EUROPEAN SOCIETY OF HYPERTENSION GUIDELINES FOR THE USE OF HOME BLOOD PRESSURE MONITORING. A SUMMARY REPORT OF THE SECOND INTERNATIONAL CONSENSUS CONFERENCE ON HOME BLOOD PRESSURE MONITORING

Short title: Home BP Monitoring Guidelines

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Abstract:

This document summarizes the available evidence and provides recommendations on the use of HBPM in clinical practice and in research. It updates the previous recommendations on the same topic issued in year 2000. The main topics addressed include the methodology of HBPM, its diagnostic and therapeutic thresholds, its clinical applications in hypertension, with specific reference to special populations and its applications in research. The final section deals with the problems related to the implementation of these recommendations in clinical practice.

Key words: home blood pressure monitoring, arterial hypertension, cardiovascular risk

1. Introduction

The need to develop the current guidelines is related to the fact that Home Blood Pressure Monitoring (HBPM) is becoming increasingly important in the diagnosis and management of arterial hypertension. The rapid diffusion of this technique has been favoured by a number of factors including 1) technical progress and wider availability of HBPM devices; 2) increasing awareness of the importance of regular BP monitoring; and 3) recognition of the usefulness of HBPM by international hypertension management guidelines [1-3].

The importance of HBPM in cardiovascular prevention, related to a deeper involvement of patients in their long-term management and to a wide diffusion of this approach in populations, is not always accompanied by an adequate knowledge on how to make proper use of this technique, which emphasizes the need of more precise recommendations. (Box 1)

Box 1: Rationale for the present guidelines

1) **Need of accurate definition of BP phenotype:**
   Accurate and frequent BP readings in and outside the office are essential for the diagnosis, management, treatment, epidemiology and research of hypertension [1].
2) **Fast worldwide diffusion of out-of-office BP measurement.**
3) **Continuing increase in the sale of electronic BP measuring devices designed for home monitoring.**
4) **Lack of sufficient knowledge among physicians and patients on how to make proper use of HBPM.**

Purpose and scope of these guidelines

The purpose of the present guidelines is to update the recommendations given in the first consensus document on HBPM published in year 2000 [4]. Like the previous document, this paper also is written to provide physicians and other health-care providers with information on the use of HBPM in clinical practice based upon the available evidence and expert opinion. An appendix to this document, which will be published separately, is devoted to patients information and training programs. These guidelines are not aimed at dealing with the technological, economical and public health related aspects of HBPM use.

Methods

HBPM is an area in which data from randomized controlled trials of sufficient power are still limited. This does not allow a formal grading of recommendations based on the available evidence. Nonetheless, the writing Committee made a great effort to provide objective recommendations, through 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 relevant English language articles on the subject of HBPM in computerized databases (Medline and Embase; Cochrane) and personal literature. The search was performed on publications using the following key words: home BP, self BP measurement, BP monitoring, BP determination with the subheadings: validity, reliability, methods, instrumentation, patient education, self-care, validation, clinical relevance, prognostic value and devices. Only non-invasive methods, clinical and cohort studies with normotensive as well as treated and untreated hypertensives were selected.

The material related to the use of HBPM was divided into a number of topics and assigned to different task forces. For each topic, several questions/issues were defined and addressed by the task force in a draft document. These draft documents were then reviewed by the Writing Committee, and subsequently presented during the Consensus Conference. Each presentation was followed by an open discussion involving all the participants. The manuscripts were amended accordingly, and finally reviewed by the Writing Committee, by experts as well by relevant organizations, leading to this final document.

2. Background: General issues related to BP measurement in and out of office. Validity of HBPM in the evaluation of hypertensive patients.

Office (O) BP measurement has been the cornerstone of hypertension diagnosis and management for over 100 years, with most evidence on the clinical importance of hypertension and benefits of treatment coming from studies using this technique [5]. However, OBP measurement has important limitations. In particular, a single OBP reading often does not represent a patient's true BP status. This is because a random error characterizes a single measurement of a variable such as BP, which continuously changes over time. There may also be a systematic error related to the patient's alerting reaction to the measurement procedure and setting (i.e. white coat effect), and to inability of OBP to collect information on BP during usual daytime activities and during sleep.

Following the pioneering work by George Pickering and Maurice Sokolow in the nineteen-sixties, several techniques have been developed to perform BP measurements outside of the physician's office in order to overcome the limitations of the OBP. Two of them have become widely used in clinical practice: 24 h ambulatory BP monitoring (ABPM, addressed extensively by other documents [6]) and HBPM, with its specific features described in Box 2.

Important differences are frequently found between OBP and out-of-office BP measurements in the same subject, which may lead to disagreement between these methods in terms of hypertension diagnosis. Such disagreement may be characterized by the presence of elevated OBP values and normal out-of-office BP (i.e. *white coat hypertension* (WCH), also known as 'isolated office hypertension') [7], or alternatively, of elevated out-of-office BP with normal OBP values (i.e. *masked hypertension* (MH), or 'isolated ambulatory hypertension') [8]. These conditions will be discussed in more detail subsequently.

Cost and availability have a major influence on the choice of the method of BP measurement. OBP measurement is cheaper than ABPM and should ideally be performed during each visit to the physician's office. The use of ABPM in routine clinical practice is confined mainly to specific conditions, due to the cost of devices and the need to have qualified personnel for ABPM management. On the other hand, the cost of HBPM devices no longer limits their widespread use in clinical practice, at least in developed countries. Moreover, the specifications for HBPM devices for low resource settings provided recently by an ad-hoc WHO–ESH committee may help to introduce out-of-office BP monitoring in places where health care resources are scarce [9].

Box 2. Summary of advantages and limitations of HBPM (Modified from 9, by permission).

Advantages	Limitations
• A number of measurements during the day and also over several days, weeks or months is possible • Assessment of treatment effects at different times of the day and over extended periods • No alarm reaction to BP measurement • Good reproducibility • Good prognostic value • Relatively low cost • Patient-friendliness (in semiautomatic devices) • Involvement of patient in hypertension management • Possibility of digital storage, printout, PC download or teletransmission of BP values (in some devices/systems) • Improvement of patients' compliance to treatment • Improvement of hypertension control rates	• Need of patient training (short for automated devices) • Possible use of inaccurate devices • Measurement errors • Limited reliability of BP values reported by patients • Induction of anxiety resulting in excessive monitoring • Treatment changes made by patients on the basis of casual home measurements without doctor's guidance. • Normality thresholds and therapeutic targets still debated • Lack of night recordings

HBPM and prognosis

The available evidence supports the notion that the prognostic value of HBPM is equal or higher than that of OBP, a method which, at present, remains the point of reference for prognostic stratification and clinical decision making in hypertension (Table 1).

Predictive value for mortality. HBP was more closely associated with the risk of cardiovascular mortality than OBP in two population studies [10-12], while in one study it was not a significant predictor of cardiovascular mortality in hypertensive patients [13]. In a study on chronic kidney disease (CKD) patients, HBP tended to be more

strongly associated with the risk of all-cause mortality [14]. Another population study reported that systolic HBP had a higher predictive value for cardiovascular mortality than diastolic HBP [15].

Predictive value for morbidity. Compared with OBP, HBP was more closely associated with the risk of stroke in one population study (no data for other outcomes) [16-20], while in another population study no prognostic superiority of HBP was found for the risk of cardiovascular events [21]. In hypertensive patients, HBP was shown to predict cardiovascular events (but not mortality) better than OBP [13]. In patients with CKD, HBP is a better predictor of progression to end stage renal disease (ESRD) [14] and of composite cardiovascular events [22] than OBP.

Other analyses. In some studies the prognostic value of HBPM was documented without comparing it with OBP, providing evidence in favor of the ability of HBP to predict mortality [23], disability [24] and target organ damage [25-35] or its regression [30, 36, 37].

Little is known on the usefulness of home measured HR, a parameter which is usually provided by automated BP devices. Out-of-office HR is more reproducible than clinic HR, but in the studies which used HR obtained with 24 h ABPM this advantage did not seem to translate into a better risk prediction, compared with conventional resting HR [38-40]. In the only study available on the prognostic relevance of home measured HR [41], a 5 bpm increase in home HR corresponded to a 17% increase in the risk of mortality, but this result was not confronted with the predictive power of clinic HR.

In conclusion, the available evidence strongly supports HBPM as a valid tool for prognostic assessment. Areas where further research is needed include the prognostic

significance of other parameters derived from HBPM such as heart rate or pulse pressure, or the relation of HBPM to individual outcomes (e.g. CHD). More prospective studies in Western populations appear to be needed.

3. Methodological Aspects

The recommendations that follow are based on previously published documents [1, 2, 4] as well as on more recent data. Unless stated differently, the current document will refer to the use of automated devices with an inflatable cuff for the upper arm (see section on devices). (Box 3)

Box 3. Key issues related to the methodology of HBPM

- Need of medical supervision and patient training
- No need of frequent calibration of automated devices
- Need of independent validation
- Need of specific validation in special populations (elderly, children, normal pregnancy, pre-eclampsia, end stage renal disease)
- Need to ensure an adequate quality of validation studies
- Importance of overall quality certification
- Debate on usefulness of checking device accuracy in individual patients at first use

3.1. Measurement conditions and procedures

BP is a variable haemodynamic phenomenon influenced by many factors, not least being the circumstances of measurement itself. Thus the considerable variability that may occur in BP from moment to moment depending on subject's activity, emotions, environmental stressors, pharmacological factors and other physiological variables [7, 43, 44] should always be considered when performing a BP measurement.

If these influences are ignored or unrecognized, erroneous diagnosis and inappropriate management may result.

The effect of these factors can be minimized by performing measurements in conditions as carefully standardized as possible, and by taking them into account when interpreting the results of HBPM. The conditions of HBPM should be similar to those recommended for OBP [6]. The patient should be relaxed in the sitting position (most data on HBPM have been obtained with sitting measurements), with the back supported, the cuff at heart level, without crossing legs, in a quiet room at a comfortable temperature and at least 5 minutes of rest should precede the measurement. Patients should not talk before and during BP measurement. When it is not possible to achieve optimum conditions, this should be reported with the BP reading [45].

Arm support. If the arm in which measurement is being made is unsupported, isometric exercise is being performed, increasing BP (up to 10%) and heart rate [46]. It is essential, therefore, for the arm to be supported during BP measurement and this is best achieved in practice by having the arm supported on a table (for sitting position).

Arm position. When the arm (i.e. the cuff) is positioned below or above heart level BP will be overestimated or underestimated, respectively. The magnitude of this error can be as great as 10 mmHg in sitting and standing positions or 5 mmHg in the supine position. Inappropriate forearm position is even more important when wrist BP monitors are used, as it introduces a large error margin on top of the limited accuracy commonly seen in these devices [47]. Because of this, some wrist devices have a built-in sensor, which indicates the correct position [48].

Arm selection. We recommend that BP measurement on both arms should only be done at the time of the first office measurement to exclude occlusive arterial disease

[49, 50]. In subjects with a consistent and significant between arm difference of (e.g. >10 mmHg systolic and/or >5 diastolic) on repeated measurements the arm with the higher BP should be selected for future measurements [6]. During HBPM measurements should be performed sequentially always on the same arm.

Cuff and bladder. The size of a bladder is important to obtain accurate BP estimates. A bladder which is too small may lead to overestimation (undercuffing) and a bladder which is too large may lead to underestimation (overcuffing) of actual BP [51]. The length of the inflatable bladder should cover 80-100% of the arm circumference and the width should be about half that of the length [6]. No satisfactory solution to the problem of cuff-size has been found so far. Different cuff sizes are recommended for patients with different arm circumferences as well as in children at different ages [52] (Box 4) and before the patients start using BP device it must be ensured that the bladder dimensions are adequate. For each measurement, the cuff should be wrapped round the upper arm with the centre of the bladder placed over the brachial artery.

The methodology of BP measurement in obese people is discussed in more detail in a dedicated section later on in this document.

Box 4- Recommended bladder dimensions in adults, children and adolescents

Recommended dimension for BP cuff bladders in adults

British Hypertension Society

Cuff type	For whom	Dimension (cm)
Small	Lean adult arms and children	12 x 18
Standard	Most adult arms	12 x 26
Large	Arms of obese patients	12 x 40

American Heart Association

Cuff type	Arm circumference (cm)	Dimension (cm)
Small adults	22 – 26	12 x 22
Adults	27 – 34	16 x 30
Large adults	35 – 44	16 x 36
Adult thigh	45 - 52	16 x 42

From : O'Brien et al [6]

Recommended dimension for BP cuff bladders in children

Age range	Width (cm)	Length (cm)	Maximum arm circumference (cm)*
Newborn	4	8	10
Infant	6	12	15
Child	9	18	22

* Calculated so that the largest arm would still allow the bladder to encircle arm by at least 80% (Modified from [52])

Data reporting. Accurate reporting of BP readings must be ensured, since it has been shown that HBPM reported by patients frequently differs from the actually measured values [53]. Not only BP but also heart rate (HR) values measured at home should be reported. This is because, as already mentioned, home measured HR provides information on cardiovascular risk [41], but also because it may help in a better interpretation of home BP values (may suggest the presence of factors which influence BP – e.g. physical or emotional stress, arrythmias etc.).

For more discussion on data reporting see the section on self BP telemonitoring.

Patient disability. Few patients are unable to perform HBPM when automated oscillometric monitors are used. This technique may be unsuitable for patients with

physical problems or mental disabilities, unless the measurements can be taken by another person (e.g. family member), which however may affect the HBP values [54].

Patient education. HBPM is most suited to hypertensive patients who wish to contribute to their own management. At present HBPM is frequently performed by patients on their own initiative using devices purchased without medical advice [55, 56]. This leads to frequent problems, such as the use of inaccurate devices and errors in measurement methodology. The knowledge of patients about appropriate cuff size is also minimal. This situation may discourage primary care physicians from making a more widespread use of HBPM in everyday practice [57]. Such an attitude could be improved if the doctors themselves become familiar with the strengths and limitations of HBPM, aware of the accuracy and reliability of the equipment being used by their patients, and informed on the state of the market for automated devices. Proper training of patients on methodology and interpretation of HBPM may reduce the likelihood of errors during measurement [55] and provide reliable assessment of HBP.

There is currently no standardized approach to educating patients about HBPM. Perhaps involvement of members of the health care team such as nurses in primary care practices, specialized nurses or pharmacists or a combination of different methods may be needed [58]. Additional resources such as CD-ROMs, booklets (see suggested readings on Journal website) or access to dedicated websites are useful for demonstrating HBPM to patients.

3.2. Device Selection And Validation (Box 5)

Monitors available for HBPM theoretically may include mercury-column sphygmomanometers, aneroid manometers and electronic semi-automatic devices.

Mercury-column sphygmomanometers are cumbersome, require the training of the patient with the auscultatory method and contribute to environmental pollution with mercury. Thus, not only they are not recommended, but they are no longer on the market in several countries [59, 60]. Aneroid manometers also require skill by the patient and training by the physician, and they can become inaccurate with use [61]. For these reasons also these devices are not recommended for routine use. Recently, mercury-free manual devices based on the auscultatory method and on use of electronic transducers have been developed. Although they also require patient training, they may be useful in subjects in whom automated measurements are not feasible, e.g. because of arrhythmias or inaccuracy of oscillometric measurement.

All currently available automated and semiautomated HBPM devices use the oscillometric technique. They are popular with patients mainly because of simplicity of use. These devices are widely advertised and sold in pharmacies and even supermarkets, usually without instructions or education from a knowledgeable health professional. In consequence, a vast array of such devices is manufactured and marketed, many of which have not been independently evaluated for use in clinical practice [see www.dableducational.org]. Three categories of these devices are available: devices that measure blood pressure on the upper arm, the wrist and the finger.

Finger devices. Devices that measure BP at the finger are not recommended, because peripheral vasoconstriction, alteration in BP in the more distal site of recording, and a particularly relevant effect of limb position on BP lead to important inaccuracies of measurement [62].

Wrist devices. Automatic wrist monitors are popular among patients, because measurement is readily obtained without the need to remove clothing. These devices,

however, are subject to the same limitations as the finger devices including distal site and limb position. Measurement with wrist devices is not only heavily influenced by the level at which the wrist is held, but also by its flexion and hyperextension. Furthermore, wrist devices are inherently less accurate because of the difficulties in producing an accurate algorithm to estimate SBP and DBP, as there are two arteries contributing to the oscillometric signal. As a result, there continue to be strong reservations about the use of wrist devices for routine clinical practice. However, additional studies have been advocated to explore the role of wrist measuring devices in special populations, such as obese or elderly individuals, in whom HBPM using the upper arm is more difficult to perform [63].

Upper arm devices. Monitors that measure BP in the upper arm (brachial artery) have been shown to be the most reliable in clinical practice and research and therefore their use is recommended for HBPM. The majority of general recommendations on BP measurement apply to these devices including the need of availability of appropriate cuff sizes. Validated electronic upper arm devices should thus be preferred for HBPM, particularly those offering the possibility to store, transmit or print measurements. The possible exceptions include patients in whom it is not possible to measure BP with these devices (patients with arrhythmias; in some patients automated measurement is not possible without an obvious reason).

Device validation. Systolic and diastolic BP values provided by oscillometric devices are derived by means of device-specific algorithms that are not disclosed by manufacturers. Because of this heterogeneity and the marketing of a multitude of devices, patients should be certain that the device they purchase has been validated according to agreed-upon criteria. Based on the experience from studies using earlier

validation protocols of the American Association for the Advancement of Medical Instrumentation (AAMI) and British Hypertension Society (BHS) [64], the Working Group on BP Monitoring of the European Society of Hypertension (ESH) has developed a simplified and updated protocol, without sacrificing the integrity of the earlier protocols. This "International Protocol" was drafted so as to be applicable to the majority of BP measuring devices on the market, and has already been used in numerous studies [65]. Apart from 'standard' validation studies the Committee also recommends independent validation of devices for use in special populations (children, pregnancy, hypertension associated with pregnancy, elderly, obesity,etc.).

Besides validation for clinical accuracy, devices should also undergo technical quality certification based on additional characteristics that make their use safe, easy and clinically useful for disease management. Recently a Quality Certification Protocol for previously validated devices was proposed, which should provide objective information on both accuracy and overall quality of BP monitors [66].

The Committee agreed on the need to define procedures for assuring the accuracy of validation studies themselves. A proposal for such procedures is currently being prepared by the Working Group on BP Monitoring of the ESH.

Since only a minority of SBPM devices on the market have fulfilled independent validation criteria, there is a need for continuous monitoring of devices on the market with information on validated recorders being distributed to health care providers and purchasers. The ESH has supported the establishment of a not-for-profit website to provide updated lists of validated BP measuring devices (www.dableducational.org). Other websites, such as that of the British Hypertension Society (www.bhsoc.org) also provide information on device validation.

Device equivalence. The need to re-validate devices that undergo minor modification without alteration to the measurement algorithm has been repeatedly queried by manufacturers [65]. The Committee supports the device equivalence procedure proposed by dabl®Educational Trust [67]. Manufacturers are requested to post statements of the equivalence of the measurement algorithm for different models on dedicated web sites.

Device calibration. Testing device accuracy in individual subjects. Electronic devices are unlikely to develop calibration errors because of the demonstrated stability of the electronic pressure transducers [68]. If such a device generates a reading it is therefore likely to be accurate. Repeated aberrant readings indicate malfunction and should dictate need for calibration checks or replacement. Regular calibration over time is therefore not recommended but as other components, such as tubing and cuffs may deteriorate and affect accuracy, individual devices should nevertheless be periodically checked and their components replaced if needed. .

Although it is known that for unexplained reasons oscillometric devices might not be accurate in some subjects, at present there is no agreement on the need of testing device accuracy against mercury sphygmomanometers in individual patients, when the device is first used. However, doing so might offer an opportunity for education and training of patients, who are often impressed by the higher readings in the doctor's office. Although such a procedure might not be very accurate, it could also be useful to check that measurements are correctly performed (including selection of proper cuff size).

Box 5- DEVICES FOR HBPM: SELECTION AND VALIDATION

- Auscultatory (aneroid or mercury) devices not recommended for home monitoring except under specific circumstances (e.g. arrhythmia)
- Finger cuff devices not recommended
- Wrist cuff devices not recommended*
- Only validated semi-automated oscillometric arm cuff devices are recommended
- Device equivalence to be checked (same devices with different names in different countries)
- Optional small and large adult cuffs should be available **

*under evaluation for possible use in special conditions (elderly, obese people). Wrist monitors with position sensors claimed to be more accurate.
**Cuff issue yet unresolved (different cuff sizes or adjustable cuff ?)

Technological Features (Box 6 and 7). Devices for HBPM must be easy to use, preferentially fully automated, with an easily readable digital display, and must be operated by a single push-button. They should have sufficient memory to enable physicians to recall previously stored readings (i.e. at least 500 readings).

Built-in software for preliminary automated data analysis and interpretation may be useful. In particular the devices providing whole period averages following the recommended diagnostic schedule (see below) should be preferred. Other features that may be useful in some patients, include: acoustic signals during cuff inflation and deflation; systems for detection of arm or body movements or of irregular heart beats; indication of high BP values; calculation of separate morning and evening averages; double memory (for simultaneous use by two subjects in the same family); programmable alarms reminding users to take readings; AC/DC adaptor to save battery life in case of frequent use; external computer connectivity; possibility of printout; automated night-time measurements; possibility to select specific time periods for statistical analysis (e.g. before and after changing therapy).

Box 6 - HBPM: TECHNOLOGICAL FEATURES

Recommended:

- **Easy to use, preferably fully automated**
- **Easily readable digital display**
- **Sufficient memory**
- **Whole period averages according to diagnostic schedule**
- **Availability of different sized cuffs**

Optional:

- **Automatic detection of arm movement or irregular heart beats**
- **Separate morning and evening averages**
- **Prompting and scheduling for BP measurment**
- **Automated night-time measurements**

BP telemonitoring systems may be useful in hypertension management

Box 7- Advantages and disadvantages of automated oscillometric BP devices.

Advantages of automated devices	Disadvantages of automated devices
• Provide print-outs with - systolic and diastolic blood pressure - mean blood pressure - heart rate - time of measurement - date of measurement • Eliminate observer error • Eliminate observer bias • Eliminate terminal digit preference • Minimal training • Store data for future analysis and comparison • Provide trend plots	• Poor record for accuracy but improving • All use oscillometric measurement - systolic and diastolic blood pressure derived from algorithm known only to manufacturer • Oscillometric technique fails in some individuals • Oscillometric technique not accurate in arrhythmias • More expensive than aneroid or mercury devices. • BP underestimation in pre-eclampsia.

HBPM and telemedicine. HBP values are usually reported in handwritten logbooks, which are frequently inaccurate and/or illegible [53, 69] and do not provide an immediate insight into the overall time course and control of BP. This may discourage physicians from using them in clinical decision making. The need for

automated HBPM data storage, analysis and reporting functions has stimulated the development of HBP telemonitoring (HBPT) systems [70]. HBPT is based on registration of BP data obtained at the patient's home and their transfer to a remote computer via telephone (stationary or mobile) or Internet connection. Automatically generated reports of these data aid the physician in more easily making therapeutic decisions, that may be communicated to the patient without the need of additional clinic visits. Several HBPT systems are available on the market, with different modalities of data transmission and reporting and additional features such as reminders of measurement and/or medication intake.

HBPT shares most advantages of traditional HBPM, while improving the quality of data reporting and facilitating their interpretation. It may also improve the control of BP and compliance with treatment [71], and be useful for faster identification of patients responding to treatment [72]. Preliminary reports suggest also a possible usefulness of HBPT for self-titration of antihypertensive medication by patients [73] . HBPT may also be valuable for comparing antihypertensive treatments in clinical trials [74]. The main disadvantage of HBPT is high cost of the system purchase and maintenance, partly counterbalanced by a reduction in the costs of patients' management compared with usual care. This is of particular importance in the light of the possibility of HBPT being reimbursed by national health care systems. Other limitations of HBPT include the need for training and the requirement of a telephonic/Internet connection. Inclusion of HBPT in integrated home care systems for cardiovascular monitoring may stimulate its further development, particularly in conditions which require close follow-up such as chronic heart failure.

3.3. User procedures - frequency and timing of HBPM (Box 8)

Selection of the optimal schedule for HBPM should consider its relation to cardiovascular risk ("outcome-based approach") and its ability to provide a reliable and reproducible assessment of the "usual" HBP of each individual ("clinical approach") [75].

Outcome-based approach. In outcome studies [11-21, 23, 24, 42] a wide variety of HBPM schedules have been used (Table 2). Irrespective of the monitoring schedule, HBPM is a powerful predictor of cardiovascular risk (see HBPM and outcome), even when only two [11, 12] or three [76] HBP readings are obtained. However, when the monitoring time is extended over a few days and the number of readings increases up to 14, and possibly 25 [16], the prognostic value improves [12, 21]. Moreover, single morning HBP measurements probably give an incomplete picture of the HBP, because of significant differences between successive readings [77] and between morning and evening BP values [78, 79] which may have different prognostic impact [20]. Thus, to achieve the optimal prognostic power of HBPM the average of at least 12 values, taken in the morning and the evening should be used.

Clinical approach. Short-term trials have investigated the optimal schedule on the basis of the reproducibility of HBP, its stability over time and its relationship with ABPM values. The reproducibility of HBP depends on the number of averaged HBP measurements [79], and its maximum level was achieved in different studies at five or six [80, 81] up to 30 [79] measurements over a few monitoring days, most of the stability being achieved over the first 2-5 days [77, 79-82]. A 7-days schedule with duplicate morning and evening HBP measurements was thus suggested as appropriate for clinical pharmacology trials [83].

Even though HBP is known to be devoid of a white-coat effect [6, 84, 85], in several studies HBP values on the initial monitoring day were shown to be higher and more unstable and the reproducibility of HBP was improved when they were discarded [16, 21, 77, 82]. Moreover, the average HBP from the initial day does not identify differences in drug efficacy [86]. These drawbacks of the initial day of HBPM persist in subsequent HBPM sessions in an individual patient.

The reliability of HBP was also verified by comparing it with average ABP values. While some authors suggested that only a few readings may suffice to achieve best results [87], according to others a large number (42 over 7 days) of heavily edited measurements is needed [88].

Recommended HBPM schedule. On the background of these observations, the optimal HBPM schedule to be used for decision making should (a) represent the usual level of HBP, (b) give a reproducible HBP level and (c) have sufficient prognostic value [89]. Based on the above data, to achieve this, a minimum of 12 measurements and up to 25 measurements over a few days might be desirable. The Committee supports thus previous suggestion by the ESH Working Group on BP Monitoring [6], according to which HBP should be monitored for 7 days, with at least two morning and two evening measurements. For clinical decision making the average of all values should be used with the exception of the first day which should be discarded.

This schedule should be used in the commencement phase, the treatment phase, and the follow-up phase. In other words, it is advisable for the patient to monitor his/her HBP using this 7-days schedule immediately before each visit to the physician's office. Some debate on this issue is still going on, however [89, 90]. No consensus was reached on whether and how HBP should be monitored in the remaining period i.e.

between visits. It should be considered that long-term BPM might lead to unnecessary and compulsive BP measurements in some patients. Moreover, the finding of isolated high BP readings may lead to inappropriate self-adjustment of drug dosage or to unnecessary visits to the emergency department. Nevertheless, many experts believe that long-term HBPM might allow a closer assessment of the stability of HBP control, improve patients' involvement and compliance with treatment and maintain their BP measurement skills at an adequate level as detailed in paragraphs 5.2 and 5.3.

Box 8 – User procedures

1) CONDITION OF MEASUREMENTS
- 5 min rest, 30 min without smoking or caffeine
- seated, back supported, arm resting on the table
- correct cuff bladder placement
- immobile, legs uncrossed, not talking, relaxing
- repeated readings at 1-2 minute intervals
- results written down if devices without memory

2) HOW OFTEN AND HOW MANY TIMES TO MEASURE
- initial assessment, assessment of treatment, and in the long-term follow-up before each clinic/office visit:
- 7 days of measurements
- two measurements for each session
- morning and evening readings per day (before drug intake and before eating)
- first day of each monitoring session to be discarded
- long-term follow-up: 1-2 measurements per week (debated)

4. Diagnostic and therapeutic thresholds

Even though the association between BP and cardiovascular risk is continuous, it is crucial for clinical decision-making to define the threshold values for HBPM above which hypertension should be diagnosed (diagnostic threshold). Another important problem is whether therapeutic targets for HBPM should also be defined, and if so, what they should be. There is worldwide consensus that the cut-off limits applicable for conventional sphygmomanometry cannot be directly extrapolated to HBPM, because

studies in unselected populations [10-12, 15-20, 24, 91] and hypertensive patients [13, 14, 37] have demonstrated that HBP is lower than OBP. The present recommendations on these thresholds are based on the evidence coming from meta-analyses [92, 93], observational studies and clinical trials, and refer also to previous guidelines [3, 4, 6, 94-102].

Review of evidence

Meta-analyses. In a meta-analysis of the aggregate data extracted from published articles, the thresholds were defined through the analysis of relative distributions of HBP and OBP values and identification of corresponding BP levels. Depending on the method used, the identified HBP thresholds were: 137/89 mmHg (2SD cut-off), 135/86 mmHg (95^{th} percentile cutoff), 129/84 mmHg (corresponding to OBP = 140/90 mmHg, regression method) and 125/79 mmHg (corresponding to OBP = 140/90 mmHg, percentile method) [92]. In a meta-analysis of individual patient data the 95th percentiles of HBP were 136/85 mmHg BP (morning), 139/86 mmHg (evening), and 137/85 mmHg (whole day) [93].

Several ***longitudinal studies*** in populations [10-12, 15-20, 24, 91] or patient cohorts [13, 14, 37] have attempted to find a justification for diagnostic cut-off limits for the HBP in terms of mortality [10-12, 15, 91] or fatal and non-fatal endpoints [13, 14, 16, 18-22, 24, 37]. Suggested thresholds differed slightly between the studies (Table 3) ranging between 135-138 mmHg for SBP and 83-85 for DBP [10, 11, 23, 24, 91]. Similar results were obtained in treated hypertensive subjects [13]. A couple of studies suggested that the HBP thresholds in high-risk patients might be lower than 135/85 mm Hg [14, 19].

Clinical trials. Until now only a few trials on the use of HBPM have been completed and published. In two of them (THOP and HOMERUS), antihypertensive drug treatment was adjusted based on either HBP or OBP, and the same threshold (140/90 mmHg) was used for both. The results of both these trials confirmed that the cut-off limit for the diastolic BP should be lower on HBP than OBP measurement [103, 104]. The ***HOMED-BP*** outcome trial, the results of which are not yet available, is aimed at defining therapeutic HBP targets by randomizing subjects to two groups with target HBP of 125–134/80–84 mm Hg and ≤125/80 mm Hg [105, 106]

Until now there is only indirect evidence on operational thresholds in pregnancy [107]. Reference thresholds for HBP in children and adolescents were also proposed [108]. These issues are discussed in more detail later in this document.

Proposal for diagnostic and therapeutic thresholds

Diagnostic thresholds. The above evidence supports the idea that hypertension should be diagnosed by HBPM starting at BP levels of **135 mmHg** systolic or **85 mmHg** diastolic in adults, older subjects and women (including pregnant women) at least until more evidence is available for special populations. Although the use of values below 120/80 mm Hg and below 130/85 mm Hg as optimal and normal, respectively, for HBPM has been proposed, the Committee agreed that they should not be recommended until more prospective data are available.

Therapeutic thresholds. The target levels of HBP to be attained on antihypertensive drug treatment are currently unknown, this issue being explored by the ongoing HOMED-BP study [109]. However, the target HBP for therapy should logically be below the threshold used to diagnose hypertension i.e. it should be **less than 135 mmHg** for systolic and **less than 85 mmHg for diastolic HBP**. As

recommended for the OBP [1], lower treatment HBP targets might be advisable in high-risk patients, such as those with diabetes mellitus, a history of stroke, coronary heart disease or renal disease. However, direct evidence supporting these lower targets is not yet available.

Even small gradients in the achieved OBP are known to significantly influence the risk of cardiovascular outcomes [110-113] and the reduction in OBP translates into a decrease in HBP, although the reduction in HBP is smaller than that of OBP. Based on the observed home-to-office ratios in the BP lowering effect [103], a decrease in systolic HBP by 2 mmHg may be expected to provide similar relative risk reductions as a decrease in office systolic BP by 3 mmHg, i.e. a 20% reduction in the incidence of stroke. It should thus be emphasised that even if the difficulties in attaining therapeutic goals [105] may be frustrating for patients and physicians, each mmHg of HBP reduction is important as it contributes to the prevention of cardiovascular complications, especially in high-risk subjects.

5. Clinical Indications

5.1 Diagnostic implication of HBPM in hypertension.

As discussed above there is agreement to use **135/85 mmHg** as cut-point for diagnosing hypertension corresponding to an OBP of 140/90 mmHg. If a regression line is drawn to demonstrate the relationship between OBP and HBP it is clear that, while there may be a good correlation between the two measurements, the scatter will be considerable. This means that each individual falls into one of four categories defined in Figure 1. Individuals with an OBP ≥ 140/90 mmHg and HBP ≥ 135/85 mmHg will be described as having sustained (uncontrolled) hypertension, whereas those with both

measurements below these diagnostic thresholds can be considered normal (sustained normotension or controlled hypertension if treated). The phenomenon of 'white coat hypertension' [5, 7, 43, 44], where high BP values seen in a medical environment (i.e. OBP) normalize during out of office BP measurement, was demonstrated many years ago using ABPM [114] and later also became apparent using HBPM [85, 115].

More recently the term 'masked hypertension' (MH) has been coined to describe patients whose OBP is normal while the out of office readings are high (Figure 1). Again, this was first studied with ABPM [8] but is equally apparent with HBPM [116].

The prevalence of these two conditions in general population is relatively consistent in the literature (15-20% WCH and 10-15% MH [117, 118]). Although most such information has been obtained using ABPM, HBPM has also provided similar estimates [119], even if the results obtained with the two techniques do not overlap completely [85, 120].

A number of studies have addressed the issue of the prognostic implications of WCH and MH. The prognostic relevance of WCH is still debated but it may be safely stated that, if anything, it increases cardiovascular risk only modestly [121]. On the other hand MH has been consistently shown to be associated with elevated risk, close to that of subjects with persistent hypertension in whom both office and out-of-office BP values are elevated [117, 122].

Despite the obvious clinical relevance of WCH and MH, so far there is no agreement on the ideal clinical approach to these conditions in the absence of supporting evidence. Out-of-office BP measurement is by definition essential to their identification and, in fact, suspected WCH and MH are among the main indications for ABPM or HBPM [1, 3, 6].

5.2 HBPM in the long-term follow-up of hypertension

An important application of HBPM lies in the possibility of its long term use in the management of every patient on antihypertensive therapy [123, 124], with the resultant reduction in the need to attend for medical check-ups [125] (Box 9). Several national and international guidelines [6, 99-102] do recommend the use of HBPM for hypertension management.

Assessment of BP control - white coat and masked hypertension in treated hypertensive subjects. HPBM has the ability to provide information about BP control outside the office, thereby allowing the identification of treated hypertensive subjects with white-coat hypertension and masked hypertension [126].

White-coat hypertension (i.e. the presence of HBP control despite elevated OBP) is highly prevalent in treated hypertensive patients [13], meaning that many patients who appear to be refractory to treatment in the doctor's office may well have adequately controlled BP at home. Although all guidelines recommend the use of ABP measurements in those patients in order to confirm or reject the diagnosis of resistant hypertension [127], also HBPM can be useful in this setting.

The identification of treated subjects with controlled OBP and uncontrolled out-of-office BP may be even more important since this condition appears to be very common (42-50% of subjects with controlled OBP had elevated HBP in some studies [13, 128]) and is associated with similar cardiovascular risk as sustained uncontrolled hypertension [13]. This condition is commonly termed “masked hypertension” (MH) as done in the diagnostic approach to untreated patients, although the mechanisms responsible for this phenomenon may be different in treated as compared to untreated

patients. Its high prevalence in treated patients may be partly explained by the fact that OBP is often taken at the time of the peak drug effect, while HBP can be taken at trough, leading to a discrepancy between these BP measurements which is particularly evident when short acting drugs are used.

Considering the difficulties in identifying patients with WCH and MH in the clinic, ideally HBPM should be performed in all treated hypertensives, even if they have controlled OBP. The recommendation to perform HBPM is even stronger in patients likely to have masked hypertension (i.e. patients with more than 60 years and high normal systolic OBP (130-140 mmHg), smokers or male patients older than 70 years) [129], as well as in patients with high normal OBP who are at high risk of developing cardiovascular disease (multiple risk factors, evidence of target organ damage, associated morbidity, such as diabetes mellitus or renal disease), and in those with diagnosed cardiovascular disease.

5.3 Use of HBPM in improving adherence to treatment and BP control

One of the most important causes of uncontrolled hypertension is poor adherence to therapy. In fact, success with lifestyle interventions in patients with chronic conditions is often improved by encouraging patients to become actively involved in their care. HBPM, being the BP measurement method which requires particular cooperation by the patient may be particularly effective in favourably affecting patients' perceptions of their hypertension and thereby may encourage them to be compliant with lifestyle modifications and antihypertensive therapy. In fact, it was shown that the use of HBPM is associated with a better compliance to treatment [130], which makes this approach a particularly valuable adjunct in patients with treatment resistant hypertension due to poor compliance [131]. Moreover, a meta-analysis of

randomized controlled trials that compared HBPM with usual care showed that HBPM resulted in better BP control than usual BP measurements in the healthcare system [123], and this result could be observed earlier than with office readings [132].

Importantly, as documented by a recent survey, HBPM is increasingly accepted and utilized by primary care physicians for the assessment of the response to antihypertensive therapy and the long term follow-up of treated hypertensive patients but also to improve patient compliance [57].

Considering the difficulties in defining the characteristics of patients with discrepancies between OBP and HBP control, the prognostic importance of masked hypertension in treated hypertensive subjects, and the likely benefits in terms of patient involvement and compliance with treatment, the Committee recommends the **use of HBPM in all patients with treated hypertension**. (Box 10)

Box 9: Indications for HBPM in treated hypertensive patients

All patients receiving antihypertensive medication
Evaluation of White coat hypertension
Evaluation of Masked hypertension
Evaluation of resistant hypertension
To improve compliance and medical adherence
To improve hypertension control rates

Box 10 - Usefulness of long-term HBPM in treated hypertensives

Advantages :
1) **Improved assessment of drug effects**
2) **Detection of a causal relationship between adverse effects and blood pressure response to antihypertensive drugs**
3) **Improvement of compliance**
4) **Detection of white coat effect and masked hypertension**

Shortcomings :
1) **Possible cause of anxiety**
2) **Risk of self-medication**

6. Special applications of HBPM (Box 11)

Box 11: HBPM-related unresolved issues in special populations

Population	Unresolved issues
Children	• Uncertain reference values • Few devices validated • Home BP monitoring schedule • Diagnostic role
Elderly	• BP variability • Patient's performance/compliance
Obese people	• Need of validation of arm cuff and wrist devices
Arrhythmias	• Reliability of automated devices • Usefulness of built-in software for arrhythmia indication
Pregnancy	• Need of specific validation of digital devices • Importance of sitting position
ESRD and diabetes	• Lack of established thresholds or management algorithms • Reduced accuracy of the oscillometric devices (due to arterial stiffness typical of these conditions ?) • Need to achieve more aggressive BP target

6.1 Children

During the last few years there has been a renewed interest in measuring BP in children and adolescents after the recognition that aside from the presence of secondary hypertension, in most cases caused by renal diseases, essential hypertension is common in adolescents. Furthermore, the long-term health risk for hypertensive children and adolescents can be substantial.

Hypertension in children has specific characteristics including a particularly poor predictive value of OBP, use of population-based percentiles rather than single thresholds for hypertension diagnosis, association with a broad spectrum of underlying diseases, predominance of secondary hypertension in the early years of life, with increasing rate of essential hypertension in adolescence [133]. Moreover, both white coat and masked hypertension have been described in children [133].

Similarly as in adult population, also in children and adolescents BP variability, observer bias and white-coat effect limit the reliability of office measurements [6].

Because of that ABPM has become an established instrument for the diagnosis of hypertension in this population [134]. However evidence supporting the accuracy of oscillometric devices in children is very limited (see www.dableducational.org).

The increasing availability of equipment for HBPM has led to increasing interest in regular HBP measurements but the data on HBPM in children and adolescents remain scarce. In particular, the factors that have limited the use of HBPM in this population include: a) very limited data about validation of HBP monitors; b) lack of established reference values; c) limited data about reproducibility; and d) difficulty in obtaining cooperation from children.

Devices. Among the few validation studies of the oscillometric monitors in the paediatric age group, some produced successful results, while others failed to pass a validation protocol (see suggested readings).

Diagnostic thresholds. OBP in childhood and adolescents increases steadily during growth and maturation, and adolescence is a fast growth period during which body mass and BP change rapidly [135]. For these reasons, reference BP values specific to sex, age, and/or height have been introduced for children and adolescents by the Task Force For Blood Pressure in Children [52]. However, in children and adolescents daytime ABP, HBP or OBP may differ to a large extent, probably due to the high level of physical activity in this population [136]. Interestingly, in younger children OBP appears to be lower than HBP and this difference is reduced with increasing age disappearing after the age of 12 years [137]. So far only one study has attempted to provide normal HBP values in a population from 6 to 18 years old [108] (Table 4).

Reproducibility of HBPM in comparison to OBP and ABP was investigated in a recent study in children and adolescents [138]. As had been previously shown in adults

[82], HBPM was found to be more reproducible than OBP and as reproducible as ABP [138].

Schedule. There are no recommendations regarding when and how frequently HBPM should be measured in children. In line with findings in adults [77, 82], in children and adolescents a short period of HBPM (duplicate morning and evening measurements on at least 3 days, preferably on 7 days) provides a reliable assessment of the level of BP at home [138].

In conclusion, while OBP measurement remains the recommended method for the evaluation of BP in children and adolescents, HBPM appears to have considerable potential for use in clinical practice and hypertension research in this population but more evidence is needed on its methodology and clinical utility.

6.2 Elderly people

There are several features of hypertension in elderly subjects which make the monitoring of BP out of physician's office particularly important in this population. First, the prevalence of WCH is higher in elderly hypertensives than in younger hypertensives [139]. Second, elderly subjects are characterized by a more pronounced BP variability when compared to younger individuals [140], which by itself may be associated with an elevated cardiovascular risk [141], especially when such high variability is related to excessive BP surge in morning hours [142]. Third, in the elderly autoregulation of the circulation of target organs during excessive BP reduction is impaired, and excessive antihypertensive medication targeting OBP can cause symptomatic hypotension, which may worsen treatment compliance.

While ABPM appears the most suitable technique to diagnose the above problems, also HBPM may be a useful tool to cope with these features and to achieve optimal individual 24 hour BP control in the elderly [143]. Role of HBPM in the elderly (but also in other patients, e.g. those with obstructive sleep apnoea) might increase with the introduction of devices able to provide nighttime BP measurements [144, 145].

The data from large prospective studies and clinical trials using HBPM in the elderly are very limited. Therefore, until more evidence is available, the threshold of HBPM for diagnosis of hypertension and the target HBP level of antihypertensive medication in the elderly should be the same as in other adults i.e. 135/85 mmHg.

In the elderly, it may be difficult to use HBPM because of physical and intellectual limitations. Integrated HBPM devices, with the ability to take multiple automated BP measurements and to provide automated storing and analysis of the data, should thus be preferred in this population and in some cases the assistance of other persons (e.g. family members) may be necessary. Importantly, HBPM in this population should be measured both in the sitting and standing positions, whenever orthostatic hypotension is suspected.

6.3 Obese people

The clinical evaluation of hypertension in obese subjects [146] is complicated by the fact that the discrepancies between office and out-of-office BP are commoner in this group than in the non-obese population. In fact, the severity of obesity seems to be associated with a higher prevalence of both WCH and MH, obesity being one of the main factors associated with a higher HBP relative to OBP [119, 147].

Another important difficulty in BP measurement (both in the office and at home) in the obese subjects is related to inappropriate cuff sizes, which may importantly affect the accuracy of measurement. The use of a regular cuff may lead to an overestimation of BP in obese subjects. Although it is possible to adjust for cuff size after measuring arm circumference by referring to standardized values, it is better and simpler to use the appropriate cuff [148]. The appropriate cuff size in obese subjects depends not only on the arm circumference but also on its shape. A conical shaped arm, common in obese subjects, makes it difficult to fit the cuff to the arm, with a potential for inaccurate BP measurement. The use of wrist devices may help avoiding these difficulties and represents a potential alternative for HBPM in obese subjects but further investigation and technological improvement are needed.

6.4 Arrhythmias

The use of HBPM in patients with arrhythmias raises special concerns. In atrial fibrillation or frequent supraventricular and ventricular extrasystoles, the stroke volume varies depending on the preceding pulse interval and causes a large variation of BP from beat to beat, often making an accurate BP measurement inaccurate or impossible. In atrial fibrillation, this phenomenon is more evident in patients without rate control than those with rate control. Moreover, in patients with arrhythmias, the use of beta-blockers or other antiarrhythmic drugs may often be the cause of bradyarrhythmia, which may also affect the accuracy of measurement.

Generally there is no universally accepted method of BP measurement in patients with arrhythmias, and BP devices vary greatly in their ability to measure BP accurately [149, 150]. In particular, BP measurement is virtually impossible with

oscillometric devices, whose software is in most cases unable to accurately compute systolic and diastolic BP values, especially in case of atrial fibrillation, unless heart rate is adequately controlled by treatment. Research of new solutions is ongoing, but as yet no devices can be considered as validated in this setting. A potentially interesting development is the availability of HBPM devices with arrhythmia detection algorithms, which may be useful as an early alert when arrhythmias occur [6]. The diagnostic accuracy of these algorithms requires validation using appropriately designed protocols, however.

Because of the above problems with automated BP monitors, auscultatory method remains a viable option for HBPM in patients with arrhythmias, if appropriately trained. Several aspects should be taken into account when auscultatory BP is measured in these patients. In patients with atrial fibrillation, systolic BP is frequently overestimated and diastolic BP underestimated, because the first Korotkoff sound is not representative of systolic BP. However, if the deflation rate is no faster than 2 mmHg per heart beat and more than 3 measurements are performed, this variability can be overcome. In the presence of a bradyarrhythmia (i.e. the ventricular response lower than 40-45 beats/min) it is important that the deflation rate is slower than for normal heart rates, as an excessive deflation rate will lead to underestimation of systolic and overestimation of diastolic BP. In summary, HBPM may sometimes be used in patients with arrhythmias, when the likelihood of HBPM results being affected by the rhythm disturbance is low. Devices with an arrhythmia detection function might be useful in this group of subjects but require further testing. In subjects with frequent or persistent arrhythmias HBPM should not be used as the sole diagnostic tool until a validated methodology for BP estimation in these subjects is developed.

6.5 HBPM in Pregnancy

While assessing hypertension in pregnancy, BP sampling errors, as found in current clinical practice, may often result in diagnostic errors. In a survey of all women with eclampsia in the UK, only just over half had both hypertension and proteinuria detected prior to their seizure, in spite of 85% being seen within a week of presenting. Although pre-eclampsia involves much more than hypertension, raised BP is a reliable way to identify this condition and home BP surveillance in addition to antenatal care can only improve its detection.

HBPM, although at present not commonly practiced in this setting, has considerable potential in improving management of pregnant women. It can reduce the number of antenatal visits and not only does not increase anxiety [151], but is actually welcome by women with previous pre-eclampsia, who are particularly anxious about having a recurrence.

There are no established thresholds or management algorithms for managing hypertension in pregnancy with HBPM, although recent community guidelines have been established for visiting health professional [152]. The differences between HBP and OBP are likely to be similar to non pregnant patients, and must be considered when advising referral thresholds. Also, given the potential immediate health risks to both mother and baby, HBPM should be implemented, and a mechanism for same day self referral must be in place to their local maternity unit or appropriate health professional.

HBPM is almost exclusively performed with oscillometric BP devices. There is concern that only a few oscillometric BP monitors are available that have been shown to be accurate in pre-eclampsia, where the altered haemodynamics often result in the BP

being underestimated. Therefore only accurate devices should be recommended. However, few devices have been validated in pregnancy by methodologically acceptable studies (see suggested readings) (Table 5). A tendency to underestimate BP, especially in pre-eclampsia, was observed, but the degree of error does not necessarily preclude their use in clinical practice. Some machines do, however, have a large unacceptable error, and the recommendation remains that each device intended for use in an obstetric population should be specifically evaluated.

As recommended for OBP, also HBPM should be performed with the woman seated or lying on a side at 45° angle, with arm at level of the heart.

6.6 HBPM in chronic renal failure

Patients with a decrease in glomerular filtration rate (GFR) are likely to have co-existing hypertension, including a reduced nocturnal dip in BP and not infrequently higher night-time than daytime BP levels [153-155], also in patients undergoing haemodialysis and continuous ambulatory peritoneal dialysis [156, 157] and after renal transplantation [158-160]. In addition to the renal disease itself, frequently used drugs in these patients (erythropoietin [161], cyclosporine [162]) also contribute to an increase in the prevalence and severity of hypertension.

It has been clearly demonstrated that in patients with chronic renal disease an adequate BP control reduces the rate of decline in renal function [153], cardiovascular morbidity and mortality. Consequently, an accurate assessment of BP status is a key to the optimum management of patient with reduced renal function.

In this scenario, HBPM is a recommended tool to help obtain more reliable BP values in order to detect patients with uncontrolled hypertension. The better prognostic

value of HBPM as compared to OBP has been recently demonstrated, in terms of prediction of composite cardiovascular events, ESRD or death, systolic HBP being an independent predictor for ESRD in patients with chronic renal failure [14, 22].

Furthermore, in patients on hemodialysis, HBP, and not predialysis or postdialysis BP, shares the combination of high sensitivity and high specificity for the diagnosis of hypertension, using ABPM as a reference standard. HBP is also a better correlate of left ventricular hypertrophy in patients on hemodialysis compared with peridialysis BP [35].

In patients on hemodialysis, HBPM should be used to assess BP during the between-dialysis period. While predialysis BP seems to be related to total body water and not to the between-dialysis weight gain [163], postdialysis BP depends on ultrafiltration. Monitoring BP at home thus carries the potential to give us information useful to select the best dialysis conditions.

Finally, it should be mentioned that in ESRD patients the accuracy of the oscillometric devices is reduced due to arterial stiffness, and only a few of them have been successfully validated in these patients [164]

6.7 HBPM in diabetes

Problems with accuracy of oscillometric HBPM devices due to arterial stiffness may be found also in patients with diabetes [165]. Nonetheless, HBPM has been studied in these patients and has been noted both to be similar or superior to OBP in predicting ABPM measurements [166]. The usefulness of HBPM in this population is particularly related to its ability to detect masked hypertension (MH). Indeed, diabetic subjects have a very high (47%) prevalence of MH, detected with HBPM and are at a higher risk of

developing brain and kidney damage [120, 167-169]. Hence, out-of-office monitoring of BP should be performed in diabetics whose OBP is normal, particularly in treated patients, because of the possibility to obtain information on trough BP levels.

While no studies specifically attempted to define the treatment target for HBPM in the diabetic population, one study demonstrated that HBP was a strong and independent predictor of the deterioration of renal function in diabetic patients and that such deterioration was present also at relatively low HBP levels [37]. Based on these observations it was suggested that this target should be lower than that of OBP [37].

7. HBPM vs. ABPM

ABPM was the first out-of-office technique that was shown to significantly improve the management of hypertensive patients [103]. However, ABPM is presently recommended in selected patients only, because of the cost of ABPM devices, the need for a trained clinic staff, and the interference with patients' usual activities [1, 6]. HBPM shares several of the advantages of ABPM and is less expensive, which supports its recommendation for large use in clinical practice [1, 3]. Indeed, in the last ESH BP Measurement Guidelines [6] ABPM and HBPM were clearly proposed as synergic and not as alternative techniques, able to provide complementary information on BP in different conditions and over different time windows. Although in some studies no statistically significant differences were found between HBPM and daytime ABPM [77, 170], lower BP values with HBPM than with daytime ABPM were reported [171-173], particularly in children and adolescents [136].

Reproducibility and diagnostic value. Both HBPM and ABPM show similar reproducibility, which is better than that of OBP [82, 174-176], although the correlation between them is not so high [88, 172]. HBP tends to correlate better with 24-h ABP than with daytime or nocturnal ABP [88]. Significant, although limited correlation was also demonstrated between the white-coat effects based on HBPM and ABPM [103]. Also the prevalence of WCH and MH diagnosed using either ABPM or HBPM were similar in several studies [116, 117, 170], however, in a direct comparison of these two methods, only half of the subjects were defined as having MH on the basis of both ABPM and HBPM, whereas in the remaining ones the diagnosis was made by one method but not by the other [116, 117]. In addition, it should be pointed out that in the majority of subjects in whom the diagnosis of MH was made with only one method the disagreement between the two methods was small (<5 mm Hg), suggesting that this discrepancy heavily depended on the fact that BP values were close to diagnostic cut-offs [103, 170].

The notion that ABPM and HBPM may have different value in WCH diagnosis led to a proposal of an algorithm whereby HBPM was used in individuals, otherwise considered at low risk, with 'office' hypertension. If HBPM is normal, an ABPM should be ordered to confirm the diagnosis of WCH. The cost-effectiveness of such approach has not been tested, but it was demonstrated that OBP and HBP may indicate sustained hypertension in almost 40 % of subjects who have WCH according to ABPM [177]. Therefore no firm recommendation can be made at this point as to the relative place of HBPM and ABPM in the diagnosis of WCH or MH. An individualized approach taking into account the patient's characteristics (BP values, cardiovascular risk, target organ damage) and availability of HBPM and ABPM seems a reasonable

option. In case of disagreement between methods, ABPM should probably take precedence because of the huge amount of outcome data available for this technique.

Prognostic value. Several, although not all [178] studies have documented that the average levels of HBP [42, 117, 179, 180] and ABP [42, 117, 180, 181] correlate with organ damage (OD) better than OBP. Direct comparisons of ABPM and HBPM did not identify significant differences between them in terms of correlation with left ventricular mass index or microalbuminuria [25, 28, 182]. Also WCH and MH diagnosed with either method have similar relationships with left ventricular mass index and wall thickness [117]. The superiority of ABP over OBP in predicting risk of morbid events is well documented [6], while few published studies support a closer relationship of HBP compared with OBP with cardiovascular outcomes (see section: *HBPM and prognosis*). The predictive value of selective and combined elevation in OBP, ABP and HBP for mortality was assessed in the PAMELA study: a selective elevation in HBP versus ABP values or vice versa carried an increased risk. The overall ability to predict death, however, was not greater for HBP and ABP than for OBP [11].

Available data indicate thus that ABP has similar or higher prognostic value than HBP, in particular when considering the prognostic value of nocturnal ABP.

BP control by treatment. Studies comparing antihypertensive treatment based on ABP and HBP instead of OBP showed in either case less intensive drug treatment and less BP control with fairly similar costs [103, 172]. These studies however, were limited by use of the same normalcy thresholds for OBP and HBP. When treatment decisions driven either by ABPM or HBPM were directly compared, no difference in BP changes was seen [183]. A relatively low (75 %) agreement between ABPM and HBPM has

been reported in the evaluation of poorly controlled hypertension, HBPM classifying a lower proportion of patients as WCH than ABPM [180].

The above considerations indicate that **HBPM should be considered not as a substitute but as a complement of ABP** (Table 6) [170]. From a clinical standpoint obtaining information on either OBP, HBP and ABP may represent the ideal clinical procedure. Low sensitivity and positive predictive value (versus ABPM) are important limitations for HBPM if it is to be considered as a screening test.

8. HBPM: research applications (Box 12)

Given the availability of validated, fully automated oscillometric BP measuring devices, it becomes more and more attractive to include HBPM in the evaluation of the BP lowering effects of antihypertensive drugs [4, 127]. HBPM has several advantages over OBP in this indication.

1) HBPM provides multiple BP readings, thereby improving the precision and the reproducibility of measurements compared with office readings [79, 132, 184] The standard deviation (SD) of the mean difference between two sets of measurements (an index of measurement stability) based on HBPM is about half as much as that derived from OBP readings [185].

2) Owing to its better accuracy and reproducibility, HBPM increases the statistical power of comparative studies, making it possible to minimize the number of patients to be included in clinical trials [184].

3) HBPM may be useful as a guide to initiate and titrate antihypertensive therapy in research setting [103].

4) HBPM allows the identification of patients with WCH or MH, and therefore better defines the BP normalization rate achieved by various drug regimens [117, 186, 187].

5) the placebo effect, frequently observed when BP is conventionally measured in a clinic setting, is minimal or even absent using HBPM [80, 132]. This facilitates greatly the design and the conduct of clinical trials.

6) HBPM offers the opportunity to assess the duration of action of antihypertensive drugs. This can be done by measuring BP at trough, before the morning dose, and again when the full effect of the drug is expected, for instance at midday or in the evening [143, 188]. Based on these measurements it is possible to calculate the morning: evening ratio, which may provide similar information with the trough : peak ratio, an index widely used to reflect the duration of action of antihypertensive drugs [132, 143].

7) HBPM can be carried-out for weeks or months, providing valuable information on the BP changes occurring during the whole trial.

8) Implementing HBPM into clinical trials may be motivating for patients, thereby contributing to an improved compliance and BP control [123].

The reliability of HBPM increases with the number of BP readings available for analysis [79, 89] therefore a proper schedule of monitoring should be implemented. To make the results of studies employing HBPM comparable it is advisable that a standardized schedule is used, unless there are specific reasons to modify it. If the results of clinical studies are to be translated in practice, an identical schedule as recommended for a clinical setting should be used also in research (see above).

In clinical trials, only validated electronic BP monitors should be used, with preference for those with memory for storage of readings or for devices with a print-out of BP values or data download on a PC, in order to prevent reporting bias [53, 189]. For this reason, ideally, the same device should be used to measure BP at home and in the clinic setting.

Box 12 - Usefulness of HBPM in clinical trials

Advantages :

1) **Availability of multiple BP readings, affording a better reproducibility**
2) **Reduction of the sample size of patients to be included**
3) **Guidance of treatment (initiation and titration)**
4) **Identification of patients with white-coat or masked hypertension**
5) **Minimization of placebo effect**
6) **Assessment of the duration of action of antihypertensive drugs (M/E ratio)**
7) **Possibility to measure BP during prolonged periods**
8) **Improvement of compliance**
9) **Management of unexplained vertigo or fatigue (SBP< 100 mmHg)**
10) **Time until antihypertensive drugs have maximum effect (in day or week) can be analysed**

9. Conclusions - Implementation of guidelines: closing the gap between experts' recommendations and medical practice

This document has summarized the information on the use of HBPM in clinical practice and in research presently available in published papers. The large amount of new data available has required a substantial revision of the previous recommendations on the same topic issued in 2000 [4]. While reviewing this material, heterogeneous data was often found. In fact when considering HBPM there are areas of convincing evidence, but also areas of uncertainty, where more studies are still needed. Further progress in this field will be made possible by future research taking advantage from the

fast development in technology of BP measuring devices. Additional knowledge will be offered by the increasing amount of evidence provided by population studies and by randomized trials on hypertension management exploring the added value related to the information provided by HBPM.

Implementation of experts' recommendations on HBPM in clinical practice requires a close interaction with general practitioners. Such interaction is presently being aimed at in different countries, and should lead to a sharing of goals and methods of HBPM between scientists and general practitioners at a local level, aimed at favouring the largest possible diffusion of this approach. Finally, further progress in this field will require closer cooperation between scientists and manufacturers. On one side scientists have to identify and propose the type of information that a given BP measuring device should be able to provide to the clinician while, on the other side, manufacturers should be receptive to suggestions, and translate them into new features for HBPM devices, to make them more responsive to the clinical needs, both in terms of hardware and software development.

This document would be incomplete without a set of instructions for patients/users. This simple how-to-do set of information is being prepared and will be published as a separate document.

When outlining the fields where **future research** could be most useful, the following topics, already highlighted in the 2000 consensus document on HBPM, should be considered:

- Development and production of "adjustable cuff" which may be applicable to all adult arms, in order to avoid the inaccuracy induced by miscuffing.

- More attention to be paid to haemodynamic parameters other than BP, that are becoming important in cardiovascular evaluation, such as heart rate, pulse pressure, central BP and pulse wave velocity.
- Application of a single international standard protocol for the validation of all BP measuring devices must be encouraged, to allow for comparison between studies performed in different places according to a similar methodology. This should be coupled with procedures to review the validation papers, to ensure their unbiased reliability.
- Determination of HBPM reference values not only for systolic and diastolic BP but also for heart rate and pulse pressure, which appear to be independently related to cardiovascular prognosis.
- More prospective studies to evaluate the prognostic values of the proposed thresholds of HBPM normality
- Studies to determine the reference values of HBP and the diagnostic usefulness of HBPM in specific populations (children, pregnant woman, elderly subjects, patients with diabetes or chronic kidney disease). These studies may be completed by the evaluation of the feasibility of HBPM and of device validity in these specific populations.
- Specific studies to compare the prognostic values of OBP, HBP and ABP measurements are needed. These studies may use markers of target organ damage and progression of hypertension as end-points in addition to or instead of mortality and morbidity. Evaluation of the prognostic impact of different HBPM protocols, and the number and the frequency of measurements, is also desirable.

- Studies to determine the role of HBPM in resistant hypertension and its comparison to the role of OBP and ABP measurements are needed in order to define the appropriate management strategy.
- Longitudinal studies to define the target value of HBP in treated hypertensives on a prognostic basis are needed.

Finally, the evidence gathered so far on the clinical value of HBPM in daily practice should promote reimbursement of the costs related to this approach by Insurance Companies as well as by Public and private Heath Care Systems

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Table 1. Home blood pressure measurements and outcomes

Study name	Population	Drug	Time of measurements	Average number of measurements	Outcome
Ohasama [12,15]	General population aged ≥40 years	(-) and (+)	Morning	21	Cardiovascular, non-cardiovascular and all-cause mortality
Ohasama [16]	General population aged ≥40 years	(-) and (+)	Morning	1 to 25	Total stroke morbidity
Ohasama [19]	General population aged ≥40 years	(-) and (+)	Morning	25	Total stroke morbidity
Ohasama [17]	General population aged ≥40 years	(-) and (+)	Morning	25	Total, haemorrhagic and ischaemic stroke morbidity
Ohasama [18]	General population aged ≥40 years	(-) and (+)	Morning and evening	47	Total stroke morbidity
Kahoku [24]	Community dwelling elderly aged ≥65 years	(-) and (+)	Morning and evening	20	Cardiovascular, non-cardiovascular and all-cause mortality
Kahoku [23]	Community dwelling elderly aged ≥75 years	(-) and (+)	Morning and evening	20	Disability, cardiovascular and all-cause mortality, cardiovascular and stroke morbidity,
SHEAF [13]	Treated hypertensives aged ≥60 years	(+)	Morning and evening	27	Cardiovascular and all-cause mortality, total cardiovascular morbidity
PAMELA [10,11]	General population aged 25 - 74 years	(-) and (+)	Morning and evening	2	Cardiovascular and all-cause mortality
CKD Veterans [14]	Veterans with CKD	(+)	Morning, afternoon and evening	Not available	Morbidity of end stage renal disease, all-cause mortality
Flanders [42]	Genaral population aged ≥60 years	(-) and (+)	Morning	3	Major cardiovascular events (cardiovascular death, myocardial infarction and stroke)
Didima [21]	General population aged ≥18 years	(-) and (+)	Morning and evening	12	Total cardiovascular morbidity and mortality

Table 2. HBPM schedule in outcome studies

	Number of subjects	Home BP Monitoring Schedule			
		Days	Morning readings	Evening readings	Total readings
Ohasama [12]	1789	28	1	0	28
SHEAF [13]	4938	4	3	3	24
PAMELA [11]	2051	1	1	1	2
Flanders [42]	391	1	3	0	3
Didima [21]	665	3	2	2	12

Table 3. Thresholds proposed in prospective cohort studies

Acronym	Year	Sample	Number	Age	Readings	Threshold
Ohasama [12, 15, 91]	1997–2006	P	1913 (58.6)	60.8 (>40)	M (28 days)	<137/84
Kahoku [23, 24]	1999	P	1186 (57.5)	73.5 (>65)	M/E (5)	125–134/…
	2005	P	461 (58.4)	80.0 (>75)	M/E (5)	<135/…
Rave [37]	1999	DM	77 (48.0)	37	M/E (2)	<138/83
SHEAF [13]	2004	HT	4939 (51.1)	70	M/E (4)	<135/85
PAMELA [10, 11]	2005–2006	P	2051 (49.4)	51.2 (25–75)	M/E (1)	<135/83
Agarwal [14]	2006	CKD	217 (3.7)	67.4	M/A/E (7)	<130/…

P indicates population sample. DM, HT and CKD refer to patients with diabetes mellitus, hypertension, and chronic kidney disease. Number indicates the number of patients enrolled with the proportion of women given between parentheses. M, A and E stand for morning, afternoon and evening with the number of measurement days given between parentheses.

Table 4. Proposed HBP thresholds for clinical use in children (with permission from [111]).

Height (cm)	*N*	Percentiles for boys (n = 347)		*N*	Percentiles for girls (n = 420)	
		50th[a]	95th[a]		50th[a]	95tha
120-129	23	105/64	119/76	36	101/64	119/74
130-139	51	108/64	121/77	51	103/64	120/76
140-149	39	110/65	125/77	61	105/65	122/77
150-159	41	112/65	126/78	71	108/66	123/77
160-169	45	115/65	128/78	148	110/66	1 24/78
170-179	91	117/66	132/78	46	112/66	125/79
180-189	57	121/67	134/79	7	114/67	128/80

Table 5. Meta-analysis of 10 studies in which validation of HBPM devices was carried out in pregnant women with and without pre-eclampsia (PE)

	Auscultatory (mercury)		Intra-arterial	
	Pregnancy	PE	Pregnancy	PE
Subjects (n)	597	176	8	30
Systolic *	- 1.13 (5.80)	- 4.60 (8.04)	4.11 (10.95)	- 17.76 (10.12)
Diastolic *	- 1.20 (6.03)	- 5.16 (7.19)	3.00 (8.00)	- 8.17 (6.59)

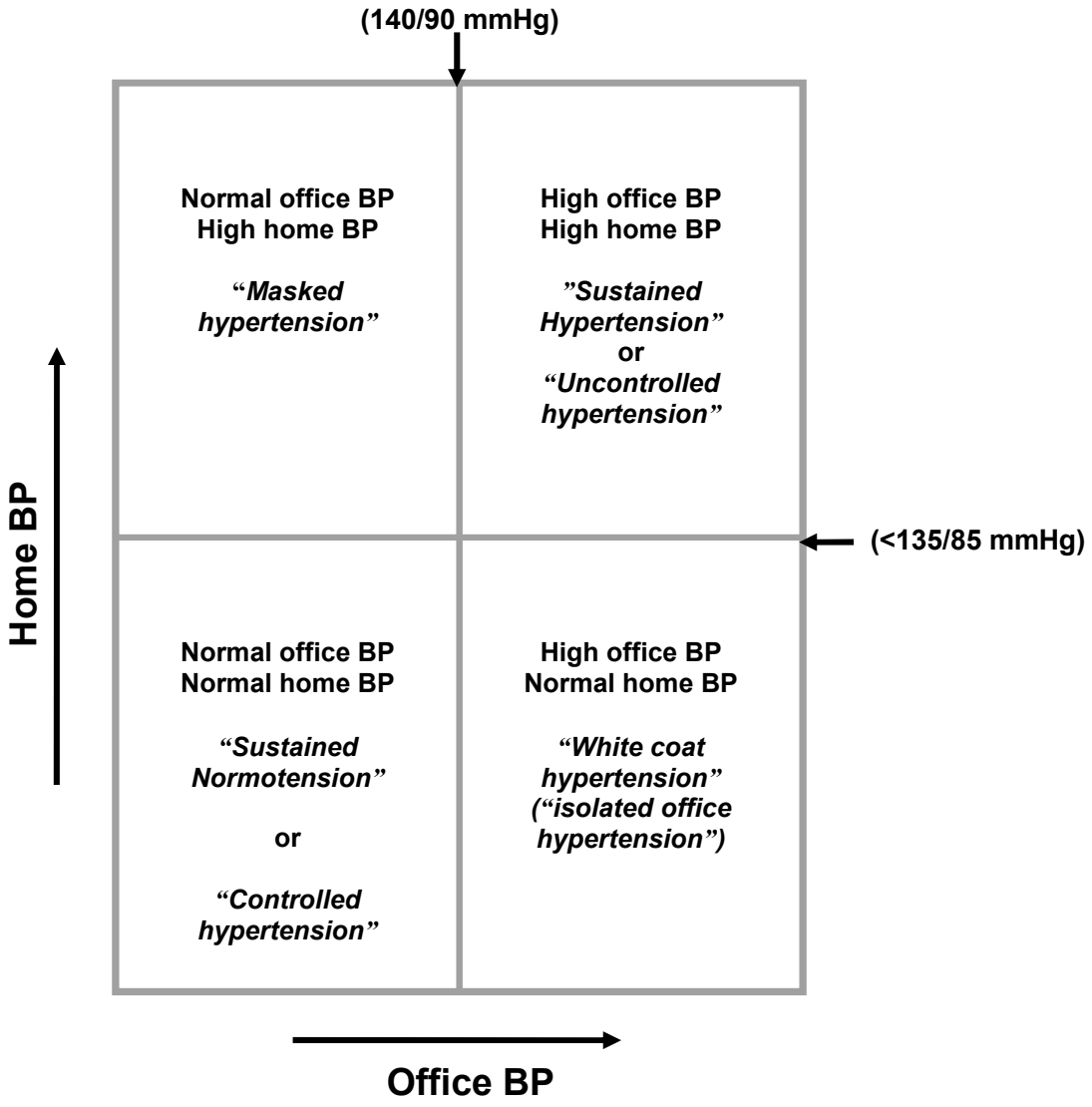
* mean pressure difference between oscillometric measurement and, respectively, auscultatory or intra-arterial measurement

Table 6. Comparison of main features of ABPM and HBPM.

Feature	ABPM	HBPM
Daytime BP	+ +	+ +
Night-time BP and dipping	+ +	-
Morning BP	+ +	+
24 hour BP variability	+ +	±
Long-term BP variability	±	+ +
WCH and MH diagnosis	+ +	+ +
Placebo effect	-	-
Reproducibility	+ +	+ +
Prognostic value	+ +	+ +
Patient involvement	-	+ +
Patient training	±	+ +
Physician involvement	++	+
Patients' acceptance	±	+ +
Monitoring treatment effects	Extensive information on diurnal BP profile, can not be repeated frequently	Appropriate for long-term monitoring, limited information on BP profile
Hypertension control improvement	+	++
Cost	High	Low
Availability	Low	High

Figure 1. Schematic relationship between Office and Home BP

True hypertensives are at greatest risk of CV events, true normotensive subjects at lowest risk. White coat and masked hypertensives lie in between with WCH having a risk close to true normotensives and masked hypertensives closer to true hypertensives.



Appendix A

Suggested readings (To be posted on the Journal of Hypertension Website)

Introduction

1. Parati G, Bilo G, Mancia G. White coat effect and white coat hypertension: What do they mean? Cardiovasc Rev Rep 2003;24:477-484
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Methodological aspects

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