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SPECIAL ISSUE

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Achieving reliable blood pressure measurements in clinical practice: It's time to meet the challenge

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A summary of statements for blood pressure (BP) measurement in the evaluation of hypertension in the 21st century by 25 international experts is provided. The status of office, home and ambulatory BP measurement techniques are discussed. Office BP measurement, whether automated (preferred), or otherwise, should only be used as a screening measurement, and diagnostic decisions for the initiation and titration of drug treatment should be based on out-of-office measurements (ambulatory or home). The hardware and software requirements and the adaptations of BP measuring devices to record other cardiovascular functions, such as arrhythmias, and adaptations for smartphone use and for electronic transmission are discussed. Regulatory bodies are urged to make accuracy and performance assessment mandatory before marketing BP measuring devices. The legal implications of manufacturing inaccurate devices are noted.

1 | INTRODUCTION

When the editor of the *Journal of Clinical Hypertension*, Michael Weber, invited us to coedit an issue of the journal devoted solely to the measurement of blood pressure (BP) in evaluating hypertension, he was acknowledging the uncomfortable reality that after more than a century of measuring BP, we do not yet have an agreed and accurate methodology on which to base the diagnosis and management of an illness that is the main underlying cause of cardiovascular disease, recently dubbed "the largest epidemic ever known to mankind."[1]

Indeed, this refrain is a recurrent issue in this anthology of measurement. The measurement of BP is the most common procedure performed in clinical medicine. BP is measured in general practice offices, in emergency departments, hospital clinics serving varying specialties, ambulances, airplanes, workplace offices, pharmacies, entertainment venues, people's homes throughout the general population, and it is a necessary measurement for insurance, pension, and employment assessments. Self-measurement is used increasingly by a healthy public as an indicator of well-being and fitness and by those with hypertension as a means of assessing progress, the response to treatment, and the adequacy of hypertension control. However, the performance of this measurement is often taken for granted and even in the scientific literature the methodology of BP measurement used is often inadequately described or not referenced at all.

Consequently, with a billion patients worldwide suffering from hypertension, there is now serious concern that the measurement on which so much depends may often be inaccurate and misleading. The 2017 American College of Cardiology/American Heart Association (ACC/AHA) guidelines on the management of hypertension, which recommend a reduction in the level of BP at which hypertension is diagnosed, will have the effect of changing the status of millions of "healthy" people across the globe into "hypertensive patients."[2] As the threshold for hypertension diagnosis is reduced and more aggressive BP control is recommended, the accuracy in assessing the BP level becomes even more important in order to prevent the consequences of overestimating BP and prescribing excessive treatment. It is imperative and timely, therefore, to reassess the methodology of BP measurement and to alert those who measure BP (healthcare practitioners) and those whose future may be decided by having BP measured (the public, our patients) that the phenotype on which so much depends is a variable physiological phenomenon that denotes either normotension, when the BP is below a certain and rather arbitrary level, or a pathological entity (ie, a disease) when it exceeds this level, and that the transformation from normality to abnormality depends exclusively on the technique of BP measurement.[3] Indeed, as doctors, we must constantly remind ourselves that our task is to treat patients with the complex syndrome of hypertension rather than merely reducing the phenotype of BP.[4]

2 | BP MEASUREMENT GUIDANCE FOR THE 21ST CENTURY

The purpose of this issue of the *Journal of Clinical Hypertension* (in which 27 experts from across the world express their views in 13 statements) is not to describe the detail of the different measurement techniques (this has been done elsewhere) but rather to provide a forum in which to summarize the current status of BP measurement and, most importantly, to lay down recommendations for the future.

Inevitably, in such an endeavor there will be some repetition of expression (not always an undesirable occurrence), but, remarkably, there is unanimous agreement among all contributors that although it is necessary to acknowledge the mistakes of the past, the resolve must be to ensure that these are not repeated in the future and that people who have their BP measured for whatever reason can be assured that the measurement will be accurate. In this paper, we summarize the recommendations as they apply to different groups of people involved in BP measurement.

3 | DISSEMINATION OF INFORMATION ON DEVICE ACCURACY

One of the dominant themes to emerge from this review is the past failure to communicate the findings of science to those people and authoritative bodies most likely to be affected by inaccuracy of BP measurement.[3,5-7] Many hundreds of important papers on BP measurement have been published over more than a half-century in scientific journals. However, in terms of disseminating information, this often merely amounts to the authors of such papers sharing knowledge with scientists, researchers, and interested clinicians who are already familiar with the shortcomings of BP measurement. Manufacturers may keep a watching brief on such publications confident that the scientific information (if negative) will not affect the consumer market of hospital and healthcare providers, retail outlets, such as pharmacies, and the ultimate consumer of their products, the public. Regulatory authorities, such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA), concentrate on the safety features of BP measuring devices but with inadequate attention being given to accuracy and performance characteristics. Moreover, recommendations from regulatory bodies can occasionally be so complex and ambiguous as to be unenforceable.[7] Recommendations from consumer organizations are often based on cost and cosmetic features rather than on the all-important feature of accuracy.[7]

So, how can communication be improved? Traditionally, the results of successful validation studies of BP monitors have been published in peer-reviewed scientific journals or presented at scientific meetings, which serve as a durable reference source, but such publications have little impact on most of the groups listed previously. A dominant recommendation is for the establishment of an organization with expertise in BP measurement to be overseen by an international board of scientists, which would be independent of funding from sources, such as device manufacturers, that might constitute a conflict of interest. The remit of such an organization would be to provide regular information on the accuracy and performance of BP measuring devices to the relevant audiences using the most effective media format - website, social media, publication, etc. - to reach the appropriate device purchasers.

4 | GENERAL RECOMMENDATIONS TO CLINICIANS AND RESEARCHERS

The first important message for practicing doctors, scientists, and researchers is that inaccurate measurement of BP has been tolerated for nearly a century and that the time has come to redress the situation. Even in the research setting, so-called "gold standard" devices have been shown to be inaccurate (examples being the Hawksley Random-zero Sphygmomanometer and the London School of Hygiene Sphygmomanometer.)[3] Influential clinical trials have been conducted and scientific papers have been published with conclusions based on results from inaccurate devices and often without stipulating the methodology of BP measurement, and devices have been endorsed as accurate despite having failed to adhere to the international protocols. An example was the Hypertension Optimal Treatment (HOT) outcome study in 18 790 patients followed for 3.8 years,[8] in which the purpose was to define the optimal BP goal with antihypertensive drug therapy, but BP measurements were made using a device that was validated for accuracy only at the end of the study with a questionable protocol.[9]

Unfortunately, even today, most of the devices available for measuring BP are inaccurate with only about 1 in 5 BP measuring devices on the market having been subjected to independent validation using an established protocol.[5,6] An important observation is that the authorship of general hypertension guidelines is often composed of experts in hypertension who do not necessarily have expertise in BP measurement, and, as a result, levels of BP are used as management or treatment thresholds without reference to the method of measurement. Indeed, this lack of expertise in measurement is also evident in published research papers on hypertension where the reviewers have failed to question the inadequately described methodology of measurement or have not sought published confirmation of the accuracy of the BP measuring device used.[6]

So, what can be done? Several validation protocols with the common purpose of improving the accuracy of BP measurement have been developed over the last 3 decades. The recent agreement between the US Association for the Advancement of Medical Instrumentation, the European Society of Hypertension, and the International Organization for Standardization to develop a universal protocol (AAMI/ESH/ISO) that will supersede all previous protocols is a landmark initiative.[10,11] International efforts need to be intensified, aiming to improve the clinical validation process and to ensure that the proposed protocols are feasible for wide use. Protective measures should be implemented to prevent protocol violations and conflicts of interest, and to ensure strict adherence to protocols and objective and unbiased reporting of results. The flawed peer review process permitting publication of papers that have violated protocol procedures should be replaced by online validation from a central center of excellence in BP measurement

with compulsory adherence to the protocol. Validation laboratories should be accredited and the aim should be to have an independent metrological organization to supervise centers testing BP measuring devices. Comprehensive listings of accredited devices should be circulated widely and regularly to both scientists and the wide public of users as discussed previously. All scientific papers on hypertension must cite published evidence that the methodology of BP measurement is acceptable and that the devices used have been independently validated.[6,11]

5 | RECOMMENDATIONS ON THE METHODOLOGY OF BP MEASUREMENT

Office blood pressure measurement (OBPM)

There is agreement that office blood pressure measurement (OBPM) will remain the commonest method of BP measurement in general use. However, although in the past it was used for the initiation of treatment and to guide the titration of therapy, it is now stipulated that it should be used only as a screening technique, with out-of-office measurements being required before diagnostic or therapeutic decisions are made.[12-15] There is general acceptance that in the past the term "office blood pressure measurement" has been used indiscriminately and loosely to describe an unstandardized measurement. Apart from the failure to standardize OBPM, the technique is subject to 2 major environmental influences that make it unrepresentative of the true BP, namely the white coat response (giving misleadingly high office measurements in the face of normal daytime average pressures), and masked hypertension (giving misleadingly low office measurements in the face of elevated daytime average pressures). These shortcomings have bedeviled scientific papers and guideline recommendations for the diagnosis and management of hypertension.

In recent years, there has been a fundamental change in the methodology of OBPM from the traditional auscultatory technique (requiring usually a mercury sphygmomanometer, a stethoscope, and a trained observer) to automated oscillometric measurement (using a validated device that may provide the average of a number - usually 3 - measurements, a printout, and/or a facility for teletransmission of measurements, an automated memory to store data, and little training of the observer required). Inevitably (and, indeed, sadly for many physicians who value this show of expertise in the clinical interaction between doctor and patient), the auscultatory technique of BP measurement, which was introduced to medicine in 1910, is now destined for the historical archives.[3]

The advent of automated devices has generated a new methodology for OBPM, named automated office blood pressure measurement (AOBP), which reduces the white coat effect and gives measurements close to average daytime pressures obtained through ambulatory BP monitoring (ABPM) or home BP monitoring (HBPM). AOBP can be either attended or unattended by a physician (or nurse). Unattended AOBP has the disadvantage of requiring more resources (separate room for measurement and more time for the procedure), whereas attended AOBP can be applied more readily in the average general practice or hospital clinic environment. Whereas more evidence is required on the threshold levels of BP for AOBP, the methodology (either physician attended or unattended) does standardize methodology and is recommended for future OBPM. The usual recommendations for accurate measurement of BP apply to AOBP; these include using only validated upper-arm cuff devices, having the patient seated in silence with legs uncrossed, and using the appropriate cuff size.[12,16]

Out-of-office blood pressure measurement

Most international guidelines now recommend out-of-office BP measurement before making diagnostic or management decisions for patients suspected of having hypertension based on office (or other) BP measurement. There are 2 methodologies for out-of-office measurement: 24-hour ABPM and HBPM.[13,14,17]

ABPM

ABPM is recommended internationally as the superior method (gold standard) for out-of-office measurement, because it identifies white coat and masked hypertension, provides nocturnal blood pressure levels (perhaps the most sensitive predictor of cardiovascular outcome) and nighttime patterns (dippers, nondippers, excessive and reverse dippers, morning surge), identifies adverse daytime patterns such as hypotension (idiopathic or due to excessive treatment, a siesta dip or postprandial fall), and can also provide important clinical information related to other hemodynamic parameters, such as heart rate, blood pressure variability (standard deviation, coefficient of variation, and other indices), arterial stiffness (ambulatory arterial stiffness index), and pulse pressure. Certain patterns, for example nocturnal hypertension, may be associated with other illnesses, such as sleep apnea.[18]

So, what messages can we take from deliberations that are unanimous in recommending ABPM as the best method of BP measurement? First, the technique needs to be readily accessible and implemented widely in clinical practice and this can be best achieved by the availability of inexpensive accurate devices and by reimbursement from healthcare systems and insurance companies. Increased short-term costs will be offset by the long-term benefits of much improved BP control. However, there are drawbacks in this approach. In Ireland, for example, generous reimbursement has been provided to primary care general practitioners (€60 per ABPM without any qualifying preconditions), and although reimbursement has undoubtedly increased the availability of the technique, it has resulted in a large increase in the marketing of ABPM devices, many of which have not been validated for accuracy. This occurrence again emphasizes the need to provide regular authoritative information on BP device accuracy and performance to users.

HBPM

HBPM is a popular, relatively inexpensive technique, which provides multiple measurements in the patient's usual environment, and it has been shown to be superior to OBPM but inferior to ABPM in that it cannot provide patterns of measurement during the day or

measurements at night (although some recently manufactured monitors can provide nighttime measurements). However, the technique can provide measurements similar to daytime ABPM and it seems to be more suitable and acceptable to users than ABPM for the long-term follow-up of treated hypertension. A schedule of twice daily measurement over 4-7 days must be followed if HBPM is used for deciding drug treatment initiation or adjustment, whereas 1 or 2 measurements per week are appropriate for long-term follow-up. Use of the technique has been shown to improve patient adherence to drug treatment and thereby hypertension control rates, and it may be helpful for adjusting drug treatment, especially if combined with data storage and teletransmission of BP measurements to a center of expertise.[19]

In summarizing the status of out-of-office BP measurement, a paradox of recommendation becomes evident, whereby ABPM is accepted as being superior to all other methods of measurement, but because of the expense and limited accessibility to the technique, compared to the availability and relatively low cost of HBPM, the latter is recommended in practice.[20] Logically unacceptable though this paradox may be, it is representative of practice and the means of overcoming the anomaly must be addressed.

6 | RECOMMENDATIONS TO REGULATORY AUTHORITIES AND CONSUMER ORGANIZATIONS

A need for clarity in the recommendations from these bodies is now considered to be imperative.[3,5-7] First and foremost, regulatory authorities, such as the FDA and EMA, must now seriously consider accuracy and performance of BP measuring devices, rather than focusing solely on the safety requirements, as is the practice at present. This current absence of mandatory accuracy approval is understandable given that the safety of a device is paramount and that the expertise required to assess accuracy is not readily found in-house. However, it is now time for mandatory accuracy validation with the universal protocol from AAMI, ISO, and ESH before marketing BP measuring devices. Consumer bodies tend to focus on the cost and cosmetic features of BP measuring devices with the result that very many of the devices on sale in pharmacy and health retail outlets are either untested for accuracy, or are inaccurate. These deficiencies again emphasize the need for an independent organization of measurement excellence capable of providing expert opinion on device accuracy to bodies that have substantial influence on the public use of BP measuring devices.

7 | RECOMMENDATIONS TO MANUFACTURERS

Device accuracy

Manufacturers, who produce the BP measuring devices on which the science and practice of medicine relating to over a billion hypertensive people worldwide are dependent, must accept that the medical profession, which is responsible for diagnosing and treating patients with hypertension, have a particular obligation to clinical practitioners and the public to ensure that only accurate BP measuring devices are used.

The regular provision of lists of validated devices to the vast array of consumers interested in BP measurement is one way in which potential purchasers of BP devices can be alerted to device accuracy. The need for independent validations of BP measuring devices is emphasized many times in this issue, as well as the need for validation in special populations, such as children, pregnancy, patients with atrial fibrillation and people with very large arms.[21]

Device cost

The market for BP measuring device ranges from the very inexpensive devices for HBPM to moderately expensive automated devices for OBPM to very highly priced devices for ABPM. The cost of some ABPM devices is prohibitively exorbitant and mitigates against the wider use of the technique.[3] Manufacturers must be urged, therefore, to reduce the cost of BP measuring devices without compromising accuracy.

Device for BP measurement in all circumstances

The present state of measurement technology should permit manufacturers to produce an accurate, inexpensive, comfortable device suitable for measurement in a particular circumstance (office, home, or over 24 hours) rather than marketing devices for a particular use.

Hardware and software requirements

Devices for OBPM should be capable of automatically recording and storing on memory 3 (or more) measurements with single activation, averaging these, and giving a mean value.[12] Devices for HBPM should have an automated memory capacity to store measurements and automated averaging, and preferably they should be capable of teletransmission.[14,19] Devices for ABPM could be greatly improved by having all the device functions (pump, display, memory) incorporated on the arm cuff, thereby removing the need for restricting tubing connected to a device strapped to the waist. The software for ABPM should be standardized and provide a single-page report and a trend report of repeated recordings to allow progress to be easily assessed.[13,17]

Incorporation of new methods and technologies

Manufacturers of all forms of BP measuring devices should be prepared to incorporate new functions/measures (blood pressure variability, pulse wave velocity, central blood pressure, atrial fibrillation detection, etc.) and novel technologies, such as smartphone apps, in their devices but all such developments must be carefully evaluated for accuracy and clinical usefulness.[19]

Legal obligations

The precedent for manufacturers to be held legally responsible for selling inaccurate devices has been established, and the potential of legal consequences of providing medical information from a BP measuring device that has not been subjected to independent validation should be taken seriously by manufacturers.[7] This issue of the *Journal of Clinical Hypertension* states clearly the medical requirements for accurate BP measurement, and emphasizes the need for users to be provided with accurate BP measuring devices.

8 | RECOMMENDATIONS TO THE PUBLIC AND OUR PATIENTS

Many of the authors of this issue have expressed the need to inform the worldwide population with hypertension, many of whom are our patients, of the importance of accurate BP measurement, which can be achieved only with accurate devices and careful attention to the methodology and circumstances of measurement. Certain groups require information to suit their needs - children, the very elderly, pregnant women, patients with other cardiovascular diseases such as diabetes and atrial fibrillation, and patients in low resource settings. We hope that this special issue on BP measurement lays down the necessary requirements for measuring the parameter on which all decisions for the diagnosis and management of hypertension are dependent.

CONFLICT OF INTEREST

EOB and GSS have conducted validation studies for various manufacturers and advised manufacturers on device development. ED has nothing to declare.

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