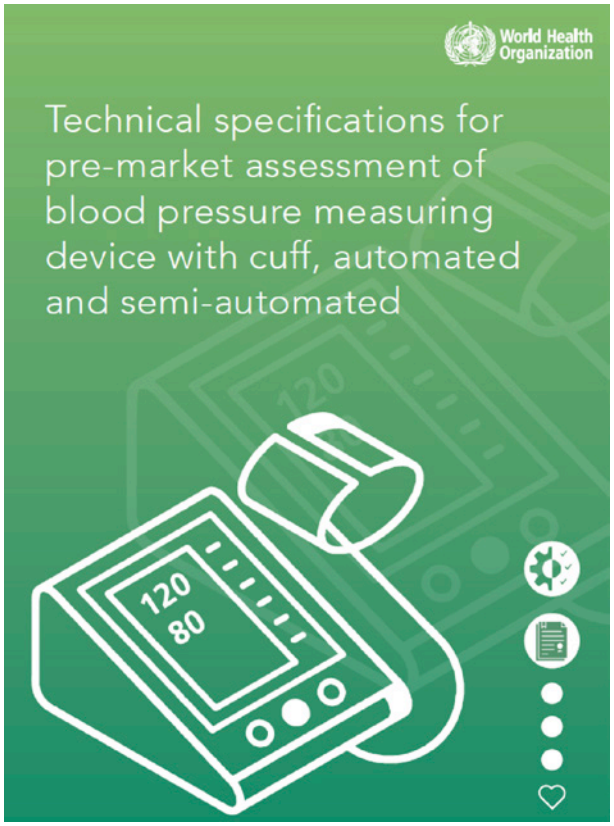
ISH NEWS AND PARTNER ACTIVITIES

News in technical and practical guidance for blood pressure measurement

World Health Organization (WHO) technical specifications for pre-market assessment of automated cuff blood pressure measuring devices

GEORGE STERGIOU

ISH Secretary, University of Athens, Greece



In 2022 the global market size of blood pressure (BP) measuring devices was estimated at US $2.5 billion, and by 2028 it is expected to reach US $5 billion, exhibiting in this period an annual growth rate of 13%.[1] Automated electronic upper arm cuff BP devices are currently recommended for clinical practice to evaluate BP by all methods, in the office/clinic, at home, and with 24-hour ambulatory monitoring.[2,3]

Normally, all the electronic BP monitors which are available on the market would be expected to be properly tested for their measurement accuracy before being approved for clinical use. However, STRIDE BP (www.stridebp.org), which is endorsed by the International Society of Hypertension, the European Society of Hypertension, and the World Hypertension League and performs independent reviews of all the published evidence on the accuracy of electronic cuff BP monitors, recommends less than 10% of those available on the market to be used in clinical practice, as only these have been properly validated using an established protocol.[4]

An important step to dealing with this issue is a recent statement published by the World Health Organization (WHO) with the purpose of ensuring that only accurate devices are available on the market for clinical use.[5] This WHO statement is intended for manufacturers and as a reference for regulators for pre-market assessment, and presents the "minimum" technical specifications for BP measuring devices. A Technical Advisory Group of international experts was appointed and coordinated by the WHO to develop this statement, with considerable contribution by International

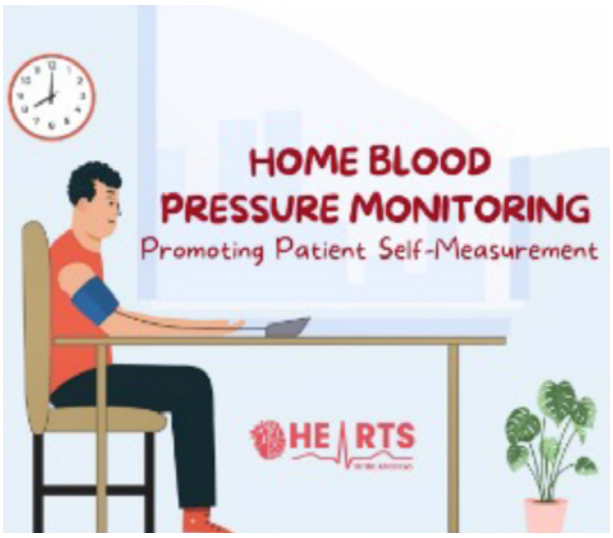
Society of Hypertension officers and members, including George Stergiou, Alta Schutte, Kazuomi Kario, and Anastasia Mihailidou.

The WHO requirements are divided into six categories: (i) regional administrative requirements, (ii) submission context, (iii) non-clinical evidence, (iv) clinical evidence, (v) labelling and promotional material, and (vi) quality management system procedures and (vii) quality management system device-specific information. Importantly, in the clinical evidence section, the 2018 Universal Standard developed by an international collaboration of the American Association for the Advancement of Medical Instrumentation (AAMI), the European Society of Hypertension (ESH), and the International Organization for Standardization (ISO) [AAMI/ESH/ISO – ISO 81060-2:2018][6] is recommended to be implemented independently by certified institutions to ensure the accuracy of devices.

Initiatives such as the development of a Universal Validation Standard for global use, the STRIDE BP lists of accurate devices, and the recent WHO statement for BP device specifications are major steps for improving the accuracy of BP evaluation. However, the next important step is to make these requirements mandatory before a device is approved to be put on the market. It is an important task of scientific organizations to persuade regulators around the world to demand that only properly validated devices are used in clinical practice.

Home Blood Pressure Monitoring Virtual Course by the Pan American Health Organization (PAHO)

All current guidelines for hypertension acknowledge that the measurement of BP in the office is important but can often be misleading, and confirmation with out-of-office BP evaluation is necessary in most cases.[2,3] Although 24-hour ambulatory BP monitoring is regarded by many as the best method currently available for diagnosing hypertension, it is not available in many settings, it is not well accepted by some patients particularly during sleep and at work, and is not suitable for repeated use. Thus, home BP monitoring appears to be the most realistic solution for out-of-office BP evaluation in clinical practice.[7] However, to be



useful for decision making home BP monitoring requires patient training to ensure that (i) an accurate device with appropriate cuff size is used, (ii) measurements are taken following proper methodology (conditions and body position), and (iii) the recommended monitoring schedule is followed. Thus, it is important to have educational tools developed specifically for patients, to guide them in obtaining home BP information which is valid and useful to the health care professionals.

The Pan American Health Organization (PAHO) has recently developed a virtual educational course aiming at promoting the wide and proper implementation of self-home BP monitoring.[8] The course is intended for the general public, and mainly for individuals with suspected, diagnosed, or treated hypertension, and is available online at https://www.campusvirtualsp.org/en/course/home-blood-pressure-monitoring-promoting-patient-self-measurement-2023. Primary healthcare providers, including general practitioners, nurses, and pharmacists, will also find this course helpful as a guidance to educate their patients. The course was developed with support by the ISH, STRIDE-BP, World Hypertension League, Hypertension Canada, Resolve to Save Lives, Lancet Commission on Hypertension Group, and Québec Society of Vascular Sciences [8]

The PAHO home BP measurement course uses a step-by-step approach providing information regarding the optimal self-measurement methodology to train people on why and how to self-measure BP at home and how to interpret the results. It includes (i) an illustrated video, (ii)

links to online resources for selecting validated automated BP measuring devices, (iii) an illustrated guide on the optimal measurement methodology, (iv) a printable 7-day self-measurement log, and (v) a final quiz to self-evaluate knowledge and a certificate is provided upon successful completion.[8]

As home BP monitoring is well accepted by most patients and is already widely used in many countries, it will probably become the primary diagnostic and monitoring method for hypertension in the future combined with telemonitoring. A problem, however, is that in routine office visits healthcare professionals do not have enough time to train their patients in proper self BP measurement. This is an important barrier in obtaining reliable out-of-office BP evaluation, which can be overcome by advancements in technology, with automated BP devices and software guiding users in proper BP measurement, and by educational modules developed specifically for patients.

STRIDE BP also has accredited educational modules for home BP monitoring, and also for office and ambulatory BP measurement, developed using modern interactive e-learning techniques (https://www.stridebp.org/training). However, these are intended for healthcare professionals and are not suitable for patients and the public. The World Hypertension League also has on its website a 12-minute infographic video to guide people in performing proper home BP monitoring (https://www.whleague.org/hypertension-resources/certification-course-blood-pressure-measurement). Educational tools developed specifically for patients, such as the one described above by PAHO, need to become available in all languages and be widely disseminated to healthcare professionals and patients to ensure that self-home monitoring is properly performed to provide trustful BP information which can influence decision making.

George Stergiou - secretary@ish-world.com

References

1. Research and Markets, Dublin, Ireland. https://www.researchandmarkets.com/reports/5642390/blood-pressure-monitoring-devices-market-global#cat-pos-2. Accessed 26 Nov. 2023.

2. Unger T, Borghi C, Charchar F, Khan NA, Poulter NR, Prabhakaran D, Ramirez A, Schlaich M, Stergiou GS, Tomaszewski M, Wainford RD, Williams B, Schutte AE. 2020 International Society of Hypertension global hypertension practice guidelines. J Hypertens. 2020;38:982-1004.

3. Stergiou GS, Palatini P, Parati G, O'Brien E, Januszewicz A, Lurbe E, Persu A, Mancia G, Kreutz R; European Society of Hypertension Council and the European Society of Hypertension Working Group on Blood Pressure Monitoring and Cardiovascular Variability. 2021 European Society of Hypertension practice guidelines for office and out-of-office blood pressure measurement. J Hypertens. 2021;39:1293-1302.

4. Stergiou GS, O'Brien E, Myers M, Palatini P, Parati G; STRIDE BP Scientific Advisory Board. STRIDE BP: an international initiative for accurate blood pressure measurement. J Hypertens. 2020;38:395-399.

5. World Health Organization. Technical specifications for pre-market assessment of blood pressure measuring device with cuff, automated and semi-automated. World Health Organization 2023. https://iris.who.int/handle/10665/372965. Accessed 26 Nov. 2023.

6. Stergiou GS, Alpert B, Mieke S, Asmar R, Atkins N, Eckert S, Frick G, Friedman B, Graßl T, Ichikawa T, Ioannidis JP, Lacy P, McManus R, Murray A, Myers M, Palatini P, Parati G, Quinn D, Sarkis J, Shennan A, Usuda T, Wang J, Wu CO, O'Brien E. 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.

7. Khan NA, Stergiou GS, Omboni S, Kario K, Renna N, Chapman N, McManus RJ, Williams B, Parati G, Konradi A, Islam SM, Itoh H, Mooi CS, Green BB, Cho MC, Tomaszewski M. Virtual management of hypertension: lessons from the COVID-19 pandemic-International Society of Hypertension position paper endorsed by the World Hypertension League and European Society of Hypertension. J Hypertens. 2022;40:1435-1448.

8. Pan American Health Organization (PAHO). Home blood pressure monitoring. Promoting patient self-measurement. Virtual Campus for Public Health of PAHO/WHO, 2023. https://www.campusvirtualsp.org/en/course/home-blood-pressure-monitoring-promoting-patient-self-measurement-2023. Accessed 26 Nov 2023