Check for updates

EDITORIAL

Journal of Human Hypertension special issue on the accuracy of automated blood pressure measuring devices

About one-third of adults have hypertension, which is the leading risk factor for global death and disability from cardiovascular disease, and estimated to account for about 10% of global health care spending [1]. To correctly diagnose hypertension and enable opportunity to deliver best-practice medical care, it is essential that blood pressure (BP) is measured accurately and error is minimized by using a standardized technique with a BP measuring device (BPMD) that has proven accuracy by having passed clinical validation testing [2]. In recent years we have learned that around 75–80% of automated BPMDs marketed globally do not have evidence of having undergone validation testing [3]. The accuracy of these devices cannot be assured, and this debility can undermine correct hypertension diagnosis and medical management, to the obvious disadvantage of individuals and society.

Efforts to redress this problem and to increase the global availability of accurate BPMDs have been initiated [4], and this special issue is part of this endeavor, which is supported by the World Hypertension League, The Lancet Commission on Hypertension Group and other organizations. A series of targeted papers to provide information and resources were led and reviewed by an international Guest Editor team of experts comprising Associate Professor Tammy Brady, Dr Pedro Ordunez, Professors Gianfranco Parati, George Stergiou, Paul Whelton and Norm Campbell. Author teams were also invited to contribute on their areas of expertise, with key components drawn from their articles to form the rationale of a policy statement and call to action. Three original articles relevant to the topic were also included in this special issue.

To many people, the method to measure cuff BP with an automated device remains a "black box" mystery as to how they work. The first paper in the series sought to provide a guide for resolving this mystery by explaining what are automated BPMDs, how they work and what they measure [5]. This article also sets the scene with brief historical background, and details the accuracy performance of automated BPMDs compared with manual auscultatory sphygmomanometers, as well as the basic principles of operation, which have remained largely unchanged in over 50 years.

Before being cleared for sale and used in clinical practice, each automated BPMD should pass rigorous accuracy testing using an accepted validation Standard. This complex field is distilled and clarified in the next article by renowned experts in conducting validation studies, Associate Professor Jennifer Ringrose and Professor Raj Padwal [6]. They offer comprehensive practical guidance on how to perform clinical validation studies and this article is a must-read for anyone considering this venture. The article also introduces the rationale and need for global use of one "Universal" validation Standard (International Organization for Standardization. ISO 81060-2:2018) [7], a critical point toward helping to achieve improved accuracy of automated BPMDs that is repeatedly interwoven throughout the special issue.

The next article turns attention toward helping health professionals and consumers understand how to find and use validated BPMDs through trustworthy online resources [8]. Unfortunately, this is not as straightforward as it should be because the online global marketplace is replete with automated BPMDs that have not been clinically validated and are more likely to produce inaccurate BP readings [3]. Currently, it is difficult to find information on validation status of automated BPMDs, and in any case it is not an issue people may be aware of, with many being surprised to learn that most devices lack robust accuracy testing [9]. Readers of this article [8] are directed toward validated device listings, including STRIDE BP (https://www.stridebp.org), led by Professors Stergiou and Parati, endorsed by the International Society of Hypertension, and providing highest quality, scientific advice to improve the accuracy of BP measurement.

The potential adverse public health impact and individual clinical consequences of having non-validated automated BPMDs infused into global systems of healthcare is illustrated in the next article by Whelton et al. [10]. Even small errors in over- or under-estimation of true BP can lead to misclassification of hypertension and incorrect medical care for individuals, but also markedly influence hypertension prevalence statistics at the population level, thus potentially misinforming public health policy. Remediating actions are provided as recommendations to all key stakeholders, from manufacturers and professional societies to governments and regulatory authorities [10].

The next two papers detail the extraordinary efforts and strategies led by Dr Pedro Ordunez et al. to promote exclusive use of validated automated BPMDs throughout the region of the Americas [11, 12]. This global exemplar of widescale translation of research knowledge is being undertaken via the HEARTS in the Americas initiative of the Pan American Health Organization to deliver best-practice cardiovascular management in primary health care (directed by the Ministries of Health of participating countries). Since 2019, a host of strategies have been adopted, and include better understanding of the regulatory frameworks governing automated BPMDs in different countries (and advocating for regulatory change) [13], raising awareness and providing information to policy makers, supporting training on how to conduct validation studies, and developing mechanisms for pooled procurement of validated BPMDs, to name but a few. The term "validated" is now part of the HEARTS glossary of terms associated with automated BPMDs, and HEARTS is currently implemented in 26 countries of the Americas, including 2117 health care centers delivering to ~20 million adults in the region.

The special issue then turns towards understanding the views about automated BPMD accuracy and validation from the manufacturers who supply devices to the world [14]. For this,

92

representatives of reputable automated BPMD manufacturers were invited to provide industry perspectives, which are clearly important but have been absent in published communications to date. In the article, led by Jim Li and Gerhard Frick, they broadly echo the recommendations proposed by non-industry scientific bodies, and support the notion that rigorous proof of validation should be a precondition of regulatory approval for automated BPMDs, and that the "Universal" ISO Standard should be used in all future validation studies, among many other interesting insights. The highly-informed and collegial opinions of the industry author team give assurance that automated BPMD manufacturers are essential stakeholders in the way forward towards ensuring wider availability and clinical use of properly validated BPMDs.

The next three original articles in the issue call further attention to various aspects of BP measurement accuracy [15–17]. Of note, are the findings of Peprah et al. [17] who undertook validation testing of five automated BPMDs according to the protocol of the "Universal" ISO Standard [7]. Three of the BPMDs tested were sold for home BP monitoring by large retail vendors in the United States, but for which there was no evidence of having been accuracy tested. Critically, none of these devices passed the accepted accuracy criteria required by the ISO Standard, thus typifying the urgency to better regulate validation of automated BPMDs.

The above sentiment is expressed alongside recommended actions in the final article of the special issue as a policy statement and call to action, endorsed by the World Hypertension League as well as multiple international societies and organizations concerned with improved BP measurement accuracy and better hypertension control [18]. The time for direct action towards achieving these objectives is well overdue, and the policy statement was designed to assist as a resource for taking to relevant stakeholders (e.g., regulatory agencies, government and Ministries of Health) to address the identified needs and rapidly ensure that only properly validated automated BPMDs are available and used in clinical practice. The editorial team and authors that contributed to this special issue encourage colleagues, friends and community around the world to use the policy statement to aid improved cardiovascular health outcomes.

James E. Sharman[1✉]
[1]*Menzies Institute for Medical Research, University of Tasmania, Hobart, TAS, Australia.* ✉email: James.Sharman@utas.edu.au

REFERENCES

1. Campbell NRC, Schutte AE, Varghese CV, Ordunez P, Zhang XH, Khan T, et al. Sao Paulo call to action for the prevention and control of high blood pressure: 2020. J Clin Hypertens. 2019;21:1744–52.
2. Padwal R, Campbell NRC, Schutte AE, Olsen MH, Delles C, Etyang A, et al. Optimizing observer performance of clinic blood pressure measurement: a position statement from the Lancet Commission on Hypertension Group. J Hypertens. 2019;37:1737–45.
3. Picone DS, Campbell NRC, Schutte AE, Olsen MH, Ordunez P, Whelton PK, et al. Validation status of blood pressure measuring devices sold globally. JAMA. 2022;327:680–1.
4. Sharman JE, O'Brien E, Alpert B, Schutte AE, Delles C, Hecht Olsen M, et al. Lancet commission on hypertension group position statement on the global improvement of accuracy standards for devices that measure blood pressure. J Hypertens. 2019;37:21–9.
5. Sharman JE, Tan I, Stergiou GS, Lombardi C, Saladini F, Butlin M, et al. Automated 'oscillometric' blood pressure measuring devices: how they work and what they measure. J Hum Hypertens. 2022. https://doi.org/10.1038/s41371-022-00693-x. Online ahead of print.
6. Ringrose JS, Padwal R. Automated blood pressure measuring devices: how are they clinically validated for accuracy? J Hum Hypertens. 2022. https://doi.org/10.1038/s41371-022-00761-2. Online ahead of print.
7. International Organization for Standardization. ISO 81060-2:2018. Non-invasive sphygmomanometers—part 2: clinical investigation of intermittent automated measurement type. 2018. https://www.iso.org/standard/73339.html.
8. Picone DS, Padwal R, Stergiou GS, Cohen JB, McManus RJ, Eckert S, et al. How to find and use validated blood pressure measuring devices. J Hum Hypertens. 2022. https://doi.org/10.1038/s41371-022-00718-5. Online ahead of print.
9. Picone DS, Peterson GM, Jackson SL, Campbell NRC, Delles C, Olsen MH, et al. Perceptions of pharmacists on the quality of automated blood pressure devices: a national survey. J Hum Hypertens. 2022. https://doi.org/10.1038/s41371-022-00670-4. Online ahead of print.
10. Whelton PK, Picone DS, Padwal R, Campbell NRC, Drawz P, Rakotz MK, et al. Global proliferation and clinical consequences of non-validated automated BP devices. J Hum Hypertens. 2022. https://doi.org/10.1038/s41371-022-00667-z. Online ahead of print.
11. Lombardi C, Picone DS, Sharman JE, Campbell NRC, Farias R, Guerre S, et al. Country experiences on the path to exclusive use of validated automated blood pressure measuring devices within the HEARTS in the Americas Initiative. J Hum Hypertens. 2022. https://doi.org/10.1038/s41371-022-00706-9. Online ahead of print.
12. Ordunez P, Lombardi C, Picone DS, Brady TM, Campbell NRC, Moran AE, et al. HEARTS in the Americas: a global example of using clinically validated automated blood pressure devices in cardiovascular disease prevention and management in primary health care settings. J Hum Hypertens. 2022. https://doi.org/10.1038/s41371-022-00659-z. Online ahead of print.
13. Lombardi C, Sharman JE, Padwal R, Picone D, Alcocea E, Ayala R, et al. Weak and fragmented regulatory frameworks on the accuracy of blood pressure-measuring devices pose a major impediment for the implementation of HEARTS in the Americas. J Clin Hypertens. 2020;22:2184–91.
14. Li J, Frick G, Herberigs K, Matsumura P, Sarkis J, Verberk WJ, et al. Industry perspectives on the global use of validated blood pressure measuring devices. J Hum Hypertens. 2022. https://doi.org/10.1038/s41371-022-00717-6. Online ahead of print.
15. Zilka Darbiani S, Friger M, Barrett O, Basok A, Wolak T. The accuracy of 8-hour ambulatory blood pressure monitoring, adjusted to seasons. J Hum Hypertens. 2022. https://doi.org/10.1038/s41371-022-00790-x. Online ahead of print.
16. McLaurin NN, Wang T, Chen LS, Tanaka H. A new and specific automated blood pressure device for exercise stress testing. J Hum Hypertens. 2022:1–5. https://doi.org/10.1038/s41371-022-00784-9. Online ahead of print.
17. Peprah YA, Lee JY, Persell SD. Validation testing of five home blood pressure monitoring devices for the upper arm according to the ISO 81060-2:2018/AMD 1:2020 protocol. J Hum Hypertens. 2023. https://doi.org/10.1038/s41371-022-00795-6. Online ahead of print.
18. Sharman JE, Ordunez P, Brady T, Parati G, Stergiou G, Whelton PK, et al. The urgency to regulate validation of automated blood pressure measuring devices: a policy statement and call to action from the world hypertension league. J Hum Hypertens. 2022. https://doi.org/10.1038/s41371-022-00747-0. Online ahead of print.