Development and Feasibility of a Community Pharmacy-Driven 24-hour Ambulatory Blood Pressure Monitoring Service

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Background

• High blood pressure is the leading cause of years of life lost in the world.
• In the United States, diagnosis and management of high blood pressure is primarily based on office-based measurements.
• Current guidelines recommend out-of-office measurements to ensure appropriate diagnosis and management of high blood pressure.

Out-of-office BP Measurement
Comparison of Office-Based to Out-of-Office BP Measurement

• Out-of-office BP measurements are a better predictor of cardiovascular events and mortality.
  – ABPM is superior to patient self-measured BP

• 24-hour ambulatory BP monitoring is the gold standard for diagnosing white coat, masked, and nocturnal hypertension.

## Ambulatory BP Phenotypes

<table>
<thead>
<tr>
<th>Phenotype</th>
<th>Office Blood Pressure (mm Hg)</th>
<th>24-hour Average Blood Pressure (mm Hg)</th>
<th>Average Sleep Blood Pressure (mm Hg)</th>
<th>Nighttime Dipping (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normotensive</td>
<td>&lt;130/80</td>
<td>&lt;130/80</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Sustained hypertension</td>
<td>≥130/80</td>
<td>≥130/80</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>White coat hypertension</td>
<td>≥130/80</td>
<td>&lt;130/80</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Masked hypertension</td>
<td>&lt;130/80</td>
<td>≥130/80</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Nocturnal hypertension</td>
<td>--</td>
<td>--</td>
<td>≥110/65</td>
<td>--</td>
</tr>
<tr>
<td>Nondipping</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>&lt;10%</td>
</tr>
</tbody>
</table>

Barriers to 24-hour ABPM

• Accessibility
• Cost of the device
• Limited reimbursement
• Lack of formal training programs
• Willingness of patients to complete test

Ireland Model for 24-hour ABPM

• 24-hour ABPM is more widely utilized in Europe and preferred over patient self-measured BP monitoring.

• In a study conducted in Ireland, BP characteristics of patients who had 24-hour ABPM provided by community pharmacies was comparable to that provided by primary care practices.

Objectives

• The *primary objective* was to develop and evaluate the feasibility of a community pharmacy-driven ABPM service.

• *Secondary objectives* included a characterization of the referrals and participants, as well as the ABPM findings with regards to BP phenotypes.
Practice Description: Sites

- Identified two community pharmacies willing to provide the service.
- Both provide progressive community pharmacy services and had established relationships with medical practices.

Clinical Lead: Joseph Jadallah, PharmD

Clinical Lead: Tana Kaefer, PharmD
Practice Description: Training

• The PI had extensive clinical and research experience with 24-hour ABPM.

• A two-hour training program was created and provided to 2 pharmacists and 1 pharmacy technician at each site.
  – Additional on-site training and setup was also provided throughout the study
Practice Description: Marketing

• Both pharmacies received a marketing budget, which focused primarily on face-to-face meetings with medical practices near their store location.

• Information flyers were created, along with a “show and tell” on the 24-hour ABPM device.
Methods

- **Design**: single-arm, clinical trial (NCT03920956)
- **Primary Outcome**: Patient satisfaction
- **Inclusion criteria**: Adults ≥18 yo suspected by their provider of white coat, masked, or sustained hypertension, hypotension, or in need of additional information to confirm an initial hypertension diagnosis
- **Exclusion criteria**: persistent atrial fibrillation, pregnant, hemodialysis, dementia
Analysis

- Descriptive statistics (means and standard deviations for continuous variables and frequencies and percentages for categorical variables) were used to summarize the data for the baseline demographics, reasons for referral, 24-hour ABPM findings, and patient satisfaction survey.
1) Provider refers patient to ABPM service at their preferred pharmacy by completing a referral form that is faxed to the pharmacy.

2) Pharmacy staff call the patient to schedule an ABPM appointment.

3) Pharmacy staff places the ABPM device on the patient, provides counseling on the device and what to expect, and schedules a return visit.

4) Pharmacist downloads the results upon return, reviews the results with the patient, then faxes the results and recommendations to the provider.

Images credit: Suntech Medical, Inc.
Referrals and Enrollment

Total referrals (n=58)

Total enrolled (n=52)

Reasons for not enrolling:
- Did not answer phone (n=3)
- Did not show for appointment (n=3)
# Patient Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N=52</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD) Age, years</td>
<td>56.6 (16.1)</td>
</tr>
<tr>
<td>Race/ethnicity, n (%)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>39 (75)</td>
</tr>
<tr>
<td>Black</td>
<td>10 (19.2)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (5.8)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>26 (50)</td>
</tr>
<tr>
<td>Medical Conditions, n (%)</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>37 (71.2)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>27 (51.9)</td>
</tr>
<tr>
<td>Current smoker</td>
<td>10 (19.2)</td>
</tr>
<tr>
<td>ASCVD</td>
<td>9 (17.3)</td>
</tr>
<tr>
<td>CKD</td>
<td>3 (5.8)</td>
</tr>
<tr>
<td>Currently monitoring BP at home, n (%)</td>
<td></td>
</tr>
<tr>
<td>Daily frequency</td>
<td>34 (65.4)</td>
</tr>
<tr>
<td>Weekly frequency</td>
<td>23 (67.6)</td>
</tr>
<tr>
<td>Monthly frequency</td>
<td>6 (17.6)</td>
</tr>
<tr>
<td>Not reported</td>
<td>3 (8.8)</td>
</tr>
<tr>
<td></td>
<td>2 (5.9)</td>
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</tbody>
</table>
### Referral Characteristics

<table>
<thead>
<tr>
<th>Referred by, n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse Practitioner</td>
<td>25 (48.1)</td>
</tr>
<tr>
<td>Physician</td>
<td>21 (40.4)</td>
</tr>
<tr>
<td>Self</td>
<td>6 (11.5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reason for referral, n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>White coat HTN</td>
<td>23 (45.2)</td>
</tr>
<tr>
<td>Sustained HTN</td>
<td>11 (21.2)</td>
</tr>
<tr>
<td>Masked HTN</td>
<td>8 (15.4)</td>
</tr>
<tr>
<td>Hypotension</td>
<td>3 (5.8)</td>
</tr>
<tr>
<td>Initial HTN diagnosis</td>
<td>1 (1.9)</td>
</tr>
<tr>
<td>Self-referral</td>
<td>6 (11.5)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Referral Visit BP Data</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD) SBP, mm Hg</td>
<td>141.8 (18.3)</td>
</tr>
<tr>
<td>Mean (SD) DBP, mm Hg</td>
<td>83.3 (12.5)</td>
</tr>
<tr>
<td>At BP goal, n (%)</td>
<td>9 (17.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Taking antihypertensives at baseline, n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ACE-I/ARB</td>
<td>22 (42.3)</td>
</tr>
<tr>
<td>Diuretics</td>
<td>12 (23.1)</td>
</tr>
<tr>
<td>Beta-blocker</td>
<td>12 (23.1)</td>
</tr>
<tr>
<td>Calcium channel blocker</td>
<td>8 (15.4)</td>
</tr>
<tr>
<td>Aldosterone antagonist</td>
<td>1 (1.9)</td>
</tr>
<tr>
<td>Other</td>
<td>6 (11.5)</td>
</tr>
</tbody>
</table>
Overall, I am very satisfied with my experience using this service.

I think the information provided by the test will be helpful in making decisions about how to diagnose and treat my blood pressure.

I think undergoing ambulatory blood pressure monitoring was worthwhile.

I was treated professionally by the pharmacy staff of the ambulatory blood pressure monitoring service.

I found it easy to return the device as instructed.

I found it easy to be fitted for the monitor.

My pharmacist clearly explained the benefit of undergoing this testing.

My doctor clearly explained the benefit of undergoing this testing.

I found it easy to go to a community pharmacy to undergo the ambulatory blood pressure monitoring.
BP Phenotypes

Potential impact:

- May prevent under- and over-treatment.
- Identify those at higher CV risk due to abnormal diurnal BP pattern.
Reimbursement

• Successful reimbursement was obtained for 3 participants with commercial insurance.
  – Pharmacies are not eligible for reimbursement under Medicare.

• The American Medical Association and American Heart Association sent a letter to CMS in 2018 advocating for expanded coverage of ABPM.

Public Comments on ABPM Coverage

• CMS received 103 comments during a 30-day open comment period.
• Mostly physicians (74%) but pharmacists (10%) also responded.

• Key issues reported by commenters:
  – Limitations of current coverage policy
  – Barriers to current use of ABPM
  – Impact of inadequate coverage on patients and providers

CMS Expanded ABPM Coverage

• Decision memo released July 2, 2019
• Removed restrictions for suspected white coat hypertension
• Added suspected masked hypertension as a covered benefit
• Revised language so interpretation can be completed by a physician “or non-physician practitioner”.
  – Does this include a pharmacist?
Future of ABPM Reimbursement

• In the interim, both pharmacies are offering the service for $50 and completed 10 tests in the first month.

• Exploring a shared reimbursement model with a cardiology practice, who would manage reimbursement process and split revenue with the pharmacy.
  – Discussions put on hold thanks to COVID-19

• Coverage by commercial payers expected to expand over time as new decision memo by CMS is implemented.
Value Proposition

• Customers
  – Patients, medical practices, health systems, payers

• Benefit
  – Improving the diagnosis of high blood pressure with **ABPM** is **cost-effective** compared to clinic and self-measured BP.
  – More accurate diagnosing will improve the management of high blood pressure and reduce the risk of over- or under-treatment.

• Why community pharmacies?
  – Easily accessible, visited frequently, reduces burden on medical practice and health system to set up their own ABPM program
  – Potential to combine with other pharmacy services, such as MTM and medication adherence, that can improve BP outcomes

Conclusion and Next Steps

• To our knowledge, this is the first study to report on the development and feasibility of a 24-hour ABPM service in community pharmacies in the United States.

• Most patients were found to either have sustained HTN, be normotensive, or have white coat HTN. Over half of patients exhibited a non-dipper pattern at night.

• Patient satisfaction with the pharmacy staff and ABPM service was high.

• Future research will focus on the clinical and economic impact of 24-hour ABPM provided by community pharmacies.
Thank you!

• VCU Co-Investigators
  – Julie Patterson, PharmD, PhD
  – Sharon Gatewood, PharmD
  – Teresa Salgado, MPharm, PhD
  – David Holdford, PhD

• VCU PharmD Student
  – Jewlyus Grigsby (Class of 2021)

• Bremo Pharmacy
  – Tana Kaefer, PharmD
  – Mary Curtis, PharmD

• Buford Road Pharmacy
  – Joseph Jadallah, PharmD
  – Lisa Hawkey, PharmD

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