



Pharmacist-Led Ambulatory Blood Pressure Monitoring in Community Pharmacy: An Operational Feasibility Case Series

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ABSTRACT

Objectives: To evaluate the operational feasibility of pharmacist-led ambulatory blood pressure monitoring (ABPM) in community pharmacy practice.

Materials and Methods: This operational-feasibility case series recruited eligible participants from four community pharmacies located in three geographical districts in Malta over a three-month recruitment period. Process feasibility included recruitment uptake and participant acceptability. Management feasibility included the completion of a valid 24-hour ABPM recording and successful tracking of post-referral outcomes. Pragmatic post-hoc benchmarks were applied: uptake of at least 60%, completion of valid recordings of at least 80%, and post-referral outcome tracking of at least 80%. Exact 95% confidence intervals (CIs) were calculated using the Clopper-Pearson method

Results: Ten of 20 invited participants consented, corresponding to an uptake rate of 50% (95% CI, 27.2–72.8%). Valid 24-hour ABPM recordings meeting the pre-defined recording quality criteria were obtained for 9 of the 10 participants, corresponding to a completion rate of 90% (95% CI 55.5–99.7). 4 participants were referred for physician review, and post-referral outcomes were obtained for all 4 participants, corresponding to a tracking rate of 100% (95% CI 39.8–100.0). Three of the 4 referred participants reported an intensification of their antihypertensive treatment.

Conclusion: Pharmacist-led ABPM in community pharmacies demonstrated operational feasibility regarding completion of valid recordings and post-referral tracking, although uptake requires improvement. Participant-reported treatment changes should be interpreted as exploratory signals, and larger implementation studies are warranted.

Keywords: Blood pressure monitoring, ambulatory, community pharmacy services, hypertension, pharmacists

INTRODUCTION

Ambulatory blood pressure monitoring (ABPM) provides repeated blood pressure (BP) measurements over 24 hours in the patient's usual environment and yields 24-hour, daytime and night-time values. ABPM is particularly useful for identifying clinically important phenotypes that cannot be reliably characterised by office BP alone, such as white-coat hypertension, masked hypertension, nocturnal hypertension, and abnormal dipping patterns.¹⁻⁷ Compared with office BP,

ambulatory BP correlates more strongly with hypertension-mediated target organ damage and predicts cardiovascular events more reliably, making it an important out-of-office method for confirming diagnosis and refining risk stratification.^{1-3,4,6}

Current guidance emphasises that ABPM and home BP monitoring (HBPM) are complementary. HBPM is valuable for longer-term follow-up and self-management, whereas ABPM is preferable when confirmation of diagnosis, assessment of apparent resistant hypertension, evaluation of nocturnal BP

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or clarification of discrepant office readings is required.^{1,4,8,9} Although ABPM is well-established for diagnosis and treatment optimisation in specialist care, access in primary care and community pharmacy settings is variable.¹⁰⁻¹² Community pharmacists are accessible healthcare professionals and may be well-placed to support out-of-office BP monitoring services, particularly when embedded within clear referral pathways. The aim was to evaluate the operational feasibility of pharmacist-led ABPM in community pharmacy practice.

MATERIALS AND METHODS

Study design and setting

This was an operational feasibility case series with follow-up. Eligible participants were recruited from four community pharmacies, selected by convenience sampling, located across three geographical districts in Malta.¹³ The study evaluated the practical delivery of a pharmacist-led ABPM service and was not designed to test clinical efficacy. Relevant STROBE items were used to guide the reporting of observational data.

Ethical considerations

Approval was obtained from the University of Malta, Faculty of Medicine and Surgery Research Ethics Committee (approval number: MED-2023-00210, dated 19.09.2023). All participants provided written informed consent.

Sample size considerations

A formal sample size calculation was not performed because the study was designed to explore operational feasibility rather than to test a clinical hypothesis. The sample comprised all eligible patients identified during a fixed three-month recruitment period. Exact 95% confidence intervals (CIs) were reported to quantify the uncertainty associated with the resulting small sample.

Eligibility and recruitment

Participants were eligible if they had been diagnosed with hypertension within the previous two months, had experienced a change in antihypertensive medication or dose within that period, or had self-reported non-adherence to antihypertensive therapy. Over the three-month study period, 20 participants met at least one inclusion criterion and were invited to undergo 24-hour ABPM.

Feasibility domains and post-hoc progression benchmarks. Feasibility outcomes were organised into three domains. The process domain included uptake, reasons for declining ABPM, and participant-reported tolerability. The management domain included the successful completion of a valid 24-hour ABPM recording and the documentation of post-referral outcomes. The referral domain included potentially abnormal ABPM patterns prompting physician review, and participant-reported actions following that review. Formal progression criteria were not specified in the original approved protocol. To support transparent interpretation and planning of a subsequent implementation study, the following pragmatic post-hoc benchmarks were applied: uptake by at least 60%

of invited eligible individuals, completion of a valid 24-hour ABPM recording by at least 80% of consented participants, and documentation of post-referral outcomes by at least 80% of referred participants. The uptake benchmark represented participation of a majority of invited individuals, whereas the completion and tracking benchmarks represented high operational reliability among individuals entering the service pathway. Failure to meet a benchmark was interpreted as indicating an aspect of the service that required modification before larger-scale implementation.

ABPM device and monitoring procedure

Participants attended two appointments with the pharmacist researcher (MV), with the second appointment scheduled 24 hours after the first. At the first appointment, an appropriately sized cuff was fitted to the non-dominant upper arm. BP was initially measured using a calibrated oscillometric upper-arm monitor (A&D® UA-651), followed by fitting GIMA® 24 hours ABPM + pulse rate monitor. The ABPM recording was initiated following confirmation that the readings obtained during fitting were comparable. The ABPM device recorded BP every 30 minutes between 06:00 and 22:00 (daytime) and hourly between 22:00 and 06:00 (nighttime). Participants received verbal instructions from the pharmacist-researcher regarding device handling and activities during the monitoring period. At the second appointment, the ABPM device was removed, and the data were downloaded to generate an individual ABPM report. A recording was considered satisfactory if the minimum criteria for valid readings were met, namely: at least 20 daytime measurements and at least 7 night time measurements.

Device validation and interpretation

The GIMA® 24-hour ABPM monitor used in this study was not listed on the STRIDE BP (an international initiative for the validation of blood pressure measuring devices) registry of validated devices. No published validation data were identified for the specific model used, and it was not possible to confirm whether the device shared its internal measurement algorithm or component design with a validated device from the original equipment manufacturer. Accordingly, the study was framed as an exploratory case series assessing service feasibility. The pharmacist researcher used ABPM outputs to identify potentially abnormal patterns warranting physician review. The physician was responsible for diagnosis and treatment decisions.

Referral workflow and follow-up

The referral process was structured but pragmatic. The pharmacist researcher reviewed the ABPM report, explained the findings to the participant, and provided a printed copy. Participants with potentially abnormal findings were given a written referral note and advised to consult their physician. The pharmacist-researcher did not diagnose hypertension phenotypes, alter medications, or prescribe treatment. The pharmacist-researcher conducted follow-up after the physician consultation to document the participant-reported outcome. Physician actions were not independently verified.

Statistical analysis

Data analysis was descriptive and focused on participant-level and service-process outcomes. Uptake was calculated as the number of individuals who consented divided by the number of individuals invited. Recording completion was calculated as the number who obtained a valid 24-hour recording divided by the number who consented. Referral tracking was calculated as the number of referred participants for whom a post-referral outcome was documented, divided by the total number of referred participants. Two-sided exact 95% CIs for the primary feasibility proportions were calculated using the Clopper-Pearson method. No hypothesis testing, inferential comparisons, or *p*-values were performed. Participant ABPM findings, referral decisions, and reported post-referral outcomes were presented descriptively. Box-and-whisker plots were used as a visual summary of the distributions of daytime and nighttime systolic and diastolic BP readings. Analyses were undertaken using IBM SPSS Statistics version 29.

RESULTS

Recruitment and recording completion

Of the 20 eligible individuals invited to participate, 10 consented, corresponding to an uptake rate of 50% (95% CI: 27.2–72.8). The post-hoc uptake benchmark of at least 60% was not met. Among the 10 individuals who declined, 6 perceived ABPM as burdensome, and 4 felt embarrassed about being seen wearing the device. One participant experienced cuff air leakage, resulting in a device error after 18 hours and yielding only 19 valid daytime readings; hence, this recording was considered invalid. Nine of the 10 consented participants completed valid 24-hour ABPM recordings, corresponding to a completion rate of 90% (95% CI 55.5–99.7). The post-hoc completion benchmark of at least 80% was met.

Participant characteristics

Among the 9 participants with valid recordings, 6 were male and 3 were female. The mean age was 57 years, ranging from 35 to 72 years. The duration of hypertension was less than 1 year (*n* = 4), 1 to 5 years (*n* = 1), 6 to 10 years (*n* = 3), and 11 to 20 years (*n* = 1). Seven participants reported no comorbidities; 2 had hypercholesterolaemia, 1 had hypothyroidism, and 1 had depression. 5 participants were receiving antihypertensive monotherapy, and 4 were receiving dual therapy. Antihypertensive medications included thiazide diuretics (*n* = 4), angiotensin-converting enzyme inhibitors (*n* = 3), angiotensin II receptor blockers (*n* = 3), and calcium channel blockers (*n* = 3).

Tolerability, referral and follow-up

ABPM was reported to be well tolerated by 5 participants. Two participants reported mild bruising, and 2 reported sleep disturbances. The pharmacist researcher's review of the ABPM reports resulted in 4 participants being referred for review by a physician. Participant 1 had normal daytime BP but elevated nocturnal readings. Participants 2 and 4 had elevated BP

throughout the 24-hour monitoring period, whereas participant 6 had normal systolic BP but elevated diastolic BP readings (Figure 1). A post-referral outcome was documented for all 4 referred participants, corresponding to a tracking rate of 100% (95% CI 39.8–100.0). The post-hoc referral-tracking benchmark of at least 80% was met. Three of the 4 referred participants reported intensification of antihypertensive treatment. Participants 1 and 4 reported initiating an additional antihypertensive medication, while participant 2 reported a dose increase. Participant 6 reported no change in treatment, but stated that the physician had advised stress reduction. These physician actions were participant-reported and were not independently verified. Participants' profiles and referral outcomes are presented in Table 1.

DISCUSSION

This operational feasibility case series suggests that pharmacist-led ABPM can be delivered in community pharmacy practice, although feasibility varies across the evaluated domains. Valid recordings were obtained for 90% of consented participants, exceeding the post-hoc completion benchmark of 80%, thereby supporting the feasibility of device fitting, participant instruction, 24-hour monitoring, device removal, and report generation. Post-referral outcomes were documented for all referred participants, thereby exceeding the 80%

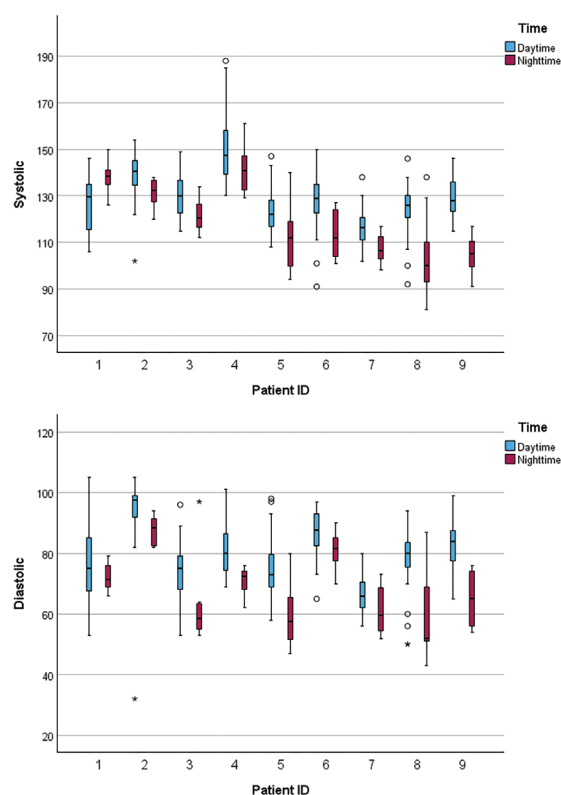


Figure 1. Descriptive distributions of daytime and night-time systolic and diastolic blood pressure readings among the 9 participants with valid 24-hour ABPM recordings. Box-and-whisker plots display the median, interquartile range and outlying values.

ABPM, ambulatory blood pressure monitoring.

Table 1. Individual participant profile and referral outcome for valid 24-hour ABPM recordings (n = 9).

Participant ID	Age/sex and eligibility criterion	Antihypertensive therapy	ABPM values	Pharmacist researcher interpretation	Referral and physician outcome
1	Female/72 years, change in medication/dose within previous two months	Dual therapy	24-hour mean BP: 131/77 mmHg; daytime mean BP: 129/78 mmHg; night-time mean BP: 138/72 mmHg	Normal daytime BP with elevated nocturnal readings	Referred; participant reported initiation of additional antihypertensive medication
2	Male/52 years, diagnosis of hypertension within previous two months	Monotherapy	24-hour mean BP: 137/93 mmHg; daytime mean BP: 138/94 mmHg; night-time mean BP: 131/88 mmHg	Elevated BP throughout 24-hour period	Referred; participant reported antihypertensive dose increase
3	Female/67 years, change in medication/dose within previous two months	Dual therapy	24-hour mean BP: 130/73 mmHg; daytime mean BP: 138/94 mmHg; night-time mean BP: 122/63 mmHg	No abnormal referral trigger reported	No physician referral required
4	Male/69 years, diagnosis of hypertension within previous two months	Monotherapy	24-hour mean BP: 149/80 mmHg; daytime mean BP: 150/82 mmHg; night-time mean BP: 141/71 mmHg	Elevated BP throughout 24-hour period	Referred; participant reported initiation of additional antihypertensive medication
5	Female/67 years, diagnosis of hypertension within previous two months	Monotherapy	24-hour mean BP: 121/72 mmHg; daytime mean BP: 123/75 mmHg; night-time mean BP: 112/60 mmHg	No abnormal referral trigger reported	No physician referral required
6	Male/36 years, diagnosis of hypertension within previous two months	Monotherapy	24-hour mean BP: 125/86 mmHg; daytime mean BP: 127/87 mmHg; night-time mean BP: 114/81 mmHg	Normal systolic BP with elevated diastolic readings	Referred; participant reported no treatment change and advice to reduce stress
7	Male/69 years, change in medication/dose within previous two months	Dual therapy	24-hour mean BP: 114/65 mmHg; daytime mean BP: 116/66 mmHg; night-time mean BP: 107/61 mmHg	No abnormal referral trigger reported	No physician referral required
8	Male/44 years, change in medication/dose within previous two months	Dual therapy	24-hour mean BP: 120/74 mmHg; daytime mean BP: 124/77 mmHg; night-time mean BP: 104/61 mmHg	No abnormal referral trigger reported	No physician referral required
9	Male/35 years, diagnosis of hypertension within previous two months	Monotherapy	24-hour mean BP: 125/79 mmHg; daytime mean BP: 130/83 mmHg; night-time mean BP: 105/65 mmHg	No abnormal referral trigger reported	No physician referral required

ABPM, ambulatory blood pressure monitoring; BP, blood pressure.

tracking benchmark. Participant uptake was 50%, below the 60% benchmark, indicating that recruitment and acceptability require modification before larger-scale implementation.

Among participants who completed monitoring, ABPM was generally tolerated consistent with previous reports,^{9–11} although mild bruising and sleep disturbance were reported. Half of the eligible individuals nevertheless declined participation because they perceived monitoring as burdensome or felt uncomfortable being seen wearing the device. These findings are consistent with patient-reported concerns described in previous qualitative research and suggest that uptake may be improved through clearer pre-test counselling, reassurance about the purpose and temporary nature of ABPM, discussion of possible discomfort or sleep disturbance, and practical guidance regarding clothing and daily activities during the monitoring period.^{14,15}

Four participants were referred because of potentially abnormal BP patterns, including nocturnal hypertension, sustained 24-hour hypertension, and isolated diastolic elevation, of whom three subsequently reported an intensification of antihypertensive treatment. These observations suggest that pharmacist-led ABPM may generate actionable information that prompts medical reassessment. However, the small sample size, self-reported follow-up, and the use of an ABPM device that has not been confirmed as validated limit the strength of clinical inferences.

The measurement validity of the ABPM device has implications for the operational performance of the referral pathway. The specific GIMA® model was not listed on the STRIDE BP registry of validated devices, and no published validation study or confirmed equivalence to a validated original equipment manufacturer device was identified. Measurement uncertainty could result in over-referral, generating avoidable consultations and additional workload for primary care physicians, or under-referral, failing to identify individuals requiring medical review.

Study limitations

This study involved a small convenience sample recruited from four community pharmacies, resulting in wide CIs and limited generalisability. The progression benchmarks were introduced post-hoc to support interpretation and future planning, and were not prospectively established. The ABPM device was not confirmed to be validated, which may have affected the identification of potentially abnormal patterns and the resulting referral decisions. Physician actions reported by participants were not independently verified. Subsequent BP control, persistence of treatment changes, and cardiovascular outcomes were not assessed. In addition, the referral pathway relied on written documentation and patient-mediated physician follow-up rather than direct or integrated electronic communication.

Implications for future research

Future implementation studies should use validated ABPM devices and prospectively specified progression criteria. Recruitment and counselling procedures should be refined

to address perceived burden, embarrassment, possible sleep disturbance, and practical concerns that are associated with wearing the device. Larger studies should evaluate patient and healthcare professional experiences, pharmacist training requirements, recording quality, referral appropriateness, clinical effectiveness, and cost-effectiveness. Referral pathways should facilitate direct and secure communication between pharmacists and physicians, and physician actions and subsequent BP outcomes should be independently verified. Integrated models combining ABPM for diagnostic clarification with HBPM for longer-term follow-up may also warrant evaluation.

CONCLUSION

Pharmacist-led ABPM in community pharmacies demonstrated operational feasibility with respect to valid recording completion and post-referral tracking, although uptake requires improvement. Participant-reported treatment changes should be interpreted as exploratory signals, and larger implementation studies are warranted.

Ethics

Ethics Committee Approval: Approval was obtained from the University of Malta, Faculty of Medicine and Surgery Research Ethics Committee (approval number: MED-2023-00210, dated 19.09.2023).

Informed Consent: All participants provided written informed consent.

Footnotes

Authorship Contributions

Concept: F.W., L.M.A., Design: M.V., F.W., L.M.A., Data Collection or Processing: M.V., Analysis or Interpretation: M.V., F.W., L.C., L.M.A., Literature Search: M.V., Writing: M.V., F.W., L.C., L.M.A.,

Conflict of Interest: The authors declare no conflicts of interest.

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