

Recommended Standards for Assessing Blood Pressure in Human Research Where Blood Pressure or Hypertension is a Major Focus

TRUE Consortium^{1,2,3,4,5,6,7,8,9,10,*}

1. American Heart Association
2. British Hypertension Society
3. Chinese Regional Office of the World Hypertension League
4. Hypertension Canada
5. International Council of Cardiovascular Prevention and Rehabilitation
6. International Society of Hypertension
7. International Society of Nephrology
8. Pan American Health Organization/World Health Organization Technical Advisory Group on Cardiovascular Diseases Prevention Through Population Wide Dietary Salt Reduction
9. World Hypertension League
10. World Stroke Organization

Abstract:

Although inaccurate, non-reproducible 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 endpoint, 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 on the patient populations described above. Readers need to use caution in interpreting studies if the standards are not met in the defined populations.

Corresponding author: Norm Campbell, 1-403-210-7961, Fax: 1-403-210-9837, 3280, Hospital Drive NW, T2N 4Z6, Email: ncampbel@ucalgary.ca

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Introduction

Standardized and rigorous methods for blood pressure measurement are necessary to ensure the comparability and accuracy of blood pressure assessments for individuals due to the effects of measurement error, diurnal variation and short- and long-term variability [1-10]. Many studies have demonstrated substantive changes in blood pressure related to methodological issues when the blood pressure assessment did not satisfy the established standards [6, 8, 11-13]. It is thought that a lack of rigor/standardization in assessing blood pressure may reduce or mask the relationship between blood pressure, lifestyle changes or antihypertensive medications and adverse outcomes. For example, the INTERHEART study assessed blood pressure status solely by asking participants if 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 6th leading risk for acute myocardial infarction, while based on numerous studies, there is a consensus that increased blood pressure is the leading risk for ischemic heart disease [15]. The INTERHEART findings could mislead policy makers that hypertension control is not as high a priority intervention as interventions on risks that ranked higher. Further, observations of non-blood pressure lowering effects of antihypertensive drugs may be attributed to inadequate assessment of blood pressure 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 blood pressure, and have not indicated the technical and methodological aspects of assessing blood pressure in clinical research studies where blood pressure 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 blood pressure measurement was viewed as a factor, creating controversy about the relationship of dietary salt to increased blood pressure and hypertension. Initially focused on setting recommended standards for assessing blood pressure in human studies on dietary salt, the mandate was expanded, recognizing low quality blood pressure assessment as a widespread issue with the potential to adversely impact all human blood pressure research.

The recommendations below are intended to be applied to human clinical and epidemiological research where: 1) blood pressure or hypertension is a major endpoint, or 2) blood pressure or hypertension is thought to be a major mediator of the research outcome (e.g. a study on an antihypertensive 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.

Recommendations

Training

The number of observers and the professional background of the observer(s) are indicated (e.g. physician, community health workers, nurse, or research assistant).

Those who directly assess blood pressure or those who train or teach subjects in blood pressure measurement protocols must be specifically trained for the blood pressure measurement as part of the quality control for the research study. This applies to office, home/self, and ambulatory blood pressure assessments.

For manual blood pressure assessment, the observer(s) are specifically trained and have passed practical tests for use of technique and accuracy of assessing blood pressure by auscultation using a double headed stethoscope [20].

There is semi-annual competency testing of those who directly assess blood pressure or those who train or teach subjects in blood pressure 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.

Technical Aspects

The measurement conditions are indicated (e.g. location, position/posture, resting period, or instructions provided for home/self or ambulatory measurement).

All aspects of patient preparation and blood pressure measurement must conform with the published guidelines of a national or international body recognized for its work in blood pressure 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.

The blood pressure measurement protocol is provided in sufficient detail so that it can be duplicated precisely by others (e.g. number of readings recorded, time intervals between readings, criteria for discarding readings, and number of readings to make the estimation).

Blood Pressure Devices

All manual devices must be assessed for

calibration at the start, every 6 months, and 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 (e.g. clean columns, and mercury 'zeroed').

All the semi-automated or automated devices used have passed accepted international or national validation standards/protocols (Medaval, <http://medaval.org>, Updated: 2015. accessed Aug 17 2015). References must be provided (e.g. peer reviewed publication, government organization verified validation, or publically accessible data) to support the validation of the devices used.

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.

Adults

Blood pressure is assessed using an automated, semi-automated, or manual device for office blood pressure measurement; or an automated device for home/self or ambulatory blood pressure monitoring.

Office blood pressure: If blood pressure is assessed in a research/clinical office, multiple blood pressure readings must be taken and averaged at each assessment. Office blood pressure evaluation on repeated occasions (visits) is preferred to establish more accurately an individual's blood pressure level both at baseline and during an intervention.

Out-of-office blood pressure: It is further preferred that out-of-office (ambulatory or home/self) blood pressure be assessed rather than only assessments in research/clinical offices. For out-of-office

assessments, it is preferred to use an ambulatory blood pressure over home/self-monitoring or to use both methods. For ambulatory blood pressure monitoring, there must be repeated blood pressure 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-blood pressure monitoring, an average of 2 readings in the morning and 2 readings in the evening conducted on 5-7 serial days is recommended to establish a person's blood pressure both at baseline and during the intervention [23-26]. The validity (assessment) of home/self-blood pressure during an intervention must be assessed (conducted) at least once.

Children

Blood pressure in children is preferred to be assessed using manual devices with auscultation, and interpreted using blood pressure percentiles/Z-scores based on appropriate pediatric normative data [7, 27-30].

The use of automated or semi-automated devices that have passed internationally accepted validation standards for children is also acceptable (www.medaval.org/, accessed Aug 15 2015).

Assessment of office blood pressure on several occasions/visits is preferred over a single assessment to establish a child's level of blood pressure both at baseline and during an intervention.

In children aged 5 years or over (or a height of 120 cm or over), out-of-office blood pressure can be assessed as a useful addition to assessments in research/clinical offices. Out-of-office assessments for children should preferably use an ambulatory blood pressure monitor [31]. There is currently inadequate research on home/self-measurement of blood pressure

to recommend its use outside of studies that are designed to further assess the usefulness of home/self-measurement [32]. For ambulatory blood pressure monitoring, there must be repeated blood pressure 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 blood pressure data for ambulatory blood pressure monitoring must be used for interpretation [33, 34]. Ambulatory blood pressure 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.

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.

Comment:

The TRUE recommendations for assessing blood pressure are not intended to impede research on blood pressure 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 blood pressure was identified as having the potential to alter and reduce the association between dietary salt and blood pressure. The TRUE steering and expert committees identified lack of standardization of BP measurement and low quality assessment of blood pressure in human research as an issue impacting all blood pressure 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 blood pressure and are mainly focused 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] b. 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 blood pressure.

The process for developing the blood pressure assessment recommendations was initiated in Jan. 2015 and consensus amongst the external blood pressure measurement experts and the sodium expert committee was completed Nov and Dec 2015 respectively. The process of achieving support from the steering committee member organizations, several which had internal review processes, was complete Aug 2016. It is recognized that these recommendations should be reviewed and updated with advancement in blood

pressure 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 blood pressure 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 blood pressure are outlined in appendices of manuscripts. In the meantime, clinicians and scientist should utilize the TRUE recommendations in interpreting the validity of past, current, and future blood pressure research. Specifically, studies with results that are dependent on an accurate assessment of blood pressure need to be viewed more skeptically where there is a lack of adherence to recommendations for accurate blood pressure assessment.

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

The member organizations and their representatives in the TRUE consortium are American Heart Association: Stephen Daniels, British Hypertension Society: Francesco P Cappuccio, Chinese Regional Office of the World Hypertension League: Liu Lisheng, Hypertension Canada: Janusz Kaczorowski, International Association of National Public Health Institutes: Antti Jula, International Council of Cardiovascular Prevention and Rehabilitation: Alison Atrey, International Society of Hypertension: Rhian Touyz, Agustin Ramirez, International Society of Nephrology: Ricardo Correa-

Rotter, Journal of Clinical Hypertension: Michael Weber, World Health Organization Collaborating Centre for population salt reduction: Jacqui Webster, Pan American Health Organization/ World Health Organization Technical Advisory Group on cardiovascular diseases prevention through population wide dietary salt reduction: Branka Legetic, World Hypertension League: Norm Campbell (Chair), World Stroke Organization: Graeme Hankey with the World Health Organization (Temo Waqanivalu) as an observing organization. The members of the TRUE sodium expert committee are Drs. Cheryl Anderson, Larry Appel, Norm Campbell (Chair), Mary Cogswell, Nancy Cook, Antti Jula, Mary L'Abbe, Graham MacGregor, Rachael McLean, Doreen Rabi, Mark Woodward, JoAnne Arcand and were supported by Tej Khalsa, Claire Johnson, Alex Leung, Birinder Mangat, and Mark Niebylski. External blood pressure assessment experts who are not part of the TRUE sodium expert committee who contributed to this specific set of recommendations include Mark Gelfer, Pedro Ordunez, Bruce Alpert, Raj Padwal, Lyne Cloutier, George Stergiou, Eoin O'Brien, Don MacKay, Martin Myers, Joseph Flynn, Janusz Feber, Michael Rakotz, Fleetwood Loustalot and Janis Dionne. This process was supported by the Heart and Stroke Foundation (Canada)-Canadian Institute for Health Research Chair in Hypertension Prevention and Control and the World Hypertension League.

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position of the Centers for Disease Control and Prevention.

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.

Jula Antti – None.

Norman Campbell – Novartis Foundation.

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 Sodium Expert Committee:

Cheryl Anderson – EGG Nutrition Center; McCormick Science Institute.

Lawrence Appel – None.

Norman Campbell – Novartis Foundation.

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TRUE Consortium Blood Pressure Expert Committee:

Bruce Alpert – Cordex Pharma Inc.; Scanadu.

Lyne Cloutier – Merck & Co. Inc.; Servier Laboratories.

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