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Blood Pressure Assessment in Adults in Clinical Practice and Clinic-Based Research: *JACC* Scientific Expert Panel

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Abstract

The accurate measurement of blood pressure (BP) is essential for the diagnosis and management of hypertension. Restricted use of mercury devices, increased use of oscillometric devices, discrepancies between clinic and out-of-clinic BP, and concerns about measurement error with manual BP measurement techniques have resulted in uncertainty for clinicians and researchers. The National Heart, Lung, and Blood Institute of the US National Institutes of Health convened a Working Group of clinicians and researchers in October 2017 to review data on BP assessment among adults in clinical practice and clinic-based research. In this report, we review the topics discussed during a two-day meeting including the current state of knowledge on BP assessment in clinical practice and clinic-based research, knowledge gaps pertaining to current BP assessment methods, research and clinical needs to improve BP assessment, and the strengths and limitations of using BP obtained in clinical practice for research and quality improvement activities.

Condensed abstract

The National Heart, Lung, and Blood Institute convened a Working Group in October 2017 to review data on BP assessment in adults in clinical practice and clinic-based research. We report on outcomes from the working group meeting, including (i) evaluation of the current state of knowledge on BP assessment in clinical practice and clinic-based research for diagnosing hypertension and evaluating response to treatment, (ii) identifying knowledge gaps pertaining to current BP assessment methods, (iii) evaluating research and clinical needs to improve BP measurement, and (iv) using BP obtained in clinical practice for research and quality improvement activities.

Keywords

blood pressure; hypertension; measurement

Introduction

Hypertension affects about 103 million adults in the US and over a billion people worldwide (1-3). The accurate assessment of arterial blood pressure (BP) levels is needed for the diagnosis and treatment of hypertension. Researchers first measured BP in the 1700s, and by the late 1800s BP assessment was introduced into clinical practice (4). However, it was not until the 20th century that observational data showed that higher BP levels were associated with increased cardiovascular disease (CVD) risk. Subsequently, randomized trials

demonstrated that lowering BP from levels which were previously considered “essential” (systolic/diastolic BP up to 210/100 mm Hg) reduced the risk of CVD and death.

The direct measurement of BP requires an intra-arterial assessment. In clinical practice and most clinic-based research studies, BP is estimated using non-invasive methods. In the current document, we use the term BP measurement for estimates obtained through non-invasive means. For much of the 20th century, BP was assessed through auscultation and the recognition of Korotkoff sounds, with mercury-based sphygmomanometer measurements serving as the reference standard. This non-invasive auscultatory approach remained the reference standard until the early 21st century.

More recently, restrictions on the use of mercury devices, increased availability of oscillometric devices, discrepancies between clinic BP and out-of-clinic BP, and an increasing recognition of the susceptibility of BP assessed using the auscultatory method to measurement error have resulted in uncertainty for clinicians and researchers. To date, hypertension treatment guidelines and quality control metrics have largely relied on BP measured in the clinic setting. Performance measures, which are often reported using data captured by electronic medical records (EMR), have expanded the role of clinic-based BP. However, different values are often obtained when BP is measured in the clinic versus outside of the clinic setting and it is recommended that out-of-clinic measurements be obtained to confirm the presence of hypertension based on clinic measurements and for the management of high BP(1,5).

The National Heart, Lung, and Blood Institute of the US National Institutes of Health convened a Working Group of clinicians and researchers in October 2017 to review data on BP assessment in adults in clinical practice and clinic-based research. BP assessment in children and adolescents is a complex topic that merits separate attention. The Working Group held a conference that was designed to complement ongoing American Heart Association (AHA) activities including the 2017 Task Force’s Guideline for Prevention, Detection, Evaluation and Management of High Blood Pressure in Adults and an update of the 2005 AHA Scientific Statement on BP measurement in humans(1,6). This statement presents the discussion and recommendations from the Blood Pressure Measurement Working Group convened by the National Heart, Lung, and Blood Institute whose aims were (1) to evaluate the current state of knowledge on BP assessment in clinical practice and clinic-based research for diagnosing hypertension and evaluating response to antihypertensive treatment; (2) to identify knowledge gaps pertaining to current BP assessment methods; (3) to evaluate research and clinical needs to improve BP assessment for the aforementioned purposes; and (4) to evaluate the use of BP obtained in clinical practice for research and quality improvement activities. In addressing these objectives, the working group focused on 2 primary topics: (1) how different measurement methods can be integrated into clinic-based research and routine clinical practice to perform accurate BP assessment and (2) how the quality of BP measurements obtained in routine clinical practice can be improved to provide better patient care and to be suitable for clinic-based research (**Central Illustration**). It is outside the scope of this document to provide practice guidelines on blood pressure measurement.

BP assessment in ambulatory clinical practice and clinic-based research: current practice and challenges

Current approaches to BP measurement—In the clinic setting, BP can be estimated by an observer listening to Korotkoff sounds with a stethoscope using the auscultatory approach and a manual manometer or with an electronic device using the oscillometric approach. Over the past 40 years, devices have been developed and validated to estimate BP outside of the clinic setting through ambulatory BP monitoring (ABPM) or self-monitoring. Self-monitored BP has been studied frequently using measurements taken in the home (referred to as home blood pressure monitoring [HBPM]), but also includes measurements taken in public settings (e.g., a pharmacy or grocery store) using a semi-automated or automated oscillometric device. Automated devices can take multiple BP readings at set intervals (e.g., one minute apart) with a single activation while semi-automated devices require manual initiation for each individual BP measurement. Most out-of-clinic BP measurements are obtained using the oscillometric approach.

BP measurement in the clinic setting—BP is typically assessed in routine clinical practice during outpatient visits. An initial BP measurement is most often performed by a medical assistant or nurse who frequently is also collecting information on other physical measurements (e.g., height, weight), relevant medical history, and current medications being taken before the patient is seen by a clinician. A follow-up BP measurement may be performed by a clinician to confirm the initial reading. The primary purposes of measuring BP in routine clinical practice are to screen for hypertension and hypotension and to monitor the response to antihypertensive treatment. There are often time constraints affecting the accuracy of completed BP measurements in clinical practice settings. Although contemporary data are sparse, training in BP measurement, equipment used, and measurement methods vary widely across clinics, and nearly always deviate from methods recommended by guidelines.

In clinical trials, the protocol used to measure BP is often standardized across sites to minimize systematic errors and variability. However, protocols often differ across trials and are not always reported in detail in publications. Differences in measurement techniques across clinical trials include the device employed, the use and duration of a rest period, the arm used, participant position during measurement, the presence of ambient noise, conversation with the participant, whether the measurement is observed or unobserved, time of day when BP is measured, trial activities that precede BP assessment, the number of measurements taken, and the number of measurement occasions(7). BP variability is increased when measurements do not follow a specific study protocol. As a result, BP readings measured in different research settings and between research and routine clinical practice can differ substantially from what they would be if a standardized protocol had been used(8).

The auscultatory approach requires good hearing, extensive training and retraining, and periodic certification to record the onset and disappearance of the Korotkoff sounds (9,10). Although rarely used anymore in clinical and research settings, the mercury sphygmomanometer is still considered the reference standard device. It remains useful for

validating oscillometric devices (11). Calibrated aneroid manometers can be considered a substitute for mercury devices (12). However, aneroid manometers are easily damaged and require frequent re-calibration to ensure their measurement accuracy(13).

Oscillometric BP devices estimate systolic BP (SBP) and diastolic BP (DBP) from the mean arterial pressure using a device-specific algorithm and the oscillometric pulse waves detected in the BP cuff, typically during deflation although some devices assess BP during inflation. Each manufacturer of oscillometric devices incorporates its own undisclosed proprietary algorithm(s) for estimating SBP and DBP. Aging and other conditions that affect arterial compliance, such as pregnancy, diabetes, kidney disease and arrhythmias, may affect the accuracy of these algorithms (14). Any oscillometric BP measurement device used in clinical or research settings should have peer-reviewed published documentation of its rigorous validation with a mercury device or non-mercury device that meets the ISO 81060–1 requirements for accuracy of a non-invasive sphygmomanometer(15). The “black box” nature of proprietary algorithms used in oscillometric devices is a limitation(16). Some updated oscillometric devices may be using modified algorithms to estimate BP, and validation studies are not always performed to confirm their accuracy. Even after devices have been validated, they still need to be used in a standardized manner. This includes correctly positioning the patient, having the BP cuff at heart level on a bare-upper-arm, using an appropriate size and correctly fitting BP cuff, and having the patient rest before the first measurement and between repeat measurements (Table 1).

In the clinic setting, several oscillometric devices that take multiple BP measurements automatically, at set intervals, are available. These automated office blood pressure (AOBP) devices can measure BP with or without an observer present (17). Some studies have suggested that BP measured with staff present (attended BP assessment) result in higher readings than those obtained with staff absent during measurement (unattended AOBP). In a pooled analysis of 8,558 adults, the mean clinic BP was 10/7 mm Hg higher when recorded by a provider in clinical practice using the auscultatory method with a mercury sphygmomanometer versus with unattended AOBP(18-24). In 2017, the Hypertension Canada guideline recommended unattended AOBP as the preferred method of clinic BP measurement(25). Unattended and attended BP measurements should ideally be compared using the same device. In randomized studies comparing unobserved and observed AOBP using the same device, the difference in BP using these two approaches has been small(26,27). Also, a secondary analysis of the Systolic Blood Pressure Intervention Trial found no difference in BP levels measured in clinical sites that had staff present versus absent during BP measurement(28). These data suggest that no differences in BP may be present when assessed using attended versus unattended AOBP as long as a BP measurement protocol is rigorously followed and an oscillometric device is used. However, as these protocols are rarely followed in routine clinical practice, unattended AOBP is useful to minimize the occurrence of protocol violations (e.g., talking during the BP measurement, insufficient amount of rest prior to and between BP measurements).

BP measurement outside of the clinic setting—ABPM and HBPM are used to obtain BP measurements outside of medical settings, without a healthcare provider, researcher or observer present. Typically, more BP readings are obtained with ABPM and

HBPM than with clinic measurements (29). Both ABPM and HBPM are typically used to assess average BP outside of the clinic, which enables the identification of mismatches between clinic hypertension and out-of-clinic hypertension including white coat hypertension and masked hypertension (defined below) (30). An important difference between ABPM and HBPM is that ABPM assesses daytime and nighttime BP typically over one 24-hour period, while a person goes about their routine daily activities. In contrast, HBPM typically assesses BP during the day, usually in the morning and early evening, over a period of days to weeks while the person is seated and resting but typically not during sleep (30).

ABPM and HBPM should not be considered interchangeable, as there is only moderate agreement between daytime values on ABPM and home BP on HBPM(31,32). Until recently, HBPM could not obtain BP readings during sleep preventing the determination of diurnal BP patterns. However, HBPM devices that can assess BP during sleep, typically three measurements at one hour intervals, have recently become available (33). There is currently insufficient evidence to decisively determine whether BP measured using ABPM or HBPM has a stronger association with risk for CVD events, although there are more data linking out-of-clinic BP on ABPM to CVD events (34). The selection of ABPM or HBPM may depend on the application. In clinical practice, ABPM may be most useful in identifying white coat, masked hypertension or nocturnal hypertension as multiple readings are taken throughout the day. HBPM may be more useful to monitor BP for patients taking antihypertensive medication as it can be used over prolonged periods of time. More data are needed on the use of HBPM devices to identify white coat and masked hypertension, phenotypes which are described below.

Oscillometric devices, often located in a booth or kiosk in pharmacies, grocery stores, fitness facilities, or other locations offer a convenient way to check BP. These devices may be configured to allow BP data to be directly transmitted to healthcare providers or to an EMR, which can then be used to help manage BP control. Although scarce evidence exists, there are some data suggesting that BP obtained in public settings may be similar to daytime ABPM (35). However, caution is needed. Many devices in public settings utilize a single size cuff that is considered too small (< 33 cm) for the many adults' arm circumferences of many adults. Most of these devices have not undergone a validation study, or manufacturers have declined to share validation data when queried(36). The devices are frequently located in noisy, high traffic areas, which are not conducive to obtaining an accurate resting BP measurement. In addition, there are no data showing the association of BP measured in a booth or kiosk and CVD risk. Furthermore, thresholds for what should be considered a normal BP level have not been determined for this setting. When BP values from measurements in a kiosk are available, it is important that the device has undergone validation and is located in a quiet setting. An alternative approach is having pharmacists measure BP. There are some data suggesting pharmacist-measured BP aligns with awake BP on ABPM(37).

Despite recommendations from the United States Preventive Services Task Force and American College of Cardiology / American Heart Association (ACC/AHA) to assess out-ofclinic BP to identify white coat and masked hypertension, out-of-clinic BP is rarely

obtained before a hypertension diagnosis is made in the US (1,5). In a qualitative research study conducted with primary care providers in Alabama and New York, cost, time requirements, lack of infrastructure including access to BP monitoring devices, and low reimbursement were reported as major barriers to performing ABPM (38). In contrast to ABPM, barriers preventing the more widespread use of HBPM relate to providers' concerns that patients will not measure their BP correctly and that patients will become pre-occupied with their BP (39,40). Device affordability may be a barrier for conducting HBPM in some populations. Also, healthcare providers may lack confidence in their own skills and knowledge to interpret out-of-clinic BP assessments from ABPM and HBPM (38).

The successful incorporation of ABPM and HBPM into clinical practice may require additional equipment, staff training and time in conducting and understanding what constitutes satisfactory recordings. Additionally, knowledge about which devices are validated and how to interpret out-of-clinic BP readings and incorporate out-of-clinic BP into clinical decision making is needed(30). Currently, there are no core clinical competencies for conducting out-of-clinic BP assessment(30). Before undergoing ABPM, patients should be instructed on proper positioning and anticipating potential mild discomfort and disturbance of sleep associated with cuff inflation and deflation while BP is being measured, to prevent removal of the ABPM device and cuff(30,41). For HBPM, patients should be instructed on proper positioning, where and when to measure their BP and how to interpret the results.

Software for downloading BP readings from ABPM is included with each device and typically generates reports that include mean daytime, nighttime, and 24-hour values as well as daytime-to-nighttime BP ratio. In addition to PC-based software, some HBPM device manufacturers have developed mobile app and internet-based software that automatically stores BP readings, making it possible for patients to share HBPM data with their healthcare providers and to prevent misreporting of self-measurements. Ideally, individual ABPM and HBPM readings can be entered into structured fields of EMRs, using automated data transfer processes; such data could be useful for quality measures and to generate summary statistics, including average BP over time. Currently, few providers and patients have access to these resources.

White coat hypertension and masked hypertension—The difference between clinic and out-of-clinic BP measurements is often substantial (42-44). Thus, there are individuals who meet the criteria for hypertension based on their clinic BP but not based on their out-of-clinic BP, and vice versa. This results in four BP phenotypes defined by the possible combinations of hypertensive/non-hypertensive clinic BP and hypertensive /non-hypertensive out-of-clinic BP: normotension, white coat hypertension, masked hypertension, and sustained hypertension (Figure 1). European guidelines have suggested defining white coat and masked hypertension using mean out-of-clinic awake, sleep or 24-hour BP(45). Specifically, it is suggested to define white coat hypertension as BP in the hypertension range when measured in the clinic but mean awake, asleep and 24-hour BP not in the hypertension range. Analogously, masked hypertension is defined by BP not in the hypertension range when measured in the clinic but mean awake, asleep or 24-hour BP in the hypertension range.

In a New York metropolitan area community sample (N=888) not taking antihypertensive medication, the prevalence of white coat hypertension among those with clinic SBP ≥140 mm Hg or DBP ≥ 90 mm Hg was 19.1%, while the prevalence of masked hypertension among those with clinic SBP <140 mm Hg and DBP < 90 mm Hg was 15.7%(42). In the Jackson Heart Study, a cohort comprised exclusively of African Americans, the prevalence of white coat hypertension and masked hypertension among those not taking antihypertensive medication was 30.2% and 25.4%, respectively(46).

When compared to normotension, masked hypertension has been associated with a two times higher risk for CVD(47,48). In some studies, the risk for CVD has been reported to be similar for individuals with masked hypertension and sustained hypertension (48,49). It is unclear if white coat hypertension is associated with a substantially increased risk for CVD compared with normotension (50,51). However, it should be recognized that a high proportion of participants with white coat hypertension in prior studies may have initiated antihypertensive medication during follow-up which would have resulted in a lower CVD risk compared to what might have been identified had they remained untreated. Also, the incidence of sustained hypertension is substantially higher for adults with white coat hypertension versus normotension (52,53).

The prevalence of white coat hypertension is higher in those who are older, female, and have lower BMI, and the prevalence of masked hypertension is higher in those who are older, male, have a higher BMI, have reduced kidney function, and are smokers (54-56). The strongest predictors of white coat hypertension and masked hypertension are clinic SBP and DBP, with the probability being highest when clinic BP is close to the threshold used for defining hypertension. Similar to BP measured in the clinic, the accuracy and reproducibility of out-of-clinic BP improves as the number of readings being averaged increases (57). However, the marginal benefit of each additional reading decreases as the total number of readings increases. The concern with diagnostic accuracy and reproducibility is compounded when using out-of-clinic BP in conjunction with clinic BP. Several studies have shown that diagnoses of white coat hypertension or masked hypertension are only moderately reproducible (58,59).

Emerging alternative approaches to BP assessment in ambulatory clinical settings—The explosion in iPhone and Android apps has made its way into the BP measurement arena. A number of apps measure BP directly while others allow for readings to be manually entered for storage (60,61). Many apps use a combination of finger plethysmography and pulse transit time calculations to estimate BP (62). Few rigorous studies assessing the validity of these apps have been conducted. One study showed poor performance for one of these apps (63). The US Food and Drug Administration (FDA) only oversees some forms of mobile health technology, and there are insufficient validation data and no outcome data supporting their use. The US FDA oversees mobile health technology that is used to diagnose and treat disease. Non-invasive BP monitors are considered moderate risk medical devices that must be cleared by the FDA. However, these devices, including mobile apps that measure BP, are only required to show “substantial equivalence” to another device that has been cleared by the FDA. There have been calls for laws requiring studies that demonstrate sufficient accuracy for new BP monitors.

Other “wearable” devices use a calibrated radial pulse waveform to estimate BP, and can do so over extended periods of time. Some devices appear to maintain calibration and be accurate for at least 24 hours and, thus, have been suggested as a surrogate for ABPM in some populations(64). An additional challenge is to ensure that measurements are obtained with the device at heart level; otherwise measured BP values will tend to under- or over-estimate actual BP depending on whether the wrist is above or below heart level, respectively.

Statistical considerations—The diagnosis of hypertension and evaluation of response to treatment require accurate assessment of BP to prevent under or over treatment. BP varies both within and between visits. While both sources of variability are important to recognize, variability is greater between versus within visits and the precision of observed mean BP depends on the number of visits and the number of measurements per visit (65). For example, in one study with one research-grade measurement obtained at a single visit, the standard errors of SBP and DBP were approximately 7.0 and 6.0 mm Hg, respectively, while three measurements at two visits resulted in standard errors of 3.7 and 3.2 mm Hg, respectively (Online Table 1). BP measured in routine clinic practice probably have larger standard errors. Hypertension screening algorithms can be determined based on a function of between-person and within-person variability, and two or more BP measurements on two or more occasions is required to accurately screen adults for high BP in the clinic (65,66). Similar approaches can be used to assess the response to treatment and require two or more pre- and post-treatment visits and a change of 5-7 mm Hg in DBP to be 80% confident that true change has occurred (67).

Special populations and clinical issues

Older adults: Because of its high prevalence in older adults, hypertension is a leading cause of preventable morbidity, mortality and premature disability and institutionalization in this population (68-71). Although mean SBP increases at older ages, the standard deviation of SBP and DBP is not substantially different when compared to younger persons with similar levels of BP (72). Additionally, in a recent meta-analysis, older age was not associated with the difference in BP when measured intra-arterially and non-invasively with a BP cuff (73). However, as in all ages, there is a subset of older adults in whom the accurate measurement of BP is challenging due to the presence of comorbidity, aging-related cardiovascular changes, arrhythmia and polypharmacy (74). For example, some older adults have non-compressible arteries which may make BP readings inaccurate (75). Additionally, an auscultatory gap might be present among older adults (76). The 2018 AAMI-ESH-ISO universal standard for the validation of BP monitors does not consider older adults a special population warranting a distinct validation of oscillometric BP monitors (15).

Orthostatic hypotension: Orthostatic hypotension is a risk factor for falls, syncope, CVD, stroke, and death (77-82). The prevalence of orthostatic hypotension increases with age, and is more common among patients with uncontrolled hypertension(79,83). While it is recommended that orthostatic hypotension be assessed in patients with a history of falls or postural dizziness, it has unclear utility in guiding BP management(84,85). Recent clinical trials have shown that lower versus higher BP goals may not increase the risk for having

orthostatic hypotension, and that there is only modest overlap between measured orthostatic hypotension and symptoms of dizziness or lightheadedness on standing (86-88). However, methodologic limitations may be responsible for these null findings. First, multiple protocols exist for performing orthostatic hypotension assessments (e.g., seated versus supine versus tilt-table) (89). Second, there is substantial heterogeneity in guidelines as to when orthostatic hypotension should be assessed, ranging from within 1 minute to after 3 minutes of standing (25,45,90), and BP measurements performed sooner after rising appear to be stronger predictors of long-term risk for adverse outcomes including falls (80,91-94). Third, current cut-points used to define orthostatic hypotension based on change in SBP or DBP (i.e., a drop of 20 mm Hg in SBP or a drop of 10 mm Hg in DBP) do not reflect natural thresholds of risk, are insensitive for orthostatic symptoms and may perform poorly among adults with hypertension (81,85). Other definitions of orthostatic hypotension have been proposed for patients with hypertension (e.g., a change in SBP of >30 mm Hg or a standing SBP<90 mm Hg) (95). However, it is possible that orthostatic symptoms are more important for long-term outcomes than protocol-based changes in BP upon standing.

Obesity: The prevalence of obesity in US adults has increased substantially in recent years(96). The measurement of BP in obese adults, including those who are morbidly obese, is an increasingly common challenge (97). Obesity with its associated increase in arm circumference requires use of larger BP cuffs (98). Selecting an appropriately-sized cuff is a key component for obtaining valid BP measurements. An extra-large cuff or “thigh cuff” has been shown to provide accurate BP measurements in obese adults. However, there are few studies comparing BP measurement approaches using extra-large cuffs with direct intra-arterial measurements, and the 2018 AAMI/ESH/ISO device validation review recommends a separate validation be performed on individuals with an arm circumference > 42 cm (15). A challenge encountered with using larger cuffs is that large arm shapes are often conic. Some extra-large cuffs are available with a conic shape for these situations. When a sufficiently large cuff is not available to obtain BP measurements in the brachial artery, a properly used validated wrist device held at the level of the heart may be more accurate than measurements taken at the brachial artery (99).

Atrial fibrillation: Atrial fibrillation (AF) is a common arrhythmia which complicates the measurement of BP(100). There are no accepted non-invasive approaches for determining BP in AF, and the accuracy of the auscultatory method which, as mentioned above, is the reference for validating BP monitors, is unknown within this population. Inter- and intra-observer variation for measuring BP is higher in AF than in sinus rhythm (101). However, BP may be reasonably accurate in patients with AF if three or more readings are obtained (102). A meta-analysis of validation studies of automated (mostly oscillometric) BP monitors in AF showed no difference in SBP compared with manual auscultatory measurements but a small, yet consistent, overestimation of DBP (103). This overestimation of DBP may be less important since most people with AF are older, a population wherein SBP has more prognostic importance (100). ABPM is feasible in AF, with similar reliability as in sinus rhythm (104). Preliminary evidence suggests that for patients with AF both auscultatory and oscillometric BP measurements are clinically relevant, as they show similar associations with intra-arterial measurements and preclinical organ damage

indices(102,105,106). Other arrhythmias, such as frequent premature atrial and ventricular contractions may also affect the accuracy of oscillometric BP measurements, but evidence is sparse.

Pregnancy: Due to hemodynamic changes and edema that often accompany pregnancy and complications including preeclampsia, oscillometric devices that are accurate in the general adult population may not be accurate in pregnant women, and it is recommended that they be separately tested for accuracy in this population(107). A systematic review of validation studies of clinic, ABPM and HBPM devices in pregnant women found 61% of devices specifically evaluated for use in pregnancy, including pre-eclampsia, met the validation criteria(108). However, only 34% of the studies wherein the device met the validation criteria were performed without any protocol violations (108). Current recommendations for the use of HBPM in pregnancy include at least weekly home measurements in women with gestational hypertension, and its use is also suggested for women with chronic hypertension and poorly controlled BP. The only recommendation for the use of ABPM in pregnancy is to rule out a diagnosis of suspected white coat hypertension prior to initiating antihypertensive medication (109). Although data are limited, approximately 30% of high-risk pregnant women have been reported to have masked hypertension on ABPM (110,111).

Pros and cons of using BP measurements obtained in routine clinical practice for research

The advantage of using BP measurements obtained in clinical practice for research is that over time, patients tend to have a large number of visits with BP readings, improving precision, and potentially reducing or even eliminating the need for research visits. Additionally, measurements obtained in clinical practice represent those used for management and decision making and are the basis for performance measures. Since BP is routinely measured at many encounters, especially in people with elevated BP or hypertension, the number and frequency of measurements may exceed those in research protocols. However, major concerns with using BP measurements obtained in clinical practice for research are the lack of standardization and the questionable accuracy of clinic BP measurements, with the potential for both systematic and random errors. Furthermore, unless BP measurements, including out-of-clinic readings, are recorded in an EMR, it may be impractical to extract them.

It is commonly believed that research-quality BP measurements are lower than the same individuals' BP measurements in the routine practice setting. However, the pressure to score well on quality measures may increase the likelihood of bias in the opposite direction (112,113). In the Multi-Ethnic Study of Atherosclerosis, a large prospective observational study, research-grade SBP measurements were on average 6.3 mmHg lower than the most proximal clinic measurement, before or after the study visit, recorded in the EMR(114). This study highlights the high likelihood for misclassification of hypertension status of patients in settings without the use of standardized BP measurement protocols and validated devices. However, the association between routine clinic and research BPs may not be consistent across sites and may be modified by patient characteristics such as age, sex, race, and comorbidities. A standardized BP measurement protocol including the use of an oscillometric device, training of medical assistants, and monitoring compliance with BP

protocols has shown promise in reducing systematic measurement errors(115). Also, when BP measurement in clinical practice is performed using established protocols and validated automated equipment, it may be acceptable for research purposes and yield similar conclusions as measurements obtained in research settings.

In clinical trials aimed at reducing BP, the statistical power to detect a between-group difference in BP change depends on two factors: the number of participants in each group and the standard deviation of the change in BP ($SD_{\Delta BP}$). The $SD_{\Delta BP}$ can be reduced by averaging multiple readings taken over multiple visits for both the pre- and post-BP assessments. Using BP measurements from routine clinic visits, where BP from more visits are available, would result in a smaller $SD_{\Delta BP}$ and, therefore, a smaller sample size required for a clinical trial. However, increasing the number of measurements obtained will not overcome intra-person variability introduced by an inconsistent technique in how BP is measured and by concurrent clinical factors (e.g., acute medical conditions) that may be present when BP is measured in routine clinical practice. ABPM and HBPM are alternative approaches that provide many BP measurements.

Emerging approaches to obtaining BP measurements for clinical practice and clinic-based research

The availability of accurate and relatively inexpensive oscillometric devices that measure BP and transmit data wirelessly represents an emerging approach to BP assessment. Data may be transmitted from a device located in a clinic or out-of-clinic setting to a wireless hub or smartphone, and from there to a secure server. BP data may also be transmitted to an EMR, provided appropriate security procedures are in place, where it can then be used for clinical care and research purposes. The development of common data models has made it possible to pool BP and other clinical data from different research organizations. Databases that include BP measurements, diagnosis codes, and pharmacy data may be used to characterize the hypertension status of large populations and to create virtual registries. EMRs are likely to be used increasingly in observational studies and in trials for recruitment, delivery of interventions, and outcome ascertainment. These data will be greatly enhanced by standardization of the BP measurement method and the use of validated devices.

Optimization of measurements in clinical practice and in clinic-based research studies

Key principles—Key aspects of the measurement process include time of day, the staff member who prepared the participant and measured BP, location (emergency room, clinic, hospital, etc.), position (lying, seated, standing), site of cuff placement (right/left side, arm/leg), cuff size and the specific BP device utilized. All BPs should be recorded in the EMR in structured data fields as individual measurements rather than the average in order to facilitate monitoring of adherence to protocols that call for two or more BP measurements at each visit and for the purpose of using the data for ongoing clinical care and research. To avoid recording errors, BP values from the clinic, HBPM or ABPM should be directly transferred from the device to the EMR, whenever possible. If the average BP is recorded without notation, it is difficult to determine whether the appropriate number of BP measurements was obtained. Documentation of BPs in the EMR should include key

components of the measurement process, listed above, along with the actual BP values (Table 2).

Training and quality control

Clinical practice: Recommendations for standardization of BP assessment have not changed substantially from JNC7 in 2003 (116) and the 2005 AHA Scientific Statement on BP measurement (6) to the 2017 ACC/AHA BP guideline (1). However, a standardized approach is rarely followed in clinical practice (6,117). Increasingly, guidelines recommend use of validated upper arm oscillometric devices in place of auscultation(25,45), which can reduce human error and bias, but does not eliminate many of the factors that contribute to inaccurate measurements and the need for trained observers (Table 3) (118).

The technician or healthcare provider remains the most important component of accurate and reliable BP measurement, and standardization of training, re-training and certification at regular intervals are recommended for everyone who measures BP(6,117). While training may occur in ambulatory settings for clinical staff, physicians are not typically trained or tested in BP measurement accuracy after medical school. Although they may not be the primary person conducting BP measurements, physicians routinely confirm abnormal BP readings obtained in examination rooms, often using auscultation, the most technically demanding method of BP measurement. These manual backup BP readings are likely to be inaccurate in the absence of using a calibrated device, selection of an appropriately sized cuff, and regular retraining (117). After initial training, auscultatory skills decline rapidly without regular retraining and accuracy testing (117). Also, although guidelines recommend averaging BP within and across visits, informal polling of clinicians has found this is rarely done(1). Using AOBP devices may facilitate obtaining the average of multiple measurements during a visit. However, devices that provide individual readings, in addition to an average, should be used.

Research Studies: In research studies, rigorous standardized protocols for measurement are needed to ensure the comparability and accuracy of BP assessments because of measurement error and physiological BP variability (119,120). An in**t**ernational conso**r**tium for q**u**ality r**e**search (TRUE) was formed in 2015 to make recommendations to improve the quality of research BP assessment (121). Table 4 summarizes recommendations which constitute a minimum standard for clinical and epidemiological research.

Regulatory approaches and partnerships—To date, efforts to improve the quality of BP measurements have focused on educating healthcare providers at an early stage of their career and on minimizing manual aspects of measurements (e.g., by using automated devices). Although contemporary evidence is sparse, prior studies have repeatedly documented poor quality of measurements as evidenced by digit preference and excess BP variability(122,123). Promulgation of recent guidelines is unlikely to be effective in improving BP measurement techniques, given prior lack of benefit when previous guidance has been published. In this context, a case can be made for regulatory and accreditation bodies, such as the Joint Commission: Accreditation, Health Care, Certification and National Committee for Quality Assurance, to develop and monitor basic standards for BP

measurement, similar to those implemented in clinical research (124). Such standards could include requiring the use of validated devices, establishing criteria to assure continued device calibration, using appropriately sized cuffs, and training and re-training technicians and providers on key features of BP measurement. These requirements would reinforce the importance of accuracy in the measurement of BP.

An approach to ensure BP measurement procedures are followed will likely require collaboration between policymakers, insurers, health care systems, EMR vendors, device manufacturers, and professional organizations (American Academy of Family Physicians, ACC, American College of Physicians, AHA, American Medical Association [AMA] and others). Agencies such as the Centers for Medicare and Medicaid Services provide incentives to health care plans/organizations for meeting quality metrics including the percent of the population with hypertension who have controlled BP. Currently, however, BP control is determined using only a single BP measurement or the lowest SBP or DBP of two or more measurements taken on the same day, rather than averaging at least two BP measurements on two or more occasions, as is recommended in clinical practice guidelines. Also, the United States Preventive Services Task Force and ACC/AHA guideline recommend out-of-clinic BP measurement to confirm the diagnosis of hypertension (1,5). No quality assurance metrics guide the appropriate measurement of BP, and little reimbursement supports the clinical procedure of BP assessment, whether inclinic or out-of-clinic, despite the potential high cost of under- and over-treatment of a condition, hypertension, that affects about half of the US adult population (2). Additionally, health insurers should provide increased time and adequate reimbursement to correctly measure BP.

Use of resources to improve the quality of BP measurements and care of patients with high BP may produce better hypertension control rates, and, more importantly, lower cardiovascular morbidity and mortality. In the US, improved management of high BP, including encouragement of standardized BP measurement, is a central component of the Centers for Medicare and Medicaid Services Million Hearts (125) and the AHA/AMA TARGET BP(126) initiatives. Globally, the World Health Organization’s Global Hearts(127) and the Vital Strategies Resolve(128) projects have similar goals. Although as yet unproven, these initiatives hold promise for improving the health of adults in the US and other countries.

Summary and conclusions

Over the past two decades, there have been several developments in the approach to BP measurement that have provided opportunities, yet presented new challenges, for clinical practice and research.

BP measurements obtained in routine clinical practice are increasingly being used for research and quality improvement activities. Despite repeated guideline recommendations and educational efforts, it appears that the quality of BP measured routinely in clinical practice remains poor. Current limitations with clinic BP measurement include lack of standardization, infrequent technician/clinician training and re-training, use of devices that have not been validated and/or regularly calibrated, not using an appropriately-sized cuff,

improper conditions and technique and inadequate documentation of the procedure. Also, despite guideline recommendations, the averaging of BP within and across visits is rarely done.

There is substantial evidence demonstrating that out-of-clinic BP measurements, using ABPM and HBPM, have stronger associations with risk for CVD events than clinic BP measurements(129). While guidelines recommend the use of ABPM and HBPM to guide the initiation and intensification of antihypertensive treatment, they are often not integrated into EMRs. Documenting out-of-clinic BP in the medical record could become more common with Healthcare Effectiveness Data and Information Set and National Committee for Quality Assurance recommendations to conduct ABPM or HBPM. It is important to recognize that despite strong observational data, ABPM and HBPM have not been used to determine eligibility for, or to guide antihypertensive treatment in large randomized controlled trials. Additionally, there has been rapid innovation with a burgeoning array of novel BP measurement devices being developed for out-of-clinic BP measurement, including some that measure BP without cuffs. However, few formal validation studies of the accuracy of these devices have been performed and, at present, these devices cannot be recommended.

EMRs provide an opportunity to document BP assessment and facilitate use of routine clinical BP measurements in research, but most of the concerns about obtaining high quality measurements persist. Efforts to standardize BP measurement procedures and improve their quality in routine clinical practice are needed. This may include documentation of BP training, selection of validated devices, and periodic device calibration by accreditation bodies. An example of this effort is the checklist used by Rakotz et al. to observe medical students measuring BP (130). Also, there is a need to develop and improve EMR functionality, including documentation of key features of BP measurement, seamless transmission of data from measurement devices, including out-of-clinic devices, to the EMR, tools to manipulate and average BP data at individual visits and over time, and improved data presentation to facilitate patient care, health system improvements, and research applications.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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ABBREVIATIONS AND ACRONYMS

ABPM	Ambulatory blood pressure monitoring
AOBP	Automated office blood pressure
BP	Blood pressure
CVD	Cardiovascular disease
DBP	Diastolic blood pressure
FDA	Food and Drug Administration
HBPM	Home blood pressure monitoring
SBP	Systolic blood pressure

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Research recommendations

A robust research portfolio is needed to provide an evidence base for future clinical practice guidelines and clinical research, particularly research on the use of routinely collected clinic BP for research purposes. The working group has identified several objectives for future research with potentially high impact (**Central Illustration**).

- **a.** Determine the variation in BP measurement approaches being used in routine clinical practice across the US and in clinical research protocols.
- **b.** Identify the aspects of the BP measurement protocol (e.g., presence of an observer, duration of wait time) that have the most substantial impact on the accuracy and precision of clinic BP. This research can guide the development of simplified BP measurement protocols for implementation in routine clinical practice.
- **c.** Evaluate the effect of interventions to improve BP measurements in routine clinical practice (e.g., use of automated devices that obtain and average multiple readings) on the accuracy and precision of clinic BP measurements and BP control rates.
- **d.** Evaluate head-to-head comparative data on the association of standardized clinic vs. out-of-clinic BP with CVD outcomes and mortality.
- **e.** Evaluate the impact of systematic and random errors on the diagnosis and management of hypertension and identify approaches to delineate real changes in BP from random error following treatment initiation.
- **f.** Assess the associations between routine clinic and research BP measurements and determine in what circumstances measurements obtained in routine clinical practice are acceptable to be utilized in research.
- **g.** Determine the optimal quality metric for BP control (e.g., using the average BP at an individual visit or across several visits, using only the last available BP reading) from the EMR.
- **h.** Evaluate the role of ABPM and HBPM in the diagnosis and treatment of hypertension; including:
  - **i.** Whether BP from ABPM versus HBPM provides a more accurate estimate of CVD risk, including the contribution of sleep measurements.
  - **ii.** The utility of using unattended AOBP and HBPM as screening tools prior to conducting ABPM among adults not taking and taking antihypertensive medication.
  - **iii.** The CVD and all-cause mortality risk reduction benefit of initiating antihypertensive medication among adults with white coat hypertension and masked hypertension and intensifying

antihypertensive medication among adults with white coat effect and masked uncontrolled hypertension.

iv. The utility of nighttime BP in the diagnosis of hypertension and the benefits of antihypertensive interventions among adults with asleep hypertension (e.g., chronotherapy).

v. Effective ways to reduce barriers to conducting ABPM and HBPM in clinical practice.

vi. The optimal protocol for using HBPM readings to diagnose and assess control of hypertension (what time of day, how many BP measurements, minimum acceptable number of measurements, duration of measurement period)

vii. Quantifying the burden associated with conducting 24-hour ABPM, including sleep disturbances and restriction on daily activities.

i. Evaluate the role of BP measured in public locations for hypertension screening and conducting follow-up BP measurements that can be used to guide antihypertensive medication titration.

j. Determine the validity of novel approaches (e.g., cuff-less devices) for BP measurement and the association of BP measured with these devices and CVD risk.

k. Assess the value of using orthostatic hypotension as part of the protocol to guide antihypertensive therapy.

l. Evaluate the prognostic impact of different orthostatic hypotension definitions with an emphasis on position (supine vs seated), timing of BP measurements after standing, and thresholds of change in BP versus self-reported orthostatic symptoms.

m. Evaluate apps for simplifying and organizing the incoming data from out-of-clinic BP measurements.

n. Evaluate approaches to measuring BP in morbidly obese adults including where (e.g., forearm, finger or wrist) BP should be measured.

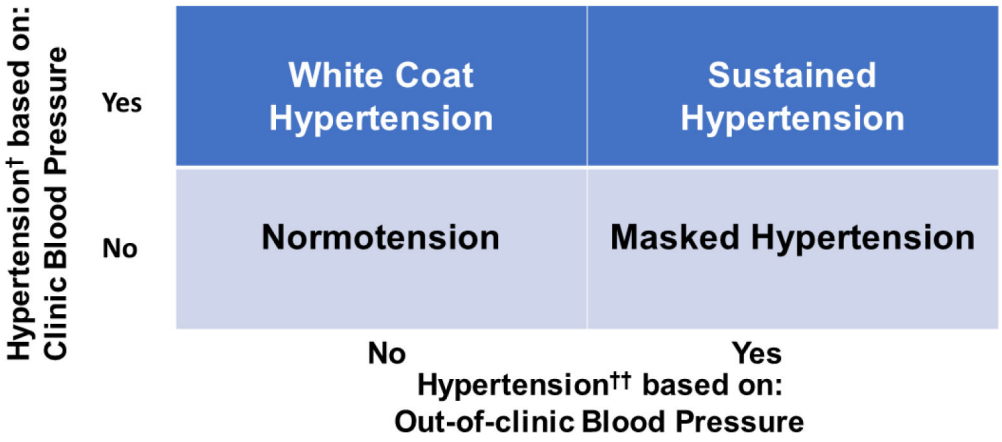
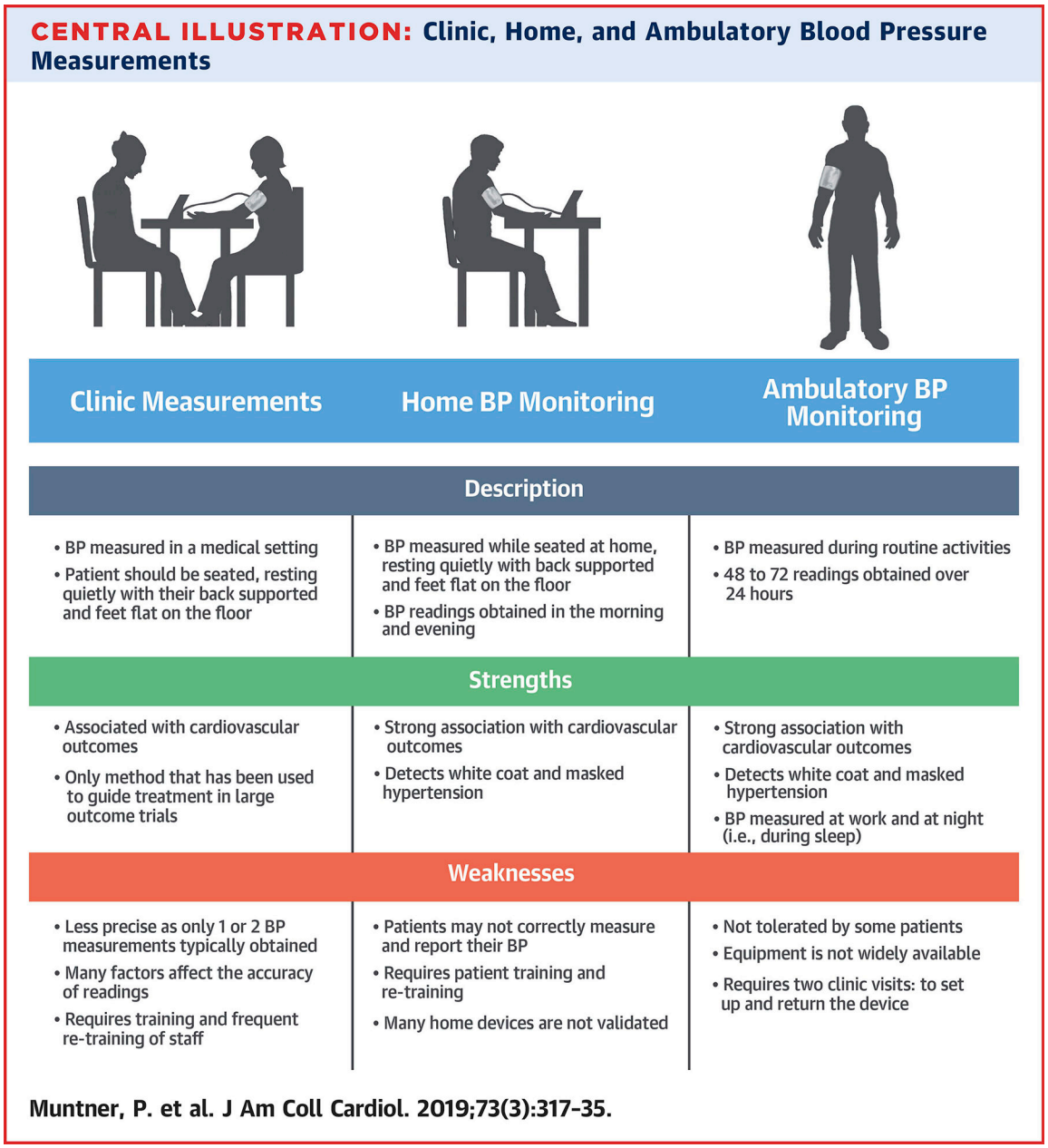


Figure 1: Blood pressure phenotypes defined by combinations clinic and out-of-clinic blood pressure.

† ≥130/80 mm Hg is the threshold for clinic blood pressure recommended in the 2017 American College of Cardiology/American Heart Association guideline (≥140/90 mmHg was the threshold for clinic blood pressure used in Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure [JNC 7]). †† ≥130/80 mm Hg is the threshold for awake and home blood pressure recommended in the 2017 American College of Cardiology/American Heart Association guideline (≥135/85 mmHg was the threshold for awake blood pressure used in JNC7). Some guidelines also recommend considering 24-hour and asleep blood pressure. The terms listed in the figure refer to untreated individuals. Among individuals taking antihypertensive medication, the corresponding terms are:

- White coat hypertension - white coat effect,
- Masked hypertension - masked uncontrolled hypertension,
- Sustained hypertension - uncontrolled hypertension
- Normotension - controlled hypertension



Central Illustration:
Clinic, home and ambulatory blood pressure measurements.

Table 1.

Key Steps and Instructions for the Proper Measurement of Clinic Blood Pressure

Key Steps for Proper BP Measurements	Specific Instructions	
Step 1: Properly prepare the patient	**1**	The patient should avoid caffeine, exercise, and smoking for at least 30 minutes before the measurement procedure begins.
	2	Ensure patient has emptied his/her bladder.
	3	Neither the patient nor the observer should talk during the rest period or during the measurement.
	4	Remove clothing covering the location of cuff placement. Be sure to avoid rolling up sleeves; this may cause a (partial) tourniquet effect.
	5	Measurements made while the patient is sitting or lying on an examining table do not fulfill these criteria.
Step 2: Use proper technique for BP measurements	**1**	Use a BP measurement device that has been validated, and ensure that the device is calibrated at recommended intervals.
	2	Obtain the patient's mid-arm circumference. For more details on how to accurately obtain mid-arm-circumference, see the Anthropometry Procedures Manual on the NHANES website
	3	Record the mid-arm circumference for future use.
	4	Support the patient's arm (e.g., resting on a desk).
	5	Position the middle of the cuff on the patient's upper arm at the level of the right atrium (the midpoint of the sternum).
	6	Use the correct cuff size, such that the bladder encircles 75% to 100% of the arm and a width that is 37% to 50% of the arm circumference.
	7	Once the patient is prepared, have him/her relax, sitting in a chair with their feet flat on the floor and back supported. The patient should be seated for five minutes without talking or moving around prior to recording the first BP reading. A shorter wait period is used for some AOBP devices.
	8	Either the stethoscope diaphragm or bell may be used for auscultatory readings.
Step 3: Take the proper measurements needed for diagnosis and treatment of elevated BP/hypertension	**1**	At the first visit, record BP in both arms. Use the arm that gives the higher reading for subsequent readings if there is a consistently higher level (e.g., ≥ 10 mm Hg) in one arm versus the other.
	2	Separate repeated measurements by 1 to 2 minutes.
	3	For auscultatory determinations, use a palpated estimate of radial pulse obliteration pressure to estimate SBP. Inflate the cuff 20–30 mm Hg above this level for an auscultatory determination of the BP level.
	4	For auscultatory determinations, place the head of the stethoscope over the brachial artery.
	5	For oscillometric devices, position the center of the blood pressure cuff over the upper arm brachial artery at least 1inch *above the crease of the elbow*.
	6	For auscultatory readings, deflate the cuff pressure 2 mm Hg per second, and listen for Korotkoff sounds.
	7	Staff retraining required at 6-month intervals.
Step 4: Properly document accurate BP readings	**1**	Record SBP and DBP. If using the auscultatory technique, record SBP as onset of the first of at least two consecutive beats and the last audible sound as DBP, Korotkoff phases 1 and 5, respectively. In case that the sounds are audible at full deflation or until very low DBP levels (<40 mmHg) then Korotkoff phase 4 (muffling of sounds) should be recorded and reported for DBP.
	2	If using the auscultatory approach, record SBP and DBP to the nearest even number.
	3	Note the time of most recent BP medication taken before measurements.
Step 5: Average the readings	Use an average of ≥2 readings obtained on ≥2 occasions to estimate the individual's level of BP.	
Step 6: Provide BP readings to patient	Provide patients their SBP/DBP readings both verbally and in writing. Information to help patients interpret their BP values should also be provided.	

AOBP, Automated office blood pressure, BP, blood pressure; DBP, diastolic blood pressure; NHANES, National Health and Nutrition Examination Survey, SBP, systolic blood pressure.

Adapted with permission from Mancia et al. (Oxford University Press), Pickering et al. (American Heart Association, Inc.), Weir et al. (American College of Physicians, Inc.) and Whelton (American College of Cardiology/American Heart Association).

Table 2.

Key components of blood pressure measurement that should be documented in the electronic medical record.

Component	Rationale/Notes/Necessary for:
Date/time	Allows for assessment of trends and diurnal variation
Location (emergency department, clinic, hospital ward, etc.)	Clinical interpretation
Staff member	Quality control including the monitoring of digit preference
Position (supine, seated, standing)	Clinical interpretation
Site of cuff placement (right/left side, arm/leg)	Clinical interpretation
Duration of quiet rest prior to the first measurement and between readings	Quality control/monitoring protocol adherence
Mid-arm circumference and cuff size used	Quality control
Device utilized	Quality control
Individual blood pressure levels	As opposed to just entering average of 2 or 3 blood pressure measurements. Allows for assessment of variability and quality control/monitoring protocol adherence (>1 blood pressure measured).
Blood pressure levels in both arms	Determine which arm is appropriate for future measurements (arm with the higher blood pressure should be used)
Pain level	Clinical interpretation

Table 3

Sources of inaccuracy in the measurement of blood pressure in the clinic setting.

	Effect on SBP, mm Hg	Effect on DBP, mm Hg
Before measurement		
Acute meal ingestion	− 6	−5 to −1.9
Acute alcohol consumption	−23.6 to +24	−14 to +16
Acute caffeine consumption	+3 to +14	+2.1 to +13
Acute nicotine use or exposure	+2.8 to +25	+2 to +18
Bladder distension	+4.2 to +33	+2.8 to +18.5
Cold exposure	+5 to +32	+4 to +23
Insufficient rest period	+4.2 to +11.6	+1.8 to +4.3
Device		
Use of a non-validated device	0% to 70% with ≥ ±3[†]	0% to 70% with ≥ ±3[†]
Device not calibrated	0% to 70%[†]	0% to 70%[†]
Patient positioning		
Standing versus sitting	−2.9 to +5.0	+7
Supine versus sitting	−10.7 to +9.5	−13.4 to +6.4
Legs crossed at the knee	+2.5 to +14.9	+1.4 to +10.8
Unsupported back	Not significant effects	+6.5
Unsupported arm	+4.9	+2.7 to +4.8
Arm lower than heart level	+3.7 to +23	+2.8 to +12
Attaching the device to the person		
Paretic arm	+2	+5
Too small cuff size	+2.1 to +11.2	+1.6 to +6.6
Too large cuff size	−3.7 to −1.5	−4.7 to −1.0
Cuff placed over clothing	Not significant effects	Not significant effects
Stethoscope placed under cuff	+1.0 to +3.1	−10.6 to −3.5
Taking the measurement		
White coat effect	−12.7 to +26.7	−8.2 to +21
Talking during the measurement	+4 to +19	+5 to +14.3
Use of stethoscope bell vs. diaphragm	−3.8 to −1.5	−1.6
Excessive pressure on stethoscope head	Not significant effects	−15 to −9
Fast cuff deflation	−9 to −2.6	+2.1 to +6.3
Observer hearing deficit	−1.6 to −0.1	+1.1 to +4.3
Recording Korotkoff phase IV versus V for DBP	Not applicable	+12.5
Short interval between measurements	Not significant effects	Not significant effects
Interpreting the measurement		
Reliance on a single measurement	+3.3 to +10.4	−2.4 to +0.6
Inter-arm differences	3.3 to 6.3[††]	2.7 to 5.1[††]

	Effect on SBP, mm Hg	**Effect on DBP, mm Hg**
Terminal digit preference	1% to 79% over-representation of terminal of 0	3% to 79% over-representation of terminal of 0

DBP – diastolic blood pressure; SBP – systolic blood pressure

† Depending on type of device used (mercury, aneroid or automated)

†† Values could be too low or too high depending on the arm used.

Adapted from N Kallioinen, A Hill, M Horswill et al. J Hypertens. 2017 Mar; 35 (3):421-441.

Table 4.

Recommendations which constitute a minimum standard for clinical and epidemiological research.

Observer Training and Testing
• Indicate number of observers trained and their background (e.g. physician, nurse, etc.).
• All staff who directly assess BP or train others in BP measurement should be trained and tested as part of quality control for research. They should also have experience conducting BP measurement on a routine basis.
• If auscultatory BP assessment used, training and testing for technique and accuracy using double-head stethoscope is recommended.
• Observer measurement competency testing should occur at least every 6 months throughout duration of a study, including assessment for measurement bias.
• Retraining should be performed whenever deficiencies are found.
• The BP measurement protocol should be provided in sufficient detail so that it can be duplicated by others.
• Measurement conditions should be clearly defined (e.g., location, position, resting period, etc.)(119)
BP Measurement Devices
• BP devices should be assessed for calibration at the start, every 6 months, and end of a study (at a minimum). Date of calibration, and when next calibration is due should be clearly marked on the device. More frequent calibration is warranted for aneroid devices.
• Data should be assessed and reported for terminal digit preference.
• When using the oscillometric approach, only devices that have passed accepted national or international validation protocols should be used (with references provided).
• For each cuff size used, specify the bladder dimensions and range of acceptable arm circumferences.
• Only upper-arm cuffs are recommended.
BP Assessment
• Multiple readings should be taken and averaged at each assessment.
• Multiple visits with BP assessments are preferred at baseline and during an intervention follow-up.
• The addition of out-of-clinic BP (ABPM or HBPM) to those measured only in research/clinical settings is preferred.
• For out-of-clinic assessments, ABPM is preferred over HBPM unless both methods can be used.

ABPM: ambulatory blood pressure monitoring, BP: blood pressure, HBPM: home blood pressure monitoring.