Non-Validated Home Blood Pressure Devices Dominate the Online Marketplace in Australia: Major Implications for Cardiovascular Risk Management

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Abstract

Self-home BP monitoring is recommended to guide clinical decisions on hypertension and is used worldwide for cardiovascular risk management. People usually make their own decisions when purchasing BP devices, which are often made online. If patients purchase non-validated devices (those not proven accurate according to internationally accepted standards), hypertension management may be based on inaccurate readings resulting in under- or over-diagnosis or treatment. This study aimed to evaluate the number, type, percentage validated and cost of home BP devices available online. A search of online businesses selling devices for home BP monitoring was conducted. Multinational companies make worldwide deliveries, so searches were restricted to BP devices available for one nation (Australia) as an example of device availability through the global online marketplace. Validation status of BP devices was determined according to established protocols. 59 online businesses, selling 972 unique BP devices were identified. These included 278 upper-arm cuff devices (18.3% validated), 162 wrist-cuff devices (8.0% validated) and 532 wrist-band wearables (0% validated). Most BP devices (92.4%) were stocked by international e-commerce businesses (e.g. eBay, Amazon), but only 5.5% were validated. Validated cuff BP devices were more expensive than non-validated devices: median (interquartile range) of 101.1 (75.0, 151.5) versus 67.4 (30.4, 112.8) AUD. Non-validated BP devices dominate the online marketplace and are sold at lower cost than validated ones, which is a major barrier to accurate home BP monitoring and cardiovascular risk management. Before purchasing a BP device, people should check it has been validated at https://www.stridebp.org

Keywords. blood pressure determination; medical device legislation; device approval; wearable electronic devices

Introduction

High blood pressure (BP) is the number one risk factor for cardiovascular disease and mortality worldwide.[1] Accurate BP measurement is important because identification and effective treatment of high BP will reduce the risk of future adverse cardiovascular events.[2] Recent data support the use of home BP for hypertension management because it provides clinical information that is prognostically superior to in-clinic BP and enhances medication adherence with lower BPs.[3-5] This evidence has led to the widespread recommendation for home BP to be used for confirming the diagnosis of hypertension and treatment titration.[6, 7]

When undertaking home BP monitoring, patients are advised to only use BP devices that have been confirmed to be validated for accuracy.[8] However, there is no regulatory requirement for manufacturers of BP devices to adhere to specific validation protocols, nor publicly share the accuracy performance results.[9] This can lead to the marketing and sale of BP devices with poor accuracy,[10, 11] and thus potentially contributing to inferior quality hypertension management and patient health outcomes. To redress this, it is recommended that validation testing be performed by investigators that are independent from manufacturers and aligned with established scientific protocols.[12] Yet, according to unpublished data, less than 15% of BP devices have undergone such validation testing.[13]

Online shopping is used for purchasing goods and services including medical devices. To our knowledge there are no peer reviewed published data regarding the online availability of BP devices that may be used for home monitoring which have been validated according to recognized international protocols. We evaluated the number, type, percentage validated (accurate) and cost of home BP devices available to purchase online.

Methods

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Study overview. This study was designed to provide evidence on the number of validated and non-validated BP devices available for purchase by online consumers. Accordingly, the search was restricted to BP devices available in one country (Australia), as an example in the global online marketplace. It was not possible to conduct a worldwide analysis because the online purchase and delivery of goods crosses international borders, and although large multinational companies have country-specific websites, they may also offer shipping to many other countries. In the first step, a search of online businesses that sell BP devices was conducted by a single reviewer (RD) between 5 and 22 December 2018. Variations of the phrase "blood pressure monitor buy online Australia" were searched and the first five pages of results were examined. The online websites of Australian pharmacies were also examined because these businesses are known to sell BP devices (full details in the Online-only Methods). Upper arm cuff, wrist cuff or wrist-band wearable (cuff-less, multi-function activity trackers) devices purporting to measure BP in an automatic or semi-automatic manner were included in the search because all these types of devices may be purchased by consumers seeking to measure BP at home. Devices targeted only for professional use (e.g. in a hospital or general practice) or those requiring manual auscultation for BP measurement were excluded (see Online-only Methods). In the second step, the validation status of each identified BP device was determined via a search of four online databases (Medaval, PubMed, Google and Dabl Educational Trust). Two blinded reviewers (RD, DSP) conducted the search between 18 January and 5 February 2019 and discordant validation results were discussed with an adjudicator (JES). The study was ruled exempt from ethical review by the Tasmanian Human Research Ethics Committee according to sections 2.1.7 and 5.1.22 of the Australian National Statement on Ethical Conduct in Human Research, 2007 (Updated 2018).

Determining BP device validation status. A device was deemed to be validated if: 1) it had passed a validation study according to an internationally recognized validation protocol for measurement of BP in the general population,[14-18] and the results were published in a peer-reviewed journal or peer-reviewed database, or; 2) the core technology was claimed by the manufacturer to be identical to a device that had previously passed a validation study (referred to as 'claimed equivalence' herein).[19] See Online-only Methods, Table S1 and Figure S1 for more detail.

Statistical analyses. Chi-square and Fisher Exact tests were used to determine if there were statistically significant differences in the number of validated or equivalent BP devices available according to the type of device and the business category (pharmacy, medical, Australian general retail or e-commerce, as per Online-only Methods). The cost of the BP devices was reported as median (interquartile range (IQR)) because the distribution of device costs was skewed. A sensitivity analysis of the number of validated devices was performed after removal of BP devices with no, or incomplete, device information (based on manufacturer name and model number). Mann-Whitney U tests were used to determine whether the costs of BP devices were significantly different based on the type of device and validation status. P values <0.05 were considered statistically significant. Analysis was conducted using R version 3.5.1.

Results

Number and types of validated home BP devices. 4301 items available for purchase from 59 unique online businesses were screened and 1501 BP devices were recorded after irrelevant search results and duplicates devices from the same online businesses were excluded (Figure 1). After duplicates across all businesses were excluded, 972 unique BP devices remained including 278 upper arm cuff, 162 wrist cuff and 532 wrist-band wearable

devices. Of the 972 devices, 6.6% were validated (n=26, 2.7%)[20-39] or claimed equivalence to a previously validated device (n=38, 3.9%).

Of the 278 unique upper-arm cuff devices, 51 (18.3%) were validated (n=18, 6.8% peer-reviewed in a journal; n=1, <1% peer-reviewed and published on Dabl Educational Trust database, http://www.dableducational.org/Publications/2015/ESH-IP%202010%20Validation%20of%20Microlife%20%20BPA3PC.pdf) [20-45] or claimed equivalence (n=32, 11.5%; Figure 2). Accompanying publicly available documents for claimed equivalence were found for 19 of the 32 devices. Of the 162 unique wrist cuff devices, 13 (8.0%) were validated (n=7, 4.3%)[37, 40-45] or claimed equivalence (n=6, 3.7%; Figure 2). Accompanying documents for claimed equivalence were found for four of the six devices. The number of upper arm cuff devices validated or claimed equivalence was significantly greater than wrist cuff devices (χ^2=8.0, p=0.0048). None of the 532 wrist-band wearable devices were validated. Listings of all validated BP devices and those devices that claimed equivalence are in the Tables S2-S3, respectively.

Number and type of validated devices according to business categories. The 59 online businesses included: 16 pharmacies, 20 medical, five Australian general retail and 18 e-commerce websites. There were 124, 79, 12 and 1286 devices available from each business category respectively (Tables S4-S7). Upper arm BP cuff devices accounted for 90.5%, 87.8% and 71.4% of the unique devices sold by pharmacies, medical and Australian general retailers respectively. Wrist cuff BP devices accounted for the remainder. 100% of wrist-band wearables were available from e-commerce businesses and these accounted for 56.5% of devices available from these websites. The remaining devices available from e-commerce businesses were upper arm cuff BP devices (26.5%) and wrist cuff BP devices (17%). Additional results relating to business categories are in the Online-only Results and Figure S2.

Device cost according to validation status. The median device cost was 47.09, interquartile range (IQR; 31.01 to 86.99 AUD; 32.08 IQR 21.14 to 59.30 USD). Upper-arm cuff BP devices were significantly more expensive than wrist cuff BP devices (85.45 IQR 48.67 to 128.75 versus 50.68 IQR 23.99 to 94.77 AUD, p<0.0001; 58.25 IQR 33.18 to 87.77 versus 34.55 IQR 16.35 to 64.61 USD), irrespective of validation status. Upper-arm and wrist cuff BP devices that were validated or claimed equivalence were significantly more expensive than non-validated BP devices (101.14 IQR 75.00 to 151.50 versus 67.37 IQR 30.40 to 112.83 AUD, p<0.0001; 68.95 IQR 51.13 to 103.28 versus 45.93 IQR 20.72 to 76.92 USD). Validated or claimed equivalence BP devices were also significantly more expensive than non-validated BP devices when upper-arm (104.00 IQR 75.90 to 174.00 versus 80.25 IQR 43.00 to 122.02 AUD, p=0.00019; 70.90 IQR 51.74 to 118.62 versus 54.71 IQR 29.31 to 83.18 USD) and wrist cuff (87.32 IQR 67.05 to 110.00 versus 44.47 IQR 23.98 to 94.00 AUD, p=0.0040; 59.53 IQR 45.71 to 74.99 versus 30.32 IQR 16.35 to 64.08 USD) BP devices were analysed separately (Figure S3).

Validation status according to available device information. Complete BP device information (manufacturer name and model number) was listed by the online businesses for 529 (54.4%) BP devices. Upper arm cuff devices more often had complete information available, while incomplete information (only manufacturer name or model number) was most common in wrist-band wearables. There was no information (only generic descriptions) available more often for wrist cuff BP devices. All devices that were validated or claimed equivalence had complete BP device information available (Table S8).

Discussion

This study has several notable findings relating to the availability of home BP devices for online purchase in Australia. First, there was an enormous quantity of devices purporting to measure BP available for consumers to purchase (n=978). Less than a third of these were

upper-arm cuff BP devices, of which only 18.3% from 278 were confirmed to have been clinically validated or claimed equivalence. Second, there were a large number of wrist cuff BP devices of which only a small percentage were confirmed validated or equivalent to another validated BP device (8.0% from 162). Third, more than half of the unique BP devices available for purchase were wrist-band wearables (532 from 972 total devices) for which none were validated. Importantly, the e-commerce websites, including large global companies (e.g. eBay, Amazon), stocked most of the BP devices available for purchase (92.5%), but only 5.5% of these were validated. Lastly, validated BP devices were significantly more expensive than non-validated BP devices. These findings reveal several issues with global implications. Most urgently, public health education is needed to counsel people and healthcare providers on how to purchase appropriately validated BP devices.

International guidelines recognize the value of measuring BP outside the clinical environment, and most advocate the use of self-home BP monitoring to confirm diagnosis and for ongoing management of raised BP.[6, 7] For this purpose, people are advised to acquire upper arm BP devices that have been validated according to an internationally accepted scientific protocol, with results published in the peer-reviewed literature.[8, 46, 47] Unfortunately, there is little practical guidance provided to consumers on how to purchase appropriately validated BP devices (nor information for clinicians on what to advise patients), and our findings show that people are faced with an overabundance of poor quality BP devices online. Since only 6.5% of the 278 upper arm cuff BP devices had been validated with the results published in a peer-reviewed journal, this means that only 18 devices from all 972 available online (1.9%) would be recommended by guidelines for people to purchase for home BP monitoring.[6, 46, 47] A further 32 devices were classed as equivalent based on technological characteristics critical to the BP measurement method being substantially equivalent to a previously validated (predicate) device.[19] This means that if a new device is

deemed equivalent to a predicate device, then the previous validation study is accepted as evidence of accuracy of the new device. However, this has been criticized as a loophole in regulatory procedures that allows clearance of BP devices of unknown accuracy without independent verification.[48] A resulting confusion is that manufacturers may claim clinical validation of a BP device based on equivalence, even though this may be disputed by independent scientific bodies. Thus, it is probable that the inclusion of equivalent devices in our list of validated BP devices will have overestimated the number of accurate BP devices available for online purchase in Australia. Altogether our observations imply a strong likelihood for people unwittingly buying BP devices that are not recommended for clinical use and are more likely to be inaccurate.[10, 11] The extent to which this could adversely influence best-practice clinical care through incorrect home BP values being provided to doctors is not known.

Our data on the prevalence of non-validated BP devices is similar to that estimated by internal company data from Medaval among more than 3000 upper arm and wrist cuff BP devices, for which 87.5% had no independent data on proven clinical accuracy.[13] Although our study was restricted to the online purchasing environment within one country, the findings may be more broadly generalizable, particularly across countries with similar regulation of health devices as Australia and where there is globally connected online trading through e-commerce providers. To our knowledge this is the first study to recognize the preponderance of low price, wrist-band wearable BP devices being marketed for online sale. In terms of validation of these devices, the IEEE Standard for Wearable Cuff-less Blood Pressure Measuring Devices was developed in 2014,[49] but has not been widely used. Therefore, investigators often use traditional validation protocols to determine the accuracy of wrist-band cuff-less BP devices.[50] Whether these devices are being used by patients to measure home BP and report results to health care providers is not known and was not tested

in this study but emphasizes the need for clinicians to clarify the type of BP devices being used by their patients.

Most online businesses do not specifically identify which home BP devices have passed validation testing according to independent protocols separate from internal processes used by manufacturers.[51] This creates a highly challenging marketplace for consumers where there is little emphasis on the importance of accuracy amongst marketing information. To our knowledge, only one study of home BP device owners has examined this issue and found that less than 1% of people purchasing a home BP device cited accuracy as a reason for making the purchase. Moreover, most people made a decision to purchase a home BP device based on ease of use or learnings from an advertisement.[10] Altogether our findings indicate that these problems need to be solved by widespread public health education to counsel people and healthcare providers on how to purchase appropriately validated BP devices. This is relevant to all consumers of BP devices, including individuals, health care providers, businesses, non-government and government organizations. Efforts in this regard are already underway[9, 52] and include the development of online listings of BP devices that have undergone independent validation testing,[53] which can be freely accessed to help people make informed purchasing decisions (see Table 1 for a list of web addresses).

There are some study limitations. Data was only recorded from online businesses and this may have underestimated the amount of BP devices available to consumers through traditional retailers selling BP devices without an online presence. Organizations such as the United States Food and Drug Administration may hold information on BP device validation that is not publicly released. Because BP device validation status was obtained from external (non-government/regulatory) sources there remains the possibility that some validated devices may have been recorded as non-validated. However, the study was designed to replicate the online consumer experience and because this information was not publicly

available, it would not have influenced the overall study conclusions relating to consumer exposure to online BP device purchasing choices. Sales data and the number of people that buy validated versus non-validated devices is unknown and could not be addressed in this study. Nevertheless, high accessibility and low costs of non-validated devices is potentially concerning because these are stocked by large, well-known e-commerce businesses. The analysis was restricted to a specific time period within a rapidly evolving online market that will be subject to change. As an example, in the time since the search was completed, a validated oscillometric wrist-wearable device has come to market, although this is not yet available in Australia.[54] The availability of different cuff sizes is also important for the accurate measurement of BP, but it was beyond the scope of this study to assess this issue. Finally, the study did not test differences in accuracy between validated and non-validated devices. However, previous studies suggest that non-validated devices are less accurate than validated ones.[10, 11]

In conclusion, this study has shown that most upper-arm and wrist cuff home BP devices and all the wrist-band wearable (cuff-less) devices available for purchase online in Australia are non-validated and are cheaper than validated devices. The preponderant online availability of non-validated wrist-band wearable BP devices is a concern because these are not trustworthy for diagnosis or follow-up of raised BP. Most of the BP devices sold online should not be used for clinical decision making, however, it is probable that they are being used for this purpose. These findings could have major implications for best-practice care of people related to high BP and emphasize the importance of widespread public education and advocacy in the area as well as regulation of the device industry to improve the availability of validated BP devices.

Perspectives

Most BP devices available for online purchase and use by patients for self-home BP monitoring have not been tested for accuracy according to internationally accepted standards. Before purchasing or using a BP device, people and health care providers should check that the device has passed international scientific validation standards at the STRIDE BP website (www.stridebp.org) or others listed in Table 1.

Health care providers managing hypertension using home BP values should check with their patients that they are using an upper arm cuff BP device and that it has been appropriately validated. Patients should not use wrist-band wearable devices to monitor home BP, as none are validated. Education, advocacy and strengthened regulatory processes are urgently required for the global improvement in BP device accuracy standards.

Additional research is needed to determine the extent to which non-validated BP devices are being used for home BP monitoring and its impact on cardiovascular outcomes.

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Disclosures

Aletta E Schutte: Has received equipment and funding from manufacturers of BP devices including IEM and Omron.

Norm RC Campbell: Was a paid consultant to the Novartis Foundation (2016-2017) to support their program to improve hypertension control in low to middle income countries which includes travel support for site visits and a contract to develop a survey. He has provided paid consultative advice on accurate BP assessment to Midway Corporation (2017) and is an unpaid member of World Action on Salt and Health (WASH).

Christian Delles reports a role in organising national and international conferences in the area of hypertension that receive, among others, support from device manufacturers.

Raj Padwal: Canadian representative to the ISO Sphygmomanometer committee and sits on the AAMI Sphygmomanometer committee. Co-Founder of a BP measurement start-up company (mmHg Inc.), based at the University of Alberta, with no products currently on the market.

George Stergiou: ISO Sphygmomanometer committee member; Chairman of European Society of Hypertension Working Group on BP Monitoring. Conducted validation studies for various manufacturers of BP measuring technologies and advised manufacturers on device and software development.

James E Sharman: His university has received equipment and research funding from manufacturers of BP devices including AtCor Medical, IEM and Pulsecor (Uscom). He has no personal commercial interests related to BP companies.

The remaining authors have no disclosures.

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Novelty and significance

What Is New?

- Most BP devices available online for self-home BP monitoring have not been validated for accuracy.
- Non-validated BP devices were more likely to be available from e-commerce websites and were cheaper.

What Is Relevant?

- From nearly one thousand BP devices available for online purchase, only a small percentage (<7%) were validated for accuracy. Non-validated devices were more likely to be wrist cuff or wrist-band wearable devices, available from e-commerce businesses and cheaper than validated devices.
- Non-validated BP devices are more likely to be inaccurate, thus these findings represent a barrier to accurate home BP monitoring and cardiovascular risk management.

Summary

This study has shown that non-validated upper-arm cuff, wrist cuff and wrist-band wearable BP devices dominate the online marketplace. Education, advocacy and strengthened regulatory processes are required for the global improvement in BP device accuracy standards.

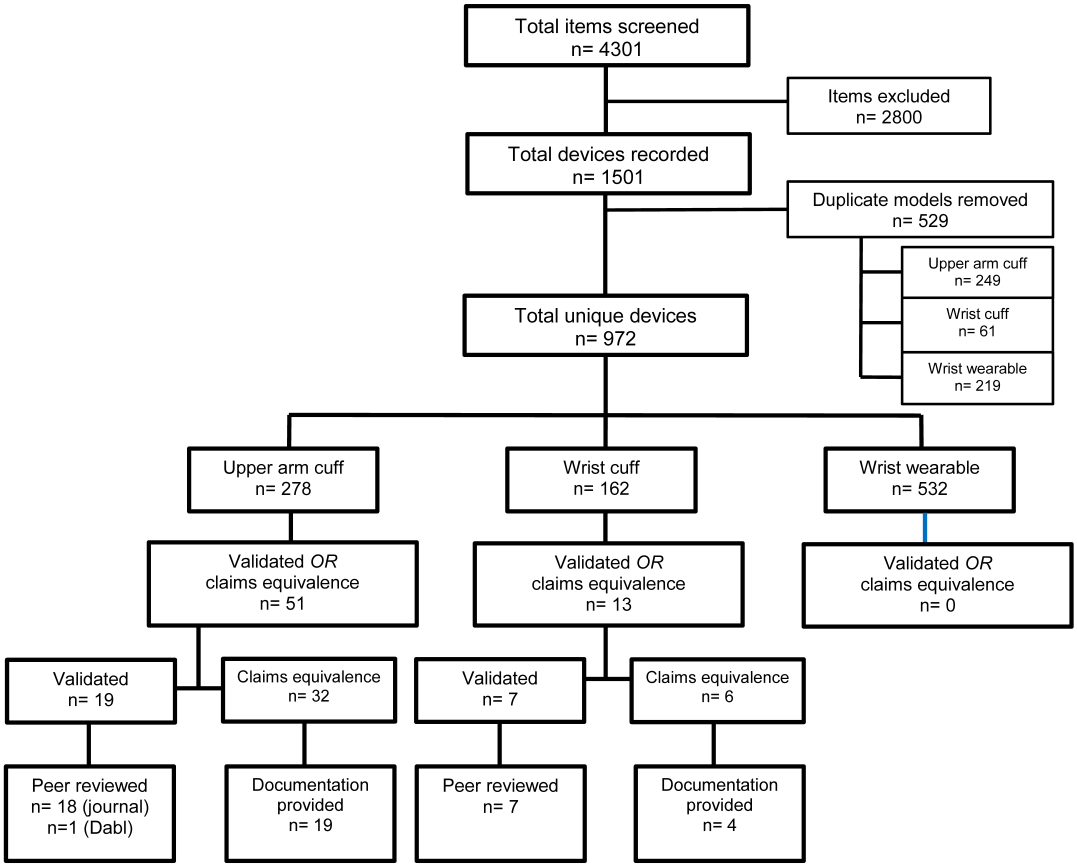
Figure legends

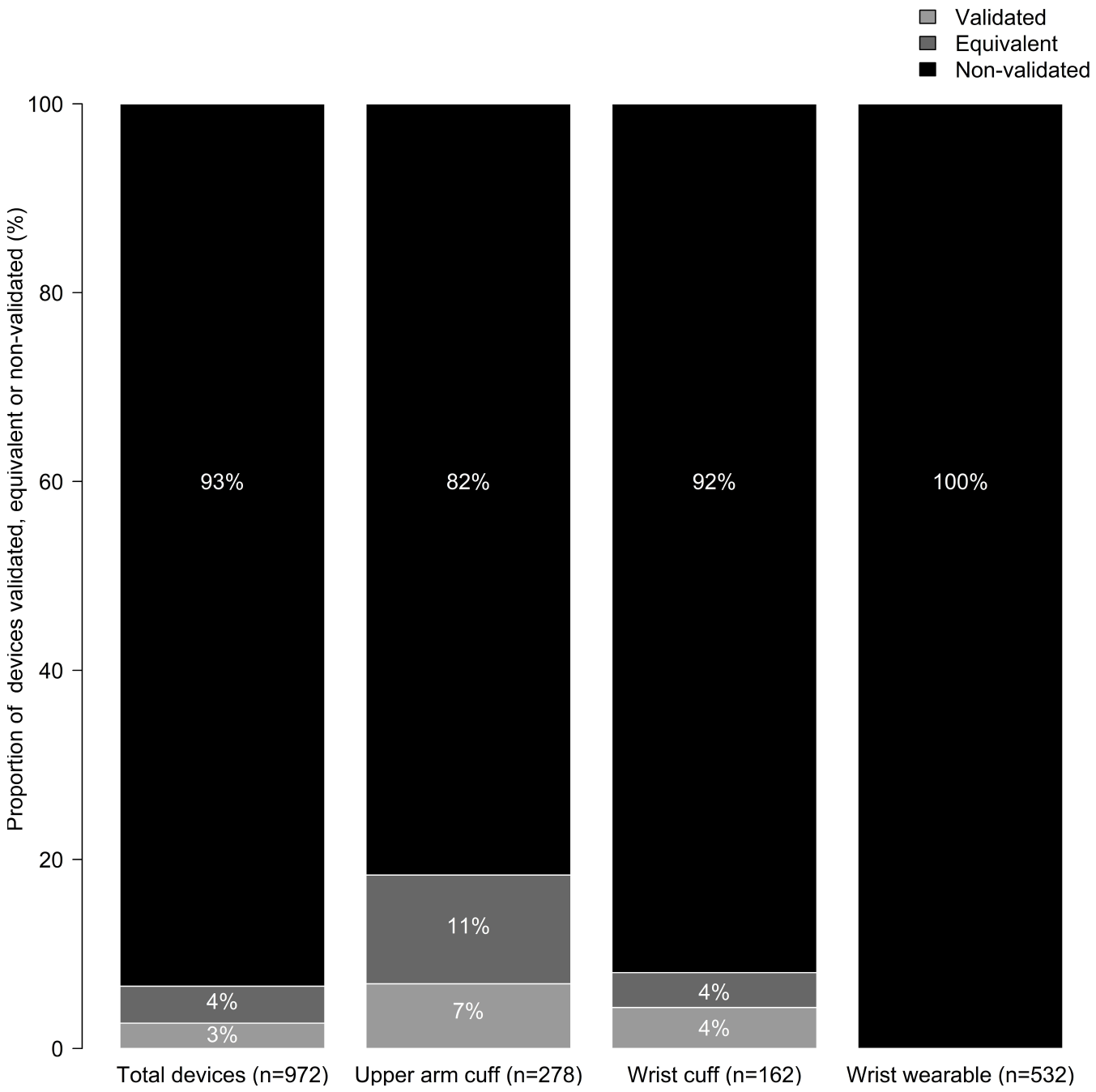
Figure 1. Flow chart of the number of blood pressure (BP) devices available to Australian online consumers. From 972 unique BP devices, only a small number were validated or claimed equivalence to another validated BP device.

Figure 2. Proportion of validated, equivalent or non-validated blood pressure (BP) devices across all devices available for purchase online in Australia. A device was defined as equivalent when there was a claim that the technology was identical to previously validated BP device.

Table 1. Summary of international entities and the web addresses to listings of blood pressure devices that have been independently assessed for accuracy according to scientific validation protocols

Entity holding a listing of validated blood pressure devices	Web address
STRIDE BP	https://stridebp.org/
British and Irish Hypertension Society	https://bihsoc.org/bp-monitors/
Hypertension Canada	https://hypertension.ca/hypertension-and-you/managing-hypertension/measuring-blood-pressure/devices/
German Hypertension Society (in German)	https://www.hochdruckliga.de/messgeraete-mit-pruefsiegel.html
Japanese Society of Hypertension (in Japanese)	http://www.jpnsh.jp/com_ac_wg1.html
Medaval	https://medaval.ie/
dabl Educational Trust (no longer actively updated)	http://www.dableducational.org/
American Medical Association Validated Device Listing	Under development


Total items screened
n= 4301
Items excluded
n= 2800
Total devices recorded
n= 1501
Duplicate models removed
n= 529
Upper arm cuff
n= 249
Wrist cuff
n= 61
Wrist wearable
n= 219
Total unique devices
n= 972
Upper arm cuff
n= 278
Wrist cuff
n= 162
Wrist wearable
n= 532
Validated OR
claims equivalence
n= 51
Validated OR
claims equivalence
n= 13
Validated OR
claims equivalence
n= 0
Validated
n= 19
Claims equivalence
n= 32
Validated
n= 7
Claims equivalence
n= 6
Peer reviewed
n= 18 (journal)
n=1 (Dabl)
Documentation
provided
n= 19
Peer reviewed
n= 7
Documentation
provided
n= 4


Validated
Equivalent
Non-validated
Proportion of devices validated, equivalent or non-validated (%)
100
80
60
40
20
0
93%
4%
3%
82%
11%
7%
92%
4%
4%
100%
Total devices (n=972)
Upper arm cuff (n=278)
Wrist cuff (n=162)
Wrist wearable (n=532)