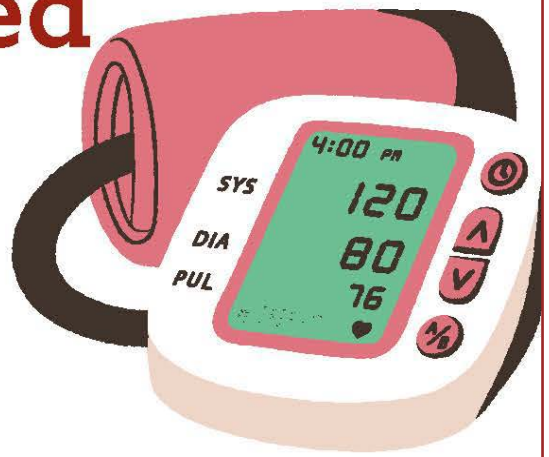
Webinar **World Hypertension Day**

World Health Organization
South-East Asia Region

Why clinically validated BP devices matter for hypertension control



18 May 2026
11:00 – 12:15 hrs (IST)

Organized by

Department of Health Promotion and Disease Prevention and Control, WHO South-East Asia Regional Office

Programme



Time (IST)	Agenda item	Speakers/moderators
11:00 HRS-11:05 HRS	**Welcome remarks**	**Dr Vinod Bura,** Ag. Director (HDC) WHO South-East Asia Regional Office (WHO SEARO)
11:05 HRS-11:15 HRS	**Importance of use of clinically validated automated blood pressure measuring devices**	**Dr Pradeep Joshi**, Technical Officer (NCD), WHO SEARO
11:15 HRS-11:25 HRS	**WHO and Global recommendation on blood pressure measuring devices**	**Dr Sok Cin Tye**, Consultant(CVD) WHO HQ
11:25 HRS-11:45 HRS	**Understanding blood pressure measuring device validation: What it means, why it matters, and how to choose a validated device**	**Dr Anupam Pathni**, Special Advisor Capacity Building and Training, Resolve to Save Lives
11:45 HRS-12:00 HRS	**Country experiences on efforts to improve access to clinically validated blood pressure measuring devices** - **Ms Tshewang Lhaden**, Program Officer, NCD Division, Department of Public Health, Bhutan - **Dr Rahat Iqbal Chowdhury**, Disease Control Division, Directorate General of Health Services, Bangladesh - **Dr Gagandeep Singh Grover**, Assistant Director-cum-State Nodal Officer (NCD) and in-charge procurement, Government of Punjab, India	Moderated by **Dr Nalika Gunawardena**, Regional Adviser (NCD), WHO SEARO
12:00 HRS-12.15 HRS	**Open forum for discussion on country level and collection actions**	



Welcome remarks

Dr Vinod Bura
Coordinator, Immunization and Vaccine Development
Ag. Director, Department of Health Promotion, Disease Prevention and Control
WHO South-East Asia Regional Office



Importance of use of clinically validated automated blood pressure measuring devices

Dr Pradeep Joshi
Technical Officer (Noncommunicable Diseases)
WHO South-East Asia Regional Office

SEAHEARTS 2030 Milestones



World Health Organization
South-East Asia

RESOLUTION

OF THE

WHO REGIONAL COMMITTEE FOR SOUTH-EAST ASIA

SEA/RC76/R5

SEAHEARTS: ACCELERATING PREVENTION AND CONTROL OF CARDIOVASCULAR DISEASES IN THE SOUTH-EAST ASIA REGION

The Regional Committee,

RECOGNIZING that cardiovascular diseases (CVD) stand out as the primary cause of premature mortality in the Region and that accelerated efforts in prevention and control of CVD is imperative for achieving faster reductions in premature mortality resulting from noncommunicable diseases,



World Health Organization
South-East Asia Region

DECISION

OF THE

WHO REGIONAL COMMITTEE FOR SOUTH-EAST ASIA

SEA/RC78(7)

Extending and expanding the Regional Milestones of SEAHEARTS: an initiative to reduce CVD burden in the WHO South-East Asia Region

The Regional Committee,

HAVING CONSIDERED the updates on specific Regional Committee resolutions

100 MILLION PEOPLE WITH HYPERTENSION TO BE PLACED ON PROTOCOL-BASED MANAGEMENT WITH **60 MILLION** HAVING CONTROLLED BLOOD PRESSURE BY 2030

100 MILLION PEOPLE WITH DIABETES TO BE PLACED ON PROTOCOL- BASED MANAGEMENT WITH **50 MILLION** HAVING GOOD CONTROL OF GLYCAEMIA BY 2030

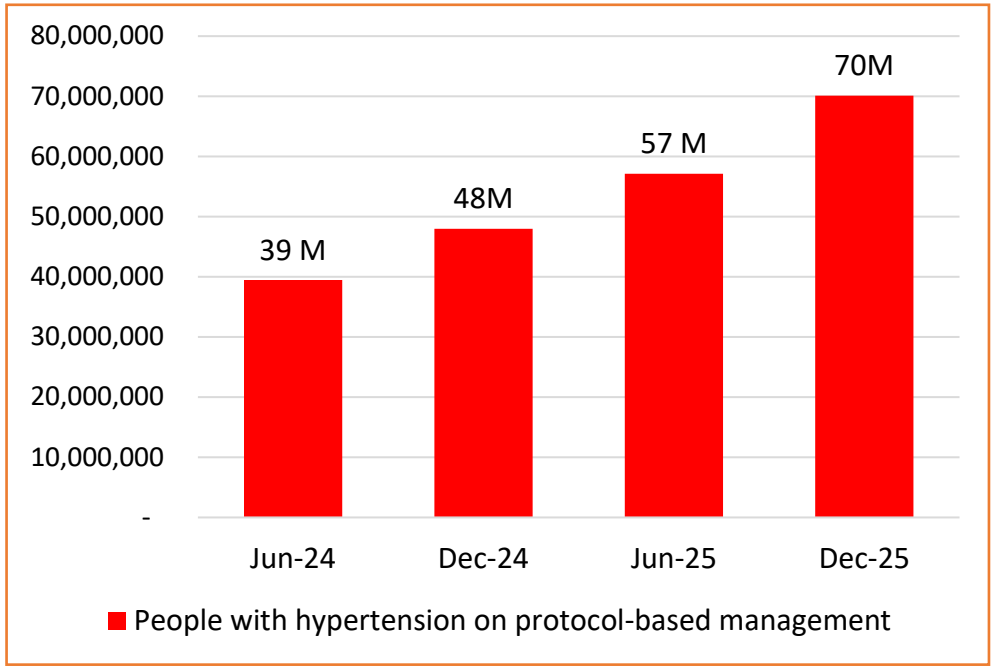
ONE BILLION PEOPLE COVERED BY AT LEAST THREE MPOWER MEASURES WITH HIGHEST LEVEL OF ACHIEVEMENT BY 2030

ONE BILLION PEOPLE COVERED WITH TWO OR MORE ADDITIONAL EVIDENCE-BASED INTERVENTIONS TO REDUCE MEAN POPULATION SALT/SODIUM INTAKE BY 2030

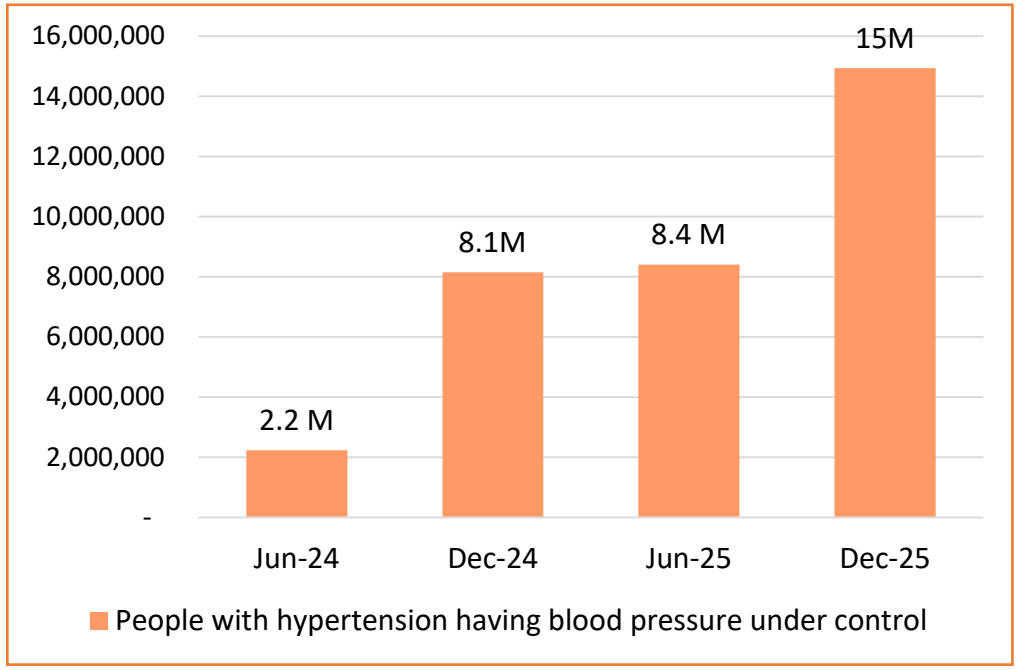
ONE BILLION PEOPLE ARE PROTECTED FROM HARMFUL EFFECTS OF TRANS FATTY ACIDS THROUGH ENACTMENT OF BEST PRACTICE, LESS RESTRICTIVE OR COMPLEMENTARY POLICIES AND EFFECTIVE IMPLEMENTATION AND ENFORCEMENT OF POLICIES BY 2030



Milestones progress till December 2025



Trends in numbers of persons put on protocol-based management for hypertension in WHO SE Asia Region, Jun 2024- Dec 2025



Trends in numbers of persons having blood pressure under control in WHO SE Asia Region, Jun 2024- Dec 2025

Source: SEAHEARTS Monitoring Platform
https://apps.searo.who.int/seahearts/

Why is it important to measure blood pressure accurately

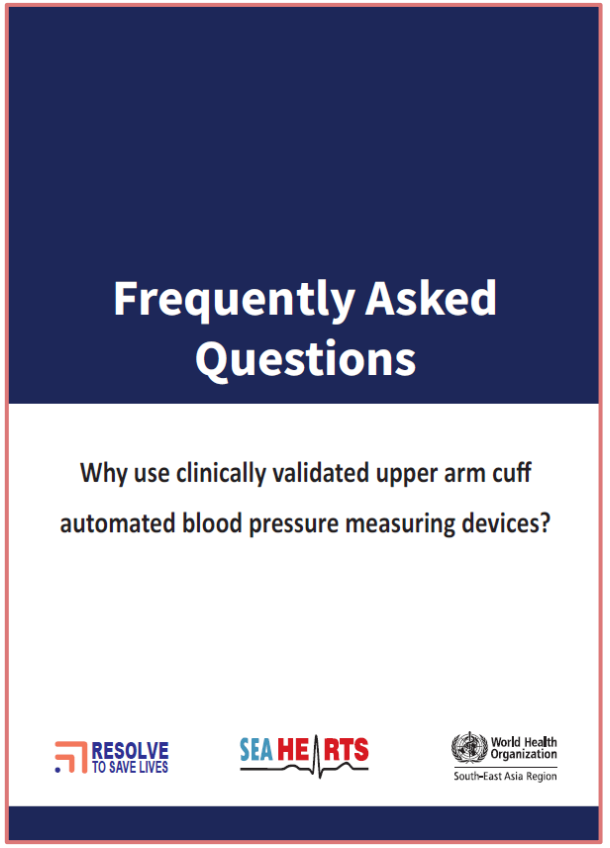


- Measurement of BP is a most commonly performed medical tests worldwide, conducted millions of times every day

- Accurate BP measurement is the foundation for hypertension diagnosis and control
  - In addition to proper measurement technique, a reliable and validated blood pressure measuring device is essential
  - Confidence among both health professionals and patients in the accuracy of BP devices is critical for quality care and hypertension management

- Unstandardized BP measurement leads to errors that can inappropriately alter management decisions in 20–45% of cases
  - leaving patients at risk for heart attacks and stroke, and premature death

- Even 10/5 mm Hg overestimation or underestimation of BP has huge impact
  - on a population-wide level, a 5-mmHg difference in SBP corresponds to an estimated 6% absolute and 30% relative change in hypertension prevalence
  - falsely decrease or increase perceived hypertension control



Link- FAQs

Sources: Padwal R, Campbell NRC, et al. *Optimizing observer performance of clinic blood pressure measurement: a position statement from the Lancet Commission on Hypertension Group*. Journal of Hypertension. 2019;37(9):1737–1745
Ordunez P, et al. HEARTS in the Americas: a global example of using clinically validated automated blood pressure devices in cardiovascular disease prevention and management in primary health care settings. J Hum Hypertens. 2023;37(2):126-129

Global recognition of clinically validated BPMDs as public health priority



- WHO declared BPMDs as one of seven general medical device priority areas requiring assessment
- Fourth WHO Global Forum on Medical Devices
  - recommended specific actions to increase the regulation of medical devices and to optimize the procurement process in low- and middle-income countries
- Delhi Declaration on Improving Access to Essential Medical Products (2018)
  - prioritize the development of legal and organizational frameworks to oversee the quality, safety, and efficacy of health technologies available on the market
- Lancet Commission on Hypertension Group
  - a mandatory global regulatory requirement that BPMDs successfully complete independent clinical validation according to the universally accepted ISO Standard (ISO 81060-2:2018)


World Health Organization South-East Asia

DELHI DECLARATION

IMPROVING ACCESS TO ESSENTIAL MEDICAL PRODUCTS IN THE SOUTH-EAST ASIA REGION AND BEYOND

We, the Health Ministers of the Member States of the WHO South-East Asia Region participating in the Seventy-first session of the WHO Regional Committee for South-East Asia in New Delhi, India

Acknowledging access to effective, safe, quality and affordable medical products (medicines, vaccines, diagnostics and medical devices) is vital to achieving Universal Health Coverage (UHC) and the 2030 agenda of Sustainable Development Goals (SDGs).

Concerned that, despite overall progress, challenges remain in providing the right medical products at the right time to those in need, and availability



Sources: World Health Organization. (2019). *Fourth WHO global forum on medical devices – report*. Geneva: WHO

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(1):21–29.

Weak and fragmented regulatory landscape across region



- **Bangladesh:** BPMDs fall under medical-device import and registration controls administered by Directorate General of Drug Administration
- **India:** Legal Metrology (General) Third Amendment Rules, 2025 explicitly introduced regulation of “non-invasive automated sphygmomanometers” (digital BP monitors)
- **Myanmar and Nepal**: regulate BP monitors through broader medical-device provisions, generally using recognized international standards
- **Sri Lanka**: National Medicines Regulatory Authority regulates medical devices including digital BP monitors, largely through general medical-device registration frameworks
- **Thailand**: Thai FDA regulates BPMDs as medical devices under the Medical Device Act, and imported/manufactured automated BPMDs

In summary, countries in the region **mostly focuses on the safety and other quality assurance aspects;** and lacks regulatory provision or framework

- regulations that applied explicitly to BPMDs under medical devices laws or regulations
- to ensure accuracy and precision validation criteria as a condition of pre-market approval
- mechanisms to remove devices from the market that did not comply with regulations

Sources: DGDA Bangladesh; CDSCO India; DDA Nepal; NMRA Sri Lanka; Thai FDA; WHO medical-device regulatory resources
Regulatory Pathway to the Exclusive Use of Validated Blood Pressure Measuring Devices WHO PAHO

Drivers behind the dominance of Non-validated BP Devices



Limited suppliers, and usually higher cost of validated BPMDs

Several BP devices passes regulatory requirements for sale but failed independent validation of measurement accuracy

Not mandatory for manufacturers to use a specific standard to assess BP measuring device accuracy

Lack of easy identifiers or certification mark on devices

Results of BP devices that fail validation studies may not be published

Published validation studies often demonstrate methodological deviations from established standard

No national registry to track compliance with quality and validation standards

Lack of education and awareness generation efforts by bringing the concept and know-how of accuracy validation into the public health agenda

Unethical manufacturers are selling cheap home BP devices on e-commerce/market and making false claims with respect to validation credentials

Lack of market landscape studies on validated vs non-validated BP devices in the region

RESEARCH ARTICLE | Originally Published 10 April 2020 |

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

Dean S. Picone, Rewati A. Deshpande, Martin G. Schultz, Ricardo Fonseca, Norm R.C. Campbell, Christian Delles, Michael Hecht Olsen, Aletta E. Schutte, George Stergiou, Raj Padwal, Xin-Hua Zhang, and James E. Sharman AUTHOR INFO & AFFILIATIONS

Review | Open access | Published: 08 April 2010

Determining which automatic digital blood pressure device performs adequately: a systematic review

Y Wan, C Heneghan, R Stevens, R J McManus, A Ward, R Perera, M Thompson, L Tarassenko & D Mant

Research Letter

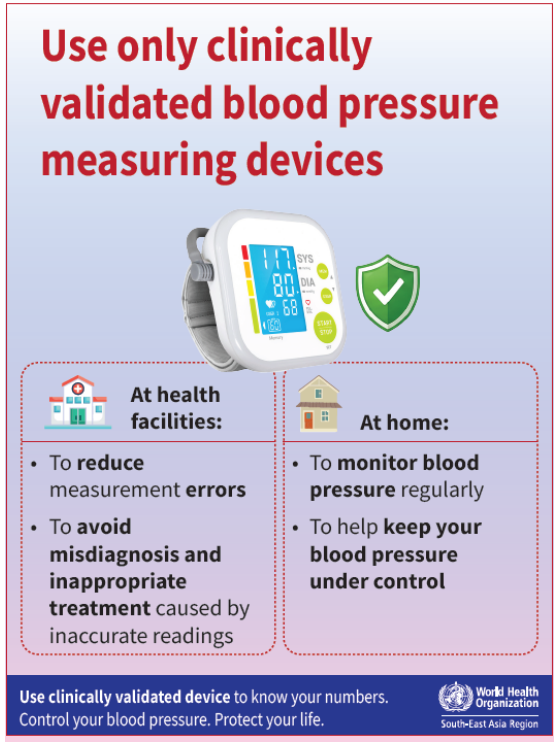
Validation Status of Blood Pressure Measuring Devices Sold Globally

Dean S. Picone, PhD[1]; Norm R. C. Campbell, MD, PhD[2]; Aletta E. Schutte, PhD[3]; et al

Health systems challenges affecting use of validated BPMDs



- Limited awareness among clinicians, programme managers and procurement authorities
- Technical specifications used for procurement of automated BPMDs are non-standardized
- National Health care Quality Assurance or Health Facility Accreditation Standards does not feature use of validated BP devices as quality assurance requirements
- Unavailability of procurement and distribution data that indicate increase purchase trends of automated BPMDs
- Lack of monitoring mechanisms to indicate availability of validated BP devices at primary health facilities
- Lack of official statements or guidance in national health policy/ strategy/ programme stressing the recommendation of only using validated automated BPMDs





WHO and Global recommendation on blood pressure measuring devices

Dr Sok Cin Tye
Consultant (Cardiovascular Diseases)
WHO Headquarter, Geneva

WHO HEARTS & PEN Technical Packages: BP Device Recommendations



HEARTS Technical Package

- Recommends validated, automated upper-arm devices for hypertension screening & management
- Core of 'R' (Risk-based management) & 'T' (Treatment protocols) modules
- Devices must meet international validation standards applicable in LMIC settings
- Standardized technique: patient seated 5 min, 3 readings, average recorded
- Specifies cuff selection, device maintenance & observer training requirements

PEN: Package of Essential NCD Interventions

- Prioritizes automated oscillometric upper-arm devices over mercury sphygmomanometers
- Device selection: clinical validation, cuff size range, durability for field/community settings
- BP thresholds: ≥140/90 mmHg for diagnosis; ≥160/100 mmHg for immediate treatment initiation
- Community health workers: use validated semi-automatic devices with appropriate training
- Includes BP measurement as a core indicator for NCD programme monitoring

Key Cross-Package Principles: ✓ Use only WHO-validated or ISO-compliant devices | ✓ Phase out mercury devices — WHO 2030 target | ✓ Ensure device maintenance, calibration & cuff-size training in all settings

Sources: WHO HEARTS Technical Package (2018, updated 2022); WHO PEN (2013, updated 2019)

What WHO is doing

Lead: Dr Dean Picone from the University of Sydney. Expert on the accuracy and quality of blood pressure devices used.

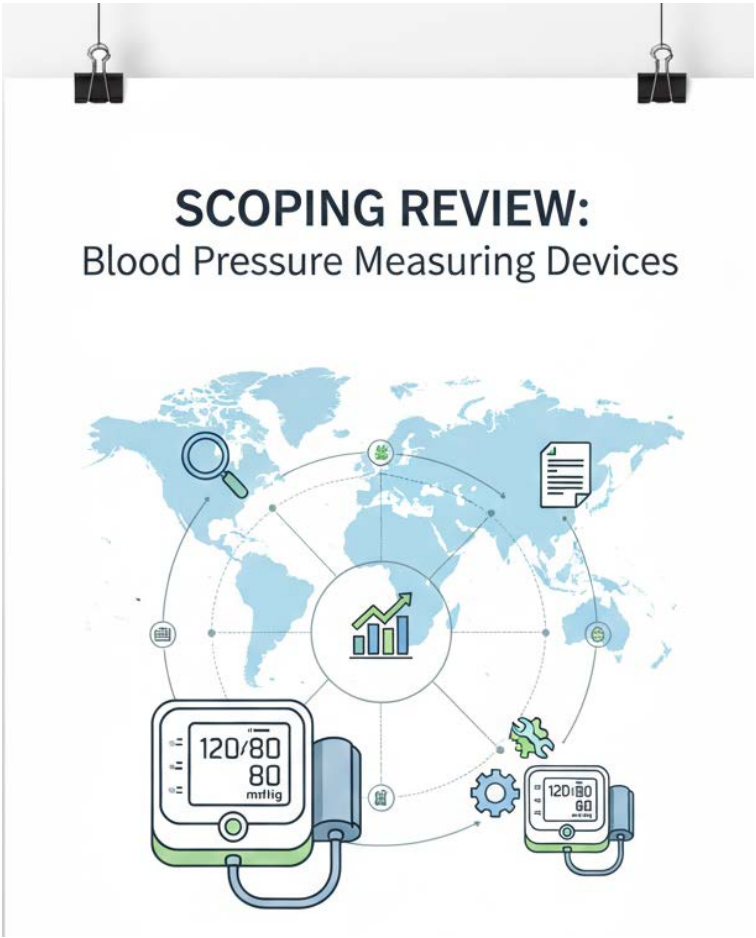
Objective:

1. Mapping of evidence on how countries procure, and implement automated BOMD
2. Present real-world consequences on the use of non-validated devices

Screening: Dual independent reviewers using tool such as Covidence

Data sources: PubMed, Embase, Scopus, Web of Science, WHO IRIS, government regulatory sites, NGO repositories

Reporting: Following PRISMA-ScR guidelines





Additional products

01

Target Product Profile

TPP for BP Devices

Procurement Officers

Context-specific requirements that make specs actionable for purchasing decisions

02

Policy Brief

Government-Facing Document

Regulators & Governments

Makes the case for regulatory reform and policy change

03

Advocacy Brief

Mobilization Tool

Civil Society & NGOs

Drives awareness and action among non-technical actors

Global Validation Standards for Blood Pressure Measuring Devices



ISO 81060-2 and the Universal Standard — the protocols for clinical accuracy validation of BPMDs

ISO 81060-2:2018 / AMD1:2020

- International standard for non-invasive BP devices with cuff replaces AAMI SP10 & ESH-IP
- Unified global standard: one protocol accepted by all major scientific bodies worldwide
- Protocol: ≥85 subjects recruited;
- Pass criteria: mean difference ≤5 mmHg; standard deviation ≤8 mmHg per device
- Amendment 1 (2020) introduced the Universal Standard sub-protocol
- WHO requires ISO 81060-2 compliance in its Technical Specifications (2020, 2023)

Universal Standard (STRIDE BP)

- Developed by STRIDE BP initiative
- Single protocol accepted by ALL major scientific societies eliminates fragmented landscape
- Free validated device registry: www.stridebp.org 700+ device models listed (2024)
- WHO HEARTS programme recommends STRIDE BP as reference for device selection
- Free online search tool available for health programmes & country offices

Country Procurement Guidance

- Only procure devices validated under ISO 81060-2 or Universal Standard protocol
- Request manufacturer's published validation reports before any procurement decision
- Avoid unvalidated wrist monitors not suitable for clinical or programme settings
- Include validation requirement in national device procurement specifications/tenders

Sources: ISO 81060-2:2018/AMD1:2020; Stergiou et al., Hypertension 2021; STRIDE BP Registry 2024

Call to Action

Governments

Enact national legislation requiring ISO 81060-2:2018 clinical validation for all BPMDs before market authorization.

Manufacturers

Submit all devices for independent clinical validation and register results on STRIDE BP or ValidateBP.

Healthcare Providers

Check STRIDE BP or ValidateBP before purchasing or recommending any blood pressure monitoring device.

Procurement Agencies

Update all tender specifications to require clinical validation evidence and reference WHO 2020 Technical Specifications.

WHO & International Bodies

Maintain and expand WHO Prequalification, keep validated device lists current, and embed standards in the HEARTS technical package.

Together, we can ensure every patient has access to an accurate, validated blood pressure monitor, a cornerstone of the global hypertension response.



Understanding Blood Pressure Measuring Device Validation

What it means, why it matters, and how to choose a validated device

Dr Anupam Khungar Pathni
Resolve to Save Lives



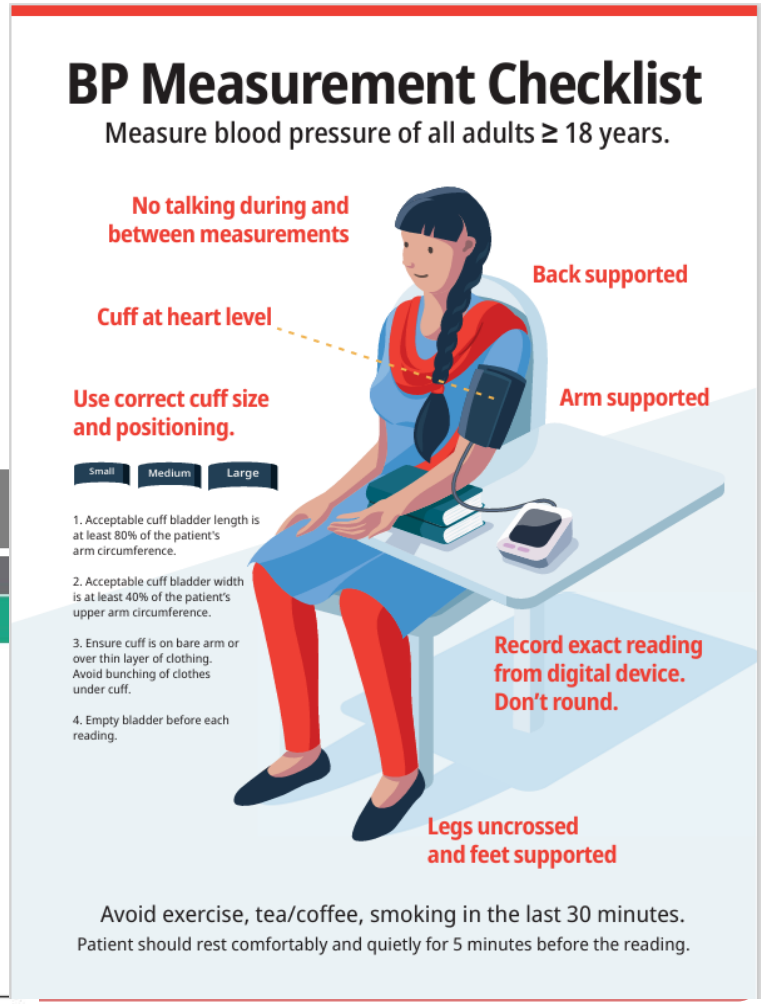
Accurate BP measurement is the foundation for effective diagnosis and control of hypertension

- Key pillars of accurate BP measurement:
  - **The device:** Accurate and well-maintained
  - **The operator:** Trained and consistent
  - **The technique:** Standardized

Types Of BP Measuring Devices

Manual / analogue		Electronic / automated	
Mercury sphygmomanometer	Aneroid sphygmomanometer	Semi-automated, cuff	Automated, cuff







Types of BP Measuring Devices (BPMDs)

Parameter	Mercury	Aneroid	Digital
Accuracy	Considered as “gold standard”	Mechanical shocks may lead to incorrect readings Need calibration at least every 6 months	Highly reliable when validated instrument is used correctly
Observer’s skills & expertise	High	High	Low
Terminal digit preference	Yes	Yes	No
Observer bias	Yes	Yes	No
Use by field workers	Difficult	Difficult	Simple
Health & environmental effects	Yes	No	No
Availability in near future	No	Yes	Yes

WHO recommends Validated Automated BPMDs in Primary Care Settings

An Easy Way to Promote Task Sharing

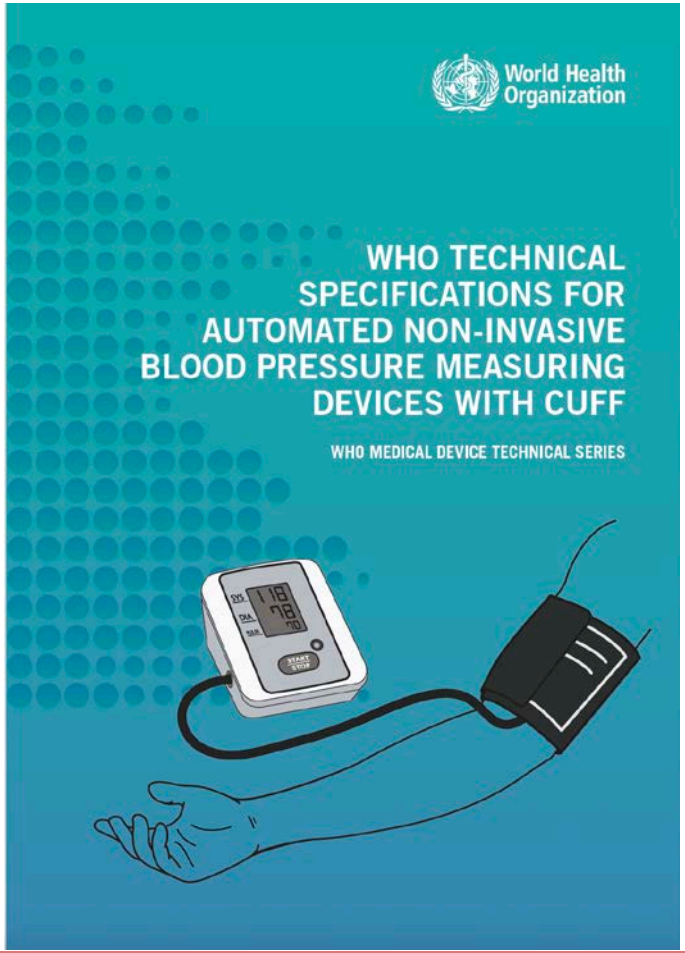
- Manual BP devices require significant training, and even experienced health workers can make mistakes.

With an Automated Digital BP Monitor:

- Health workers can focus on positioning the patient, improving accuracy.
- Health workers with less experience and training can take accurate measurements.
- Health workers can be confident in the results.



MANUAL BP DEVICES Complex measurement process with significant opportunity for human error	AUTOMATED DIGITAL BP DEVICES Simplified, expedited measurement process
Incorrect cuff pressure	Cuff automatically inflates to correct pressure
Health worker hand fatigue from pumping up the cuff repeatedly	No health worker hand fatigue
Incorrect deflation rate	Cuff automatically deflates at the correct rate
Difficulty hearing Korotkoff sounds in a busy, noisy clinic	Listening is not required
Misreading or misremembering BP measurement value on the meter or column	Digital display of values on an easy-to-read screen eliminates misinterpretation
Rounding the observed values (terminal digit preference)	Values stay on the screen until the device is reset or turned off; no need to rely on health worker memory
Miscalibration	Does not require calibration





What is Validation of Automated BPMDs

- **What it is:** A process that proves an automated BPMD model gives accurate, safe, and clinically reliable readings.
- **How it is done:** Validation involves rigorous objective clinical testing of a specific device model in human subjects using internationally recognized protocols. Device readings are compared with a reference standard under controlled conditions by an independent organization (not manufacturer).
- **Scope:** Validation is done once per device model and confirms it can measure BP accurately and reliably in real-world settings.
- **Transparency:** Validation results must be publicly available.

Validation confirms that a BPMD model can measure blood pressure accurately and reliably in real clinical settings.



Why Validation Matters

- **Accuracy and reliability**
  - In a large UK study, 96% of validated BPMDs passed accuracy testing vs 64% of unvalidated devices.*
  - Ensures trustworthy BP readings across all settings.
- **Patient safety**
  - Inaccurate BP readings can lead to misdiagnosis and improper treatment jeopardizing patient safety.
  - Validated devices reduce these risks, protecting patients from harm
- **Effective hypertension management**
  - Accurate devices empower health care providers to make correct treatment decisions, dose titration and monitoring
  - Leads to improved BP control and better health outcomes.
- **Cost savings**
  - Higher upfront cost, but long-term savings through fewer repeat measurements, fewer unnecessary treatments, and prevention of complications.

** Br J Gen Pract. 2020 Jul 30;70(697):e548-e554.*



Validation versus Calibration

	Validation	Calibration
• **Purpose**	Confirms that the BPMD **model** can measure accurately and consistently in real clinical settings.	Ensures each **device** continues to give accurate readings over time.
• **Process**	Involves rigorous clinical testing of a device model against a reference standard using internationally accepted protocols	A routine maintenance activity comparing and adjusting readings against a known pressure standard.
• **Scope**	Done once per model, not per individual unit.	Done for each physical device, not the model.
• **Frequency**	One-time process before market approval or procurement.	Periodic (e.g., every 6–12 months) during device use
• **Responsibility**	Conducted by independent organisation or authority.	Performed by authorized service agencies or trained technicians.
• **Outcome**	Demonstrates that the device can measure BP correctly on real patients.	Confirms that the gauge or sensor still reflects true cuff pressure.
• **Applicability**	Required before procurement of automated BP devices.	Required during implementation, especially for manual (aneroid) devices.
• **Key distinction**	Proves clinical accuracy by design.	Maintains mechanical accuracy over time.



Protocols for Validation of Automated BPMDs

Validation protocols have been developed by several independent international bodies including:

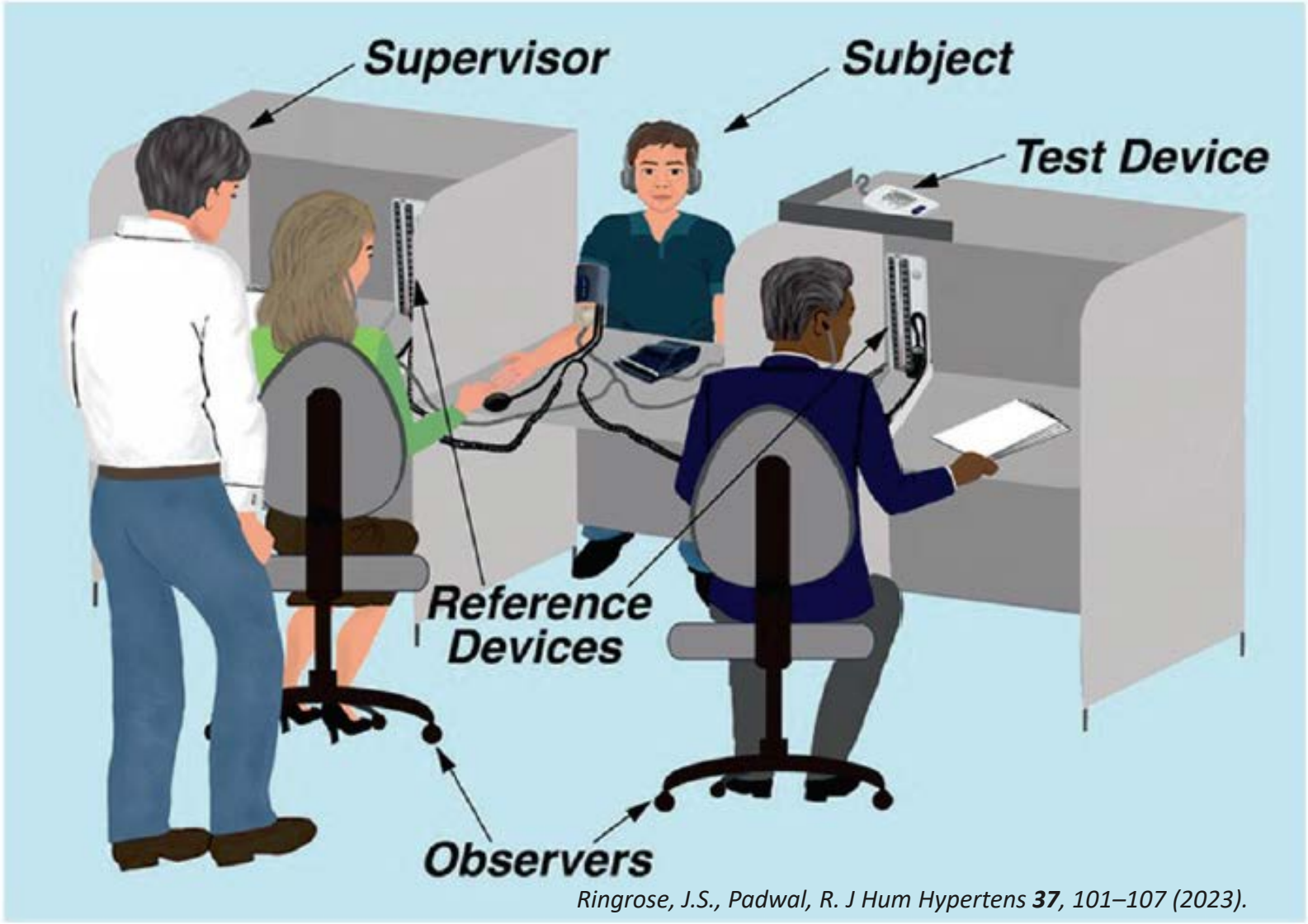
- Association for the Advancement of Medical Instrumentation (AAMI), 1987, 1992, 2002
- British Hypertension Society (BHS), 1990, 1993
- European Society of Hypertension (ESH), 2002, 2010
- International Organization for Standardization (ISO), 2009
- American National Standards Institute (ANSI), AAMI and ISO, 2009, 2013
- AAMI, ESH and ISO, 2018: **Universal Standard ISO 81060-2:2018** adopted to replace all other previous standards/protocols. It consolidates previous guidelines and includes additional specifications for special populations, such as children and pregnant women.



Universal Standard Validation Protocol: Key Features

Criteria	Requirement
Efficacy measure	Threshold for accepting accuracy of BP measurement at estimated probability of tolerable error (≤10 mm Hg) ≥ 85%
Sample size	• General population study: 85 participants • Special population studies include ≥ 35 participants (after successful general population study).
Participating populations	• General population: participants >12 years. • Special populations (<3 years; 3-11 years; pregnancy; arm circumference > 42 cm; atrial fibrillation; others) • Pregnancy: N = 45 (15 normotensive, 15 gestational hypertension, 15 preeclampsia). • Children: N = 35 aged 3-12 years can be included and analyzed together with 50 older participants.
Reference BP	Mercury sphygmomanometers or accurate non-mercury devices
Data collection	Same-arm sequential BP measurement is preferred.

How is the Clinical Validation study conducted?



*Ringrose, J.S., Padwal, R. J Hum Hypertens **37**, 101–107 (2023).*

Types of Validated BPMDs





- **Home use models**
  - Can last up to 30,000 readings
  - Suitable for low-volume facilities



- **Clinic use (Professional) models**
  - Can last up to 100,000 readings
  - Recommended for high-volume healthcare facilities

All BPMDs used in health facilities, whether clinic or home-use models must be validated and supported by adequate annual maintenance contracts.



How to Identify Validated BPMDs

Not all BPMD models — even from reputed brands — are clinically validated.

- Check device validation status using trusted online registries:
  - **STRIDE BP:** www.stridebp.org
  - **BIHS:** British & Irish Hypertension Society
  - **MEDAVAL:** medaval.ie
  - **DABL Educational Trust:** www.dableducational.org
  - **Validate BP:** www.validatebp.org

75%–80% of automated BPMDs marketed globally are not clinically validated for accuracy.





How to Identify Validated BPMDs: Demo

- **STRIDE BP:** www.stridebp.org

Not all BPMD models — even from reputed brands — are clinically validated.



STRIDE BP

JOINT INITIATIVE WITH

European Society of Hypertension

International Society of Hypertension

World Hypertension League

Validated blood pressure monitors



Home

Download



Office/Clinic

Download



Ambulatory

Download



Children

Download



Pregnancy

Download

STRIDE BP

JOINT INITIATIVE WITH

European Society of Hypertension

International Society of Hypertension

World Hypertension League

Blood pressure monitors

Search e.g. device model

Preferred devices rules

* Equivalent/Identical devices rules

Market Availability | Population | Use | Manufacturer | Measurement Site | Measurement Method

Device Description	Market Availability	Measurement Site	Use	Population	
A&D TM-2420	Not Available	Upper arm cuff	24h Ambulatory	Adults	Read more →
A&D TM-2430	Not Available	Upper arm cuff	24h Ambulatory	Adults Children	Read more →
A&D TM-2440 *	Available	Upper arm cuff	24h Ambulatory	Adults Diabetics	Read more →

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Blood Pressure Monitors - Validations, Papers and Reviews

Home
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Validation
Devices
Library
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Founding Sponsor

dabl®

The most advanced online system for Clinical Trials.
Links to a range of validated monitors for immediate validation of uploaded and entered data.

CLASSIFICATION | RECOMMENDED DEVICES | CURRENT DEVICES | DISCONTINUED DEVICES
DEVICE INDEX | CLINICAL USE TABLES | SELF/HOME BP TABLES | 24hr ABPM TABLE

Sphygmomanometers for Self-measurement of Blood Pressure (SBPM)

| UPPER ARM DEVICES | WRIST DEVICES | COMMUNITY DEVICES |

The following tables are lists of currently available Upper Arm and Wrist devices for Self-measurement of Blood Pressure and Devices for Measuring Blood Pressure in the Community. Discontinued devices are shown on a separate table. A complete list of all devices is available on our Device Index.

Upper Arm Devices for Self-measurement of Blood Pressure

FTS: Study evaluated prior to publication using the dabl®Educational Fast Track validation Service

Printable version>>

Device	Mode	AAMI	BHS	ESH 2002	ESH 2010	ISO 81060-2:2013	ISO 81060-2:2018	Circumstance	Recommendation Ref
A&D UA-611Plus	Osc		A/A					UA-1020 Equivalence	Recommended E194
A&D UA-631 (UA-779 Life Source)	Osc			Pass				At rest, Recruitment violations	Recommended 4
A&D UA-651	Osc				Pass			Study (96) extended to ESH-IP 2010 requirements	Recommended 97
					Pass			With a wide range cuff study extended to ESH-IP 2010 requirements	Recommended 106
A&D UA-651Plus	Osc		A/A					UA-1020 Equivalence	Recommended E193
A&D UA-651SLPlus	Osc		A/A					UA-1020 Equivalence	Recommended E192
A&D UA-654MR	Osc				Pass			UA-651 Equivalence	Recommended E191
A&D UA-704	Osc		A/A					Study details omitted	Questionable 8
A&D UA-705	Osc		A/A					At rest	Recommended 18
A&D UA-767	Osc	Pass	A/A					At rest; not high BP	Recommended 3
A&D UA-767F	Osc				Pass			UA-651 Equivalence	Recommended E119
A&D UA-767S	Osc				Pass			UA-651 Equivalence	Recommended E120
A&D UA-774 (UA-767 Plus)	Osc		A/A					At rest; tables incomplete	Recommended 11
			A/A					At rest; Recruitment violations; Simultaneous readings	Questionable 2

dabl Educational Trust

Automated Devices for Clinical Use

For a complete list of devices see our Device Index and for discontinued devices see our Discontinued Devices Index.

FTS: Study evaluated prior to publication using the dabl®Educational Fast Track validation Service

Printable version>>

Device	Mode	AAMI	BHS	ESH 2002	ESH 2010	ISO 81060-2:2013	ISO 81060-2:2018	Circumstance	Recommendation Ref
A&D TM-2564G	Osc	Pass	A/A					Serious protocol violations	Questionable 18
A&D TM-2655	Osc	Pass	A/A					Methods poorly explained	Questionable 70
A&D TM-2656	Osc	Pass	A/A					At rest	Recommended 56
A&D TM-2657	Osc	Pass	A/A					A&D TM-2656 Equivalence	Recommended E136
A&D UM-201	Osc				Pass			At rest Cuff sizes of 16-24, 22-32, and 31-45 cm.	Recommended 80
A&D UM-211	Osc				Pass			At rest Cuff sizes of 16-24, 22-32 and 31-45cm.	Recommended 81
Andon KD-595	Osc				Pass			At rest	Recommended 73
Andon KD-5031	Osc				Pass			At rest	Recommended 72
Andon KD-5917	Osc				Pass			At rest	Recommended 66
B.Well PRO-33	Osc						Pass (+2:2024)	General Population	Recommended 274
B.Well PRO-35	Osc						Pass (+2:2024)	B.Well PRO-33 Equivalence	Recommended E403
B.Well PRO-36	Osc						Pass (+2:2024)	B.Well PRO-33 Equivalence	Recommended E404
Beurer BM45	Osc				Pass			Grandway G.Lab MD2680 Equivalence	Recommended E228
Beurer BM85	Osc				Pass			iHealth BP3 Equivalence	Recommended E126
BpTRU BPM-100 BPM-300	Osc	Pass	A/A					At rest. Pressure ranges	Recommended 5, 6
		Pass						Children	Questionable 12
								Mixed adult/paediatric population	



Quantification & Budgeting

- Estimate the number of devices required **based on the number of service delivery points and patient load.**
  - **Conduct a facility-level assessment** to identify all points where BP is routinely measured. E.g.: Out-patient departments, Inpatient wards, Community clinics, Mobile medical units, etc
  - Health facilities with **≥ 30 BP measurements/day** should ideally opt for a **clinic use type** device (one or more based on patient load)
  - Health facilities with **< 30 BP measurements/day** can opt for a **home use type** validated BPMD.

- Calculate the budget requirement based on the number of devices needed and their procurement price,



Validated automated BPMDs are a non-negotiable quality standard - central to patient safety, program trust, and effective hypertension control



Resources

- Videos:
  - Why automated blood pressure measuring devices
  - How to select blood pressure devices
- WHO technical specifications for automated non-invasive blood pressure measuring devices with cuff. Geneva: World Health Organization; 2020.
- Blood pressure measurement device selection in low resource settings: Challenges, compromises, and routes to progress. *J Clin Hypertens*. 2020:22;792–801.
- Automated blood pressure measuring devices: how are they clinically validated for accuracy? *J Hum Hypertens. 2023:37;101–107*.



RESOLVE TO SAVE LIVES

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Country experiences on efforts to improve access to clinically validated blood pressure measuring devices

- Bhutan
- Bangladesh
- India

Moderated by:
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Bhutan



Bhutan has implemented the SEAHEARTS approach, enrolling over 55,000 individuals with hypertension on protocol-based management, with a current control rate of approximately 25%. The country has set an ambitious target of achieving an 80% control rate by 2030.

The National Health Survey, 2023 also initiated discussion among policy makers on the use of validated BP devices during household survey or home visits considering high prevalence on raised blood pressure found during visits

Questions:

What is the current procurement policy of Bhutan related to BPMDs at the facility level?

Has the country assessed the status of validity of the BPMDs being used?

What challenges has the country encountered in procuring and accessing clinically validated blood pressure devices?

What is the current procurement policy of Bhutan related to BPMDs at the facility level?
Has the country assessed the status of validity of the BPMDs being used?



- Bhutan is scaling up hypertension management to achieve an ambitious 80% control rate by 2030. Reaching the target of hypertension control require accurate BP measurement with validated devices.

- **Current procurement policy**

- The government procurement system currently recommends the use of manual BPMDs in Bhutan.
- However, digital BPMDs are being used across health facilities either supplied by the government or purchase by health facilities to meet increasing demand across health facilities and ease to work.
- All the medical devices including BPMDs are centrally procured and distributed across health facilities
- Device requirements are quantified based on Health facility's requirement following each facilities annual indent.
- Every years the Department Medical Product will quantify and place procurement following government procurement process. All the indenting, and procurement and supply happens once in a year

- **Assessment of the status of validity of the BPMDs**

- Bhutan has conducted a preliminary assessment of validity of available BP measuring devices nationwide.
- 80% of automated BPMDs currently in use are not listed in any clinically validated registries.
- Wide variety of brands- about 26 different brand with most common Omron, Rossmax, Mindray, Biolight and MCP)

Challenges in procuring and accessing the clinical validated BP devices?



- **Coordination between procurement division and NCD programme**

  There is a need for more cohesive interaction between procurement team and programme team primarily for developing technical specifications, procurement planning, and device distribution to facilities

- **Limited programme budgets and high cost of professional BPMDs**

  Competing health priorities affecting procurement decisions, particular in context of Bhutan's provision of home-based care which increases the need at least two BP devices per health facility

- **Lack of clear guidance and policy direction on the use of clinically validated BP devices among partners, academic institutions, donors, and NGOs**

  BP measurement is part of different implementation and research projects. Once projects conclude, the devices remain within health facilities, which can further contribute to the continued use and availability of non-validated BPMDs.



Bangladesh

Bangladesh has made significant progress under its Hypertension Control Initiative, implemented through over 500 facilities, with more than ***800,000 people enrolled*** *and a* ***current blood pressure control rate of around 50%.***

This initiative, led by the Ministry of Health and Family Welfare in collaboration with the National Heart Foundation, has generated valuable insights, including strong evidence supporting the critical role of blood pressure measuring devices (BPMDs) in screening, diagnosis, and long-term management.

Questions:

1. How does Bangladesh plan to expand access to clinically validated blood pressure measuring devices (BPMDs) across all Community Clinics and Upazila Health Complexes?
2. What strategies is the Government planning to implement to progressively phase out non-validated BPMDs across all healthcare facilities and replace them with clinically validated devices?



Q1: Expanding validated BPMDs across all UHCs and community clinics

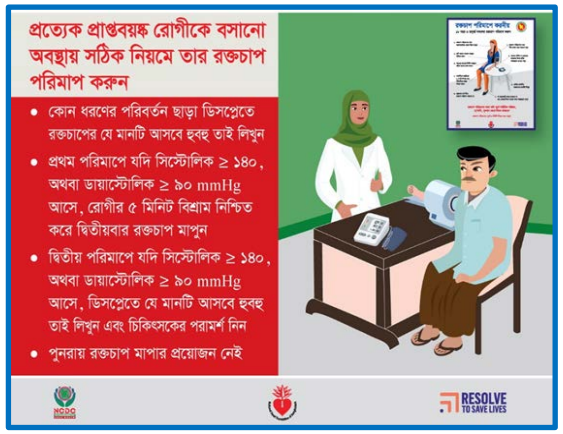
- **Today:** NCD Corners now in every Upazila – BHCI-327 ; the rest field implemented by BRAC, JICA, ICDDR,B, BUHS, Asian Arsenic Network and others.
- **Devices in use:** Omron HEM-7121, HBP-1120, A&D TM-2657P at NCD Corners; Omron HEM-7121 and Microlife VSA at community clinics – **all clinically validated.**
    - **Step 1 – Harmonise across all NCD Corners:** One validated-device standard, regardless of which partner implementing, monitoring and supervising the NCD corner.
    - **Step 2 – Reach community clinics via CCHST:** Mandate validated digital BPMDs in all future Community Clinic Health Support Trust procurement.
    - **Step 3 – Secure a permanent yearly budget:** The core challenge – ringfenced government allocation for BPMDs, antihypertensives and logistics as patient demand keeps growing.
    - **Step 4 – Bluetooth-connected BPMDs:** Direct device-to-Simple-app sync at NCD Corners – no manual entry, cleaner data into DHIS-2.

Q2: Phasing out non-validated BPMDs – Government strategy



- **The gap:** Aneroid and scattered non-validated digital devices still in use at community clinics – supplied outside NCDC.
  - **Strategy 1 – Validated-only procurement:** CMSD and CCHST tenders restricted to WHO/ESH/AHA-validated devices (e.g. STRIDE BP).
  - **Strategy 2 – Phased replacement:** BHCI sites NCD corners first, then community clinics through CCHST.
  - **Strategy 3 – Calibration & warranty:** Built into the procurement cycle to keep devices accurate over time.
  - **Strategy 4 – Train and standardise:** WHO technical specs, NCD management model measurement protocol and Simple-app SOPs deployed with every device.
  - **Strategy 5 – Track on the dashboard:** 720,744 registered, 55% controlled (target 61% by end-2026) – the proof point.

IEC Materials Developed for accurate measurement from BPD machines in NCD Corners











India

India's State Programme Implementation Plans emphasize the procurement of clinically validated professional BPMDs for use at healthcare facilities. However, it is estimated that nearly 75% of blood pressure devices available in the market are not validated, posing a significant challenge.

Question:

As a procurement officer and NCD programme manager, how have you ensured the availability of clinically validated BPMDs in such a market environment?

What procurement challenges have you faced, how were they addressed, and what practices are in place for the maintenance and replacement of these devices?



Early Challenges

- **Limited awareness** regarding clinically validated BP devices across health facilities
- Widespread perception that **all BP devices perform similarly**
- Market largely dominated by **low-cost non-validated devices**
- Concerns regarding **higher procurement cost** of validated automated devices



Policy Shift by Punjab Government

GOI Procurement ceiling revised from **~₹2,000 to ~₹8,000** for professional BP devices on request of Punjab and other States

State procurement specifications aligned with **international validation standards**

Emphasis on transitioning from non-validated to **clinically validated automated BP devices**



Procurement & Quality Assurance Mechanism

- Centralized procurement undertaken through **Punjab Health Systems Corporation (PHSC)**
- Competitive bidding through **government e-tendering procurement platform**
- Technical specifications included:
  - Clinical validation requirements
  - Professional-use standards
- Warranty and service obligations
- Validation and quality criteria incorporated during **technical bid evaluation**



Implementation Experience

Deployment across **District Hospitals and Sub-Divisional Hospitals** under NHM support

Automated arm-in BP devices demonstrated:

Reduced workload in high-patient-volume facilities

Improved standardization of BP measurement

Consistent performance compared with conventional mercury devices



Maintenance & Sustainability

ANNUAL MAINTENANCE CONTRACTS (AMC) ESTABLISHED FOR SERVICING AND REPLACEMENT

PERIODIC MAINTENANCE COORDINATED THROUGH PHSC

REPLACEMENT AND FUNCTIONALITY MONITORING INTEGRATED INTO PROGRAMME REVIEW SYSTEMS



Capacity Building

- **Orientation and training for:**
- Medical Officers
- Staff Nurses
- Frontline healthcare workers

- **Focus areas:**
- Importance of validated BP measurement
- Standard BP measurement protocol
- Correct use and handling of automated devices



Way Forward

Policy support is essential for scaling validated BPMDs

Procurement specifications determine device quality

Centralized procurement improves standardization

Maintenance systems are critical for sustainability

Capacity building is necessary for correct BP measurement

Accurate BP measurement is foundational for hypertension control

Validated BP devices are not merely equipment, they are a critical investment in quality hypertension care



Open discussion

Moderated by

WHO South-East Asia Regional Office



Thank you