Global marketing and sale of accurate cuff blood pressure measurement devices

Running title: Accurate cuff blood pressure devices

James E. Sharman PhD,[1] Raj Padwal MD, PhD,[2] Norm R.C. Campbell MD.[3]

Affiliations
[1]Menzies Institute for Medical Research, University of Tasmania, Hobart, Australia.
[2]Department of Medicine, University of Alberta, Edmonton, Alberta, Canada.
[3]Department of Medicine, Physiology and Pharmacology and Community Health Sciences, O'Brien Institute for Public Health and Libin Cardiovascular Institute of Alberta, University of Calgary, Calgary, Alberta, Canada.

Keywords: Blood Pressure Monitors; Diagnostic Equipment; Standards; Cardiovascular Disease.

Hypertension is the leading single risk factor for cardiovascular disease, stroke and death worldwide. Accurate measurement of blood pressure (BP) is one of the most important of all medical tests, yet there is global marketing and sale of BP measurement devices (BPMDs) for home or clinical use that have not undergone rigorous accuracy (validation) testing. A key factor underlying this problem is that many regulatory authorities do not require manufacturers to conduct validation testing according to standardized international protocols. This means that manufacturers can obtain approval for the sale of BPMDs even though they have only conducted 'in house' testing, using variable and undisclosed methods to assess and report the accuracy of BPMDs. There is also no requirement that results of the internal company testing be made publicly available. Many other validation study 'loopholes' exist that altogether create a clear commercial conflict of interest that raises meaningful concerns over the quality of BPMD validation results that are provided to regulatory authorities.[1]

It is perhaps not surprising then, that some BPMDs cleared for sale by regulatory authorities do not pass accuracy testing when assessed by parties independent from the manufacturer using rigorous standardized international protocols. In one study that evaluated accuracy among 74 automated BPMDs used by people in the community for home BP monitoring, only 15% of non-validated BPMDs were found to be within 4 mmHg of simultaneously measured mercury auscultation compared with 68% among the more rigorously validated BPMDs.[2] It is hard to predict whether a BPMD will over- or under-estimate BP as compared with mercury auscultation as the measurement standard, and a systolic BP error magnitude greater than 10 mmHg is not uncommon. This is a serious clinical concern potentially contributing to inappropriate medical care, either through unnecessarily prescribed medication in response to falsely high BP results or failure to recognize and treat high BP in the setting of falsely low BP results. Widespread commercial availability of non-validated BPMDs with inherent inaccuracy of measurements could undermine efforts to reduce the global burden from cardiovascular disease.[1]

Hypertension guidelines and professional associations worldwide have repeatedly emphasized that home BP monitoring must only be undertaken using BPMDs that have passed accepted national or international validation protocols.[3] Recommendations to exclude manufacturer personnel from involvement in analysis or publication of validation studies have also been made. Yet, this above advice has failed to prompt remediating action, and we now

have a situation whereby more than 3300 BPMDs worldwide are currently marketed (by 450+ companies), but less than 15% of these BPMDs have undergone independent validation testing. A recent market scan of BPMDs available for online purchase in Australia showed that only 18.3% of upper arm cuff BPMDs had passed international validation protocols. More concerningly, only 5.5% of all BPMDs sold by major international e-commerce enterprises were rigorously validated. This study also identified a large and emerging online presence of cuff-less wrist-band BP devices for sale, none of which is validated.[4] The extent to which patients may be using these wrist-band type BPMDs are not known, but represents yet another potential adverse influence on best-practice care related to hypertension. Unaware of the problems, even consumer advocacy agencies recommend purchase of non-validated BP devices.

Oscillometric BPMDs generally estimate mean arterial pressure and employ a propriety algorithm to estimate systolic and diastolic BP that may or may not be extrapolatable to diverse populations with different ages, body mass index, and various co-morbidities. Several BP-related organizations have made repeated calls for action related to these issues, including better identification of appropriately validated BPMDs. This has led to the development of several region-specific validated device listings that people can access online, including the U.S.-based BPMDs endorsed by the American Medical Association (Table 1). Clinicians and patients can search for validation information on BPMDs on the weblinks relevant to their geographic region. Attention should be paid not only to the specific BPMD manufacturer but also to the specific device model, as each model from a single company may not achieve the same ratings. Users will note variability in the quality of search engines, as well as some discrepancy in recommendations provided between different listings, which can create confusion. This is due to subtle variations in the criteria used among organizations to denote acceptable validation, and emphasizes the need for one universally accredited list of BPMDs, a recommendation of the Lancet Commission on Hypertension Group.[1] This group has also developed a practical guide for consumers to identify BPMD validation credentials (Table 1).

Moving forward, we believe that independent validation testing should be conducted for all marketed BPMDs.[1] Rigorous validation process should be performed according to the International Organization for Standardization (ISO) 81060-2:2018 protocol[5], which was developed by experts from the US Association for Advancement of Medical Instrumentation, as well as the European Society of Hypertension. The proof of compliance should be made publicly

available, preferably by publication in the peer-reviewed literature. The ISO protocol has major similarities to most previous protocols, which all fulfil the mutual aim of establishing the minimum accuracy standards for BPMDs.[5] The ISO protocol requires a minimum sample size of 85 participants and a minimum of 255 valid pairs of measurements recorded simultaneously by two observers who have been trained in proper methodology using a double stethoscope (deflation rate 2 – 3 mmHg/s). Our recommendation for independent validation testing before BPMDs are marketed and sold is relevant to all consumers of BP devices, from individuals seeking to self-measure BP at home,[3] to retailers, health care providers, government and non-government organizations alike. We invite all interested stakeholders to support us in this call to action and advocate for the marketing and sale of BPMDs restricted to those that have been independently validated as a fundamental prerequisite to improving global BP control. Efforts are also needed to disseminate this information to healthcare providers and general public to promote an uptake in the use of validated BPMDs.

Conflict of interest disclosures

Dr Sharman's university has received equipment and research funding from manufacturers of BP devices but he has no personal commercial interests related to BP companies.

Dr Padwal is the Canadian representative to the ISO Sphygmomanometer committee and sits on the AAMI Sphygmomanometer committee. He is co-founder of a digital health company (mmHg Inc.), based at the University of Alberta creating software innovations in BP measurement.

Dr Campbell was a paid consultant to the Novartis Foundation (2016–2017) to support their programme to improve hypertension control in low-to-middle income countries which includes travel support for site visits and a contract to develop a survey. He has provided paid consultative advice on accurate BP assessment to Midway Corporation (2017) and is an unpaid member of World Action on Salt and Health (WASH).

Acknowledgements

The following people provided support to the authors as part of collaborations to improve the global availability of accurate cuff blood pressure measurement devices: Michael Hecht-Olsen, Aletta E. Schutte, Christian Delles, Vivekanand Jha, Reinhold Kreutz, Andrew E. Moran, Marcelo Orias, C Venkata S Ram, Robert A. Harrington, Karen Sliwa and Xin-Hua Zhang.

References

1. Sharman JE, O'Brien E, Alpert B, et al. Lancet Commission on Hypertension Group Position Statement on the Global Improvement of Accuracy Standards for Devices That Measure Blood Pressure. *Journal of Hypertension*. 2020;38:21-29.
2. Akpolat T, Dilek M, Aydogdu T, et al. Home Sphygmomanometers: Validation Versus Accuracy. *Blood Pressure Monitoring*. 2009;14:26-31.
3. Shimbo D, Artinian NT, Basile JN, et al. Self-Measured Blood Pressure Monitoring at Home: A Joint Policy Statement from the American Heart Association and American Medical Association. *Circulation*. 2020;141 Epub Ahead of Print.
4. Picone DS, Deshpande R, Schultz MG, et al. Non-Validated Home Blood Pressure Devices Dominate the Online Marketplace in Australia: Major Implications for Cardiovascular Risk Management. *Hypertension*. 2020;75:1593-1599.
5. Stergiou GS, Alpert B, Mieke S, et al. A Universal Standard for the Validation of Blood Pressure Measuring Devices: Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (Aami/Esh/Iso) Collaboration Statement. *Hypertension*. 2018;71:368-374.

Formatted: Font color: Red

Table 1. Weblinks to listings of blood pressure devices that have been independently assessed for accuracy according to scientific validation protocols

Society, organisation or company	Weblink
American Medical Association	~~www.~~validatebp.org
British and Irish Hypertension Society	https://bihsoc.org/bp-monitors/
dabl Educational Trust (no longer actively updated)	http://www.dableducational.org/
German Hypertension Society (in German)	https://www.hochdruckliga.de/messgeraete-mit-pruefsiegel.html
Hypertension Canada	https://hypertension.ca/hypertension-and-you/managing-hypertension/measuring-blood-pressure/devices/
Japanese Society of Hypertension (in Japanese)	http://www.jpnsh.jp/com_ac_wg1.html
Medaval ~~(for profit)~~	https://medaval.ie/
STRIDE BP (European based)	https://stridebp.org/

A consumer guide to using these resources can be found at:
https://www.menzies.utas.edu.au/documents/pdfs/Blood-pressure-devices.pdf

~~Note: For profit companies may be subject to conflict of interest.~~

Field Code Changed