Perspective

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# How a cloud based platform can make ambulatory blood pressure monitoring more efficient, accessible, and evidence based

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# Abstract

Ambulatory blood pressure measurement (ABPM) is the gold-standard method for blood pressure assessment. However, it is markedly underutilized, in part because legacy software provided with ABPM devices is archaic and inefficient. Herein, we illustrate an example of a recently developed cloud-based ABPM platform. Such a platform offers several distinct advantages: (1) the ability to guide users through the testing process; (2) synchronizing inputs of the technician, patient, physician, and administrative assistant so that testing can be successful and efficient; (3) providing guideline-concordant study interpretations that can be e-signed, reducing physician interpretation times; (4) enabling central expert oversight and peripheral deployment of testing, thereby increasing accessibility of quality testing; and (5) facilitating integration into electronic medical records, improving dissemination of results. It is envisioned that increased use of cloud-based ABPM platforms will lead to the expansion of quality ABPM testing, thus improving the care of patients with known or suspected hypertension.

Keywords: Hypertension, diagnosis, ambulatory blood pressure monitoring, digital health, cloud-based software

# INTRODUCTION

High blood pressure (BP) or hypertension is the leading cause of death and disability globally, affecting one-



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third of or nearly 1.3 billion individuals globally, and accounting for 8.5 million deaths annually<sup>[1]</sup>. Ambulatory blood pressure measurement (ABPM) is endorsed strongly by clinical practice guideline committees worldwide as the best method to assess BP yet is likely the most underutilized gold standard test in medicine<sup>[2-5]</sup>. Major indications for ABPM include confirming an initial diagnosis of hypertension; assessing for resistant, white coat, and masked hypertension; measuring BP lability in patients with known or suspected autonomic dysfunction; and evaluating of the duration of action of antihypertensive drugs<sup>[6]</sup>.

#### Indications for ABPM use

ABPM testing is valuable for two major reasons. First, it confers superior BP assessment and prognostication because ABPM provides an assessment of the entire 24 h BP profile, including nighttime BP, which is important because nocturnal BP is the single best predictor of subsequent cardiovascular events<sup>[7,8]</sup>. It should also be noted that some published trial data also support the premise that bedtime dosing of antihypertensive drugs to lower sleep-time BP reduces subsequent cardiovascular events, but these findings have generated debate, and the outcome of confirmatory trials before implementing bedtime chronotherapy is awaited by most experts<sup>[9,10]</sup>. Second, ABPM is useful in phenotyping patients, because it is the gold standard method for evaluating for white coat hypertension, white coat effect, masked hypertension, and masked effect<sup>[11-13]</sup>. White coat hypertension in untreated patients, or white coat effect in treated patients, is present when clinic BP is elevated, and ABPM is normal. It has a prognosis similar, perhaps slightly worse, than true normotension, and current recommendations are that drug therapy not be initiated or up-titrated<sup>[2-5]</sup>. Conversely, masked hypertension (untreated patients) or masked effect (treated patients) occurs when clinic BP is normal, and ABPM is elevated<sup>[14]</sup>. The presence of this phenotype portends increased cardiovascular risk, similar to uncontrolled hypertension, and the current consensus is that treatment should be initiated or up-titrated<sup>[2-5]</sup>.

The superior performance of ABPM is a function of collecting multiple measurements throughout the 24 h period. BP is a highly dynamic variable, constantly changing in response to numerous exogenous and endogenous stimuli. Accordingly, office BP, which provides only a snapshot of the BP level at one time and in an environment that may promote an alerting response, cannot possibly be expected to provide information as valuable as ABPM and reflective of the true underlying BP. Prior studies using office BP have demonstrated that it is only through serial measurements over a span of 4-5 visits that a stable BP is achieved<sup>[15]</sup>. Waiting this long to decide on the direction of therapy is clearly not practical enough to be implemented in routine clinical care delivery workflows, which results in the unfortunately common practice of usually using a single office reading from a single visit to make a diagnosis of hypertension or titrate drug therapy.

# Barriers and disincentives to the use of ABPM

Despite the advantages of ABPM, clear shortcomings exist that pose challenges to its adoption in routine clinical care. In the United States (US), depending on the population being studied, whether publicly insured Medicare beneficiaries or commercially insured members, use of ABPM is woefully low, at 0.1%-0.3% of eligible patients<sup>[16,17]</sup>. These may vary across jurisdictions, but typically include the following:

1. Relatively high cost of ABPM devices: The typical cost for a single, clinically validated ABPM unit is between \$2000-3000 USD<sup>[18]</sup>. Clinics wishing to invest in multiple units to start a program thus face significant initial costs.

2. Cumbersome-to-use legacy software: The free software included with ABPM devices is serviceable, but not terribly efficient:

(1) These software programs were initially developed 2-3 decades ago and are CD-ROM-based, which require installation on the hard drive of a computer, which, relative to a cloud-based approach, limits the degree to which testing can be scaled and made accessible. Installation is often performed on computers located in the office of the provider responsible for performing testing (technician or nurse). Once installed, the technician/nurse is often required to initialize the test on this dedicated computer, take the device to the clinic room and apply the device to the patient. Furthermore, once the study is completed, finalized, and sent to the interpreting physician, if subsequent changes are required (such as deletion of a BP measurement felt to be an outlier, or correction of erroneously entered sleep/wake times), the technician/nurse must return to that computer, regenerate the study, and resend it to the interpreting physician. Even the act of sending studies to the interpreting physician is inefficient because the physician may not be physically present in the clinic when the study is generated. Consequently, scanning/uploading to the electronic medical record (EMR) or faxing to the physician is required. Once interpretation is performed, the study must be reuploaded to the EMR and/or faxed to the referring physician.

(2) Connections between the ABPM device and the computer are USB-based, which requires extra steps compared to Bluetooth connectivity, reducing test efficiency. In addition, existing platforms may use infrared port connections, which can make initialization and download processes less user-friendly because of the need to use specific purpose-built cables and connectors and/or because they may cause unstable alignment and lead to signal transmission difficulties.

(3) Software updates and enhancements are done infrequently because they require new CD-ROM versions to be manufactured.

(4) Some companies, such as Spacelabs Healthcare, offer enterprise installation for larger health institutions or systems; however, this requires dedicated IT time and increases expenses (by \$3500-4000 USD for two network licenses)<sup>[18]</sup>.

3. Lack of provider reimbursement for performing ABPM testing: ABPM testing is not optimally reimbursed in Canada and the US, the two markets with which we are familiar. In Canada, reimbursement for medical services is set at the provincial or territorial level. ABPM is reimbursed in Alberta, Saskatchewan, and Quebec, but not in the other seven provinces or three territories. Publicly performed test reimbursements are low relative to other medical tests that require similar amounts of time, ranging from approximately \$27 to \$80 Canadian. In other provinces, such as British Columbia and Ontario, patients are direct billed for the costs of ABPM testing, with fees ranging from approximately \$40 to \$120 CDN.

In the US, ABPM testing is reimbursed by Medicare, a national health insurance program covering approximately 55 million Americans. In an analysis of 1970 Medicare beneficiaries, for whom white coat hypertension was the chief indication for reimbursement, the median reimbursement rate was \$52 USD (range \$33-65)<sup>[19]</sup>. To qualify, documentation of masked or white coat hypertension using office and home BP measurements is required, and these additional bureaucratic requirements likely further constrain use. Median reimbursement rates are higher in the US commercially insured sector, at \$89 USD per test (interquartile range \$62-132)<sup>[20]</sup>.

4. Lack of provider expertise in ABPM: In our experience, expertise amongst physicians and trainees on how to perform and interpret ABPM tests is low. We feel that this limits ABPM uptake, because physicians, through lack of training or experience, do not feel confident in their ability to oversee an ABPM program. In addition, there is a lack of knowledge of the evidence base underpinning use of ABPM and the wellestablished benefits of performing the test<sup>[21]</sup>.

# ABPM workflow and overcoming challenges to optimal ABPM use

The aforementioned challenges and barriers to performing ABPM testing, despite its central importance to the diagnosis and management of hypertension, illustrate the need for innovation. To understand how best to improve the delivery of ABPM, one must first appreciate the four individuals who contribute to an optimal testing workflow:

1. Technician: This is the primary individual - typically a nurse, Holter technician, or pharmacist - responsible for performing ABPM testing. Tasks include rooming the patient, initializing and configuring the ABPM unit and software, applying the cuff and device to the patient, delivering patient education and instruction, recovering the device, and downloading the results and sending them to the interpreting physician.

2. Patient: The patient is required to comply with testing, adhere to instructions, and keep a diary of events, including meals, daytime/nighttime periods, and activities. Although self-report of daytime/nighttime (awake/asleep) periods do not differ from using pre-set fixed times in terms of cardiovascular risk prediction, they do more accurately reflect the actual sleep-wake times (using actigraphy as the reference standard) and are therefore preferred<sup>[22,23]</sup>. Therefore, by using a patient app, the patient is able to enter the actual sleep-wake times that occurred during the study period. In cases where the patient cannot use the app, the technician is able to define patient sleep-wake times based on patient self-report prior to finalizing the study. Widely accepted BP thresholds for normal are overall 24 h means of < 130/80 mmHg, daytime means of < 135/85 mmHg, and nighttime means of < 120/70 mmHg<sup>[24]</sup>. These are the default software settings, but can be customized if alternative thresholds are desired.

3. Physician: The physician is responsible for test interpretation. They may also be tasked with overseeing the ABPM program, ensuring that testing is performed in accordance with recommended clinical practice<sup>[24]</sup>. This includes ensuring that only clinically validated ABPM devices are procured. Clinically validated devices are ones that have been tested for accuracy using an internationally accepted validation standard, such as the standard developed by the International Organization for Standardization committee<sup>[25]</sup>.

4. Administrative assistant: This individual ensures that the test is sent to the physician for interpretation, and the fully interpreted test is sent to the referring physician. Often, this involves downloading/uploading reports in the EMR and/or faxing. In some programs, the nurse/technician assumes responsibility for these administrative tasks.

In our experience, being in the position of viewing ABPM tests performed in programs that do not appear to have any expert physician oversight, ABPM test delivery is often not optimally performed according to the workflow outlined above. We have seen ABPM studies that use the incorrect thresholds to determine normal/elevated BP levels, lack a patient diary (therefore, do not correctly identify true sleep/wake times), and, most commonly, do not include any expert-signed interpretive report. Lack of expert interpretation is particularly troublesome when these studies are given to patients. They, in turn, expect their primary care provider, who may have no expertise in ABPM, to interpret and act on the results.

# DEVELOPMENT OF A CLOUD-BASED ABPM PLATFORM TO AUTOMATE, PROTOCOLIZE, AND OPTIMIZE TEST DELIVERY

Optimization of the integrity and efficiency of ABPM testing can be accomplished by using a cloud-based platform that is designed to support even novice users to implement guideline-concordant test procedures. The chief advantages of such a platform are:

1. The ability to automate or protocolize test procedures, reducing overall testing time, and reducing the need for specialized expertise at the site of deployment; and

2. The capability to centralize oversight of an ABPM program, presumably in the hands of an ABPM expert, while simultaneously deploying testing at an essentially unlimited number of peripheral sites, that can be geographically dispersed. This enables the implementation of test delivery in sites closer to and more accessible by patients, such as in rural and remote jurisdictions, increasing the availability of this gold-standard and under-utilized test. We note that it is not necessary to have a centralized set-up, as a single peripheral site can use the solution as a stand-alone platform, including the use of the study auto-interpretation feature.

The Heart Track ABPM software platform (mmHg Inc., Edmonton, Canada), developed in collaboration with A&D Company, contains multiple features designed to overcome existing challenges to optimal ABPM use<sup>[26,27]</sup>.

1. Cloud-based, tablet-enabled deployment: Instead of requiring a CD-ROM-based install using a USB cord, the software is downloaded from the Apple App Store or Google Play Console through a wireless connection and is operated on a tablet (or smartphone). This allows ABPM technicians to bring the software (tablet) to the bedside and quickly initialize and configure the test for a new patient. The four-step study initialization process is designed to maximize efficiency, combining a simple user interface with drop-down menus and the ability to save default settings, to minimize the time required to initiate a new study [Figure 1]. When the test is finished, and the patient returns to the clinic to return the device, the study is automatically uploaded wirelessly into the cloud and is ready for physician interpretation.

2. Guideline-concordant, efficient care delivery:

(1) Patient instructions: These are delivered via a simple tutorial using pictograms that is accessible to patients via a freely downloadable smartphone app [Figure 2]. Delivering ABPM test instructions in this manner eliminates the need for the technician to spend time on this repetitive task. The same app is used by the patient to enter sleep/wake times and diary events through a simple digital entry process [Figure 3]. These entries synchronize automatically in the cloud, are viewable by the interpreting physician, and are used to auto-define the daytime/nighttime periods used during study interpretation. As ABPM testing for the purposes of making an initial diagnosis of hypertension tends to be done in young to middle-aged individuals, the use of a smartphone app is not a barrier to testing, although it is acknowledged that some elderly individuals may find apps use challenging. In cases where a smartphone is not usable or available, the use of a paper diary and subsequent entry of this information (including sleep/wake times) into the platform (as is done when using legacy software systems) is required to be performed by the technician.

(2) ABPM study interpretation and guideline-reporting: This process is streamlined by sending the interpreting physician an email link that leads to the secure interpretation portal. After signing in with a registered username and password, the study can be viewed by the interpreting physician. The information

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Figure 2. Test instructions delivered using smartphone application.

presented includes patient demographics, details of the ordering and interpreting physicians and site of testing, medication history, mean BP levels color-coded according to whether results are above or below threshold, and a graphical, interactive display of ABPM readings containing embedded patient-entered diary events [Figure 4]. A study .pdf file can be generated that also includes details of individual readings and failed readings. A hypertension expert-developed, guideline-concordant study auto-interpretation is generated for physician review, including assessment of technical adequacy, BP levels, and an overall conclusion [Figure 4]. The physician quickly reviews these results and e-signs the study, which is then routed to their administrative assistant or technician for onwards transference to the referring physician. It should also be noted that the referring physician and interpreting physician can be the same individual.

(3) Electronic medical record integration: This is performed on a site-by-site basis and facilitates e-storage and e-faxing of the study, eliminating the need to generate paper copies and use manual faxing methods.

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Figure 3. Patient diary entry using smartphone application.



Figure 4. Clinician web portal and guideline-concordant study auto-interpretation.

(4) Additional automated innovations to prevent failed studies: In our clinic, the proportion of failed studies is approximately 5%. The ability to push-notify patients via the smartphone app if readings are consistently failing (e.g., because of motion artifact or obstructed tubing) and predict whether or not a study will have an acceptable capture rate is made possible by a cloud-based platform if real-time data transmission is a device feature. Prolonging a study that may otherwise fail to enable the capture of a suitable number of successful readings is a viable alternative to repeating the entire study or trying to make use of a study with a sub-optimal capture rate.

3. Centralized data collection and oversight: Use of cloud-based technology enables all data elements to be collected automatically, including individual BP values and not just the mean BP levels. This creates an efficient and robust mechanism for comprehensive, real-time data collection, useful for reporting, quality improvement, or research purposes. Clinician administrators can view practice level summary metrics, such as the number of devices that are currently deployed and where deployment has occurred if multiple peripheral testing sites have been implemented, average number of devices being used per week or month, percentage of failed studies, and aggregate statistics on their patient panels. The ability to download the study data in an easily processable format (i.e., Excel or .csv) is under development. Merging of existing

ABPM datasets collected using legacy systems into the cloud-based repository is theoretically also possible, but is not a task we have performed to date because it would require that the legacy data be accessible in a data format that facilitates combining datasets.

4. Security: Data security is ensured throughout the ABPM platform via the implementation of end-to-end data encryption and security practices. Standardized encryption algorithms are implemented to ensure that data is secured at rest using Advanced Encryption Standard 256-bit, and during transit using Hypertext Transfer Protocol Secure Transport Layer Security. Data are always stored within the country of origin, hosted on local servers managed by Amazon Web Services (AWS) or a similarly secure entity that follows industry-leading security practices, including compliance with National Institute of Standards and Technology 800-53, Federal Risk and Authorization Management Program and the following Service Organization Control (SOC) reports: AWS SOC 1 Report (SSAE No. 18); AWS SOC 2 Privacy Type I Report; AWS SOC 2 Security, Availability & Confidentiality; AWS SOC 3 Security, Availability & Confidentiality Report.

# CHALLENGES TO DEPLOYMENT OF CLOUD-BASED ABPM

Although cloud-based technologies have many advantages, they also have unique challenges that include:

1. Additional cost: Cloud-based software deployment incurs development and maintenance costs (e.g., security and servers for data storage), which must be factored into the cost of ABPM. We have successfully trialed per-test and subscription pricing to minimize overall cost increases. Pricing must be flexible and set at sustainable levels so as to not deter uptake and depends on the nuances and economics of the local market - for example, if public per-test reimbursement is available, a few percent of the overall fee code can be charged, akin to a credit card transaction fee. In cases where there is limited capacity to pay, bundled pricing with devices should be considered, and in this case, the device company subsidizes the software cost because the overall product is more compelling to users. Alternatively, converting the up-front, one-time cost of a device to a lower annual subscription fee can be considered. In this manner, a higher initial cost is converted to a reduced annual cost, which is more manageable for the customer on a cash-flow basis, and more desirable to the device company because software-as-a-service revenues are assigned higher valuations than one-time device sales.

2. Wireless communication: Must be robust to accommodate slow connection speeds, and safeguards must be implemented to ensure that studies are downloaded in their entirety.

3. Software security: This is of paramount importance to protect patient health data according to PIPEDA requirements in Canada, HIPAA requirements in the US, and similar regulations globally.

4. Adoption of innovative technologies: Health systems have traditionally been slow to adopt innovative technologies because administrators and decision makers may have a conservative mindset and lack familiarity with cloud-based technologies. However, cloud-based technological adoption is increasing and is expected to accelerate in the post-COVID reality.

# CONCLUSIONS

The procedure for performing ABPM, which is likely the most underutilized gold-standard test in medicine, is in dire need of modernization. Legacy software predominates and does not take advantage of modern technological innovations. There is also a need for standardization of ABPM measurement procedures, which includes standardization of how data are shared between referring physicians and sites running

ABPM programs. The need to easily share data in a uniformly accepted format is of particular relevance given how the COVID-19 pandemic resulted in lockdowns and restriction of physical mobility and inperson clinical assessments, underscoring the necessity for robust virtual data sharing systems<sup>[28,29]</sup>.

A cloud-based, tablet-deployed solution has many benefits that enable efficient test delivery in a guidelineconcordant manner. Such a platform can address the requirement that multiple individuals contribute to a successful ABPM test, by protocolizing, automating, and synchronizing multi-user contributions in the cloud and in a manner that increases the efficiency of testing in a manner consistent with best practice. Another major advantage of a cloud-based platform is the ability to centrally oversee and peripherally deploy ABPM. It is hoped that this will increase access and improve the quality of ABPM testing in patients with known or suspected hypertension.

#### DECLARATIONS

#### Authors' contributions

Initial draft of the manuscript: Padwal RS Review and editing of the manuscript as well as preparation of: Ringrose JS, Wood PW

#### Availability of data and materials

Not applicable.

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#### **Conflicts of interest**

Raj S. Padwal, Jennifer Ringrose and Peter Wood are founders of mmHg Inc., a digital health company specializing in medical software development and remote patient monitoring. mmHg is the creator and marketer of the cloud-based ABPM platform currently deployed in various markets and discussed in the present article.

Ethical approval and consent to participate

Not applicable.

### **Consent for publication**

Not applicable.

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