Consensus Document

OPEN

Lancet commission on hypertension group position statement on the global improvement of accuracy standards for devices that measure blood pressure

James E. Sharman[a], Eoin O'Brien[b], Bruce Alpert[c,*], Aletta E. Schutte[d], Christian Delles[e]
Michael Hecht Olsen[f,g], Roland Asmar[h], Neil Atkins[i], Eduardo Barbosa[j], David Calhoun[k]
Norm R.C. Campbell[l], John Chalmers[m], Ivor Benjamin[n], Garry Jennings[o], Stéphane Laurent[p]
Pierre Boutouyrie[p], Patricio Lopez-Jaramillo[q], Richard J. McManus[r], Anastasia S. Mihailidou[s]
Pedro Ordunez[t], Raj Padwal[u], Paolo Palatini[v], Gianfranco Parati[w,x], Neil Poulter[y]
Michael K. Rakotz[z], Clive Rosendorff[aa,bb], Francesca Saladini[cc], Angelo Scuteri[dd]
Weimar Sebba Barroso[ee], Myeong-Chan Cho[ff], Ki-Chul Sung[gg], Raymond R. Townsend[hh]
Ji-Guang Wang[ii], Tine Willum Hansen[jj], Gregory Wozniak[z], and George Stergiou[kk],
on behalf of the Lancet Commission on Hypertension Group

The Lancet Commission on Hypertension identified that a key action to address the worldwide burden of high blood pressure (BP) was to improve the quality of BP measurements by using BP devices that have been validated for accuracy. Currently, there are over 3000 commercially available BP devices, but many do not have published data on accuracy testing according to established scientific standards. This problem is enabled through weak or absent regulations that allow clearance of devices for commercial use without formal validation. In addition, new BP technologies have emerged (e.g. cuffless sensors) for which there is no scientific consensus regarding BP measurement accuracy standards. Altogether, these issues contribute to the widespread availability of clinic and home BP devices with limited or uncertain accuracy, leading to inappropriate hypertension diagnosis, management and drug treatment on a global scale. The most significant problems relating to the accuracy of BP devices can be resolved by the regulatory requirement for mandatory independent validation of BP devices according to the universally-accepted International Organisation for Standardization Standard. This is a primary recommendation for which there is an urgent international need. Other key recommendations are development of

Journal of Hypertension 2019, 37:000–000

[a]Menzies Institute for Medical Research, University of Tasmania, Hobart, Tasmania, Australia, [b]The Conway Institute, University College Dublin, Dublin, Ireland, [c]University of Tennessee Health Science Center, Memphis, Tennessee, USA, [d]Hypertension in Africa Research Team, Medical Research Council Unit for Hypertension and Cardiovascular Disease, North-West University, Potchefstroom, South Africa, [e]Institute of Cardiovascular and Medical Sciences, University of Glasgow, Glasgow, UK, [f]Department of Internal Medicine, Holbaek Hospital, Holbaek, [g]Centre for Individualized Medicine in Arterial Diseases (CIMA), Odense University Hospital, University of Southern Denmark, Odense, Denmark, [h]Foundation-Medical Research Institutes, Geneva, Switzerland, [i]Medaval Ltd., Dublin, Ireland, [j]Hypertension League of Porto Alegre, Porto Alegre, Rio Grande do Sul, Brazil, [k]Vascular Biology and Hypertension Group, University of Alabama at Birmingham, Birmingham, Alabama, USA, [l]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, [m]The George Institute for Global Health, University of New South Wales, Sydney, New South Wales, Australia, [n]American Heart Association, Dallas, Texas, USA, [o]Sydney Medical School, University of Sydney and Baker Heart & Diabetes Institute, Melbourne, Victoria, Australia, [p]Department of Pharmacology, European Georges Pompidou Hospital, Assistance Publique Hôpitaux de Paris, Inserm UMR 970 and University Paris Descartes, Paris, France, [q]FOSCAL, Instituto Masira, Facultad de Ciencias de la Salud, UDES, Bucaramanga, Colombia, [r]Nuffield Department of Primary Care Health Sciences, University of Oxford, Radcliffe Observatory Quarter, Oxford, UK, [s]Cardiovascular & Hormonal Research Laboratory, Department of Cardiology & Kolling Institute, Royal North Shore Hospital and Faculty of Medicine and Health Sciences, Macquarie University, Sydney, New South Wales, Australia, [t]Department of Non Communicable and Mental Health, Pan American Health Organization, Washington, District of Columbia, [u]Department of Medicine, University of Alberta, Edmonton, Alberta, Canada, [v]Studium Patavinum, University of Padova, Padua, [w]Department of Cardiovascular, Neural and Metabolic Sciences, Istituto Auxologico Italiano, IRCCS, San Luca Hospital, [x]Department of Medicine and Surgery, University of Milano-Bicocca, Milan, Italy, [y]Imperial Clinical Trials Unit, Imperial College London, London, UK, [z]American Medical Association, Improving Health Outcomes, Chicago, Illinois, [aa]Department of Medicine (Cardiology), Mount Sinai Heart, Icahn School of Medicine at Mount Sinai, New York, [bb]The James J. Peters VA Medical Center, Bronx, New York, USA, [cc]Cardiology Unit, Department of Medicine, University of Padova, Town Hospital of Cittadella, Padova, [dd]Department of Medical, Surgical, and Experimental Sciences, University of Sassari, Sassari, Italy, [ee]Hypertension League, Department of Cardiology, Federal University of Goiás, Goiânia, Brazil, [ff]Department of Internal Medicine, Chungbuk National University College of Medicine, Cheongju, [gg]Division of Cardiology, Department of Internal Medicine, Kangbuk Samsung Hospital, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea, [hh]Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, USA, [ii]The Shanghai Institute of Hypertension, Ruijin Hospital, Shanghai Jiaotong University School of Medicine, Shanghai, China, [jj]Steno Diabetes Center Copenhagen, Gentofte, Denmark and [kk]Third Department of Medicine, Hypertension Center STRIDE-7, National and Kapodistrian University of Athens, School of Medicine, Sotiria Hospital, Athens, Greece

Correspondence to James E. Sharman, Menzies Institute for Medical Research, University of Tasmania, Hobart, Tasmania, Australia. Tel: +61 0 3 6226 4709; e-mail: james.sharman@utas.edu.au

*Retired.

Received 7 June 2019 **Revised** 5 August 2019 **Accepted** 14 August 2019

DOI:10.1097/HJH.0000000000002246

validation standards specifically for new BP technologies and online lists of accurate devices that are accessible to consumers and health professionals. Recommendations are aligned with WHO policies on medical devices and universal healthcare. Adherence to recommendations would increase the global availability of accurate BP devices and result in better diagnosis and treatment of hypertension, thus decreasing the worldwide burden from high BP.

Keywords: biomedical technology, diagnostic equipment, international health, reference standard

Abbreviations: AAMI, advancement of medical instrumentation; BP, blood pressure; CEN, European Committee for Standardization; ESH, European Society for Hypertension; FDA, Food and Drug Administration; ISO, International Organisation for Standardization

INTRODUCTION

High blood pressure (BP) is the leading modifiable risk factor for cardiovascular disease, contributing to the greatest global burden of disease [1,2]. There are major deficiencies with respect to optimal awareness, diagnosis and treatment of high BP, and these problems persist across low-income, middle-income and high-income countries, altogether emphasizing the need for widespread population-level improvement [3]. Reassuringly, if the presence of high BP can be correctly identified with appropriate use of accurate BP devices and BP measurement protocols, the risk of future cardiovascular events can be reduced significantly with BP-lowering medications [4], dietary and lifestyle interventions [5].

The accurate measurement of BP and the diagnosis of hypertension are crucial because misclassification can have serious clinical consequences [6]. An overestimation of BP based on inaccurate measurement could lead to the initiation, and potential lifelong continuation, of unnecessary medications with possible side effects as well as unwanted social effects including anxiety, workplace absenteeism [7] and increased costs from insurance and medications [8]. Conversely, if inaccurate measurement results in underestimating BP, an opportunity to prevent avoidable cardiovascular events may be missed. These are nontrivial problems, in that relatively small systematic inaccuracies can lead to misclassification of many millions of people at the population level [9]. Thus, accurate BP measurement has been cited as one of the most important tests in clinical medicine [10]. The accuracy of BP measurement is a serious and frequent problem of contemporary clinical practice that should be considered as an issue of patient safety.

One of the key actions of The Lancet Commission on Hypertension was to improve BP evaluation from better quality of BP measurements through endorsed protocols and validated (accurate) BP monitors [11]. Manufacturers must adhere to strict regulatory processes to bring a BP device legally to market. However, many loopholes have been identified which lead to BP devices of poor or unknown accuracy being widely available for clinic use, including for self-monitoring at home [12–19]. The effects of unknown BP errors can influence the clinical environment, epidemiology and research, and even contribute to discrepancies among hypertension guidelines [20]. From about 3000 cuff-based BP measuring devices on the market today, less than 15% have published evidence on accuracy performance [21]. These nonvalidated BP devices are used in clinical practice and are more likely to be inaccurate [22–24]. Furthermore, a variety of new BP measurement technologies using sensors and cuffless techniques are also now emerging for sale, but there is minimal guidance on appropriate standards for accurately testing them.

The aim of this article is both to summarize the current situation regarding the regulatory requirements and accuracy standards for BP measuring devices, and also to redress the problems mentioned above by providing recommendations and actions towards improving validation and reporting standards for BP measuring devices. This article is fully aligned with the WHO policies on medical devices and can assist to catalyse the full implementation of the related World Health Assembly resolutions [25,26]. Ultimately, this work seeks to facilitate the global availability of validated BP measuring devices, thereby increasing the probability of better BP management and decreasing the worldwide burden of high BP.

HOW A BLOOD PRESSURE DEVICE BECOMES APPROVED FOR SALE

Many countries have legal processes in place, whereby a manufacturer of a BP device must demonstrate compliance with regulatory requirements before being given clearance for sale of the device. It is beyond this review to detail the specific regulatory processes among different countries, as these differ across the world and involve substantial complexity. However, the general overriding principles of regulatory processes are to ensure that BP devices meet acceptable standards of quality, safety, reliability and effectiveness (e.g. suitability for intended purpose).

If a company decides to market a BP device, it must submit an application that is reviewed by the regulatory authority within the jurisdiction of sale [e.g. the US Food and Drug Administration (FDA, USA); Therapeutic Products Directorate (Canada); or Therapeutic Goods Administration (Australia), to name a few]. If the information provided by the manufacturer meets the local regulatory requirements, a licence (or clearance) is issued for sale of the device within that country. In general, there are increasing levels of regulatory requirements and assessments as the level of potential risk from the device to the consumer rises. Thus, as BP devices are classified as low-to-moderate risk, the regulatory requirements are lower than those for high-risk medical devices.

Although not required by law, a common way for the manufacturer of a medical device to demonstrate compliance with regulatory requirements is to show that the device conforms with published standards relevant to that device. Standards are documents designed to set out the specifications, procedures and guidelines to ensure the quality, safety and effectiveness of devices. The International Organisation for Standardization (ISO) develops

standards for use globally, but separate national or regional standards may also exist.

STANDARDS FOR ASSESSING THE ACCURACY OF BLOOD PRESSURE MEASURING DEVICES

Efforts to validate BP devices formally started in the 1980s [27]. In 1987, the US Association for the advancement of medical instrumentation (AAMI) developed a clinical validation protocol for BP devices [28,29], which was followed by a similar protocol from the British Hypertension Society [30,31]. In 1999, the German Hypertension League developed another protocol [32] and in 2002 the European Society of Hypertension (ESH) Working Group on BP Monitoring developed their International Protocol, which they revised in 2010 [33,34]. These protocols have been revised by adopting more stringent criteria [29,31,34]. In 2004, the European Committee for Standardization (CEN) published another standard [35], and in 2009 the ISO also developed a standard [36] largely based on the AAMI and CEN standards. This was adopted by AAMI [37]. In 2013, a revised version of the AAMI/ISO Standard was published [38].

While the abovementioned validation protocols and standards have similarities in concept and core procedures, they also have several methodological differences regarding important issues such as the sample size required, selection criteria for the participants, the validation procedure, the efficacy measure and the criteria to pass [39]. This variation has confused researchers, physicians, consumers and manufacturers as to which protocol should be preferred and why. Furthermore, even when allegedly following recommended protocols, investigators can make incorrect claims about validation [40]. After three decades of persistent efforts by several prestigious organizations for optimizing the validation process there is no doubt that science, the public, the regulatory bodies and industry would be best served if a single standard for validation of BP monitors is agreed and universally accepted.

In 2017, an international initiative to establish a universally acceptable standard for evaluating the accuracy of BP measuring devices was put in place by the AAMI, ESH and ISO committees [41]. This Standard (ISO 81060-2:2018) [42] consolidates previous evidence and will progressively replace all previous protocols used around the world. In order for this initiative to achieve global impact for increasing the availability of BP devices validated for clinical accuracy, it would be necessary to make it mandatory to use the universally accepted ISO Standard for assessing the accuracy of BP measuring devices before they are put on the market for use in the medical, community and home settings.

REGULATORY PATHWAY PROBLEMS AND OUTCOMES FOR BLOOD PRESSURE DEVICES

There are significant problems in the transmission of scientific data on BP device accuracy to the actual users of such devices [15,16,41,43–45]. Many important articles on the deficiencies of BP measurement have been published over many decades [10,46], but the information is rarely disseminated beyond the researchers and health professionals who are already familiar with the problems. Manufacturers may be aware of the limitations with respect to BP device accuracy, but while the consumer market remains unaffected, there is little impetus to modify practice.

A fundamental regulatory problem is that authorities focus mainly on the physical safety features of BP devices rather than accuracy and performance characteristics [15,43]. Indeed, manufacturers are not required to test accuracy according to specific unified standards, nor to share results of the accuracy testing publicly. Regulations can also be difficult to enforce due to ambiguities and high levels of complexity [15]. In addition, recommendations from consumer organizations are often based on cost, usability and cosmetics rather than accuracy. Most insidiously, unethical manufacturers are selling cheap home BP devices online and making false claims with respect to validation [47]. This implies that consumers may be more likely to purchase lower priced, nonvalidated devices, but this needs to be confirmed. Many other problems, summarized in Table 1, have resulted in a marketplace replete with BP devices of unknown or questionable accuracy [21–24].

EMERGING NEW BLOOD PRESSURE DEVICE METHODS AND TECHNOLOGIES

Clinical guidelines for the diagnosis and management of hypertension have been developed based on evidence from auscultation or oscillometric arm cuff BP devices, which remain the recommended standard for clinical practice. These methods rely on analysis of haemodynamic signals in the brachial artery, which were originally believed to be a good estimate of the central aortic pressure load [48] as the most clinically relevant BP [49–53]. In reality, cuff BP devices vary greatly as to whether the measurements represent central aortic or even brachial BP, and there may be large individual variation in the SBP at the central aorta compared with the brachial artery (e.g. difference >30 mmHg) [54]. There are a variety of devices available that purport to measure central aortic BP, as distinct from standard cuff BP [55]. However, beyond recommendations of professional societies [56], there are no regulatory standards to assess performance of these devices.

There is also a burgeoning of new BP measurement technologies that seek to measure BP in entirely different ways than cuff BP. These include different types of cuffless sensors at various arterial sites (e.g. chest, face, upper arm, wrist, finger) with continuous or 'snapshot' monitoring of BP using a variety of direct or indirect recording and signal processing methods (e.g. reflectance pulse oximetry, radio frequency sensors, microstructure strain gauge fibres, optoelectronic, applanation tonometry, pulse transit time, smartphone applications) over durations that may extend to weeks or months, and may incorporate software programs with clinical decision-support functionality [57–66]. Some of these methods are not user-friendly and many still rely on calibration to a conventional cuff-based BP measurement, which are limiting features. Nonetheless, this is an evolving

TABLE 1. Summary of regulatory and validation study problems, results and consequences related to accuracy of blood pressure devices

Problem	Result	Overall consequences
Not mandatory for manufacturers to use a specific standard to assess BP measuring device accuracy	Variable methods used to assess and report on the accuracy of BP measuring devices	1. Inaccurate BP devices are widely available for sale and use by clinicians and the general public who are unaware of the problem 2. Incorrect diagnosis and treatment decisions are made 3. Opportunity is lost to perform best-practice clinical care and increase the efficacy of cardiovascular disease prevention
Not mandatory for validation testing to be performed by independent parties	Internal company testing performed with questionable expertise and conflict of interest	
Several published validation studies deviate from established protocols	Questionable results and unjustified conclusions of studies evaluating BP monitors	
Several BP devices have passed regulatory requirements for sale but failed independent validation of measurement accuracy	Erroneous messaging with respect to the accuracy of individual BP devices	
BP devices may fail to produce accurate readings in people with large or small arms but still used in such cases	Individuals with too small or too large arms may have inaccurate BP evaluation	
The assumption that a BP device 'cleared' by regulatory authorities and commercially available is accurate	Confusion as to which BP device available on the market has acceptable accuracy	
Regulatory requirements focus on safety rather than accuracy (performance)	BP devices perform well with regard to safety but may not be accurate	
Results of BP devices that fail validation studies may not be published	Lack of widespread communication and transparency on the results of validation studies	
Exact BP device used in the validation study is unclear	Confusion as to whether the BP device has undergone validation testing	
Unethical companies are selling cheap home BP devices online with false validation credentials	Consumers may favour purchase of cheap products, and this could have particular impact among people in lower income countries	
Consumer organizations do not give due attention to BP device accuracy	Inappropriate advice on best BP devices to use is promulgated to the general public	

BP, blood pressure.

field with major opportunities to improve hypertension evaluation and control, and also to advance systems of healthcare delivery by merging with electronic medical records. However, these diverse technologies also pose new regulatory challenges in providing suitable oversight regarding clinical performance, accuracy, safety and utility [67].

RECOMMENDATIONS AND ACTIONS TO ADDRESS IDENTIFIED PROBLEMS

Recommendation 1: Convergence toward the global regulatory requirement for mandatory independent validation of BP devices according to the universally accepted ISO Standard (ISO 81060-2:2018) with publication preferably in a peer reviewed journal

According to the WHO, high-quality health technologies, such as validated BP devices, are indispensable for effective universal healthcare delivery [25]. Indeed, the WHO Global Model Regulatory Framework for Medical Devices presents a stepwise approach to implementing and enforcing regulatory controls for medical devices [68]. Regulatory convergence is when the regulatory requirements across different regions become aligned due to the adoption of internationally recognized technical documents or regulatory mechanisms that align with achieving a common public health goal [69]. The ISO Standard fulfils the urgent need for a single, universally accepted protocol for BP device validation. The standard has already been adopted by the United States, as well as many other countries and, if made a global mandatory regulatory requirement, will redress the majority of problems relating to BP device accuracy associated with current frameworks. For this to occur there are numerous actions that need to be undertaken across a wide spectrum of key stakeholders that include: government organizations (e.g. FDA or other regulatory agencies); nongovernment organizations (e.g. hypertension societies); researchers, health professionals; journals that publish material related to BP; manufacturers of BP devices and the consumers who purchase BP devices. Nongovernment organizations have many important roles to play. Indeed, endorsement of a standardized validation protocol by a hypertension society has been shown to influence manufacturers to pursue independent validation of BP devices [39]. A summary of required actions is detailed in Table 2.

Recommendation 2: Development of specific standards for the validation of new BP measuring technologies that cannot be tested using the ISO Standard (ISO 81060-2:2018)

The worldwide inundation of new technology that claims to measure BP brings challenges to regulatory authorities that are also encouraging ways to find innovative solutions [67]. Rather than repeating past regulatory problems experienced with standard cuff BP devices, there is an opportunity for developing international standards that are specific to new BP technologies, and that appropriately evaluate accuracy and clinical validity. Table 2 sets out the actions required to achieve this recommendation. As with Recommendation 1, both government and

TABLE 2. Recommendations and required actions by key stakeholders for the global improvement of blood pressure device accuracy standards

Recommendations	Key stakeholders to effect actions	Actions
Convergence towards the global regulatory requirement for mandatory independent validation of BP devices according to the universally accepted ISO Standard (ISO 81060-2:2018) with publication preferably in a peer reviewed journal	Government regulatory organizations (e.g. US Food and Drug Administration, European Database on Medical Devices, Australian Therapeutic Goods Administration)	Legislate for mandatory independent validation of BP devices according to the ISO Standard before approval for sale Stipulate that validation studies of BP devices are registered in an accepted repository before approval for sale Regulate enforcement of the ISO Standard Monitor compliance with the ISO Standard Support efforts of the WHO to implement WHA resolutions to ensure effective use and strengthened regulatory systems for BP devices[a]
	Nongovernment organizations (e.g. hypertension societies, cardiovascular advocacy groups)	Develop repositories for the registration of BP device validation studies conducted around the world (similar concept to ClinicalTrials.gov) Certify research facilities for performing BP device validation studies Advocate and lobby to legislate for use of the ISO Standard Endorse the use of BP devices that have passed validation according to the ISO Standard Educate members on the importance of using BP devices that have passed the ISO Standard Educate patients on the importance of BP device accuracy and access to validated devices
	Researchers	Register BP device validation studies in an accepted repository Transfer knowledge on BP device accuracy for the benefit of the wider scientific, clinical and general community
	Health professionals	Only use validated BP devices in clinical practice Ensure ongoing accuracy of BP devices used in clinical practice by undertaking maintenance checks according to the manufacturer's instructions Educate patients to only use validated BP devices for self-home monitoring
	Peer reviewed journals	Only accept articles in which BP has been measured using devices that have passed validation according to the ISO Standard
	Manufacturers	Evaluate the accuracy of BP devices using the ISO Standard through independent researchers Publish results of validation testing on company websites Use a specific common identifier for each BP device that may be sold by distributors under different names Provide instructions to purchasers on the process for regular maintenance of the specific device purchased
	Consumers	Only purchase BP devices that have passed validation Ensure ongoing accuracy of BP device by undertaking regular maintenance according to the manufacturer's instructions Only purchase BP devices when accuracy can be confirmed through accredited online lists[b]
Development of specific standards for the validation of new BP measuring technologies that cannot be tested using the ISO Standard (ISO 81060-2:2019)	Nongovernment organizations	Develop international standards specifically for new BP measuring technologies that cannot be tested using the current ISO Standards Endorse the use of international standards for new BP measuring technologies
	Government organizations	Legislate for mandatory independent validation of new BP devices according to the ISO Standard (developed by nongovernment organizations) before approval for sale Regulate enforcement of the international standards Monitor compliance with the international standards
	Researchers and biomedical engineers	Participate in the development of international standards for new BP measuring technologies Develop new technologies to accurately measure BP Conduct research to determine the ability of new BP technologies to enhance clinical care
	Health professionals	Avoid using new BP measuring technologies until proven to enhance clinical care
Accredited online lists of BP devices detailing the published results of the validation studies[b]	Government and nongovernment organizations	Endorse and promote accredited online lists of BP devices Develop and maintain one universally accepted accredited list of BP devices Promote access to the accredited online lists of BP devices through the WHO Essential Medicines and Health Products Program[c] Facilitate acquisition of validated BP monitors (from accredited lists) to increase quality and affordability through initiatives such as the PAHO Strategic Fund[d]
	Researchers	Participate in expert advisory groups to oversee the scientific credibility of accredited online lists of BP devices

BP, blood pressure; ISO, International Organization for Standardization.
[a]WHA, World Health Assembly resolutions WHA60.29 and WHA67.20 https://www.who.int/healthsystems/WHA60_29.pdf and http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf.
[b]Current online lists of BP devices and validation information can be found at https://bihsoc.org/bp-monitors/, https://hypertension.ca/hypertension-and-you/managing-hypertension/measuring-blood-pressure/devices/ https://medaval.ie/device-category/blood-pressure-monitors/ and https://stridebp.org/.
[c]WHO Essential Medicines and Health Products Program https://www.who.int/medicines/about/en/.
[d]PAHO, Pan American Health Organisation, Strategic Fund https://www.paho.org/hq/index.php?option=com_content&view=article&id=12167:faqs-strategic-fund&Itemid=1694&lang=en#1.

nongovernment organizations will need to undertake actions to develop the specific standards and legislate for their mandatory use before approval for sale, but also endorse, regulate and monitor compliance with the new standards. Health professionals should avoid using new BP technologies to inform clinical management until the method in question can be proven to enhance clinical care.

Recommendation 3: Accredited online lists of BP devices detailing the published results of the validation studies

There is an urgent need to establish means of informing the scientific and general community as to which BP devices have been tested and found to have acceptable accuracy. This can be achieved through online lists of BP devices that detail the results of validation studies carried out according to international standards [43]. The lists should be developed and maintained by organizations with sufficient expertise to ensure scientific rigor and remain independent from BP device manufacturers. Such lists have been developed by national scientific societies in the United Kingdom [70] and Canada [71]. The American Medical Association and the American Heart Association [72], as well as an international group of BP measurement experts (STRIDE-BP organization) have also developed similar resources for general use, which are important nonprofit initiatives. As we move towards a single, universally-accepted ISO Standard, so too we should work towards developing one universally accepted accredited list of BP devices to consolidate information for best effect. Table 2 summarizes the actions and key stakeholders to achieve this recommendation.

IMPLEMENTATION ACTIONS BY THE LANCET COMMISSION ON HYPERTENSION GROUP

A co-ordinated program of activities to implement the recommendations and actions set out in Table 2 is being led by an executive team from the Lancet Commission on Hypertension Group. This team will be guided by an advisory team of invited members with relevant expertise across diverse skills (e.g. scientific, technical, advocacy, implementation science) and representing organizational sectors (e.g. government and nongovernment organizations, professional societies) in different world regions. Lobbying key decision-makers at national Department of Health level is recognized as critical for successful knowledge transfer. The executive team is also keen to leverage opportunity for implementation through existing international programmes and resources, such as the WHO Programme on Cardiovascular Disease, and among individual countries through local champions and relevant organizations (e.g. Heart and Stroke Foundations). The outcomes of these activities will be evaluated and published. Interested partners can contact the corresponding author of this article.

CONCLUSION

Measurement of BP is a fundamental medical test performed daily on many millions of people worldwide, and health professionals together with consumers should have confidence in the accuracy of the BP devices that they use for screening, diagnosis and management of hypertension. On the contrary, due to a host of well known problems, the global marketplace has been inundated with BP devices that are either known to be inaccurate or are of unknown accuracy. This can have serious implications for being able to achieve best-practice care of people related to BP control. The problem also threatens to be compounded by widespread introduction of new technology purporting to measure BP. Fortunately, most identified problems could be resolved by the mandatory requirement for independent validation of BP devices according to the recently developed ISO Standard. Other key needs are the development of specific standards for the validation of new BP technologies and accredited online lists of BP devices that are accessible to health professionals and consumers. An executive team of the Lancet Commission on Hypertension Group is currently working towards implementation of the recommendations provided in this position statement. Adherence to these recommendations would align with WHO policy to result in more accurate diagnosis and treatment of hypertension and a decrease in the worldwide burden from high BP.

ACKNOWLEDGEMENTS

The Lancet Commission on Hypertension Group members are Michael H. Olsen, Sonia Y. Angell, Samira Asma, Pierre Boutouyrie, Dylan Burger, Julio A. Chirinos, Albertino Damasceno, Christian Delles, Anne-Paule Gimenez-Roqueplo, Dagmara Hering, Patricio López-Jaramillo, Fernando Martinez, Vlado Perkovic, Ernst R. Rietzschel, Giuseppe Schillaci, Aletta E. Schutte, Angelo Scuteri, James E. Sharman, Kristian Wachtell, Ji-Guang Wang.

The following organisations and institutions endorse this position statement: Lancet Commission on Hypertension Group, American Heart Association, American Medical Association, Artery Society, Brazilian Society of Cardiology, British and Irish Hypertension Society, Chinese Hypertension League, Danish Heart Foundation, Danish Society of Hypertension, European Society of Hypertension Working Group on Blood Pressure Monitoring and Cardiovascular Variability, Finnish Hypertension Society, French Society of Hypertension, High Blood Pressure Research Council of Australia, Hypertension Canada, International Society of Vascular Health, Korean Society of Hypertension, Latin American Society of Hypertension, National Heart Foundation of Australia, Norwegian Society of Hypertension, Pan American Health Organisation, Resolve to Save Lives, Swedish Society of Hypertension, Stroke and Vascular Medicine, World Hypertension League.

No funding was received for this work.

Conflicts of interest

J.E.S.'s university has received equipment and research funding from manufacturers of BP devices including AtCor Medical, IEM and Pulsecor (Uscom). He has no personal commercial interests related to BP companies. E.O. conducted validation studies for various manufacturers of BP measuring technologies and advised manufacturers on

device and software development. B.A. conducted validation studies for various manufacturers of BP measuring technologies and advised manufacturers on device and software development. A.E.S. has received equipment and funding from manufacturers of BP devices including IEM and Omron. C.D. and M.H.O. have no conflicts. R.A. conducted validation studies for various manufacturers of BP measuring technologies and advised manufacturers on device and software development. N.A. is the Chief Analytics Officer of Medaval Ltd., which provides validation information and listings to the public and validation and equivalence services to manufacturers; has conducted validation studies for various manufacturers of BP measuring technologies and has advised manufacturers on device and software development. E.B. and D.C. have no conflicts. N.R.C.C. 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 blood pressure assessment to Midway Corporation (2017) and is an unpaid member of World Action on Salt and Health (WASH). J.C. has received a research grant from Idorsia for the SPIRIT study of resistant hypertension. G.J. has no conflict. S.L. has received equipment and research funding from manufacturers of BP devices including AtCor Medical and Omron. P.B. has received honorarium and grants from Withings. P.L.-J. has no conflict. R.M. has received BP monitors for research from Omron. He chairs the British and Irish Hypertension Society's Working Group on Blood Pressure Measurement. A.M., P.O. and S.A. have no conflicts. R.P. is the Canadian representative to the ISO Sphygmomanometer committee and sits on the AAMI Sphygmomanometer committee. Co-Founder of a BP measurement start-up company (mmHg Inc.), based at the University of Alberta, with no products currently on the market. P.P. has received income from Hingmed (China), Novacor (France) and A&D (Japan). G.P. conducted validation studies for various manufacturers of BP measuring technologies and advised manufacturers on device and software development. N.P.: The International Society of Hypertension received BP devices from Omron to carry out a screening campaign when Dr Poulter was President of the Society. M.K.R. is the Vice President, Improving Health Outcomes at American Medical Association. C.R. has received digital BP monitors for research from Omron. F.S. conducted validation studies for various manufacturers of BP measuring technologies. A.S., W.S.B., M.-C.C. and K-CS have no conflicts. R.R.T.: Advisory Board Consultant for Hill_Rom. J.-G.W. conducted validation studies for various manufacturers of BP measuring technologies and advised manufacturers on device and software development. T.W.-H. has no conflicts. G.W.: Director, Outcomes Analytics at American Medical Association. G.S.: ISO Sphygmomanometer committee member; Chairman of European Society of Hypertension Working Group on BP Monitoring and envoy to the ISO Sphygmomanometer committee. Conducted validation studies for various manufacturers of BP measuring technologies and advised manufacturers on device and software development.

REFERENCES

1. Gakidou E, Afshin A, Abajobir AA, Abate KH, Abbafati C, Abbas KM, *et al*. Global, regional, and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet* 2017; 390:1345–1422.
2. Lawes CM, Vander Hoorn S, Law MR, Elliott P, MacMahon S, Rodgers A. Blood pressure and the global burden of disease 2000. Part II: Estimates of attributable burden. *J Hypertens* 2006; 24:423–430.
3. Chow CK, Teo KK, Rangarajan S, Islam S, Gupta R, Avezum A, *et al*. Prevalence, awareness, treatment, and control of hypertension in rural and urban communities in high-, middle-, and low-income countries. *JAMA* 2013; 310:959–968.
4. Ettehad D, Emdin CA, Kiran A, Anderson SG, Callender T, Emberson J, *et al*. Blood pressure lowering for prevention of cardiovascular disease and death: a systematic review and meta-analysis. *Lancet* 2016; 387:957–967.
5. Whelton PK, He J, Appel LJ, Cutler JA, Havas S, Kotchen TA, *et al*. Primary prevention of hypertension: clinical and public health advisory from The National High Blood Pressure Education Program. *JAMA* 2002; 288:1882–1888.
6. Williams B, Mancia G, Spiering W, Agabiti Rosei E, Azizi M, Burnier M, *et al*. 2018 ESC/ESH Guidelines for the management of arterial hypertension: the Task Force for the management of arterial hypertension of the European Society of Cardiology and the European Society of Hypertension: the Task Force for the management of arterial hypertension of the European Society of Cardiology and the European Society of Hypertension. *J Hypertens* 2018; 36: 1953–2041.
7. Haynes RB, Sackett DL, Taylor DW, Gibson ES, Johnson AL. Increased absenteeism from work after detection and labeling of hypertensive patients. *N Engl J Med* 1978; 299:741–744.
8. Campbell NR, McKay DW. Accurate blood pressure measurement: why does it matter? *CMAJ* 1999; 161:277–278.
9. Jones DW, Appel LJ, Sheps SG, Roccella EJ, Lenfant C. Measuring blood pressure accurately: new and persistent challenges. *JAMA* 2003; 289:1027–1030.
10. Pickering TG, Hall JE, Appel LJ, Falkner BE, Graves J, Hill MN, *et al*. Recommendations for blood pressure measurement in humans and experimental animals: Part 1: Blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. *Hypertension* 2005; 45:142–161.
11. Olsen MH, Angell SY, Asma S, Boutouyrie P, Burger D, Chirinos JA, *et al*. A call to action and a lifecourse strategy to address the global burden of raised blood pressure on current and future generations: the Lancet Commission on hypertension. *Lancet* 2016; 388: 2665–2712.
12. Alpert BS. Can 'FDA-cleared' blood pressure devices be trusted? A call to action. *Blood Press Monit* 2017; 22:179–181.
13. Campbell NR, Gelfer M, Stergiou GS, Alpert BS, Myers MG, Rakotz MK, *et al*. A call to regulate manufacture and marketing of blood pressure devices and cuffs: a position statement from the World Hypertension League, International Society of Hypertension and Supporting Hypertension Organizations. *J Clin Hypertens (Greenwich)* 2016; 18: 378–380.
14. O'Brien E, Alpert BS, Stergiou GS. Accurate blood pressure measuring devices: influencing users in the 21st century. *J Clin Hypertens (Greenwich)* 2018; 20:1138–1141.
15. O'Brien E, Stergiou GS, Turner MJ. The quest for accuracy of blood pressure measuring devices. *J Clin Hypertens (Greenwich)* 2018; 20:1092–1095.
16. Stergiou GS, Alpert BS, Mieke S, Wang J, O'Brien E. Validation protocols for blood pressure measuring devices in the 21st century. *J Clin Hypertens (Greenwich)* 2018; 20:1096–1099.
17. Hodgkinson J, Koshiaris C, Martin U, Mant J, Heneghan C, Hobbs FR, McManus RJ. Accuracy of monitors used for blood pressure checks in English retail pharmacies: a cross-sectional observational study. *Br J Gen Pract* 2016; 66:e309–e314.
18. Erdem DG, Erdem E, Dilek M, Aydogdu T, Selim N, Demiray F, *et al*. Accuracy of sphygmomanometers at pharmacies. *Kidney Blood Press Res* 2009; 32:231–234.

19. Ringrose JS, Polley G, McLean D, Thompson A, Morales F, Padwal R. An assessment of the accuracy of home blood pressure monitors when used in device owners. *Am J Hypertens* 2017; 30:683–689.
20. Sharman JE, Marwick TH. Accuracy of blood pressure monitoring devices: a critical need for improvement that could resolve discrepancy in hypertension guidelines. *J Hum Hypertens* 2018; 33:89–93.
21. Medaval Ltd. *Blood pressure monitors*. Dublin, Ireland: Medaval Ltd; 2018 ; https://medaval.ie/device-category/blood-pressure-monitors/. [Accessed 27 September 2017].
22. Jung MH, Kim GH, Kim JH, Moon KW, Yoo KD, Rho TH, Kim CM. Reliability of home blood pressure monitoring: in the context of validation and accuracy. *Blood Press Monit* 2015; 20:215–220.
23. Akpolat T, Dilek M, Aydogdu T, Adibelli Z, Erdem DG, Erdem E. Home sphygmomanometers: validation versus accuracy. *Blood Press Monit* 2009; 14:26–31.
24. Dilek M, Adibelli Z, Aydogdu T, Koksal AR, Cakar B, Akpolat T. Self-measurement of blood pressure at home: is it reliable? *Blood Press* 2008; 17:34–41.
25. World Health Organisation. Health technologies.*Sixtieth World Health Assembly resolution WHA60.29*. Geneva, Switzerland: World Health Organisation; 2007https://www.who.int/healthsystems/WHA60_29.pdf. [Accessed 10 January 2019].
26. World Health Organisation. Regulatory system strengthening for medical products.*Sixty-Seventh World Health Assembly resolution WHA67.20*. Geneva, Switzerland: World Health Organisation; 2014 ; https://www.who.int/healthsystems/WHA60_29.pdf. [Accessed 10 January 2019].
27. O'Brien E, Stergiou GS. The pursuit of accurate blood pressure measurement: a 35-year travail. *J Clin Hypertens (Greenwich)* 2017; 19:746–752.
28. Association for the Advancement of Medical Instrumentation. *The national standard of electronic or automated sphygmomanometers*. Arlington, VA: Association for the Advancement of Medical Instrumentation; 1987.
29. Association for the Advancement of Medical Instrumentation. *American National Standard. Electronic or automated sphygmomanometers*. Arlington, VA: Association for the Advancement of Medical Instrumentation; 1993.
30. O'Brien E, Petrie J, Littler W, de Swiet M, Padfield PL, O'Malley K, *et al*. The British Hypertension Society protocol for the evaluation of automated and semi-automated blood pressure measuring devices with special reference to ambulatory systems. *J Hypertens* 1990; 8:607–619.
31. O'Brien E, Petrie J, Littler W, de Swiet M, Padfield P, Altman DG, *et al*. The British Hypertension Society protocol for the evaluation of blood pressure measuring devices. *J Hypertens* 1993; 11 (Suppl 2):S43–S62.
32. Tholl U, Luders S, Bramlage P, Dechend R, Eckert S, Mengden T, *et al*. The German Hypertension League (Deutsche Hochdruckliga) Quality Seal Protocol for blood pressure-measuring devices: 15-year experience and results from 105 devices for home blood pressure control. *Blood Press Monit* 2016; 21:197–205.
33. O'Brien E, Pickering T, Asmar R, Myers M, Parati G, Staessen J, *et al*. Working Group on Blood Pressure Monitoring of the European Society of Hypertension International Protocol for validation of blood pressure measuring devices in adults. *Blood Press Monit* 2002; 7:3–17.
34. O'Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R, *et al*. European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults. *Blood Press Monit* 2010; 15:23–38.
35. Noninvasive sphygmomanometers – Part 4: Test procedures to determine the overall system accuracy of automated noninvasive sphygmomanometers. European Committee for Standardization EN 1060-4:2004. https://shop.bsigroup.com. [Accessed 27 February 2018].
36. Noninvasive sphygmomanometers: clinical validation of automated measurement type. International Organization for Standardization (ISO) 81060-2, 2009. www.iso.org. [Accessed 27 February 2018].
37. Noninvasive sphygmomanometers – Part 2: Clinical validation of automated measurement type. American National Standards Institute. ANSI/AAMI/ISO 81060-2, 2009. http://webstore.ansi.org. [Accessed 27 February 2018].
38. Noninvasive sphygmomanometers – Part 2: Clinical investigation of automated measurement type. American National Standards Institute. ANSI/AAMI/ISO 81060-2:2013. http://webstore.ansi.org. [Accessed 27 February 2018].
39. Stergiou GS, Asmar R, Myers M, Palatini P, Parati G, Shennan A, *et al*. Improving the accuracy of blood pressure measurement: the influence of the European Society of Hypertension International Protocol (ESH-IP) for the validation of blood pressure measuring devices and future perspectives. *J Hypertens* 2018; 36:479–487.
40. McManus R, Lacy P, Clark C, Chapman N, Lewis P, British Irish Hypertension Society Blood Pressure Measurement Working Party. Reporting of blood pressure monitor validation studies. *Blood Press Monit* 2018; 23:214–215.
41. Stergiou GS, Alpert B, Mieke S, Asmar R, Atkins N, Eckert 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.
42. International Organization for Standardization. ISO 81060-2:2018. Noninvasive sphygmomanometers – Part 2: Clinical investigation of intermittent automated measurement type. https://www.iso.org/standard/73339.html. [Accessed 7 December 2018].
43. O'Brien E, Dolan E, Stergiou GS. Achieving reliable blood pressure measurements in clinical practice: it's time to meet the challenge. *J Clin Hypertens (Greenwich)* 2018; 20:1084–1088.
44. Giles TD, Kostis JB, Fernandez C. Blood pressure is a beautiful (but imperfect) biomarker of hypertension. The quixotic quest that fuels the hypertension guideline industry. *J Clin Hypertens (Greenwich)* 2018; 20:840–841.
45. Stergiou GS, Parati G, McManus RJ, Head GA, Myers MG, Whelton PK. Guidelines for blood pressure measurement: development over 30 years. *J Clin Hypertens (Greenwich)* 2018; 20:1089–1091.
46. Bordley J 3rd, Connor CA, Hamilton WF, Kerr WJ, Wiggers CJ. Recommendations for human blood pressure determinations by sphygmomanometers. *Circulation* 1951; 4:503–509.
47. Atkins N. *Open letter to experts and manufacturers concerning (EU) 2017/745 and the coalescence of order from chaos*. Medaval; 2018.
48. Booth J. A short history of blood pressure measurement. *Proc R Soc Med* 1977; 70:793–799.
49. Kim H-L, Seo J-B, Chung W-Y, Kim S-H, Kim M-A, Zo J-H. Association between invasively measured central aortic pressure and left ventricular diastolic function in patients undergoing coronary angiography. *Am J Hypertens* 2015; 28:393–400.
50. Danchin N, Benetos A, Lopez-Sublet M, Demicheli T, Safar M, Mourad JJ. Aortic pulse pressure is related to the presence and extent of coronary artery disease in men undergoing diagnostic coronary angiography: a multicenter study. *Am J Hypertens* 2004; 17:129–133.
51. Safar ME, Blacher J, Pannier B, Guerin AP, Marchais SJ, Guyonvarc'h PM, London GM. Central pulse pressure and mortality in end-stage renal disease. *Hypertension* 2002; 39:735–738.
52. Vlachopoulos C, Aznaouridis K, O'Rourke MF, Safar ME, Baou K, Stefanadis C. Prediction of cardiovascular events and all-cause mortality with central haemodynamics: a systematic review and meta-analysis. *Eur Heart J* 2010; 15:1865–1871.
53. Kelly RP, Gibbs HH, O'Rourke MF, Daley JE, Mang K, Morgan JJ, Avolio AP. Nitroglycerin has more favourable effects on left ventricular afterload than apparent from measurement of pressure in a peripheral artery. *Eur Heart J* 1990; 11:138–144.
54. Picone DS, Schultz MG, Otahal P, Aakhus S, Al-Jumaily AM, Black JA, *et al*. Accuracy of cuff-measured blood pressure: systematic reviews and meta-analyses. *J Am Coll Cardiol* 2017; 70:572–586.
55. Millasseau S, Agnoletti D. Noninvasive estimation of aortic blood pressures: a close look at current devices and methods. *Curr Pharm Des* 2015; 21:709–718.
56. Sharman JE, Avolio AP, Baulmann J, Benetos A, Blacher J, Blizzard CL, *et al*. Validation of noninvasive central blood pressure devices: ARTERY Society task force consensus statement on protocol standardization. *Eur Heart J* 2017; 38:2805–2812.
57. Kumar N, Khunger M, Gupta A, Garg N. A content analysis of smartphone–based applications for hypertension management. *J Am Soc Hypertens* 2015; 9:130–136.
58. Goldberg EM, Levy PD. New approaches to evaluating and monitoring blood pressure. *Curr Hypertens Rep* 2016; 18:49.
59. Bilo G, Zorzi C, Ochoa Munera JE, Torlasco C, Giuli V, Parati G. Validation of the Somnotouch-NIBP noninvasive continuous blood pressure monitor according to the European Society of Hypertension

International Protocol revision 2010. *Blood Press Monit* 2015; 20: 291–294.
60. Raichle CJ, Eckstein J, Lapaire O, Leonardi L, Brasier N, Vischer AS, Burkard T. Performance of a blood pressure smartphone app in pregnant women: the iPARR trial (iPhone App Compared With Standard RR Measurement). *Hypertension* 2018; 71:1164–1169.
61. Chandrasekhar A, Kim CS, Naji M, Natarajan K, Hahn JO, Mukkamala R. Smartphone-based blood pressure monitoring via the oscillometric finger-pressing method. *Sci Transl Med* 2018; 10:eaap8674.
62. Butlin M, Shirbani F, Barin E, Tan I, Spronck B, Avolio AP. Cuffless estimation of blood pressure: importance of variability in blood pressure dependence of arterial stiffness across individuals and measurement sites. *IEEE Trans Biomed Eng* 2018; 65:2377–2383.
63. Mukkamala R, Hahn JO, Inan OT, Mestha LK, Kim CS, Toreyin H, Kyal S. Toward ubiquitous blood pressure monitoring via pulse transit time: theory and practice. *IEEE Trans Biomed Eng* 2015; 62: 1879–1901.
64. Nair D, Tan SY, Gan HW, Lim SF, Tan J, Zhu M, *et al*. The use of ambulatory tonometric radial arterial wave capture to measure ambulatory blood pressure: the validation of a novel wrist-bound device in adults. *J Hum Hypertens* 2008; 22:220–222.
65. Lee SS, Nam DH, Hong YS, Lee WB, Son IH, Kim KH, Choi JG. Measurement of blood pressure using an arterial pulsimeter equipped with a Hall device. *Sensors* 2011; 11:1784–1793.
66. Wang C, Li X, Hu H, Zhang L, Huang Z, Lin M, *et al*. Monitoring of the central blood pressure waveform via a conformal ultrasonic device. *Nat Biomed Eng* 2018; 2:687–695.
67. Shuren J, Patel B, Gottlieb S. FDA regulation of mobile medical apps. *JAMA* 2018; 320:337–338.
68. WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices: WHO Medical device technical series 2017. https://www.who.int/medical_devices/publications/global_model_regulatory_framework_meddev/en/. [Accessed 28 January 2019].
69. US Food and Drug Administration: regulatory harmonization and convergence. https://www.fda.gov/BiologicsBloodVaccines/InternationalActivities/ucm271079.htm. [Accessed 26 January 2019].
70. British and Irish Hypertension Society. *BP monitors*. Leicester, UK: BIHS; 2017/2018 ; https://bihsoc.org/bp-monitors/. [Accessed 4 December 2018].
71. Hypertension Canada. *Blood pressure devices recommended by Hypertension Canada*. Markham, Ontario, Canada: Hypertension Canada; 2018 https://hypertension.ca/hypertension-and-you/managing-hypertension/measuring-blood-pressure/devices/. [Accessed 4 December 2018].
72. AMA. AHA developing list of validated BP monitors. https://wire.ama-assn.org/delivering-care/ama-aha-developing-list-validated-bp-monitors. [Accessed 15 August 2018].