

## AMA, AHA developing list of validated BP monitors

JUN 21, 2018

**Sara Berg, MS**

Senior News Writer

---

The 2017 hypertension guideline from the American College of Cardiology (ACC) and the American Heart Association (AHA) recommends that all BP monitors have peer-reviewed publications showing they have been tested using internationally accepted protocols for the validation of clinical accuracy. Yet it is not easy for patients and physicians to find out which BP monitors on the market meet that criterion, so the AMA is working with the AHA to create a validated device listing.

This would provide patients and physicians with a comprehensive, unbiased resource to use when selecting a self-measured blood pressure device to accurately measure BP. As a first step in developing this resource, the AMA and AHA are inviting BP device manufacturers to provide comments and feedback on draft criteria for the clinical accuracy of BP devices. This comment period opened June 18 and extends to July 20.

*AMA Wire®* spoke with two experts about plans to create a validated device listing for BP-measurement devices.

Michael Rakotz, MD, a family physician, is vice president of health outcomes at the AMA. Raymond R. Townsend, MD, a nephrologist, is director of the Hypertension Program at the Hospital of the University of Pennsylvania.

### **Why is accuracy an issue for BP monitors used outside the office?**

**Dr. Townsend:** We have rules and validation codes for how to get the best blood pressure recording on an automatic machine, but most of the blood pressure monitors that you can buy, especially for clinical care, whether they are for a hospital, an office or for home use, have not been validated according to the existing protocols.

And they may be accurate, but we don't know because they have not been put to the test. Consequently, it is a caveat emptor market right now—it's buyer beware. If you act on bad information, you can expect a bad outcome.

### **How does a patient using a BP monitor outside the office affect clinical care?**

**Dr. Rakotz:** Guideline recommendations are that, ideally, anyone suspected of having a new diagnosis of hypertension has out-of-office confirmation of office-based blood pressure readings prior to a diagnosis of hypertension being made and treatment initiated.

When a patient has uncontrolled high blood pressure and comes back to have effectiveness of treatment assessed, the new suggested course of action is to use out-of-office BP measurements to make sure they don't have white coat effect or a masked effect impacting their blood pressure from being in a clinical setting. Being aware of blood pressures that happen when a person is living their life outside of a clinical setting helps clinicians treat patients based on what is most likely their blood pressure in the real world. Out-of-office blood pressures correlate better with future cardiovascular events than conventional manual office-blood pressures. So it makes sense for clinicians to be aware of these blood pressures.

### **How can someone tell if a device is validated?**

**Dr. Townsend:** It may say it on the box, but truth in advertising is always the issue. They may say that this has been cleared by the Food and Drug Administration or approved by the FDA and those words are kind of interchanged sometimes. Consequently, a lot of them are marketed because they are substantially equivalent to some other device that has already been cleared by the FDA—but you don't know how well they work.

**Dr. Rakotz:** This is one of the reasons the AMA, AHA, and a group of experts came together to create a blood pressure validated device listing. It is very difficult to find out whether a device has been validated for clinical accuracy just by looking at the box.

And it is very difficult to go online and start searching for which devices that have been validated for clinical accuracy, and what the results of those tests are. Not all devices for sale have gone through validation testing for clinical accuracy.

### **How does this effort relate to the work of Target: BP?**

**Dr. Rakotz:** The cornerstone of Target: BP™ is measuring blood pressure accurately every time it is measured, whether it is in an office setting or out of the office in the community or at home. In order to get accurate blood pressure measurements, guidelines and experts recommend that people should

use BP measurement devices that have been validated with an internationally accepted protocol with results published.

**Dr. Townsend:** The AMA is committed to having 80 percent of patients with their hypertension under control—that’s part of the target in the Target: BP campaign. And the way you get there is not necessarily through the office blood pressures per se because everyone knows that there are people who go to the doctor’s office and it scares the bejeebers out of them, so their blood pressures are higher in the office. Well, let’s make sure.

Let’s use a validated device that we’ve checked in that patient—so we can trust the readings—and then treat the patient’s home blood pressures rather than the 20 or 30 points higher that it is in the office setting.

### **Why is it important to include manufacturers in this process?**

**Dr. Townsend:** The one thing we don’t want to get wrong is to exclude devices that have been validated. We’re doing our best to try and look for published data or commercially available data. Some companies will make their data on a validation study available, even if it is not published.

**Dr. Rakotz:** One of the goals of having a validated device listing is the hope that manufacturers will follow recommendations for having either peer-reviewed publications of their validation testing or independent third party testing that is done on their devices for clinical accuracy.

This list will contain devices from manufacturers who choose to do that. We’re not ranking devices or saying this device is better than that device. We’re just creating a place for devices that meet these criteria to be listed so that physicians, patients, and pharmacists can go to a website and know that any device listed there has been validated for clinical accuracy.