PREFERENCE.

The Coordinating Center will provide monthly reports on digit preference of certified blood pressure technicians. Because of the numbers of analyses, it is assumed that some of these reports will indicate "significant" digit preference by chance alone. Many others will serve as evidence of mild digit preference. Since there are five possible terminal digits for each blood pressure (0, 2, 4, 6, 8), the expectation of any large number of readings is that 20% of readings will end in each of those digits. For the purposes of responding to digit preference reports on individual technicians involving 30 or more blood pressure readings, the Coordinating Center will act as follows:

1. No statistically significant digit preference: report to centers; center will share individual data with each technician.

2. Statistically significant digit preference, but no terminal digits occurring less than 16% or greater than 29% of the time: report to centers; center will share individual data with technician and counsel to be careful about technique.

3. Statistically significant digit preference and one or more digits reported on 30-39% or 10-15% of readings: report to centers; center will share individual data and review technique

with technician.

- Statistically significant digit preference of this magnitude persists on next report: formal recertification must occur within one week of second report; observation and counseling should follow.
- Statistically significant digit preference absent on next report and observed distribution includes no digits >29% or <16%: return to usual monitoring schedule.
- Digit preference improved, but still statistically significant: review technique; monitor for continued digit preference; if significant on third consecutive report, regardless of range, recertification is required within one week of receipt of the third report. If more than one week elapses, the technician must cease taking blood pressure measurements until such time as he or she is recertified.

4. Statistically significant digit preference; one or more digits reported $\geq$40% and/or $\leq$10% of the time and/or odd numbered terminal digits reported: Coordinating Center will notify PI/project director and discuss case individually; recertification required as soon as possible, but in no case later than one week after notification.

In addition, the Coordinating Center will raise for discussion any situations that appear to be problematic for the trial. This might include individual technicians exhibiting extremes of digit preference or repeated, uncorrected levels of digit preference, or centers that collectively exhibit unusual levels of digit preference. The Steering Committee may take action specific to such cases at its discretion. Coordinating Center report on digit preference will not reveal the specific digit that is biased.

In addition to the monthly digit preference reports, the CC will periodically issue additional blood pressure QC reports for review by the measurement and quality control committee. These will include, for example, reports on the variation in readings during a given test session. The measurement committee will develop appropriate action levels after review of these reports.

Responsibilities of the Coordinating Center and the BP Trainers

It is the responsibility of the Coordinating Center to centrally train and certify the BP Trainers. While it is primarily the responsibility of the trainers to return to the clinical centers and train other technicians, these technicians must still be certified by the Coordinating Center before being allowed to take official study measurements.

Each site is required to have at least two certified trainers. If, between recertifications, the Coordinating Center and/or a trainer has evidence that a problem may exist with a technician, the three parties will discuss the matter. It may be necessary for the Coordinating Center to temporarily rescind a certification and for the clinical center to retrain the technician. In this case, until the technician is recertified, he or she may not take blood pressure measurements.

It is also the responsibility of the Coordinating Center to monitor the specific activities of the BP trainers. In addition to the continuous monitoring of all incoming blood pressure data (e.g., for digit preference or bad values), the files of the biannual blood pressure checklists and maintenance logs (Forms #302, 306, 307, 320) will be reviewed at each site visit for completeness and accuracy. Finally, the master trainers are recertified centrally twice each year. If a technician takes fewer than four readings in any three month interval, she must be observed by a blood pressure master trainer, and Form #305 must be completed. The Coordinating Center will notify sites and follow up to make sure the observation was completed. Once participant screening is completed, unblinded master trainers will recertify quarterly using the Y-tubing process (Form #304), since they will not be able to take follow-up blood pressure measurements on participants. Two of these quarterly certifications occur at the central training, and two are done locally.

Maintenance of Random-Zero and Conventional Sphygmomanometers

Introduction

Each clinical center is responsible for the proper operation and maintenance of its BP equipment. Responsibility for proper maintenance is assumed by the clinic coordinator or designated person, and all staff are instructed to report promptly any real or suspected equipment problems to that person. All checks, inspections, and cleanings are documented and recorded by date in a permanent log maintained separately for each unit. All maintenance logs and biannual checklists (Forms #306, #307) should be stored in the permanent log binder. Problems and solutions are also recorded there. Logs will be reviewed by CC staff at periodic site visits and the CC will periodically make requests for copies of these documents for quality control checks.

The standard and RZ manometers should be checked during each use for problems in the following areas:

1. The zero level of the standard manometer
2. Mercury leakage
3. Dirt or mercury oxide deposit in the manometer column
4. The condition of all tubing and fittings

The standard and RZ manometers and cuffs should have a quarterly inspection on the following:

1. Valves and tubing of cuffs should be in good workable order
2. Should be free of dirt or mercury oxide deposit in the manometer columns
3. No mercury leakage
4. Tubing and fittings on both should be tight and free of leaks
5. Bellows valve on RZ should be free moving

The Standard and RZ manometer and cuffs should be thoroughly inspected and cleaned (if

necessary) biannually. The inspection should include the following:

1. Y tubing of RZ and Standard to check comparison
2. Screw cap should be tight
3. Valves of cuffs should be moving freely
4. Both the min and max zero levels should be checked
5. Both machines should be level on the stand
6. Bellows valve on RZ should be free moving
7. Dirt or mercury oxide deposits in the manometer columns should be cleaned
8. No visible Mercury leaks
9. Tubing and fittings should be tight and free of holes or leaks

The equipment should be cleaned if inspection indicates that cleaning is necessary, or at least once per year. In addition, every three months the accuracy of the RZ device should be checked using a standard manometer and a Y-tube and RZ zero levels should be checked. All sphygmomanometers used in PREMIER should be sent in for an overhaul prior to screening if they have not been used on a regular basis in the past year or if they have not been overhauled in the past 5 years text .

Anaeroid sphygmomanometers (if used for home visits) should also be inspected quarterly and cleaned once per year, or more often as needed. Anaeroid sphygmomanometers should be checked for accuracy every three months while in use by Y-tubing with a correctly functioning standard sphygmomanometer.

Equipment Maintenance and Safety

The condition of the instruments for blood pressure measurement is too often ignored in common practice and should be a special responsibility of the trainer or other designated staff member. This person **should be acquainted with mercury toxicity safety procedures** as well as construction and function of all the blood pressure equipment. The cleanliness and general working order of the cuffs and stethoscopes can usually be determined by simple inspection. For both the conventional and random-zero (RZ) type manometers, however, proper handling of breakable parts and of mercury and oxidized waste requires more careful attention. Guidelines for maintenance of the manometers are outlined here in some detail.

General 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 mmHg at the top of the mercury meniscus. The “zero” levels for the random-zero (RZ) device should have a range of approximately 20 mmHg between the maximum and the minimum “zero” level. 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 comparison to zero levels obtained during actual readings taken with the device.

2. These devices should be cleaned and checked thoroughly on a quarterly basis or approximately every three months. Quarterly inspections should ensure there has been no mercury spillage or leakage and no obvious malfunction of the device. These inspections should include checks for: 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 RZ Manometer (RZM) are outlined below. 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.
4. **Work area and mercury spillage.** All blood pressure devices used in PREMIER contain mercury, which is a volatile metal at room temperature. In view of the problem of spillage and retrieval of this material, a definite work area should be designated for all manipulations. This area should be in a well-ventilated room. Rugs should not be present. The work bench should be a flat, smooth surface which can be easily cleaned, with adequate space. All work should be done in a large tray or basin with edges that will contain any mercury spill that may inadvertently occur in the process of maintaining the machines. A mercury cleaning solution which inactivates elemental mercury and prevents it from vaporizing should be kept in stock in the work area and the person doing the work should wear gloves and a lab coat with no pockets and should remove rings, watches or other metallic objects from his/her hands. A procedure should also be developed for proper handling of accidental mercury spills and all staff made aware of the procedure. Institutional safety regulations at each site should be reviewed and followed.

Common Problems with—and Solution for—both Manometers

Dirty manometer column

- This is due to dirty or oxidized mercury and is usually evident near the zero. Oxide and dirt near RZM "zero" can result in too high "zero" readings because mercury hangs 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 actual zero.
- Remove the glass manometer column. See Baum instructions for removal of column from conventional manometer.
- 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 pushing through, and brush the soiled end of the cleaner into the container.

Mercury leakage

This can be due to any of the following:

- loose or leaky screw cap at top of manometer
- manometer column cracked, chipped, or improperly seated
- leaky manometer column gaskets
- tilting RZM with mercury reservoir valve open
- loose or leaky RZM bellows air bleed screw cap

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

- 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.
- By a process of pinching the tubing at 1-2 inch intervals up to the cuff and then down to the bulb, you will locate an air leak.
- If an air leak is found to be in the cuff bladder or the tubing other than the connections, the bladder may need to be replaced.
- If the air leak is found in the connections or in the bulb valve, a little silicone spray may alleviate the problem.

Inspection of the Random-Zero Manometer

Unless obviously damaged due to dropping or other accident, the RZM is expected to operate without disturbance of its measurement performance. Quarterly 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 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 R-Z system and check for mercury leaks.

Using a 30 ml or larger syringe and a length of tubing, apply greater than 200 mmHg pressure to the mercury column. (A syringe gives faster and better control than a cuff and a bulb for this purpose, but the technician 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 rise 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

- The bellows valve should be in the "OPEN" position, and no pressure should be in the cuff. The cam should rotate freely.
- 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.)
- Inflate the cuff above 200 mmHg and maintain it at this pressure until the chamber wall has come to rest against the bevel of the cam.
- Turn the valve to "CLOSE," wait a full five seconds, and deflate and disconnect the cuff.
- Record the zero level. It should match the maximum value on the label that was placed on the face of the manometer by the trainer. If it does not, a new label should be created at the site by the person responsible for RZ maintenance.

6. Verify the minimum "zero" obtainable

- Repeat exactly as for (5) above, except 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 produce the lowest "zero" level for the amount of mercury in the device at this time.)
- 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.
- Turn the bellows valves to "CLOSE," and deflate and disconnect the cuff.
- Record this zero level. It should match the minimum value on the label that was placed on the face of the manometer by the trainer.

7. Adjust zero levels if needed

There should be a 20 mm difference between the maximum and minimum values. 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 or removed from the system. If the minimum or maximum zero levels consistently exceed the determined levels, or any other peculiar problems are noted, notify the Coordinating Center.

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 Boulevard, 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, that gloves and lab coat be worn, and that the area is well ventilated.

If the minimum zero level is below 0:

- 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.
- 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 a pinhole at its apex. Note that some mercury will stick on and in the paper, so handle with care, and dispose of the paper properly). About 400 grams (or 14 ounces) of mercury are needed to fill an instrument for a zero range of near 10 to 30 mm.
- 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.
- 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.
- Determine zero range and adjust as needed.

If the minimum zero level is greater than 4, or the maximum is greater than 24:

- 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.

8. <u>Check whether the spin wheel and cam spin freely.</u>

- 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.
- 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.
- Adjust the spin by slightly loosening or tightening the mounting screw at the end of the cam.
- After any such adjustment, recheck the spinning wheel repeatedly to ensure against 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:

    - Set the cylindrical cam for maximum bellows volume, and open the bellows control valve.
    - Raise the reservoir pressure to about 280.
    - Close the bellows valve and release pressure on the reservoir.
    - Tilt the RZM 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 RZM on its right side, with the spin wheel above the table surface.
    - The manometer column may now be removed.

10. Maintenance requirements are minimal, but essential.

    - A very occasional drop of light machine oil is recommended on moving parts, including the bellows plate centering pin.
    - Do not, however, oil the bellows control valve stem or the mercury reservoir valve.
    - Ensure that moving parts are free without too much slack.

For BP Trainers Use Only

Procedures for Training and Certifying BP Technicians—<u>For Trainers' Use Only</u>

Before presenting information the trainers should read the section on Preparation for Trainers. Lectures 1-4 (two with slides) are offered in this section to acquaint the technician with the subject of blood pressure and its measurement. The training of potential blood pressure technicians should begin with a general discussion of blood pressures and some of the history of blood pressure measurement. The first lecture, "Blood Pressure Measurements—Problems and Solutions," addresses three 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 <u>any</u> technician 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 HDFP, TOHP, DASH, and DASH2. Procedures for using both the conventional and the random-zero devices are given.

The fourth lecture "Equipment Maintenance and Mercury Toxicity Safety" gives guidelines for maintenance procedures.

Trainers in the Clinical Center

There are three distinct sections involved in the responsibility of the local trainers. 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 Coordinating Center.

Preparation for Trainers

Gather all the blood pressure equipment:

- Both the conventional and random-zero manometers
- All four basic sizes of blood pressure cuffs with bulbs
- 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.

Gather all the Training Materials

- This training manual
- Blood Pressure Written Exam and answer key (Form #303)
- Blood Pressure Certification Form (Form #304)
- Blood Pressure Observation Checklist (Form #305)
- Videotape Exam (Form #319)
- 2x2 slide projector and carousel
- Videotape machine
- Black ball-point pen
- Slides and videotape

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 technicians. Be sure you have plenty of photocopies of all the forms (the Written Examination [Form #51], Blood Pressure Certification Form [Form #52], and the Videotape Test Sheet [Form #58]). Familiarize yourself with the operation of the slide projector and videotape machine.

Training Tips

- Schedule the training sessions over a period of days. An unhurried schedule gives the technician 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.
- 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.
- The certification of the technician and duties as a technician should not be planned for the same day. The technician cannot complete the certification and begin taking participant blood pressures that same day. Plan time to allow for entry of the written exam (Form #303), the video exam (Form #319) into the data entry/management application, and generation of the notice of certification from the application.

Documentation of Certification

- Each person in the clinical center that will be filling out any part of a blood pressure form will need a staff ID code. This includes the blood pressure technicians. Only one code number should ever be assigned to one person, no matter how many changes in status might occur.

- The Written Examination (Form #303) should be taken by the technician and graded by the trainer. If there are any differences in responses, it should be discussed and clarified. The trainer should indicate those responses that were discussed by initializing them.
- The Blood Pressure Certification Form (Form #304) should be carefully followed to ascertain that the technician has a clear understanding of the procedures. This evaluation should be completed by the trainer as a passive observer. Avoid prompting the technician. The technician 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 technician.
- When the videotape test (Form #319) is taken, remind the technician to insert leading zeros where necessary and to complete the entire form. The test will be graded upon entry into the data entry/management application on the PREMIER file server. If a systematic problem is discovered via computer scoring, the Coordinating Center will instruct you as to the type of problem discovered. The specific problem would not be identified to the technician, as this may artificially bias the technician'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 technician would need to be hearing tested and, if correction is not possible, excluded from taking blood pressures. If a hearing correction is possible, the technician will need to be retested. The Coordinating Center needs to have complete documentation of the certification. We suggest the trainer keep the originals and send photocopies to the Coordinating Center. The Coordinating Center will instruct the trainer when recertification should be scheduled, on a biannual basis.

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 observation is an informative summary of the specific sounds he described: "On the basis of his observation, 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, done 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 manometer 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 fade 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 technician 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 technicians, sometimes as large as 15 mmHg..., (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—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 reading be taken in the sitting position, only after a minimum period of five minutes seated at rest, according to carefully prescribed procedures. As to differences between technicians, a systematic difference as large as 15 mmHg would indeed be alarming, and in fact, unacceptable. In still another publication dealing with measurement of blood pressure, Rose presented in greater detail some components of the remaining technician 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 technicians 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 be observed taking actual live blood pressure readings with a Y-tube stethoscope. 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 trainer. 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 technician. 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 technicians.

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 aspect that a mechanical addition allows the mercury level in the column to be varied for each reading and concealed from the technician until the systolic and diastolic readings have been completed. This arrangement thus avoids the technician bias which is often at play when the technician 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. Copies of the slides are maintained at the Baltimore clinical center (copies will be distributed to all sites and to the Coordinating Center). Listed below is the script to accompany each slide.

Slide# 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 righthand 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.
3. The manometer column, the cuff and its connections, and one notable feature: a lever controlling the reservoir outlet. This lever is always closed (i.e., turned to the left) for carrying the device and opened (i.e., turned to the right) for operating it. You might notice also that the mercury rests at a level well 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 trainer 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 disk up above, which is ringed with its rubber seal.
6. From directly behind you can seen 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 technician 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 long 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 contains the rubber rim of the wheel and spins at the same time (and its beveled forward end which extends forward in varying degrees depending on 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 technician to make objective readings unaffected by the knowledge of the true reading.

Lecture #3—Procedures in Blood Pressure Recording

These procedures in 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 criteria for measurement, we specify methods for the entire sequence of steps in blood pressure recording. For all technicians, 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. Copies of the slides are maintained at the Baltimore clinical center (copies will be distributed to all sites and to the Coordinating Center). Listed below is the script to accompany each slide.

Slide# Script for Slide

Equipment and Supplies (Slides 1-11)
Arm Measurement (Slides 12-21)
Preparation for Actual Readings (Sides 22-27)
Pulse (Slides 28-37)
First Blood Pressure Reading (Slides 38-49)

Between Readings (Slide 50)
Second and Third Blood Pressure Reading (Slides 51-53)

1. The equipment needed by each technician includes a random-zero sphygmomanometer in good condition, and
2. A conventional sphygmomanometer.
3. Access is needed to the full set of 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 technician.
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 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.
10. The appropriate study form must be in place before measurement begins.
11. Stand for RZ and standard monitor so equipment can be read at eye level.
12. The right arm should always be used for measurements unless there is a medical reason not to use the right arm.
13. Measurement of the arm is required for selection of the proper cuff. For this measurement, the arm should be bare.
14. The measurements are taken on the right arm, with the participant standing, holding the forearm horizontal.
15. Arm length is measured from the acromion or bony extremity of the shoulder girdle,
16. To the olecranon, or tip of the elbow.
17. The full arm length from acromion to olecranon is measured, and
18. The midpoint is marked on the dorsal surface of the arm.
19. 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.

20. The chart of arm circumference measurements and corresponding cuff sizes is consulted, and
21. The proper cuff size is checked. Indicate the cuff size on the form.
22. The participate 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 must be applied must be bare. The bend of the elbow should be at heart level.
23. Legs should be uncrossed and feet comfortably flat on the floor.
24. The brachial artery is located by palpation and marked (just medial to and above the antecubital fossa).
25. As is the midpoint of the rubber bladder within the cuff. Often this point is marked on the cuff itself.
26. 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.
27. Allow a five minute wait before taking the BP. Conversation should be limited during this time. You should leave the room after a brief explanation.
28. After the period of 5 minutes at rest has been completed, the radial pulse is counted for a timed interval of exactly 30 seconds.
29. The 30-second count is recorded.
30. The standard mercury sphygmomanometer is then connected with the cuff.
31. The manometer is positioned so that the midpoint of the column is at the technician's eye level when in position to carry out the measurement of blood pressure.
32. The radial pulse is located, and palpated.
33. The cuff is inflated quickly to 80 mmHg.
34. Slowly inflate at 10 mmHg at a time until the radial pulse can no longer be felt.
35. The cuff is quickly and completely deflated.
36. Record the pulse obliteration pressure (POP).
37. Calculate and record the peak inflation level (pulse obliteration pressure + 60). The peak inflation level used for BP measurement must be >180 mmHg.
38. To perform the measurement of blood pressure itself, the brachial artery is again palpated. Note that the arm remains bare.
39. The wheel of the random-zero is gently spun with the valve in the OPEN position.
40. The stethoscope ear pieces are put in place with the ear pieces positioned forward.
41. 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.

42. With the valve still in the OPEN position, the cuff is inflated quickly and smoothly to the peak inflation level or to 180 mmHg, whichever is higher. Hold the mercury at this pressure for five seconds.
43. The valve is then turned to the CLOSE position.
44. The cuff is then deflated very steadily at 2 mmHg per second,
45. To a level 10 mmHg lower than the level of the last Korotkoff sound heard.
46. The mercury level is now dropped quickly to the "zero" level for this reading.
47. The observed values for the SBP, DBP, and "zero" values are recorded.
48. Remove stethoscope ear pieces.
49. Disconnect the cuff and record the zero reading. DO NOT SUBTRACT THE ZERO READING UNTIL ALL THREE MEASUREMENTS ARE COMPLETED.
50. Have participant raise arm for five seconds, then rest arm on table for 25 seconds.
51. The second and third readings are carried out exactly as the first.
52. After finishing both RZ BP measurements subtract the zero value from the readings to get the actual systolic and diastolic values.
53. All arithmetic must be done with a calculator after both readings have been completed.

Lecture #4—Equipment Maintenance and Mercury Toxicity Safety

(This lecture is essentially a repeat of the material covered under pages 17-22).

The condition of the instruments for blood pressure measurement is too often ignored in common practice and should be a special responsibility of the trainer or other designated staff member. This person **should be acquainted with mercury toxicity safety procedures** as well as construction and function of all the blood pressure equipment. The cleanliness and general working order of the cuffs and stethoscopes can usually be determined by simple inspection. For both the conventional and random-zero (RZ) type manometers, however, proper handling of breakable parts and of mercury and oxidized waste requires more careful attention. Guidelines for maintenance of the manometers are outlined here in some detail.

General 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 mmHg at the top of the mercury meniscus. The "zero" levels for the random-zero (RZ) device should have a range of approximately 20 mmHg between the maximum and the minimum "zero"

level. 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 comparison to zero levels obtained during actual readings taken with the device.

2. These devices should be cleaned and checked thoroughly on a biannual basis or approximately every six 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. If your biannual check and bimonthly fall in the same month complete both maintenance logs.
4. Procedures for inspecting the RZ Manometer (RZM) are outlined below. 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.
5. **Work area and mercury spillage.** All blood pressure devices used in PREMIER contain mercury, which is a volatile metal at room temperature. In view of the problem of spillage and retrieval of this material, a definite work area should be designated for all manipulations. This area should be in a well-ventilated room. Rugs should not be present. The work bench should be a flat, smooth surface which can be easily cleaned, with adequate space. All work should be done in a large tray or basin with edges that will contain any mercury spill that may inadvertently occur in the process of maintaining the machines. A mercury cleaning solution which inactivates elemental mercury and prevents it from vaporizing should be kept in stock in the work area and the person doing the work should wear a lab coat with no pockets and should remove rings, watches or other metallic objects from his/her hands. A procedure should also be developed for proper handling of accidental mercury spills and all staff made aware of the procedure. Institutional safety regulations at each site should be reviewed and followed.

Common Problems with—and Solution for—both Manometers

Dirty manometer column

- This is due to dirty or oxidized mercury and is usually evident near the zero. Oxide and dirt near RZM "zero" can result in too high "zero" readings because mercury hangs 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 actual zero.
- Remove the glass manometer column. See Baum instructions for removal of column from conventional manometer.
- 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 pushing through, and brush the soiled end of the cleaner into the container.

Mercury leakage

This can be due to any of the following:

- loose or leaky screw cap at top of manometer
- manometer column cracked, chipped, or improperly seated
- leaky manometer column gaskets
- tilting RZM with mercury reservoir valve open
- loose or leaky RZM bellows air bleed screw cap

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

- 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.
- By a process of pinching the tubing at 1-2 inch intervals up to the cuff and then down to the bulb, you will locate an air leak.
- If an air leak is found to be in the cuff bladder or the tubing other than the connections, the bladder may need to be replaced.
- If the air leak is found in the connections or in the bulb valve, a little silicone spray may alleviate the problem.

Inspection of the Random-Zero Manometer

Unless obviously damaged because of dropping or other accident, the RZM 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 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 R-Z system and check for mercury leaks.

Using a 30-ml or larger syringe and a length of tubing, apply greater than 200 mmHg pressure to the mercury column. (A syringe gives faster and better control than a cuff and a bulb for this purpose, but the technician 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 rise 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

    - The bellows valve should be in the "OPEN" position, and no pressure should be in the cuff. The cam should rotate freely.
    - 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.)
    - Inflate the cuff above 200 mmHg and maintain it at this pressure until the chamber wall has come to rest against the bevel of the cam.
    - Turn the valve to "CLOSE," wait a full five seconds, and deflate and disconnect the cuff.
    - Record the zero level it should compare closely (within 4 mmHg) with the value on the label on the face of the manometer.

6. Verify the minimum "zero" obtainable

    - Repeat exactly as for (5) above, except 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 produce the lowest "zero" level for the amount of mercury in the device at this time.)
    - 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.

- Turn the bellows valves to "CLOSE," and deflate and disconnect the cuff.
- Record this zero level; it should match the value determined when the machine was calibrated, which is listed on the label.

7. Adjust zero levels if needed

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 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 Boulevard, Newark, NJ 07102. It is recommended that all work be done in a container such as a plastic dishpan when mercury is to be transferred, that gloves and lab coat be worn, and that the area is well-ventilated.

If the minimum zero level is below 0:

- 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.
- 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 a 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.
- 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.
- 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.
- Determine zero range and adjust as needed.

If the minimum zero level is greater than 4 or the maximum is greater than 24:

- 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.

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

    - 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.
    - 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.
    - Adjust the spin by slightly loosening or tightening the mounting screw at the end of the cam.
    - After any such adjustment, recheck the spinning wheel repeatedly to ensure against 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:

    - Set the cylindrical cam for maximum bellows volume, and open the bellows control valve.
    - Raise the reservoir pressure to about 280.
    - Close the bellows valve, and release pressure on the reservoir.
    - Tilt the RZM 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 RZM on its right side, with the spin wheel above the table surface.
    - The manometer column may now be removed.

10. Maintenance requirements are minimal, but essential.

    - A very occasional drop of light machine oil is recommended on moving parts, including the bellows plate centering pin.
    - Do not, however, oil the bellows control valve stem or the mercury reservoir valve.
    - Ensure that moving parts are free without too much slack.