Validation of the *Instant Blood Pressure* app

Timothy B. Plante, MD
Bruno Urrea, MD
Zane T. MacFarlane
Roger S. Blumenthal, MD
Edgar R. Miller III, MD PhD
Lawrence J. Appel, MD MPH
Seth S. Martin, MD MHS

Presented by: Timothy B. Plante, MD @tbplante #EpiLifestyle16
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Disclosures

• I have no relevant disclosures
• AuraLife, the maker of the Instant Blood Pressure app is not associated with the Johns Hopkins University or any of its affiliates
• AuraLife was not involved in this trial
Blood pressure (BP)

- Home BP monitoring is recommended for adults with hypertension
  – USPSTF grade A
- Guidelines recommend validation of home blood pressure devices
Mobile health (mHealth) technology

• Portable technology in health care
• Largely unregulated by the FDA
• In 2015 there were >160,000 mHealth apps available for iOS and Android
• 58% of smartphone owners have downloaded an mHealth app
Instant Blood Pressure (IBP) app

- IBP app measures BP with the iPhone’s internal sensors
  - No cuff required
- Not independently validated
- The method by which it measures BP is proprietary and is undisclosed
Commercial success of IBP app

Popularity ranking among all for-sale iPhone apps

IBP App

Angry Birds

From AppFigures.com

≥950 sales/day (n=156 days)
Medical use of IBP app

• IBP app disclaimer: “…for recreational use only.”

• Apple user reviews document use of IBP app in managing:
  – Hypertension
  – Postural orthostatic tachycardia syndrome
  – End-stage renal disease
  – Post-heart transplant care
Objectives

• Our objective was to perform a validation study of IBP app to understand its:
  – Accuracy
  – Sensitivity and specificity of detecting hypertensive levels of BP

• Based on 2013 AAMI/ANSI/ISO validation guidelines
Eligibility criteria

• Inclusion criteria:
  – Interested adults (age $\geq$18 years), referred by their doctor

• Exclusion criteria:
  – Internal devices (e.g., pacemaker)
  – Active arrhythmia
  – Unable to use the app
Study conduct

- August & September 2015
- 85 adults with or without hypertension in 5 ambulatory clinics:
  - General internal medicine (n=1)
  - Cardiology (n=2)
  - Nephrology (n=1)
  - ProHealth research clinic (n=1)
Study design

• BP measurements (order randomized):
  – 2 IBP app measurements
  – 2 standard measurements

• 60 seconds between measurements
IBP app measurements

• Research staff followed manufacturer recommendations
• Devices: iPhone 5s and 6
  – iOS version 8.3
  – IBP app version 1.2.3
• Staff entered self-reported date of birth, sex, height, and weight for each measurement
IBP app instructional video

https://www.youtube.com/watch?v=ovZ3MEO8luQ
Standard BP measurement

• Trained and certified research staff followed a standard protocol
• Devices: Validated, calibrated, automated sphygmomanometers used in NHANES
  – Omron 907
  – Omron 907 XL
Analysis

• Outcomes:
  – Mean absolute difference between IBP app and standard
    • British Hypertension Society (BHS) accuracy grade
  – Sensitivity and specificity for detection of hypertensive measurements
• Visual displays with Scatterplots and Bland-Altman Plots
Baseline characteristics

<table>
<thead>
<tr>
<th>N=85</th>
<th>Mean (SD) or %</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, y</td>
<td>57 (16)</td>
<td>18-81</td>
</tr>
<tr>
<td>Male sex, %</td>
<td>48</td>
<td></td>
</tr>
<tr>
<td>White race, %</td>
<td>61</td>
<td></td>
</tr>
<tr>
<td>Black race, %</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>28 (6)</td>
<td>18-45</td>
</tr>
<tr>
<td>Standard systolic BP, mm Hg</td>
<td>126 (17)</td>
<td>91-174</td>
</tr>
<tr>
<td>Standard diastolic BP, mm Hg</td>
<td>69 (11)</td>
<td>32-101</td>
</tr>
<tr>
<td>Hypertension, %</td>
<td>53</td>
<td></td>
</tr>
<tr>
<td>On medications, %</td>
<td>91</td>
<td></td>
</tr>
<tr>
<td>Owns BP machine, %</td>
<td>65</td>
<td></td>
</tr>
<tr>
<td>Has a smartphone, %</td>
<td>84</td>
<td></td>
</tr>
</tbody>
</table>
### Mean absolute difference: IBP app minus standard BP

<table>
<thead>
<tr>
<th></th>
<th>Mean absolute difference (SD), mm Hg</th>
<th>BHS Accuracy Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic BP</td>
<td>12.4 (10.5)</td>
<td>D (lowest grade)</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>10.1 (8.1)</td>
<td>D (lowest grade)</td>
</tr>
</tbody>
</table>

- **Systolic BP**
  - Mean absolute difference: 12.4 mm Hg
  - BHS Accuracy Grade: D (lowest grade)

- **Diastolic BP**
  - Mean absolute difference: 10.1 mm Hg
  - BHS Accuracy Grade: D (lowest grade)
Systolic BP

Scatterplot

- Falsely elevated BP by IBP app
- Falsely low BP by IBP app

Spearman $\rho = 0.44$ (P<0.001)

Bland-Altman Plot

- At low BP IBP app overestimates
- At high BP IBP app underestimates

IBP App Measurement (mm Hg) vs. Standard Measurement (mm Hg)
Diastolic BP

**Scatterplot**
- Falsely elevated BP by IBP app
- Spearman $\rho=0.41$ ($P<0.001$)

**Bland-Altman Plot**
- At low BP: IBP app overestimates
- At high BP: IBP app underestimates
- Falsely low BP by IBP app

March 3, 2016
@tbplante #EpiLifestyle16
Sensitivity and specificity

• IBP app detection of hypertensive measurements*
  – Sensitivity: 0.225
  – Specificity: 0.922

*Systolic $\geq$140 and/or diastolic $\geq$90 mmHg
Strengths and limitations

**Strengths**
- Accepted validation protocol
- Diverse study participants
- Rigorous design with trained observers
- Followed IBP app manufacturer recommendations

**Limitations**
- Few elevated diastolic BP measurements
- Android IBP app not evaluated
Conclusions

• IBP app is inaccurate
  – Mean absolute difference of 12.4 mm Hg for systolic and 10.1 mm Hg for diastolic
• IBP app achieved the lowest possible BHS accuracy grade
• In our study, 78% of hypertensive readings were misclassified as non-hypertensive
Policy implications

• Relevant mHealth apps should be validated prior to their release
• IBP app and ‘me too’ apps should be recalled
  – Instant Blood Pressure Measure and Monitor
  – Blood Pressure Pocket
Why recall

• This technology is being used by individuals with BP-related conditions
• IBP app sold >148,000 copies and still functions
• ‘Me too’ apps are still available for purchase and have not been validated
RESEARCH LETTER

Validation of the Instant Blood Pressure Smartphone App

Timothy B. Plante, MD; Bruno Urrea, MD; Zane T. MacFarlane; Roger S. Blumenthal, MD; Edgar R. Miller III, MD, PhD; Lawrence J. Appel, MD, MPH; Seth S. Martin, MD, MHS

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  – Zane T. MacFarlane
  – Roger S. Blumenthal, MD
  – Edgar R. Miller III, MD PhD
  – Lawrence J. Appel, MD MPH
  – Seth S. Martin, MD MHS

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  – Jeanne Charleston, RN

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  – Haitham Ahmed, MD

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  – Bayview Nephrology
  – ProHealth Research Unit

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# Regression

<table>
<thead>
<tr>
<th>BP</th>
<th>Male sex</th>
<th>Height (in)</th>
<th>Weight (lb)</th>
<th>Age (y)</th>
<th>HR (BPM)*</th>
<th>Constant</th>
<th>$R^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IBP app</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>-0.246</td>
<td>0.594</td>
<td>0.172**</td>
<td>0.240**</td>
<td>0.024</td>
<td>41.2</td>
<td>0.68</td>
</tr>
<tr>
<td>Diastolic</td>
<td>-0.498</td>
<td>0.144</td>
<td>0.096**</td>
<td>-0.110**</td>
<td>0.029</td>
<td>55.3</td>
<td>0.85</td>
</tr>
<tr>
<td><strong>Standard</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>-0.519</td>
<td>0.604</td>
<td>0.042</td>
<td>0.327**</td>
<td>0.014</td>
<td>59.5</td>
<td>0.12</td>
</tr>
<tr>
<td>Diastolic</td>
<td>-0.199</td>
<td>0.077</td>
<td>0.073**</td>
<td>0.050</td>
<td>0.308**</td>
<td>28.3</td>
<td>0.20</td>
</tr>
</tbody>
</table>

*As measured by the same device (e.g., IBP app or standard)
**$P<0.05$
## Primary outcome* – Mean absolute difference

Mean difference, IBP app minus standard BP (SD), mm Hg

<table>
<thead>
<tr>
<th></th>
<th>Relative</th>
<th>*Absolute</th>
<th>BHS Accuracy Grade[ref]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic BP</td>
<td>-1.2 (16.2)</td>
<td>12.4 (10.5)</td>
<td>D (lowest grade)</td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>7.1 (10.8)</td>
<td>10.1 (8.1)</td>
<td>D (lowest grade)</td>
</tr>
</tbody>
</table>

### Systolic BP

![Graph showing individual measurements for systolic blood pressure](image1)

### Diastolic BP

![Graph showing individual measurements for diastolic blood pressure](image2)
## Accuracy and precision

### Accuracy

<table>
<thead>
<tr>
<th></th>
<th>Mean relative difference IBP app minus standard</th>
<th>Mean absolute difference IBP app minus standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP</td>
<td>-1.2 (16.2)</td>
<td>12.4 (10.5)</td>
</tr>
<tr>
<td>DBP</td>
<td>7.1 (10.8)</td>
<td>10.1 (8.1)</td>
</tr>
</tbody>
</table>

### Precision

<table>
<thead>
<tr>
<th></th>
<th>Mean relative difference standard#1 minus standard#2</th>
<th>Mean absolute difference standard#1 minus standard#2</th>
<th>Mean relative difference IBP#1 minus IBP#2</th>
<th>Mean absolute difference IBP#1 minus IBP#2</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP</td>
<td>&lt;0.1 (5.6)</td>
<td>4.6 (3.2)</td>
<td>-0.2 (5.2)</td>
<td>3.0 (4.2)</td>
</tr>
<tr>
<td>DBP</td>
<td>-0.2 (3.4)</td>
<td>2.7 (2.1)</td>
<td>-0.1 (1.9)</td>
<td>1.2 (1.5)</td>
</tr>
</tbody>
</table>
Precision

Standard measurement, mm Hg

IBP app measurement, mm Hg

Systolic BP

Diastolic BP

Systolic BP

Diastolic BP

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CONSORT flow diagram

Assessed for eligibility (n=105)

Excluded (n=4)
- Atrial fibrillation (n=1)
- Pacemaker (n=3)

Enrolled (n=101)

Discontinued because of sphygmomanometer errors (n=3)

Met prespecified dropping rules for high sphygmomanometer variance (n=13)
- SBP >12 mmHg (n=9)
- DBP >8 mmHg (n=6)

Final analysis (n=85)