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SPECIAL ISSUE

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Accurate blood pressure measuring devices: Influencing users in the 21st century

Eoin O'Brien MD, DSc, FRCP[1] | Bruce S. Alpert MD[2] | George S. Stergiou MD, PhD, FRCP[3]

[1]The Conway Institute, University College Dublin, Dublin, Ireland

[2]Department of Pediatrics, University of Tennessee Health Science Center (Retired), Memphis, TN, USA

[3]Hypertension, Hypertension Center STRIDE-7, School of Medicine, Third Department of Medicine, Sotiria Hospital, National and Kapodistrian University of Athens, Athens, Greece

Correspondence
Eoin O'Brien, DSc, FRCP, Adjunct Professor of Molecular Pharmacology, The Conway Institute, University College Dublin, Dublin, Ireland.
Email: eobrien@iol.ie

Hypertension is now recognized as a major global cause of morbidity and death. All decisions relating to the epidemiology, diagnosis, and management of hypertension are dependent on being able to measure blood pressure accurately. Scientists have developed protocols to assess the accuracy of blood pressure–measuring devices, but little attention has been given to informing users which devices are accurate and inaccurate. This article identifies a recipient audience of researchers, clinicians, and scientists, the public, healthcare executives and administrators, and consumer and regulatory bodies, and discusses how best to communicate the results of device accuracy to these groups with the aim of improving the accurate measurement of blood pressure.

1 | INTRODUCTION

High blood pressure (BP) is a global healthcare crisis. According to 2016 Centers for Disease Control estimates, 67 million American adults have high blood BP, and only half of them have their BP controlled. Hypertension causes approximately 1000 deaths per day in the United States, and costs the US healthcare system US$ 47.5 billion annually in direct medical expenses.[1] It is often forgotten that these daunting statistics, and indeed all surveys, guidelines, and recommendations are based on a measurement—a measurement that is assumed (erroneously) to be accurate.[2] Many protocols have been developed over the past 50 years to improve the accuracy of BP-measuring devices, and the leading bodies involved in device validation have recently agreed to develop a universal protocol for the evaluation of future BP-measuring devices.[3] Desirable and commendable though this initiative will be, a universal protocol to evaluate the accuracy of BP-measuring devices is of little practical use unless the results of the validation procedures leading to accuracy recommendations are communicated effectively to the desired recipient community. This audience has not been clearly categorized, and, consequently, the most effective means of communication has not been defined.[2]

2 | RECIPIENT AUDIENCE

At least five groups constitute the recipient audience that would benefit from BP device accuracy information, some of which have common characteristics.

- *Researchers, clinicians, and scientists*: BP measurement working parties of a number of bodies, such as the European Society of Hypertension, the World Hypertension League, the British Hypertension Society, and other organizations, such as the American Association for the Advancement of Medical Instrumentation and the International Organization for Standardization all share major aspirations, namely to uphold the necessity for accuracy and the importance of device validation. However, even among clinicians, many of whom are involved in research, the complexity of achieving device accuracy in the community is often not appreciated. This deficiency within bodies interested in hypertension is even greater in other specialties, such as cardiology and diabetology, where the potential consequences of inaccurate BP measurement may result in erroneous assessments and therapeutic recommendations.
- *The public:* This most important group includes healthy people who wish to protect their cardiovascular health, but also, and of greater concern, patients with hypertension and other associated illnesses who may have treatment prescribed or adjusted on the basis of BP measurement. It is forecast that the global BP monitoring market will exceed US$ 2.6 billion by 2020[4]—an estimate that is based on the current practice of being able to market devices of unknown accuracy to a largely unquestioning public. The sale of inaccurate devices to "healthy" people may be dismissed as being of no significant consequence, but if incorrect normal results are provided, when in fact the BP values are elevated,

diagnosis and timely treatment may be delayed, whereas incorrect elevated measurements may lead to unnecessary anxiety, investigation, and costs. However, the sale of inaccurate devices to patients with hypertension has much greater potential to cause harm because therapeutic decisions may be influenced by these measurements.

- *Healthcare executives and administrators*: This category is composed of the decision purchasers in hospitals, healthcare trusts, pharmacies, and clinical practices, who have an important role in deciding which devices to purchase for operating theaters, wards, and clinics throughout the healthcare system. Unfortunately, there is evidence that without adequate guidance the cost of BP-measuring devices, rather than their accuracy, may be of more importance, or unfounded and unchecked accuracy claims by manufacturers for devices may prove persuasive.
- *Consumer bodies*: Consumer organizations have not given due attention to the scientific requirements to assess BP device accuracy. In a review of BP monitors, a popular consumer magazine in the United Kingdom, *Which?*, with a following of 1.5 million people, although stating that the devices were tested according to international protocols, shows no evidence that the devices were tested in the patients with hypertension as is stipulated in these protocols.[5] This is crucial in determining the accuracy of a device, because a device that is accurate in patients with normotension may well be inaccurate in the patients who will use it most, namely patients with elevated BP. Of the 14 devices listed in the Which? evaluation, the only one to fulfil the criteria of the 2010 European Society of Hypertension International Protocol was categorized in the "Don't Buy" category. This example illustrates the difference between consumer and scientific processes of evaluation and highlights the need for closer collaboration to achieve the common goal of providing users with the most accurate BP-measuring device.[3]
- *Regulatory bodies:* There are many national and international regulatory bodies for medical devices and it is outside the scope of this review to examine these in detail. The major regulatory body in the United States is the Food and Drug Administration (FDA). Although its authority is operational in the United States, its influence is international.[6] Unfortunately, however, it is assumed that if a device is cleared by the FDA, it will provide accurate results. This belief is incorrect, and the ensuing confusion is dangerous, confounding the diagnosis and treatment of high BP and contributing directly to nearly 1000 deaths per day.[7] The FDA, while acknowledging that "all NIBP manufacturers must demonstrate basic safety and essential performance and be subjected to a clinical validation as part of demonstrating substantial equivalence to a predicate device" admits that "the standards currently do not require the testing to be completed by an independent third party."[8,9]

  The FDA clears devices (but does not approve or recommend) through what is known as the 510(k) process. This is part of a law passed in 1976, which allows substantial equivalence to a device already cleared and marketed. This FDA process is primarily aimed at safety, with less emphasis on accuracy, for which the term "effectiveness" is used instead. An update of the 1976 law, enacted in 1990, permits substantial equivalence to an existing post-1976 device. The Institute of Medicine (IOM), a "gold standard" evaluation organization, has published a review of the effectiveness of this entire process.[8] The IOM found that the 510(k) process cannot serve as a valid test of accuracy of a new device as long as the definition of substantial equivalence is not enforced. The IOM report and the authors of this article believe that for every device with significant changes from an already cleared previous version, a separate complete validation study must be performed. The data showing the accuracy of the new device should be available either online or on demand from the manufacturer. We believe that for the United States, for example, Congress should pass new laws to mandate the FDA to perform thorough investigations (including accuracy assessment) of new medical devices proposed for marketing.

  In Europe, non-invasive blood pressure monitors are regulated as medical devices and once CE marked in accordance with the Medical Devices Directive 93/42/EEC they can be placed on the market anywhere in Europe. However, whereas the major focus has previously been on safety rather than accuracy, a new regulatory system for medical devices - the Medical Device Regulation (MDR) 2017/745 - will apply from 2020, and this is likely to give greater attention to performance, ie accuracy, than has previously been the case.[10,11] However, for both regulatory bodies, the major focus is on safety rather than accuracy and although the importance of device accuracy is often stressed, the expertise to make definitive recommendations in this regard is frequently lacking and validation studies performed according to accepted international protocols are cited without critical appraisal. Hence, devices appearing on the market must fulfill stringent safety requirements but are not required to have undergone accuracy testing according to one of the above-mentioned protocols. The collaboration already noted between the Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization bodies is, therefore, a critical initiative that will result in the internationally accepted "universal" protocol for the assessment of BP device accuracy.[3]

3 | METHODS OF COMMUNICATION

Traditionally, the results of successful validation studies have been published in scientific journals or presented at scientific meetings, which serve as a durable reference source, but the results of devices failing validation studies are usually not published.[12] Unfortunately, publications of successful validation studies reach a relatively small group of scientists and have little impact on most of the groups listed above. Website communication of validation results could be an effective means of reaching a broader audience, but the recommendations denoting accuracy or inaccuracy of devices on such sites must be overseen by independent scientists to avoid the conflicts of interest that may influence recommendations.[2]

4 | LEGAL CONSIDERATIONS

Living as we do in a litigious age, it is perhaps surprising how little consideration has been given to the potential legal consequences of inaccurate BP measurement. The failure to provide ambulatory BP monitoring to determine BP over 24 hours in patients with hypertension has been acknowledged.[13] However, until recently, the legal consequences of a device giving erroneous information to patients with the consequent potential for incorrect diagnostic or therapeutic action has gone unchallenged. The most celebrated instance was the collapse of the biotech startup company Theranos, which had attracted investment amounting to more than US$ 700 million.[14] Of greater relevance to BP measurement is the recent ruling by the US Federal Trade Commission in that the "marketers of a mobile app designed to measure blood pressure have agreed to settle Federal Trade Commission (FTC) charges that they deceived consumers with claims that their Instant Blood Pressure (IBP) app was as accurate as a traditional blood pressure cuff." The FTC ruled that: "The stipulated federal court order prohibits the defendants from making the deceptive claims alleged in the complaint. It also prohibits them from making any claims about the health benefits of any product or device without the scientific evidence to support the claims."[15] The company, with sales of more than US$ 600 000 in 1 year, had done so with a deceptively simple technique—the user had only to place the right index finger over the rear camera lens of a mobile phone and hold the base of the phone over the heart to obtain a BP "measurement." Not surprisingly, when the device was tested, it was shown to be grossly inaccurate. The important outcome of this case is that patients who use devices to manage their own illness, or medical personnel who use devices to manage patients, can seek redress if they are sold inaccurate devices or if manufacturers make spurious claims for devices without sound scientific evidence.[2]

5 | CONCLUSIONS

The global patient monitoring device market reached US$ 15.9 billion and US$ 16.9 billion in 2014 and 2015, respectively. The market is expected to reach US$ 23.8 billion in 2020, increasing at a compound annual growth rate of 7.1% from 2015 to 2020.[16] This massive fiscal potential for measurement devices is expected to be the most lucrative in the field of cardiovascular health and illness.

It is imperative for the health and protection of people using devices for medical measurements that they can be assured measurement accuracy. As scientists, we must ensure that sufficiently stringent validation protocols are available, that validation studies are monitored properly, that the application of device equivalence is scientifically supervised, that accurate devices are readily identifiable by the medical community and the public, and that a source of reliable information for healthcare professionals, healthcare administrators, and the public is provided. It is clearly also desirable that manufacturers are influenced by scientific considerations to produce more accurate BP-measuring devices, and this is one of the major objectives of all validation protocols.

As scientists our future goal should be to ensure that unvalidated devices cannot be sold to the public. Indeed, this aspiration is endorsed by the *Lancet* Commission on hypertension, which has called, in effect, for regulation of BP-measuring devices: "Ideally, devices should comply with the validity guidelines of scientific societies, rather than just internal testing by the manufacturer, and this information should be clearly available for the customer. Professional societies could also consider providing a seal of approval or certification of blood pressure devices meeting appropriate accuracy standards, which is particularly important given the rapid developments in wearable technologies marketed without validation testing according to current international expectations. ...The seal of approval could, in turn, be used by manufacturers for marketing... a close collaboration between a wide range of stakeholders such as governments, the mobile communications industry, healthcare professionals, the pharmaceutical industry, and professional societies not to only develop and distribute inexpensive, validated, and certified blood pressure monitors, but also to ensure correct use through simple mobile apps and online education endorsed by the professional societies."[17]

CONFLICT OF INTEREST

EOB., G.S., and B.A. have conducted validation studies for various manufacturers and advised manufacturers on device development.

ORCID

Eoin O' Brien http://orcid.org/0000-0001-5417-7977
George S. Stergiou http://orcid.org/0000-0002-6132-0038

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