Guidelines for the use of self-blood pressure monitoring: a summary report of the first international consensus conference

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Introduction

The present guidelines come at a critically important time for the management of hypertension and particularly for the use of the blood pressure measurement methods. In fact, the last international guidelines for the management of hypertension highlighted the need of a precise estimation of the global cardiovascular risk stratification in individuals [1,2]. This estimation has to be performed on the basis of accurate blood pressure assessment in the clinic. Concurrently, considering the variability of the blood pressure, they recommended the use of blood pressure measurements outside the doctor office (home or ambulatory monitoring) to overcome some of the limitations of the clinic blood pressure measurements in specific situations. Beside these general aspects and indications, no specific guidelines have been recommended for the use of these methods and especially the home or self-blood pressure monitoring (selfBPM).

Moreover, the present guidelines come at a critically important time for the methods of measuring blood pressure. In fact, we have experienced an extraordinary advance and development of the methodological aspects of blood pressure measurements over the last decade which may be related to different reasons: the possibility that the use of the so-called classic mercury sphygmomanometer is restricted and mercury banned from clinical use in the near future because of its toxicity; the extraordinary development of computer processing, microprocessors and their miniaturization which allows their integration in suitable devices; the publication of official standards which define the general and specific requirements for non-invasive sphyg-

momanometers, and the recent obligation to obtain EC certification for all marketable medical equipment in Europe. One of the consequences of this remarkable development is the availability of automated devices, which not only measure blood pressure at different arterial sites, but also allow measurements to be stored, thus providing a better documentation of blood pressure measurements over time.

The present guidelines also come at a critically important time for the prevention of cardiovascular disorders. In fact, it is well established that successful management of chronic disease, such as hypertension, is considerably facilitated by the active involvement of the patient in his treatment procedure. This personal involvement, which influences the compliance to the treatment, is usually obtained by patient education and information about his/her disease. In this regard, the different public health programmes of cardiovascular prevention are modifying the role of practitioners to become providers of information and education to the patient who should become an active participant in his/her health care management. The result of these changes in health management is the continuing increase of the sale of electronic blood pressure measuring devices designed for self-measurement, an increase that is largely independent of any medical influence. Despite the large use of selfBPM, measurements are almost never performed according to accepted protocols and guidelines, because of inadequate training and lack of information for both doctors and patients. Therefore, there is a need for guidelines, information and training of doctors and other healthcare providers as well as information and patient training programmes.

Purpose and scope of guidelines

The purpose of the present guidelines is to establish the first consensus document on selfBPM. The guidelines are written to inform physicians and other healthcare providers on available evidence and experts' opinions on the use of selfBPM. Part of this document may also be used for patient information and training programmes. These guidelines concentrate on the pragmatic aspects of the use of selfBPM. They do not deal with the technical details of selfBPM devices and their algorithms, or with the economical aspects and impacts of using selfBPM and possible reimbursement by public health systems or private insurance.

Methods

Rigorous methodologies have been suggested for the preparation of guidelines, which categorize the strength of available evidence according to rigid criteria [3–4]. Many experts, however, do not agree with this approach [5–6], which appears particularly difficult to follow when evaluating information on selfBPM, an area where that evidence-based medicine considers to be the most solid evidence, namely data from randomized controlled trials of sufficient power and their meta-analyses, are not available. Nonetheless, objectivity was attempted by carrying out an extensive retrieval of published data, and by establishing task forces to prepare and discuss separate documents on specific topics.

Retrieval of published data was performed by identifying in computerized databases (Medline and Embase) and personal literature, relevant English language articles on the subject of home or selfBPM. Research was performed on the last 10 years using the following keywords: blood pressure measurement, blood pressure determination with the subheadings: validity, reliability, methods, instrumentation, patient education, self-care, validation, devices. Additional and crossing matched keywords were used to search for appropriate publications in accordance with the specific subject of each task force or subcommittee group. Only non-invasive methods, clinical and cohort studies with normotensive as well as treated and untreated hypertensives, were selected.

The various topics related to the use of selfBPM were divided into six different subjects each to be treated by one task force. Each task force comprised two chairmen and three to four jury members. For each task force, a number of questions and topics related to its specific subject were suggested. Each task force submitted a proposal for consensus guidelines. The proposal of the various task forces was circulated to all the participants before the consensus conference. During the conference, the chairmen of each task force presented the arguments in support of the consensus proposal. Pre-sentations were followed by an open discussion with all the participants, and the manuscripts amended accordingly, and finally reviewed by experts as well as by relevant organizations.

Devices and validation

As we approach the end of the 20th century, we are assisting the birth of a new era in blood pressure measurement. Automated devices that provide an assessment of blood pressure behaviour over time are now available. The sale of electronic devices designed for selfBPM is not necessarily subject to medical influence. This growing public desire to know more about health, has resulted in the marketing of a vast array of such devices, few of which have been evaluated according to the procedures considered necessary for blood pressure measuring equipment. Recommendations on these devices, their validation procedure and the identification of those which have been satisfactorily validated, are summarized hereafter.

Developments which may influence devices
Banning mercury
Mercury is likely to be banned from clinical use in the near future because it is a toxic and bioaccumable substance [7]. Participants in the 'Final declaration from the third International Conference on the Protection of the North Sea' have resolved to reduce mercury to 'levels that are not harmful to man or nature before the year 2000' [8]. The result of this change is that hospitals and doctors may replace mercury sphygmomanometers with unreliable and inaccurate devices. In fact, many automated devices have had a poor record for accuracy, whereas others have satisfied the stringent criteria of the validation protocols of the British Hypertension Society (BHS) and the Association for the Advancement of Medical Instrumentation (AAMI) [9,10].

Replacing the millimetre of mercury with the kilopascal?
Banning mercury from clinical use raises another issue of importance for clinical medicine. The *Système International* (SI) unit for pressure is the kilopascal (kPa), and although the use of this unit for blood pressure has been postponed in favour of mmHg [11], we may face a strong pressure by regulatory authorities to adopt the kPa if mercury manometers are banned. Before a movement in direction of the kPa is accepted, or resisted, careful consideration should be given to the consequences that a sudden change of reference numbers will have on doctors' performances and patients' understanding and compliance.

Solving the cuff controversy
As accurate as we strive to make devices for self-measurement of blood pressure, there will remain one inherent inaccuracy, namely that induced by miscuff-

ing. Undercuffing has the effect in clinical practice of overdiagnosing hypertension and overcuffing leads to hypertensive subjects being diagnosed as normotensive [12]. A number of approaches have been used over the years to cope with the difficulty of mismatching; none of them has been fully satisfactory. The design features for an 'adjustable cuff', which would be applicable to all adult arms was proposed and is now being tested [12].

New technologies
At present, automated blood pressure measuring devices rely, almost exclusively, on either auscultatory detection of Korotkoff sounds using one or more microphones, or oscillometric analysis of the pulse waveform. However, there has been such a significant shift from auscultatory to oscillometric devices in the last decade that it may be anticipated that, in the near future, microphone recording of sounds will no longer be used and that some of the other innovative methodologies will be applied to the selfBPM.

Most devices for self-measurement utilize an occluding cuff placed either on the upper arm, a finger or the wrist; the latter site has become increasingly popular. One of the major problems, however, with wrist (and finger) devices is that of ensuring that the hand or wrist is kept at the heart level during measurement. If this is not done serious errors occur.

Present validation requirements
Safety and mechanical considerations
The European and the American standards provide criteria governing the safety aspects of blood pressure measuring devices [13–16]. The European Standard defines the general requirements of non-invasive blood pressure machines and the precision of the pressure calculated in the cuff, which should be of ± 3 mmHg at all levels of pressure. The EC directive 93/42/CEE relating to medical equipment requires each manufacturer to obtain EC certification, which certifies that the device has been subjected to quality assurance evaluation in conformity with written procedures [13–15].

Accuracy and performance characteristics
In 1987, the AAMI published a standard for sphygmomanometers, which included a protocol for the evaluation of the accuracy of devices; this was followed by the protocol of the BHS; both protocols have since been revised [9,10]. Though testing the precision of the overall system is not obligatory, it is highly recommended that blood pressure measuring devices should be subjected to such evaluation.

The international standard validation protocol
Proposed revision of BHS/AAMI protocol
It would seem appropriate for both the AAMI and BHS

to join together in producing a revised common protocol for the validation of blood pressure measuring devices which might be acceptable as an international standard validation protocol.

Simplification of the validation procedure
There are seven major areas in which the validation procedure might be modified:

Eliminating pre-validation phases Assuming (as it has been recommended above) that all devices for self-measurement have passed the ECS requirements to obtain an EU certificate, it is not necessary to subject these devices to the pre-validation phases.

Observer participation Observer recruitment and training could be improved and made less difficult by utilizing audiovisual technology to record comparative measurements. The Sphygmocorder has been designed to overcome these difficulties [17]. Since not all validation centres will have the Sphygmocorder, the protocol must give consideration to the role of education and certification of observers. Towards this end, two developments are to be welcomed. First, two CD-ROMs are available for training and assessing observers [18,19]. Second, Colson Ltd. (Paris, France) has developed an observer kit with two connected observer stations, each with a mercury column, steady deflation mechanism and a recording facility.

Reduction in number of recruited subjects Analysis of 19 validation studies has shown that reducing the number of subjects recruited from 85 to 33 is possible without affecting the accuracy of the validation. Thus the validation process may be divided into two phases: a primary phase in which three pairs of measurements are performed in 15 subjects in predefined pressure ranges, and a secondary phase, in which a further 18 subjects (total of 33) are recruited, in whom comparisons must fulfil the criteria shown in Appendix 1.

Relaxing the range of blood pressures Experience has shown that recruiting subjects at the extremes of high and low pressures is impractical. Making these requirements less stringent as shown in Appendix 1, with an equal number of subjects being recruited in each range would facilitate the validation procedure without unduly affecting results.

Eliminating 'hopeless' devices If a device does not satisfy the criteria shown in the primary phase (Appendix 1), it cannot fulfil the validation criteria and should be eliminated at this stage.

Computer analysis A software program, developed by the Groupe Evaluation & Mesure of the French Society

of Hypertension has been devised to provide a full statistical analysis, and to plot the data according to the recommended criteria.

Algorithm integrity and design modification   Devices using a validated algorithm might not need to be revalidated, provided that algorithm integrity can be proven.

Other considerations   Careful attention must also be given to validation of devices in special groups, such as the obese and the elderly.

State of the market

There is an enormous market for automated devices that permit selfBPM. However, the number of devices on the market for self-measurement which have fulfilled independent validation criteria is small; manufacturers must be encouraged to have their products evaluated according to recognized protocols [20]. Moreover, the state of the market needs to be assessed regularly with the results being easily accessible to prospective purchasers (Table 1).

Recommendations

(i) Automated devices for selfBPM should continue to provide blood pressures in mmHg, but addition of kPa may help preparation to a possible change in measurement units in the future.

(ii) If current testing gives satisfactory results, manufacturers should be encouraged to produce an 'adjustable cuff', which would be applicable to all adult arms.

(iii) Devices for selfBPM must have an EC certificate.

(iv) Devices for selfBPM should be subjected to independent accuracy validation under clinical conditions.

(v) The AAMI and BHS should finalize a common validation protocol that would effectively become the international standard protocol for the validation of all blood pressure measuring devices.

(vi) The Working Group on Blood Pressure Monitoring of the European Society of Hypertension should consider giving accreditation to laboratories with an interest and expertise in device validation.

(vii) An annual 'State-of-the-market' review listing the validated devices for selfBPM should be published.

Reference values: diagnostic thresholds

The association between blood pressure and cardiovascular risk is continuous without no threshold above which the risk suddenly increases. However, clinical decisions must be based on diagnostic or operational thresholds. In this regard, there is an agreement that the thresholds currently applicable for conventional sphygmomanometry, performed by a doctor or a nurse, cannot be extrapolated to automated measurements, particularly when operated at home by the subject. Different methodological approaches may be used for the approximate determination of threshold values. Some of them are based on statistical analysis of the observed values in normotensives and hypertensives; others are based on prognosis and the predictive power value for endpoint and surrogate measures for cardiovascular target organ damages. Since limited data are available on the prognostic value of selfBPM (cf. prognostic value of selfBPM), the proposals hereafter considered the statistical analysis approach, although admittedly this has serious limitations.

Table 1   Automated blood pressure measuring devices for self-measurement available on the market which have been subjected to validation by the BHS* and AAMI** protocols

Device	Mode	AAMI	BHS	Circumstance
Omron HEM-400C	Osc	Failed	Failed	Rest
Philips HP5308	Aus	Failed	Failed	Rest
Healthcheck CX-5 060020	Osc	Failed	Failed	Rest
Nissei Analogue Monitor	Aus	Failed	Failed	Rest
Philips HP5306/B	Osc	Failed	Failed	Rest
Systema Dr MI-150	Osc	Failed	Failed	Rest
Fortec Dr MI-100	Osc	Failed	Failed	Rest
Omron HEM-705CP	Osc	Passed	B/A	Rest
Philips HP5332	Osc	Failed	C/A	Rest
Nissei DS-175	Osc	Failed	D/A	Rest
Omron HEM 706	Osc	Passed	B/C	Rest
Omron HEM 403C	Osc	Passed	??	Protocol violation
Omron HEM-703CP	Osc	Passed	NA	Intra-arterial
Omron R3	Wrist	Passes	NA	Intra-arterial

Grades A–D according to BHS protocol; A = best agreement, D = worst agreement with mercury standard. Note that in the first seven devices grading criteria had not been established, though BHS protocol was in operation. *Criteria for fullfillment of BHS protocol: devices must achieve at least grade B/B. **Criteria for fullfillment of AAMI standard: mean difference ≤ 5 mmHg/SD ≤ 8 mmHg Osc, oscillometric mode; Aus, auscultatory mode; NA, not applicable; BHS, British Hypertension Society; AAMI, Association for the Advancement of Medical

Diagnostic thresholds in adults

Two meta-analysises attempted to determine an operational diagnostic threshold for selfBPM. A recent meta-analysis of the summary statistics of 17 published articles attempted to define these thresholds values [21]. Seventeen studies, including a total of 5422 subjects, were reviewed: eight studies included both normotensive and untreated hypertensive subjects, while nine others included only normotensives. For each study an operational cut-off point between normotension and hypertension was derived in normotensive subjects by adding 2 SD to the means of the self-recorded blood pressure and/or by determining the 95th percentiles of the distributions of the self-recorded blood pressure in normotensive subjects. The results of this meta-analysis showed that the selfBPM averaged 115/71 mmHg in normotensive persons and 119/74 mmHg in untreated subjects not selected on the basis of their blood pressure level. In normotensive subjects, cut-off thresholds for selfBPM determined from 95th percentiles (135/86 mmHg) or by adding 2 SD to the means (137/89 mmHg) were concordant within 2/3 mmHg. The second meta-analysis pooled data from individual subjects in an international database [22]. The 95th percentile of selfBPM in 2401 normotensive persons was 136/85 mmHg for the measurements obtained in the morning, 139/86 mmHg for those taken in the evening and 137/85 mmHg for selfBPM regardless of the time of day. This meta-analysis based on individual data concluded that a selfBPM above 137 mmHg systolic or 85 mmHg diastolic should be considered as hypertensive. This approach has the advantage of simplicity and of being founded on a large number of subjects from different countries. Its main limitations are the selection of the 'normotensive' subjects considered (if many of them are in the 'high normal' group, the reference values will be somewhat increased), and the fact that the upper level of normality for conventional blood pressure measurements has not been determined by calculating standard deviations or 95th percentiles.

In another approach, self-recorded blood pressure is regressed on conventional blood pressure to determine values corresponding to a conventional blood pressure of 140/90 mmHg [23]. The cut-off points derived by regression analysis with 95% confidence intervals (CI) were 124/79 mmHg and 130/83 mmHg, respectively. These thresholds observed with this statistical approach are somewhat lower than those observed using the meta-analysis methodology, but the upper values of the 95% confidence interval (CI) of the regression calculated threshold differ slightly from the 95th percentiles of the meta-analysis data [systolic blood pressure (SBP) 130 versus 135, and diastolic blood pressure (DBP) 83 versus 85 mmHg]. Of course, the regression analysis approach also has methodological limitations, one being

the fact that there is a considerable overlap between normotensives and hypertensives with regard to the distributions of their self-recorded blood pressure.

Considering the results mentioned here and the fact that determination of normality values using calculation methods includes more or less acceptable approximations, clinicians have to be aware of the limits of normal values determined on the sole basis of statistical evaluation. Therefore, such diagnostic thresholds need to be further validated in clinical trials and prospective outcome studies. Until prospective evidence becomes available, the more conservative value of self-measured blood pressure of 135/85 mmHg may be considered as the upper limit of normality. More prudent or more aggressive doctors may use the lower limit of 130/85 mmHg calculated from regression analysis.

Diagnostic thresholds in special populations

Some specific populations such as the obese, the elderly, pregnant woman, etc. may require special attention with regard to the use of selfBPM both in terms of its feasibility and its diagnostic thresholds. The need of specific validation protocols to assess the accuracy of the automated devices designed for selfBPM in these populations has been highlighted above.

Elderly

Studies have shown that automatic equipment is more precise and easier to use than semi-automatic equipment in elderly people [24]. Specific validation of automated devices in subjects over 65 years showed that devices such as the Omron HEM 722C and HEM 735C, satisfied the validation criteria of the BHS protocol and therefore can be used for selfBPM in elderly patients [25]. Recently, selfBPM has been shown to be acceptable by patients older than 75 years; feasibility is optimal in those patients in which the autonomic and cognitive functions are preserved and who were hypertensives [26]. Few data in regard to the reference values in this population are available. Using the regression method, selfBPM values of 133/82 mmHg have been reported as the upper limit of normality corresponding to the office pressure of 140/90 mmHg [27]. These values were concordant with the figure of 133/86 mmHg observed in the Dübendorp study [28]. Considering that these findings are in agreement with those observed in the adult population within 2/3 mmHg, the same thresholds proposed for the general adult population may be used in elderly patients.

Pregnancy

In pregnancy, home blood pressure values also have been found to be lower than those observed in the clinic. Several advantages have been reported in the

use of selfBPM by pregnant patients who have border-line or mild hypertension [29]. Several observations indicate that selfBPM is feasible in pregnancy, is particularly helpful to patients who live a long distance from the clinic and that devices using data offloading via telephone may be easily implemented. Despite these advantages to using selfBPM in pregnancy, there is paucity of data concerning the validation of the devices and the normal values in this population.

Recommendations

(i) Since limited data are available on the prognostic value of selfBPM, the present proposed diagnostic thresholds are obtained from statistical evaluation. Values of 135/85 mmHg may be conservatively considered as the upper limit of normality.

(ii) Determination of the selfBPM reference values should provide values of SBP and DBP, and also of other parameters such as heart rate and pulse pressure.

(iii) The proposed threshold values for selfBPM need to be further validated in prospective outcome studies on the prognostic value of selfBPM.

(iv) SelfBPM using automatic devices is feasible in elderly patients with preserved autonomic and cognitive functions. Until the results of prospective prognostic studies are available, the same threshold diagnostic values than those of general adult population may be considered.

(v) SelfBPM is feasible in pregnancy and is of value in the management of pregnant patients with hypertension. Studies to determine the reference normal values in this population are needed.

User procedure

During recent years, the use of self blood pressure measurements in diagnosing and treating arterial hypertension has considerably increased. Furthermore, the use of selfBPM as a complementary method of measuring blood pressure has been recommended by both national and international authorities, without any precise guidelines with regard to user procedure. To overcome this lack of information, the aim of this section is to provide recommendations on the following points: measurement procedure and protocol, documentation and data analysis, choice of the suitable device, patient and physician education.

Measurement procedure and protocol
Patient conditions
The recommendations for selfBPM regarding the patient conditions do not vary from existing guidelines for office blood pressure measurement. As a general rule, measurements are taken with the patient seated after a 5 min rest, with the device cuff maintained at the heart

level. The arm with the highest blood pressure level should be used.

Frequency of measurements
Frequency of measurements using selfBPM may vary according to the indication and the objective of its use. The validity of selfBPM is measured by the extent to which the blood pressure levels obtained can accurately predict the subsequent hypertensive target organ damage. This will be discussed below. Suffice to say that no study has analysed the number of measurements needed to maximize the prognostic value of selfBPM: such studies are needed. The reliability of selfBPM has been shown to be superior to office blood pressure measurements only if sufficient measurements are taken in each patient [30], and one study suggested that blood pressure should be measured a minimum of four times a day (twice in the morning and twice in the evening) for at least three working days [31].

Particular attention has been given to criteria for the best use of selfBPM in the evaluation of the effects of antihypertensive drugs, as reported subsequently.

Data report and analysis
The unreliability of selfBPM levels reported by patients themselves was recently shown in a study carried out using an automatic data storage system [32]. There was a tendency for the patients to reject both low and high blood pressure values from their logbook. Despite this discrepancy, the average values reported by the patients were generally similar to the true readings. Memory-equipped devices have the potential to reduce this observer bias.

Data obtained on the first day after the initiation of selfBPM and the patient instruction are significantly higher than those recorded during the following days and can be excluded from the analysis. Some studies provide information on the methods to define and handle outliers; the elimination of such values does not seem to affect significantly mean selfBPM calculations, but must alter their standard deviation. The use of devices with memory capacity is therefore recommended

Choice of an appropriate device
In most cases, the use of validated automated equipment for selfBPM is recommended. These devices, allow easy measurement of blood pressure, require a short-period for training and eliminate some bias of blood pressure determination, thus allowing theoretically more reliable measurements [33]. Patients should be informed of the need for calibration and maintenance of the equipment as well as the use of cuffs of suitable size. Preference should be given to apparatus using a brachial cuff and offering the possibility to store

or transmit or print measurements. Wrist instruments are to be considered with caution due to the risk of errors when used inappropriately (the wrist should be held at heart level), manual devices based on the auscultatory method are to be considered for patients suffering from irregular cardiac rhythm.

Training of doctors, nurses and patients

At present, selfBPM is performed mostly by patients on their own initiative using devices bought on the free market, without medical control [31]. On the other hand, the method is used in some specialized hypertension clinics but general practitioners are reluctant to advise its use, despite the official recommendations and a wide availability of instruments [34]. SelfBPM should be conceived as a method aiming to improve blood pressure control and treatment performed by motivated and informed patients, under the supervision of their doctor.

A prerequisite to selfBPM implementation is the completion of a specific training course by doctors, nurses and patients aiming to master the knowledge of blood pressure measurement. Training of doctors and nurses aims to achieve good clinical practice and to make them aware of frequent deviations from guidelines, to inform them on selfBPM with special emphasis on validated equipment and protocol in use, to provide information on the state of the market for automated devices and to train them in basic methods of adult education [35].

Training of patients should enable them to obtain valid blood pressure readings, improve their cardiovascular risk factors understanding and treatment compliance. Few patients are unable to perform selfBPM. Patients with physical problems, or mental disabilities that make them unable to perform or to understand the measuring technique, represent the limits of the method. Self-measurement is feasible in elderly patients provided that their cognitive function is preserved. SelfBPM has been accused of increasing anxiety in some patients, even though this fear appears to be more theoretical than real [36]. Practical recommendations on selfBPM are scarce, although those from the Canadian Coalition for High Blood Pressure Prevention and Control are among the most appropriate [36,37].

Recommendations

(i) SelfBPM should be performed after a period of rest of 5 min with the device cuff maintained at the heart level, on the arm with the highest blood pressure level.

(ii) Frequency of SelfBP measurements remains a matter of discussion. For clinical purposes, 2 measurements in the morning and in the evening for at least 3 working days as advised. This frequency will vary from one to several times a week, according to the severity of hypertension and the need for changing drugs or doses. For pharmacological studies, a higher frequency of measurement may be used.

(iii) Due to the lack of reliability of patients diaries, the use of printer or memory-equipped devices for selfBPM would be desirable. All the recorded data, with the exception of those obtained on the first day, should be used to calculate the mean selfBPM value which represents the most significant parameter.

(iv) SelfBPM should be performed with validated fully automated devices using a brachial cuff. A wrist instrument has to be considered with caution due to the risk of errors when used inappropriately. A manual device should be used by patients suffering from irregular cardiac rhythm. Reimbursement should be considered for hypertensive patients using validated devices, adequately trained and supervised.

(v) SelfBPM should be performed by trained patients under expert supervision. Training must be performed by skilled staff in hypertension centres and ultimately in general practice. SelfBPM may be recommended for hypertensive patients motivated into their health management. Patient education must include information about hypertension and cardiovascular risk, blood pressure measurement procedure, advice on equipment and their use, protocol and data interpretation. Patient proficiency must be checked. Annual reevaluation is desirable.

Usefulness of selfBPM in the diagnosis of hypertension
Usefulness of selfBPM in general conditions

The potential usefulness of selfBPM in the management of hypertension depends on its ability to overcome or avoid some of the limitations of clinical blood pressure measurements to assess an accurate blood pressure level.

An inherent physiological characteristic of blood pressure is its extreme variability over time. The biological sources of blood pressure variability are numerous: seasonal and circadian variations, short-term oscillations linked to respiratory frequency and to vasomotion, non-oscillatory changes due to physical and psycho-sensorial stimulations, etc. The 'white coat' effect also has to be considered as a particular feature of the link between blood pressure and psychological stress [38,39].

The accuracy of blood pressure measurement may be improved by increasing the number of clinical blood pressure measurements at a given visit, but very large ranges of SBP and DBP variations have been found over longer periods of time, along with large standard deviations of the differences in blood pressure from

visit to visit, resulting in an important regression towards the mean [40]. Therefore, more accurate blood pressure assessments may be obtained by increasing the number of visits, which is not easy to achieve in medical practice, or by increasing the number of occasions in which blood pressure is measured, which can be more easily done by selfBPM.

In a study comparing clinical and home measurements, the clinic pressure at the first visit was higher than the home pressure, but there was no consistent difference between the final clinic pressure and the home pressure. Thus, it was concluded that home blood pressures can be used to predict the results of repeated clinic measurements [41].

SelfBPM has been shown not to be accompanied by a white coat effect [38], and the use of selfBPM has been proposed as a useful alternative to ambulatory blood pressure monitoring (ABPM) in the detection of white coat hypertension [42] (Table 2). However, a disagreement in the classification of clinical reactors was found in approximately 20% of cases by other authors [43–45], and according to Nesbitt [46], the specificity of selfBPM to detect hypertension correctly is 0.93, but the sensitivity is only 0.43.

SelfBPM could be used as a screening test which, if positive (low home blood pressure), should be confirmed by ambulatory monitoring, but if negative (high home pressure), no further testing is needed [33,47]. Finally, due to its high specificity and low cost, selfBPM seems appropriate for the long-term follow-up of patients with white coat hypertension [46–49].

Economical aspects and cost impacts of selfBPM in hypertension management

In a study by Soghikian et al. [50], in which patients were randomly assigned to a usual care (UC) group or to a selfBPM group, it was found that the selfBPM patients made 1.2 fewer hypertension-related office visits than UC patients, and that the mean adjusted cost for hypertension care was 29% less in the selfBPM group than in the UC group. The annual cost of implementing the home blood pressure system was approximately $28 per patient during the study year and would currently be approximately $15. Appel and Stason [42] compared the costs of ABPM and selfBPM, and estimated that the resource cost of an ABPM test was approximately $120, giving an additional direct cost of $6 billion per year in the USA if all hypertensives were screened. In contrast, the resource costs associated with selfBPM are modest, and were estimated to be less than $50 per year, so that the total cost of the routine use of self-measurement devices would be $2.5 billion.

Usefulness of selfBPM in particular conditions
Usefulness of selfBPM in the elderly

In the SMART study [51], age did not predict the magnitude of the difference between office and home readings, although it was found that in the elderly the home–ambulatory difference was generally greater than in the young [27]. SelfBPM has been shown to be feasible in the elderly population and helpful in the management of hypertension.

Usefulness of selfBPM in pregnancy

A potential advantage of self-monitoring of blood pressure during pregnancy is that, in a large proportion of the women, less medication may be prescribed because pressure appears to be lower than in the office [52], but caution towards possible undertreatment should be used until more information is obtained on 'normal' values of selfBPM in pregnant women.

Table 2   Characteristics of three blood pressure measurement methods

	Casual blood pressure	Ambulatory blood pressure	Home blood pressure
Characteristic	Including reactive pressor response	Measurements under several mental and physical conditions	Measurements under relatively stable condition
Measurement bias	+	−	±
Measurement frequency	Few	Many	Many
Estimation of circadian or short-term blood pressure variation	Impossible	Possible	Possible only in daytime
Estimation of night-time blood pressure	Impossible	Possible	Impossible
Estimation of long-term blood pressure	Inadequate	Inadequate	Adequate
Estimation of drug effect	Insufficient due to placebo effect, regression to the mean, white coat effect	Occasionally insufficient due to regression to the mean	Adequate
Estimation of duration of drug effect	Impossible	Possible	Adequate
Estimation of drug resistance	Inadequate	Adequate	Adequate
Estimation of white-coat effect	Impossible	Adequate	Adequate
Improvement of patient adherence	?	?	Possible
Reducing cost		Possible	Possible
Estimation of paroxsimal hypertension or episodic hypotension	Impossible	Adequate	Occasionally possible
Prediction of prognosis	Poor	Good	Good
Reflection of target organ damage	Poor	Good	Good

Usefulness of selfBPM in diabetes

There is increasing evidence that tight blood pressure control improves the cardiovascular and microvascular complications of diabetes. It has recently been shown that home pressures predict the progression of diabetic nephropathy better than clinic pressures [53]. The use of selfBPM automated devices has also been reported as feasible by diabetic children and is of value in the management of diabetic children [54].

Recommendations

(i) Newly diagnosed hypertensives: in patients with a 10-year absolute cardiovascular risk lower than 20%, there is a need for hypertension to be confirmed. SelfBPM is likely to substantially shorten the length of the observational period since it has been shown that home blood pressure can predict the results of repeated clinic measurements. However, the low sensitivity and positive predictive value of selfBPM have to be kept in mind so that patients with a mean selfBPM > 135/85 mmHg may be considered as hypertensive subjects and therapy may be initiated; in patients with selfBPM < 135/85 mmHg it seems reasonable to perform ABPM before assuming the diagnosis of white coat hypertension.

(ii) Follow-up of white coat hypertensives: selfBPM may be appropriate for the long-term follow-up of patients with white coat hypertension.

(iii) The use of selfBPM in diabetic hypertensives, pregnant women and the elderly is encouraged, but needs further evaluation.

Prognostic significance of selfBPM

SelfBPM may offer some advantages in the management of hypertensive patients. These advantages have been identified by the World Hypertension League,

the Sixth Joint National Committee of Prevention and Treatment of Hypertension (JNC-VI) and the 1999 WHO/ISH guidelines [1,2,55]. However, each of these reports also emphasized the main limitation of this method, namely that there are very few data available concerning the prognostic value of selfBPM (Table 3).

Target organ damage and risk factors

Results of cross-sectional studies have shown that the degree of left ventricular hypertrophy (LVH) determined by electrocardiography and by echocardiography is better correlated to selfBPM than it is to clinical blood pressure [56–59]. In these studies, the frequency of blood pressure measurements in the clinic or at home was variable (Table 3). Abe *et al.* [60] related clinic blood pressure and selfBPM to an aggregate measure of target organ damage (retinopathy, electrocardiogram-LVH, heart size on the chest radiograph and serum creatinine levels) in hypertensive patients. When a subset of patients with clinic SBP between 160 and 179 mmHg was divided into two groups, i.e. 'high' and 'low' selfBPM, target organ damage was more pronounced in the 'high' group. In the Tecumseh Study [61,62], young subjects with borderline hypertension and white coat hypertension diagnosed by selfBPM had a family history of hypertension, higher heart rates, higher vascular resistance, overweight, higher plasma triglycerides, lower high-density lipoprotein and higher insulin than normotensive subjects. The results of this study suggested that selfBPM is a possible surrogate measure for future development of hypertension.

Prospective study

To date, only pilot epidemiological data (Ohasama Study, Tecumseh study) are available to indicate that selfBPM may predict morbidity and mortality from

Table 3 Prognostic value of self-blood pressure measurements

	Reference	Type of study	Subjects	Drug	Device	Measurement frequency	Surrogate measure or endpoint
Ibrahim *et al.*	[56]	Clinical study	Patients	(+)	Auscultation	14	LVH
Kleinert *et al.*	[57]	Clinical study	Patients	(−)	Auscultation	63	LVH
Verdecchia *et al.*	[58]	Clinical study	Patients	(+)	Auscultation	4–12	LVH
Mancia *et al.*	[59]	Cohort study (cross-sectional)	Patients	(+)	Semiautomatic	2	LVH
Abe *et al.*	[60]	Clinical study	Patients	(+)	Semiautomatic	7	LVH, CTR retinal change
Julius *et al.*	[61]	Cohort study (cross-sectional)	Population	(−)	Auscultation	14	Family history, haemodynamic parameters, metabolic parameters
Jamerson *et al.*	[62]	Cohort study (cross-sectional)	Population	(−)	Auscultation	14	Blood pressure reactivity, family history
Imai *et al.*	[63]	Cohort study (prospective)	Population	(−) and (+)	Semiautomatic	20.8 ± 8.3	Cardiovascular mortality
Tsuji *et al.*	[64]	Cohort study (prospective)	Population	(−) and (+)	Semiautomatic	20.8 ± 8.3	Overall mortality
Sakuma *et al.*	[65]	Cohort study (prospective)	Population	(−) and (+)	Semiautomatic	23.0 ± 7.5	Stroke morbidity
Ohkubo *et al.*	[66]	Cohort study (prospective)	Population	(−) and (+)	Semiautomatic	20.8 ± 8.3	Cardiovascular, non-cardiovascular, and overall mortality
Nesbitt *et al.*	[46]	Cohort study (prospective)	Population	(−)	Auscultation	14	Sustained hypertension
Amerena *et al.*	[67]	Cohort study (prospective)	Population	(−)	Auscultation	14	Diastolic function

LVH, left ventricular hypertrophy; CTR, cardio-thoracic ratio; Scr, serum creatinine; U prot, urinary protein.

cardiovascular disease or progression of hypertension. (Table 3). The several publications from the Ohasama [63–66] have reported (i) a significant difference in the survival distribution among self-measured SBP and DBP quintiles with individuals in the highest quintile showing the poorest survival (Fig. 1); (ii) a J-shaped relationship between self-measured DBP and all cause mortality, and a linear one between self-measured SBP and all cause mortality; and (3) the lowest risk of stroke in subjects with self-measured SBP of 117–123 mmHg and self-measured DBP of 66–70 mmHg, with a significantly increased stroke risk in subjects in the quintile with the highest self-SBP measurement (≥ 133 mmHg) and self-DBP measurement (≥ 81 mmHg). All these relationships were non-significant or weaker when casual blood pressure was used. When selfBPM and casual blood pressure were simultaneously incorporated into the Cox models as continuous variables, only the average of multiple (taken more than three times) self-measured SBP was strongly related to the cardiovascular mortality risk [66].

Significant increases in relative hazard (RH) ratio were found in the highest quintile of self-measured SBP (the highest quintile, ≥ 138 mmHg; RH = 5.74, 95% CI 1.33–24.9) and self-measured DBP (≥ 83 mmHg, RH = 3.17, 95% CI 1.15–8.71), as well as in the highest quintile of ambulatory SBP (≥ 133 mmHg, RH = 5.53, 95% CI 1.26–24.26); no such tendency was observed for casual blood pressure.

The Tecumseh study also provides some predictive data, although not on hard endpoints. Nesbitt *et al.* [46] found that only the selfBPM can predict future sustained hypertension and normotension, and Amerena *et al.* [67] reported that selfBPM can predict deterioration of left ventricular diastolic function in hypertensive subjects.

Prognosis based threshold values for selfBPM

The most clinically relevant reference threshold value would be one derived from results of long-term prospective studies. Such preliminary prognostic criteria may be derived from the Ohasama study, with obvious

Fig. 1
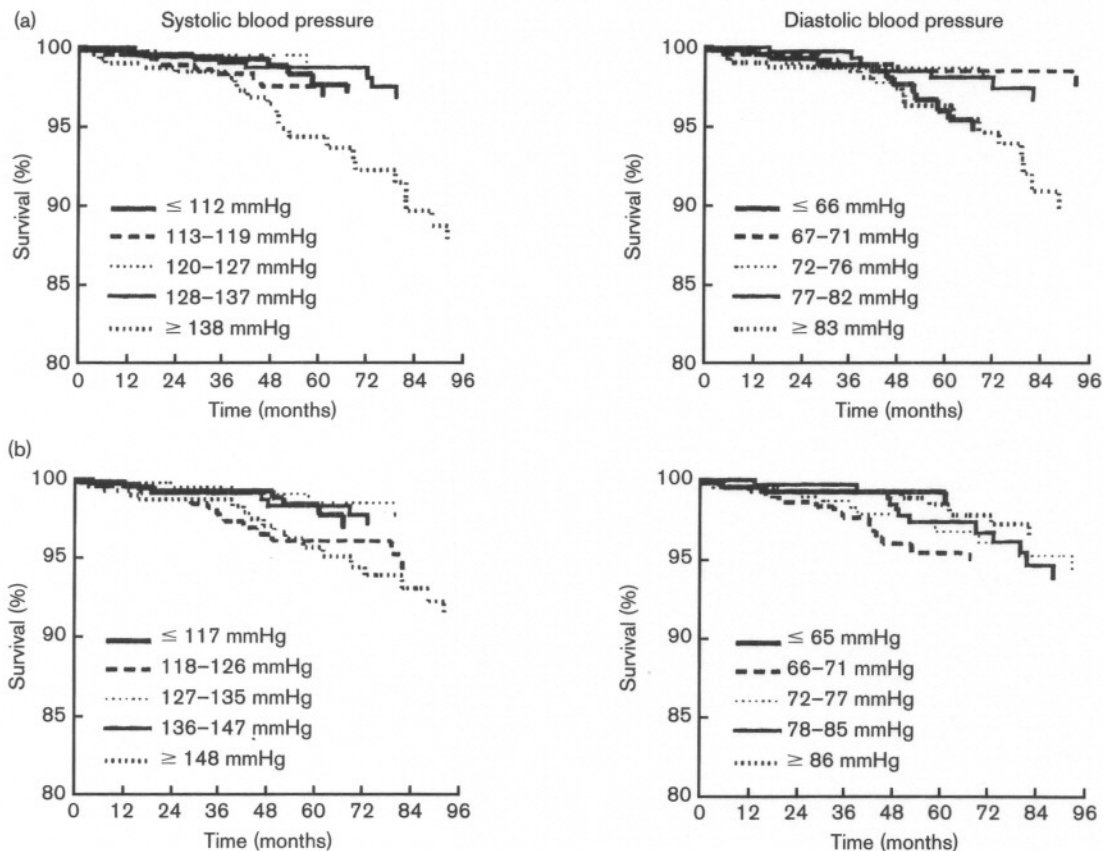
Kaplan–Meier estimate of event probability (cardiovascular mortality) based on (a) home ($n = 1789$) and (b) screening ($n = 1789$) blood pressure levels. Blood pressure levels are classified into quintiles and survival rate is illustrated for each quintile, adapted with permission [63].

reservations due to the limited power of the study and to the fact that quintiles are more suitable for defining ranges than thresholds. In this regard, Tsuji *et al.* [64] proposed 137/84 mmHg as a reference selfBPM value for hypertension. These values are very close to the threshold diagnostic values of selfBPM determined using a statistical approach (within 2/1 mmHg) and therefore corroborate the use of 135/85 mmHg as a preliminary reference of the upper limit value of normality.

Recommendations

(i) SelfBPM is more strongly correlated to the hypertension target organ damage than clinical blood pressure measurements; such accurate information is observed using multiple measurements of selfBPM.

(ii) SelfBPM presents a stronger predictive power for cardiovascular and overall mortality as well as stroke morbidity than casual blood pressure; this more accurate information is obtained using multiple measurements of selfBPM.

(iii) The predictive value of multiple selfBPM may not be dissimilar to that of ABPM.

(iv) The prognostic results of a single long-term cohort prospective study suggests 137/84 mmHg as the selfBPM reference threshold value for hypertension which corroborate the use of 135/85 mmHg as the upper limit value of normality.

## Applications of selfBPM in therapy and clinical trials

SelfBPM is of special interest for assessing blood pressure effects of antihypertensive therapy. This is true both in routine follow-up of hypertensive patients and in the evaluation of blood pressure-lowering medications in clinical trials.

The role of selfBPM in clinical trials

Office blood pressure (OBP) measured by physicians with a mercury sphygmomanometer remains the reference standard in hypertension because it demonstrates a relationship with cardiovascular prognosis. However, the evaluation of the effect and duration of antihypertensive drugs is limited by the reliability of this method of blood pressure measurement with a high variability and observer bias [68]. SelfBPM can improve the assessment of blood pressure measurement in hypertension management and in clinical trials. In fact, selfBPM was shown to be a sensitive tool [69] (small changes of blood pressure can be detected) and its measurements are as reliable as those performed with calibrated aneroid sphygmomanometers using the conventional auscultatory technique [70]. The placebo effect observed with OBP measurements may be considerably limited or may not even occur with selfBPM [71,72].

SelfBPM improves the reproducibility of blood pressure measurements. This reduction in variability depends mainly on the number of readings (Fig. 2) [73]. Measuring blood pressure in the home environment under similar everyday conditions and in the absence of a doctor or a nurse avoids the white coat effect and allows a reduction in variability [45]. The average of multiple blood pressure readings taken semi-automatically increases blood pressure reproducibility compared to office readings, with reproducibility values being achieved that are similar to those obtained by ABPM. In clinical trials, this reproducibility is expressed as the standard deviation of the mean difference (SDD) of blood pressure measurements made on two different occasions. A decrease of the SDD is usually observed with selfBPM. It has been shown in hypertensive patients that selfBPM measurements can halve the SDD between two readings and give SDD comparable to ABPM [30,71,74] (Table 4). It seems that at least three monitoring days (duplicate measurements twice daily), with exclusion of data of the initial day from analysis (average of eight measurements), is the minimum programme that does not increase the SDD and thus the reliability of blood pressure measurements.

Fig. 2
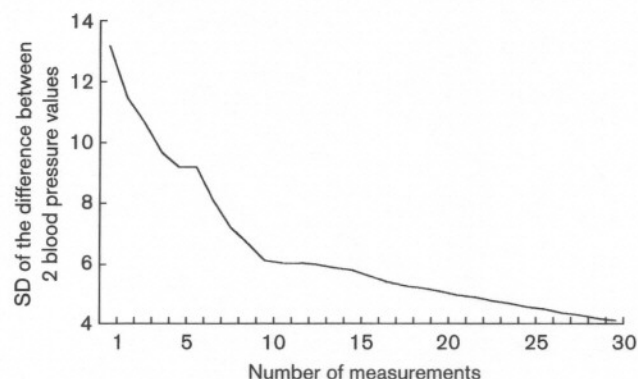
Line graph shows a reduction of SD of the difference between two means by increasing the number of blood pressure (BP) measurements contributing to each mean. Adapted with permission [73].

Table 4

SDD (SBP/DBP)	Reference	OBP (mmHg)	ABP (mmHg)	SBP (mmHg)
Mengden *et al.*	[30]	10.4/8.3		5.4/4.3
Vaui *et al.*	[71]	9/6		5/4
Denolle	[74]	9.0/7.4	4.8/3.4	5.0/3.4

Reproducibility of office blood pressure (OBP), ambulatory blood pressure (ABP) and self blood pressure (SBP) assessed by standard deviation of the differences of two sets of blood pressure measurements: taken 2 weeks apart under similar conditions in 16 mild hypertensive patients [74]; taken days 1–3 (first period) and days 5–7 (second period) in 127 normo- and hypertensive patients [30]; and taken 4 weeks apart during a double-blind trial in the placebo group (10 hypertensive patients) [71].

The use of this method of blood pressure measurement with better reproducibility than OBP increases the power of comparative trials, allowing either the inclusion of fewer patients or the detection of a smaller blood pressure difference. This increase in power seems to be comparable or perhaps even greater than that of ABPM [30,74–77] (Table 5).

By selfBPM, the duration of action of an antihypertensive drug can be assessed by the ratio of the morning decrease in selfBPM to the evening decrease in selfBPM. This morning/evening decrease in the selfBPM ratio has been proposed as a complement and/or an alternative to the trough/peak ratio usually calculated by casual or ABPM [77,78] to assess the duration of drug action. The measurements can also be taken at midday, or 3–4 h after the dose, according to the expected pharmacodynamic effect of the drug.

SelfBPM can be carried out for several weeks or at given times during clinical trials [73,78]. It is relatively easy to teach to patients, can be integrated into the patients' lifestyle, and it is feasible in the majority of hypertensive patients. In general practice, more than 60% of the patients are able to perform selfBPM correctly but less than 50% perform selfBPM correctly at baseline and during the treatment period [51]. This poor performance may probably be explained by insufficient information and instruction. When patients are selected and taught beforehand, 80% of patients or more provide the required measurements [73,79].

The role of selfBPM in resistant hypertension
Some patients with uncontrolled blood pressure in the doctor's office may have adequately controlled blood pressure at home. Such patients with so-called 'isolated office (white-coat) hypertension' need to be detected. The use of selfBPM or ABPM have been recommended for their identification whenever clinical suspicion is raised [1,2]. In the evaluation of patients with resistant hypertension, but no signs of target organ damage, the first step recommended may be to use selfBPM. If selfBPM values are low, ABPM may be indicated because there is a disagreement between

these two techniques in diagnosing isolated office hypertension in approximately 20% of cases [45]. We do not yet know which of the two techniques can be considered as the gold standard. Nevertheless, the predictive value, the greater specificity and the lower cost of selfBPM compared to ABPM supports its role as a screening test. Moreover, the choice of either selfBPM or ABPM may be also influenced by the patient personality and characteristics.

One of the most important causes of refractory hypertension is poor compliance to therapy. SelfBPM may favourably affect patients' perceptions of their hypertension problems and improve adherence to treatment. The use of selfBPM is generally associated with a better compliance to treatment and, in some studies, with a better blood pressure control [48,49,80–84].

Target value of selfBPM in treated hypertensive patients
To date, the target value of selfBPM in treated hypertensive patients cannot be precisely defined and no prognostic therapeutical trials are available. Until such results become available, the therapeutic thresholds for selfBPM can only be determined from the reference values and thresholds for diagnosis of hypertensive subjects. In this regard, a selfBPM of 130–135 mmHg systolic and 85 mmHg diastolic may be considered as the upper limit of normalcy, and tentatively suggested as target for treatment.

Recommendations
(i) SelfBPM offers several advantages over office blood pressure measurements and may be proposed to assess the antihypertensive effect in clinical practice and in clinical trials.

(ii) SelfBPM may be recommended in treated hypertensives with uncontrolled clinic blood pressure in order to identify those with isolated office hypertension whenever clinical suspicion of this condition arises.

(iii) SelfBPM appears to be a particularly valuable adjunct in patients with resistant hypertension and poor treatment compliance.

(iv) It is tentatively suggested that the treatment target should be (a selfBPM) lower than 130–135/85 mmHg.

Future research
SelfBPM is largely dependent on cuff occlusion. Because the technique is prone to inaccuracy induced by miscuffing, manufacturers are encouraged to develop and to produce an 'adjustable cuff' which may be applicable to all adult arms.

Increasing attention should be paid to haemodynamic parameters other than blood pressure that are becoming

Table 5

Method	Number of patients	
	Systolic	Diastolic
Casual	55	118
ABPM	44	70
SBPM	31	56

Number of patients needed to detect at a two-sided α risk of 5% and a statistical power of 80% a systolic blood pressure difference of 10 mmHg and a diastolic difference of 5 mmHg. ABPM, ambulatory pressure blood monitoring; SBPM, self blood pressure monitoring. Adapted with permission [76].

important in cardiovascular evaluation, such as heart rate, pulse pressure and pulse wave velocity.

Application of one international standard protocol for the validation of all blood pressure measuring devices must be encouraged. The use of such a protocol will allow comparison between studies performed in different places according to a similar methodology.

Determination of selfBPM reference values has to consider SBP and DBP but also heart rate and pulse pressure, which appear to be independently related to cardiovascular prognosis.

Prospective studies to evaluate the prognostic values of the proposed thresholds of selfBPM normality, calculated on the sole basis of statistical evaluation, are desirable.

Studies to determine the reference values of selfBPM and the diagnostic usefulness of selfBPM in several specific populations, particularly children and pregnant woman, are needed. These studies may be completed by the evaluation of the feasibility of selfBPM and the assessment of the device validation in these specific populations.

Specific studies to compare the prognostic values of casual, self and ambulatory blood pressure measurements are needed. These studies may use, in addition or alternatively to mortality and morbidity endpoints, organ damage markers and progression of hypertension. Evaluation of the value of different selfBPM protocols, and the number of frequency of measurements, is also desirable.

Studies to determine the role of selfBPM in resistant hypertension and its comparison to those of clinic and ABPM are needed in order to define the management strategy in resistant hypertension.

Longitudinal studies to define the target value of selfBPM in treated hypertensives on a prognostic basis are needed.

Implementation
Translating the guidelines and the research findings into daily clinical practice remains a challenge. In fact, the principal goal of the guidelines is to improve the quality of care received by patients; whether this is achieved in daily practice is less clear. This is partly because patients, doctors and payers define quality differently and because current evidence concerning the effectiveness of guidelines is incomplete. Elsewhere, the development of good guidelines does not ensure their use in practice. Therefore, to maximize the likelihood that a clinical guideline will be used,

there is a need for coherent dissemination and implementation strategies; this is beyond the direct capacity or resources of our group, but it is hoped that such penetration to the healthcare providers can be achieved through alliance and partnerships with national societies and leagues involved in cardiovascular prevention.

The full manuscripts of the guidelines are being published in the *Blood Pressure Monitoring Journal*. Translation of the summary report into many languages and distribution to local medical practitioners is already being organized in many countries. The summary report will be available for implantation on the web sites of the scientific societies which express interest. It is hoped that such recommendations could be integrated to the national and regional education and information programs.

Organization and list of participants
The First International Consensus Conference was organized by the Groupe Evaluation & Mesure (Professor R. Asmar, chair) of the French Society of Hypertension at the initiative of the French Health Ministry (Professor J. Ménard, Director). The organizing committee included Professor R. Asmar (Paris) and Professor J.M. Mallion (Grenoble).

The conference was organized with the collaboration of the Working Group on blood pressure monitoring of the European Society of Hypertension (Professor E. O'Brien, Chair) and under the auspices of the French (Professor P.F. Plouin), the European (Professor A. Zanchetti) and the International (Professor K. Rahn) Societies of Hypertension.

The participants of the Consensus Conference were appointed by the Groupe Evaluation & Mesure and the organizing committee. They were chosen to represent a range of experience, viewpoints and geographical regions, and were from various disciplines: clinician, methodologist, epidemiologist and research workers. Four different medical device manufacturers and distributors also participated in the open discussion during the Consensus Conference.

List of participants: R. Asmar (France), E. Agabiti Rosei (Italy), G. Bobrie (France), B. Chamontin (France), X. Chanudet (France), N.P. Chau (France), M. De Buyzere (Belgium), J. De Champlain (Canada), R. De Gaudemaris (France), P.W. De Leeuw (The Netherlands), T. Denolle (France), G. Germano (Italy), X. Girerd (France), T. Hedner (Sweden), D. Herpin (France), Y. Imai (Japan), S.E. Kjeldsen (Norway), J.M. Mallion (France), J. Ménard (France), T. Mengden (Germany), E. O'Brien (Ireland), P.L. Padfield (UK), J.L. Palma-Gamiz (Spain), G. Parati (Italy), T.G. Pickering (USA), P. Poncelet (France), P.F. Plouin

(France), J. Staessen (Belgium), G.S. Stergiou (Greece), B. Vaisse (France), G.A. Van Montfrans (The Netherlands), B. Waeber (Switzerland), B. Weisser (Germany), M. Wilson (USA), A. Zanchetti (Italy).

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Appendix 1

Synopsis of proposals for the 'International' standard validation protocol

Seven points of modification

(i) Eliminate pre-validation phases.

(ii) Utilize observer aids: Sphygmocorder; Colson kit; and CD-ROMs for training.

(iii) Relax pressure ranges for subject recruitment.

(iv) Reduce the number of subjects recruited.

(v) Eliminate 'hopeless' devices.

(vi) Computer analysis.

(vii) Check algorithm integrity to avoid validation of devices with the same algorithm.

Validation methodology

(i) Comparison to standard mercury sphygmomanometer.

(ii) Measurements performed on the arm by two trained and 'blinded' observers.

(iii) Double Y stethoscope and two calibrated mercury column connected to the same cuff.

(iv) Utilize the Sphygmocorder.

(v) Measurements performed according to simultaneous or sequential methodology.

Pressure range requirements

MmHg	Low	Medium	High
SBP	< 130	130–160	> 160
DBP	< 60	80–100	> 100

Primary Phase: five subjects in each category, + 15 subjects; Secondary Phase, six subjects in each category; total of 33 subjects.

Procedure

Sequential measurements are performed on the 15 first subjects. If the 45 comparisons reach at least one of the criteria shown in the table below, and evaluation is then performed on 18 other subjects: if not, the validation is stopped and the device rejected.

Evaluation criteria for devices using sequential same-arm measurement

	$\leqslant$ 5 mmHg	$\leqslant$ 10 mmHg	$\leqslant$ 15 mmHg
Primary phase (15 subjects)			
45 comparisons must reach at least one of the following	20	30	35
Secondary phase (15 previous + 18 new subjects)	$\leqslant$ 5 mmHg	$\leqslant$ 10 mmHg	$\leqslant$ 15 mmHg
99 comparisons must reach at least two of the following	50	75	90
99 comparisons must reach all of the following	45	70	85