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Public-use blood pressure measurement: the kiosk quandary

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Abstract

Out-of-office blood pressure (BP) measurement has led to improvements in diagnosis and management of medical conditions, especially hypertension. Public-use kiosks are readily available, especially in pharmacies, retail stores and worksites. There are more than one million kiosk BPs performed every day in the United States. Blood pressure data from kiosks are being incorporated into health records. There are two major issues concerning many of the currently available kiosks. First, many appear to lack proper validation testing required to ensure accuracy. Second, the BP cuff incorporated into most devices is too small for about 50% of the US adult populations, and an even higher percentage of hypertensive US adults. Concerned physicians and scientists are working with the FDA to correct the issues. Fortunately, there is one currently available kiosk that has successfully addressed both points and can be recommended by physicians for their patients and for purchase to be placed in public sites.

Key words: Out-of-office BP; kiosk; public-use BP; AAMI/ISO Standard testing; small cuff effects on BP

Clinical management of hypertension and other medical conditions often now includes out-of-office blood pressure (BP) measurement. This can be done in various ways, including home measurement of BP, 24-hour ambulatory BP monitoring (ABPM), and public-use BP kiosks. These additional data have led to improvements in the diagnosis and management of hypertension. Twenty-four hour ABPM has high "value" but is expensive, has limited availability, and its performance is generally not reimbursed by health care providers. Home-use BP devices may be very helpful for the health care professional in patient management decisions, but many devices have not undergone acceptable clinical validation testing to show their accuracy for BP measurements. Many home devices offer multiple cuff options, but they are sold separately and the consumer often does not understand the importance of purchasing a cuff of the correct size.

The third mode of out-of-office BP measurement is the public-use kiosk, an automated device frequently located in retail pharmacies and worksites. Such devices offer convenience, low-cost, data tracking, and, in some cases, integration into clinical systems. Assuming the devices provide validated results, they offer physicians, pharmacists and patients an important opportunity both to screen for hypertension and to assist in hypertension management decisions. The aims of this scientific statement are to discuss two major criteria that define a clinically acceptable BP kiosk: proper validation testing to an accepted national standard, and a cuff that is suitable for the particular arm circumference of the patient. Ensuring that these criteria are met can then assure the accuracy of the BP values so measured. Using an incorrect cuff size in the process of measuring BP may lead to misdiagnosis and/or improper treatment. In fact, the FDA has

recently published a consumer update on the importance of using an appropriately sized cuff (<http://www.fda.gov/forconsumers/consumerupdates/ucm402287.htm#cuff>).

Blood pressure kiosks are used at least 1,000,000 times per day in the United States alone.¹ Health professionals tasked with diagnosing and treating hypertension assume that FDA clearance given to a kiosk ensures that the readings are accurate enough to be utilized in the clinical management of the disease. Due to a variety of circumstances, this assumption is not valid, requiring the application of due diligence by the healthcare community. This paper is meant to support health professionals in understanding the key issues, and in recommending an acceptable BP kiosk to their patients.

FDA Clearance

In January of 2014, Dr. Alpert, Dr. Dart, and eight other "concerned citizens" met with FDA officials at the FDA headquarters to discuss the process by which kiosks are cleared for use. During this meeting the FDA acknowledged that much of the 510(k) submissions for these devices, including the raw clinical data, is considered proprietary and confidential and can only be disclosed by the company that owns the 510(k) submission. This can make it very difficult for the public to review the clinical validation information that supported the 510(k) clearance. Further, the FDA is often obligated to clear certain Class II products as long as they meet the basic performance standards of a legally marketed device. For new non-invasive blood pressure devices, this includes an assessment of the device in a patient population, which is defined by the applicable national/international standards. However, for changes to existing devices, clinical evaluation may or may not be required. In addition, the clinical validation testing that is

performed is based on the arm circumference defined for the device. As has been stated earlier, this is often applicable to less than 50% of the general population, despite the kiosk being available to the entire population. In summary, the “concerned citizens” group determined that the FDA 510(k) clearance of public-use BP devices does not guarantee validity or suitability for the general public.

Peer-reviewed Validation

Given the regulatory environment described above, the gold standard for the assessment of the accuracy of measurements made by public-use BP devices is, therefore, peer-reviewed, published validation studies. Over the past two decades investigators have found that certain brands of kiosks do not meet accepted accuracy standards.²⁻⁴ With the exception of an independently validated device manufactured by PharmaSmart, we have been unable to find supporting evidence published in peer-reviewed journals to support the validity of other BP kiosks on the market. In 2012 Alpert published a survey of the seven major manufacturers/suppliers of the kiosks available in the United States.⁵ In preparation for the survey Alpert reviewed the websites of these seven companies and found no references to published validation studies, except for PharmaSmart.^{6,7} Alpert then sent a questionnaire by registered mail to the Regulatory Directors of all seven companies. This was followed by telephone calls in cases of non-response to the mailing. The questionnaire requested the data summaries from validation studies performed per AAMI/ISO or any other recognized standard. Despite multiple requests, the six other companies provided no supporting data from completed studies.

Validated Arm Circumference Range

At health care facilities a trained individual (nurse, aide, physician, etc.) selects an appropriate BP cuff size/width from the available selection. It is generally accepted that the width of the cuff should be at least 40% of the upper arm circumference. For home devices, there might be an individual (e.g., pharmacist) to aid in the selection of an appropriate size cuff. Often such a cuff is not available for the device.

Public-use BP kiosks are unattended, single cuff systems. The patient often has no option to select an appropriate size cuff. Measurements with a cuff that is too small will result in falsely elevated BP readings. A decade ago Graves⁸ brought to light that most of the kiosks at that time used a cuff (33 cm maximum circumference) that was too small for 37% of the general USA population, and too small for 50% of the hypertensive adult USA population. Making matters worse, more recent data from the NHANES data sets⁹ demonstrate the continued "growth" of the arms of the USA population. For example, the "mean" US adult male arm circumference is now 34.1 cm, meaning the average male adult arm circumference is outside the optimal performance range of such devices. However, not all devices have such a limited performance range. The PharmaSmart device⁵ includes a very wide-range BP cuff that accurately accommodates almost all US adults.

The AAMI Sphygmomanometer Committee is responsible for the writing of the American National Standard for validation testing of automated sphygmomanometers. The current and recent versions of the American National Standard have been developed in association with the International Standards Organization Sphygmomanometer

Committee and are accepted world-wide with few exceptions. In May, 2014, the AAMI committee met and approved an amendment relating to kiosk BP measurement. The new requirement, which is in the process of final AAMI approval, states that the kiosk intended for public use must be validated on a range of arm sizes representing 95% of the general adult population. There were additional amendment provisions to improve the labeling and instructions such that individuals with arms outside the intended range (i.e., the range for which the cuff is designed) are made aware that the device may not give accurate BP values. The FDA stated during the January 2014 meeting that they would welcome the updated standard, and that once finalized, and if recognized through the standards recognition process, the FDA would apply the standard for any new 510(k) submission claiming to meet it. This does not resolve the current regulatory issues, but it is a step in the right direction.

Summary

It is important to note the opportunity that validated public-use kiosks offer the US healthcare system in terms of ease of public access, reduced cost of screening/monitoring, and the opportunity to support coordinated care between physicians, pharmacists, and patients. It is equally important to recognize that all public-use BP kiosks are not equivalent. Members of the AAMI Sphygmomanometer Committee and other "concerned citizens" are working with FDA officials to try to improve both device validation and cuff range performance of these devices. In reality, regulatory changes will be slow to take effect, and for the foreseeable future the burden of device accuracy assessment lies with the private sector and the public.

There is a device currently available that has undergone full validation testing⁵ and offers a wide-range cuff validated for almost all US adult arms. We recognize the importance of innovation in out-of-office BP measurement. Therefore, in the interest of public health, we strongly urge those business professionals buying such devices, and those health professionals advising patients on their use, to become better informed and more discriminant in their device selection.

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