AHA/ASH/PCNA Scientific Statement

Call to Action on Use and Reimbursement for Home Blood Pressure Monitoring

A Joint Scientific Statement From the American Heart Association, American Society of Hypertension, and Preventive Cardiovascular Nurses Association

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Abstract—Home blood pressure monitoring (HBPM) overcomes many of the limitations of traditional office blood pressure (BP) measurement and is both cheaper and easier to perform than ambulatory BP monitoring. Monitors that use the oscillometric method are currently available that are accurate, reliable, easy to use, and relatively inexpensive. An increasing number of patients are using them regularly to check their BP at home, but although this has been endorsed by national and international guidelines, detailed recommendations for their use have been lacking. There is a rapidly growing literature showing that measurements taken by patients at home are often lower than readings taken in the office and closer to the average BP recorded by 24-hour ambulatory monitors, which is the BP that best predicts cardiovascular risk. Because of the larger numbers of readings that can be taken by HBPM than in the office and the elimination of the white-coat effect (the increase of BP during an office visit), home readings are more reproducible than office readings and show better correlations with measures of target organ damage. In addition, prospective studies that have used multiple home readings to express the true BP have found that home BP predicts risk better than office BP (Class IIa; Level of Evidence A). This call-to-action article makes the following recommendations: (1) It is recommended that HBPM should become a routine component of BP measurement in the majority of patients with known or suspected hypertension; (2) Patients should be advised to purchase oscillometric monitors that measure BP on the upper arm with an appropriate cuff size and that have been shown to be accurate according to standard international protocols. They should be shown how to use them by their healthcare providers; (3) Two to 3 readings should be taken while the subject is resting in the seated position, both in the morning and at night, over a period of 1 week. A total of $\geq$12 readings are recommended for making clinical decisions; (4) HBPM is indicated in patients with newly diagnosed or suspected hypertension, in whom it may distinguish between white-coat and sustained hypertension. If the results are equivocal, ambulatory BP monitoring may help to establish the diagnosis; (5) In patients with prehypertension, HBPM may be useful for detecting masked hypertension; (6) HBPM is recommended for evaluating the response to any type of antihypertensive treatment and may improve adherence; (7) The target HBPM goal for treatment is $<$135/85 mm Hg or $<$130/80 mm Hg in high-risk patients; (8) HBPM is useful in the elderly, in whom both BP variability and the white-coat effect are increased; (9) HBPM is of value in patients with diabetes, in whom tight BP control is of paramount importance; (10) Other populations in whom HBPM may be beneficial include pregnant women, children, and patients with kidney disease; and (11) HBPM has the potential to improve the quality of care while reducing costs and should be reimbursed. **(*Hypertension.* 2008;52:10-29.)**

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The standard method for the measurement of blood pressure (BP) in clinical practice has traditionally been to use readings taken with the auscultatory technique by a physician or nurse in a clinic or office setting. Although such measurements are likely to remain the cornerstone for the diagnosis and management of hypertension for the foreseeable future, it is becoming increasingly clear that they often give inadequate or even misleading information about a patient's true BP status. All clinical measurements of BP may be regarded as surrogate estimates of the "true" BP, which may be regarded as the average level over prolonged periods of time. In the past 30 years, there has been an increasing trend to supplement office or clinic readings with out-of-office measurements of BP, taken either by the patient or a relative at home (home or self-monitoring [home BP monitoring; HBPM]) or by an automated recorder for 24 hours (ambulatory blood pressure monitoring [ABPM]).

Of the 2 methods, HBPM has the greatest potential for being incorporated into the routine care of hypertensive patients in the same way that home blood glucose monitoring performed by the patient has become a routine part of the management of diabetes. The currently available monitors are relatively reliable, easy to use, inexpensive, and accurate and are already being purchased in large numbers by patients. Despite this, their use has been only cursorily endorsed in current guidelines for the management of hypertension, and there have been no detailed recommendations in regard to the manner in which they should be incorporated into routine clinical practice. In addition, despite the fact that there is strong evidence that HBPM can predict clinical outcomes and improve clinical care, the cost of the monitors is not generally reimbursed. It is the purpose of this call-to-action article to address the issues of the incorporation of HBPM into the routine management of hypertensive patients and its reimbursement.

Health and Economic Consequences of Hypertension and Its Inadequate Control in the United States

Hypertension affects >65 million persons in the United States, according to analyses of data from the National Health and Nutrition Examination Survey (NHANES), 1999–2000.[1] In this analysis, a person was classified as having high BP by having a systolic BP of ≥140 mm Hg or a diastolic BP of ≥90 mm Hg, taking BP-lowering medications, or being told at least twice by a physician or other health professional that they had high BP.[1] This estimate may be considered conservative because it does not include the additional persons with systolic BP of ≥130 mm Hg or diastolic BP of ≥80 mm Hg with either diabetes mellitus or chronic kidney disease who would be classified as having high BP according to the definition put forward by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7).[2] Worldwide estimates approach 1 billion people with high BP.[3]

High BP increases the risk of total mortality; mortality due to heart disease, stroke, chronic kidney disease, and heart failure; and morbidity associated with nonfatal cardiovascular disease (CVD) events.[2] On the basis of estimates of population-attributable fractions, high BP may account for 27% of total CVD events in women and 37% in men,[4] 14% of myocardial infarctions in men and 30% in women,[5] 35% of ischemic strokes,[6] 39% of chronic heart failure events in men and 59% in women,[7] and 56% of chronic kidney disease.[8] These results, based on North American populations, are supported by global estimates. In the Global Burden of Disease Project, a systolic BP threshold of 115 mm Hg was used to distinguish between optimal and nonoptimal BP levels. Globally, 62% of stroke, 49% of coronary heart disease, and 14% of other CVD was attributable to nonoptimal BP. Approximately 12.8% of all deaths (7.1 million) and 4.4% of all disability life-years lost (64.3 million) in the year 2000 were due to CVD attributable to nonoptimal BP levels.[9] Clearly, high BP is a major cause of mortality and morbidity in the United States and worldwide.

Randomized controlled trials have provided convincing evidence that BP-lowering treatment reduces the risk of total mortality, stroke, coronary heart disease, heart failure, and chronic kidney disease.[2] Consequently, clinical practice guidelines have been promulgated in the United States and elsewhere to promote detection, treatment, and control of high BP.[2] Despite 30 years of attention to high BP control in the United States, current levels of control are suboptimal. On the basis of data from NHANES 2003–2004, 76% of persons with high BP had been told that their BP was high, 65% were on treatment with BP-lowering medications, and only 37% were controlled to BP levels <140 mm Hg systolic and <90 mm Hg diastolic.[10] These proportions mask ethnic disparities. The proportion aware of having high BP was 67% among non-Hispanic whites, 66% among non-Hispanic blacks, and 63% among Mexican Americans. The proportion on treatment varied from 55% among non-Hispanic blacks, to 54% among non-Hispanic whites, and 48% among Mexican Americans. The proportion with controlled BP was highest in non-Hispanic whites (35%), intermediate in non-Hispanic blacks (29%), and lowest in Mexican Americans (26%).[10]

The direct and indirect cost of high BP and its complications was estimated to be $63.5 billion in the United States in 2006.[11] This figure is almost certainly an underestimation of the true costs of the complications of high BP because, in this analysis, the cost attributable to hypertensive disease was distinguished from the costs attributed to coronary heart disease ($142.5 billion), stroke ($57.9 billion), and chronic heart failure ($29.6 billion),[11] and, as documented above, high BP is a major contributor to these forms of CVD. Given the substantial mortality, morbidity, and cost associated with poorly controlled BP in the United States and other countries, identification of low-cost strategies to improve control of high BP should be a high priority.

Recommendations of Professional Organizations on the Use of HBPM

The use of HBPM is recommended by several national and international guidelines for the management of hypertension, including the European Society of Hypertension,[12] the American Society of Hypertension,[13] the American Heart Association,[14] the British Hypertension Society,[15] the European Society of Hypertension,[16] the Japanese Hypertension Soci-

ety,[17] the World Health Organization–International Society of Hypertension,[18] and JNC 7,[2] which is the generally accepted guideline for the United States. For the most part, the recommendations from the various organizations are similar, as outlined below, although there are some minor differences.

1. The levels of HBPM considered normal by the majority of the guidelines are a BP of <135 mm Hg systolic and 85 mm Hg diastolic. The Japanese guidelines regard "definite normotension" as a pressure <125/75 mm Hg and "definite hypertension" as >135/85 mm Hg, and the British Hypertension Society stated that home BP levels of <130/85 mm Hg can probably be regarded as normal.[15] The World Health Organization–International Society of Hypertension Guidelines recommended an upper limit of 125/80 mm Hg.[18]
2. The use of accurate and properly validated automated digital BP monitors is strongly encouraged. Monitors must have passed at least 1 of 3 accepted validation protocols.
3. Adequate patient education on the use of BP monitors should precede any recommendation for self-monitoring of home BP.
4. The indications for HBPM include the assessment of white-coat hypertension and the monitoring of effective BP control in conjunction with office BP measurement.
5. There is a lack of data on the accuracy and use of HBPM in pregnant women and obese patients.

Current Usage of HBPM

The use of home monitors has been increasing steadily over the past few years. A Gallup poll of hypertensive patients conducted in 2005[19] obtained the following results:

- The number of patients monitoring their BP at home has increased steadily over the past 5 years, being 38% in 2000 and 55% in 2005, an increase of 17%.
- The proportion of patients owning a monitor has increased from 49% in 2000 to 64% in 2005.
- In 2000, 35% of patients reported that a physician recommended their using a home monitor, and in 2005 this was 47%.
- Eighty-six percent of patients who had been advised to purchase a monitor had done so; only 46% of patients who had received no recommendation from their physicians had bought monitors.
- The use of home monitors is more common in older and more affluent patients.
- Thirty-five percent of hypertensive patients now check their BP at least once a week.
- The most commonly used monitors are those that are placed on the upper arm and are self-inflating; the use of wrist monitors is growing rapidly, and they now are used by 22% of patients who own monitors.
- Of patients who do not own monitors, 14% said that expense was the reason.

A recently published survey of 855 hypertensive patients attending specialized clinics in Italy found that 75% were regularly performing HBPM.[20] Users tended to be younger and better educated than nonusers; 58% used electronic devices that recorded from the upper arms, and 19% used wrist monitors.

Physicians are also becoming enthusiastic about the use of HBPM. A survey of family practitioners in Hungary found that 90% recommended the use of HBPM.[21] The physicians' main concerns were the use of nonvalidated devices, the possibility that patients would become obsessive about their BP, and the lack of proper training in the use of the monitors. A survey of pediatric nephrologists in Germany found that 70% prescribed the use of HBPM for children with renal disease and hypertension.[22]

Techniques for Performing HBPM

When HBPM was first used, BP was measured with the auscultatory technique,[23] but this has now been almost completely supplanted by the use of oscillometric devices specifically designed for use by patients in the home. These are mostly fully automatic, so that the patient only needs to wrap the cuff around the upper arm and press a button for the machine to take a reading and display the values for systolic and diastolic pressure on a screen. Some require the patient to inflate the cuff manually.

Arm Monitors

Monitors that measure the BP in the brachial artery with a cuff placed on the upper arm continue to be the most reliable and have the additional advantage that the brachial artery pressure is the measure that has been used in all the epidemiological studies of high BP and its consequences. For the majority of patients, this is the preferred type of monitor.

Wrist Monitors

Wrist monitors are the most convenient type to use and are preferred by many patients. They have the potential advantage that they can be used in obese individuals in whom putting a cuff on the upper arm is difficult. A potential disadvantage is that the wrist must be held at the level of the heart when a reading is being taken, which increases the possibility of erroneous readings.[24] A recently introduced model avoids this problem by taking readings only when the wrist is held over the heart. Experience with wrist monitors is relatively limited at present, and most of the monitors that have been tested have failed the validation studies (see http://www.dableducational.org). They are therefore not generally recommended for routine clinical use.

Finger Monitors

These devices have been found to be very inaccurate and should not be used.[25]

Testing and Validation of Monitors

Patients should be advised to use only monitors that have been validated for accuracy and reliability according to standard international testing protocols. The original 2 protocols that gained the widest acceptance were developed in the United States by the Association for the Advancement of Medical Instrumentation in 1987 and the British Hypertension Society in 1990, with revisions to both in 1993. These required testing of a device against 2 trained human observers

in 85 subjects, which made validation studies difficult to perform. One consequence of this has been that there are still many devices on the market that have never been validated adequately. More recently, an international group of experts who are members of the European Society of Hypertension Working Group on Blood Pressure Monitoring have produced an international protocol that is replacing the 2 earlier versions[26] and is easier to perform. Briefly, it requires comparison of the device readings (4 in all) alternating with 5 mercury readings taken by 2 trained observers in 33 patients. Devices are recommended for approval if both systolic and diastolic readings taken are within at least 5 mm Hg of each other for at least 2 of each subject's 3 readings in 22 of the 33 subjects.

Unfortunately, only a few of the devices that are currently on the market have been subjected to proper validation tests such as the Association for the Advancement of Medical Instrumentation and British Hypertension Society protocols, and several devices have failed the tests. An up-to-date list of validated monitors is available on the Dabl Educational Web site (http://www.dableducational.org) and the British Hypertension Society Web site (http://www.bhsoc.org/default.stm).

The fact that a device passed a validation test does not mean that it will provide accurate readings in all patients. There can be substantial numbers of individual subjects in whom the error is consistently >5 mm Hg with a device that has achieved a passing grade.[27] This may be more likely to occur in elderly[28] or diabetic patients.[29] At least 1 home monitor has been found to be accurate in patients with end-stage renal disease.[30] For this reason, it is recommended that each oscillometric monitor should be validated on each patient before the readings are accepted. No formal protocol has yet been endorsed for doing this, but if sequential readings are taken with a mercury sphygmomanometer and the device as described below, major inaccuracies can be detected.

Checking Monitors for Accuracy

When patients get their own monitor, it is very important to have them bring it into the clinic to check their technique as well as the accuracy of the monitor. A simple and practical version of the European Society of Hypertension Protocol has been developed for this purpose and can be done in <10 minutes by the physician or other healthcare provider and the patient. The patient sits at the physician's desk with the monitor set up and the arm resting on the desk. Five sequential same-arm BP readings are recorded with a gap of no more than ≈30 seconds between readings. The first 2 (D1 and D2) are taken by the patient using the patient's device; the third (M1) by the physician using a mercury sphygmomanometer; the fourth (D3) by the patient; and the fifth (M2) by the physician. There is a tendency for the BP to decline during this process (Figure 1). The accuracy of the device can be assessed by comparing the device and mercury readings, although exact criteria for determining acceptability have not been established.

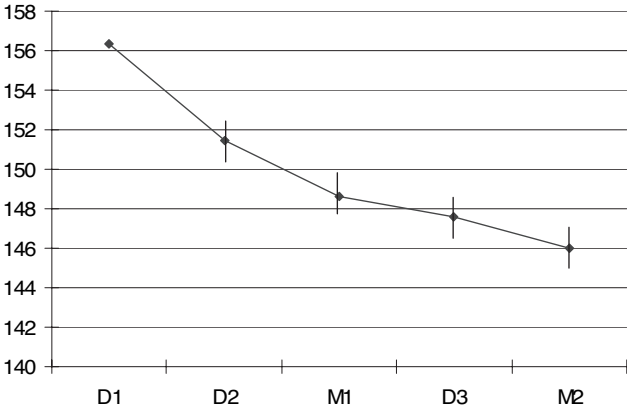

Figure 1. Systolic BP recorded during clinical validation of home monitors in 92 consecutive patients. D1 to D3 are readings taken with the patient's device, and M1 and M2 are mercury readings taken by a physician (Pickering TG, Eguchi K, unpublished data, 2007).

Patient Education

It is critical that patients should be educated in the proper use of home monitors. Automated oscillometric devices are much easier to use than auscultatory monitors but still require some training. Patients should be advised to only purchase monitors that have been validated according to standard protocols (see above), and their upper arm circumference should be measured so that they can be advised if they need a large cuff. They should be told that readings should be taken when they are sitting quietly after resting for 5 minutes, with the arm supported on a flat surface, such that the upper arm is supported at the level of the heart. The patient's back should be supported, and both feet should be flat on the floor. The cuff should be positioned so that its mid portion lies over the brachial artery. Most patients find it easiest to measure BP in the nondominant arm, and this should be encouraged unless there is a marked difference between the 2 arms, which is relatively rare in the absence of obstructive arterial disease.[31] The patient should not have indulged within the 30 minutes preceding the measurement in activities such as smoking, drinking coffee, or exercising, which are likely to affect BP. It is recommended that at least 2 and preferably 3 readings be taken at 1 time and the value for each reading written down, unless the device has a memory that stores the readings automatically. The interval between readings can be as little as 1 minute.[32] Readings should routinely be taken first thing in the morning (preferably before the subject takes medications) and at night before the subject goes to bed. The frequency of readings can be determined by the physician. Patients should not be encouraged to take readings at other times, such as when they think they are under stress or that their BP is high. Patients need not routinely keep diaries, but it may be helpful to record if they missed taking their medications. Patients should be advised that the variability of readings is high and that individual high or low readings have little, if any, significance.

Once a monitor has been purchased, it is recommended that the patient should bring it into the office to verify both the patient's technique and the accuracy of the device. This procedure should be repeated annually. Unlike aneroid and mercury devices, however, it has been found that the accuracy of the measurement of the cuff pressure does not deteriorate over time with oscillometric monitors.[33]

Contraindications to HBPM

There are some patients in whom HBPM is contraindicated. The oscillometric method may not work well in patients who have atrial fibrillation or other arrhythmias such as frequent ectopic beats. In such patients, it may be worth checking the ability of a monitor to measure BP in the clinic by comparing the monitor readings against those taken with the auscultatory method.

Some patients may become obsessed about taking readings. The inherent variability of BP means that there will inevitably be some high readings, which in anxious patients may exacerbate their anxiety, leading to further increases of BP and effectively setting up a vicious cycle. In such patients frequent checking of their BP should be discouraged, and in extreme cases it should be discontinued altogether.

Information Provided by HBPM

Although office BP measurement has been the foundation of the diagnosis and management of hypertension, when the Korotkoff sound technique is used, there are many sources of inaccuracy (eg, noisy environment, impaired hearing, soft Korotkoff sounds, leaky bulb).[34] Additionally, office BPs have been reported to be less reliable than both home and ambulatory measurements; they have also been found to vary depending on the healthcare provider conducting the measurement and subject to terminal digit preference (observer tendency to record measurement using certain digits, eg, 0 in the units position, more frequently than other digits, eg, 7).[35–41] Importantly, office measurements are associated with white-coat hypertension and the risk of false-positive diagnoses of hypertension and needless prescription of medications.[42,43]

HBPM as an alternative to the office BP reading can no longer be overlooked as a significant adjunct to assessment and treatment of individuals with hypertension. The following paragraphs will review data about the quality and type of increased information that HBPM can provide healthcare providers.

Information Is Reliable and Reproducible

One of the advantages of HBPM is that large numbers of readings can be used to define a patient's BP level. Stergiou et al[44] compared the reproducibility of BP measured in the office (5 visits within 3 months), in the home (6 workdays within 2 weeks), and by ABPM (twice, 2 weeks apart). Reproducibility was quantified with the use of the standard deviation of the differences between repeated measurements. The researchers found that home BP readings provided the lowest standard deviation of the differences (6.9/4.7 mm Hg for systolic and diastolic pressures) compared with clinic (11.0/6.6 mm Hg) and ambulatory pressures (8.3/5.6 mm Hg) and therefore had superior reproducibility. Home readings may be more stable than ABPM readings because the conditions in which they are taken are less variable.

Long-term reproducibility was examined in a sample of 136 untreated subjects who measured their BP at home at least 3 times on at least 3 days in each of two 4-week periods separated by 1 year.[45] Two clinic BPs were also obtained from subjects at each of 2 health examinations also separated by 1 year. The mean differences between the first and second home BP readings (0.8 ± 7.7 mm Hg for systolic BP and 0.9 ± 5.5 mm Hg for diastolic BP) were significantly smaller than those for the clinic BP (-3.9 ± 13.8 mm Hg for systolic BP and -3.1 ± 10.2 for diastolic BP) ($P<0.001$ for both comparisons). These findings suggest that home BP measurements are more reproducible over time than office BP measurements.

Another aspect of the reliability of HBPM is the accuracy of patients in reporting the readings displayed by the monitors. This issue has been examined by providing patients with monitors that, unknown to the patients, have memory. When patients' reported readings are compared with those stored in the memory, it has been found that there is often poor agreement between them. In 1 study, 20% of readings were reported with an error of >10 mm Hg, and the error rate was higher in patients with less well controlled hypertension.[46] In another there was a consistent tendency for high readings to be underreported.[47] Thus, patients may tend to make their home readings look better than they really are, and for this reason monitors with memory are to be encouraged.

Number of Home BP Measurements Needed to Ensure a Reliable Estimate of True BP

The reproducibility of home BP measurements is heavily dependent on the number of measurements that are averaged. One study demonstrated that the maximal reduction in the standard deviation of the mean difference between the average values of 2 HBPM sessions is obtained when the average value is based on ≥30 readings (3 measurements per day for 10 days).[48] Others have suggested that no further improvement is obtained by increasing the number >5[49] and that improvement in measurement precision is obtained with ≥6 home measurements.[50,51]

There is some agreement that correlations with ambulatory BP are more reliable if the first day's home BP readings are discarded.[52,53] Two recent analyses have recommended taking between 8 and 15 readings in total,[53,54] and we recommend following the last set of European Society of Hypertension guidelines to take ≥2 morning and 2 evening readings every day for 1 week[16] but to discard the readings of the first day, which gives a total of 12 readings on which to make clinical decisions. Getting multiple readings is particularly important for the initial diagnosis of hypertension, but the same procedure is also recommended to be performed at intervals in patients whose condition is thought to be stable and who require long-term follow-up. Patients should be instructed to record all the readings that they take.

Information About True BP Level

BP fluctuates continuously in a 24-hour period, and the variability is influenced by neural, mechanical, and humoral factors.[55,56] Patient-related factors, for example, hurrying to get to a clinic visit or impatience over waiting to be seen, are also associated with BP variability. BP readings in the office tend to reflect the patient's status at the moment and may not

be a true representation of the BP outside the office.[57] It is difficult to determine true BP level on the basis of 1 or 2 BP measurements at the time of an office visit. HBPM is a simple and inexpensive way to obtain a large number of readings, representative of usual BPs over long periods of time, that are unaffected by the white-coat effect (the increase of BP that occurs during an office visit) or other factors influencing variability that are present in the office.[58] Patterns of BP rather than isolated measurements can be important in confirming the diagnosis of hypertension. For patients found to be hypertensive in the office, high BPs measured at home may confirm the diagnosis, whereas low home BP levels may indicate a need for further assessment with ambulatory BP measurement for identification of white-coat hypertension.[59]

A recent development in the measurement of clinic BP is the introduction of automated oscillometric devices that can take multiple (2 to 6) readings in the clinic in the absence of a physician. They have the potential advantage over traditional clinic measurement in that they reduce the white-coat effect (hence, they are consistently lower than physicians' readings)[60] and are closer to the daytime average measured with ABPM.[61] Data are lacking for comparisons with HBPM.

Another technique that has been used by patients to monitor their BP out of the office is the use of automated devices in malls and supermarkets. These devices may be inaccurate, and their use is not encouraged.

Information About BP at Different Times of the Day

The pattern of BP change over the day may vary considerably from one patient to another, depending on their daily routine. Thus, in Japanese studies, the evening pressure tends to be lower than in the morning, which has been related to the fact that Japanese people often take baths in the evenings, after which the BP is reduced.[62] Other studies have found that evening readings are higher.[63,64] The morning pressure may be higher if the patient has drunk alcohol the night before[65] or has sleep apnea.[66] Antihypertensive treatment may also have a major influence.[67] There is some evidence that the morning pressure may be a better predictor of risk than the evening pressure.[68,69] For these reasons, it is generally recommended that patients should take readings both in the early morning and at night. The main limitation of home monitors in comparison with 24-hour ambulatory monitors is that nighttime readings cannot be taken. However, monitors are being developed that can be programmed to take a limited number of readings during the night.

HBPM for Diagnosing Hypertension

The diagnosis of hypertension may be expedited by HBPM, particularly in individuals with stage 1 hypertension, in which the elevation of BP is relatively modest (typically those without diabetes, chronic kidney disease, or target organ damage). Often individuals with white-coat hypertension may make multiple office visits over a prolonged period of months before the diagnosis of hypertension is established. Home BP is usually lower than office BP (as a result of the white-coat effect) and may suggest a diagnosis of white-coat hypertension. However, in ≈10% of patients it may be higher, indicating a possible diagnosis of masked hypertension.[70] As described below, there is increasing evidence that home BP may provide a better prediction of risk than office BP, and therefore any discrepancies between office and home BP should be taken seriously.

Evaluation of White-Coat Hypertension and White-Coat Effect

National hypertension guideline committees from the United States,[2] Europe,[16] Canada,[16,71] and Japan[17] have all endorsed the use of HBPM to confirm or refute the diagnosis of white-coat hypertension, which is defined as high BP occurring only in a medical care setting and that has been reported in as many as 20% of patients in whom hypertension has been diagnosed by office BP.[72–74] The phenomenon that leads to it is called the white-coat effect, which is usually defined as the difference between the office BP and the BP measured at home or during the day by ABPM, and which has been attributed to anxiety, a hyperactive alerting response, or a conditioned response.[42] The white-coat effect is typically positive and is present in the majority of hypertensive patients, but in some patients with low office BP it may be negative (home BP higher than office BP). If the home BP is normal (<135/85 mm Hg), a diagnosis of white-coat hypertension may be considered.

White-coat hypertension is more common in the elderly and is generally associated with a relatively benign prognosis similar to that seen in truly normotensive subjects, as shown by several prognostic studies comparing office BP and ambulatory BP.[75,76] However, with longer-term follow-up (eg, 6 to 11 years), there have been reports of higher CVD event rates that are similar to those seen in patients with sustained hypertension.[77,78] The implication of these results is that out-of-office monitoring (HBPM and/or ABPM) should be conducted long term in all patients diagnosed with white-coat hypertension.

White-coat hypertension cannot be diagnosed reliably on clinical examination alone. The average BP levels obtained by multiple home readings and those recorded by ABPM while the patient is awake are very close, and both are lower than BPs measured in the office.[37] In a study of 247 untreated hypertensive patients, investigators examined the extent to which HBPM can be an alternative to ABPM to diagnose white-coat hypertension. Using ABPM as a reference, they found that the specificity of HBPM to detect white-coat hypertension was 88.6%, and the sensitivity was 68.4%.[79] Although home BPs may not be completely without white-coat effects,[80] they may serve better as a screen for white-coat hypertension than for the final diagnosis. The Ohasama study was the first to show the superior predictive value of home BP over office BP, such that patients with white-coat hypertension were at relatively low risk.[81] The Pressioni Arteriose Monitorate e Loro Associazioni (PAMELA) study evaluated prognosis with office, home, and ambulatory BP over an 11-year follow-up.[78] Although they found that patients with high office BP and normal home BP or ambulatory BP (ie, white-coat hypertension) were at increased risk, the thresholds were different. Thus, the systolic BP level that would confer a risk of cardiovascular death over an 11-year period

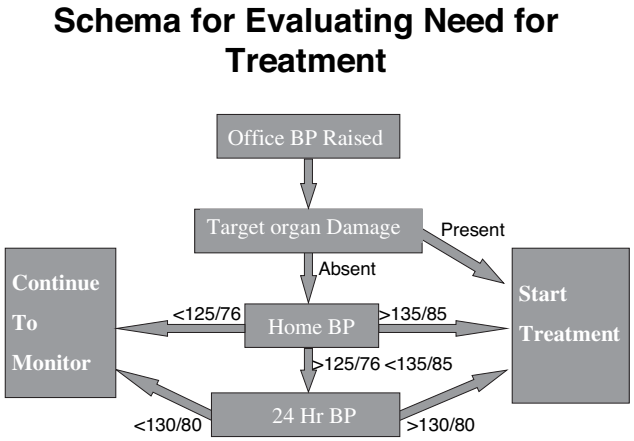

Figure 2. Schema for evaluating BP status of hypertensive patients, which can be used in patients in whom the decision to start treatment may be uncertain on the basis of the office BP, which may be just above or below the cutoff point defining adequate control. HBPM may be used to aid the diagnosis if necessary in conjunction with ABPM.

of 10% was 179 mm Hg for office BP, 163 mm Hg for home BP, and 157 mm Hg for daytime ambulatory BP.[82] This is consistent with the recommendation that a lower cutoff level should be used for home BP than for office BP.

Algorithm for Use of HBPM in Clinical Practice

An algorithm that uses both HBPM as an initial screening test and ABPM to make the definitive diagnosis has been proposed by a panel of the American Society of Hypertension[13] and by the First International Consensus Conference for Self-Blood Pressure Monitoring,[83] as shown in a modified version in Figure 2. The rationale for this is that the exclusive reliance on office BP for making therapeutic decisions may lead to both undertreatment and overtreatment in individual patients because of both the inherent variability of BP and the white-coat effect. As originally proposed, this algorithm would be applied only to patients who have a persistently high office BP (>140/90 mm Hg), but it might also be applicable to those with high-normal BP (eg, a patient who has had some readings >140/90 mm Hg but on rechecking has a slightly lower level), in whom masked hypertension may be suspected. In addition, in patients with diabetes or kidney disease, it may be used if the office BP is ≥130/80 mm Hg. In patients who have evidence of target organ damage that is thought to be the result of hypertension, it may be decided to start treatment on the basis of the high office BP, although HBPM is still valuable for monitoring the response to treatment. The rationale here is that numerous studies have shown that even subclinical markers of organ damage such as microalbuminuria or left ventricular hypertrophy have been shown to increase CVD risk, as reviewed in the recent European guidelines on the management of hypertension,[84] which may justify more aggressive treatment.

In those in whom the decision to start treatment remains unclear, HBPM is an appropriate next step, with the goal of obtaining a minimum of 12 readings taken both in the morning and at night over a period of 7 days. If the average value is >135/85 mm Hg, there is a high probability (85%) that the ambulatory BP will also be high,[85] and a decision to start treatment can be made. If the home BP is <125/76 mm Hg, the probability of missing a diagnosis of true hypertension is quite low.[85] Because BP varies with time, whichever method of measurement is used, a diagnosis of white-coat hypertension is not cast in stone, and all patients in whom the diagnosis is made require long-term monitoring of BP, for which HBPM is ideally suited.

Evaluation of Masked Hypertension

HBPM may also be useful in detecting masked hypertension, also known as reverse white-coat hypertension or isolated home or isolated ambulatory hypertension. Masked hypertension occurs when a patient's office BP is <140/90 mm Hg but ambulatory or home readings are in the hypertensive range (typically >135/85 mm Hg).[86] It conveys the same cardiovascular risk as sustained hypertension, and therefore it is important that it is detected.[87,88]

The prevalence of masked hypertension may be ≈10% in the general population,[81,87,89] but at the present time there is no consensus in regard to how it should be detected or treated in people who have not been diagnosed as hypertensive. However, in patients with treated hypertension that is thought to be well controlled (ie, an office BP <140/90 mm Hg), it may be equally common. In the Self-Measurement of Blood Pressure at Home in the Elderly: Assessment and Follow-up study (SHEAF) of 4939 elderly treated hypertensive patients being followed in family practices in France, the prevalence of masked hypertension (defined by an office BP <140/90 plus home BP >135/85 mm Hg) was 42% of the patients with a normal office BP.[87] In a descriptive study of 438 Turkish patients receiving care in an internal medicine clinic, all patients had their BP measured in the office, by 24-hour ABPM, and by HBPM twice a day for 10 days.[90] The prevalence of masked hypertension was <5% until the seventh decade of life, and it was 7.6% in the seventh and 16.6% in the eighth decade of life. There were no significant differences in the prevalence of masked hypertension depending on whether ambulatory or home BPs were used to define it. In the Japan Home versus Office BP Measurement Evaluation (J-HOME) study[91] of treated hypertensive patients in Japan, >50% of patients with controlled office BP had masked hypertension (home BP >135/85 mm Hg). These patients tended to be older and were more likely to have a past history of coronary heart disease or chronic kidney disease. This high prevalence in patients whose BP appears to be controlled by conventional clinical criteria makes the case that HBPM should be used routinely in treated hypertensive patients.

Evaluation of Prehypertension

Approximately 28% of American adults, or 59 million people, have prehypertension, defined as BP in the range of 120 to 139/80 to 89 mm Hg.[2,11] Because this is normally diagnosed by office BP, some will have white-coat hypertension. Regular and consistent monitoring of BP should begin

Table 1. Prospective Studies Relating Home BP and Office BP to Cardiovascular Events and Mortality

Study	Population Studied	No. of Subjects	Home BP Schedule				Outcome
			Days	AM	PM	Total	
Ohasama[81]	Population	1789	28	1	0	28	Strokes and mortality predicted better by HBPM
SHEAF[99]	Treated hypertensive patients	4939	4	3	3	24	CV morbidity and mortality predicted better by HBPM
PAMELA[82]	Population	2051	1	1	1	2	CV and total mortality predicted better by HBPM
Belgian[100]	Referred	391	1	3	0	3	Combined CV events predicted better by HBPM
Didima[98]	Population	662	3	2	2	12	CV events predicted by both HBPM and office BP

CV indicates cardiovascular.

during prehypertension to establish the need for treatment or help to establish a firm baseline for determining response and change. Limited information is available on the use of HBPM in this situation, but it is ideally suited to these needs. One study (the Tecumseh study) found that in prehypertensive individuals (n=735) diagnosed by office readings, home BP (average of 14 readings, 7 days with morning and afternoon or evening readings) was more predictive than office BP of future BP status after 3 years, even when the same number of measurements was used for both methods.[92]

Evaluation of Resistant Hypertension

HBPM may be helpful for evaluating resistant hypertension in patients exhibiting high office BP under antihypertensive therapy. Patients who appear to be refractory to treatment in the office may have adequately controlled home BP[93] and consequently may require less intensification of drug treatment than those whose home BP is also high.

HBPM for Predicting Cardiovascular Risk

HBPM has been shown to be useful in predicting target organ damage, CVD mortality, and CVD events. In a small study conducted in Italy, Mulè et al[94] compared office, ambulatory, and home BP measurements and their relationship to various indices of target organ damage. Subjects underwent ECG recordings, echocardiographic studies, and microalbuminuria assays. Neither systolic nor diastolic BP recorded in the office showed a significant correlation with left ventricular mass or albumin excretion rate. However, home BP, especially during the second day of monitoring, correlated significantly with left ventricular mass, albumin excretion rate, and global target organ damage.

Several other cross-sectional studies have shown that BP measured at home correlates with hypertensive target organ damage. Kleinert et al[23] found that the degree of left ventricular hypertrophy determined by echocardiography was more strongly correlated to multiple self-measurements than to office BP. Abe et al[95] found that the correlation between BP levels and target organ damage for self-measured readings at home and office readings was similar. Hypertensive complications were equally related to home and office BPs.[95] Jula et al[96] compared multiple office and home BP and ambulatory BP measurements in the clinical evaluation of hypertension using a sample of 239 untreated hypertensive adults. They found that office and home BPs predicted albuminuria and left ventricular hypertrophy at least equally to ABPM. Left ventricular mass index correlated slightly more strongly with morning home systolic BP/diastolic BP than evening readings (r=0.46/0.43, P<0.001 and r=0.41/0.37, P<0.001 for morning and evening BPs).

Other investigators have used cross-sectional designs to evaluate the usefulness of HBPM in diabetics. Researchers examined whether BP elevations in the morning detected by HBPM were more predictive than office BP for microvascular (nephropathy and retinopathy) and macrovascular complications (coronary heart disease and cerebral vascular disease) in type 2 and type 1 diabetic patients.[69,97] In both groups, home BP but not office BP was strongly related to nephropathy. There were no significant differences between the groups for the other measures of target organ damage.

Five prospective studies (all with several publications) have compared the prediction of morbid events with the use of both conventional office BP and home BP (Table 1).[99,100] Three were based on population samples, and 2 recruited hypertensive patients. Four studies found that home BP was the stronger predictor of risk. The fifth (Didima) reported that both home BP and office BP predicted risk equally well.[98]

The first was the population-based Ohasama study, which was conducted in 1789 subjects aged >40 years who were followed for a mean of 6.6 years.[81] Subjects were asked to measure their BP at home within 1 hour of waking over a 4-week period. The mean number of measures recorded was 20.8±8.3. As part of annual screening visits, 2 consecutive measures of BP were recorded by a nurse or technician after 2 minutes of rest. When HBPM and BPs taken during annual screening were included in a Cox regression model, only home systolic BPs were significantly related to cardiovascular mortality risk (multiple home systolic BP relative hazard=1.012, P=0.048; screening systolic BP relative hazard=1.000, P=0.972; multiple diastolic BP relative hazard=1.013, P=0.414; screening diastolic BP relative hazard=1.006, P=0.642). Moreover, the average of 2 home BP measures showed a stronger relationship to mortality than the screening BPs taken by nurses and technicians.

More recently, the Ohasama data have been examined to determine the predictive value of HBPM on the risk of transient ischemic attack and hemorrhagic and ischemic stroke.[101] Of the 1789 patients in the original study, mean duration of follow-up was 10.6 years. Home BP values were linearly related to risks for total, hemorrhagic, and ischemic stroke. A 10-mm Hg elevation in home systolic BP was associated with 29%, 32%, and 30% increases in the risk of total, hemorrhagic, and ischemic strokes, respectively. Fi-

nally, home BP values showed a significantly greater relation to the risk of both hemorrhagic and ischemic stroke than screening BP values ($P<0.02$). In another analysis, Ohkubo and colleagues[102] found that the predictive value of stroke risk increased for all measures of home BP but was greatest when at least 14 measurements were obtained. The original reports were based on readings taken in the morning, but a later analysis included evening readings and found that both measures predicted strokes, but morning readings were superior in patients taking antihypertensive medications.[68] The Ohasama study also included ABPM and has reported that the average BP during the first 2 hours after waking is an independent predictor of risk.[103] These findings emphasize the importance of taking BP readings early in the morning.

The second prospective study was the SHEAF study, a 3-year prospective cohort study designed to determine the prognostic value of HBPM compared with office measures in an older population (>60 years) with hypertension seen in general practice settings in France.[99] Treated patients with hypertension were followed in 2 phases: Phase 1 included an evaluation of office and home BP over 1 month, and phase 2 included a 3-year observational phase without specific recommendations with regard to the management of hypertension. Phase 1 office measures included triplicate measures on each of 2 visits. HBPM was done over a 4-day period with 3 consecutive measurements taken in the morning and repeated in the evening. At the end of follow-up, neither method of measurement was significantly related to CVD events or mortality. However, with the use of a Cox model to control for predictors such as age, CVD history, and smoking status, HBPM was predictive of cardiovascular events. Each 10-mm Hg increment of systolic BP measured at home increased the risk of a cardiovascular event by 17.2%, and each 5-mm Hg increase in diastolic BP increased the risk by 11.7%. Conversely, when the model was applied to office measures controlling for the same predictors, there was no significant increase in CVD events. In patients with masked hypertension (ie, normal office but raised home BP, who comprised 9% of the total sample), the risk was increased (hazard ratio, 2.06) and much higher than in patients with high office and normal home BP (hazard ratio, 1.18).

The third study was PAMELA, a population-based survey of 2051 Italian subjects who were evaluated with HBPM (2 readings: 1 in the morning and 1 in the evening), office BP (3 readings taken with a sphygmomanometer on each of 2 visits), and ABPM.[82] Approximately half of the subjects were hypertensive. Over a 10-year follow-up, there were 186 deaths. All 3 measures of BP predicted mortality. The steepest association between BP and outcomes was with the nighttime BP, but this may be attributed to the fact that nighttime BP shows much less variation than other measures. The goodness of fit, which is a better measure of the strength of the relationship, was strongest for the home BP. In a subsequent publication,[78] it was reported that elevation of any of the 3 measures of BP was associated with increased risk. Thus, a high home BP should not be ignored, even if other measures are normal.

The fourth study was conducted in Belgium and compared the prognostic significance of office and home BP, both measured by a physician (who visited the patients' homes), and ambulatory BP in a sample of 391 adults ≥60 years of age who were being seen in a primary care setting.[100] Home and office examinations were performed within 2 weeks of one another. Health outcomes (ie, aggregate of stroke, myocardial infarction, and cardiovascular death) were determined after a median follow-up of 10.9 years. Home BP and daytime and nighttime ambulatory BP predicted cardiovascular events, independent of office BP. BP measured by the primary care physician in the office was not independently predictive of future cardiovascular events. Diastolic but not systolic home BP added prognostic precision to daytime and nighttime ambulatory BP. In sum, the prognostic value of BP measured in the patient's home was at least equal to that of daytime ambulatory BP. This study is of particular interest because it suggests that the relatively poor predictive value of office BP in comparison with home BP is not because of the confounding effects of the physician but rather because of the medical setting itself.

The fifth study is a long-term (8.2 years) follow-up of 662 subjects in the Didima Study,[98] which is a population-based study of the inhabitants of Didima, a village in Greece. The average age was 54 years, and hypertension was diagnosed in 28%, of whom 55% were on antihypertensive drug treatment. Office BP was evaluated on 2 days (3 readings each day) by the village family physician. Home BP was taken as duplicate readings morning and evening for 3 days. The main finding was that both the office and the home BP predicted CVD events, but neither was clearly superior. After adjustment for age and gender, the hazard ratio for a 1-mm Hg increase of systolic BP was 1.016 (CI, 1.004 to 1.029; $P=0.01$) for home BP and 1.021 (CI, 1.009 to 1.034; $P=0.001$) for office BP. When fully adjusted (including history of CVD, antihypertensive treatment, diabetes, and smoking), neither measure of systolic BP predicted events. For diastolic pressure, the office BP was superior to the home BP and was the only measure to predict events after fully adjusting for covariates (hazard ratio, 1.034; CI, 1.008 to 1.061; $P=0.01$). The authors concluded that the CIs were too wide to draw firm conclusions about the relative importance of the 2 methods for predicting risk.

A sixth study performed in Kahoku, a rural town in Japan, on 1186 elderly people (mean age, 74 years) reported a U-shaped relationship between home BP and mortality (evaluated from death certificates).[104] There was no comparison with office BP, however, and therefore it is not included in the table.

Three longitudinal studies have examined the ability of HBPM to predict the progression of renal disease. One found that systolic home BP was a stronger predictor of end-stage renal disease and death than office BP among 217 veterans with chronic kidney disease who had a median follow-up of 3.5 years.[105] The second followed 77 patients with diabetes for 6 years and concluded that home BP was a better predictor of progression of diabetic nephropathy than office BP measurements.[106] The third used a sample of 113 hypertensive patients with nondiabetic chronic kidney disease who were followed for 3 years and found that home BP measured in the

morning was a better predictor of the decline in glomerular filtration rate.[107]

These studies thus present a very consistent picture showing that HBPM can give a better prediction of cardiovascular risk than office BP (class IIa; level of evidence A).

Information About BP Control

HBPM has the ability to provide information about BP control outside the office setting. Using data (n=3400) from the J-HOME study, investigators examined the characteristics of BP control based on home and office measurement.[108] Although 42% of the sample had their BP controlled by office BP criteria (<140/90 mm Hg), only 34% also had home BP control (<135/85 mm Hg). Other investigators have also demonstrated the value of HBPM in determining BP control outside the office.[109–111] The SHEAF study described above found that the 9% of patients with normal office BP but elevated home BP (ie, masked hypertension) had twice the risk of CVD events as the group in whom both office and home BP were controlled.[99]

Use of HBPM to Guide and Evaluate Treatment

HBPM may provide important information about the responsiveness of individuals to antihypertensive treatment. In the Study on Ambulatory Monitoring of Blood Pressure and Lisinopril Evaluation (SAMPLE), investigators compared 3 measures of BP (office, ambulatory, and home) with changes in BP resulting from treatment with an angiotensin-converting enzyme inhibitor on regression of left ventricular hypertrophy.[112] Improvements in left ventricular mass, an intermediate measure of target organ damage, were predicted best by both ambulatory BP and home BP, whereas no changes were correlated with the changes in office BP. Thus, this trial showed the benefit of the use of HBPM to monitor the response to treatment, with important physiological implications.

Findings about adjusting antihypertensive treatment on the basis of home BPs are mixed. Two studies have compared the effects of treating according to home BP compared with office BP. In a blinded randomized controlled trial (Treatment based on Home or Office blood Pressure [THOP]) that compared the use of office BP versus HBPM to adjust hypertension treatment, more participants in the home measurement group had their antihypertensive treatment stopped (25.6% versus 11.3% in the office measurement group; $P<0.001$) but had higher final office and 24-hour ambulatory BP than the office measurement group.[113,114] A second study, with a very similar design, was the Home versus Office Measurement: Reduction of Unnecessary Treatment Study (HOMERUS), in which 430 patients with uncontrolled hypertension were randomized to HBPM or usual care. Their physicians were blinded regarding their treatment group and were provided with the BP levels measured either in the office or by HBPM. In both cases, the target BP was <140/90 mm Hg. At the end of 1 year, the patients in the HBPM group were on less antihypertensive medication. The office BPs were the same in both groups, but the 24-hour ambulatory BP was significantly higher in the HBPM group.

Thus, in both studies, treatment based on HBPM appeared to lead to less intensive drug treatment and thus less tight BP control. However, the differences between the 2 groups in both studies can be explained by the fact that home BP tends to be lower than office BP, although the target BP level was the same for both groups. It remains unclear whether the HBPM group was undertreated, but the study provided evidence for the feasibility of basing treatment on home readings.

Studies of the effects of placebo drugs have found that they have little effect on home BP, in contrast to their much larger effect on office BP.[49] By having patients take readings both in the early morning and in the evening, the adequacy of BP control throughout the day (and the trough-to-peak ratio) can be assessed.[115] Thus, HBPM may be regarded as the method of choice for monitoring the effects of antihypertensive treatment.

Use of HBPM as an Intervention for Improving Medication Adherence and BP Control

Although most of the attention paid to HBPM is for its value as a diagnostic tool, there is increasing evidence that it may also serve as an intervention to improve BP control. Success with behavioral or lifestyle interventions in patients with chronic conditions is often improved by encouraging the patient to become actively involved in his or her care, which may include self-monitoring. In the case of obesity, 75% of people who are successful with long-term weight loss report weighing themselves regularly.[116]

Effects on Medication Adherence

If HBPM does improve BP control, a potential mechanism is by improved medication adherence, which is supported by recent evidence. Ogedegbe and Schoenthaler[117] reviewed 11 randomized controlled trials that tested the effects of HBPM on medication adherence in various settings, including nonclinical sites. Nine of the 11 trials reviewed were complex interventions that tested the effects of HBPM in combination with other adherence-enhancing strategies such as patient education,[118,119] counseling on medication adherence by nurses, pharmacists, or through a telephone-linked system,[120–122] use of timed-medication reminders,[123] monthly home visits,[124] and nurse case management.[125] Fifty-four percent of the trials (6 of 11) reported statistically significant improvement in medication adherence attributed to HBPM, and the intervention effects were greatest in trials that tested HBPM along with other adherence-enhancing strategies. Because of the heterogeneity of the adherence measures used, the authors could not perform a meta-analysis of the intervention effects. However, when the intervention effects were categorized on the basis of the type of medication adherence measure employed in each of the individual trials, all 3 studies that employed objective electronic monitoring of medication adherence reported positive intervention effects,[123,125,126] and 3 of 5 trials that utilized pill counts reported significant improvement in medication adherence,[120,122,127] whereas all the studies that utilized self-report measures or pharmacy refill data reported negative find-

ings.[118,119,121,124,128] The authors concluded that the data on the effects of HBPM on patients' medication-taking behavior are mixed and that HBPM should be considered a useful adherence-enhancing strategy, especially when used in combination with other approaches such as patient counseling, patient reminders, and use of nurse case managers. Not included in this systematic review was a Spanish study that tested the effect of HBPM compared with usual care in improving medication adherence assessed with electronic monitoring. Among the 200 study participants with newly diagnosed or uncontrolled hypertension, 92% of the intervention group were compliant (ie, took at least 80% to 100% of prescribed antihypertensive medications) compared with only 74% of the control group ($P=0.0001$).[128]

Effects on BP Control

There is also evidence that HBPM is associated with better BP control. A meta-analysis of 18 randomized controlled trials that compared HBPM with usual care found that HBPM resulted in better BP control.[129] Although these BP effects were small (2.2/1.9 mm Hg), the implications from a prognostic standpoint and as a population-based strategy are significant. Taken together, these findings suggest that HBPM on its own will not necessarily result in better BP control, but it has the potential to do so if the data are communicated regularly to the healthcare providers and appropriate action is taken. Further study is needed in this area.

Need for HBPM in Special Populations

The Elderly

It is well established that the white-coat effect tends to be greater in older than in younger patients. Because there are also potential hazards of excessive BP reduction in older people, the case for using out-of-office monitoring such as HBPM is very strong. The difference between the office and home BP (the white-coat effect) increases progressively with age, so that office BP tends to overestimate the out-of-office BP more in older than in younger people.[130] The variability of systolic home BP readings also increases with age.[130] HBPM can also be used to detect orthostatic BP changes if readings are taken with the subject both sitting and standing.

Patients With Diabetes

BP control is one of the most important aspects of managing patients with diabetes,[131] and as in patients without diabetes, the home BP is superior to the office BP for predicting the 24-hour BP level.[132] In 1 study the home BP was not consistently lower than the office BP.[51] It is not uncommon for home BP to be elevated (>130/80 mm Hg) even when office BP is controlled.[133] In the J-HOME study, 7% of patients with diabetes with an office BP below the target level (<130/80 mm Hg) had elevated home BP (>130/80 mm Hg).[109] It has been reported that home BP, particularly when measured in the morning, correlates better with target organ damage such as diabetic nephropathy than office BP.[69] In this study, two thirds of patients with normal office BP had elevated home BP in the morning hours. Thus far, only 1 study has examined the ability of out-of-office BP monitoring in patients with diabetes to predict cardiovascular outcomes,[134] and, as in patients without diabetes, ambulatory BP monitoring predicted risk independent of office BP. One study has examined the role of home BP monitoring (in conjunction with glucose monitoring and nurse case management) and found a small but significant reduction of BP (3.4/1.9 mm Hg) compared with the control group.[135] There are at present no official guidelines for the home BP level equivalent to an office BP of 130/80 mm Hg in patients with diabetes, although 1 study used 125/75 mm Hg.[51]

Although there is less evidence for the benefits of HBPM in patients with diabetes, existing data are entirely consistent with observations in those without diabetes, and because there is strong evidence that aggressive reduction of BP is more effective in patients with diabetes in lowering CVD risk, a strong case can be made for the wider use of HBPM in patients with diabetes. The International Diabetes Federation has advocated its use,[136] but the American Diabetes Association has remained silent on this issue.

Pregnancy

The accurate measurement of BP during pregnancy is one of the most important aspects of prenatal care, and preeclampsia, which is the most common cause of maternal and fetal death, can develop quite rapidly. The situation in pregnancy is essentially dynamic: BP first falls and then rises, and therefore the best way of detecting an abnormal pattern that presages preeclampsia may be to monitor its changes very frequently throughout the course of pregnancy. Thus, the earliest manifestation of preeclampsia is a failure to decrease BP, or a premature increase of BP, during the second trimester. HBPM is theoretically ideal for monitoring changes in BP during pregnancy because it is the best technique for providing multiple readings recorded at the same time of day over prolonged periods of time.[137] Several monitors have been validated for use in pregnant women.[138] Although some studies have been done to show that HBPM is practical[139] and has the potential to reduce clinic visits,[140] the extent to which it will improve the evaluation and management of hypertension during pregnancy has yet to be shown.

White-coat hypertension is not uncommon and may lead to unnecessary early termination of pregnancy.[141] This should be detectable with the use of HBPM.

Chronic Kidney Disease

Hypertension is highly prevalent in patients with chronic kidney disease and also in the dialysis population, but the BP is very variable, and measurements made in dialysis centers provide a poor prediction of clinical outcomes.[142] HBPM has been advocated in these patients but thus far has been used infrequently.[143] Despite the fact that arterial stiffness is greatly increased in such patients, oscillometric monitors may still be accurate in patients with end-stage renal disease.[30,144,145] HBPM has been shown to be superior to measurements made in the dialysis unit for predicting ambulatory hypertension.[146]

Children

Increasing attention is being paid to the issue of hypertension in children, particularly because, with the epidemic of obe-

sity, it is likely that its prevalence will increase; guidelines for its evaluation were published in 2004.[147] The phenomenon of white-coat hypertension occurs in children just as in adults,[148] and therefore it makes sense to use out-of-office monitoring in addition to clinic measurements. Thus far, there are relatively few studies of HBPM in children. One useful study was performed by Stergiou et al[149] in 55 children aged 6 to 18 years, of whom 26 were hypertensive by office BP criteria. There were strong correlations between office and home BP (0.73 for systolic and 0.57 for diastolic pressure) and also between home BP and ambulatory BP (0.72/0.66). In the hypertensive children, the systolic home BP was lower than both office and ambulatory BP, whereas in normotensive children the ambulatory BP was higher than both the office and home BP. The authors concluded that home BP is difficult to interpret in children. Another study found that home BP was better than office BP at predicting ambulatory BP in children with renal disease.[150] Thus, HBPM appears to be of great potential value in children when the proper cuff size is used, although more studies are needed in this area.

Cost-Effectiveness of HBPM

The potential for HBPM to be cost-effective for the diagnosis and management of hypertension has received little attention. In principle, there are 2 types of situations in which it is used: (1) for the diagnosis of hypertension and hence the need for treatment, for which monitoring need only be done for a limited period of time; and (2) for the evaluation of treatment, for which long-term monitoring is appropriate. Other potential advantages for use of HBPM are a reduced need for office visits but with increased need for alternative communication by telephone or telemetry, as well as more accurate assessment of overtreatment and the opportunity of reducing medication in some patients.

In contrast to HBPM, it has been shown that use of ABPM can be cost-effective when applied to the diagnosis of hypertension (specifically white-coat hypertension).[151,152] If HBPM and ABPM were fully equivalent with regard to detection of white-coat hypertension, then any difference in cost between the 2 methods would be a basis for choosing the one that costs less. Currently, Medicare reimburses ABPM for patients with suspected white-coat hypertension. This requires the patient to meet the following criteria: (1) office BP >140/90 mm Hg on at least 3 separate office visits with 2 separate measurements made at each visit; (2) at least 2 BP measurements taken outside the office that are <140/90 mm Hg; and (3) no evidence of end-organ damage. The charges allowed by the Centers for Medicare & Medicaid Services for ABPM in the United States to confirm the diagnosis of white-coat hypertension vary from ≈$70 to ≈$105 (data from Centers for Medicare & Medicaid Services Web site). This reimbursement (*Current Procedural Terminology* code 93784) includes both the monitoring procedure for ≥24 hours, per se, and an interpretation provided by the physician.

There is no recognized *Current Procedural Terminology* code for HBPM (without the memory and computational equivalents to ambulatory monitoring) and no systematic basis for how reimbursement might be developed. However, several known costs and likely factors allow for an argument that HBPM be considered for reimbursement if incorporated into a systematic plan for management of individual hypertensive patients. These are summarized below.

Cost of Home BP Devices

Many devices for HBPM are available for purchase by consumers who want to take their own BP or measure that of others in their household or at screening sites. Devices are available at drug stores and many other sources. Purchase through Web sites is firmly established and was reviewed in 2005.[153] Prices vary from <$50 to ≈$100 (sources: Web sites for CVS Pharmacy [www.cvs.com], Rite Aid Drugstore [www.drugstore.com], and Walgreens [www.walgreens.com]). Lower-priced units have aneroid sensors without any memory storage, use hand-pumped bulbs for compression, and require stethoscopes so that the patient is fully responsible for all elements of taking and recording each measurement. By contrast, higher-priced devices have electric-powered cuff pumps (battery and/or wall outlet), oscillometric detectors, printers, and/or memory storage, which may include a time and date stamp. It is recommended that the best devices for HBPM have electric inflation of cuffs, oscillometric detection, and memory.[54] These recommendations are based on 2 concerns: (1) errors that may be introduced by self-inflation of the cuff[154] and (2) selection bias that may affect the recording and reporting of pressures if patients choose the values to report.[47,155] Thus, the out-of-pocket cost to a patient for purchase of a recommended device for HBPM will be in the range of $80 to $100 unless reimbursement is provided from that patient's health insurance provider or the cost is offset by an incentive, such as a tax-free purchase. Buying a large adult cuff, which is not standard, may add to the overall cost.

As described above, the use of HBPM is growing rapidly in the United States, and many patients are buying units without prescriptions from physicians. A small study of 13 randomly selected subjects using an intensive interview method found a wide range of ideas about hypertension and its treatment. Most welcomed the opportunity to perform HBPM, but others preferred management by the physician alone.[156] A 1-year experience with HBPM combined with telephone transmission to a central server and reports to treating physicians found that initial enthusiasm for HBPM was followed by a decrease in use, so that only 50% preferred to continue HBPM for the second year.[157] A survey comparing patients' attitudes with different methods of obtaining accurate BP measurements found that HBPM was preferred over other methods (which included ABPM and measurement by either the physician or nurse in the office).[158] Will patients want to pay for HBPM as an add-on for management? Studies on "willingness to pay" in the context of telemedicine indicate that hypertensive patients are very "cost-sensitive" in making decisions about what they say they will pay for in contrast to those with heart failure who state that they will pay more out-of-pocket for a "telemedicine" visit. A survey by structured questionnaire using "contingent valuation" found that for a telemedicine visit charge of $20, 30% of those with

hypertension would accept the charge, whereas 45% to 50% of those with chronic heart failure would accept that charge.[159]

Costs and Savings Related to Implementation and Use of HBPM

In theory, incorporation of HBPM into the treatment of hypertension may appear to lessen the cost of care.[160] A study from Japan, where a large fraction of the population have home BP devices, predicts that a substantial reduction in cost for management of hypertension might be realized.[161] Savings could come from reduced need for office visits with replacement by telephone calls, as has been reported.[162] Several studies have demonstrated that effective control of hypertension can be achieved when patients using HBPM can communicate with their providers (either trained nurse clinicians or physicians) to adjust medication as needed to achieve goals for treatment.[125,163–165] The significance of apparent control of hypertension with the use of HBPM with regard to prevention of cardiovascular morbidity and mortality is not established. In the aforementioned study, which compared HBPM with office management for hypertension and used the same BP goal for both office and home assessment,[113] the cost of treatment (medication) was slightly lower for the HBPM group because less medication was required for control, but the target level of BP (a diastolic pressure of 80 to 89 mm Hg) was higher than generally recommended. These reports lend support to the simple view that HBPM can reduce costs for treatment of hypertension (reduced visits and perhaps less medication) while increasing or at least maintaining the effectiveness of treatment for prevention of CVD, given the relatively low cost to purchase a home BP device. A large multicenter trial (HOMERUS) has been performed to compare the cost of treatment for office management with an HBPM strategy.[166,167] The effect of using HBPM was to reduce the amount of medications prescribed, which, even after allowing for the cost of the monitors, resulted in a net cost saving. However, the results are difficult to interpret because the same target BP was used for both groups, and the HBPM group had a higher 24-hour BP.

Other Cost Considerations

There are several hidden or offsetting factors that should be taken into account when the actual costs for use of HBPM are calculated. First, there are costs related to the necessary validation of each device and training of each patient in the proper use of each device for measurement of BP and recording and/or transmission of measurements, which are not well established. Next, there are costs related to the review of HBPM data and advice to patients regarding change in treatment. There is need for some calculation of equivalency to ensure reimbursement for the provider, should office visits be replaced by an HBPM strategy that still requires the time and resources of the provider. Here, differences in medical care systems may be relevant. Those who practice in fee-for-service modes may be reluctant to give up the reimbursements related to office visits unless some incentive is evident. By contrast, those with high-volume capitated practices may welcome a strategy that reduces office visits but reimburses for hypertensive patients enrolled and managed by HBPM. Going further, it might be suggested that providers expanding use of HBPM be given incentives for this effort, should outcome studies justify this approach.

It should be recognized that the long-term cost of care for hypertension is dominated by costs for drug treatment rather than for visits to providers or testing.[168–170] However, costs for the first year of management tend to be higher than for subsequent years (more tests and visits). Drug choices then determine the greatest fraction of costs, so that over a 5-year period the cost for treatment of a patient may vary from $1700 to $3000. In general, emphasis on guideline-based drug selection (diuretics and β-blockers initially) is associated with lower combined treatment costs.[168,170] Thus, use of HBPM to reduce the cost of treatment will be most effective when implemented to detect white-coat hypertension and reduce the need for drug treatment, as has been shown for ABPM.[151]

The impact of HBPM for overall cost of management for hypertensives in community practice who are placed on drug treatment is less certain. If telemedicine methods are used, what will the costs be for receiving and processing information? Who will pay for such services? Can the methods be made so efficient that there is minimal demand for time by the provider? What financial incentives are available to support providers for their responsibilities? These questions pose the need for research in the healthcare systems that link patients with hypertension to physicians and practices via the various financial structures that pay for medical care.[171] Without such research, the actual impact of HBPM on cost-effectiveness for prevention of CVD cannot be calculated.

Part II: Action Plan

Given the amount of accumulated evidence about the value of HBPM, it is time to make HBPM a part of routine management of hypertensive patients, especially those with diabetes, coronary heart disease, chronic kidney disease, suspected nonadherence, or a substantial white-coat effect. Table 2 provides recommendations[13,16,32,34,54,55,71,83,172–176] for its use.

Additionally, because HBPM is part of evidence-based care, it should be reimbursed. Regular use of HBPM will improve the quality and cost of delivering care to the 72 million people with hypertension and should lead to improved control of hypertension. Reimbursement is critically important to hypertensive patients and to their providers. Cost should not be a barrier to patients receiving the documented benefits of HBPM. Reimbursement will improve access to recommended health care for the impoverished, isolated, medically vulnerable, and/or disadvantaged minority groups. Improved access may contribute to reductions in hypertension-related disparities among disproportionately affected groups.

Table 2. Summary of Recommendations for HBPM

Procedure	Recommendation
Technical aspects of BP measurement	Measure BP:
	No tobacco or caffeine for 30 minutes preceding measurement
	After 5 minutes of rest
	With arm at heart level; back supported and feet flat on the ground
	On nondominant arm (or arm with the highest BP)
BP monitor	Use a fully automated device with an upper arm cuff that has been validated by British Hypertension Society, Association for the Advancement of Medical Instrumentation, or International Protocol for the Validation of Automated BP Measuring Devices
	Monitors with memory that are able to store measurements are preferred
Training of patients	Patients should be trained by their healthcare provider, and the monitor readings should be checked against mercury
	Education content: hypertension and cardiovascular risk, BP measurement procedure, use of a validated monitor, cuff size, protocols for measuring BP, interpretation of BP readings, and monitor for their use only
	Reevaluate patient technique and accuracy of the device annually
Target BP goal	135/85 mm Hg or 130/80 mm Hg if patient has diabetes, coronary heart disease, or chronic kidney disease (*Class IIa; Level of Evidence B*)
Frequency and schedule of measurement	Initial values (when patients begin HBPM at home):
	Base decisions on a 7-day measurement period with 2–3 measurements each morning and 2 to 3 measurements in the evening at prestipulated times (an average of 12 morning and evening measurements)
	Exclude first-day measurements from the analyses; take average of these values as the reference parameter in the subsequent dose-titration phase
	Dose-titration phase (titration of initial dose and adjustment of therapy):
	All measurements should be made under identical conditions and at the same times of day as the initial values
	HBPM data should be ascertained as trough values (ie, before medication taken) in the morning and again at night
	Use the average of BPs measured after 2 to 4 weeks to assess the effect of treatment
	Long-term observation:
	For stable normotensive (controlled) patients, patients should conduct HBPM a minimum of 1 week per quarter (an average of 12 morning and evening measurements under conditions described above)
	Measurement should be made more frequently in patients with poor compliance

It is recommended that patients be reimbursed for the purchase of a monitor prescribed by their healthcare provider (physician and/or nurse practitioner) and that providers be reimbursed for services related to HBPM (ie, initial patient education regarding correct HBPM technique; yearly or as-needed assessments to validate that individuals self-measure their BP accurately; interpretation of BPs stored in the monitor memory; in-person, telephone, and/or e-mail consultation to deliver medical advice–based analysis of BP reports generated from the monitor). Monitors should be renewable after 5 years or if they are shown to be inaccurate.

Need for Future Studies

There are a number of areas in which there is a need for future studies using HBPM. These include the following:

1. Measurement of nighttime BP. There is increasing evidence that the nighttime BP has important prognostic significance. HBPM devices are being developed that can be preprogrammed to take readings during the night.
2. Use of HBPM in conjunction with office BP for making diagnostic and therapeutic decisions.
3. Use of HBPM for improving BP control in treated patients.
4. Use of HBPM in patients with diabetes. Tight BP control is of paramount importance in patients with diabetes, but the use of HBPM has not been adequately explored.
5. Use of HBPM in pregnancy. HBPM is ideally suited to detecting early increases of BP that herald preeclampsia.
6. Use of HBPM in children. The decision to start treatment is particularly difficult in children, and HBPM may help to establish the need for this.
7. Cost-effectiveness of HBPM. Although HBPM has the potential of saving costs while improving BP control, few studies have evaluated this systematically.

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David Goff	Wake Forest University School of Medicine	None	None	None	None	Pfizer*	None
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*Modest.

†Significant.

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