

Research Article

Comparison of an in-pharmacy automated blood pressure kiosk to daytime ambulatory blood pressure in hypertensive subjects

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Abstract

The objective of this study was to compare serial readings from an in-pharmacy automated blood pressure (BP) kiosk to mean daytime ambulatory BP. A total of 100 community-dwelling adults with hypertension underwent (1) three baseline automated office readings; (2) three in-pharmacy readings on each of four visits (12 total) using the PharmaSmart PS-2000 kiosk; and (3) 24-hour ambulatory BP monitoring between in-pharmacy visits two and three. Paired *t*-tests, Bland-Altman plots, and Pearson correlation coefficients were used for analysis. Mean BPs were $137.8 \pm 13.7/81.9 \pm 12.2$ mm Hg for in-pharmacy and $135.5 \pm 11.7/79.7 \pm 10.0$ mm Hg for daytime ambulatory (difference of $2.3 \pm 9.5/2.2 \pm 6.9$ mm Hg [$P \leq .05$]). Bland-Altman plots depicted a high degree of BP variability but did not show clinically important systematic BP differences. With ambulatory BP as the reference standard, in-pharmacy device results were similar to automated office results. The PharmaSmart PS-2000 closely approximated mean daytime ambulatory BP, supporting the use of serial readings from this device in the assessment of BP. *J Am Soc Hypertens* 2014; ■(■):1–7. © 2014 American Society of Hypertension. All rights reserved.

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Introduction

High blood pressure (BP) affects 40% of adults worldwide, 30% of Americans, and 22% of Canadians.^{1,2} Despite being highly treatable, it is the leading cause of death or

disability in the world.^{3,4} Accurate BP measurement is a critically important initial step in ensuring that hypertension is optimally diagnosed and followed.⁵ Because in-office manual BP measurements taken in everyday clinical practice are poorly standardized and consequently,

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inaccurate, use of out-of-office BP measurement has been strongly endorsed by guideline committees.^{6–8}

Ambulatory BP monitoring (ABPM) and home BP are the two most widely used and strongly endorsed out-of-office measurement methods, with ABPM widely regarded as the gold standard.^{6–8} Public use of blood pressure kiosks, a third out-of-office measurement modality, has received considerably less attention. These devices are commonly found in retail pharmacies and worksites in North America and convenient to access. They are used frequently by both patients with a diagnosis of hypertension and by the general public, with an estimated one million measurements performed daily in the United States.⁹ To date, hypertension experts and health care providers have not widely endorsed their use, and they have not been integrated into clinical information systems on a widespread scale.⁹

Concerns have been raised regarding the accuracy of BP measurements from public-use kiosks, and this has likely limited their uptake and integration into clinical practice.^{9,10} One device — the PharmaSmart PS-2000 — has met the Association for the Advancement of Medical Instrumentation (AAMI)/International Organization for Standardization (ISO) clinical validation standards when tested under ideal conditions (ie, with subjects resting undisturbed in a quiet room).^{11,12} The PharmaSmart device is noted for its wide-range cuff, which accommodates approximately 97% of US adults — a documented improvement over existing kiosk cuffs with a limited arm circumference range.⁹ The device also affords patients the option to record serial readings electronically using a personal “Smart Card.”

To our knowledge, no study has compared serial readings from the PharmaSmart device (or any other automated in-pharmacy kiosk device) with ABPM. Thus, the objective of this study was to compare in-pharmacy PharmaSmart PS-2000 kiosk readings to daytime ambulatory BP in a real-world setting. Our primary hypothesis was that this device would produce a mean systolic BP within 5 mm Hg and a mean diastolic BP within 2.5 mm Hg of corresponding mean daytime ambulatory BP.

Methods

Subjects

Community dwelling adults aged ≥ 18 years with a history of treated or untreated hypertension were enrolled. Subjects were recruited using newspaper advertisements and in-store advertisements at Rexall pharmacies and from the Hypertension Clinic at the University of Alberta in Edmonton, Canada. Severe hypertension (systolic BP [SBP] > 180 mm Hg or diastolic BP [DBP] > 110 mm Hg), pregnancy, inability to understand or comply with study procedures, and non-sinus rhythm were exclusion criteria. The University of Alberta Research Ethics Board

approved the study protocol. Written informed consent was obtained from each subject.

Baseline Data Collection

Baseline data were collected in the Alberta Diabetes Institute Clinical Trials Unit and included socio-demographics (age, gender, ethnicity) and self-reported medical history. Medication use was self-reported and, if necessary, corroborated by electronic pharmacy records. Subjects were instructed not to change medications or doses during the study period.

Weight was measured to the nearest 0.1 kg using a calibrated scale (Pelstar, McCook, IL), and height was measured to the nearest 0.1 cm. An electrocardiogram was performed to verify the presence of normal sinus rhythm. Mid-arm circumference was measured to determine proper cuff size. Baseline office BP and heart rate were measured according to recommended guidelines using a Microlife WatchBP Office (Widnau, Switzerland) automated oscillometric device using the appropriate size cuff.⁶ This device has met international validation standards and closely approximates mean daytime ambulatory BP.^{13,14} Three readings spaced 1 minute apart were taken simultaneously in both arms with the subject seated alone in a quiet room and after 5 minutes of rest. Only left arm readings are reported in this study because they correspond to the readings taken from the in-pharmacy device.

After baseline data collection, each subject was instructed in the use of the PharmaSmart PS-2000 kiosk, using a demonstration model located in the Clinical Trials Unit. The kiosk contains a patented, non-detachable BP cuff that comfortably accommodates arm circumferences of 20–43 cm. The cuff is oriented such that readings must be taken from the left arm. The kiosk is designed such that the patient's feet are supported. The PharmaSmart PS-2000 does not have a back support, and all PS-2000 readings were taken without back support. Following this brief training session, each subject received an encrypted PharmaSmart Smart Card containing a unique identifier recorded in the subject file. Patients were instructed not to talk during in-pharmacy BP measurements and to take three readings approximately 1 minute apart, with the initial reading performed after 5 minutes of rest.

In-pharmacy Visits

Subjects visited their local Rexall pharmacy four times within a 2-week period. After inserting their PharmaSmart smart card into the kiosk, BP was measured from their left arm according to recommended procedures. Three readings were performed per visit, for a total of 12 readings overall. Readings were automatically and securely transmitted electronically to a secure PharmaSmart server, and these were

sent back to the study coordinator in an encrypted, password-protected format. As a secondary data check, subjects were instructed to print out a hard copy of their in-pharmacy measurements using the PharmaSmart kiosk printer and return these to the study coordinator.

24-hour ABPM Studies

Between pharmacy visits two and three (ie, after six in-pharmacy readings), subjects underwent 24-hour ABPM recording using a Space Labs 90207 or 90217A monitor (Snoqualmie, WA), with the cuff placed on the left arm. BP measurements were taken every 20 minutes between 7:00 am and 10:00 pm and every 30 minutes from 10:00 pm to 7:00 am. Subjects received instructions on ABPM measurement, were given a diary to record sleep and wake times, and were instructed not to exercise during the monitoring period. Daytime and night-time periods were defined according to self-reported sleep and wake times. A minimum threshold of 75% successful daytime readings was required for a valid 24-hour study.

Outcomes

The primary outcome was the difference between the mean 12-reading in-pharmacy SBP and the mean daytime ambulatory SBP. The corresponding difference in mean DBP was the major secondary outcome. The mean automated office readings obtained at baseline were compared with the mean daytime ambulatory BP readings to provide a parallel device-to-reference standard comparison. In secondary analyses, mean daytime ambulatory SBP and DBP values were compared with the corresponding means of the first three, first six, and first nine in-pharmacy readings.

Statistical Analysis

Descriptive analyses were first performed, including calculation of means, medians, and proportions. For the primary analysis, paired *t*-tests were used to compare mean BP readings between devices. Subsequently, Pearson correlation coefficients comparing (1) mean in-pharmacy and daytime ambulatory BP readings and (2) mean baseline automated office and daytime ambulatory BP readings were calculated. Bland-Altman plots comparing the difference between 12-reading in-pharmacy and daytime ambulatory BP readings across the range of mean SBP and DBP values were generated.¹⁵ The sensitivity and specificity of the in-pharmacy and automated office measurements to detect uncontrolled BP (defined as a daytime ambulatory BP $\geq 135/85$ mm Hg) was determined.

P-values < 0.05 were considered statistically significant. Adjustment for multiple comparison testing was not performed.

Sample Size Calculation

The sample size calculation was based upon unpublished pilot data (Luc Trudeau, MD) from 11 subjects recruited from the Jewish General Hospital in Montreal, Canada. Assuming an alpha of 0.05, a beta of 0.05 (95% power), to detect a 5 mm Hg minimum difference in mean SBP between the in-pharmacy device (mean of 12 readings) and daytime ambulatory BP given a 13.3 mm Hg within-pair standard deviation (SD) of this difference, we calculated that 94 subjects were required.¹⁶ We enrolled 100 subjects to account for inaccuracy in this estimate. For DBP, 100 subjects provided 92% power to detect a 2.5 mm Hg mean difference between the in-pharmacy device and daytime ambulatory BP, assuming a within-pair difference SD of 7.3.

Results

Exclusions and Baseline Characteristics

Of the 111 subjects who attended a screening visit, nine dropped out prior to completing the study, and two were excluded because they required antihypertensive drug adjustments in the middle of the study.

In the 100 subjects completing the study, mean age was 59.7 ± 12.8 and mean body mass index (BMI) was 30.5 ± 7.5 kg/m². Fifty-three percent were female, 41% had a history of type 2 diabetes, and 6% had prior cerebrovascular disease. Mean arm circumference was 31.2 cm. Two patients had an arm circumference above 43 cm. Other baseline characteristics are summarized in Table 1.

Primary Analysis

BP measurements are summarized in Table 2. Mean baseline automated office BP was $135.7 \pm 14.2/79.4 \pm 10.0$ mm Hg. The in-pharmacy 12-reading BP average was $137.8 \pm 13.7/81.9 \pm 12.2$ mm Hg, and the daytime ambulatory BP average was $135.5 \pm 11.7/79.7 \pm 10.0$ mm Hg. Mean in-pharmacy readings were higher than mean daytime ambulatory BP readings by 2.3 ± 9.5 mm Hg for SBP (*P* = .01) and 2.2 ± 6.9 mm Hg for DBP (*P* = .002).

Mean automated office SBP and DBP were nearly identical to corresponding daytime ambulatory averages with differences of 0.2 ± 12.1 mm Hg for SBP and -0.3 ± 8.3 mm Hg for DBP. For both SBP and DBP, the standard deviation of this difference was higher than the corresponding standard deviations for 12-reading in-pharmacy device (12.1 vs. 9.5 for systolic and 8.3 vs. 6.9 for diastolic; Table 2). However, similar three-reading standard deviations compared with daytime ambulatory were found for both the automated office device and the in-pharmacy device (Table 2).

The proportion of subjects with absolute differences between the mean of 12 in-pharmacy measurements and daytime ambulatory BP systolic readings above and below

Table 1

Baseline characteristics

Variable	Result
Age (y), mean \pm standard deviation	59.7 \pm 12.8
Female, no. (%)	53 (53)
Ethnicity	
Caucasian, no. (%)	80 (80)
East or South Asian, no. (%)	13 (13)
African Canadian, no. (%)	3 (3)
Other, no. (%)	4 (4)
Weight (kg), mean \pm SD	85.5 \pm 23.7
Body mass index (kg/m ²), mean \pm SD	30.5 \pm 7.5
Arm circumference (cm), mean \pm SD	31.2 \pm 4.5
Arm cuff size (WatchBP)	
Small (18–26 cm), no. (%)	2 (2)
Regular (24–32 cm), no. (%)	62 (62)
Large or extra large (32–52 cm), no. (%)	36 (36)
Antihypertensive drug treatment, no. (%)	78 (78)
Type 2 diabetes, no. (%)	41 (41)
Dyslipidemia, no. (%)	38 (38)
Coronary artery disease, no. (%)	5 (5)
Cerebrovascular disease, no. (%)	6 (6)

5, 10, and 15 mm Hg are shown in Table 3. Overall, the proportions of patients with systolic readings above these thresholds were greater for the in-pharmacy device and the proportions of patients with diastolic readings above these thresholds were higher for the automated office device.

Pearson correlation coefficients comparing 12 readings of the in-pharmacy device to daytime ambulatory BP

were 0.73 for SBP and 0.83 for DBP ($P < .0001$ for both). Corresponding correlation coefficients for the first three readings of the in-pharmacy device were 0.68 for SBP and 0.78 for DBP ($P < .0001$) and, for automated office readings (compared with daytime ambulatory BP), were 0.58 for SBP and 0.66 ($P < .0001$ for both).

The Bland–Altman plots for SBP (Figure 1) and DBP (Figure 2) comparing the in-pharmacy device with daytime ambulatory BP readings did not show evidence for systematic differences over the range of SBP values examined. For DBP values <72 mm Hg, readings from the in-pharmacy device appeared lower; otherwise, no systematic differences were apparent.

Twelve in-pharmacy readings had a sensitivity of 86% and a specificity of 65% to detect elevated daytime ambulatory BP. The positive predictive value was 77%, and the negative predictive value 78%, with a ‘disease’ prevalence of 57%. Automated office BP was 80% sensitive and 70% specific, with a positive predictive value of 78% and a negative predictive value of 73%.

Results were nearly identical after excluding the two subjects with arm circumferences above 43 cm (data not shown).

Secondary Analyses

Results for the secondary analyses were consistent with the primary analysis and are summarized in Table 2. As the number of readings used to calculate the in-pharmacy mean BP decreased, the difference between mean in-

Table 2

Blood pressure (BP) measurements*

Measurement	Mean \pm SD	Mean Difference from Daytime ABPM (95% CI)	SD of Mean Difference
In-pharmacy kiosk device (PharmaSmart PS–2000)			
All 12 readings, systolic	137.8 \pm 13.7	2.3 (0.4–4.2)	9.5
All 12 readings, diastolic	81.9 \pm 12.2	2.2 (0.8–3.6)	6.9
First 9 readings, systolic	138.4 \pm 14.1	2.9 (1.0–4.8)	9.7
First 9 readings, diastolic	82.3 \pm 12.4	2.7 (1.2–4.1)	7.2
First 6 readings, systolic	138.9 \pm 15.0	3.4 (1.3–5.6)	10.7
First 6 readings, diastolic	82.4 \pm 12.7	2.7 (1.2–4.2)	7.7
First 3 readings, systolic	139.3 \pm 16.1	3.9 (1.5–6.2)	11.8
First 3 readings, diastolic	82.7 \pm 13.1	3.0 (1.4–4.7)	8.2
24-hour ambulatory blood pressure (Spacelabs 90207 or 90217A)			
Daytime, systolic	135.5 \pm 11.7	–	–
Daytime, diastolic	79.7 \pm 10.0	–	–
Nighttime, systolic	122.2 \pm 13.8	–	–
Nighttime, diastolic	68.4 \pm 9.0	–	–
24-hour, systolic	131.6 \pm 11.2	–	–
24-hour, diastolic	76.5 \pm 9.3	–	–
Automated office (WatchBP)			
All 3 readings, systolic	135.7 \pm 14.2	0.2 (–2.2 to 2.6)	12.1
All 3 readings, diastolic	79.4 \pm 10.0	–0.3 (–1.9 to 1.3)	8.3

ABPM, Ambulatory blood pressure measurement; CI, confidence interval; SD, standard deviation.

* All measurements taken in left arm.

Table 3

Proportion of subjects with absolute differences from daytime ambulatory blood pressure of +5, +10, or +15 mm Hg (top) and –5, –10, –15 (bottom)

Measurement Parameter	≥5 mm Hg No. (%)	≥10 mm Hg No. (%)	≥15 mm Hg No. (%)
In-pharmacy kiosk (PharmaSmart): 12 readings over 4 visits			
Systolic	35	20	11
Diastolic	32	12	3
Either systolic or diastolic	50	23	11
In-pharmacy kiosk (PharmaSmart): 3 readings from first visit			
Systolic	48	32	17
Diastolic	40	16	8
Either systolic or diastolic	58	37	21
Automated office (WatchBP): 3 readings at baseline			
Systolic	29	20	9
Diastolic	24	9	3
Either systolic or diastolic	35	21	9
Measurement Parameter	≥–5 mm Hg No. (%)	≥–10 mm Hg No. (%)	≥–15 mm Hg No. (%)
In-pharmacy kiosk (PharmaSmart): 12 readings over 4 visits			
Systolic	22	9	4
Diastolic	13	3	1
Either systolic or diastolic	27	11	5
In-pharmacy kiosk (PharmaSmart): 3 readings from first visit			
Systolic	22	15	7
Diastolic	12	5	2
Either systolic or diastolic	23	17	8
Automated office (WatchBP): 3 readings at baseline			
Systolic	36	22	7
Diastolic	28	11	3
Either systolic or diastolic	47	27	8

pharmacy readings and daytime ambulatory BP readings increased, but the absolute change was slight.

The initial PharmaSmart reading taken on each visit was higher than the two subsequent visit readings by an average of 6.4 ± 5.9 mm Hg systolic and 1.6 ± 3.2 mm Hg diastolic ($P < .0001$ for both). The standard deviations around the SBP and DBP changed very little after elimination of the first reading on each visit.

Discussion

In this study of 100 hypertensive subjects, serial readings taken on automated in-pharmacy BP kiosks over four visits closely approximated mean daytime ambulatory BP readings and were also similar to automated office readings. The 12-reading in-pharmacy average was closest to the mean daytime ambulatory BP value; however, even the first

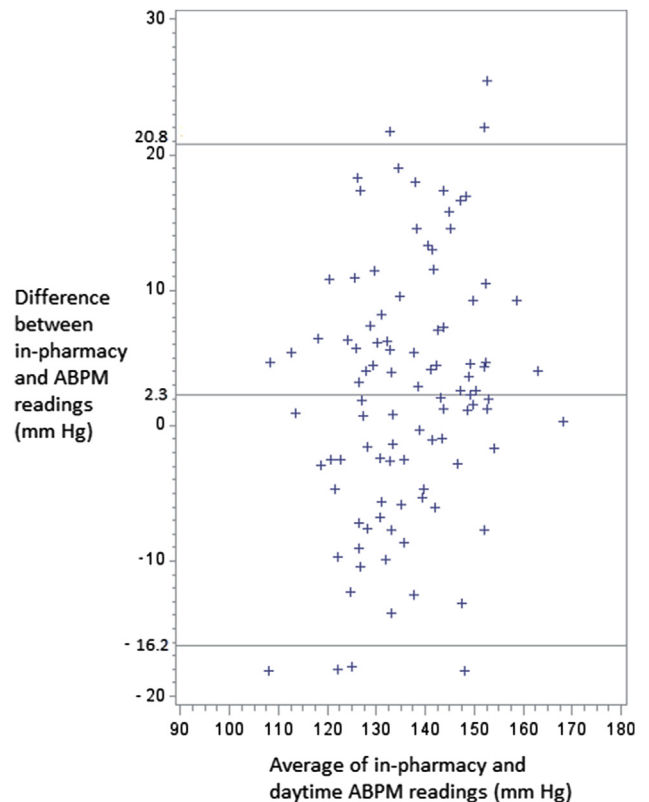


Figure 1. Bland–Altman plot assessing agreement between 12 in-pharmacy measurements and daytime ambulatory systolic blood pressure readings. ABPM, Ambulatory blood pressure measurement.

three- and first six-reading averages were within 5 mm Hg systolic and 3 mm Hg diastolic of corresponding daytime ambulatory BP mean. There were no systematic differences observed through the range of SBP levels but, relative to the ABPM device, lower DBP was observed at values <72 mm Hg. This latter finding is unlikely to be clinically important. At the very least, despite the noisier and busier in-pharmacy environment, these results indicate that the automated kiosk produces mean results comparable to daytime ambulatory BP and automated office measurement.

We are not aware of any other published study that has compared in-pharmacy kiosk readings to daytime ambulatory BP readings. Four prior studies that were performed over two decades ago that compared an in-pharmacy Vita-Stat device to standardized manual measurement concluded that the device was not comparable to the reference standard.^{17–20} More recently, in a validation study of 85 subjects, the PS-2000 met AAMI/ISO standards when tested using the AAMI/ISO evaluation protocol (ie, not in a pharmacy), with mean differences of 0.07 ± 7.0 mm Hg systolic and -0.3 ± 6.6 mm Hg diastolic when compared with standardized manual BP measurements.¹¹ In a recent study enrolling three subjects, mean differences of $-1.8 \pm 8.2/1.7 \pm 5.6$ mm Hg between in-pharmacy devices (VitaStat

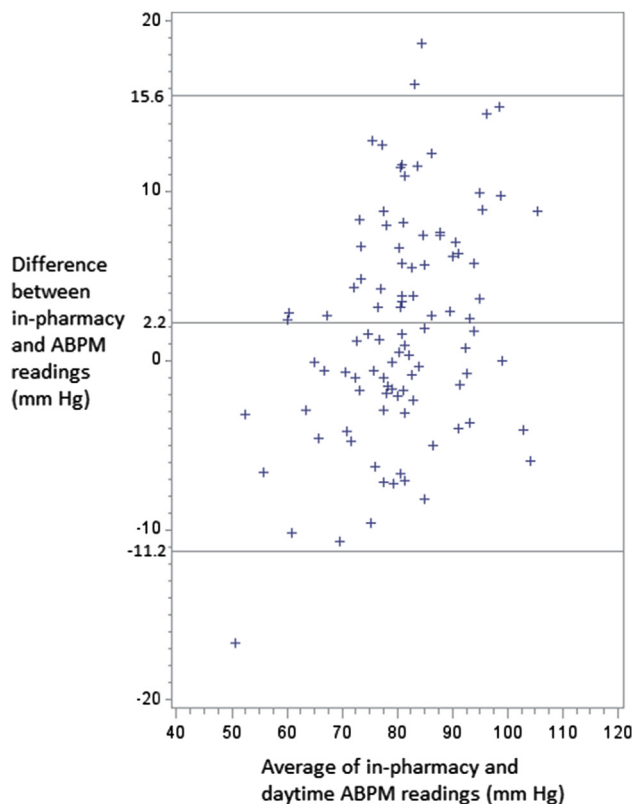


Figure 2. Bland–Altman plot assessing agreement between 12 in–pharmacy measurements and daytime ambulatory diastolic blood pressure readings. ABPM, Ambulatory blood pressure measurement.

and PharmaSmart) and an Omron BP742CAN automated device were reported.²¹ In a study of 108 community pharmacy shoppers, two in–pharmacy kiosk readings taken from a VitaStat device were compared with two standardized manual measurements taken using a mercury sphygmomanometer.¹⁰ Mean differences in readings were $4.4 \pm 9.4/1.0 \pm 6.2$ mm Hg. In this study, the Omron HEM–705CP (Kyoto, Japan) was also compared with the reference standard, and produced slightly better mean differences but similar standard deviations ($1.6 \pm 9.3/0.6 \pm 6.4$ mm Hg).

We note there was substantial variance around the mean difference between the in–pharmacy device and the reference standard observed even though the individual mean BPs were similar. However, we do note that variability was similar to the automated office device, which is widely used in the assessment and management of hypertension.^{6,22} BP variability is inherent, and expected in any comparative BP evaluation. In this evaluation, approximately 1 week elapsed between automated office and ABPM readings, and up to 1 week between in–pharmacy and ABPM readings; such temporal gaps will increase the potential for variability around the mean. Until more is learned about the observed variability, we recommend

that values should be verified using home or ABPM before management decisions such as initiating or titrating antihypertensive drugs are undertaken.⁶

Despite overwhelming evidence of the value of ABP and home BP, the majority of patients are still assessed solely on in–clinic measurement. The barriers to adoption of home BP and ABP in usual care are significant, and new out–of–office methods should be welcomed. Not all in–pharmacy kiosks can be recommended for patients, but properly validated kiosks capable of serialized reporting have the potential to fill an important gap in hypertension management. Our findings indicate that serial PharmaSmart PS–2000 kiosk measurements taken in a pharmacy setting are clinically useful and should be integrated into clinical practice, where available. We also advocate for more validity studies of all in–pharmacy kiosk devices.

This study has several limitations. First, automated office BP readings were taken at baseline and not repeated between the second and third in–pharmacy visit (ie, at the time that 24–hour ABPM was performed). Furthermore, automated office readings were used for baseline measurement and thus were not performed in a random sequence to in–pharmacy or ABPM readings. Although this does not appear to have adversely affected the automated office mean (which was nearly identical to daytime ambulatory), we cannot exclude the possibility that variability for the automated office measurements was increased because these were the initial study BPs taken in all patients. Second, in–pharmacy readings were taken between 1 and 7 days apart from the reference ABP, which likewise may have increased variability from the reference ABP. Third, we evaluated only one in–pharmacy device, the validated PharmaSmart PS–2000 kiosk. Oscillometric algorithms and cuff technologies vary significantly between kiosk manufacturers, and our results cannot be generalized or applied to other in–pharmacy devices.

In conclusion, serial in–pharmacy kiosk readings measured using a PharmaSmart PS–2000 kiosk and averaged over one to four visits produced readings comparable to mean daytime ambulatory BP for assessing the BP status of patients. In–pharmacy PS–2000 readings should be combined with automated office BP, home BP and, when indicated, ABPM in the diagnosis and management of hypertension.

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