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WHO technical specifications for BP devices

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Draft Report

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Supported by

- Resolve To Save Lives
- WHO team for Management of Noncommunicable Diseases
- WHO EML/ Innovation, Access and Use team

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- An expert consultative group

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Audience

Intended for regulators, policy-makers, programme managers, biomedical engineers, BP device manufacturers and industries, procurement officers and health care providers.

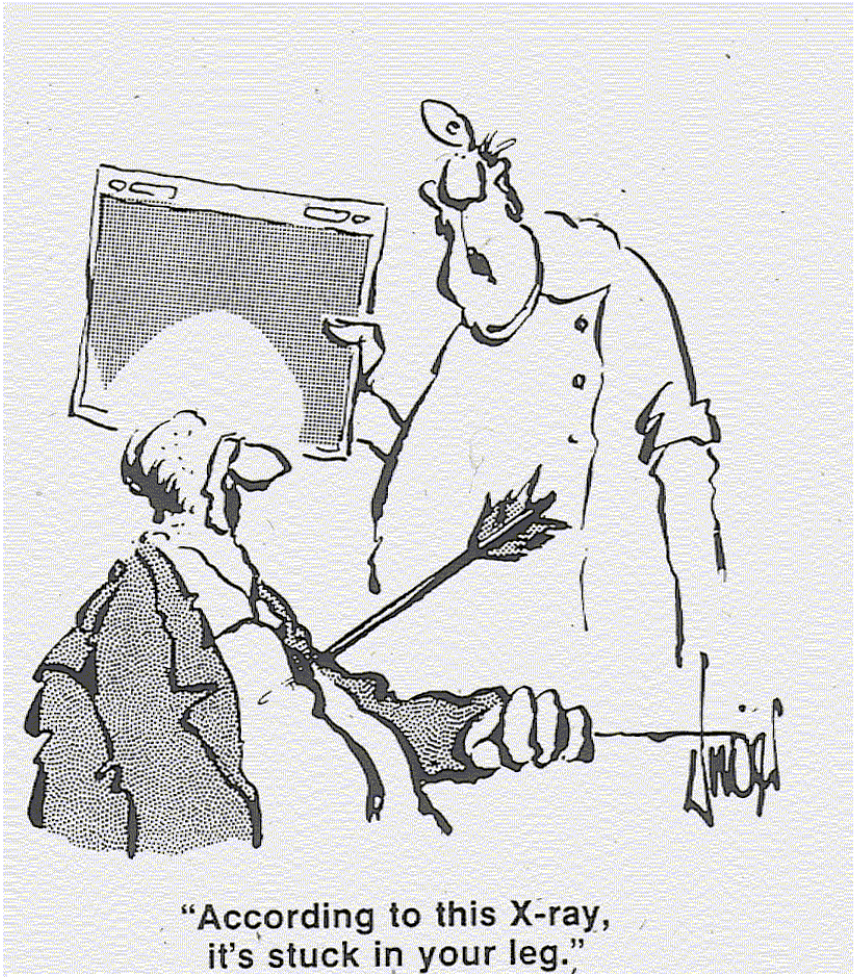
Focus is Low to Middle Income countries but equally applicable to High Income Countries.

Background

- Builds on previous WHO documents including,
  - 4th WHO Global Forum on Medical Devices, 13–15 December 2018, in India.
  - WHO Affordable technology blood pressure measuring devices for low-resource settings 2003.
  - Phasing out mercury thermometers and sphygmomanometers in health care 2015.
- Driven by increased recognition of widespread inaccuracy in BP measurement, new technological advances and the phasing out of devices containing mercury.

Background

- Blood pressure assessment one of the most important and common clinical tests.
- A strong need for accuracy and reproducibility.
- Wide-spread inaccuracies in clinical BP assessment
  - >50% misclassification of BP as hypertensive/normotensive by usual clinical measurement.


"According to this X-ray,
it's stuck in your leg."

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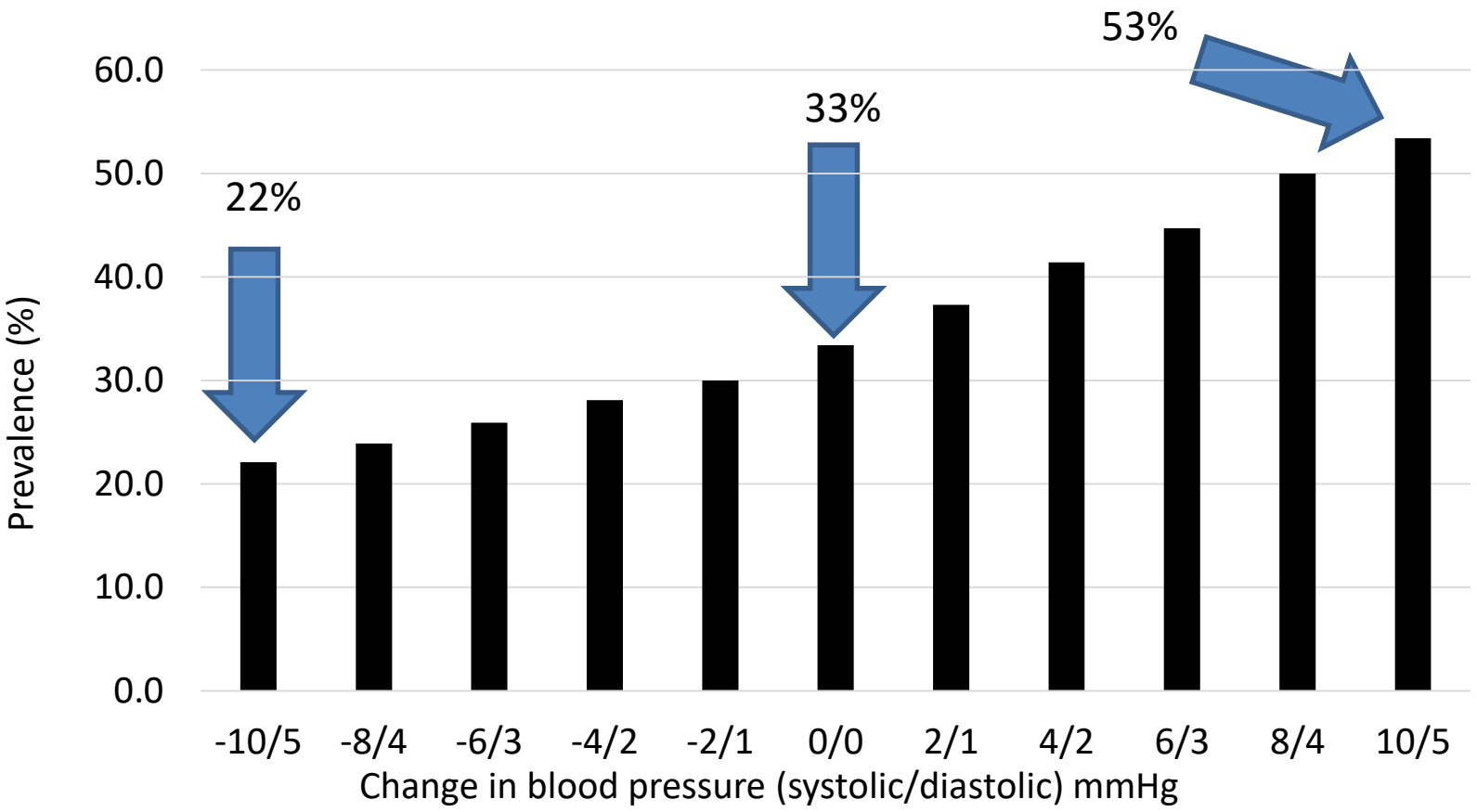
Impact of systematic error on hypertension prevalence



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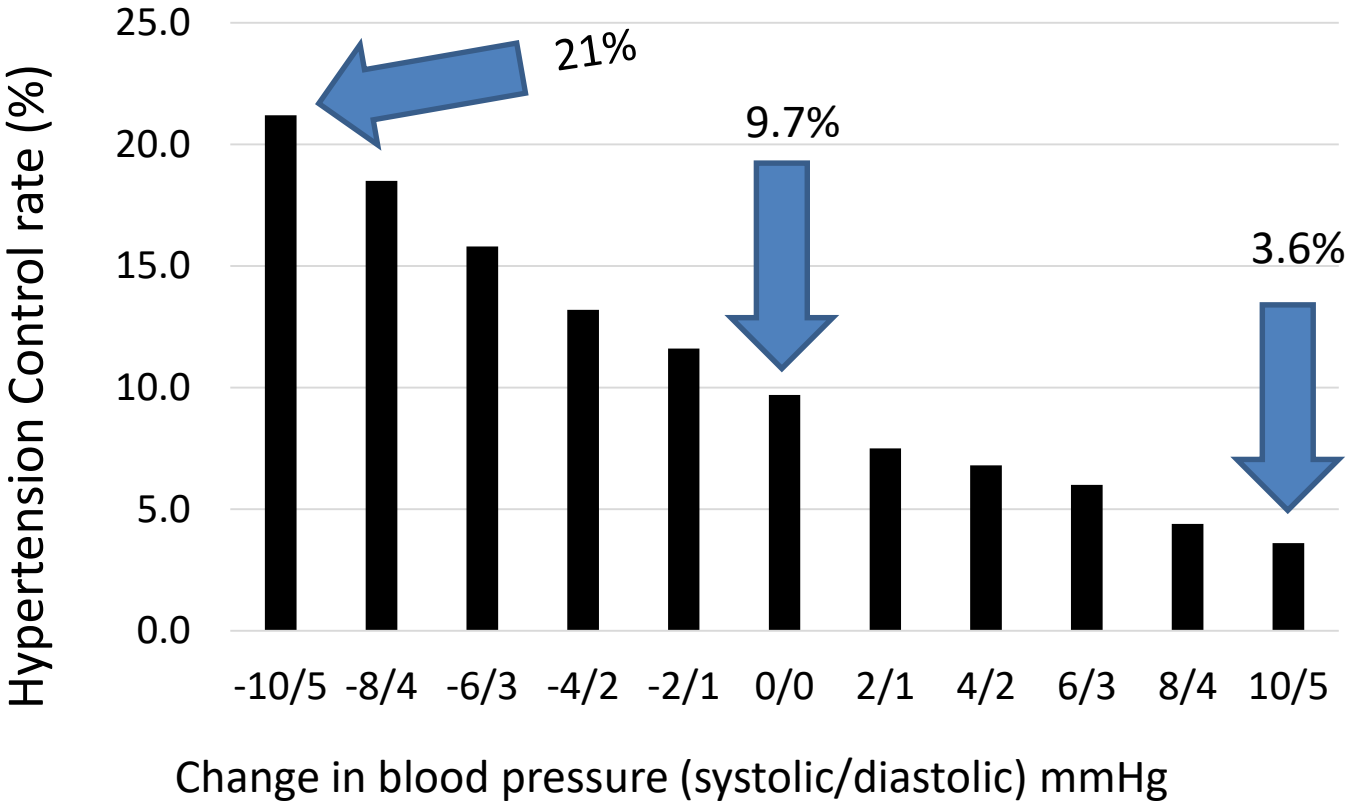
Impact of systematic error on hypertension control rate



Background

- Accuracy and reproducibility issues relate to
  - Patient preparation (e.g. no coffee, no full bladder, pain free, calm, rested)
  - Environment (e.g. quiet, comfortable temperature, no stimulation)
  - Observer (good hearing for manual readings, no talking or stimulus)
  - Standardized measurement technique (e.g. arm supported at heart level)
  - Appropriate equipment (e.g. cuff size, accurate manometer)
- Errors in BP assessment of 10/5 mmHg common and can double or half the perceived prevalence and control of hypertension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Focus is on automated clinical office and home blood pressure upper arm devices

- Builds on the Minamata Convention on Mercury.
- Consistent with widespread lose of calibration in aneroid devices.
- Consistent with inability to train, assess and maintain clinician skills for manual BP assessment.
- Advances in technology to manufacture accurate oscillometric automated devices.
- Advances in standards to assess the accuracy of automated oscillometric devices.
- Acknowledges new technologies that are not currently able to be assessed for accuracy (cuff-less devices).

WHO technical specifications for automated non-invasive blood pressure measuring devices

Contents

- Executive summary
- Invasive and non-invasive devices.
- Electronic blood pressure devices with upper-arm cuff.
- Measuring blood pressure
- Manual blood pressure devices
- Innovation and research
- Conclusions

Key messages for Member States, governments, health and scientific communities

1. Member States are encouraged to strengthen their regulatory capacity to ensure that only certified, validated BP devices are marketed and to identify institutions in which independent validation can be conducted. Low- and middle-income Member States are encouraged to acquire, allocate and use validated BP devices.
   - Member States should enforce quality assurance by mandating manufacturers to clearly state on packaging whether their BP device has passed validation testing for accuracy.
   - Non-validated BP devices should not be marketed, purchased or used for clinical diagnosis.

Key messages for Member States, governments, health and scientific communities

2. Appropriate resources should be maintained for use of manual auscultatory BP devices for special clinical or testing purposes, and the capacity of trained professionals (clinical engineering and other technical professionals) to appropriately maintain BP devices should be assured.

3. Governments, health and scientific communities and BP device manufacturers should ensure the availability of affordable, validated electronic BP devices in low-resource settings with or without a reliable electricity supply.

Key messages for Manufacturers

- Electronic BP measuring devices (automated and semi-automated) should undergo independent validation testing with a rigorous international protocol (e.g. ISO 80160-2; 2018). Endorsement should be indicated on the label.
- Manufacturers should specify the range of arm circumferences for which the device or cuff size is intended and clearly mark the cuffs for the arms for which they are intended to be used.

Key messages for Health care institutions and professionals

- Validated electronic BP devices with appropriately sized upper-arm cuffs should be used in routine clinical and community screening.
- Certification courses and annual training and re-training of health care professionals should be required to ensure accurate BP measurement. Training should include patient preparation, cuff selection and BP measurement technique. In order to minimize additional training for manual BP measurements, only automated non-invasive BP devices should be used.
- Health care facilities in which manual BP devices containing mercury cannot yet be replaced by validated electronic BP devices should inform their communities about the hazards of mercury and develop procedures for safe operation of the devices and for decommissioning.

Conclusion

- WHO's technical specifications for BP devices is a significant step providing guidance to improve the accuracy of blood pressure assessment.
- It focuses on recently trained and certified observers using accuracy validated automated upper arm devices.
- It moves away from poorly trained health care professionals using manual devices.