A comparison of the British Hypertension Society and Association for the Advancement of Medical Instrumentation protocols for validating blood pressure measuring devices: can the two be reconciled?

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Background: Experience with the original protocols of the Association for the Advancement of Medical Instrumentation (AAMI) and the British Hypertension Society (BHS) for validating blood pressure has provided valuable insight into the methodological problems associated with device validation and has influenced both the BHS and the AAMI in revising their protocols.

Objectives: To review the revisions of the original BHS and AAMI protocols; to compare the protocols; and, using the BHS protocol as a framework for validation, to determine how it should be modified to a protocol that will fulfil the criteria of both the AAMI and the BHS.

Conclusions: The revised protocols have many similarities but there are some important differences. These differences merit consideration so as to facilitate manufacturers seeking to validate devices for acceptance in both Europe and the United States. Of the two protocols, the BHS protocol is the more elaborate in that (1) it takes particular care to ensure that observers are trained to a very high standard, (2) it makes provision for special group validation and (3) it recommends in-use validation of all devices. By modifying the BHS protocol, it is possible to validate blood pressure measuring devices (ambulatory devices require special consideration) to satisfy the criteria of both protocols.

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Introduction

The problem of device inaccuracy, which was well-recognized in the early days of sphygmomanometry [1], has been voiced strongly in recent years by hypertension researchers, as shown by the growing number of publications on the subject [2]. In the 1960s and 1970s individual groups, frustrated by the failure of manufacturers to produce evidence of accuracy to match their claims for device performance, began to validate blood pressure measuring systems according to a variety of protocols and so illustrated the need for independent device validation [3–6]. However well-intentioned such protocols may have been, they had the serious disadvantage of not permitting comparison of one device with another because of the differing methodologies of validation [7]. In 1986, the Association for the Advancement of Medical Instrumentation (AAMI) published a standard for automated blood pressure measuring devices that included a protocol for the evaluation of device accuracy [8]. This was followed in 1990 by the protocol of the British Hypertension Society (BHS) [9]. These protocols, which differed in detail, had a common objective: the standardization of validation to establish minimum standards of accuracy and performance and to facilitate comparison of one device with another [10]. These two protocols, both of which have been revised recently [11–14], are likely to govern the effective procedures for device validation for the next few years. Although the protocols have many similarities, there are differences of considerable practical importance to manufacturers who may wish to have their equipment validated according to criteria acceptable to both the European and the American markets. Of the two, the BHS protocol is more elaborate than the AAMI

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protocol in that it takes particular care to ensure that observers are trained to a very high standard, it makes provision for special group validation and it recommends in-use validation of all devices. Unlike the AAMI protocol, which has been adopted as a national standard, the BHS protocol does not address manufacturing requirements or recommend intra-arterial comparison (an optional test in the AAMI protocol).

This paper has three aims: first, to review briefly the experience gained with the original BHS and AAMI protocols that has influenced the changes made in the revised protocols; second, to compare one protocol with the other; and, finally, using the BHS protocol as a framework for validation, to determine how it should be modified so as to devise a protocol that will fulfil the criteria of both the AAMI and the BHS.

Experience with the AAMI and BHS protocols

Since the AAMI standard was first published in 1987 a number of devices have been validated according to its recommendations [15–19] and the AAMI criteria for accuracy have been applied to a number of validations performed according to the BHS protocol [20–32]. Since the BHS protocol was first published in 1990 it has been applied to the evaluation of eight ambulatory systems [20–26,28]. Additionally, the BHS protocol, either in its entirety or partially, has been used to evaluate seven devices of self-measurement of blood pressure [29], the Hawksley random zero sphygmomanometer [30], and the Dinamap 8100 [31]. The collective experience with these protocols has illustrated some major aspects of validation that were not apparent when the protocols were originally drawn up.

The importance of indicating device modification

The original BHS protocol emphasized the importance of manufacturers indicating by a change in model number any modifications made to blood pressure measuring devices [9]. The importance of this stricture is well-illustrated by the conflicting reports from a number of laboratories on the accuracy of the Takeda TM-2420 [15–19,25,27,32], many of which used the AAMI or BHS validation procedures. The results of the individual studies on this device, which have been reviewed in detail elsewhere [33], show that apparent differences between laboratories can be accounted for by different models being submitted for validation by the manufacturers without the users being aware that modifications may have been made to the device. This trend has hopefully passed, and it is perhaps significant that the two latest reports on the Takeda stipulate the version being used [18,26].

Another example of device modification affecting accuracy is that reported by Hansen and Orskov [34], who observed apparently inexplicable variations in mean arterial blood pressure in a longitudinal study, which were inconsistent with the observed changes in systolic and diastolic blood pressure. It became apparent that the software programs of the SpaceLabs 90202 monitors used at the beginning of the study had been updated by the manufacturer when the monitors were repaired. Also, new devices supplied by the manufacturers during the study, though ostensibly the same 90202 mode, also contained the updated software. The company readily admitted that it had modified the software program for mean arterial pressure in the interests of greater accuracy and that the modification had resulted in mean arterial pressure being 3–4 mmHg higher with the new program, but they had not disclosed this to the user [34].

The importance of device modification is also illustrated in the evaluation of the Profilomat ambulatory system [21]. The Profilomat was developed for use in general practice by modifying the more expensive and elaborate CH-Druck ambulatory system [20]. During validation it became evident that the Profilomat was providing fewer valid measurements during ambulatory use than the parent CH-Druck, because the facility for repeating measurements in the event of a failed measurement had been removed; when it was replaced the modified recorders comfortably fulfilled the protocol requirements [21].

The revised BHS protocol emphasizes, therefore, that it is incumbent upon manufacturers to indicate clearly all modifications in the technological and software components of automated devices by changing the device number. Furthermore, modified devices must be subjected to renewed validation [14].

The effect of blood pressure level on device accuracy

During the validation of six ambulatory devices in our laboratory [20–25], a tendency was noted for accuracy to deteriorate with increasing levels of blood pressure [35]. When the data were analysed according to tertiles of pressure for low, medium and high pressure ranges all six devices held their overall grading, or improved them slightly in the low and medium pressure ranges, but in the high pressure range the devices lost accuracy. A similar tendency has also been reported by Pannarale and colleagues for oscillometric measurement [36].

The revised BHS protocol recommends, therefore, that the validation analysis should be performed not alone for the overall pressure range but also according to tertiles of pressure [14].

The effect of age on device accuracy

Miller and colleagues [37] have observed that discrepancies between an ambulatory device and mercury standard were systematically related to characteristics of the study participants, such as age, sex and race, with age demonstrating the strongest correlation. Clark and colleagues [38] have noted a tendency for ambulatory systems, especially those using the oscillometric technique, to be less accurate in the elderly. These results suggest that ambulatory systems for use in the elderly should be evaluated specifically in an aged population and that the

effects of age and blood pressure level on accuracy should be examined carefully [39].

Both revised protocols acknowledge the influence of age on the accuracy of blood pressure measurement and the BHS protocol has a special group validation procedure for devices that might be used particularly in the elderly.

The importance of in-use testing

To overcome the problem of devices losing accuracy under the stress of everyday use, the BHS protocol stipulates that validation should take place only after the device has had a reasonable period of use [14]. This test serves a number of functions. First, devices may fail to function during the in-use phase [29] and it would be clearly wasteful of resources to proceed to the main validation procedure with such a device. The test serves, therefore, as an indicator of the ability of the device to stand up to the stresses of everyday use. The value of the in-use phase in highlighting inadequacies in the device that may be amenable to easy correction by the manufacturers has been illustrated by the account cited above of the Profilomat having had the facility for a repeat measurement removed in the interests of reducing the cost of the device [21]. The period of use also permits some expression by the user as to the ease of use and comfort of the device, and sometimes useful recommendations can be made to the manufacturer that result in improved equipment [20–25].

The BHS protocol retains the in-use phase in the revised version [14] and the AAMI protocol has incorporated an in-use phase for devices measuring ambulatory blood pressure [12].

Importance of adhering to the protocols

The importance of adhering meticulously to the AAMI or BHS protocols is that devices validated with the protocols can be compared. However, if the protocols are modified such comparisons are not possible. This arises, for example, in two validation studies in pregnancy [20,40] in which the protocols were modified by substituting the Hawksley random zero sphygmomanometer for the standard mercury sphygmomanometer stipulated in both the AAMI and BHS protocols [8,9]. The inaccuracy of ambulatory devices in detecting diastolic blood pressure in pregnancy noted in these studies must be viewed critically as the comparative standard (the Hawksley) has itself been shown to be inaccurate [30].

Comparison of the revised BHS and AAMI validation protocols

The revised standard of the AAMI [57] and the protocol of the BHS [59] have many similarities but there are some important differences. These differences, which merit consideration so as to facilitate manufacturers seeking to validate devices for acceptance in both Europe and the United States, have been reviewed in detail elsewhere [33], and are briefly summarized in Table 1.

Can the AAMI and BHS protocols be reconciled?

Of the two protocols, the BHS protocol is the more elaborate in that it takes particular care to ensure that observers are trained to a very high standard, it makes provision for special group validation and it recommends in-use validation of all devices [14]. It does not recommend intra-arterial comparison, an optional test in the AAMI protocol [12]. Taking the BHS protocol as a framework for validation, how should it be modified so that it meets the AAMI criteria as well? To answer this question it is necessary to consider separately devices designed for measuring blood pressure in static conditions (the majority of devices) and those designed specifically for measuring ambulatory blood pressure.

Devices for static measurement

Phase I (before-use device calibration), Phase II [in-use (field) assessment] and Phase III (after-use device calibration) can be conducted without change, as in the revised BHS protocol [14]. Phase IV (static device validation) should be conducted as published but the following additional features should be included to comply with the AAMI protocol.

Participant selection

The BHS protocol allows a distribution of study participants with a range of arm circumferences by chance, whereas the AAMI stipulates that 10% of participants should have an arm circumference less than 25 cm and 10% an arm circumference greater than 35 cm. Both protocols recommend that participants should be above or below similar limits of blood pressure, but the AAMI standard states this in percentages and the BHS protocol in absolute numbers. In practice this means that to comply with both protocols nine participants (rather than at least eight as in the BHS protocol) should have pressures in each of the following categories: systolic blood pressure > 180 and < 100 mmHg; diastolic blood pressure > 100 and < 60 mmHg.

Measurement to the nearest 1 mmHg

Measurements should be taken to the nearest 1 mmHg rather than to the nearest 2 mmHg. As this modification is, in theory at least, more accurate than measuring to the nearest 2 mmHg it will not be necessary also to measure to the nearest 2 mmHg, as recommended in the BHS protocol. It should be borne in mind that the markings at 2 mmHg intervals on most mercury sphygmomanometers are likely to bias an observer towards rounding measurements to the nearest 2 mmHg.

Sequential versus simultaneous same-arm measurements

Both revisions of the protocols stipulate that opposite-arm comparisons should not be performed because of the problem of inter-arm difference. The revised BHS protocol recommends only a sequential same-arm test. However, the sequence of measurement stipulated in the BHS protocol [14] can be modified if the inflation

Table 1. Main features of and differences between the Association for the Advancement of Medical Instrumentation (AAMI) and the British Hypertension Society (BHS) protocols.

	AAMI	BHS
Publication	Summary paper in *Hypertension* [11] Full standard from AAMI for fee	Summary paper in *J Hypertens* [13] Full protocol in *J Hypertens* [14]
Scope	National standard	Validation protocol
Protocol design	Six parts (1) Requirements for a national standard (2) Rationale for a standard (3) Non-invasive validation (4) Intra-arterial validation (5) Data analysis and reporting (6) Assessment of ambulatory systems	Seven phases (Fig. 1) (1) Before-use calibration (2) In-use assessment (3) After-use calibration (4) Static device validation (5) Grading of device (6) Special group validation (7) Validation in special circumstances
Observers	Two observers Observer accuracy not tested Observers not necessarily blinded Observer agreement after study	Two observers Observer accuracy tested Observers blinded Observer agreement before and during study
Device calibration	Not a provision	Calibration agreement of three devices
In-use assessment	Ambulatory devices only	All devices
Participants for validation	85 participants 255 paired measurements No exclusion criteria AC stipulated BP range not specified General proviso for special groups	85 participants 255 paired measurements Exclusion: AF. Sounds to zero AC not stipulated No. participants per quartiles of BP Special groups/circumstances stipulated
Accuracy criteria	Grading: 95% within 10 and 85% within 5 mmHg Mean difference ≤5 mmHg SD ≤8 mmHg	Revised grading with A, B and C categories Mean difference ≤5 mmHg SD ≤8 mmHg
Reference standard	Hg manometer/nearest 1 mmHg	Hg manometer/nearest 2 mmHg
Measurement analysis	Simultaneous or sequential	Sequential only
Accuracy/BP level	Not included	Accuracy at low/medium/high BP
Intra-arterial comparison	Permitted	Rejected
Basic information	Not addressed	Detailed report

AC, arm circumference; AF, atrial fibrillation; BP, blood pressure.

mechanism of the device permits simultaneous comparison using the following sequence, which merely requires the observers to measure additional pressures during the measurement of the test instrument at blood pressure comparisons 2, 4 and 6 (Table 2).

This sequence provides the data necessary for analysis by both the sequential and the simultaneous techniques, thereby fulfilling the requirements of both protocols.

Accuracy criteria

In addition to grading the test device according to the BHS accuracy criteria, the accuracy criteria of the AAMI and a percentage grading can be applied to the data (Table 1).

Devices for ambulatory measurement

The requirements demanded for validating devices for static measurement also apply to those for measuring blood pressure under ambulatory conditions, but other considerations must also be given attention. Both revisions of the BHS and AAMI protocols acknowledge that if the ambulatory system being evaluated has been designed to measure blood pressure intermittently during the 24-h period when the participant has been instructed to cease activity and to keep the arm still during measurement, the static validation test is all that is required. Both protocols stipulate, however, that the ambulatory system must be subjected to an in-use assessment and that calibration should be tested after use. The revised BHS protocol acknowledged that the recommendations made

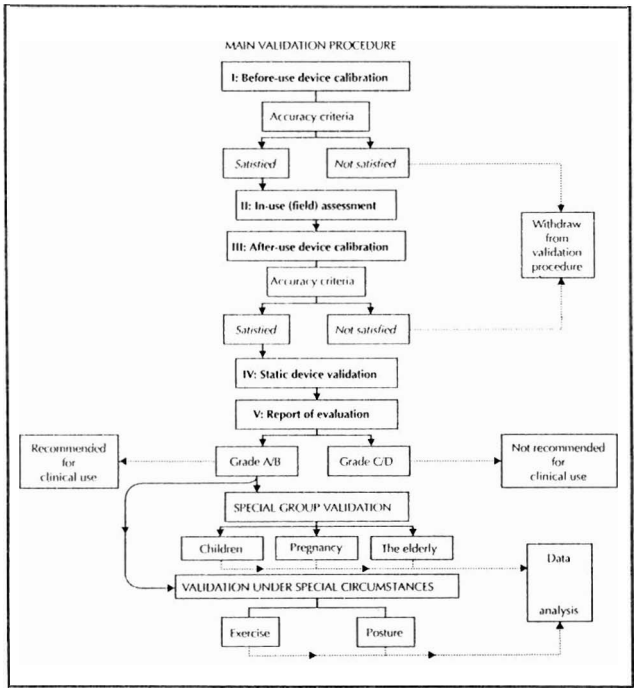

Fig. 1. British Hypertension Society validation procedures. From [14].

in the original protocol for recordings every 15 min during the day had proved onerous for participants and in the revised protocol 30-min intervals are stipulated for the day and night-time periods. However, the revised AAMI protocol adopts the original BHS requirement of 15-min intervals during the day. Both protocols stipulate that three devices should be tested but the requirement for the AAMI is for 30 24-h studies in 10 participants and the BHS requirement is for 24 24-h studies in 24 participants, half of whom should be normotensive and half hypertensive. To comply with both protocols, therefore, it will be necessary to increase the number of 24-h studies in the BHS protocol from 24 to 30 and to increase the day-time recordings from 30- to 15-min intervals.

Table 2. Blood pressure (BP) comparisons.

BPA	Observers 1 and 2
BPB	Observer 3 with test instrument
BP1	Observers 1 and 2 with mercury standard
BP2	Observer 3 with test instrument and observers 1 and 2 with mercury standard
BP3	Observers 1 and 2 with mercury standard
BP4	Observer 3 with test instrument and observers 1 and 2 with mercury standard
BP5	Observers 1 and 2 with mercury standard
BP6	Observer 3 with test instrument and observers 1 and 2 with mercury standard
BP7	Observers 1 and 2 with mercury standard

Both protocols acknowledge that posture may affect accuracy. The revised BHS protocol recommends that ambulatory systems be subjected to testing for posture in a subgroup of 30 participants in the standing, supine and sitting positions. The revised AAMI protocol stipulates that a full validation be performed in the supine, sitting and standing positions so that there are 765 paired measurements for analysis. This stipulation assumes that the device can be validated by simultaneous comparison, whereas our experience is that most devices cannot be validated in this way because of their inflation/deflation characteristics. Because of this the BHS protocol makes provision only for sequential comparison. We believe that the AAMI requirement for full validation in three positions in 85 participants will be practical, albeit at a high cost, only for the few devices suitable for simultaneous comparison, and that it will be impractical for devices requiring sequential comparison. At this stage we can only alert manufacturers of ambulatory systems to this serious problem and suggest that the decision as to which protocol to follow should be based on a number of considerations, not least of which would be the feasibility of performing simultaneous comparison.

Finally, the revised BHS protocol recommends a non-invasive assessment during exercise for ambulatory systems that claim accuracy during motion [14]. The revised AAMI protocol recommends comparison in opposite arms using direct intra-arterial measurement either during bicycle exercise with standard intra-arterial techniques or during ambulatory activity using the Oxford system to provide continuous recording [12]. The BHS protocol does not advocate intra-arterial testing [14], and though this is included in the AAMI protocol, it is not mandatory [12]. Moreover, both revised protocols recommend that opposite-arm comparisons should not be used because of inter-arm differences.

In summary, the following modifications to the BHS protocol will fulfil the criteria of both the revised BHS and AAMI protocols for all blood pressure measuring devices:

(1) consideration of arm circumference and limits of blood pressure in participant selection (Table 1);
(2) measurement to the nearest 1 mmHg in the main validation test;
(3) sequential and simultaneous (when feasible) comparison using the sequence outlined in Table 2;
(4) analysis to include the AAMI accuracy criteria of mean difference ≤ 5 mmHg with standard deviation of differences ≤ 8 mmHg, and 95% of device measurements within 10 mmHg and 85% within 5 mmHg for systolic and diastolic blood pressures;
(5) for ambulatory devices, the number of 24-h studies to be increased from 24 to 30 and the day-time recording intervals from 30 to 15 min; careful consideration has to be given to the choice of validation procedure.

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