HEARTS

IN THE AMERICAS

REGULATORY FRAMEWORKS AND VALIDATION OF BLOOD PRESSURE MEASURING DEVICES

QUITO, ECUADOR
3-4 MARCH, 2020

WWW.PAHO.ORG/HEARTS-AMERICAS WWW.SALUD.GOB.EC

PAHO Pan American Health Organization World Health Organization Regional Office for the Americas

MINISTERIO DE SALUD PÚBLICA

Lenín Toda una Vida

EL GOBIERNO DE TODOS

DAY 1: TUESDAY, 3 MARCH 2020

08:30 - 09:00 **Welcome ceremony**
Representatives of the Ministry of Public Health and PAHO

09:00 - 09:15 **Introduction to the agenda, objectives, expected results and structure of the meeting**
Dr. Pedro Orduñez, Regional Advisor, Cardiovascular Diseases, PAHO

09:15 - 09:30 **Hypertension: magnitude of the problem and key actions for its diagnosis and control**
Dr. Norm Campbell, Professor Emeritus, University of Calgary

09:30 - 09:45 **Accuracy of blood pressure measurement: a matter of quality of health services and patient safety.**
Dr. James Sharman, Deputy Director of the Menzies Institute for Medical Research, University of Tasmania

09:45 - 10:00 **Validation of electronic blood pressure measuring devices: what are validation studies and why are they important.**
Dr. Raj Padwal, Professor of Medicine and Co-Director of the Hypertension Dyslipidemia Clinic, University of Alberta

10:00 - 10:15 **PAHO/WHO policies on medical devices towards access and Universal Health Coverage**
Alexandre Lemgruber, Regional Advisor, Health Technologies, PAHO

10:15 - 10:25 **Working groups orientation and group photo**

10:25 - 10:45 **Coffee Break**

10:45 - 12:30 WORKING GROUPS

Regulatory Frameworks - Dr. James Sharman and Dr. Cintia Lombardi

- **Introduction of the participants**
- **Objectives and directions**
- **Country presentations on regulatory environments: legal framework, components, and responsible agencies**
- **Discussion**

Clinical Validation Studies for Accuracy and Precision - Dr. Raj Padwal and Dr. Pedro Orduñez

- **Introduction of the participants**
- **Objectives and directions**
- **General description of the different standards of validation studies**
- **Detailed review of the global ISO 2018 protocol and 2019 amendment**
- **Equipment and configuration of the measuring station**
- **Measurement techniques**

12:30 - 13:30 **Lunch**

13:30 - 16:00 **WORKING GROUPS**

Regulatory Frameworks - Dr. James Sharman and Dr. Cintia Lombardi

- **Country presentations on mechanisms for acquiring blood pressure measuring devices for use in health services and the availability in primary health care services**
- **Gaps and facilitators**
- **Feasible steps in the current circumstances**
- **Legal and regulatory framework "best practices"**

Clinical Validation Studies for Accuracy and Precision - Dr. Raj Padwal and Dr. Pedro Orduñez

- **Measurement practice**

16:00 **Closure**

DAY 2: WEDNESDAY, 4 MARCH, 2020

08:30-08:40 **Program of the day**
Dr. Pedro Orduñez, Regional Advisor on Cardiovascular Diseases, PAHO

08:40-08:55 **Importance of the regulation of electronic blood pressure measuring devices and examples of best practices**
Dr. James Sharman, Deputy Director of the Menzies Institute for Medical Research, University of Tasmania

08:55-09:10 **Regulatory environments and situation in primary health care in HEARTS countries: Results of the PAHO review**
Dr. Cintia Lombardi, HEARTS Consultant, PAHO

09:10-09:25 **Lists of validated blood pressure measuring devices**
Dr. Raj Padwal, Professor of Medicine and Co-Director of the Hypertension Dyslipidemia Clinic, University of Alberta

09:25-09:40 **WHO's technical specifications for blood pressure measuring devices (pending WHO publication)**
Dr. Norm Campbell, Professor Emeritus, University of Calgary

9:40 - 9:50 **Working groups orientation**

09:50 - 10:00 **Coffee Break**

10:10 - 12:00 WORKING GROUPS

Regulatory Frameworks - Dr. James Sharman and Dr. Cintia Lombardi

- **Objetives and directions**
- **Brainstorm to promote and guarantee access to validated blood pressure measuring devices in primary health care services**

Clinical Validation Studies for Accuracy and Precision - Dr. Raj Padwal and Dr. Pedro Orduñez

- **Objetives and directions**
- **Validation study methods: sample, data record, statistical analysis**
- **Writing up and publication**
- **Additional measurement practice**

12:00 - 13:00 **Lunch**

13:00 - 15:00 WORKING GROUPS

Regulatory Frameworks - Dr. James Sharman and Dr. Cintia Lombardi

- **Working plan to develop and implement regulatory frameworks that promote access to validated electronic blood pressure measuring devices in primary health care**

Clinical Validation Studies for Accuracy and Precision - Dr. Raj Padwal and Dr. Pedro Orduñez

- **Working plan to carry out local clinical validation studies and to strenghten local capacity**

15:00 - 16:00 PLENARY

15:00 - 15:45 **Moderators:** Dr. Norm Campbell, Dr. James Sharman and Dr. Raj Padwall

- **Reports of the working groups on plans regarding the development and implementation of regulatory frameworks and local capacity building for validation studies**

- **Discussion of joint strategic action to expand knowledge, strengthen clinical, academic and regulatory capacitya**

15:45 - 16:00 **Next steps at the Regional level**
Dr. Pedro Orduñez, Regional Advisor, Cardiovascular Diseases, PAHO

16:00 **Closure**

PAHO STRATEGIC FUND

List of Core Antihypertensive Medications in the PAHO Strategic Fund

1. AMLODIPINE 5 mg
2. CHLORTHALIDONE 12.5 mg; 25 mg
3. LISINOPRIL 20 mg; 40 mg
4. LISINOPRIL + AMLODIPINE 10 mg + 5 mg; 20 mg + 5 mg; 20 mg + 10 mg
5. LISINOPRIL + HYDROCHLOROTHIAZIDE 10 mg + 12.5 mg; 20 mg + 12.5 mg; 20 mg + 25 mg
6. TELMISARTAN 40 mg; 80 mg
7. TELMISARTAN + AMLODIPINE 40 mg + 5 mg; 80 mg + 5 mg; 80 mg + 10 mg
8. TELMISARTAN + HYDROCHLOROTHIAZIDE 40 mg + 12.5 mg; 80 mg + 12.5 mg; 80 mg + 25 mg

Electronic Non-Invasive Blood Pressure Measuring Devices for Clinical Use[1]

What are the Essential Required Specifications for Procurement by Health Authorities?

- Use: The device(s) must be designed for professional use in clinical settings.
- Validation: The device(s) must have undergone a clinical validation study for accuracy and precision using the following specifications:
  - The ISO 81060-2; 2018 protocol ("single universal standard" which replaces all other previous standards/protocols, also known as the AAMI/ESH/ISO protocol) for devices introduced to the market from 2020 onwards.
  - The British Hypertension Society, AAMI/ISO 2013, or European Society of Hypertension (ESH) standard for devices pre-2020. The former two are preferred.
  - Conducted by independent investigators (that is, with no commercial ties to the manufacturer) with results made publicly available, preferably by publication as full papers in peer-reviewed scientific journals.
- Cuff Size: At least three cuff sizes (minimum two cuffs to be supplied for each machine): small, medium, large (highly recommended) or one wide-range cuff (recommended).

  Also, there must be the availability of replacement cuffs.
- Warranty: Two years warranty as minimum.
- Other:
  - Rate of inflation/deflation to be specified by vendor.
  - Low battery and error indicators.
  - Operable with both batteries and electrical outlets (220V) and capable of 150 -200 measurements when fully charged.
  - Built-in surge protection to prevent damage to instrument in case of power surge.

How to Find Out Which Models of Blood Pressure Measuring Devices are Validated?

Lists of validated blood pressure measuring devices have been developed by professional organizations worldwide, with those available in English listed in Table 1.

[1] This document focuses on clinical office devices, but the specifications can also extend to home devices.

Table 1. Weblinks to listings of blood pressure devices that have been independently assessed for accuracy according to scientific validation protocols:

SOCIETY, ORGANIZATION OR COMPANY	WEBLINK
British and Irish Hypertension Society	https://bihsoc.org/bp-monitors/
DABL Educational Trust*	http://www.dableducational.org/
Hypertension Canada	https://hypertension.ca/hypertension-and-you/managing-hypertension/measuring-blood-pressure/devices/
Medaval	https://medaval.ie/
STRIDE BP**	https://stridebp.org/
American Medical Association***	Under development

* No longer actively updated.

** Developed by an international group of blood pressure measurement experts, using data from validation studies published as full papers in peer-review PubMed journals, newly performed independent validation studies (complete reports signed by the principal investigator), and data on new devices provided by manufacturers showing 'equivalence' with previously validated devices.

*** The American Medical Association has been facilitating a process to make a U.S.-based validated device listing available for public use (Cohen JB, Padwal RS, Gutkin M, et al. History and Justification of a National Blood Pressure Measurement Validated Device Listing. Hypertension 2019; 73(2): 258-64).

This fact sheet was prepared in March 2020 with content adapted from:

- Resolve to Save Lives. Required specifications of professional blood pressure monitors and bid requirements (unpublished).
- Resolve to Save Lives. How to Choose an Automated Blood Pressure Monitor Recommendations for Low- and Middle-Income Country Settings (unpublished)
- WHO technical specifications for automated non-invasive blood pressure measuring devices (report in preparation).
- Sharman JE et al. Lancet Commission on Hypertension group position statement on the global improvement of accuracy standards for devices that measure blood pressure. Journal of Hypertension 2020, 38:21–29.
- Padwall R et al. Optimizing observer performance of clinic blood pressure measurement: a position statement from the Lancet Commission on Hypertension Group. J Hypertens 2019 37:000–000. DOI:10.1097/HJH.0000000000002112.