

Recommended standards for assessing blood pressure in human research where blood pressure or hypertension is a major focus

TRUE Consortium (inTernational consoRtium for qUality resEarch on dietary sodium/salt)[†]

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Although inaccurate, nonreproducible blood pressure values can result from non-standardized assessments, recommended approaches to standardize blood pressure measurement are often not followed in research studies. An expert consensus of national and international health and scientific organizations developed recommended minimum standards for assessing blood pressure in research subjects where: (1) blood pressure or hypertension is a major end point, or (2) blood pressure is likely a major mediator of the research outcome. Minimum research standards are presented for training of observers, technical aspects of assessing blood pressure, and equipment for both adults and children. The standards are based on prior recommendations, some of which did not conform to current evidence based-methods. All new research should require adherence to these minimum standards in the patient populations described above. Readers need to use caution in interpreting studies if the standards are not met in the defined populations.

Standardized and rigorous methods for blood pressure (BP) measurement are necessary to ensure the comparability and accuracy of BP assessments for individuals due to the effects of measurement error, diurnal variation, and short- and long-term variability.¹⁻⁹ Many studies have demonstrated substantive changes in BP related to methodological issues when the BP assessment did not satisfy the established standards.^{6,8,11-13} It is thought that a lack of rigor/standardization in assessing BP may reduce or mask the relationship between BP, lifestyle changes, or antihypertensive medications and adverse outcomes. For example, the INTERHEART study assessed BP status solely by asking participants whether they had been diagnosed with hypertension in many countries where awareness of hypertension diagnosis was low.¹⁴ Not surprisingly, the INTERHEART study found hypertension to be the sixth leading risk for acute myocardial infarction, while, based on numerous studies, there is a consensus that increased BP is the leading risk for ischemic heart disease.¹⁵ The INTERHEART findings may mislead policy makers that hypertension control is not as high a priority intervention as interventions on risks that ranked higher. Further,

observations of non-BP-lowering effects of antihypertensive drugs may be attributed to inadequate assessment of BP or inadequate assessment of BP could limit the ability to detect cardiac effects of non-cardiovascular drugs or their interaction with other medications.¹⁶⁻¹⁸ Nevertheless, many investigators historically have not published the training and accuracy testing of those assessing BP, and have not indicated the technical and methodological aspects of assessing BP in clinical research studies where BP was a major focus.¹⁹

An International Consortium for Quality Research on Dietary Sodium/Salt (TRUE) was formed to make recommendations to improve the quality of research on dietary salt. Lack of standardization and quality of BP measurement was viewed as a factor, creating controversy about the relationship of dietary salt to increased BP and hypertension. Initially focused on setting recommended standards for assessing BP in human studies on dietary salt, the mandate was expanded, recognizing low quality BP assessment as a widespread issue with the potential to adversely impact all human BP research.

The recommendations below are intended to be applied to human clinical and epidemiological research where: (1) BP or hypertension is a major end point, or (2) BP or hypertension is thought to be a major mediator of the research outcome (eg, a study on an antihypertensive

[†]Details about the TRUE Consortium are mentioned in Appendix B.

therapy or lifestyle change with a cardiovascular outcome). The recommendations constitute a minimum standard for the conduct and report of each human clinical and epidemiological research study.

1 | RECOMMENDATIONS

1.1 | Training

1. The number of observers and the professional background of the observer(s) are indicated (eg, physician, community health workers, nurse, or research assistant).
2. Those who directly assess BP or those who train or teach persons in BP measurement protocols must be specifically trained for BP measurement as part of the quality control for the research study. This applies to office, home/self-, and ambulatory BP assessments.
3. For manual BP assessment, the observer(s) are specifically trained and have passed practical tests for technique and accuracy in assessing BP by auscultation using a double-headed stethoscope.²⁰
4. There is semiannual competency testing of those who directly assess BP or those who train or teach persons in BP measurement protocols when indicated in studies of a longer duration. The observers need to be evaluated, and quality of performance needs to be periodically assessed using statistical tables to detect bias in recorded measurements. Technician retraining is necessary where deficiencies are found.

1.2 | Technical aspects

5. The measurement conditions are indicated (eg, location, position/posture, resting period, or instructions provided for home/self- or ambulatory measurement).
6. All aspects of patient preparation and BP measurement must conform with the published guidelines of a national or international body recognized for its work in BP measurement.^{1,2,4-6,21,22} The specific set of technical recommendations used in the study must be referenced and all modifications to the recommended techniques and procedures disclosed.
7. The BP measurement protocol is provided in sufficient detail so that it can be duplicated precisely by others (eg, number of readings recorded, time intervals between readings, criteria for discarding readings, and number of readings to make the estimation).

1.3 | BP devices

8. All manual devices must be assessed for calibration at the start, every 6 months, and at the end of the study, and the data are to be assessed and reported for terminal digit preference.

References are provided for protocols verifying calibration of manual devices. Mercury devices, if used, must have been serviced before the study (eg, clean columns and mercury "zeroed").

9. All semiautomated or automated devices used must have passed accepted international or national validation standards/protocols (Medaval, <http://medaval.org>, updated: 2015. Accessed August 17, 2015). References must be provided (eg, peer-reviewed publication, government organization-verified validation, or publicly accessible data) to support the validation of the devices used.
10. The inflatable bladder dimensions of each cuff size used and range of arm circumferences used for each cuff size are specified. Only upper arm cuffs are recommended.

1.4 | Adults

11. BP is assessed using an automated, semiautomated, or manual device for office BP measurement, or an automated device for home/self- or ambulatory BP monitoring.
 - a. Office BP: If BP is assessed in a research/clinical office, multiple BP readings must be taken and averaged at each assessment. Office BP evaluation on repeated occasions (visits) is preferred to more accurately establish an individual's BP level both at baseline and during an intervention.
 - b. Out-of-office BP: It is preferred that out-of-office (ambulatory or home/self-) BP be assessed rather than assessments obtained only in research/clinical offices. For out-of-office assessments, it is preferred to use ambulatory BP over home/self-monitoring or both methods. For ambulatory BP monitoring, there must be repeated BP measurements over a minimum of 24 hours during a person's routine day. The ambulatory monitoring must be performed at baseline and at least once during the intervention. For home/self-BP monitoring, an average of two readings in the morning and two readings in the evening conducted on 5 to 7 serial days is recommended to establish a person's BP both at baseline and during the intervention.²³⁻²⁶ The validity (assessment) of home/self-BP during an intervention must be assessed (conducted) at least once.

1.5 | Children

12. It is preferred that BP in children be assessed using manual devices with auscultation and interpreted using BP percentiles/Z scores based on appropriate pediatric normative data.^{7,27-30}
 - a. The use of automated or semiautomated devices that have passed internationally accepted validation standards for children is also acceptable (www.medaval.org/. Accessed August 15, 2015).

- b. Assessment of office BP on several occasions/visits is preferred over a single assessment to establish a child's level of BP both at baseline and during an intervention.
 - c. In children 5 years or older (or a height of 120 cm or more), out-of-office BP can be assessed as a useful addition to assessments in research/clinical offices. Out-of-office assessments for children should preferably use an ambulatory BP monitor.³¹ There is currently inadequate research on home/self-measurement of BP to recommend its use outside of studies that are designed to further assess the usefulness of home/self-measurement.³² For ambulatory BP monitoring, there must be repeated BP measurements over a minimum of 24 hours during a child's routine day. The ambulatory monitoring must be performed at baseline and at least once during the intervention. Appropriate pediatric normative BP data for ambulatory BP monitoring must be used for interpretation.^{33,34} Ambulatory BP is limited by the very small number of devices that have been tested according to international standards in children and incomplete evidence on normative data.
13. An upper arm cuff with the length of the cuff's bladder at least 80% of the arm circumference and the width at least 40% of the arm circumference must be used, and the criteria for selecting an appropriately sized cuff is indicated.

2 | COMMENT

The TRUE recommendations for assessing BP are not intended to impede research on BP and hypertension in humans but to standardize and improve the quality and reliability of such research. The recommendations originated from a process to develop recommended standards for research on dietary salt where low-quality research was viewed as a major factor in creating controversy around lowering dietary salt. Low-quality assessment of BP was identified as having the potential to alter and reduce the association between dietary salt and BP. The TRUE steering and expert committees identified lack of standardization of BP measurement and low-quality assessment of BP in human research as an issue impacting all BP research and approved the process to set these recommendations.

The process for developing the TRUE recommendations had a potential limitation. The recommendations were based on existing national and international guidelines on how to assess BP and mainly focus on clinical practice.¹⁻⁸ Many of these processes used extensive literature searches but did not use current methods of assessing the quality of evidence or grading of evidence. A notable exception was the Canadian Hypertension Education Program.³ The Canadian recommendations did not differ substantively from recommendations of other processes. New recommendations were not developed by this process and a literature search was not performed. Experts of the TRUE process and external experts reviewed the proposed recommendations to ensure consistency with currently accepted and published recommendations. Where there was a difference in recommendations

between different guidelines, and a consensus was not achieved, the TRUE process did not specify a recommendation to be followed. Hence, the recommendations from this process may not be as rigorous as those in some clinical guidelines. Therefore, the TRUE recommendations can be viewed as a minimum standard for research studies. It was identified that there is a need for an international process to systematically review the literature, assess the quality of studies, and to grade the evidence in setting recommended standards for assessing BP.

The process for developing the BP assessment recommendations was initiated in January 2015 and consensus among the external BP measurement experts and the sodium expert committee was completed in November and December 2015, respectively. The process of achieving support from the steering committee member organizations, several of which had internal review processes, was complete in August 2016. It is recognized that these recommendations should be reviewed and updated with advancement in BP assessment research.

The introduction of the TRUE recommendations will require time to allow the research community to adapt. It is suggested that researchers immediately apply these recommendations to all research protocols where accurate BP assessment is important to the research results. For journal editors and article reviewers, it should be expected that research initiated after the release of these guidelines adhere to the TRUE recommendations. Further, based on this guidance, at this time editors and reviewers can ensure the detailed methods used to assess BP are outlined in appendices of manuscripts. In the meantime, clinicians and scientists should utilize the TRUE recommendations in interpreting the validity of past, current, and future BP research. Specifically, studies with results that are dependent on an accurate assessment of BP need to be viewed more skeptically where there is a lack of adherence to recommendations for accurate BP assessment.

It is recognized that innovative research on how to better assess BP will test methods that are not included in these recommendations. Research using new methods of assessing BP should compare the new methods with established methods that incorporate the TRUE recommendations.

The member organizations and their representatives in the TRUE consortium include the American Heart Association: Stephen Daniels; the British Hypertension Society: Francesco P. Cappuccio; the Chinese Regional Office of the World Hypertension League: Liu Lisheng; Hypertension Canada: Janusz Kaczorowski; the International Association of National Public Health Institutes: Antti Jula; the International Council of Cardiovascular Prevention and Rehabilitation: Alison Atrey; the International Society of Hypertension: Rhian Touyz, Agustin Ramirez; the International Society of Nephrology: Ricardo Correa-Rotter; *the Journal of Clinical Hypertension*: Michael Weber; the World Health Organization Collaborating Centre for population salt reduction: Jacqui Webster; the Pan American Health Organization/World Health Organization Technical Advisory Group on Cardiovascular Diseases Prevention through Population-Wide Dietary Salt Reduction: Branka Legetic; the World Hypertension League: Norm Campbell (Chair); the World Stroke Organization: Graeme Hankey with the World Health Organization (Temo Waqanivalu) as

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CONFLICTS OF INTEREST

Specific conflicts of interest for each member of the TRUE Consortium can be found in Appendix A. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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APPENDIX A

Conflicts of Interest – Members of the TRUE Consortium have previously received funding or financial contributions from, or are otherwise associated with the following sources:

TRUE Consortium Steering Committee:

Alison Afrey – None.

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Ricardo Correa-Rotter – Abbvie Inc.; AMGen; AstraZeneca; Blood Purification; FibroGen Inc.; Nephrology and Hypertension; Nefrologia; Nefrologia Latinoamericana; Revista de Investigación Clínica; Roche Holding AG.

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TRUE Consortium Supporting Members

JoAnne Arcand – None.

Claire Johnson – None.

Tej Khalsa – None.

Alex Leung – None.

Birinder Mangat – Servier Laboratories.

APPENDIX B

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^AAmerican Heart Association.

^BBritish Hypertension Society.

^CChinese Regional Office of the World Hypertension League.

^DHypertension Canada.

^EInternational Council of Cardiovascular Prevention and Rehabilitation.

^FInternational Society of Hypertension.

^GInternational Society of Nephrology.

^HPan American Health Organization/World Health Organization Technical Advisory Group on Cardiovascular Diseases Prevention Through Population Wide Dietary Salt Reduction.

^IWorld Hypertension League.

^JWorld Stroke Organization.