# Project aims to validate clinical accuracy of BP measurement devices

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In the U.S., physicians have not had access to readily available information regarding clinical accuracy of BP measurement devices. To address this gap, hypertension experts began to meet in 2015 to create a framework for what would demonstrate validation of a BP device for clinical accuracy . Together, with this group and others, the AMA formalized a set of criteria to aid in determining which BP devices have been validated for clinical accuracy in the U.S.

With criteria established, the AMA provided funding to the National Opinion Research Center (NORC) at the University of Chicago to assist in the design and management of an independent process to determine which BP devices meet the Validated Device Listing™ (VDL) criteria. This independent process resulted in a list of BP devices that have been validated for clinical accuracy.

“With the expected increase in telehealth visits, the need for accurate self-measured blood pressure readings taken at home has never been more important,” said Karen S. Kmetik, PhD, AMA group vice president for Improving Health Outcomes. “Until now, U.S. health care professionals have not had a convenient way to determine whether a patient’s BP device has been validated for clinical accuracy.

“The new US Blood Pressure Validated Device Listing™ is an important step towards a game-changing capability,” said Kmetik. “Utilizing it will help patients and physicians better partner to manage high blood pressure.”

## Independent review of devices

An all-volunteer Independent Review Committee (IRC) was formed to review documents submitted by BP manufacturers. This committee works together to determine alignment with the VDL™ Criteria and come to a consensus on which BP devices qualify for inclusion on the list.

The IRC includes experienced, qualified professionals who are selected based on the following evaluation criteria:

- Extensive publication history on topics related to BP device testing, measurement and clinical impact.
- Knowledge of international validation protocols for BP measurement devices.
- Prior experience conducting clinical testing with BP devices or similar medical devices.
- Prior experience reviewing documentation in certification, standards development, and clinical trials, in a similar capacity.

Each member is cleared by the AMA to ensure relevant expertise in BP measurement and to limit or address potential conflicts. Manufacturer-submitted documentation is distributed by NORC and reviewed by at least two members of the IRC. The members deliberate as needed, and any outstanding questions are brought back to NORC to communicate with the manufacturers. Any manufacturer contacted by NORC is given the opportunity to reply and provide clarifying documentation.

Sixteen BP measurement devices have been approved for the initial release of the VDL, and can be viewed at ValidateBP.org. Additional manufacturer submissions will be accepted, assigned by NORC and reviewed by the IRC on an ongoing basis.

Manufacturers interested in submitting a BP device for inclusion in the VDL can email NORC at VDLsubmission@norc.org for additional information. The next deadline for device submission is June 24, 2020.