Author Contributions: Dr Xu had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Concept and design: Davis, Volkow, Xu. Acquisition, analysis, or interpretation of data: All authors. Drafting of the manuscript: Wang, Volkow, Xu. Critical revision of the manuscript for important intellectual content: Wang, Davis, Kaelber, Volkow, Xu. Statistical analysis: Wang. Obtained funding: Xu. Administrative, technical, or material support: Davis, Kaelber, Volkow, Xu. Supervision: Davis, Kaelber, Volkow, Xu.

Conflict of Interest Disclosures: Dr Davis reported receiving grants from the National Institutes of Health outside the submitted work. No other disclosures were reported.

Funding/Support: The study was supported by the National Institute on Alcohol Abuse and Alcoholism (grant R01AA029831), the National Institute on Aging (grants AG057557, AG061388, and AG062272), the National Institute on Drug Abuse (grant UG1DA049435), the National Cancer Institute (grant R25CA22718), and the Clinical and Translational Science Collaborative of Cleveland (grant UL1TR002548-01).

Role of the Funder/Sponsor: The study funders had no role in the design and conduct of the study; collection, management, analysis, or interpretation of the data; preparation, review, or approval of the manuscript; or decision to submit the manuscript for publication.


Validation Status of Blood Pressure Measuring Devices Sold Globally

Elevated systolic blood pressure (BP) causes more than 10 million deaths every year.1 To identify and manage elevated BP, guidelines from hypertension societies recommend BP measurement using automated cuff-based devices that are clinically validated for accuracy. Validated devices are more likely to be accurate compared with devices without evidence of validation.2 However, regulations in many countries permit devices to be cleared for marketing without evidence of validation. A recent Australian study revealed that only 18% of 278 upper arm cuff and 8% of 162 wrist cuff devices were validated.3 Whether these results are representative is unknown. We analyzed the only validated device listing with information on devices marketed globally, including validated devices as well as those without evidence of validation.

Methods | Analysis was conducted on the publicly available Medaval database current to January 11, 2021.4 Direct database access was provided after contacting the company. Medaval is a for-profit company that provides services for device manufacturers, including checks of validation studies for complete protocol adherence and performing validation studies, which are published in peer-reviewed journals.

Medaval identifies validation studies from monthly searches of PubMed (key words validation, accuracy, evaluation, and blood pressure monitor) and all articles published in the journal Blood Pressure Monitoring. A device was defined as validated if there was evidence of it having passed an internationally accepted validation protocol.5 Devices without evidence of validation were identified via regular, ongoing searches of manufacturer websites, “recommended” lists from consumer organizations, and medical trade fairs. New devices with measurement technology identical to that of previously validated devices are considered “equivalent” in terms of measurement accuracy and can bypass validation testing (details reported in the Supplement). Devices listed as validated, equivalent, or possibly equivalent were considered to have evidence of validation. Inclusion criteria were that devices were automated or semi-automated, were available on the market, and were upper arm cuff or wrist-based (comprising wrist cuff or cuffless wrist wearables together).

The analysis was completed to determine the number of devices, the number of unique device manufacturers, and the percentage of validated devices overall and separately for upper arm cuff and wrist-based devices.

Results | There were 4287 devices, but after exclusions for manual operation (n = 681), measurement at sites other than the upper arm or wrist (n = 61), and obsolescence (n = 134), 3411 blood pressure monitors were included. From 2486 upper arm cuff devices, 248 (10.0%) were validated, 327 (13.2%) were equivalent, and there was no evidence of validation for 1816 (73.0%) (Table). Devices were from companies that distribute across Asia, Europe, Africa, Oceania, North America, and South America, as well as by e-commerce.

From 2486 upper arm cuff devices, 248 (10.0%) were validated, 327 (13.2%) were equivalent, and there was no evidence of validation for 1816 (73.0%) (Table). From 925 wrist-based devices, 52 (5.6%) were validated, 51 (5.5%) were equivalent, and there was no evidence of validation for 768 (85.0%). The median number of upper arm cuff and wrist-based devices listed from each manufacturer was 3 (IQR, 1-7) and 2 (IQR, 1-4), respectively.

Discussion | A minority of automated upper arm cuff and wrist-based devices globally have evidence of validation for accuracy.

Lack of validation may undermine optimal medical practice through increased potential for incorrect hypertension diagnosis and inappropriate care. Global and national policy frameworks, including regulations with enforcement, are
needed, with the goal that all devices meet minimum requirements for independent validation before premarket clearance. Currently, to determine if a device is validated, consumers should check a validated device list.4 A study limitation is that Medaval is a private, for-profit company, which could lead to bias. However, the validation criteria are publicly available, and any unsubstantiated support for manufacturers can be identified independently.

Dean S. Picone, PhD
Norm R. C. Campbell, MD, PhD
Aletta E. Schutte, PhD
Michael Hecht Olsen, MD, PhD
Pedro Ordunez, MD, PhD
Paul K. Whelton, MB, MD, MSc
James E. Sharman, PhD

Author Affiliations: Menzies Institute for Medical Research, University of Tasmania, Hobart, Australia (Picone, Sharman); Department of Medicine, University of Calgary, Calgary, Alberta, Canada (Campbell); School of Population Health, University of New South Wales, Sydney, Australia (Schutte); Department of Medicine, University of Southern Denmark, Odense, Denmark (Olsen); Department of Non-communicable Diseases and Mental Health, Pan American Health Organization, Washington, DC (Ordunez); Department of Epidemiology, Tulane University School of Public Health and Tropical Medicine, New Orleans, Louisiana (Whelton).

Accepted for Publication: December 20, 2021.

Corresponding Author: James E. Sharman, PhD, Menzies Institute for Medical Research, University of Tasmania, Private Bag 23, Hobart 7000, Australia (james.sharman@utas.edu.au).

Author Contributions: Drs Picone and Sharman had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Concept and design: Picone, Campbell, Sharman. Acquisition, analysis, or interpretation of data: Picone, Schutte, Olsen, Ordunez, Whelton, Sharman. Drafting of the manuscript: Picone. Critical revision of the manuscript for important intellectual content: Campbell, Schutte, Olsen, Ordunez, Whelton, Sharman. Statistical analysis: Picone. Administrative, technical, or material support: Ordunez, Sharman. Supervision: Schutte, Sharman.

Conflict of Interest Disclosures: None of the authors have any interests (commercial or otherwise) in Medaval. Dr Picone reported having served as a consultant on BP device validation for HEARTS in the Americas, an initiative of the Pan American Health Organization and that he is supported by a postdoctoral fellowship (T04774) from the National Heart Foundation of Australia. Dr Campbell reported receiving personal fees from Resolve to Save Lives, the World Health Organization, the Pan American Health Organization, and the World Bank and being a special advisor to the World Hypertension League Board. Dr Schutte reported receiving speaker honoraria from Omron, Servier, Sanofi, Novartis, Sun Pharmaceuticals, and Abbott and serving as a consultant on BP device validation for HEARTS in the Americas. Dr Olsen reported receiving personal fees from Astra Zeneca. Dr Sharman reported having served as a consultant on BP device validation for HEARTS in the Americas and being principal investigator of a National Health and Medical Research Council partnership grant (S002665) on cardiovascular disease risk assessment; among the partners listed on that grant is Uscom Limited, a medical technology company that manufactures a central BP monitor. No other disclosures were reported.

Disclaimer: The authors alone are responsible for the views expressed in this article; those views do not necessarily represent those of the Pan American Health Organization.

Additional Contributions: We thank Raj Padwal, MD, PhD (University of Alberta, Canada), and Christian Delles, MD (University of Glasgow, Scotland), for their feedback on the manuscript for important intellectual content, for which they were not compensated.


Table. Validation Status of Blood Pressure Measuring Devices Overall, for Upper Arm Cuff Devices, and for Wrist-Based Devices

<table>
<thead>
<tr>
<th>Validation statusa</th>
<th>No. (%)</th>
<th>Upper arm cuff devices (n = 2486)</th>
<th>Wrist-based devices (n = 925)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validated</td>
<td>300 (8.8)</td>
<td>248 (10.0)</td>
<td>52 (5.6)</td>
</tr>
<tr>
<td>Equivalent</td>
<td>378 (11.1)</td>
<td>327 (13.2)</td>
<td>51 (5.5)</td>
</tr>
<tr>
<td>Validated plus equivalent</td>
<td>678 (19.9)</td>
<td>575 (23.1)</td>
<td>103 (11.1)</td>
</tr>
<tr>
<td>No published evidence of validation</td>
<td>2602 (76.3)</td>
<td>1816 (73.0)</td>
<td>786 (85.0)</td>
</tr>
<tr>
<td>Nonpublished study</td>
<td>36 (1.1)</td>
<td>32 (1.3)</td>
<td>4 (0.4)</td>
</tr>
<tr>
<td>Nonstandard study</td>
<td>24 (0.7)</td>
<td>17 (0.7)</td>
<td>7 (0.8)</td>
</tr>
<tr>
<td>Validation failed</td>
<td>11 (0.3)</td>
<td>8 (0.3)</td>
<td>3 (0.3)</td>
</tr>
<tr>
<td>Medaval audit in process</td>
<td>60 (1.8)</td>
<td>38 (1.5)</td>
<td>22 (2.4)</td>
</tr>
</tbody>
</table>

a Validated indicates a device that has passed scientifically accepted validation protocols; equivalent, a device that is considered technically equivalent or possibly equivalent to a device that has previously been validated; validated plus equivalent, the sum of validated and equivalent devices, to display the total number and percentage of devices with evidence of validation for accuracy. No published evidence of validation indicates a device without published evidence of validation testing; nonpublished study, validation study that has not undergone peer review; nonstandard study, a study testing the accuracy of a device that has not followed a scientifically accepted validation protocol. Medaval audit in process indicates that Medaval is performing an audit of data to determine device validation status and/or equivalence to a previously validated device.

b Percentages in the “all devices” column sum to 100.1% because of rounding.

jama.com

© 2022 American Medical Association. All rights reserved.