

VALIDATED BLOOD PRESSURE DEVICE PROCUREMENT POLICY & PROCEDURE TEMPLATE

Intended uses: Health care organizations and employers are encouraged to use this model policy developed by the American Heart Association (AHA) and American Medical Association (AMA)

Implementation guidance

1. Explore existing procurement options available to the organization including contracted medical supply vendors and distributors, and group purchasing organization arrangements.
 2. Explore distribution options with vendors including direct to patient delivery, durable medical supply, pharmacy partners, or storage and inventory management within the organization
 3. Some vendors provide drop shipping directly to patients to minimize the facility storage and time/expenses associated with distribution by ambulatory care offices and staff
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PURPOSE: Policy Objectives

1. Create a systematic approach for using institutional resources in alignment with current clinical guidelines
2. Ensure equal and equitable patient access to high quality devices and avoid the potential for creating tiered or disparate access to validated devices through a supportive and inclusive structural policy

CONTEXT: Underlying Evidence & Principles

3. Nearly half of Americans have high blood pressure (BP) and many do not know it. Among U.S. adults with hypertension, fewer than half have their BP controlled, a trend that is worsening.
4. Accurate BP measurement is essential to correctly categorize the level of BP for diagnosis, assessing CVD risk, and appropriately managing BP.
 - “Underestimating SBP by 10 mmHg is estimated to result in 10-40% increase in fatal myocardial infarctions and strokes^{i, ii}; overestimation by 5 mmHg would unnecessarily increase treatment intensity in 30 million people.ⁱⁱⁱ”
5. Validated (and regularly calibrated) blood pressure devices for clinical/institutional and personal/home use are an essential element of accurate measurement for diagnosis and treatment.
 - “The use of non-validated and infrequently calibrated BP monitors, inadequate staff training, and/or lack of a standardized measurement protocol can result in a misleading estimation of an individual’s true level of BP.”
 - Validated devices intended for in office, home, and community settings are currently listed on the U S Blood Pressure Validated Device Listing (VDL™) accessible at validateBP.org.
6. Ensuring equitable access to validated devices is essential to providing equitable care and achieving equitable outcomes.

- All clinics, employers, and health plans engaged in the care of patients with hypertension should use validated devices to ensure the best quality of care.
- All patients with hypertension who engage in self-measurement should have access to validated BP devices, regardless of insurance status.
- All health systems that support clinical diagnosis and management of BP with validated devices ensure that individuals have the resources needed to utilize the BP device and share the information with the clinical team.

Policy

1. Organizational **resources** will only be used for validated blood pressure (BP) measurement devices. Resources include but not limited to:
 - a. Directed budget operating or capital expenses for medical supply or device procurement.
 - b. Grant funds received from an external entity that may be allocated to medical supply or device procurement.
 - c. Sponsorship funds received from an external entity that may be used for medical supply or device procurement.
 - d. Grant funds provided by the organization and awarded to an external entity that may be allocated to medical supply or device procurement.
 - e. In-kind gifts provided by the organization to patients, professionals, or organizations of validated BP devices.
 - f. In-kind gifts received from an external entity including sample, demo model, or overstock BP devices
 - g. Community benefit dollars for validated device procurement and/or development of community-based initiatives to provide training in device use in communicating results with clinical teams.
2. Organizational resources will only be used for validated blood pressure devices including but not limited to the **following purposes**:
 - a. Ambulatory clinical practice
 - b. Internal or external blood pressure measurement training and demonstration activities
 - c. Blood pressure screening events
 - d. Blood pressure device loaner programs
 - e. Research and practice grant activities
 - f. Blood pressure device gifts, donations, or grants to patients, health care professionals, or other health care or community organizations
 - g. Employee workplace blood pressure stations (i.e. kiosks)
 - h. Employee benefits coverage

Procedure

1. When purchasing any blood pressure device, follow bidding procedures (consistent with existing procurement policies) for validated devices meeting the needed specifications.

- a. Consider needed cuff sizes as part of the bid specifications, noting that not all validated devices have been tested for clinical accuracy with all of the cuff sizes available with a particular model (refer to the VDL™ accessible at validateBP.org).
2. Ensure that device distribution is coupled with a plan for:
 - a. In-clinic use: Healthcare professionals training resources for proper measurement technique and calibration.
 - b. In-home use: Patient education resources for proper measurement, recording, calibration, plan for relay of information to provider.
 - c. Appropriate cuff sizing with the patient.

References

ⁱ Piper MA, Evans CV, Burda BU, *et al.* Diagnostic and predictive accuracy of blood pressure screening methods with consideration of rescreening intervals: a systematic review for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2015; 162:192-204.

ⁱⁱ Bundy JD, Li C, Stuchlik P, *et al.* Systolic blood pressure reduction and risk of cardiovascular disease and mortality: a systematic review and network meta-analysis. *JAMA Cardiol.* 2017; 2:775-81(Suppl).

ⁱⁱⁱ Jones DW, Appel LJ, Sheps SG, *et al.* Measuring blood pressure accurately: new and persistent challenges. *JAMA.* 2003;289(8):1027–1030. doi:10.1001/jama.289.8.1027.