

CHRONIC KIDNEY DISEASE IN CHILDREN COHORT STUDY
SECTION 28: BLOOD PRESSURE MEASUREMENT
QUALITY CONTROL

28.1 Overview

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

In addition to these, CKiD 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 every year.
3. Retraining of observers having difficulties with standardized measurements.
4. Annual observations, using the “Live Blood Pressure Evaluation” checklist at the end of this section. One checklist is used for each blood pressure observer. The original should be kept on file and will be reviewed at site visits.
5. Continuous editing and analysis of data by the Data Coordinating Center.
6. Presentation of data analyses to the Clinical Coordinating Centers by the Data Coordinating Center to provide feedback twice per year (i.e., digit preface).
7. Annual Calibration.
8. Documentation of the “Live Blood Pressure Evaluation” Checklist will be sent to the DCC. The dates of the Mabis Medic-Kit Aneroid Sphygmomanometer annual calibration checks will be entered on a data collection form.

28.2 Annual Recertification and Retraining

As with the initial certification process this recertification process (every year) includes the successful completion of:

- * a BP DVD test sheet
- * a Live Evaluation Checklist

It is recommended that person performing blood pressure measurements demonstrate the live evaluation centrally each year.

The recertification procedures will be conducted at the clinical sites. However, scoring of the DVD tests will be done by the DCC. The Live Evaluation Checklist and DVD test should be faxed to the DCC. The confirmation from the DCC showing all staff members measuring blood pressures have successfully completed the DVD test should also be faxed to the clinical centers. The DCC is responsible for identifying who is a certified blood pressure observer. A report based upon the results of these tests may be presented to the Steering Committee. This report would describe how well the observers are measuring blood pressure levels under standardized conditions, and how many observers had difficulty being recertified.

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

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

28.3 Monitoring for Digit Preference

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

NO OBSERVER SHOULD EVER HAVE A DIGIT PREFERENCE.

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

28.4 Responsibilities of the Data Coordinating Center

It is the responsibility of the Data Coordinating Center to provide training and to monitor the certification of members conducting BP measurements. **It is primarily the responsibility of the person receiving training to train at least one other observer.** However, only the Data Coordinating Center is able to certify an observer, as described above.

If, between re-certifications, the Data Coordinating Center has evidence that an observer is not performing well, the DCC will contact the site to discuss the matter. It may be necessary for the Data Coordinating Center to temporarily rescind a certification and retrain the observer. In this case, until the observer is recertified, he or she may not take blood pressure measurements for CKiD.

It is also the responsibility of the Data Coordinating Center to monitor the specific activities of the bp Observers. In addition to the continuous monitoring of all incoming blood pressure data (e.g., for digit preference or bad values), and the files of the "Live Blood Pressure Reading Performance Evaluation" checklists and should be faxed to the DCC and will be reviewed at each site visit for completeness and accuracy. Also at these site visits, the observers themselves will undergo checklist monitoring.

28.5 **LIVE BLOOD PRESSURE EVALUATION CHECKLIST**
(Used for Certification/Recertification and for Quality Control)

The original should be kept on file at the Clinical Site and a copy should be sent to the DCC.

Trainee's Name: _____

Date: ___/___/_____

Site: _____

Site #: ___

A. Equipment and Supplies

The trainee should indicate that all equipment and supplies needed for blood pressure measurements are present. Check each item as identified:

- _____ (1) Mabis Medic-Kit Aneroid Sphygmomanometer
- _____ (2) Mabis Medic-Kit Cuffs - full set of 5 sizes
- _____ (3) Stethoscope with a bell
- _____ (4) Mayo stand or bedside table
- _____ (5) Accusplit (model 80226) Stopwatch (provided in CKiD starter package)
- _____ (6) Measuring tape
- _____ (7) Black ball point pen
- _____ (8) Physical Exam Form (PE Form)

B. Arm Measurements

The following steps are properly carried out:

- _____ (1) Participant standing
- _____ (2) Arm bare from elbow to shoulder
- _____ (3) Arm at 90 degree angle
- _____ (4) Arm length measured from the acromion (or bony extremity of the shoulder girdle) to the olecranon (or tip of the elbow)
- _____ (5) Midpoint of arm marked at dorsal aspect
- _____ (6) Arm relaxed at side
- _____ (7) Circumference measured with tape horizontal
- _____ (8) No indentation of skin
- _____ (9) Mark at midpoint of arm
- _____ (10) Value checked with chart to ascertain proper cuff size
- _____ (11) Proper cuff size checked on study form (PE Form)

C. Preparation for BP Readings

- _____ (1) Brachial artery palpated
- _____ (2) Midpoint of bladder within the cuff located
- _____ (3) Cuff applied with midpoint of bladder over brachial artery
- _____ (4) Arm positioned with midpoint of cuff width at "heart" level; lower edge 2 to 3 cm (1 inch) above crease
- _____ (5) Wait 5 minutes
- _____ (6) Mabis Medic-Kit Aneroid sphygmomanometer connected to cuff
- _____ (7) sphygmomanometer scale (midpoint) is at eye level
- _____ (8) radial pulse located
- _____ (9) cuff is inflated quickly to 60 mm Hg
- _____ (10) cuff is further inflated slowly by increments of 10 mm Hg (if pulse present at 60 mm Hg) until the pulse is no longer felt.
- _____ (11) cuff is quickly and completely deflated
- _____ (12) Observed Pulse Obliteration value is correctly recorded on the form
- _____ (13) the Correct Pulse Obliteration Pressure + 30 are added to get the Peak Inflation Level

D. Measurement of Blood Pressure

- _____ (1) Brachial artery palpated
- _____ (2) Stethoscope in ears
- _____ (3) Bell over artery, without cuff or tubing contact
- _____ (4) Cuff inflated quickly and smoothly to the Peak Inflation Level
- _____ (5) Deflation at 2 mm Hg/second to 10 mm Hg below K5
- _____ (6) Cuff quickly and completely deflated
- _____ (7) Cuff disconnected
- _____ (8) Recording of SBP and DBP values

E. Between Readings

- _____ (1) Cuff removed or tubing disconnected if uncomfortable
- _____ (2) Arm raised passively overhead for 15 seconds. (Make sure the patient is not supporting the arm at all)

- _____ (3) Arm lowered and cuff replaced with attention to brachial artery and midpoint of bladder; lower edge 2 to 3 cm (1 inch) above crease of the elbow. Note: There is a total of 30 seconds between readings.
- _____ (4) Cuff reconnected

- F. Second Seated Blood Pressure Reading
_____ (1) Conforms with procedures as in E and F above
- G. Third Seated Blood Pressure Reading
_____ (1) Conforms with procedures as in E above
- H. Completion
_____ (1) Complete PE Form
_____ (2) Closure of Mabis Medic-Kit Aneroid manometer case for storage

I certify that all steps were followed correctly and according to the CKID Cohort Protocol.

BP Observer Signature

Remarks:
