Innovations in blood pressure measurement and reporting technology: International Society of Hypertension position paper endorsed by the World Hypertension League, European Society of Hypertension, Asian Pacific Society of Hypertension, and Latin American Society of Hypertension

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Blood pressure (BP) is a key contributor to the lifetime risk of preclinical organ damage and cardiovascular disease. Traditional clinic-based BP readings are typically measured infrequently and under standardized/resting conditions and therefore do not capture BP values during normal everyday activity. Therefore, current hypertension guidelines emphasize the importance of incorporating out-of-office BP measurement into strategies for hypertension diagnosis and management. However, conventional home and ambulatory BP monitoring devices use the upper-arm cuff oscillometric method and only provide intermittent BP readings under static conditions or in a limited number of situations. New innovations include technologies for BP estimation based on processing of sensor signals supported by artificial intelligence tools, technologies for remote monitoring, reporting and storage of BP data, and technologies for BP data interpretation and patient interaction designed to improve hypertension management (''digital therapeutics''). The number and volume of data relating to new devices/technologies is increasing rapidly and will continue to grow. This International Society of Hypertension position paper describes the new devices/technologies, presents evidence relating to new BP measurement techniques and related indices, highlights standard for the validation of new devices/technologies, discusses the reliability and utility of novel BP monitoring devices, the association of these metrics with clinical outcomes, and the use of digital therapeutics. It also highlights the challenges and evidence gaps that need to be overcome before these new technologies can be considered as a user-friendly and accurate source of novel BP data to inform clinical hypertension management strategies.

Keywords: ambulatory blood pressure monitoring, blood pressure, blood pressure monitors, digital technology, home blood pressure monitoring, hypertension

Abbreviations: AAMI, Association for the Advancement of Medical Instrumentation; ABPM, ambulatory blood pressure monitoring; AI, artificial intelligence; ANSI, American National Standards Institute; BP, blood pressure; CI, confidence interval; ESH, European Society of Hypertension; HBPM, home blood pressure monitoring; HR, hazard ratio; ICT, information and communication technology; IEEE, Institute of Electrical and Electronics Engineers; ISH, International Society of Hypertension; ISO, International Organization for Standardization; PAT, pulse arrival time; PPG, photoplethysmography; PTT, pulse transit time

INTRODUCTION

Blood pressure (BP) is a key determinant of an individual's risk trajectory with respect to cardiovascular disease, organ damage and mortality throughout the lifespan. However, the use of a brachial cuff sphygmomanometer for BP measurement has not changed substantially since the time of Riva Rocci and Korotkoff at the turn of the 20th century.

Given that BP can vary considerably minute-to-minute, throughout the day, and over both the short and long term, clinic-measured BP readings are typically measured infrequently and under resting and standardized conditions to reduce variability and therefore do not capture BP values during the normal activity of daily life [1]. In addition, systolic (but not diastolic) BP values appear to be underestimated when determined using the auscultatory versus oscillometric method [2].

As a result, the importance of out-of-office BP measurements – ambulatory BP monitoring (ABPM) and especially home BP monitoring (HBPM) – is emphasized in current hypertension management guidelines, with the aim of obtaining multiple BP readings in the usual environment of each individual [3–7]. However, ABPM is usually an isolated monitoring session, and while home BP provides more frequent measurements these are usually taken at rest.

Although advances in the application of the brachial cuff sphygmomanometer from clinic measurement to ABPM and HBPM have shown considerable benefits in the diagnosis, risk profiling, and management of hypertension [3], the upper-arm cuff oscillometric method can still only provide intermittent BP readings under static conditions or in a limited number of situations [3]. Furthermore, even gold-standard, conventional cuff-based BP measurements such as ABPM have been shown to be susceptible to measurement artefacts [8] and the possibility of different readings being obtained simultaneously from cuffs placed on different arms [9]. Other important limitations of automated cuff-based BP measurement devices relate to comfort and disturbance of sleep and/or daily activities due to the obtrusive nature of cuff inflation [10,11] and their limited measurement accuracy in individuals [8,9].

There is, therefore, a strong rationale and need for new, improved techniques and devices to accurately and precisely measure BP, provide a greater frequency of measurements, including continuous monitoring, and relay intelligent summaries of BP readings to patients and care providers, helping all stakeholders to gain a better understanding of BP profiles beyond static and intermittent measurements. In addition, from a practical perspective, the COVID-19 pandemic accelerated the use of virtual hypertension management, particularly the wider use of self BP measurement at home, embedding or expanding some approaches into everyday practice [12,13].

We are now entering an era in which we are likely to see the accelerated application and uptake of new digital technologies and practices for the measurement of BP and their incorporation into clinical practice (Fig. 1). This reflects a desire, and some would say a need, to move beyond static BP measurement based on an upper arm cuff. However, how these various new technological and data science-driven approaches to measure (or in most cases estimate) BP and, more importantly, whether they are reliable, has been less clear.

Therefore, the International Society of Hypertension (ISH) established an expert working group on "Innovations in Blood Pressure Measurement". This position paper distils the work of this ISH working group, and presents and discusses currently available evidence relating to new BP measurement techniques and the indices they can provide, the validation and reliability of new devices/technologies, monitoring systems utilizing digital technology, and digital therapeutic interventions. Indeed, the importance of development and promotion of research into new approaches for BP monitoring and their integration in systems of care is underwritten in the Society's commitment to reduce the burden of hypertension around the world [14]. The aim is to provide more in-depth information than can be contained in existing guidelines, not least because many of these technologies have not yet been adequately validated and approved for clinical practice. Our goal was to develop a consensus on the current state of play. The document covers the following topics: BP measurement and new technologies; validation, reliability and utility of novel BP measurement devices; association of measurements from novel BP devices with cardiovascular risk, organ damage and clinical outcomes; current challenges and the role of future technologies; and digital interventions.

PROCESS OF WRITING

This position paper summarizes data and recommendations compiled by an ISH panel of experts from 11 countries convened by the ISH. Separate groups of experts were then assigned specific topics based on their area of expertise and developed draft text and recommendations by consensus based upon review of the published information and evidence. Revisions were made by all authors and then submitted for external review internationally. Representatives of the World Hypertension League (WHL), the European Society of Hypertension (ESH), the Asian Pacific Society of Hypertension (APSH), and the Latin American Society of Hypertension (LASH) reviewed and endorsed the document.
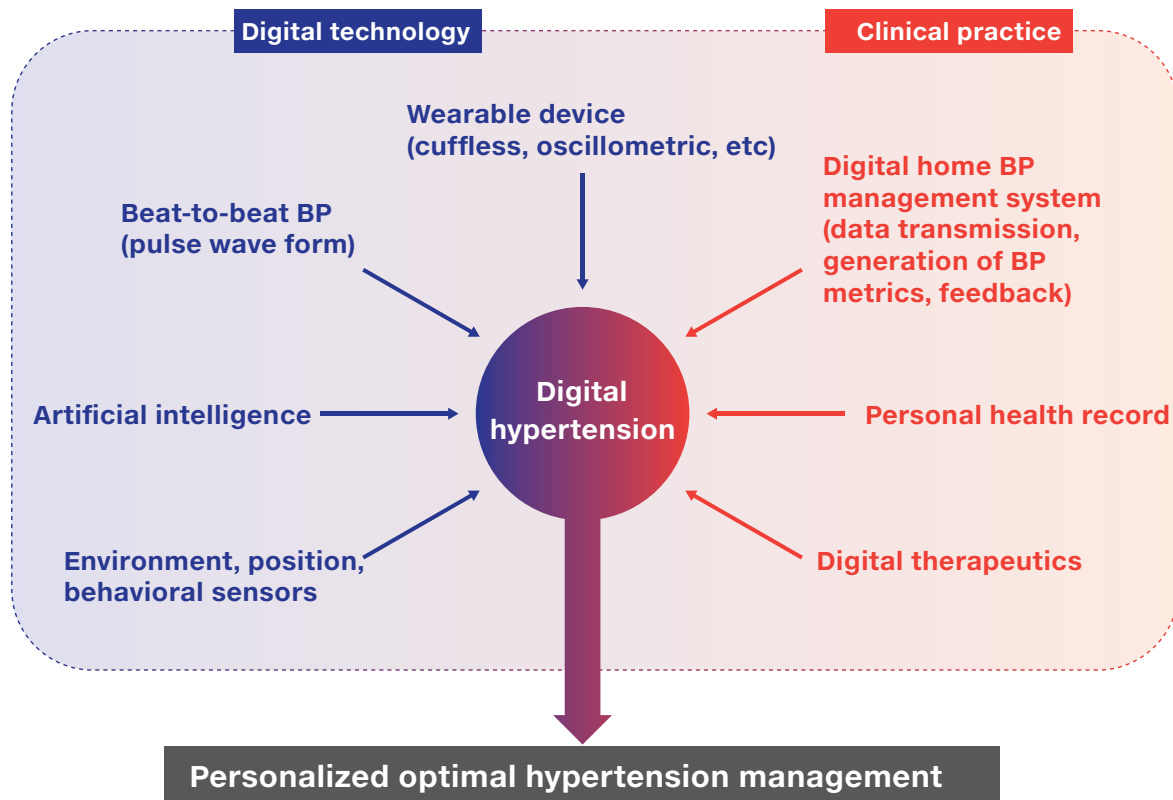
FIGURE 1 Integration of new digital technologies into clinical practices, resulting in the personalized optimal management of hypertension. BP, blood pressure.

BP MEASUREMENT AND NEW TECHNOLOGIES

Conventionally, sphygmomanometers with an inflatable cuff that use a stethoscope by a human observer (manual auscultatory BP monitoring device) or oscilloscope (automated electronic oscillometric BP measuring device) to estimate intra-arterial pressure (which is considered to be represented by cuff pressure) have been widely used for both clinic and out-of-office BP monitoring. However, these devices can only perform occasional measurements, require user activation (manual measurement), or are preset for timed measurements (i.e., ABPM and nighttime HBPM) [15]. The ideal wearable BP monitoring device would provide continuous monitoring of 24-hour BP, including the nighttime and daytime periods, so that patterns of BP that might contribute to elevated cardiovascular risk are not missed due to the infrequent and intermittent timing of BP readings [16]. Additionally, new technologies and devices aspire to be both non-invasive and unobtrusive, facilitating BP measurement for screening, diagnosis and treatment, thereby increasing patient acceptance and the possibility of more widespread implementation of hypertension control interventions, especially in low- and middle-income countries [17]. Transitioning to cuffless devices would be a major step in increasing the acceptance and availability of BP measurement [18].

New technology mainly focuses on analyzing the pulse wave shape and/or the velocity of pulse wave propagation along the arterial tree. In most cuffless devices, there is generally no direct measure of force that is related to arterial pressure, but rather, BP is estimated from a signal that is related to changes in blood volume [e.g. photoplethysmography (PPG)] or arterial stiffness [determined based on measures such as the pulse transit time (PTT) or pulse arrival time (PAT)]. This adds an extra layer of complexity and uncertainty in relation to both the accuracy and precision of the measurement [19]. Although, errors can also occur when estimating intra-arterial pressure with cuff-based devices using surrogate signals such as Korotkoff sounds (auscultatory technique) or the change in pressure-dependent arterial compliance (oscillometric technique).

Many novel devices and technologies have been developed, some of which are now commercially available [20]. Details of the new approaches to BP measurement using new technology are detailed below and summarized in Table 1.

Non-traditional cuff-based techniques

Cuff-based, wrist-worn devices
The Omron HEM-9601T is an automatic wrist-watch type device for self-measurement of BP incorporating a wrist cuff and that allows occasional self-measurement of BP by manual activation of the device by the user, and automated measurement of nocturnal BP. This device has been validated according to the standards of the American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI)/International Organization for Standardization (ISO) guidelines and shows good performance for day and night BP measurements

TABLE 1. Types and definitions of novel blood pressure measurement devices and technologies

		Cuff-based techniques		Cuffless techniques		
Technologies	Definition	Cuff-based, wrist-worn devices	Finger cuff devices	Wrist-worn devices	Smart rings	Smartphones using PPG
Wearable	Can be worn during daily activity (i.e., wrist-watch type, ring-type, upper-arm type)	○	Δ [31]	○	○	
cf. non-wearable	Used for occasional measurement in static condition or limited situations (i.e., auscultatory, upper-arm type)		○			○ᵃ
Cuffless	Measures BP using techniques such as photoplethysmography, tonoarteriography, electrocardiography, ballistocardiography, electrical bioimpedance, seismocardiography, or ultrasound, or a combination of these technologies, and artificial intelligence			○	○	○
cf. cuff-based	Measures BP using an inflatable cuff worn on the upper arm, wrist, or finger (i.e., auscultatory, oscillometric)	○	○			
Continuous	Can continuously monitor BP and output readings every ≤30 seconds		○	Δ [50]	○	
cf. intermittent	Monitors BP with output intervals of >30 seconds (i.e., oscillometric)	○		Δ [37,38]		○
Beat-to-beat	Can detect BP values on a beat-to-beat basis (a subset of continuous BPM) (i.e., tonometry, volume clamp, or pulse transit time method)		○	Δ [50]		

ABPM, ambulatory blood pressure monitoring; BP, blood pressure; BPM, blood pressure monitoring; c.f., compared with; HBPM, home blood pressure monitoring; PPG, photoplethysmography.
○, applicable; Δ, applicable for some devices.
ᵃPortable but not wearable.

[21,22]. This device may be particularly useful for measuring nighttime BP with minimal sleep disturbance and for measuring BP during sleep over a number of nights [23]. A similar wearable watch-type wrist-cuff oscillometric device was developed by Huawei and validated according to the ANSI/AAMI/ISO standard [24–27]. Although wrist-worn devices give acceptable measurements when the hand is steady and the wrist is at the heart level, they are subject to error due to the positioning, and pronation and supination of the hand and forearm [22]. Thus, although having less impact on sleep quality, BP measurement at the wrist level is open to artefacts and errors due to arm movements at night and to variations over time in the hydrostatic height difference between the wrist and the level of the heart.

Finger cuff devices using the vascular unloading technique

The finger-cuff device, developed originally as the Finapres, enabled continuous measurement of BP using the servo-controlled vascular unloading technique [28–30]. The device functions with an external pump and control unit. Recent developments have produced a pump and control unit that is sufficiently small to be placed on a ring worn on the finger. This is an interesting development in wearable BP measurement because the device is self-contained, small enough to be comfortably worn on the finger, and does not require external calibration [31]. However, while this approach is useful for following acute BP changes and is therefore suited to environments where this is a priority, it is not well suited for precise BP level estimation and the diagnosis of hypertension, partly because of its high sensitivity to artefacts (e.g. movement).

Cuffless techniques

Many of the commercially available wearable BP monitoring devices use cuffless technology, and are classified as cuffless BP monitoring devices, which are wearable or implemented in smartphones or other dedicated devices [32–34]. A cuffless device is one that produces BP readings without the use of an inflatable cuff. Cuffless devices use one or a combination of various technologies to estimate BP, mainly including PPG (measurement of the pulse wave via an optical sensor), PTT (the time taken for the pulse wave to propagate from a more central to a more peripheral site), PAT (the time delay between the R-wave of the ECG and the subsequent arrival of the pulse wave at a measurement site), tonoarteriography (detection of oscillations in the arterial pressure wave via a pressure sensor), electrocardiography, ballistocardiography (the measurement of the body motion generated by the ejection of the blood at each cardiac cycle), electrical bioimpedance, seismocardiography (a measure of the vibration created by the contraction of the heart) or ultrasound [18,20,35,36]. Most of these devices require individual user calibration using BP measurement by the user with a cuff device or biometric data, and incorporate AI and machine learning [18,20,35,36].

Wrist-worn devices

Cuffless, wrist-worn devices have been developed to track BP based on pulse wave analysis. BP readings from a wrist-band device (Aktiia) underwent a validation study using an extended version of the ANSI/AAMI/ISO standard for cuff devices (which is not appropriate for validating cuffless devices; see VALIDATION OF NOVEL BP MEASUREMENT

DEVICES section), where the device was initially calibrated with cuff measurements and subsequently used for one month in an outpatient setting [37]. However, an independent study using 24-h ambulatory BP monitoring showed that this device has limited capacity to track the magnitude of BP change during nighttime sleep [33]. The Samsung Galaxy watch measures BP using PPG signals obtained from the upper part of the wrist. The measurement has been shown to be readily accepted by users in large cohorts, although there are issues relating to the frequency of calibration, precision of measurements, and systematic bias of measurements toward a calibration point that need to be addressed in subsequent device development [38,39].

Smart rings

Wrist-worn devices detect the PPG signal at the wrist, and because of the form factor of the watch, the signal detected on the upper part of the wrist can be of varying quality. However, PPG signals detected by a ring at the lower phalanx of the finger can be comparatively stronger and more stable. This has facilitated development of ring devices, which are less prone to movement due to the snug fitting of the ring on the finger. Recent developments incorporated in the Sky Labs Cart-BP Ring involve the analysis of finger PPG using machine learning algorithms addressing a range of intra-individual BP variations from calibrations. Early studies reported promising results for continuous BP measurement [34]. A clinical study published in 2024 indicated that the device showed good agreement with ISO requirements [40] and strong correlation with conventional ABPM devices for both daytime and nighttime BP measurements [41]. However, calibration of the ring using cuff BP measurement was performed immediately before the accuracy testing component, and the testing was not performed in accordance with recent ESH recommendations developed specifically for cuffless devices [15].

Smartphones using photoplethysmography

Smartphones can also be used to acquire a PPG signal for pulse wave analysis. Typically, the user places their finger on the camera, which is illuminated using the flashlight, and a PPG signal is obtained by extracting the pulsatile variation from a video recording [42]. The OptiBP app uses this approach and has passed validation testing criteria according to the AAMI/ESH/ISO Universal Standard for cuffed BP devices [43]. The validation study was conducted with participants in the seated position and the smartphone at left ventricle level, but stability of calibration to assess longer term accuracy was not assessed. Alternatively, a contactless PPG signal can be obtained from the user's face via the mobile phone camera. This approach has also been assessed in a preliminary study, but the BP from the user's face via this device appears to have significant systematic errors at present [44].

Smartphone oscillometric finger pressing method

Technology is in development to enable smartphones to be used as oscillometric finger BP sensors. The user presses their finger against the smartphone force-sensitive screen under a range of pressures, allowing systolic and diastolic BP values to be estimated from the pressures at which smartphone-derived pulse waves appear and disappear [45]. Potential approaches to measure the applied pressure include: incorporating a force transducer into smartphone design [45]; and a custom attachment that relays pressure information to the phone via the camera [46].

Ultrasound

The theory underlying the measurement of arterial BP using ultrasound involves quantitative measures of changes in vessel diameter. The value of an ultrasound-based approach to BP measurement is that the standard technology is widely available and could allow simultaneous assessment of other structural or functional vascular parameters to provide an integrated assessment of vascular aging. However, compared with other cuffless BP approaches, there has been little development in this field because the technique does not necessarily facilitate better approaches or improved convenience compared with automated cuff-based devices [47].

Continuous BP monitoring

Continuous BP monitoring is defined as having a BP reading output interval of ≤30 s (ISO 81060-3: 2022) [48]. In contrast, BP monitoring that provides a BP reading output interval of >30 s is defined as intermittent BP monitoring (Table 1). Non-invasive methods of continuous BP measurement include tonometry, volume clamp, or PAT/PTT/pulse wave velocity-based approaches [20,49,50]. These techniques enable continuous acquisition of the arterial pulse waveform and capture beat-to-beat changes in BP (called continuous beat-to-beat BP monitoring) [20,49,50]. However, there remain a number of challenges to the use of continuous BP monitoring devices in daily life, including usability, discomfort, and calibration frequency [18]. Thus, at the present time, such techniques are relevant to situations where fast BP changes are important, such as in critical care (intensive care unit) and during anesthesia. Therefore, invasive intra-arterial BP measurement is the reference method for such technologies [48]. Continuous BP monitoring would also be useful to detect fast BP changes occurring during sleep in patients with obstructive sleep apnea and/or nocturnal periodic leg movements, which are not easily identified using intermittent BP monitoring at a low sampling rate.

Novel BP monitoring devices with specific features

Another innovation in BP monitoring devices is the incorporation of functions that are additional to BP measurement. Multisensor BP monitoring devices also have the capability to provide biological, physical, or environmental data through additional sensors that detect parameters such as oxygen saturation and/or temperature, humidity and barometric pressure [51,52]. There are also automated nighttime HBPM devices that are activated at specific times, and can measure nighttime BP while an individual is sleeping [23,53].

Key points

- The ideal cuffless wearable BP device provides continuous monitoring of 24-h BP.
- New cuffless BP devices and technologies need to be non-invasive and unobtrusive for the user.
- Transitioning to cuffless devices would be a major step in increasing the acceptance and availability of BP measurement.
- Most cuffless BP measurement devices estimate BP from a signal that is related to changes in blood volume.
- There remain a number of challenges to the use of continuous BP monitoring devices in clinical practice, including usability, discomfort, and calibration frequency.
- Multisensor BP monitoring devices can also provide data on parameters such as oxygen saturation and environmental conditions.

VALIDATION OF NOVEL BP MEASUREMENT DEVICES

There is international consensus on how to validate the automated cuff BP measuring devices currently recommended for clinic, home, and ambulatory BP measurements taken for clinical decision-making in hypertension [54]. In 2018, the AAMI, the European Society of Hypertension (ESH) and the ISO developed the AAMI-ESH-ISO Universal Standard (ISO 81060−2:2018) for global use for the validation of automated cuff BP measuring devices [54]. This standard requires a study in at least 85 individuals with manual auscultatory BP measurement by two observers as the reference for validation in a general population. To be validated, the new device must meet Criterion 1 for individual readings ($n = 255$; average test-reference difference in mean systolic and diastolic BP of $\leq 5 \pm 8$ mmHg) and Criterion 2 for individual participants ($n = 85$; maximum permissible standard deviation threshold of the differences dependent on the average difference of the BP readings) [54]. The AAMI-ESH-ISO Universal Standard requires additional smaller studies for special populations (e.g., children, pregnancy). Clear guidance has been provided for the performance and reporting of validation studies of BP measuring devices [55]. Device validation requirements in individuals with a large arm circumference (>42 cm) and patients with atrial fibrillation are currently under development by ISO committees.

The AAMI-ESH-ISO Universal Standard is not appropriate for cuffless BP devices because they use different measurement principles and have special accuracy issues, necessitating different testing [15,18,19,32,35,56]. Continuous cuffless BP measurement devices (reading output every ≤30 s) [15,35] require intraarterial BP measurement as the reference. Intermittent cuffless BP measurement devices (reading output every >30 s) [15,35] usually need to be calibrated for an individual user before use, such as by the input of a classic cuff BP measurement and/or demographic information [15,35]. The assessment of their ability to track BP changes is vital [15]. Also, measurements are often taken with the device not at heart level, resulting in potential measurement error due to differences in hydrostatic pressure, and recalibration may be required because accuracy might decline over time after the initial calibration [15].

The Institute of Electrical and Electronics Engineers (IEEE 2014) [57,58], the ISO (ISO 81060-3, 2022) [48] and

the ESH Working Group on BP Monitoring and Cardiovascular Variability (2023) [15] developed validation protocols specifically for cuffless BP devices (Table 2). The IEEE standard [57,58] presented all the key issues and aspects for properly validating cuffless BP devices, but did not propose procedures for testing the ability of these devices to track BP changes, which is essential [15,35]. On the other hand, the ISO 81060−3 was developed for continuous BP monitoring devices, mostly used in critical care to track fast BP changes, and thus has intra-arterial BP as the reference method [48]. The 2023 ESH protocol presented detailed recommendations on stepwise procedures for pragmatic clinical validation of intermittent cuffless BP monitoring devices for the diagnosis and management of hypertension and was developed to be applicable in many research centers [15,35]. The ESH protocol includes six validation tests (Table 3), and different combinations of these tests are required for each cuffless device type according to its features, function, and intended use [15]. The ISO has recently started the development of a new standard (ISO 81060-7), which is intended specifically for intermittent cuffless BP measurement devices.

Key points

- There are established standards for the validation of automated cuff-based BP measurement devices but these standards are not appropriate for cuffless BP measurement devices.
- Cuffless BP devices require validation using specific standards, mainly testing their accuracy in tracking BP changes, evaluation of position and movement issues, and the stability and accuracy of readings.
- The ESH protocol for cuffless BP devices recommends six validation tests, and combination of these is used for each cuffless device (depending on its features, function, and intended use).
- An ISO standard for intermittent cuffless BP measurement devices is in development.

THE RELIABILITY AND UTILITY OF NOVEL BP MONITORING DEVICES

Every year, >140 new patents are registered for BP monitoring devices [35], which clearly indicates a rapidly growing market. For any new BP device to be useful for clinical decision-making, it must be safe and must meet the following three key criteria:

1. *Accuracy* (including the ability to predict outcomes). For this, new devices must demonstrate comparable outputs to the tried-and-tested conventional cuff-based devices, for which an overwhelming amount of outcome data exist. Many technology companies also target the general community, primarily those interested in monitoring their health. In such instances, estimations of other BP metrics, such as the percentage change during sleep or during the morning surge, may be presented. It is also important to validate the accuracy of these BP metrics.

2. *Usability and acceptability*. These need to be demonstrated before new devices can be introduced into clinical practice [59]. Applying usability engineering principles would allow the identification and minimization of predictable human errors to ensure the safety of the user interface [60]. Another key aspect is whether the technology is

TABLE 2. Validation protocols for novel cuffless blood pressure measuring devices. Modified from Stergiou *et al.* [15]

	Institute of Electrical and Electronics Engineers (IEEE) 2014–2019 [57,58]	International Organization for Standardization (ISO) 2022 [48]	European Society of Hypertension (ESH) 2023 [15]
Device type	Wearable	Continuous	Intermittent
Study sample	≥85	30–120	85–175
Reference method	Manual auscultatory	Intra-arterial	Manual auscultatory; ambulatory oscillometric
Validation tests			
Post calibration	Yes	Yes	Some devices
Different positions	Yes	Yes	Some devices
Tracking BP change	Acute	Acute	Acute and long-term (sleep/treatment)
Before recalibration	Yes	Yes	Some devices
Test/reference BP measurements	Simultaneous; sequential	Simultaneous	Sequential; ambulatory simultaneous
Acceptable error, mmHg	≤7	≤6 ± 10	≤5 ± 8

BP, blood pressure.

TABLE 3. Validation tests for cuffless blood pressure measuring devices recommended by the European Society of Hypertension Working Group on Blood Pressure Monitoring and Cardiovascular Variability [15]

Validation test	Cuffless device types	Sample size[a]
1. Static test	Immediately post calibration; for calibration-free and demographic-calibrated devices	≥35 or ≥85
2. Position test	For wearable devices with sensors not worn at heart level	≥35
3. Treatment test	For cuff- or demographic-calibrated devices	≥35
4. Awake-asleep test	Versus 24-hour ambulatory cuff BP monitoring; for automated wearable devices	≥35
5. Exercise test	Bicycle or handgrip; for cuff- or demographic-calibrated devices	≥35
6. Recalibration test	For cuff-calibrated devices requiring periodic recalibration	≥35

[a]Based on Monte Carlo simulation analyses (see the supplemental digital content accompanying Stergiou *et al.* [15]; http://links.lww.com/HJH/C212).

acceptable to both users and medical professionals. The utility of new BP measurement devices, the parameters that they could generate (such as BP variability, morning surge, nighttime dipping), and the potential value that they may add to medical practice have not yet been determined.

3. *Reliability*. The reliability of novel BP measurement devices is also related to their precision, which refers to the repeatability of measurements over time. This is highly relevant for new devices that monitor BP over weeks and months, and therefore aim to provide estimates of long-term BP variation.

Several studies have compared novel cuffless BP devices to oscillometric cuff-based 24-h ABPM. Reports from these studies include significant discrepancies in methodology (e.g. number of participants), and some report clear differences between classic and novel devices [39,61–63]. Furthermore, some report mixed results [64] and others report acceptable agreement [65–67]. These differences are likely caused by differences in comparison protocols and by variances in the ability of the new devices to adequately track BP over a 24-h period. It is also important to note that these studies take place in the context of physiologic variability in BP over 24 h, along with the limited intra-individual reproducibility of BP values from 24-hour ABPM [9,68].

Some manufacturers also compare new BP device readings with intra-arterial BP [34,69]. This approach would be acceptable for "continuous" cuffless devices where monitoring of rapid BP changes is important (such as in the intensive care unit), and for which the ISO 81060-3:2022 standard was developed [48]. However, if the intended use of a new BP device is the clinical monitoring of BP, then the reference should be cuff-based BP readings, because this is what is currently used in clinical practice for the diagnosis,

treatment and management of hypertension, and for which there is strong evidence for association with outcomes. It is still unclear which protocol should apply for continuous monitors to be used in clinical practice because neither the ISO nor the ESH standard would be fully adequate. Although, of these, the ISO standard is the most applicable.

Several new cuffless BP devices have obtained formal clearance from some regulatory authorities, such as the US Food and Drug Administration [70] or the CE-mark [71]. However, it is important to recognize that regulatory approval in this context is largely focused on the safety of the device, and does not guarantee rigorous validation of the accuracy of BP measurements required for clinical use [72], highlighting the need to address communication gaps between stakeholders. Collaboration between regulatory entities and scientists, manufacturers and clinicians is essential to share harmonized concepts and standardized protocols for effective validation [73]. This also facilitates the implementation of multidisciplinary collaborations from the design phase (co-design) of new solutions – an approach that can accelerate the innovation process.

Key points

- There are three key criteria for any new BP measurement device to be useful for clinical decision making: accuracy, usability/acceptability, and reliability.
- Accuracy relates not only to BP measurements but also the ability for BP values to predict outcomes.
- Several new cuffless BP devices have obtained formal clearance from regulatory authorities, but this largely relates to device safety and might not always reflect rigorous validation of the accuracy of BP measurements for clinical use.
- Multidisciplinary co-design of new devices could help to accelerate the innovation process.

ASSOCIATION WITH CARDIOVASCULAR RISK, ORGAN DAMAGE AND CLINICAL OUTCOMES

Although clinic BP and out-of-office ambulatory and home BP form the basis of current evidence-based management of hypertension, emerging BP measurement technologies show promise for having an increasingly important role in the digital hypertension era and may probably provide incremental value for risk assessment and therapeutic monitoring.

BP measurements from wearable devices, albeit still intermittent, have shown varying degrees of association with hypertension-mediated organ damage [74,75]. Nonetheless, when integrating several biological markers, such as pulse rate, blood oxygen saturation, respiratory rate, cuffless systolic and diastolic BP, body temperature, stroke volume, cardiac output, and systemic vascular resistance, cuffless devices may be able to generate more precise risk scores for the evaluation of arterial stiffness [76] and health status [77], an issue that deserves further study.

Tonometry-based pulse wave analysis is another possible technique for beat-to-beat BP monitoring. This technique may detect nocturnal pulse wave surges in seconds. Nocturnal BP surge in seconds has been shown to be associated with left ventricular hypertrophy [50] and arterial stiffness [78], although the possibility of confounding cannot be entirely excluded.

Wearable BP measurement devices offer the possibility of BP measurement under various conditions, such as acute stress. In addition, these devices could include additional sensors to measure parameters such as barometric pressure and ambient temperature, and/or an accelerometer to determine movement and activity. There may also be a role for multisensory BP monitoring devices to detect BP responses in a variety of specific conditions such as heart failure [79], mountaineering and high altitudes [80], and psychological stress [81], and therefore help to inform the management of hypertension and other clinical problems. The potential of these cuffless technologies is clearly exciting but we are still in the foothills of knowledge about their clinical utility and incremental predictive value in risk assessment, over and above conventional BP measurement.

Automatic (timed) HBPM is the only emerging technique that has been investigated in large cross-sectional and longitudinal clinical studies [82]. There is quite strong evidence that at least six nocturnal BP measurements from a dedicated home BP monitor are associated with the risk of preclinical organ damage and cardiovascular events to at least a similar extent to ambulatory BP measurements, and independent of clinic BP and morning and evening home BP [83–92]. In the Japanese study that included the largest number of participants ($n = 2545$) studied to date, nighttime home BP was measured at 2 a.m., 3 a.m. and 4 a.m. for 14 consecutive days using a validated, automatic oscillometric home BP device [86]. Mean ± standard deviation values for clinic, morning home, and nighttime home systolic/diastolic BP were $140 \pm 15/82 \pm 10$ mmHg, $137 \pm 15/79 \pm 10$ mmHg, and $121 \pm 15/70 \pm 9$ mmHg, respectively. During a mean follow-up of 7.1 ± 3.8 years (18 116 person-years), a 10-mmHg increase in nighttime home systolic BP was associated with a significantly higher risk of cardiovascular events after adjustment for covariates including clinic and morning home systolic BP [hazard ratio (HR) 1.20, 95% confidence interval (CI) 1.05–1.38]. An additional analysis of data from this study [90] showed that nocturnal hypertension detected using HBPM (defined as a nighttime home systolic/diastolic BP of ≥120/70 mmHg and an average morning and evening home systolic/diastolic BP of <135/85 mmHg) was associated with a significantly higher risk of cardiovascular events (HR 1.57, 95% CI 1.00–2.46). In an analysis of participants who had both home and ambulatory BP monitoring data, nocturnal hypertension detected using HBPM (but not ABPM) was associated with a significantly increased risk of coronary artery disease events (HR 1.78, 95% CI 1.00–3.15) and stroke (HR 2.65, 95% CI 1.14–6.20), independent of clinic systolic BP [90].

Key points

- Emerging BP measurement technologies have the potential to provide additive value for risk assessment and therapeutic monitoring.
- A contributor to this might be their potential to obtain and integrate data from several biological markers in addition to BP. (e.g. heart rate, oxygen saturation, cardiac output, body temperature).
- Wearable BP measurement devices provide the ability to obtain BP measurements under a variety of real-life conditions.
- Knowledge about the clinical utility and incremental risk prediction value of cuffless BP measurement devices is in its infancy.

CHALLENGES AND THE ROLE OF FUTURE TECHNOLOGIES

Current clinical challenges in BP measurement

BP measurement devices need to be clinically validated before their clinical use and once validated, periodic calibrations are needed to ensure that the cuff pressure continues to reflect exactly what the device is estimating as the BP. There are additional limitations to the auscultatory method, including improper placement of the stethoscope, digit preference, inappropriately fast cuff deflation rate, and observer prejudice, bias and hearing deficits [93,94]. Inappropriate cuff size also has an important impact on the accuracy of BP measurements; a cuff size that is too small for the patient's arm circumference (i.e. "under-cuffing") leads to systolic BP values that are up to approximately 20 mmHg higher than they should be [94,95]. When using oscillometric-based BP measurement devices, the amplitude of the oscillations is generally weak, indicating that things like clothing, breathing, speech, or body movement can easily affect measurement accuracy. Also, oscillations are irregular when the heart is not in sinus rhythm and therefore oscillometric-based BP measurements could be inaccurate. For example, in individuals who have atrial fibrillation and a high ventricular rate, BP values can be underestimated by up to 5 mmHg [96]. In addition, the algorithms used in oscillometric measurement devices are not adequately validated for these patients, and an agreed validation standard for this condition is lacking.

Although out-of-office BP monitoring with oscillometric-based devices is recommended to rule out phenomena such as white-coat hypertension or masked hypertension, and to monitor therapy initiation or intensification [3], current BP measurement devices only provide intermittent data on BP, which may contribute to incorrect classification or conclusions about the BP level.

Potential benefits of new BP measurement devices

Innovative new BP measurement devices have the potential to overcome the limitations of existing cuff-based methods, allowing continuous BP monitoring, facilitating better phenotyping of BP, and contributing to better understanding of the pathophysiology and management of hypertension and the mechanisms by which hypertension contributes to cardiovascular risk.

Specifically, wearable cuff-based or cuffless devices could allow more accurate BP measurement in special populations, such as those with large upper arms, atrial fibrillation, or extremely high or low BP values. The use of wearable devices could also make it easier to accurately detect white-coat hypertension or masked hypertension by providing a greater number of readings (or even continuous readings) that do not have be triggered by the individual [97].

Better phenotyping of nocturnal BP based on readings from new-generation cuffed or cuffless devices may be possible through the use of triggered monitoring, whereby the device records various physiological signals and then triggers a measurement of BP when certain clinical criteria are met (e.g. hypoxia or activity).

The ability to take a much greater number of measurements with intermittent or continuous cuffless BP monitoring without any user awareness compared with cuff-based measurements should allow better characterization of time at target [59], provide more comprehensive information that can be used to inform best practice management of hypertension, and deliver unprecedented insights into cardiovascular physiology and disease mechanisms [18].

Challenges for new BP measurement devices

Monitoring of BP over time has shown that BP measurements are not strictly reproducible when using any of the available technologies, not least because BP itself (as a physiologic characteristic of pulse wave amplitude) is a highly variable parameter. Thus, new technologies should not necessarily be expected to offer more "reproducible" BP data. Instead, they might provide more information on patterns of BP variability under different conditions. However, this creates a challenge regarding the clinical interpretation of the data provided by new technologies.

Current evidence gaps relating to new BP monitoring devices, and the challenges that remain to be addressed are detailed in Table 4. Evidence gaps include the lack of data relating to the role, efficacy, and effectiveness of these new devices in clinical practice, including the association of BP values obtained using novel BP measurement devices with cardiovascular disease and other clinical outcomes. Clinical interpretation of BP values obtained during a variety of daily activities is another important issue to address in a clinical setting. When making clinical decisions, healthcare workers are now required to rely on BP values obtained through carefully standardized BP measurements, according to the indications specified in available guidelines. Under such conditions, based on previous outcome or correlation data, BP values can be classified as "normal" or "elevated". At present there is no evidence to properly classify the BP values obtained through wearable devices in the highly dynamic conditions of daily life as "normal" or "elevated". Under such conditions, individual reactivity patterns, based on person-specific cardiovascular control mechanisms, may lead to different BP responses to the same daily life challenges in different individuals. There is also a lack of validation data for the use of new devices in diverse patient populations based on age, ethnicity and clinical characteristics. Such data are essential to allow widespread and equitable implementation of novel BP monitoring technologies in clinical practice. Technical issues include the need for repeated calibration, proprietary barriers, and limited storage capacity for BP readings and other data. Human factors relate to the level of training provided to allow users to obtain accurate BP readings, alert fatigue, the number of false positives or false alerts leading to unwarranted patient-clinician contacts, increased patient anxiety related to the availability of many more BP readings (potentially also increasing the number of patient-clinician contacts), a lack of trust in the new devices, and misplaced trust in unvalidated devices. System factors include complex regulatory approval and reimbursement processes, and lack of linkage and integration with electronic health records. Before these new devices can be included into clinical guidelines there also needs to be randomized trial evidence for their effectiveness, usefulness and acceptability to patients and healthcare providers. One such study, the NEXTGEN-BP trial is currently underway, and will provide evidence for the effectiveness and safety of a hypertension management strategy based on wearable cuffless BP monitoring [98]. Finally, a major organizational challenge is that hypertension guidelines, BP validation experts, regulatory bodies, clinicians, and providers must be aligned for these devices to be successfully implemented for hypertension diagnosis and management.

Key points

- Innovative new BP measurement devices have the potential to overcome the limitations of existing cuff-based methods, including more accurate BP measurement in special populations.
- The use of intermittent or continuous cuffless BP monitoring could provide additional information that can help to improve hypertension phenotyping and management, and deliver insights into cardiovascular pathophysiology.
- There are numerous evidence gaps relating to new BP monitoring devices, and multiple challenges that remain to be addressed.
- Before new devices can be included into clinical guidelines there needs to be randomized controlled trial evidence supporting their effectiveness, usefulness and acceptability to patients and healthcare providers.

DIGITAL INTERVENTIONS

Digital interventions are typically web-based or based on mobile apps that combine health information with tele-monitoring and decision support to create behavior change

TABLE 4. Challenges for novel blood pressure measuring devices

Area	Challenges
Evidence gaps	- Lack of or limited data to inform clinical decisions - Lack of or limited data on prevention and detection of high BP - Lack of or limited data on improvement of BP in adults with high BP who are taking antihypertensive medication - Lack of validation data for older individuals, non-White racial and ethnic groups (who may have darker skin tones), and special populations (obese, pregnancy, etc.) - Lack of data on reproducibility/reliability of BP data - Lack of data on tolerability of devices for out-of-office BP measurement - Lack of data on patient adherence to the use of new devices for out-of-office BP measurement - Lack of data linking BP determined using new devices and cardiovascular outcomes, and whether reducing BP determined using new devices is associated with a reduction in cardiovascular risk - Lack of data on the BP thresholds used to define ''high BP'' based on readings from the new devices. - Although the new devices might help to identify and define new BP phenotypes, the clinical significance of these phenotypes remains to be determined
Technical issues	- Need for novel validation procedures specifically designed for such devices and tailored to device type (this is more demanding than for cuff BP devices) - Need for repeated calibration of new cuffless monitoring devices - The use of proprietary technologies (it is not clear whether BP recorded with different devices is similar); this is most relevant for cuffless BP measurement devices. - ''Black box'' methods may be more difficult to understand than oscillometric methods (e.g. machine learning/deep learning/neural networks) - The need for devices to have enough storage for recording measurements or transmitting data to apps - The need for apps with system alarms that do not over-alert the patient and/or healthcare team
Human factors	- Risk of out-of-office BP monitoring information overload for clinicians - Increased patient anxiety because of repeated out-of-office BP measurements (some of which may be high or very high) resulting in patients contacting clinicians more often - Lack of patient and clinician trust of using new monitoring devices
System factors	- Regulatory approval process is complex - Reimbursement for using new monitoring devices is unclear - Lack of Electronic Health Record linkage and incomplete feedback loop back to the clinical team for decision making

BP, blood pressure.

in people with hypertension and/or other conditions [99]. The ISH recognizes the potential benefits of digital solutions to facilitate the required adherence to treatment and lifestyle changes [100]. The use of digital interventions represents an interesting perspective to improve hypertension care, in combination with BP measurement technology, both conventional and novel, often utilizing wireless connection and mobile phone connectivity [101] (Fig. 2).

Effectiveness
Emerging evidence supports the role of digital interventions in managing uncontrolled hypertension. Systematic reviews and meta-analyses published in 2023 and 2024 reported that digital interventions were effective in reducing systolic and diastolic BP, promoting lifestyle changes, and improving medication adherence compared with standard care, irrespective of the mode of delivery [102–105]. Most of the studies included in these analyses used conventional BP measurement, but digital interventions are ideally suited to linking with novel BP measurement technologies, including cuffless measurement, when validated. In addition, tailored digital initiatives could help to mitigate disparities in hypertension outcomes [103]. Nevertheless, the robustness of the conclusions from the systematic reviews and meta-analyses may be limited due to the heterogeneity, quality, and small sample size of the included studies [102–105]. Future research should consider digital intervention mediators and moderators to refine effectiveness and implementation strategies.

Care delivery
Globally, smartphone applications, including m-health applications, are becoming increasingly popular. In resource-limited settings, m-health technology may be an unexplored opportunity to address health equity

challenges that limit the ability to deliver and achieve optimal and universal health coverage [106]. A recent systematic review included studies from thirteen regions and found similar evidence of the effectiveness of digital interventions regardless of country income level [104]. However, power was limited in some subgroups [104]. Apps may optimize clinician care and reduce workload burden, improve hypertension self-management and medication adherence, and offer continuous patient support, resulting in cost-effective healthcare. This is especially useful in individuals with difficult-to-treat hypertension, high-risk patients in whom tight control is vital, and/or those with poor medication adherence [101]. The global relevance of these new approaches is due to evidence showing that these challenges are more often encountered in low- and middle-income countries. Other important factors to consider are disparities and limitations in the ability to participate in digital interventions. These include cultural, age-related and education-related factors, the availability and reliability of access to electricity, the internet and mobile phone or computer hardware, digital knowledge/capability, health infrastructure, and reimbursement paradigms. These issues will vary between countries, within countries/regions, and even between individuals in the same region.

Care enhancement
Hypertension digital interventions that incorporate multiple BP readings or continuous BP readings from wearable devices, with data delivered to interdisciplinary health care teams, have the potential to advance precision hypertension care [12]. The large volumes of data generated in these settings can be integrated with emerging multi-omics data on hypertension [107] using AI to better predict hypertension onset [108], and diagnose and identify optimal
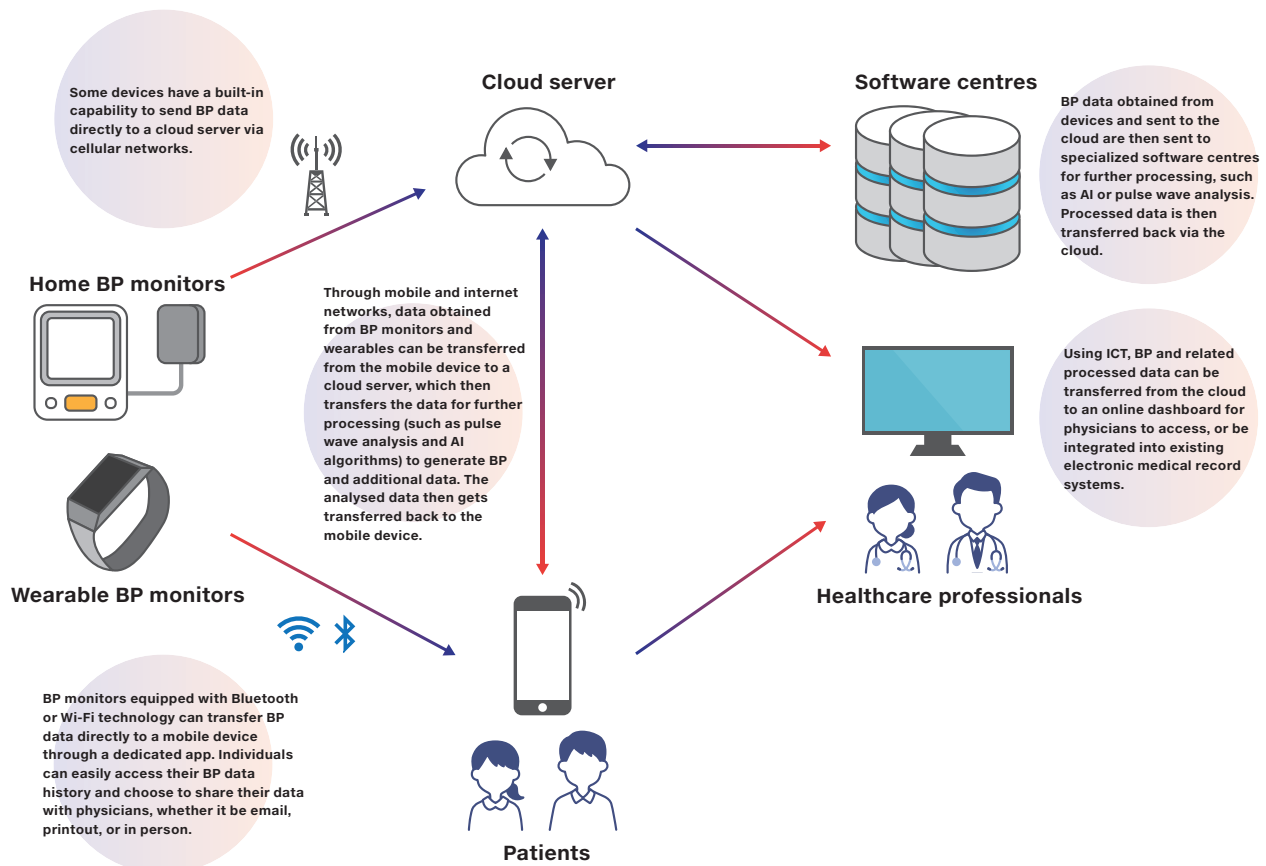
FIGURE 2 Digital interventions and technology in hypertension. AI, artificial intelligence; BP, blood pressure; ICT, information and communication technology.

hypertension treatment pathways [109]. In a US study published in 2023, machine learning algorithms identified antihypertensive treatment options that were associated with a 70% greater reduction in systolic BP compared with standard-of-care prescribing [110].

Although these data are in their infancy, enhanced remote BP monitoring paired with advanced artificial intelligence (AI) methods may assist primary care providers in understanding complex patterns in large volumes of BP data, which could facilitate superior risk prediction, resource targeting and personalized pharmacotherapy options [111]. Beyond BP values alone, wearables can also provide data on other relevant metrics such as arterial stiffness via the measurement of arterial waveforms and signal processing of these waveforms using pulse wave analysis and AI. Cloud computing enables the large volumes of data obtained from wearables to be transferred and stored for the complex processing required for these analyses without sacrificing device size or battery power [112].

Overall, digital interventions for hypertension are a promising but still evolving component of disease management and patient care. They offer the possibility of enhanced precision and high-quality care in a wide variety of settings while increasing patient involvement. Innovative technologies, including AI, have a great deal of promise but the emerging regulatory framework governing these tools requires a novel and collaborative approach and is likely to be complex. Therefore, it remains to be seen whether this will translate into real benefits for hypertension care worldwide.

Key points

- Emerging evidence supports the role of digital interventions in managing hypertension.
- Novel BP measurement devices and technologies are ideally suited for integration with digital interventions for hypertension.
- Digital tools have the potential to improve hypertension management in resource-limited settings.
- Although digital interventions could help to reduce health disparities in hypertension, several factors could limit equitable access to digital tools, including access to hardware, the internet or reliable electricity, digital literacy, health infrastructure, and reimbursement.
- The application of machine learning and artificial intelligence tools to analyze the large volumes of data generated by new devices and digital approaches could facilitate the identification of optimal treatment pathways and medication regimens for individual patients.

PERSPECTIVES & CONCLUSIONS

Developments in technology have allowed significant improvements in BP monitoring over the last century. Recent advances in ICT have made it easier to access health data, including BP measurements, for both individuals and physicians alike. Many affordable HBPM devices are now fitted with Bluetooth or Wi-Fi technology, allowing users to seamlessly transfer BP data from the monitor to their mobile device via a dedicated app. This allows individuals and care

providers to easily track their BP changes over time and can increase engagement, contributing to better medication adherence and greater reductions in BP [113]. Beyond the development of innovative devices and mobile apps, internet and cloud computing enables the streamlining of out-of-office BP measurements to physicians via online dashboards [114] or integration with existing electronic health record systems [115], potentially increasing physician engagement with hypertension management and making BP control more efficient [116,117].

To effectively predict and mitigate cardiovascular risk, the ideal situation would be to have continuous 24-hour BP monitoring every day throughout an individual's lifetime. While technological advances mean that this may be within reach, we are not there yet and a number of challenges remain to be overcome before novel BP measurement technologies are suitable for widespread and equitable implementation. These include sensor accuracy, the robustness of ICT systems, data privacy and protection, digital capability of users, the need for data in a range of ethnic groups and regions, and widespread access to technology and internet connectivity. In addition, current devices are in the relatively early stages of development and require proper validation using standardized protocols specifically developed for such devices to ensure that BP measurements are accurate [15,35]. Studies are also needed to evaluate the prognostic significance of BP measurements obtained using novel technologies. Despite these challenges, novel BP measurement technologies have the potential to play an important role in future hypertension diagnosis and management strategies.

For new BP measurement technologies to fulfill that promise of providing user-friendly, reliable and high-frequency BP data that can be used to help eliminate hypertension-related cardiovascular disease and end-organ damage, researchers and commercial providers need to work together to develop and objectively validate these devices, and to determine their contribution to, and place in, personalized hypertension care pathways.

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Conflicts of interest

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