Are kiosk blood pressure readings trustworthy?

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Background

Out-of-office blood pressure (BP) measurements have been shown to improve BP assessment and is now an accepted and critical part of the diagnosis and management of hypertension. Traditionally, we think of two out-of-office options – ambulatory BP (ABPM) and home BP. Whereas ABPM provides high-value clinical data, the cost of ABPM and its limited availability severely hinder its widespread use. Home BP is a valuable alternative, but many home BP devices have not undergone independent testing to ensure their accuracy and validity. Wrong cuff size and selective data reporting have also been cited as serious concerns while implementing home BP in clinical decision-making.

This statement addresses a third source of out-of-office BP measurement that has excellent potential: automated BP kiosks.

Blood pressure kiosks

Automated BP kiosks are commonly found in pharmacies and worksites across the USA. According to an industry website, these devices allow more than one million self-service BP tests in the USA per day [1]. It appears that the public, and medical caregivers, believe in the accuracy of the devices. Certainly the devices carry the implied endorsement of the pharmacy chain or employer that sponsors the service.

But are they accurate? BP kiosks have been available to the public for decades. A number of independent studies have questioned the validity of various kiosk devices [2–4], and, in the absence of published supporting science, most manufacturers have been unable to counter the criticism.

Another well-documented concern with kiosk accuracy is cuff size. Inappropriate cuff size is a leading cause of inaccurate BP results. Most of the kiosk devices found in pharmacies use a cuff size that is too small for about 63% of the hypertensive population and for 50% of the general population in the USA [5].

In 2004, in this journal, I published a validation study of the PharmaSmart BP kiosk that featured a wide-range cuff of novel design accommodating most adult arms [6]. The device passed both the Association for the Advancement of Medical Instrumentation (AAMI) and BHS standards. This experience caused me to reconsider BP kiosks as a measurement option, and I hoped the clinical validity of BP kiosks being utilized in the USA would be acceptable.

In late 2011 and through 2012, a number of major pharmacy chains announced deployment of new, high-tech BP kiosks. A review of the websites of the BP kiosk manufacturers involved in these announcements revealed a number of accuracy and regulatory claims, but no supporting references or documentation.

As co-chair of the AAMI Sphygmomanometer Committee (which writes the USA National Standard for accuracy for sphygmomanometers), I felt it was time to investigate the clinical validity of BP kiosks being used in public settings. I wanted to see if these BP kiosks had passed AAMI standard testing, or any other standardized testing.

The survey

I conducted a survey of the seven leading North American manufacturer websites and found that only one of the companies provided clinical validation data on their website. I then sent a questionnaire, by registered mail, to the Regulatory Directors of the seven manufacturers asking them to share their validation data and information about their FDA submissions. By the deadline I had set, I had received a response from only one company. Six weeks after the deadline, I called the remaining companies and spoke to (or left messages for) the responsible parties. After that round of calls, a second company sent in a partial response. Three companies openly refused to participate, and two companies implied they would participate but did not.

Only one company provided a complete and satisfactory response (PharmaSmart). The other company that responded provided data from a modified validation protocol conducted internally. They indicated that they were planning to submit a 510-K application. The other five companies provided no data that their products had ever passed AAMI, ISO, or any other standardized testing.

Discussion

Every day, over one million Americans measure their BP in BP kiosks. Because the kiosks may not be accurate, unvalidated devices could lead to large-scale misclassification

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of patients; hence, hypertensive patients are left untreated and normotensive patients are treated unnecessarily.

Device buyers should be mandating peer-reviewed studies confirming AAMI (ISO) compliance, but they likely assume that the FDA has done its due diligence during the market clearance process. The continued deployment of unproven BP kiosks will continue unless thought leadership within the hypertension community improves awareness around this issue.

We should encourage the FDA to take a more proactive role. It is critical that the FDA ensure that all BP kiosk devices cleared for market meet or exceed the AAMI (ISO) standards. Further, the 'off label' use (now allowed by the FDA) of medium cuff sizes by patients with large or obese arms is unacceptable and needs to be addressed. The Sphygmomanometer Committee of AAMI will try to influence the American Heart Association and other influential organizations (the American Academy of Family Practice, American College of Cardiology, American Society of Hypertension, etc.) to exert influence on the FDA in this area. I encourage other leaders within the BP community to do the same.

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

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