Guidelines for the validation of home blood pressure measurement devices

General notes

- Because of environmental concerns of the toxicity of mercury, mercury sphygmomanometers are gradually being phased out in many clinical centres in Australia. The accuracy of other available devices is dependent on the product chosen. Several devices have been validated and recommended for clinical use by the British Hypertension Society (www.bhsoc.org/blood_pressure_list.stm). Mercury sphygmomanometers should be calibrated at least once a year. If another form of sphygmomanometer is used in a clinic, it should be validated regularly against a mercury sphygmomanometer to make sure it is accurate.

- The Heart Foundation recommends that home blood pressure devices (HBPD) are checked every six months to monitor and maintain their accuracy.

- Correct storage will prolong the life of the HBPD. This includes:
  - keeping it out of direct sunlight to protect its rubber tubing
  - storing it in a box with a lid or in a drawer to protect it from dust
  - storing it in a dry place
  - cleaning its cuff as necessary.

- When possible, validation of the patient’s HBPD against a mercury sphygmomanometer should be done using the ‘simultaneous same arm approach’.
  - A mercury column is connected by a ‘Y’ connector to the cuff tubing of the HBPD.
  - A stethoscope is applied over the brachial artery allowing an observer to take a mercury reading, at the same time and on the same arm that the digital or aneroid HBPD takes its measurement. The two measurements are then compared. The average difference after several measurements should be less than 4 mmHg.

- More specific advice for checking specific components of digital and aneroid HBPDs is given below.

Digital devices

Note: There are many brands and models of digital HBPDs on the market. Therefore it may be necessary to adapt one or more of the steps below to validate the device.

- Turn on the HBPD. The device should register ‘zero’. If this does not happen, the device will need to be serviced by the manufacturer.

- Where possible, the HBPD air valve should be adjusted to obtain the optimal deflation rate of no more than 2–3 mmHg per beat. If the deflation rate exceeds 3 mmHg per beat and access to the air valve is not possible, the device will need to be serviced by the manufacturer.
Step 1. Check inflation readings
Check the digital HBPD using the one length of rubber tubing and ‘Y’ connector.

- Remove the HBPD air plug from the device and then from the cuff.
- Attach the HBPD air plug to the length of rubber tubing and plug into the HBPD. Attach the free end of tubing to the ‘Y’ connector.
- Wrap the cuff around the stand of the mercury sphygmomanometer or suitable item of arm size and attach to the ‘Y’ connector.
- Attach the ‘Y’ connector to the mercury column’s rubber tubing.
- Inflating a number of times to verify and confirm HBPD readings against those of the mercury column. Observe smooth deflation of air.
- Some digital devices will have various settings for inflation levels. Validate all inflation levels.

Step 2. For digital HBPDs that have a bulb attachment
- Remove the bulb and replace with the mercury sphygmomanometer bulb. Inflation readings can now be assessed because the air valve can be closed.
- Inflate to various levels to verify and confirm HBPD readings against those of the mercury sphygmomanometer.
- Replace the mercury sphygmomanometer bulb with the HBPD bulb and repeat inflation test several times.
- Check the HBPD bulb for obvious signs of wear and tear and replace as necessary.

Step 3. Cuff and bladder
The cuff can be checked using Step 3 from the ‘Aneroid devices’ section below.

Aneroid devices
The Heart Foundation recommends that the various components of the aneroid device be assessed for accuracy and performance (gauge, bulb and air valve, cuff and bladder and stethoscope).

Step 1. Gauge
- Remove the gauge from the HBPD.
- Attach two lengths of rubber tubing to the ‘Y’ connector. Then attach the ‘Y’ connector to the rubber tubing of the mercury column. Attach the bulb from the mercury sphygmomanometer to one length of rubber tubing, and connect the gauge to the other.
- Inflating the gauge to 300 mmHg on the mercury column.
- Deflate, stopping at intervals of no more than 30 mmHg to verify readings.
- Inflate and deflate a number of times to various levels to confirm the HBPD readings against the mercury column. The readings should be within 3 mmHg. Gauges registering a difference of more than 3 mmHg should be repaired or replaced.
- The gauge needle at the start and end of inflation/deflation should be pointing towards the ‘zero’. When deflating, the needle of the gauge should move downwards with a smooth rhythm. If the needle does not point to zero and/or the needle does not have a smooth downward rhythm, the gauge should be repaired or replaced.

Step 2. Bulb and air valve
The HBPD bulb can be checked using the procedure described in Step 1 above after removing the sphygmomanometer bulb and attaching the HBPD bulb.
- The air valve, situated at the end of the bulb, should allow free movement of air in and out for inflation and deflation. Check to see if the air valve has become clogged or blocked and replace the bulb if necessary.
- No air loss should be noticeable on the gauge of the HBPD or on the mercury column. Inability to hold the rate of deflation at 1 mmHg per second or less may indicate a faulty valve. Replace the air valve if necessary.
- The air-release valve screw should feel free of movement upon opening of the valve and should rotate freely. Replace the air valve if necessary.
Step 3. Cuff and bladder

- The cuff can be wrapped around the stand of the sphygmomanometer or suitable item of arm size. Inflate the cuff up to 300 mmHg a number of times. When the cuff is inflated and the air valve is closed, no air should escape. If a ‘hissing’ sound is heard, check for cracks in the rubber tubing where it is attached to the bulb and gauge. Air leaks often occur here. Cut away a small section (approx 0.5 cm) at the end of the rubber tubing with a sharp pair of scissors. Re-attach the bulb and/or the gauge. Recheck.

- If air is escaping with no obvious signs of an air leak, it may be necessary to remove the bladder from inside the cuff and immerse the bladder in a sink or bucket of water. Inflate the bladder and look for any air bubbles rising from the water. Should this occur replace the bladder. Some new models of cuff have an attached bladder that cannot be removed. Replace as necessary.

Step 4. Stethoscope

Clean the stethoscope every six months or as necessary.

- Unscrew the plastic ear pieces, wash in warm soapy water (keep plug in sink during this procedure) and dry.

- Remove tubing from metal attachment. Blow through the metal head attachment and the tubing to check for blockages.

- Check the diaphragm of the stethoscope for signs of wear and tear. Replace as necessary.

- Put the stethoscope back together and put the ear pieces in your ears. Gently tap diaphragm and listen for resonating sounds.

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