HOME BLOOD PRESSURE TELEMONITORING WITH PHARMACIST CASE MANAGEMENT:
18-MONTH OUTCOMES OF A CLUSTER-RANDOMIZED TRIAL

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• No conflicts of interest to disclose
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Adverse Events
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Background

- U.S. adults with hypertension visit a physician an average of 4 times per year
- Only about half have controlled blood pressure as defined by JNC7 guidelines
- Practical, effective, and sustainable models are needed to improve blood pressure management in primary care
- A few previous studies show nurse- or pharmacist-led care combined with strategic use of telemedicine can significantly improve hypertension management
  - Limitations: Excluded more severe hypertension & co-morbidity, short duration, lacked post-intervention follow-up
Study Design

- Cluster-randomized controlled trial
- Adult patients with uncontrolled hypertension
- Primary care clinics randomly assigned to 2 groups:
  - Usual care (UC)
  - Telemonitoring Intervention (TI) combining pharmacist-led care management and home BP telemonitoring
Setting

HealthPartners Medical Group

• Multispecialty group in Minneapolis-St. Paul, MN
• Integrated with health plan but accepts all insurance
• 200,000 adult patients, 150 primary care providers
• 23 primary care clinics
• 16 clinics have Medication Therapy Management (MTM)
  • MTM Pharmacists work in primary care team under collaborative practice agreements with physicians
  • Optimize drug therapy to improve therapeutic outcomes
Study Population

Recruited from the 16 primary care clinics with MTM pharmacists

Inclusion criteria:
- Age 21 or older
- Within last year, 2 most recent BP in EMR $\geq 140/90$
- Measured BP in research clinic $\geq 140/90$ ($\geq 130/80$ if diabetes/CKD)

Exclusion criteria:
- Recent acute coronary event or stroke (3 mo)
- Class III or IV heart failure
- Stage 4 or 5 kidney disease
- Known secondary hypertension
- Pregnancy
- No land telephone line (cell phone only permitted late in study)
Telemonitoring Intervention

• Home blood pressure telemonitor
  – Transmits stored BP via telephone modem
  – Patient measures BP 3 days per week, a.m. and p.m. (6 readings /week)
  – Pharmacist accesses BP data remotely from clinic

• Pharmacist case management
  – Visits with patients primarily by phone
  – Adjusts antihypertensive therapy using algorithm from collaborative practice agreement with PCP
  – Emphasizes lifestyle strategies and medication adherence

• Intervention for 12 months, 6 months post-intervention observation
  – Months 0-6: One in-person intake visit, phone visits every 2-4 weeks depending on BP control
  – Months 7-12: phone visits every 2 months
  – Months 13-18: return to care of PCP without telemonitoring
## Visit Schedule

<table>
<thead>
<tr>
<th>Week</th>
<th>Research Clinic Visits (TI and UC)</th>
<th>MTM In-Person Visit</th>
<th>MTM Phone Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>Screening/Baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td></td>
<td>×</td>
<td></td>
</tr>
<tr>
<td>Week 4</td>
<td></td>
<td>×</td>
<td></td>
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<tr>
<td>Week 6</td>
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<td>×</td>
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<tr>
<td>Week 8</td>
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<td>×</td>
<td></td>
</tr>
<tr>
<td>Week 10</td>
<td></td>
<td>×</td>
<td></td>
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<tr>
<td>Week 12</td>
<td></td>
<td>×</td>
<td></td>
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<tr>
<td>Week 14</td>
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<td>×</td>
<td></td>
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<tr>
<td>Week 16</td>
<td></td>
<td>×</td>
<td></td>
</tr>
<tr>
<td>Week 18</td>
<td></td>
<td>×</td>
<td></td>
</tr>
<tr>
<td>Week 20</td>
<td></td>
<td>×</td>
<td></td>
</tr>
<tr>
<td>Week 22</td>
<td></td>
<td>×</td>
<td></td>
</tr>
<tr>
<td>Week 24</td>
<td>6-month clinic visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Month 8</td>
<td></td>
<td>×</td>
<td></td>
</tr>
<tr>
<td>Month 10</td>
<td></td>
<td>×</td>
<td></td>
</tr>
<tr>
<td>Month 12</td>
<td>12-month clinic visit</td>
<td>×</td>
<td></td>
</tr>
<tr>
<td>Month 18</td>
<td>18-month clinic visit</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Intensive Intervention (0-6 months)**

**Maintenance Intervention Phase (6-12 months)**
## MTM algorithm for drug initiation & titration

<table>
<thead>
<tr>
<th>Patient drug status</th>
<th>Patient BP status</th>
<th>Pharmacist Action</th>
</tr>
</thead>
</table>
| Not on drug treatment | BP above goal by < 20 / 10 mmHg | • Begin with diuretic  
• Reinforce lifestyle modification |
| Not on drug treatment | BP above goal by ≥20 /10 mmHg | • Begin with combination of diuretic and 2<sup>nd</sup> line drug  
• Reinforce lifestyle modification |
| Any BP drugs, adherent | BP controlled according to JNC-7 | • Continue present treatment  
• Reinforce lifestyle modification |
| 1-2 BP drugs, adherent | BP above goal by < 20 / 10 mmHg | • Add thiazide-like diuretic if not part of regimen, otherwise add synergistic 2<sup>nd</sup> line drug  
• Reinforce lifestyle modification |
| 1-2 BP drugs, adherent | BP above goal by ≥20 /10 mmHg | • Add synergistic combination of two more drugs  
• Reinforce lifestyle modification |
| 4+ BP drugs, adherent | BP uncontrolled according to JNC-7 | • Probe more for non-adherence  
• Consult PCP regarding reasons for resistant hypertension  
• Refer for work-up for secondary hypertension if needed |
| Any BP drugs, not adherent | BP uncontrolled according to JNC-7 | • Address reasons for non-adherence  
• Adjust regimen, monitor adherence |
| Any drug status | BP ≥180/110mmHg | • Probe more for non-adherence  
• Consult PCP regarding resistant hypertension  
• Refer for work-up for secondary hypertension if needed |
Data Collection

- Baseline, 6, 12 and 18 months:
  - Blood pressure
  - Demographics, lifestyle, quality of life
  - Medications, adherence, self-efficacy
- Satisfaction with care
  - Consumer Assessment of Health Providers and Systems (CAHPS)
  - Patient Assessment of Chronic Illness Care (PACIC)
- Cost of care
  - Pharmacist, equipment
  - Medications
  - Labs
  - Other health care utilization and expenditures
Aims and Outcomes

- To compare UC to TI over 18 months of follow-up
- Primary Outcome: BP control at 6 and 12 months of intervention
  - Measured in research clinic
  - Defined as BP <140/90, or <130/80 if diabetes or kidney disease
- Secondary Outcomes:
  - BP control at 18 months
  - Change in systolic BP and diastolic BP
  - Satisfaction with care
  - Costs of care
Analysis

- Generalized linear mixed models with logit link for binary outcomes
- General linear mixed models for continuous outcomes
- Models include random terms to account for randomization at the clinic level and repeated patient data
- Models include patient variables not balanced at baseline
- Missing data handled using likelihood-based ignorable methods implemented in SAS proc mixed
- Holm’s step-down procedure for multiple comparisons involving key endpoints
Participant recruitment

Recruitment

Mailed letters to **14,692** patients
With elevated BP in EMR

Patients: no response (7361), not interested (3126), not reached (2185)

Screening & enrollment

Patients interested and screened (**2020**)

Patients: ineligible (920), opted out (442), not reached (152), no show (56)

Enrolled **450** eligible patients
Linked to 16 clinics

Randomization

Randomized to Intervention (8 clinics)
**N=228** patients

Randomized to Usual Care (8 clinics)
**N=222** patients
Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>61 years</td>
</tr>
<tr>
<td>Female</td>
<td>45%</td>
</tr>
<tr>
<td>White race</td>
<td>82%</td>
</tr>
<tr>
<td>Hispanic ethnicity</td>
<td>2%</td>
</tr>
<tr>
<td>College degree or higher</td>
<td>48%</td>
</tr>
<tr>
<td>Obese</td>
<td>54%</td>
</tr>
<tr>
<td>History of CVD</td>
<td>10%</td>
</tr>
<tr>
<td>Diabetes or kidney disease</td>
<td>32%</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>148/85</td>
</tr>
</tbody>
</table>

- All baseline characteristics balanced by clinic and treatment group, except for Hispanic ethnicity.
Results

% Blood Pressure Control Over Time

<table>
<thead>
<tr>
<th>Time</th>
<th>Baseline</th>
<th>6 months</th>
<th>12 months</th>
<th>18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>71.8</td>
<td>45.2</td>
<td>52.8</td>
<td>57.1</td>
</tr>
<tr>
<td>12 months</td>
<td>71.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 months</td>
<td>71.8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*P < 0.0001 for all comparisons*

Telemonitoring Intervention
Usual Care
Baseline

6, 12, & 18 months

Blood Pressure Control Composite periods

Telemonitoring Intervention

Usual Care

P = .001

P = .002

Composite % Blood Pressure Control

% Blood Pressure Control

0 0

6, 12, & 18 months

0

Baseline

Composite time periods

Telemonitoring Intervention

Usual Care


**Systolic Blood Pressure**

<table>
<thead>
<tr>
<th>Time from baseline, months</th>
<th>Telemonitoring Intervention</th>
<th>Usual Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>148</td>
<td>148</td>
</tr>
<tr>
<td>6 months</td>
<td>127</td>
<td>137</td>
</tr>
<tr>
<td>12 months</td>
<td>126</td>
<td>135</td>
</tr>
<tr>
<td>18 months</td>
<td>127</td>
<td>133</td>
</tr>
</tbody>
</table>

P-values: P<.0001, P<.0001, P=.004
### Diastolic Blood Pressure

<table>
<thead>
<tr>
<th>Time from baseline, months</th>
<th>Diastolic Blood Pressure, mmHg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>84 (Telemonitoring Intervention) 85 (Usual Care)</td>
</tr>
<tr>
<td>6 months</td>
<td>75 (Telemonitoring Intervention) 82 (Usual Care)</td>
</tr>
<tr>
<td>12 months</td>
<td>75 (Telemonitoring Intervention) 81 (Usual Care)</td>
</tr>
<tr>
<td>18 months</td>
<td>75 (Telemonitoring Intervention) 79 (Usual Care)</td>
</tr>
</tbody>
</table>

- **P<.0001** for Baseline vs. Usual Care at 6 months
- **P=.0003** for Baseline vs. Usual Care at 12 months
- **P=.07** for Baseline vs. Usual Care at 18 months

**Legend:**
- Blue: Telemonitoring Intervention
- Red: Usual Care
## Other study outcomes

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>6 Months</th>
<th>12 months</th>
<th>18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TI N=228</td>
<td>UC N=222</td>
<td>TI N=206</td>
<td>UC N=197</td>
</tr>
<tr>
<td></td>
<td>TI N=197</td>
<td>UC N=191</td>
<td>TI N=188</td>
<td>UC N=182</td>
</tr>
<tr>
<td>Number hypertension medication classes, mean</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TI N=228</td>
<td>UC N=222</td>
<td>TI N=206</td>
<td>UC N=197</td>
<td>TI N=197</td>
</tr>
<tr>
<td>1.6</td>
<td>1.4</td>
<td>2.2***</td>
<td>1.6</td>
<td>2.2***</td>
</tr>
<tr>
<td>Perfect self-reported adherence to antihypertensive medication, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>66.7</td>
<td>66.9</td>
<td>77.4*</td>
<td>61.0</td>
<td>68.6</td>
</tr>
<tr>
<td>Used BP home monitor previous time period, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50.6</td>
<td>42.8</td>
<td>94.1***</td>
<td>43.7</td>
<td>95.4***</td>
</tr>
<tr>
<td>Can include home BP monitoring in weekly routine, mean</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.6</td>
<td>4.5</td>
<td>4.7***</td>
<td>3.8</td>
<td>4.2**</td>
</tr>
<tr>
<td>Can keep BP under control, mean</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.8</td>
<td>3.9</td>
<td>4.2**</td>
<td>3.9</td>
<td>4.2**</td>
</tr>
<tr>
<td>Add salt to food at table, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21.1</td>
<td>19.4</td>
<td>10.3*</td>
<td>18.9</td>
<td>10.4*</td>
</tr>
<tr>
<td>Add salt to food while cooking, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27.3</td>
<td>25.4</td>
<td>15.3*</td>
<td>24.6</td>
<td>13.4*</td>
</tr>
</tbody>
</table>

*P<0.05  **P<0.01  ***P<0.001
Adverse Events

- 60 in Usual Care, 49 in Telemonitoring Intervention
- Most non-cardiovascular hospitalizations
- Events possibly related to study or CVD events
  - 2 allergic reactions to BP meds (both in UC)
  - 7 hypotension events (6 in TI, all with goal <130/80)
  - 7 strokes (5 in UC, 2 in TI)
  - 3 TIA (all in UC)
  - 2 atrial fibrillation (1 in each)
  - 1 MI (in UC)
  - 1 unstable angina (in TI)
  - 2 CABG (both in UC)
Cost of Intervention - Preliminary

- Direct program cost per intervention patient: $1045 over 12 months
- 48% of program costs for MTM Pharmacist services
  - Intervention patients averaged 11 visits with their MTM pharmacist
  - Visits, including preparation and charting, were 34 minutes on average
- 52% of program costs for telemonitoring services
  - Intervention patients used telemonitoring device and data transmission service an average of 10 months each
- Under prevailing market rates: estimate program costs $1350 per pt
- Further utilization cost and cost-effectiveness analyses underway
  - Medications, labs, other healthcare utilization and expenditures
## Other BP Telemonitoring Trials

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Length of Intervention</th>
<th>BP Control Results</th>
<th>Δ SBP</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bosworth, 2011</td>
<td>593</td>
<td>18m</td>
<td>63%</td>
<td>70%</td>
<td>-4</td>
</tr>
<tr>
<td>McManus, 2010</td>
<td>527</td>
<td>12m</td>
<td>N/A</td>
<td>N/A</td>
<td>-5</td>
</tr>
<tr>
<td>Green, 2008</td>
<td>778</td>
<td>12m</td>
<td>31%</td>
<td>56%</td>
<td>-9</td>
</tr>
<tr>
<td>Magid, 2013</td>
<td>348</td>
<td>6m</td>
<td>35%</td>
<td>54%</td>
<td>-12</td>
</tr>
</tbody>
</table>
Conclusions

• Home BP telemonitoring with pharmacist-led care management was safe and highly effective at improving BP control and lowering BP over 12 months

• Improved BP in intervention group was maintained for 6 months after end of intervention and return to primary care

• Resource-intensive, but costs may be reduced by better targeting, individual tailoring and negotiating discounts on telemonitoring

• This intervention may be cost-effective for managing patients with uncontrolled BP, especially if results are sustained during longer follow-up
  • Long-term follow-up study for up to 5 years just started
Questions?

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