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POLICY STATEMENT FROM THE WORLD HYPERTENSION LEAGUE

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The Accuracy in Measurement of Blood Pressure (AIM-BP) collaborative: Background and rationale

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This project is unfunded. Raj Padwal is Co-Founder and CEO of mmHg Inc, a University of Alberta based startup creating software and hardware solutions to improve blood pressure measurement. Richard J McManus has received BP monitors for research purposes from Omron. Norm Campbell was a paid consultant to the Novartis Foundation (2016-2017) to support their program to improve hypertension control in low- to middle-income countries which includes travel support for site visits and a contract to develop a survey; 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). Bruce Alpert is a consultant for development of BP technology for Welch Allyn/

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Hill Rom, Midmark, and Aktiia. Donald DiPette serves as a consultant to the Centers for Disease Control (CDC), World Health Organization (WHO), and the Pan American Health Organization (PAHO). Michael Hecht-Olsen received a part-time research grant from Novo Nordic Foundation (2013-2018). Michael Rakotz and Gregory Wozniak are employees of the American Medical Association. Aletta Schutte has received speaker honoraria from Novartis, Omron, Takeda, and Servier and paid consultative advice to Abbot Pharmaceuticals. She is funded by the South African Medical Research Council and National Research Foundation (SARChI). James Sharman has no personal disclosures; however, his university has received equipment and research funding from manufacturers of BP devices including AtCor Medical, IEM, and Pulsecor (Uscom). Kei Asayama is a consultant for Omron Healthcare. Richard McManus is Chair of the British and Irish Hypertension Society BP measurement working party and has received BP monitors for research use from Omron, and his institution has received research grants from The National Institute for Health Research (NIHR) and Stroke Association/British Heart Foundation for work on self-monitoring of hypertension.

Blood pressure (BP) measurement, a technique first described over a century ago, is an essential component of clinical care and critical for the detection and management of hypertension.¹ Accordingly, the ramifications of inaccurate BP measurement, which is a persistent and pervasive problem worldwide, are profound.² Assuming a global prevalence of hypertension of 1.4 billion,³ a 5-mmHg error in BP measurement has been estimated to result in the incorrect classification of hypertension status in at least 84 million individuals worldwide.⁴ In addition, incorrect classification has important ramifications for individual patients, whether it leads to misdiagnosis and inappropriate prescribing of antihypertensive drugs, or to lack of recognition of an clinical condition that can cause devastating cardiovascular consequences. The continued rise in the global prevalence of hypertension has made work related to optimizing BP measurement even more critical, and notwithstanding similar initiatives that have been conducted or are ongoing, additional efforts to improve BP measurement on a global scale are clearly needed.⁵

The Accuracy in Measurement of BP (AIM-BP) Collaborative, which has been formed to advance and amplify past and current work, is focused on advocating for and implementing optimal BP measurement practices globally. This collaborative is intended to be complimentary, and not competitive to, existing efforts in the field of BP measurement. The Lancet Commission on Hypertension Group and the World Hypertension League are lead organizations. AIM-BP is comprised of academics, clinicians, professional societies, non-governmental organizations, and additional stakeholders that have expertise and interest in the field of BP measurement. An advisory group of members from industry has also been created because these stakeholders can make important contributions, but their input remains independent of priority setting. Three major initial objectives have been identified: 1. publish a series of articles in the Journal of Clinical Hypertension detailing developments and challenges in the field; 2. host a webpage on the World Hypertension League website that summarizes critical information and resources for clinicians and patients; and 3. advocate for policies that are supportive of accurate BP assessment (eg, certification of training in BP assessment, accreditation of health facilities, mandating use of validated BP devices, etc). It is expected that this work will catalyze further initiatives and collaborative efforts moving forward.

Many unresolved issues and challenges exist in the field (Table 1). Lack of performance of standardized measurement in clinical settings continues to be a major contributor to inaccurate BP measurement.⁴ Use of validated, automated devices and protocolized technique is recommended to simplify the measurement process, ensuring closer adherence to recommended practice. Training of observers (healthcare providers measuring BP) is critical but needs to be done efficiently and with little or no added cost. An example is to use short, simple, web-based, whiteboard animation educational videos to summarize the essentials of BP measurement. These can be quickly viewed and reviewed as needed. A series of videos on this topic has been produced at Johns Hopkins University, and these are easily and freely accessible (https://www.youtube.com/watch ?v=T9J3RE4Eins). Dissemination of these resources and translation into multiple languages are needed to reach the global audience. Similar videos could be made to provide guidance on related topics in BP measurement—such as describing how best to implement a BP measurement station in a busy clinic to maximize accuracy and clinical efficiency.

Another major issue of interest is use of automated BP measurement, which is the primary method recommended for simplifying the BP measurement process. Clinical validation of these oscillometric BP measurement devices to confirm accuracy relative to blinded, two-observer auscultation should be performed before such devices are released into the market. Unfortunately, this is not mandated by global regulatory agencies, and consequently, many devices available worldwide are not validated.⁶ The widespread availability of unvalidated oscillometric devices is a major barrier to accurate BP measurement. Additional important issues that require clarification (Table 1) include achieving consensus on which clinical validation protocols should be used, determining how best to make validated device listings available to clinicians and patients in a user-friendly format that is locally relevant, and empowering local contract research organizations to perform validations at a cost that does not deter manufacturers from performing such studies.

With increasing emphasis being placed on out-of-office BP measurement as the preferred means of diagnosing and following up patients with hypertension, there is a need to ensure that recommended procedures for performing home BP and 24-hour ambulatory BP monitoring are followed.⁷⁻⁹ Recently published data have confirmed that patients do not often follow proper home BP measurement and reporting protocols.¹⁰ While a substantial amount of effort has been invested in outlining procedures for out-of-office BP measurement, relatively little time has been spent on implementing mechanisms that enable these procedures to be done correctly and this is expected to be an additional focus of AIM-BP.

The need for an easy to access, free central repository for the general public, patients, and physicians that summarizes reliable and essential information and displays links to useful resources is clear. Providing a venue to promote regional, national,

TABLE 1 A	AIM-BP collaborative	priority areas in	BP measurement
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Category	Item
Automated (oscillometric) devices	 Clinical validation Improving validation standards and device accuracy assessment Adopting and implementing new standards and retiring old protocols Comparing/contrasting existing and forthcoming regional and global validated device listings Identifying and removing barriers to performing validation, particularly in low- to middle-income settings (eg, cost, insufficient training) Identifying reputable centers in different countries that perform validation studies. Facilitating access to validation information for end-users (clinicians, patients, general public, researchers) Assessing accuracy in special populations (eg, children, pregnancy, arrhythmia, vascular disease) Strengthening regulatory requirements for approval Identifying best practices for static calibration
Self-measurement of BP	 Ensuring optimal technique (including proper cuffing) Improving device accuracy in individual patients Need for individualized algorithms Patient-specific calibration Emerging modalities (e.g., "cuffless" devices and continuous measurement) Optimizing recording, summarizing, reporting, and interpreting Removing barriers to access
Measurement by observers (clinicians)	 Ensuring recommended technique (in-office, ABPM, in-pharmacy). Providing training, certification, and ongoing maintenance of competence in a format that is free, accessible, and efficient. Using team-based care and telemonitoring. Transitioning care from childhood to adulthood
Global initiatives and sharing of best practices	 Promote regional, national, and international BP measurement accuracy improvement initiatives Advocate for governmental regulation of devices and policies to require certification of health care professionals Advocate for changes to health care facility accreditation that facilitate accurate BP assessments Detail and discuss reimbursement-related initiatives Discuss regional and country-specific challenges in BP measurement.

and international initiatives aimed at improving BP measurement is also a necessary element for a successful program. In this regard, the participation of the Lancet Commission on Hypertension Group, Journal of Clinical Hypertension, and World Hypertension League in the AIM-BP collaborative is of critical importance because these entities are committed to the open access of information and dedicated to improving hypertension on a global level. It is important that information be presented in an actionable and user-friendly format.

A foundational element of AIM-BP is that it is an inclusive and collaborative initiative. As such, membership is open, and we invite individuals or entities with an interest in promoting evidence-based, accurate BP measurement to join. Although much needs to be done, we anticipate that our combined efforts will result in improved BP measurement and, ultimately, better diagnosis and assessment of BP-related conditions on a global scale.

AIM-BP ORGANIZATIONAL MEMBERS

World Hypertension League (lead), Lancet Commission on Hypertension Group (lead), American Medical Association, Hypertension Canada, British and Irish Society of Hypertension, Japanese Society of Hypertension, and Danish Hypertension Society.

AIM-BP INDUSTRY ADVISORY MEMBERS

David Quinn (Hillrom), Josh Sarkis (PharmaSmart), and Jim Li (Omron).

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