APhA2017 MAKING AN IMPACT IN PATIENT CARE

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Annual Meeting & Exposition

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American Pharmacists Association
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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: LCDR Garrette Martin-Yeboah
(Name)

2/24/17 **U.S. Public Health Service**
(Date) **(Organization)**

Subject: Support for clinically-validated blood pressure measurement devices

Motion: Move that APhA adopt the following statements:

1. APhA supports the use of clinically validated blood pressure measurement devices.
2. APhA supports regulations and peer reviewed clinical validation testing for blood pressure measurement devices.
3. APhA promotes public awareness on accuracy of blood pressure measurement devices.
4. APhA promotes pharmacist involvement in blood pressure monitoring.

Background:

This background information is intended to provide a basis for APhA and other pharmacy organizations to consider joining with international hypertension organizations in calling on the private healthcare sector and governments worldwide to address the issue of inaccurate blood pressure (BP) devices and to advocate for accurate BP measurement to ensure proper patient diagnosis and treatment decisions.

Approximately 18-months ago, the APhA Foundation engaged with the American Medical Association (AMA), Association for the Advancement of Medical Instrumentation (AAMI), American Heart Association (AHA), American Society of Hypertension (ASH), and Canadian Hypertension Education Program (CHEP) to form the Coalition for Accurate Measurement of Blood Pressure (CAMBP) with the intent to develop a publicly available Validated Blood Pressure Device Listing (VDL). This VDL will provide consumers and healthcare professionals with a common point of reference for self-measured, clinical use, and ambulatory blood pressure measurement and is expected to be available through CAMBP efforts in November, 2017.

The APhA Foundation's collaboration with AMA has been based on the three following tenets:

1. Our collective intent is to improve care for the patients who we serve, to improve availability of accurate and objective information for clinical decision making, and to enhance meaningful patient-centered, team-based care.
2. We agree that it is important to communicate effectively about the importance of relying upon standards to assure the public that blood pressure measurements are precise, accurate, and trustworthy.
3. We believe that one of the best ways forward is having medicine and pharmacy work together on a clear, concise, collaborative initiative that presents a united front about the necessity of obtaining and utilizing valid blood pressure measurements in our healthcare delivery system.

The 2016 Centers for Disease Control and Prevention (CDC) publication, *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists*, supported by APhA and AMA also emphasizes the importance of measuring blood pressure accurately.

FDA 510(k) Clearance Issues

First, it's important to understand that the FDA classifies non-invasive BP devices as "low risk", and are therefore "class II", subject to the lesser standard of the FDA 510(k) pathway. This is different from the more rigorous FDA "PMA" pathway for "high risk" medical devices. The differences are described here: http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194468.htm

The 510(k) pathway is fundamentally flawed due to poor US legislation, and there is very little staff within the FDA can do within the confines of US law to ensure the safety and efficacy of devices falling under the purview of the 510(k) program. Reference this 2011 congressional report by the Institutes of Medicine (IOM) that called for legislative action to correct the 510(k) issues in the interest of public health and safety: http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years/510k%20Clearance%20Process%202011%20Report%20Brief.pdf

The IOM report outlines the myriad issues concerning the 510(k) program. Please review their comments carefully, including their conclusion:
"The committee concludes that the FDA 510(k) process lacks the legal basis to be a reliable premarket screen of the safety and effectiveness of moderate-risk devices and, furthermore, that it cannot be transformed into one."

From direct experience working with blood pressure device manufacturers, and within standards organizations, and from multiple meetings with the FDA on the specific topic of BP Devices, the following concerns exist about the 510(k) program:

1. **No Transparency:** The public has no access to fundamental information about device performance. The manufacturer has 2 options with their submissions – submit a "Summary" or a "Statement" about the performance testing. The "summaries" posted on the FDA website contain little to no useful data in assessing the quality of the validation study. The "Statement" contains less, and the manufacturers that used the "statement" option are supposed to provide data to individuals asking for such data in a timely manner. As Dr. Alpert discovered in his published survey of kiosk manufacturers such inquiries are generally met with silence. The public can make a freedom of information request of the FDA but this process takes years, and the manufacturer in this case STILL has great flexibly to redact data as they see fit – clearly not a solution.

2. **No Assurance of Independent Testing:** It is common for manufacturers to perform "in-house" clinical testing of BP devices on their employees, by their employees, in the employer setting, with employees drafting the data analysis and submitting the reporting to file, or to the FDA. This raises obvious conflict of interest issues and calls into question the legitimacy of such data. Further, there is no way for the public to know whether a device has been cleared based on independent tests data, or "in-house" test data.

3. **Unclear Standards Applied:** FDA representatives have informed the AAMI Standards committee that the AAMI standard is used as a "guideline" for reviewing data, but that it is at the discretion of the reviewer to make exceptions when applying the standard. It is also possible that other, less rigorous worldwide standards (such as the ESH protocol, which is not recognized by ISO) may be deemed acceptable to certain FDA reviewers.

4. **No Peer Review:** Clinical data are not peer reviewed by experts outside the FDA prior to pre-market approval, and it is unclear the quality of the training nor knowledge of FDA peer reviewers in the highly specialized domain of BP device validation.

5. **Substantial Equivalence (SE):** The SE ruling is the most commonly applied ruling in 510(k) pre-market clearances. Despite the complexities of device algorithms, cuff design variations, module hardware changes, software changes, etc, devices can be cleared with "no testing required" based on a manufacturer claim of substantial equivalence to a predicate device.

6. **Letter to File:** Many manufacturers release re-engineered BP device models under existing 510(k) numbers without making any submission to the FDA under the "letter to file" option. In these instances, there is clearly no supervision and enforcement/inspection is severely lacking.

7. **No Intended Use Enforcement:** In the case of BP Kiosks, many devices have been cleared for which the intended use is "general public", yet the same clearance documents (and the required labelling) make it clear that the devices are not appropriate for large arms (approximately 45% of the US adult population). The 510(k) legislation mandates that if the labeling is accurate the device is legal, and essentially it is up to the public to ensure they are following the labeling instructions (with are generally not visible to the public). During one meeting between concerned citizens and the FDA, the FDA representative stated that they "can't regulate against ignorance". In this case the FDA is essentially clearing the way for off-label use of a BP device on a massive scale. The same is true with many other devices sold in the market that are intended for limited arm sizes.

8. **No Enforcement of False Claims:** Many device manufacturers tout their status as "FDA Approved", which is a false claim implying a much higher standard of validity than the 510(k) ever intended with its industry-friendly premarket approval approach. Devices are not "approved"; they are cleared to be legally marketed. There is apparently no proactive program within the FDA to monitor and enforce such false manufacturer claims.

The multi-layered issues with the 510(k) program indicate the issues are intractable and that small "adjustments" will not reestablish public confidence in the 510(k) ability to ensure the "safe and effective" use of BP devices across the US. Short of a legislative overhaul of the 510(k) program, the best solution will be the implementation of transparent and open device review programs driven through clinical organizations such as the AMA, APhA, AHA, and others. No opaque and secretive device validation and review process will be sufficient to establish the trust of the clinical community. The device validation process must be exposed to the light of public scrutiny. The healthcare stakes are extremely high, and unfortunately the required reform cannot happen with the confines of existing government regulatory framework.

Blood Pressure Kiosk Issues

APhA posted a Facebook page story in May of 2016 (see link below) about a local news reporter investigating the accuracy of in-store blood pressure kiosks. Two of the pharmacists interviewed admitted that they devices were not clinically sound. It seems counter intuitive that APhA does not have a position or policy statement on the appropriate use of clinically validated BP measurement devices by pharmacists.
http://www.ksby.com/story/31846334/ksby-news-investigates-how-accurate-are-in-store-or-at-home-blood-pressure-monitors

APhA should join with international hypertension organizations calling on the private healthcare sector and governments worldwide to address the issue of inaccurate blood pressure (BP) devices. Noting inadequate regulatory control and lack of published evidence for many devices, the authors of the "Position Statement" described below called for immediate action to ensure accurate patient diagnosis and treatment decisions.

Recent position statements on Public-Use Blood Pressure (BP) kiosks from both the American Society of Hypertension (ASH) (2015) and the World Hypertension League (WHL) (2016), warned healthcare providers against the use of clinically questionable, pharmacy-based blood pressure kiosks, many of which are not designed for patients with large arm sizes, and/or which have not been subject to peer-reviewed clinical validation testing. In addition, the FDA has issued a consumer alert, advising the public some BP Kiosk devices, while cleared by the FDA, fail to provide accurate results for many users. Both ASH and WHL indicated that accurate and reliable BP Kiosk options are commercially available, and stated that it is the responsibility of healthcare professionals to make informed and buying decisions in the best interests of their patients.

BP kiosks are located in over 25,000 US pharmacy locations, performing approximately one million BP tests every day. It is critical to the profession of pharmacy that the APhA provide strong leadership on this topic in the interest of patient safety and optimal patient care.

US hypertension leaders view insufficient regulatory oversight as a major impediment to improved blood pressure control rates. Because inaccurate measurement confounds the diagnosis and management of hypertension, it also undermines efforts to reduce incidences of stroke, heart attack, diabetes, and other cardiovascular conditions linked to hypertension.

According to the American Society for Hypertension:

"The Food and Drug Administration (FDA) published a consumer health information bulletin in 2014 referencing the shortcomings of many kiosks and the frequently inaccurate BP values obtained. The FDA recommended to the public that if a person had questions relating to BP kiosks that he/she should ask his/her doctor for advice.

Kiosks are free-standing units. The kiosk has a single-size cuff designed into the unit. The user does not have the opportunity to select a cuff of appropriate size for his/her arm. Blood pressure readings performed with a cuff that is too small for an arm may give erroneously high BP values.

Alpert et al summarized the current arm sizes of United States citizens and stated that the average United States male has an arm circumference of 34.1 cm. For most kiosks, the maximum arm circumference that can fit into the cuff is 33-34 cm. That means almost half of the United States population cannot expect to use those kiosks and obtain an accurate BP reading. In the United States alone, there are over a million kiosk readings done per day. The public health implications of this magnitude of incorrect BP readings being used for diagnosis and management of disease are of serious concern.

Clinicians are often faced with the decision as to whether the occasional in-office reading is an adequate basis for developing or modifying a treatment plan for hypertension or whether out-of-office readings can be reliably substituted to derive an optimized antihypertensive medication regimen. The kiosk approach to BP measurement presents a quandary to both patient and physician if it may not provide reliable information as when the kiosk has not undergone ANSI/AAMI/ISO validation and if an inappropriate size cuff is used, raising management questions.

Blood pressure measurement is not a recreational activity, it is a clinical service that has major implications on clinical decisions and health outcomes. Among other professional organizations recognizing the impact of accurate blood pressure management are the American Medical Association and the American Heart Association. They have joined together to

create Target:BP. This initiative is designed to raise awareness about the dangers of hypertension, and to provide resources to help patients effectively manage their blood pressure.

Dr. Mark Niebylski, CEO of the World Hypertension League (WHL) has stated, "There is a growing global consensus for improved BP device quality. New guidelines in the US call for self-measurement outside the office setting, but patients and providers are unsure what devices can be trusted. The WHL supports urgent regulatory action in the US, and internationally, to address this healthcare issue."

Asked about the role of community pharmacy, Dr. Niebylski added, "Pharmacies have an enormous opportunity to support improved BP control in the US, and to coordinate care with primary care physicians. But as the FDA and multiple clinical organizations have pointed out, recreational and 'gamification' blood pressure kiosks are providing inaccurate readings to millions of Americans. This is unacceptable to the WHL, and the clinical community in general. We urge pharmacies to upgrade into clinically valid BP Kiosk devices so that they can become an integral part of the hypertension care team. This issue goes to the core of professional trust between physicians and pharmacists."

Recreational kiosk companies (those with no clinical accuracy validation) have claimed that their devices generate 'meaningful health data'. How can their blood pressure data be 'meaningful' when the FDA and multiple physician groups have issued warnings about their technology in order to protect patient health? Additionally, millions of pharmacy customers use recreational blood pressure kiosks 'off-label', meaning the cuff is not designed to properly accommodate their large arm size. The situation is dangerous to patients, damages the reputation of the pharmacy profession, and is contrary to the hard-fought efforts of pharmacists nationwide to earn healthcare provider status.

Per the ASH and WHL recommendations, this policy should recommend that pharmacies use blood pressure kiosks that a) have been validated through peer-reviewed clinical trials to be clinically accurate (in accordance with the existing ISO standards), and b) employ a cuff size proven to accommodate at least 95% of the US adult population. In order to maintain their position as trusted health care professionals, pharmacists should not support use of unproven, or "recreational" medical devices in their professional environment or place of business.

Ensuring high standards for blood pressure measurement across the pharmacy profession will increase the trustworthiness of the profession, and will support efforts to contract with payers or providers for hypertension-related clinical services.

In conclusion, kiosk BP values can be of use in the diagnosis and treatment of patients, especially for the diagnosis of hypertension. The physician and patient need to be aware of the validation status, not just FDA clearance, and be knowledgeable about proper cuff size effects on BP measurement accuracy. It is our hope that all kiosk BP manufacturers will undergo independent validation of their devices using AAMI recommendations, or another acceptable standard, to foster confidence in the ability of kiosks to provide BP readings accurate enough to be useful in clinical care management."

References

1. http://onlinelibrary.wiley.com/doi/10.1111/jch.12782/abstract
2. https://www.ash-us.org/documents/files/2015/150422-DOCUMENT-Guide-Public-Use-BP-Kiosks-%283%29.pdf
3. http://onlinelibrary.wiley.com/doi/10.1111/jch.12671/epdf
4. http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm402287.htm

Current APhA Policy & Bylaws:

2016 Point-of-Care Testing

1. APhA recognizes the value of pharmacist-provided, point-of-care testing and related clinical services, and it promotes the provision of those tests and services in accordance with the Joint Commission of Pharmacy Practitioners Pharmacists' Patient Care Process.

2. APhA advocates for laws, regulations, and policies that enable pharmacist-provided, point-of-care testing and related clinical services that are consistent with the pharmacists' role in team-based care.

3. APhA opposes laws, regulations, and policies that create barriers to the tests that have been waived by the Clinical Laboratory Improvement Amendments (CLIA) and that are administered and interpreted by pharmacists.

4. APhA encourages use of educational programming and resources to facilitate practice implementation of pharmacist-provided, point-of-care testing and related clinical services.

5. APhA supports patients taking active roles in the management of their health, including their ability to request and obtain pharmacist-provided, point-of-care tests and related clinical services.

6. APhA advocates for access to, coverage of, and payment for both pharmacist-provided, point-of-care tests and any related clinical services.

1991 Mission of Pharmacy

APhA affirms that the mission of pharmacy is to serve society as the profession responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes.

(Am Pharm NS31(6):29 June 1991) (Reviewed 2004) (Reviewed 2010) (Reviewed 2015)

2012, 2002, 1964 Health Education: Selection of Pharmacist

APhA supports education of consumers about the importance of selecting their personal pharmacist to assist them in the proper use of all medications and medical devices.

(JAPhA NS4:429 August 1964) (JAPhA NS42(5):Suppl. 1:S62 September/October 2002) (Reviewed 2007)(JAPhA NS52(4) 459 July/August 2012)

2002, 1984 Depiction of Pharmacists in Public Media

APhA supports the development of guidelines or standards to enhance the depiction of the pharmacy profession in all public media.

(Am Pharm NS24(7):60 July 1984) (JAPhA NS42(5: Suppl. 1:S62 September/October 2002) (Reviewed 2006)(Reviewed 2011)

2013, 1995 Pharmacists' Role in the Development and Implementation of Evidence-Based Clinical Guidelines

1. APhA advocates direct involvement of pharmacists in the development, evaluation, and implementation of evidence-based clinical guidelines. Well-designed guidelines promote an interdisciplinary team approach to patient care that utilizes pharmacists' expertise in optimizing patient outcomes.

2. APhA believes that evidence-based clinical guidelines should promote optimal patient care built on the best available scientific data. These guidelines should be developed using an interdisciplinary approach and should be evaluated regularly to ensure that they reflect current practice standards.

3. APhA should promote educational programs, products, and services that facilitate the participation of pharmacists in the development, evaluation, and implementation of evidence-based practice guidelines in all practice settings.

4. APhA advocates the use by pharmacists, in all practice settings, of evidence-based practice guidelines for pharmaceutical care built on the best scientific data to optimize patient outcomes. These guidelines should be developed using an interdisciplinary approach and should be evaluated regularly to ensure that they reflect current practice standards.

(Am Pharm NS35(6):37 June 1995) (Reviewed 2003) (Reviewed 2008)(JAPhA53(4):366 July/August2013)

****Phone numbers will only be used by the New Business Review Committee in case there are questions for the delegate who submitted the New Business Item Content.**

New Business Items are due to the Speaker of the House by **February 22, 2017** (30 days prior to the start of the first House session). Consideration of urgent items can be presented with a suspension of the House Rules at the session where New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email at hod@aphanet.org.