Received: 14 March 2020 | Revised: 20 March 2020 | Accepted: 25 March 2020

DOI: 10.1111/jch.13868

OPINION

WILEY

The Hypertension Canada blood pressure device recommendation listing: Empowering use of clinically validated devices in Canada

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1 | INTRODUCTION

Automated blood pressure (BP) devices promote standardization of the BP measurement process and enable performance of unattended and out-of-office measurements.[1] Consequently, authors of hypertension clinical practice guidelines and BP measurement consensus statements have strongly endorsed use of automated BP devices proven accurate in a clinical validation study in place of manual auscultation.[2-4] However, resistance to automated BP measurement is widespread among clinicians (especially in developing countries)—partly, due to the proliferation of low-quality, inaccurate devices, which has eroded health care provider confidence in the accuracy of all automated BP measurement.[5] Less than 15% of automated devices sold internationally are validated, underscoring the importance making device validation a pre-requisite to marketing.[2]

To encourage appropriate use of automated BP measurement, end-users must have ready access to a reliable validated device listing so that accurate devices can be easily identified. Several such online listings currently exist, each possessing unique characteristics (Table 1). In a previous introductory paper authored by members of the Accuracy in Measurement of Blood Pressure (AIM-BP) Collaborative, the need to provide further description of these different device listings, including their design, rationale, and unique characteristics, was identified.[6] As creators of the Hypertension Canada Recommended BP Device Listing, we herein detail the rationale for its creation, operational process, areas of uncertainty, and future plans.

2 | RATIONALE FOR THE HYPERTENSION CANADA LISTING

The Hypertension Canada Recommended BP Device Listing, hosted at https://hypertension.ca/bpdevices, re-launched in September 2017, from a legacy device listing. The principal iterative changes from the prior registry were as follows:

1. Host the listing online to ensure ready public accessibility and usability, with digital proximity to the Hypertension Canada Clinical Practice Guidelines.
2. Include contemporary devices and models by requiring manufacturers to re-apply for inclusion.
3. Create a symbol (Figure 1) to indicate clearly to end-users that the device has been clinically validated and the strength of protocol used in the validation study.

The rationale for a national validated device listing, rather than directing Canadians to an international source (Table 1) was threefold:

1. To raise awareness of and emphasize the need for manufacturers to validate devices sold on the Canadian market and for practitioners and the public to use them.
2. To ensure local relevance by using product names, numbers and photographs specific to Canada. Given manufacturers often name and promote the same device differently across markets, it can be difficult for users to easily identify if a locally marketed device model is an equivalent derivative of one previously validated. If between-model differences do not affect the BP measurement process and a clinical validation has been performed, the Hypertension Canada policy is to consider the clinical validation protocol applicable to the original model and derivative device model (further defined next section).
3. To ensure that Hypertension Canada policies were followed in Canada and those incongruent were avoided. For example, the Hypertension Canada Listing ranks the Association for the Advancement of Medical Instrumentation (AAMI)/International Organization for Standardization (ISO) protocol as a "gold standard" protocol on the basis of its larger sample size (85 subjects versus the 33 recommended by the European Society of Hypertension [ESH]), ability to perform subgroup analyses, and more rigorous methods for evaluating reference cuffs and selecting reference standard measurements.[7,8] Conversely, the dabl Educational Trust international BP device listing classifies devices validated using the AAMI/ISO protocol alone as "questionable" yet accepts devices validated using the European Society of Hypertension (ESH) protocol as "recommended."

3 | OPERATIONAL PROCESS FOR THE HYPERTENSION CANADA LISTING

The listing is administered by Hypertension Canada, which collects fees from manufacturers to be listed and for the optional use of the Listing's logo. The process is as follows:

1. The manufacturer submits a request to have a device evaluated for inclusion in the listing using a standardized form. This includes the manufacturer name and contact details, device name and model number, validation standard used in the device's clinical evaluation(s), device type (home, ambulatory, automated office, in-pharmacy kiosk), and cuff sizes. A copy of the clinical validation(s) is appended. Wrist-based home devices are eligible because the Hypertension Canada Clinical Practice Guidelines recommend use of wrist cuffs if an upper arm cuff cannot be used.[3]
2. Applications for derivative devices must include a notarized verification that the BP measurement apparatus of the derivative device is identical to that of the original. A derivative device is one that is identical to a previously validated device in all the components affecting BP measurement. Device components considered to affect BP measurement include the following:
   a. cuff
   b. pressure transducer, amplifier, and digital signal conversion process
   c. inflation/deflation control system including valve, pump, and software

TABLE 1 Currently available major validated device listings

Listing	Scope	Comments
British and Irish Hypertension Society https://bihsoc.org/bp-monitors/	National	1. Divides devices in to home use and specialist use 2. Contains a listing of devices that have failed validation 3. Accepts the BHS or ESH protocol
Hypertension Canada https://hypertension.ca/bpdevices	National	1. Accepts the AAMI/ISO, BHS and ESH protocols 2. Ranks devices into Gold (AAMI/ISO or BHS) or Silver (ESH) status
Validated Device Listing (VDL) for United States Blood Pressure Devices Validatebp.org	National	1. Accepts the AAMI/ISO and BHS protocols 2. Initiative of the American Medical Association 3. Launched in 2019 and will be live in 2020
Japanese Society of Hypertension http://www.jpnsh.jp/com_ac_wg1.html	National	1. Japanese language only
German Hypertension League Quality Seal Protocol https://www.hochdruckliga.de/messgeraete-mit-pruefsiegel.html	National	1. German only
dabl Educational Trust http://www.dableducational.org	International	1. Lists devices validated using the AAMI/ISO protocol as "questionable." Accepts BHS and ESH protocols.
STRIDE BP https://stridebp.org/bp-monitors	International	1. Accepts validations performed using the AAMI/ISO, BHS, and ESH protocols 2. Has sections on home, office, ambulatory, children, and pregnancy 3. Joint initiative of the ESH, International Society of Hypertension, and World Hypertension League
MEDAVAL https://medaval.ie	International	1. Contains information on BP monitors, blood glucose monitors, and pulse oximeters

FIGURE 1 Hypertension Canada Device Recommendation Listing Logo

d. filtering and signal processing software, including waveform processing and interpolation
e. BP derivation algorithm

Examples of device components that are not considered to affect the BP measurement include the casing, BP measurement display, and memory.

3. The application is processed and two conflict-free reviewers from our pool provide independent reviews. All reviewers must have demonstrated expertise in BP measurement and familiarity with BP validation standards, and must declare potential conflicts at least annually.
4. Reviewers indicate whether or not the device has passed requirements for validation and determine the validation ranking. Gold status includes the AAMI/ISO and British Hypertension Society standards, by virtue of their larger sample size and more rigorous methodology, and silver status is assigned to devices using the ESH protocol.[7-10] The latest iteration of each standard is preferred but older versions are, for now, still accepted.
5. Disagreements between reviewers are resolved by a third reviewer, if necessary.
6. The decision is communicated to the manufacturer, and approved devices are added to the listing at https://hypertension.ca/bpdevices displayed by type, brand, model name and number, recommendation level, and available cuff sizes. Manufacturers may then opt to license the Listing's logo for marketing and promotional purposes, including display on their device's packaging.
7. The manufacturers' marketing claims are then monitored to ensure the Lising policies are upheld. Further, the broad Canadian BP device market is monitored to identify and address false accuracy claims (repeated false claims are reported to the national regulator).

As of end-2019, the listing contained 67 distinct BP device models from 13 different manufacturers, of which 48% were gold status (ie, validated by AAMI/ISO or British Hypertension Society standards). This includes 57 home monitoring devices, four in-pharmacy kiosks, three automated office devices, and three ambulatory monitors. Since its relaunch, the device listing website has been accessed 55 837 times as of December 31, 2019. Although not empirically substantiated, we estimate that the vast majority of home BP devices sold in Canadian pharmacies are included in the listing. However, additional research is needed to verify this and examine the impact of the listing on the availability of validated devices in Canada.

4 | AREAS OF UNCERTAINTY AND FUTURE DIRECTIONS

A number of areas of uncertainty in the Listing's criteria have been identified for reassessment and future resolution:

1. *Incomplete reporting*: Published validation studies often contain reporting deficiencies, which may, in some cases, be due to journal word count restrictions. Description of the reference cuff is often missing. To promote validation and encourage manufacturers to perform clinical validation studies, our practice has been to accept studies even if such deficiencies exist, provided that critical elements of the study are present (such as sample size, entry criteria, and accuracy criteria). However, this practice will become more stringent in the future, with full reporting of all elements of a clinical validation required.
2. *Acceptance of different clinical validation protocols*: As described above, AAMI/ISO, BHS, as well as ESH protocols are currently accepted. Although the ESH protocol was to be retired at the end of 2019 and all subsequent clinical validations performed using ISO 2018,[11] we continue to accept the ESH for now to allow manufacturers time to revalidate using ISO 2018.
3. *Acceptance of different versions of the same protocol*: Our current practice is to accept all versions of a protocol, which functionally results in older validation studies being accepted as equivalent to newer studies performed with greater methodologic rigor. This practice will be reassessed going forward.
4. *Guidance on BP device calibration assessment not given*: A device can be clinically validated yet inaccurate in a given patient, possibly because the algorithm is a poor match for that patient or because of unique patient characteristics (eg, vascular stiffness, obese arm).[12] This issue, known as patient-specific calibration, has been discussed elsewhere[13] and requires further assessment and consensus on best practice.
5. *Devices supported by multiple clinical validations*: To date, and absent published evidence demonstrating that devices with multiple validation studies are more accurate than those with single validations, no distinction has been made between devices supported by a single validation study and those supported by multiple studies.

5 | CONCLUSIONS

The Hypertension Canada Recommended BP Device Listing serves as an important repository of validated automated devices sold on

the Canadian market, assisting consumers, patients, and care providers in choosing or recommending a validated BP device. It helps to optimize automated BP measurement in this country and provides useful information specific to Canada. It is hoped that the information provided herein will prove useful to stakeholders in other countries or regions that are considering establishing a similar device listing. We view the establishment of a national device listing as an essential step to implementing national and international clinical practice recommendations emphasizing the importance of using automated BP measurement.

ACKNOWLEDGMENTS

This manuscript was produced as part of the Accuracy in Measurement of Blood Pressure (AIM-BP) Collaborative, an initiative advocating for best measurement practices globally. AIM-BP members and their affiliations can be found on the World Hypertension League web site. The contents of this paper reflect the opinions of its authors and not necessarily all members of AIM-BP.

CONFLICT OF INTEREST

The Hypertension Canada Device Recommendation Listing is funded and administered by Hypertension Canada. RP and JR are Co-Founders of mmHg Inc, a University of Alberta based start-up creating software and hardware solutions to improve blood pressure measurement. AB is CEO of Hypertension Canada. The remaining authors have no conflicts to declare.

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REFERENCES

1. Padwal R, Campbell NRC, Schutte AE, et al. Optimizing observer performance of clinic blood pressure measurement: a position statement from the Lancet Commission on Hypertension Group. *J Hypertens*. 2019;37:1737-1745.
2. Sharman JE, O'Brien E, Alpert B, et al. Lancet Commission on Hypertension Group position statement on the global improvement of accuracy standards for devices that measure blood pressure. *J Hypertens*. 2020;38:21-29.
3. Nerenberg KA, Zarnke KB, Leung AA, et al. Hypertension Canada's 2018 guidelines for diagnosis, risk assessment, prevention, and treatment of hypertension in adults and children. *Can J Cardiol*. 2018;34:506-525.
4. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on clinical practice guidelines. *Hypertension*. 2018;71:e13-e115.
5. Frieden TR, Varghese CV, Kishore SP, et al. Scaling up effective treatment of hypertension-A pathfinder for universal health coverage. *J Clin Hypertens*. 2019;21:1442-1449.
6. Padwal R, Campbell NRC, Weber MA, et al. The accuracy in measurement of blood pressure (AIM-BP) collaborative: background and rationale. *J Clin Hypertens*. 2019;21:1780-1783.
7. Association for the Advancement of Medical Instrumentation. *ANSI/AAMI/ISO 81060–2:2013 Non-Invasive Sphygmomanometers – Part 2: Clinical Investigation of Automated Measurement Type. 2013*. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2013. www.aami.org. Accessed April 10, 2020.
8. O'Brien E, Atkins N, Stergiou G, et al. European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults. *Blood Press Monit*. 2010;15:23-38.
9. O'Brien E, Petrie J, Littler W, et al. The British Hypertension Society protocol for the evaluation of automated and semi-automated blood pressure measuring devices. *J Hypertens*. 1993;11:S43-S62.
10. Ruzicka M, Hiremath S. Accuracy-limiting factor of home blood pressure monitors. *Am J Hypertens*. 2017;30:661-664.
11. O'Brien E, Stergiou G, Palatini P, et al. Validation protocols for blood pressure measuring devices: the impact of the European Society of Hypertension International Protocol and the development of a Universal Standard. *Blood Press Monit*. 2019;24:163-166.
12. Ringrose JS, Polley G, McLean D, Thompson A, Morales F, Padwal R. An assessment of the accuracy of home blood pressure monitors when used in device owners. *Am J Hypertens*. 2017;30:683-689.
13. Cohen JB, Padwal RS, Gutkin M, et al. History and justification of a national blood pressure measurement validated device listing. *Hypertension*. 2019;73:258-264.

How to cite this article: Padwal R, Berg A, Gelfer M, et al; for the Accuracy in Measurement of Blood Pressure Collaborative. The Hypertension Canada blood pressure device recommendation listing: Empowering use of clinically validated devices in Canada. *J Clin Hypertens*. 2020;22:933–936. https://doi.org/10.1111/jch.13868