Recommendations from the HEARTS in the Americas Workshop on Regulatory Frameworks and Procurement of Blood Pressure Measuring Devices for Use in Primary Health Care

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Objective

To ensure that validated automated blood pressure measuring devices are widely available and affordable to support the implementation of HEARTS in the Americas and improve hypertension control in the Region of the Americas.

Focus

The recommendations emerging from this workshop focus on inaccuracies of aneroid blood pressure measuring devices and the need to use accurate validated automated electronic monitors. This position is consistent with the HEARTS Module *Access to Essential Medicines and Technology* (page 37, Table 7), which indicates that validated automated electronic devices are preferred, and with the Lancet Commission on Hypertension (Sharman J et al., 2020).

Background

Increased blood pressure is the leading risk for death in the Americas [1] according to the Global Burden of Disease Study (GBD). Approximately 1 in 4 adults has high blood pressure or hypertension (defined as ≥ 140/90 mm Hg) including 40% of those over 25 years of age. About half of ischemic heart disease, heart failure and strokes are caused by hypertension, which is also a major risk for kidney failure and dementia. More than 4 in 10 deaths in people with diabetes are related to hypertension, which is also the leading risk for maternal and fetal death.

Preventing strokes and heart disease by lowering blood pressure with antihypertensive drugs is a very effective intervention. Critical components of hypertension control include: 1) assessing the blood pressure of all adults at risk, 2) diagnosing hypertension in those who screen high, 3) controlling hypertension with a combination of lifestyle modification and two or more drugs and, 4) closely monitoring the performance of the program, clinics and health care providers.

Measuring blood pressure is likely the most common clinical test and doing it accurately is critical to the management of hypertension. Common inaccuracies can misclassify a very high proportion of people as having a high or normal reading. A consistent small (2-3 mm Hg) error in assessing diastolic blood pressure can impact the proportion of people perceived to have hypertension by 17-30%. Despite its importance, blood pressure is rarely accurately assessed in clinical practice. Error in measuring blood pressure as high as 10 mmHg is not uncommon and can impact the diagnosis of a person as hypertensive or not in half of adults.

Mercury devices were the old standard for blood pressure measurement but are being phased out due to environmental concerns related to mercury toxicity. Aneroid devices are commonly used in clinical practice in most countries in the Region but lose accuracy over time and require 3-6 monthly accuracy assessments and calibration which rarely occur. Further, they require significant skill, good hearing, training and regular retraining. Few health care professionals are adequately trained and rarely retrained in the use of aneroid devices. Hence repeated surveys confirm widespread inaccuracies in blood pressure measurement using these devices. These factors have led to calls to abandon their use.

[1] For ranking of your country, contact Dr Norm Campbell at ncampbel@ucalgary.ca.

Since 2003, replacing aneroid devices with **automated electronic devices** has been recommended, as the latter:

- maintain their accuracy to a much greater extent,
- require considerably less skill and little training, and
- are much easier to use in clinical practice.

To ensure that these devices are accurate and precise, protocolized standards for assessing accuracy and precision, known as validation standards, have been developed. These protocols refer to rigorous procedures to test a device on a sample of individuals, and determine the mean difference between the device being tested and a control standard. To obtain the control standard BP, a blinded two-observer auscultation must be performed (Padwal et al., 2019). The tests must be conducted by independent investigators and the results published in peer-reviewed scientific journals.
must

The most recent international protocol (ISO 81060-2 2018) was agreed on by the American Association for Medical Instrumentation (AAMI), European Hypertension Society (ESH) and International Organization for Standardization (ISO) representatives as the basis for a single universal validation protocol and been published by ISO in 2018 (with a cuff amendment published in 2019). This standard consolidates all the available evidence and is intended to replace previous protocols. As it was only recently published, most electronic devices available in the market have not yet been tested using this standard. Some of those which have been tested, have failed to meet the accuracy standard.

Recommendations

It is recommended that countries:

1. Develop and implement policies and regulations to facilitate universal access to validated electronic devices, including marketing, labeling and procurement of electronic BPMDs that have met an international validation standard; and

2. Manifest their interest in using the PAHO Strategic Fund mechanisms for the procurement of these devices to lower costs, guarantee quality and increase the feasibility that blood pressure will be measured using validated electronic devices in the Region.

Recommended validated electronic devices are those that:

1. Have been validated using the ISO 81060-2 2018 protocol and 2019 cuff amendment (1:2019-09-12); or

2. Have been validated using an older protocol: a) 2013 American Association for Medical Instrumentation (AAMI); b) 2010 European Hypertension Society (ESH), or c) 1993 British Hypertension Society (BHS). This allows time for manufacturers to validate their devices using the ISO 2018 standard. It is further recommended that this allowance, as in recommendation (2), be discontinued by January 2022, and that from that point forward, only devices validated with ISO 2018 be accepted.

References

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Supplemental Reading

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