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1. Background and rationale

Blood pressure measurements will be recorded to document blood pressure, and individuals with extremely high levels of blood pressure may be excluded from selected measurements and referred to their primary care providers for medical care.

2. Equipment and supplies

- conventional jewel movement sphygmomanometer or automated, oscillometric device (e.g., Dinamap 100 or Dinamap 1846 SX/P)
- blood pressure cuffs (adult cuff sizes small, regular, large, and thigh)
- stethoscope: standard stethoscope and earpieces with bell, tubing to be maximum of 14 inches long (if using jewel movement sphygmomanometer)
- tape measure
- eyebrow pencil
- chair with back support
- digital stopwatch

2.1 Maintenance of blood pressure equipment

Automated Oscillometric Device

With each use:

- 1) Device is turned off at the completion of each participant's examination.
- 2) Squeeze all air from cuff.
- 3) Confirm that the connection of the cuff to the tubing is secure and tubing is not kinked.

Monthly:

- Inspect cuff and tubing for cracks or tears. If a leak is suspected place the cuff around an unopened, full, 12-ounce can, start the Dinamap using the manual Dinamap switch, and submerge the cuff in water. If there is a leak, air bubbles will start to rise from the area of the leak. Replace the cuff if a leak is detected.
- 2) Wipe the exterior of the monitor with a clean cloth slightly dampened with mild detergents.

MOST

 Check the blood pressure cuffs to assure all sizes of cuffs are available. Document the monthly checks of the Dinamap equipment on your Monthly Automated Oscillometric Blood Pressure Device Check Log.

General:

Inspect the tape used to measure arm circumference for damage or wear twice a year.

Conventional sphygmomanometer

With each use:

- 1) Check the sphygmomanometer for correct zero. Place the instrument flat on the table and disconnect the inflation system. With eyes level with the zero line, make sure that the dial is at zero.
- 2) Check the dial to make sure that it starts at zero and comes back to zero.

Monthly:

- 1) Check that the needle rises smoothly and that the dial does not bounce noticeably when the valve is closed.
- 2) Check dial to make sure it starts at zero.
- 3) Check the cuffs, pressure bulb, and manometer and stethoscope tubing for cracks or tears.
- 4) Check the pressure control valve for sticks or leaks.
- 5) Check the stethoscope diaphragm for cracks.
- 6) Never attempt to repair the equipment yourself. Send the instrument for repair if any of the above checks reveal a problem.
- 7) Check the sphygmomanometer for air leaks. Roll the cuff around a plastic bottle or tin can and secure in place. Close the valve on the air-flow system and inflate the instrument until the needle rises to 240 mm Hg. Close the valve. The dial should remain stable. If the needle continues to fall, there is an air leak and the system should be re-inflated until the needle rises to 200 mm Hg. Pinch the tubing at various locations to localize the area of the leak, then replace the leaking tubing, cuff, or valve.

Check the blood pressure cuffs on a monthly basis to assure all sizes of cuffs are available. Document the monthly checks of the sphygmomanometer on your Monthly Sphygmomanometer Equipment Check Log.

Inspect the tape used to measure arm circumference for damage or wear twice a year.

3. Safety issues and exclusions

Participants will not have their blood pressure taken on their right arm if there are medical or post-surgical reasons e.g., mastectomy, or amputation. Then the blood pressure will be taken on the left arm. If the blood pressure cannot be taken on either the right or left arm, do not measure blood pressure.

4. Participant and exam room preparation

Participants should not drink any caffeine (from coffee, tea, or soda), should not eat or do any heavy physical activity, smoke, or ingest alcohol for 30 minutes prior to recording the blood pressure. Room temperature should be between 70 degrees and 76 degrees Fahrenheit.

4.1 Arm circumference

The blood pressure is taken on the right arm. If the participant's right arm is injured or missing, or if the participant reports a compelling reason to avoid measurement in this arm, such as a mastectomy on the right side, use the left arm for the blood pressure measurement. Measure the participant's arm to determine the appropriate cuff size before allowing the participant to rest.

Use the following procedures to measure the participant's arm and determine the appropriate cuff size:

- Proper measurement requires that the participant's arm is bare to the shoulder. The participant should be wearing a loose-fitting top.
- Request the participant to stand facing away from the examiner with the right elbow bent 90 degrees at the elbow with the hand on the stomach. The upper arm should be at a 90-degree angle to the lower arm.
- Measure arm length from the bony prominence of the shoulder girdle (acromion) to the tip of the elbow (olecranon process) using a tape measure.
- Mark the midpoint on the dorsal (back) surface of the arm.
- Ask the participant to relax their arm along the side of the body.
- Wrap the tape measure horizontally around the arm at the midpoint mark, but do not indent the skin. Make the measurement to the nearest 0.5 cm.
- Use the measurement to determine the correct cuff size.

Do not use the markings on the blood pressure cuff for reference. Instead, use the following criteria for determining the appropriate cuff size for the participant:

Arm Circumference (cm/in.)	Cuff's Bladder Size (cm)
19 – 25.9 cm (7.5 - 10.2 in)	small cuff (9.0 cm)
26 – 32.9 cm (10.3 - 12.9 in)	regular cuff (12.0 to 14.0 cm)
33 – 40 cm (13 - 15.8 in)	large cuff (15.0 to 16.0 cm)
> 40 cm (>15.8 in)	thigh cuff (17.5 to 18.0 cm)

Keep the above chart of arm circumference measurements and corresponding cuff sizes readily available for easy reference.

5. Detailed measurement procedures

Before measuring the participant's blood pressure, the participant <u>should rest for approximately</u> <u>5 minutes with their feet flat on the floor and legs and ankles uncrossed</u>. If using the conventional sphygmomanometer, the maximal inflation level should be determined. The automated oscillometric device automatically determines the required maximal inflation level. One blood pressure reading will be obtained in MOST.

5.1 Application of the cuff

- Ensure that the participant is seated comfortably in a chair with back supported and both feet are flat on the floor.
- Make sure that the participant's arm is resting on the table at a 90-degree angle with the palm facing up.
- Palpate the brachial artery.
- Mark the brachial artery with an eyebrow pencil.
- Place the appropriate-sized cuff around the upper right arm, approximately at heart level, with the participant's palm facing upward (the participant may rest their forearm and elbow on a table or arm of the chair). Place the lower edge of the cuff with its tubing connections about one inch above the natural crease across the inner aspect of the elbow.
- Wrap the cuff snugly about the arm, with the inflatable inner bladder centered over the area of the brachial artery. The brachial artery is usually found at the crease of the arm, slightly toward the body. Secure the wrapped cuff firmly by applying pressure to the

locking fabric fastener over the area that it overlaps the cuff. You should be able to insert the first joint of two fingers under the cuff.

• If it is not feasible to measure blood pressure using the right arm, the left arm will be used. Mark which arm is used for the measurement on the data collection form.

5.2 Rest period

The blood pressure can be measured after any period where the participant has been sitting quietly (no talking or completing forms) for 5 or more minutes, and at least 30 minutes after ingestion of caffeine.

5.3 Determining the maximal inflation level (MIL)

The automated oscillometric device (Dinamap) automatically determines the maximal inflation level. When using the conventional sphygmomanometer the examiner must determine the maximal inflation level.

5.3.1 Auscultatory gap

An auscultatory gap is the fading or disappearance of sound after the first Korotkoff sounds are heard. The sound then reappears at a level well above the diastolic pressure. This phenomenon is seen more frequently in older persons.

This means that in an adult with an auscultatory gap, the real systolic pressure may be missed and read as a much lower BP. For example:

Real systolic is 172 but sounds fade at: 168 and reappear at 152 and disappear at 98.

If the correct procedure (inflating to MIL) for BP measurement is not used, this participant's BP may be read as 152/98 instead of 172/98. The only way to avoid this error is to obtain the MIL before BP measurement.

Determine the pressure to which you must inflate the cuff for the measurement of the systolic blood pressure. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and allows you to hear the first Korotkoff sound.

The procedures for determining maximal inflation level using the conventional sphygmomanometer are as follows:

• Attach the cuff tubing to the jewel movement dial sphygmomanometer.

- Palpate the radial pulse (if the radial pulse is difficult to palpate, the brachial pulse may be used).
- Inflate the cuff to 70 mm Hg on the dial. Then increase by 10 mm Hg increments until the radial pulse is no longer felt (palpated systolic).
- Deflate the cuff quickly and completely.
- Inflate the cuff to **30 mm Hg above the palpated systolic pressure** for all subsequent readings.
- Repeat the MIL if the first attempt was unsatisfactory or you have had to readjust the cuff after measuring the MIL. Wait 30 seconds before making a second attempt if the first is unsatisfactory. If the second attempt is unsatisfactory, terminate the procedure and note the problem on the form.
- If the radial pulse is still felt at a level of 270 mm Hg or higher (which means that the MIL is 30 mm Hg higher) repeat the MIL. If the MIL is still 300 mm Hg, terminate the blood pressure measurements and write in "300/MIL" on the form. On the Participant Report Form, indicate the blood pressure as 270 palpated, and refer the participant to see their primary care physician.
- Wait 30 seconds before taking blood pressure measurement.

5.4 Performing the blood pressure measurement

Automated Oscillometric Device

- Select the Manual Blood Pressure mode from the main menu on the Dinamap monitor. Immediately after you select <u>Manual Blood Pressure</u>, the monitor will start the blood pressure measurement.
- Record the systolic and diastolic values in the spaces provided on the form.

Conventional sphygmomanometer

- Place the ear pieces of the stethoscope, with the tips turned forward, into your ears.
- Apply the <u>bell</u> of the stethoscope over the brachial artery with light pressure, ensuring skin contact at all points. Effective use of the bell requires careful palpation of the brachial artery to know exactly where to place the bell. Place the bell just below, but not touching, the cuff or tubing.
- Close the thumb valve and squeeze the bulb, inflating the cuff at a rapid but smooth and continuous rate to the maximal inflation level. *Note:* Your eyes should be level with the mid-range of the manometer scale and focused on the level to which you will raise the pressure.

• Open the thumb valve very slightly and maintain a constant rate of deflation at no more than 2 to 3 mm per second, allowing the cuff to deflate. Listen throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the first regular sound is heard) until 10 mm Hg below the level of the diastolic reading (i.e., 10 mm Hg below the level where you hear the <u>last</u> regular sound).

The systolic value (Phase I) is the pressure at which you hear the first of two or more knocking sounds in appropriate rhythm. The diastolic sound (Phase V) is the pressure at which you hear the <u>last</u> muffled sound.

- Deflate the cuff fully by separating the tubing and remove the stethoscope earpieces.
- Record the systolic and diastolic values in the spaces provided on the form.

5.5 Criteria for systolic and diastolic blood pressure

Automated Oscillometric Device

The monitor immediately begins a stepped deflation sequence that first determines systole, then mean arterial pressure, then diastole. The transducer measures minute pressure oscillations within the cuff. The monitor deflates the cuff one step each time it detects two pulsations of relatively equal amplitude. Time between deflation steps is dependent on the frequency of these matched pulses, or 1.6 seconds, whichever is less.

Conventional sphygmomanometer

To correctly identify systolic (Phase I) and diastolic (Phase V) Korotkoff values, listen carefully via the stethoscope while reading and interpreting the dial reading.

- The systolic value is the pressure level at which you hear the first of two or more knocking sounds in the appropriate rhythm. *Note:* A single sound heard in isolation (i.e., not in rhythmic sequence) before the first of the rhythmic sounds (systolic) does not alter the interpretation of blood pressure.
- The diastolic value can be identified as the pressure level at which you hear the <u>last</u> of these rhythmic sounds (usually muffled).
- Make the needle on the dial drop at 2 to 3 mm Hg per second, from the maximum inflation pressure until 10 mm Hg below that of the last regular sound heard. <u>The control of the deflation rate at 2 to 3 mm Hg per second is essential for accurate readings</u> and depends on the handling of the control valve.

5.6 Guidelines for blood pressure readings

Automated oscillometric device

• Record the systolic and diastolic readings as they appear on the digital display.

Conventional sphygmomanometer:

- Record all readings to the nearest even digit, rounding up (i.e., read any value that appears to fall exactly between the markings on the dial to the next higher even marking).
- When the pressure is released too quickly from a high level, it cannot be read accurately. Allow a few moments for it to reappear before reading the manometer or doing a repeat measurement.
- Repeat the MIL whenever a systolic blood pressure reading is less than 10 mm Hg from the MIL, or if sounds are heard immediately.
- If a measurement was interrupted, repeat the MIL only if the cuff was removed or more than 5 minutes has lapsed between the MIL and the blood pressure reading.
- If the blood pressure sounds are not heard during the first measurement, review your technique, check stethoscope position for loose connections or tubing kinks, and maintain a quiet environment. Relocate the brachial pulse and apply the stethoscope bell directly over the pulse point. Take care to wait at least 30 seconds between measurements, and elevate the participant's arm for 5 seconds to relieve any blood pooling.

6. Seated blood pressure alert values/Follow-up/Reporting to participants

Below the participant's actual systolic and diastolic blood pressure results that will be written on the Participant Results Report are listed three main categories of blood pressure results:

	Systolic		Diastolic
Normal:	Less than 120	and	less than 80 mm Hg
Prehypertension:	120-139	or	80-89 mm Hg
Hypertension:	140 and above	or	90 and above mm Hg

Also, based on the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure guidelines, there are five categories to check on the blood pressure portion of the Participant Results Report:

• If the participant's systolic blood pressure is normal, i.e., <120 systolic, and < 80 diastolic or prehypertension, 120-139 systolic, or 80-89 diastolic, check "Have your blood pressure checked within 1 year" on the Participant Results Report. Suggest to the

participant that they have their blood pressure checked by their primary care provider within 1 year.

- If the participant's systolic blood pressure is 140 to 159, <u>or</u> their diastolic blood pressure is 90 to 99, check the box on the Participant Results Report that says "Have your blood pressure rechecked by your doctor within 2 months." Suggest to the participant that they have their blood pressure rechecked by their primary care provider within 2 months.
- If the participant's systolic blood pressure is 160 to 179, <u>or</u> their diastolic blood pressure is 100 to 109, check the box on the Participant Results Report that says "See your doctor about your blood pressure in 1 month." Suggest to the participant that they see their primary care provider within one month.
- If the participant's systolic blood pressure is 180 to 209, <u>or</u> their diastolic blood pressure is 110 to 119, check the box on the Participant Results Report that says "See your doctor about your blood pressure in 1 week." Suggest to the participant that they see their primary care provider about their blood pressure within one week.
- If the participant's systolic blood pressure is ≥ 210, <u>or</u> their diastolic blood pressure is ≥ 120, check the box on the Participant Results Report that says "See your doctor about your blood pressure immediately." Instruct the participant to contact their primary care provider about their blood pressure immediately.

Instruct the participant to talk with their primary care provider about any specific questions that they may have about their blood pressure.

7. Quality assurance

7.1 Training requirements

Clinical experience with blood pressure measurement is required. In addition, training should include:

- Read and study manual
- Attend MOST training session on techniques (or observe administration by experienced examiner)
- Practice on other staff or volunteers
- Discuss problems and questions with local expert or QC officer

7.2 Certification requirements

- Complete training requirements
- Explain and demonstrate daily and monthly checks of Dinamap device and sphygmomanometer
- Explain procedure if measurement is interrupted
- Performs exam according to protocol as demonstrated on completed QC checklist
- Three readings of systolic and diastolic measurements recorded by the staff member agree with those of the QC officer within 4 mm Hg, with the average of the three readings within 3 mm Hg.

7.3 Quality assurance checklist

- Explains procedure
- \Box Measures for cuff size
- □ Wraps cuff snugly, centering bladder over brachial artery
- Five minute rest period before measurement
- Palpates radial artery (or brachial, if radial pulse is difficult to palpate)

[conventional sphygmomanometer only:

- Determines maximal inflation level using sphygmomanometer
- ☐ Inflates rapidly to maximal inflation level
- □ Places bell on brachial pulse
- Deflates cuff 2 to 3 mm Hg per second]

[Dinamap only:

- Selects the Manual Blood Pressure mode from the main menu on the Dinamap monitor
- Records the systolic and diastolic readings as they appear on the digital display]
- Records reading and disconnects tubes
- \Box Reviews forms for completeness
- Correctly completes forms
- Tells participant BP reading and refers to primary care physician as indicated
- Writes blood pressure reading on Participant Results Report

Acknowledgments:

Women's Health Initiative Operations Manual. Volume 2, Section 9.2: Blood Pressure. 8/30/95. WHAS Operations Manual. Section 3.5 Blood Pressure Measurements. 6/18/93.

8. Data collection form

	47970	Visit MOST ID #		Acrostic		
		O 60-month O 84-month				MOST
0	od Pressure					
	What cuff size w	as used?				
	⊖ Small	O F	Regular	⊖ Large	01	「high
	What arm was us (Examiner Not e		blood pressure?	e are contraindica	tions.)	
	⊖ Right	οL	.eft			
	Maximal Inflation (MIL) Was blood pressu		30 *	* Add 30 to Palp to obtain Maxim ** If MIL is ≥ 300 MIL is still ≥ 300 pressure measu	al Inflation Le mm Hg, repe mm Hg, term rement.	evel. eat the MIL. If ninate blood
	O Yes	01			init ig allor of	soona roading.
j.		stolic	mm Hg			
re	nminer Note: If the ater than 109 mm ength - sEMG data	Hg (diastolic)), mark "Yes" on F	greater than 199 Page 39, Question	mm Hg (syste #1 of the Isol	olic) or kinetic
			◆Page 32•	•		47970
	_				MOST Follow-up	47970