

# Proposals for simplifying the validation protocols of the British Hypertension Society and the Association for the Advancement of Medical Instrumentation

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## Introduction

Experience with the protocols of the British Hypertension Society (BHS) and the Association for the Advancement of Medical Instrumentation (AAMI) has provided valuable insight into the methodological problems associated with validation of devices [1–7]. The two protocols have many similarities but there are some important differences. These differences merit consideration in order to help manufacturers seeking to validate devices for acceptance both in Europe and in the USA. One of the objectives of the working group of the European Society of Hypertension is to consider the possibility of having a common protocol, which would be accepted as the international standard for the validation of blood-pressure-measuring devices [8]. Such a protocol would be welcomed by manufacturers and by those involved in performing validation procedures. Representatives of the AAMI and BHS have met on a number of occasions to exchange views on the feasibility of producing a common protocol and both organizations are committed to producing a common simplified protocol.

## Simplification of BHS / AAMI validation procedure

In striving for methodologies that best test the accuracies of blood-pressure-measuring devices, both the BHS and the AAMI have designed protocols that are complex, lengthy and expensive to perform. With the experience derived from nearly a decade of using these protocols, there is now evidence demonstrating that a revised common protocol could be simplified in some areas, with an overall rationalization of the methodological procedures. In doing so, it must be acknowledged that both protocols have features that have stood the test of time and that have provided robust data, so the temptation to over-simplify the procedures in the interest of expediency must be resisted. The BHS and AAMI protocols have previously been reconciled [7].

## Eliminating phases

The BHS protocol is divided into two parts [9]. Part I comprises the main validation procedure and has five phases: before-use calibration; an in-use (field) phase; after-use calibration; static validation; and reporting results of evaluation [9]. Part II of the BHS protocol consists of validation procedures for special groups and circumstances: pregnancy, the elderly, children, during

Table 1 Primary-phase requirements

	Comparisons must reach at least one of the following		
	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
Simultaneous	25	35	40
Sequential	20	30	35

Figures are percentages of readings within 5, 10, or 15 mmHg

exercise and various postures. Part II is performed only if the device obtains grade A or B during part I of the validation. Assuming (as has been recommended above) that all devices for self-measurement have passed the Comité Européan de Normalisation requirements to obtain a European Union certificate, it is not necessary to subject these devices to the first three phases of the BHS protocol.

The main changes proposed for a joint AAMI/BHS protocol will concentrate, therefore, on the fourth phase of the BHS protocol [9] and the validation procedure of the AAMI protocol [10]. In an attempt to unify the two protocols and to simplify the validation procedures, we have examined the data from 19 device-validation studies performed by us to test how results would have been affected had we used smaller samples and different recruitment ranges [11]. There are three major areas in which the two protocols could be changed. First, recruitment and training of observers can be improved and made less difficult by utilizing audio-visual technology to record comparative measurements. Second, the range of blood pressures required when recruiting subjects for clinical validation can be relaxed. Finally, the numbers of subjects recruited can be reduced.

### Participation by observers

The most fallible component of blood-pressure measurement is the human observer. The traditional technique of measuring blood pressure does not allow the result of the measurement to be checked by independent observers, thereby leaving the method open to bias. Another major difficulty with the BHS protocol has been training observers and ensuring that they remain in agreement for the duration of the validation study.

We designed the Sphygmocorder to overcome these difficulties. In this system, a number of components used to measure blood pressure have been combined with audio-visual recording technology to provide recorded data of the comparative measurements. The Sphygmocorder removes the expensive need to employ observers throughout the validation procedure and has greatly facilitated validation of devices [12]. Briefly, the Sphygmocorder consists of a mercury sphygmomanometer, an occluding cuff, an automatic inflation/deflation source, a stethoscope, a microphone capable of detecting Korotkoff sounds, a camera and a display screen. During recording only one trained observer need be present to ensure that high-quality recordings are obtained, and the recorded video tapes can later be checked by another trained observer and replayed by two trained observers if the sounds are not clear, of low intensity, distorted by artefactual sounds or of poor quality, whereupon a decision regarding their inclusion in the study can be made. The Sphygmocorder, which has been described previously, has itself been validated for accuracy against the trained human observer using the protocol of the BHS [12].

It is recognized, of course, that not all validation centres will have the Sphygmocorder and, where observers are being used, the protocol must give consideration to the role of education and certification of observers. Two developments towards this end are to be welcomed. First two CD-ROMs are available for training and assessing observers [13,14]. Second, a French manufacturer is developing an observer kit with two connected observer stations blinded relative to each other, each with a mercury column, a steady deflation mechanism and a recording facility [personal communication].

Table 2 Secondary-phase requirements

	99 Comparisons must reach at least two of the following		
	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
Simultaneous	65	85	90
Sequential	50	75	90
	99 Comparisons must reach all of the following		
	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
Simultaneous	60	80	90
Sequential	45	70	85

Figures are percentages of readings within 5, 10, or 15 mmHg

Table 3 Range requirements

	Primary phase: five subjects in each category Secondary phase: 11 subjects in each category		
	Low	Medium	High
SBP (mmHg)	< 130	130–160	> 160
DBP (mmHg)	< 60	80–100	> 100

SBP, systolic blood pressure; DBP, diastolic blood pressure.

**Validation procedure**

The validation should be performed using sequential same-arm comparisons against a mercury standard, as described in the BHS protocol [9]. Intra-arterial comparisons are not considered ethical for the validation of self-measuring devices for use on adults.

**Reduction in numbers**

Reducing the number of subjects required for validation would simplify the procedure greatly and there are now sufficient data from the many validation studies performed to allow us to reconsider the number of subjects required [11]. The use of simulators to augment the comparative measurements also shows promise as a means of reducing the number of hypertensive subjects demanded at present by the protocols, but simulators themselves will have to be validated before they can substitute for human subjects [15].

The AAMI and BHS protocols both require a sample size of 85 subjects with three pairs of measurements for each. Original power calculations were based on 85 pairs of measurements, which did not allow for the fact that the sample size required to prove the accuracy of a difference decreases as that difference increases, which means that a smaller sample is required to prove that a device is very inaccurate than is required to prove that a device is accurate. Our data support dividing the validation process into two phases: a primary phase in which three pairs of measurements are performed on 15 subjects with blood pressures in the stipulated ranges and a device failing in this phase (Table 1) is not subjected to further testing, whereas one passing it proceeds to a secondary phase, in which a further 18 subjects (33 in total) are recruited, for whom comparisons must fulfil the criteria shown in Table 2. These alterations did not substantially alter the results of any of our studies, but they would have greatly simplified the process of validation [11].

**Range of blood pressures**

Experience has shown that recruiting subjects with blood pressures at the extremes of high and low blood pressures is impractical. Furthermore, because variability of blood pressure is greater at these extremes, sequential comparisons are often not reliable. The relaxation of these requirements to those shown in Table 3 with an equal number of subjects for each range facili-

tates the validation procedure without unduly affecting results [11].

**Analysis of data**

The data from a modified, simplified validation procedure based on the above will need to be analysed and the software program devised by De Gaudemaris is ideal for such a purpose, in that it not only performs a full statistical analysis but also plots the data according to the recommended criteria [personal communication].

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