

CHRONIC KIDNEY DISEASE IN CHILDREN COHORT STUDY

**SECTION 27: BLOOD PRESSURE MEASUREMENT
TRAINING AND CERTIFICATION**

27.1 OVERVIEW

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

The certification process includes training and the successful completion of:

- Review Training Blood Pressure (BP) DVD (every year)
- A live evaluation (every year)

The training strategy is a two-stage program.

Each site must have at least one staff member who is certified in blood pressure measurement.

The first stage of the program is the successful completion of the BP DVD test provided by the DCC. The data coordinating center (DCC) will send these tests to each clinical site. The Blood Pressure Observer(s) must successfully complete this BP DVD test at the time of certification and every year. An observer will be considered certified if they obtain a score of 85% on the DVD test.

In this second stage, each Blood Pressure Observer will be asked to perform a live evaluation. The Blood Pressure Observer is then responsible for completing the "Live Blood Pressure Evaluation" checklist (see Section 16.2 for the BP Measurement Step-by-Step and Section 28.5 for the Live Blood Pressure Evaluation Checklist). The clinical site will fax the "Live Blood Pressure Evaluation" checklist and BP DVD test to the DCC.

The DCC is responsible for identifying who is certified. The Data Coordinating Center will, in addition, remain responsible for overall monitoring and quality control (as will be described in Section 28).

27.2 TRAINING MATERIALS

27.2.1 Overview of Training Materials

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

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

A general discussion of blood pressure, the history of its measurement, and some of the problems and solutions inherent in its measurement. (Lecture #1)

2. The Mabis Medic-Kit Aneroid Device (lecture)

An explanation of the mechanics and the principles of the operation of this device and the importance of regular calibration checks. (Lecture #2)

3. Blood Pressure Recording Procedures (lecture)

Step-by-step instructions on how to measure blood pressure using the Mabis Medic-Kit Aneroid Sphygmomanometer. (Lecture #3 and Sections 27.2.4 – 27.3.10)

4. Local Blood Pressure Equipment Maintenance and Mercury Toxicity Safety Responsibility (notes).

For those using mercury manometers for calibration checks.

Step-by-step instructions on how to perform routine maintenance duties on both the Mabis Medic-Kit Aneroid and conventional mercury sphygmomanometers (used for calibration checks every year) (Section 27.2.11).

27.2.2 General Plan

The observer must review the BP DVD and successfully pass, with a score of 85%, the BP DVD test every year. The test involves watching aneroid sphygmomanometer and listening to the simultaneous Korotkoff sounds during blood pressure measurements, then recording the systolic and diastolic levels for each on the BP DVD test sheet. The BP DVD test sheet is then faxed to the DCC following the outlined instructions enclosed in the mailing. Finally, the observer must demonstrate one or more complete and correct blood pressure determination procedures for 1) cuff selection by correct arm measurement, 2) determination of pulse, 3) determination of peak inflation level using the Mabis Medic-Kit Aneroid, and 4) correct blood pressure measurement following the protocol. The Live Evaluation checklist should be faxed to the DCC.

27.2.3 Lecture presentations.

27.2.3.1 Lecture #1

Blood Pressure Measurement - Problems and Solutions

Important problems in blood pressure measurement exist, random variation within each subject, and systematic variation sub-classified as follows: "(i) alarmingly large differences in estimation between observers, sometimes as large as 15 mm Hg..., (ii) effects of the circumstances of measurement, both emotional and physical (especially recent physical activity or change of position), (iii) seasonal changes, and (iv) relatively small errors due to overestimation of pressures in fat arms...."

What can be done to deal with these problems: 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. As to differences between observers, these are considered as of two types, one type affecting chiefly the mean of a series of measurements, the other type chiefly distorting the reported frequency distribution of readings. This latter type includes terminal digit preference, which is the unconscious tendency to choose one digit over others in assigning the value of a reading and the prejudice against certain values. Factors affecting mean differences between observers include mental concentration or reaction time, hearing acuity, confusion of auditory or visual cues, interpretation of sounds, rates of inflation and deflation of the cuff, and reading of the moving column of mercury.

These problems can largely be overcome by training followed by satisfactory performance on the BP DVD test. The method of training and its specific objectives are therefore worth brief discussion now.

Training in blood pressure measurement will take two forms. First, there will be a viewing of the training BP DVD with demonstration to acquaint you with the proper procedures for measuring blood pressure and also to familiarize you with the Mabis Medic-Kit Aneroid device. Second, you will take actual live blood pressure readings and complete the Live BP Evaluation Checklist. Your ability to measure blood pressure accurately as a result of this training will be tested using a DVD 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.

27.2.3.2 Lecture #2

Mabis Medic-Kit Aneroid Device

Aneroid sphygmomanometers have achieved widespread acceptance in recent years, chiefly as an alternative to mercury devices and their associated disadvantages. An inherent drawback to aneroid devices is the fact they must be checked for calibration at regular intervals (every year in CKiD) and adjusted if necessary. Mercury manometers are still considered the gold standard in blood pressure measurement. **Annual calibration checks for the Mabis Medic-Kit Aneroid must be done.** If clinical sites are unable to use mercury sphygmomanometers for calibration checks at their site, you can send your Mabis Medic-Kit Aneroid Device to the data coordinating center for calibration as

described in Section 27.2.11. Sites must complete the Calibration Check form each time the device is calibrated. If the site sends the aneroid device to the DCC for calibration, the Calibration Check Form should be sent with the device. The DCC will calibrate the device and indicate on the Calibration Check Form that the device was calibrated. When the clinical site receives the calibrated device and completed Calibration Check Form, they must fax the form to the DCC for data entry.

27.2.3.3 Lecture #3

Blood Pressure Recording Procedures

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

27.2.4 Equipment and Supplies

1. The equipment needed by each observer includes a Mabis Medic-Kit Aneroid sphygmomanometer in good condition,
2. Access is needed to the full set of Mabis Medic-Kit cuff sizes. These are commonly referred to as the infant, child, adult, large adult and thigh cuffs, respectively.
3. The inflation bulb should operate smoothly and should perhaps be individualized to each observer.
4. The stethoscope, in good condition, should be switched for use of the bell in listening to the Korotkoff sounds.
5. A stop watch (provided in the CKiD Starter package), is needed for measurement of the pulse.
6. A Graham-Field disposable measuring tape (provided in the CKiD Starter Package) in metric units is required for determination of the correct cuff size for each participant.
7. A ballpoint pen should be used for all data recording, preferably with medium or larger point, and black ink.
8. Requirements for furniture are simple but must provide for a comfortable resting position of the arm with mid-cuff at heart level and feet resting, not dangling (i.e., place feet on phonebook, stool, storage bin).
9. The Physical Examination (PE) form must be in place before measurement begins.

27.2.5 Arm Measurement

10. Measurement of the arm is required for selection of the proper cuff. For this measurement, the arm should be bare.
11. The measurements are taken on the right arm, with the participant standing, holding the forearm horizontal. Arm length is measured from the acromion or bony extremity of the shoulder girdle, to the olecranon, or tip of the elbow. The full arm length from acromion to olecranon is measured, and the midpoint is marked on the dorsal surface of the arm. 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.
12. On the PE Form, the chart of arm circumference measurements and corresponding cuff sizes is consulted, and
13. the proper cuff size is checked. Indicate this cuff size on the form. (Note: If an arm measures 33.0, 33.0 will be entered for question E1 (Midpoint circumference of arm being used) on the PE Form. **(Try to use the same size cuff for every measure for a participant.)**)

27.2.6 Preparation for Actual Readings

14. The participant should then be seated with the elbow and forearm resting comfortably on a table with the palm of the hand turned upward. The area to which the cuff is to be applied must be bare.
15. The brachial artery is located by palpation and marked, as is the midpoint of the rubber bladder within the cuff. Often this point is marked on the cuff itself; however, it may not be accurate. Therefore, you should identify the midpoint by folding the bladder.
16. 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.
17. The Mabis Medic-Kit Aneroid sphygmomanometer is then connected with the cuff.
18. The manometer is positioned so that the observer's can read the dial without a glare.
19. The radial pulse is located.
20. While palpating the radial pulse, observe the dial of the aneroid sphygmomanometer and quickly inflate to 60 mmHg and then slowly inflate in increments of 10 mmHg until the pulse is no longer felt. If the pulse is still detected, the cuff is inflated slowly by increments of 10 mmHg until the pulse disappears. Either the first or the second of these procedures identifies the Observed Pulse Obliteration Pressure.
21. The cuff is quickly and completely deflated.
22. The observed value and 30 mmHg are used to calculate (by addition) the Corrected Pulse Obliteration Pressure. Both are recorded on the PE form.
23. The sum of the two equals the Peak Inflation Level (PIL)

27.2.7 First Blood Pressure Reading

24. To perform the measurement of blood pressure itself, the brachial artery is again palpated and marked with a pen. Note that the arm remains bare.
25. The stethoscope earpieces are put in place with the earpieces positioned forward, and
26. 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.

27. The cuff is quickly inflated to the Peak Inflation Level.
28. The cuff is then deflated very steadily at 2 mmHg per second, to a level 10 mmHg lower than the level of the last Korotkoff sound heard.
29. The manometer level is now dropped quickly to the zero level for this reading.
30. The cuff is then disconnected and the stethoscope removed.
31. The observed values for the SBP, DBP, are recorded on the PE form.

27.2.8 Between Readings

32. If the cuff is uncomfortable for the participant you may remove it.
33. The observer will raise the participant's arm overhead for 15 seconds without the participant's assistance.
34. The arm is then lowered gently for an additional 15 seconds. There is a total of 30 seconds between readings.
35. If the cuff was removed it should be replaced, and the Mabis Medic-Kit Aneroid sphygmomanometer is reconnected.

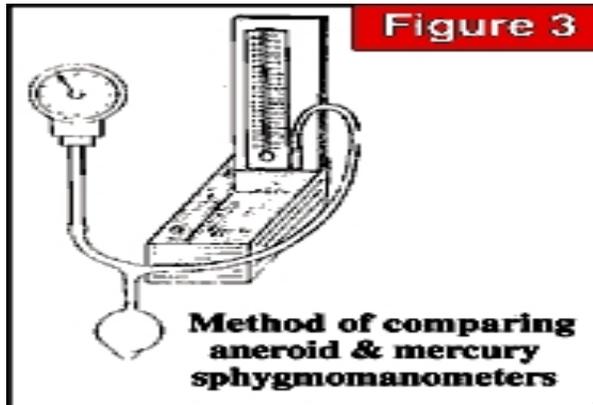
27.2.9 Second Blood Pressure Reading

36. The second reading is carried out exactly as the first.
37. The observed SBP, DBP, are recorded,

27.2.10 Between Readings/Third Blood Pressure Readings

- The cuff may be removed once again and the entire sequence is repeated from having the observer raise the participant's arm overhead for 15 seconds, lowering the arm and waiting an additional 15 seconds before taking the third Blood Pressure Reading. Note: There is a total of 30 seconds between blood pressure readings.
- As before, the observed SBP, DBP, are recorded on the PE form.
- The second and third readings are averaged to get the average systolic and diastolic for the visit.

27.2.11 Calibration of the Mabis Medic-Kit Aneroid



Calibration checks are done annually. You will need the following equipment:

- Mercury sphygmomanometer
- “Y” connector
- Inflation bulb and valve attached

To calibrate the aneroid device do the following and record calibration checkpoints on the Blood Pressure Aneroid Calibration Check Form:

1. Connect one tube to the mercury manometer.
2. Connect the Mabis Medic’s aneroid dial to the other tube. (Cuffs and bags are not used when conducting calibration checks.)
3. Slowly inflate the instruments to 250 mmHg and compare the readings.
4. They should be the same; however a deviation of +/- 4mmhg is acceptable.
5. Record the readings you obtain.
6. Repeat the procedure at 160 mmHg.
7. Repeat at 70 mmHg.

If, when averaged, there is a deviation of greater than +/-4mmHg at any level, the aneroid device being tested is inaccurate and should be mailed to the DCC. Email Jeanne Charleston @ jeannec@jhmi.edu and cc KIDMAC @ ckidship@jhps.edu prior to shipping the device. If necessary, the DCC will send the device back to the manufacture for repair.

Note: Remember, the mere fact that the needle points to zero on the dial of the aneroid manometer when the compression is deflated does not necessarily mean that the instrument is accurate over the entire pressure range. “Primer Of Clinical Blood Pressure Measurement,” by George E. Burch, M.D. and Nicholas D. Pasquals, M.D.

“The readings on the dial at different pressures should check with those of a properly constructed and functioning mercury manometer. The fact that the pointer indicates zero may be no guarantee of accuracy over the whole pressure range”. American Heart Association, “Recommendations for Human Blood Pressure Determinations by Sphygmomanometers”.

If CKiD clinical sites cannot perform annual calibration checks, the site should send their equipment to the following site:

Jeanne Charleston
C/O Johns Hopkins ProHealth
1849 Gwynn Oak Ave, Suite 1
Baltimore, MD 21207
Telephone: 410-281-1138
Email: jeannec@jhmi.edu

Clinical sites must contact Jeanne Charleston, prior to shipping the aneroid device for calibration.

27.2.12 Inspection of the Mabis Medic-Kit Aneroid Manometer

Unless obviously damaged due to dropping or other accident, the Mabis Medic-Kit Aneroid sphygmomanometer is expected to operate without disturbance of its measurement performance. Annual calibration checking must be done to ensure against undetectable accuracy problems.

27.2.13 Documentation of Certification

- A. Each person in the clinical site that will be filling out any part of a blood pressure form will need to be certified. This includes all blood pressure observers.
- C. The Live Blood Pressure Evaluation Checklist should be carefully followed to ascertain that the trainee has a clear understanding of the procedures. This evaluation should be completed by the supervisor as a passive observer. Avoid prompting the trainee. The trainee should complete one or more complete and uninterrupted exercises of the full procedure. Errors of procedure should be reviewed, discussed and corrected during BP certification. When carried out without procedural errors, this record should be completed, signed and faxed to the DCC.
- D. Do not overexpose the trainee to the actual BP DVD test. The test should be faxed to the DCC following the outline of instructions enclosed in the mailing. If a systematic problem is discovered, the DCC will instruct you as to the type of problem discovered. The specific problem should not be identified to the trainee, as this may artificially bias the trainee's responses. If the problem is not corrected within three DVD tests, the DCC will contact the site to discuss the problems identified and provide instructions over the phone. The Data Coordinating Center will need to have complete documentation of the certification before the trainee can be employed as a blood pressure observer. We suggest keeping the originals in the CKiD Blood Pressure Manual Binder and fax to the Data Coordinating Center. The Data Coordinating Center will instruct the Clinical Coordinating Center who will inform the site when re-certifications should be scheduled, every year.

27.3 CERTIFICATION PROCEDURES AND CRITERIA

27.3.1 Two Steps Needed For Certification

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

1. The first step is a series of blood pressure readings presented on a BP DVD to test the observer's identification of the systolic and diastolic Korotkoff sounds. This DVD mimics the actual blood pressure measurement setting by providing a series of blood pressure readings which consist of both aneroid and mercury sphygmomanometers and the audible Korotkoff sounds. An observer is certified if the criteria of the scoring procedure are successfully met. The criteria for the scoring procedure are not available to the Clinical Center or to the observers. The scoring will be done at the DCC.
2. The second is the successful completion of The Live Blood Pressure Evaluation. Each observer is to verify the correct procedure for blood pressure measurement by observing the observer in one or more complete and uninterrupted exercises of the full procedure. When carried out without procedural errors, this record should be completed, signed and faxed to the DCC. Errors of procedure should be reviewed, discussed and corrected, until one completed determination is accomplished without error.

As a means of maintaining a high level of quality and standardization over time, blood pressure observers will be recertified in the BP DVD and live evaluation every year. Re-certification will involve, repeated testing by viewing the BP DVD and submitting a completed DVD test sheet, as well as live measurement evaluation. The Data Coordinating Center will notify the clinical sites as to the schedule and requirements of the recertification. A further description is in Section 27.3.2.

27.3.2 Instructions for Taking the DVD Test

Viewing of the BP DVD, may be done in a group or individually. The DVD consists of twelve systolic and diastolic sequences. After each sequence, the observer should record, on the recording sheet provided, the systolic and diastolic reading for that sequence. All entries should be completely legible and written in black ink. Leading 0's should be entered if appropriate. The manometer in the BP DVD is read exactly as one would be read in actual practice. Each blood pressure should be read to the nearest even digit. The DVD also includes a blood pressure with an auscultatory gap.

27.3.3 The Study Forms Required For Certification Procedures

The two study forms required for certification every year include:

1. The BP DVD Test Sheet; and
2. The Live Blood Pressure Evaluation Checklist.