Devices and validation

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Introduction

Sphygmomanometry has evolved over nearly three centuries but conventional sphygmomanometry, the technique with which we are all so familiar in clinical practice, was introduced just over a century ago by Riva Rocci in 1896 and modified by Korotkoff in 1905 [1]. However, as we approach the end of the twentieth century, several developments, not least being the availability of accurate automated devices, herald the demise of so-called classical sphygmomanometry and the dawning of a new era in measurement of blood pressure. Automated devices that not only measure blood pressure but also, by allowing measurements to be stored, provide an assessment of behaviour of blood pressure over time, are now available.

The sale of electronic blood pressure measuring devices designed for self-measurement is not necessarily subject to any medical influence. Such devices can be bought by patients without discussion with their doctors and can be advertised outside the pharmacy or medical distribution system, without medical constraint. This lack of medical control, coupled with a growing public desire to know more about health and illness, has resulted in the manufacture and marketing of a vast array of such devices, few of which have been evaluated according to the procedures considered necessary for blood-pressure-measuring equipment used in clinical practice.

The objective of the session 'Devices and Validation' of the First Consensus Conference on Self Blood Pressure Measurement was to identify areas of importance in the production and development of blood-pressure-measuring devices for self-measurement, to make recommendations regarding how such devices should be validated and to identify which among those on the market have satisfactorily been validated.

Developments that may influence devices

Banning use of mercury

Mercury will be banned from clinical use in the near future because it is a toxic, persistent and bio-accumable substance, many tons of which are distributed throughout the world to hospitals and countless individual doctors and little of which is returned for disposal. It finds its way back into the environment through evaporation, in sewage or in solid waste, damaging the marine environment, and it accumulates in soil and in sediments, thereby entering the food chain [1–4]. Signatories of the final declaration from the Third

International Conference on the Protection of the North Sea resolved to reduce mercury in the environment to 'levels that are not harmful to man or nature before the year 2000' [5].

One of the consequences of the impending ban on use of mercury is that authoritative bodies, government health agencies and purchasing authorities have been reluctant to make recommendations and give guidance to doctors and the public. Rather it falls upon bodies such as the Working Group on Blood Pressure Monitoring of the European Society of Hypertension and the Groupe Evaluation et Mesure to evaluate practice and make recommendations. The result, however, of this ambivalence is that hospitals and doctors may replace mercury sphygmomanometers by unreliable and inaccurate devices, such as aneroid sphygmomanometers, which become inaccurate with use and should not, therefore, be substituted for the mercury instrument [6]. Many automated devices have had a poor record for accuracy [7], but automated devices [8] have recently satisfied the stringent criteria of the validation protocols of the British Hypertension Society (BHS) [9] and the Association for the Advancement of Medical Instrumentation (AAMI) [10].

The passing of mercury sphygmomanometers should not in itself be a cause for concern. In fact, it might be argued that the sooner we rid ourselves of an inaccurate technique, on which we base so many important decisions of management, the better. This is not to blame the mercury sphygmomanometer (a most reliable instrument) but rather to impugn the most fallible part of the whole procedure, the human observer [2]. Automated devices can remove observer error and provide in addition a printout of the measurement with the date and time of the measurement, or the measurement can be stored for display in a computer program.

Replacing the millimetre of mercury by the kilopascal

Banning mercury from clinical use raises another issue of importance for clinical medicine. The Système International (SI) unit for pressure is the kilopascal, but the use of this unit for blood pressure (and the replacement of the millimetre of mercury by the kilopascal) has been postponed until such time as there is a suitable alternative to the mercury sphygmomanometer [11,12]. If the millimetre of mercury were no longer the unit of measurement for blood pressure, the mainstay of the medical argument for retaining the millimetre of mercury as a unit of measurement, namely that we measure what we see, would also disappear.

Solving the cuff controversy

However accurate we strive to make devices for self-measurement of blood pressure, there will remain one inherent inaccuracy, namely that induced by miscuffing. Self-measurement of blood pressure is largely dependent on occlusion of the arm (or wrist) by a cuff and, in common with measurement in clinical practice, the technique is prone to the inaccuracy induced by miscuffing [13].

A review of the literature on the century-old controversy relating to the error that can be introduced into measurement of blood pressure by using a cuff with a bladder of inappropriate dimensions for the arm for which it is intended has shown that miscuffing is a serious source of error that must inevitably lead to incorrect diagnosis in practice and erroneous conclusions in research into hypertension [13]. There is unequivocal evidence that either too narrow or too short a bladder (undercuffing) will cause overestimation of blood pressure and there is growing evidence that too wide or too long a bladder (overcuffing) can cause underestimation of blood pressure. Undercuffing has the effect in clinical practice of overdiagnosing hypertension and overcuffing leads to hypertensive subjects being diagnosed as normotensive. Either eventuality has serious implications for the epidemiology of hypertension and clinical practice. Several approaches to coping with the difficulty of mismatching have been used over the years; these have included the application of correction factors, using a range of cuffs (or cuffs containing a variety of bladders) and using a cuff that would encircle the majority of arms [13]. None of these solutions has been satisfactory and on the basis of a thorough examination of the literature and aware of the advances in cuff design, the design features for an 'adjustable cuff', which would be applicable to all adult arms, were proposed in 1996 [13] and such a cuff is now being tested by one manufacturer (A.C. Cosor & Sons Ltd. (Surgical), London, UK).

New technologies

At present automated blood pressure measuring devices rely, almost exclusively, either on auscultatory detection of Korotkoff sounds using one or more microphones, or on oscillometric analysis of the pulse waveform. However, there has been such a significant shift from auscultatory to oscillometric devices during the last decade that it can be expected that, in the near future, the microphonic recording of sounds will no longer be used [14]. Some devices use alternative measurement techniques to auscultation and oscillometry (for review [14]) and it can be expected that, as technology develops, at least some of these innovative methodologies will be applied to the self-measurement of blood pressure.

Most devices for self-measurement use the oscillometric method, with an occluding cuff placed on the upper

arm, a finger or the wrist. The latter site for measuring blood pressure has become increasingly popular. It is estimated that wrist measuring devices have gained 50% of the market share of the 1.2 million blood-pressure-measuring devices sold annually in Germany for self-measurement of blood pressure [15]. One of the major problems, however, with wrist (and finger) devices is that of ensuring that the hand or wrist is kept at heart level during measurement. Serious errors occur if this is not done.

Present validation requirements

Safety and mechanical considerations

The European standard (parts I–III of which were published in 1997 [16–18] and the American standard [19] provide criteria governing the safety aspects of blood-pressure-measuring devices, such as their operation under certain environmental conditions. The European standard defines the general requirements for the European market of non-invasive blood-pressure-measuring machines and includes details on cuff, screen display and levels of temperature and relative humidity at which the functioning of the machine is guaranteed [18]. The evaluation of the precision of the blood pressure calculated with the cuff is the object of a clearly defined methodology and the machine should have a precision of ± 3 mmHg at all levels of blood pressure (maximum steps of 50 mmHg) for a range of temperature between 15° and 25°C and a relative humidity between 20% and 85%. The European Commission directive 93/42/CEE of the 14 June 1993 [20], relating to medical equipment in general, requires each manufacturer to obtain from the European Commission certification, which certifies that the device has been subjected to quality assurance evaluation in conformity with written procedures verified by an external auditor and in conformity with predefined technical norms.

Accuracy and performance characteristics

In 1987, the AAMI published a standard for electronic or automated sphygmomanometers that included a protocol for the evaluation of the accuracy of devices [19] and in 1990 the protocol of the BHS was published [21]. These protocols, which differed in detail, had a common objective, namely the standardization of validation in order to establish minimum standards of accuracy and performance and to facilitate comparison of one device with another [22]. Both protocols have since been revised [9,10]. Though other countries, such as Germany [23] and Australia [24], have included recommendations for testing the accuracy of blood pressure measuring devices in their national standards, no validation studies using these protocols had been published until 1997, when one validation study performed according to the protocol 58 130 of the German Institute of Validation was published [15]. Ng and Small have reviewed the differences among national protocols for validation in considerable detail [25–27]. Clinical validation to test the precision of the overall system is not obligatory in the European standard, but it is recommended that blood-pressure-measuring devices should be subjected to clinical evaluation according to the BHS, AAMI or German protocols [18].

Proposed revision of BHS/AAMI protocol

International protocol

Experience with the AAMI and BHS protocols has provided valuable insight into the methodological problems associated with validation of devices [28–34]. 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. Of the two protocols, the BHS protocol is the more elaborate in that it specifies that particular care must be taken to ensure that observers are trained to a very high standard, makes provision for validation for special groups and also makes recommendations for in-use validation of all devices. By making modifications to the BHS protocol, it is possible to devise a consensus validation protocol, which (with the exception of ambulatory devices which require special consideration) satisfies the criteria of both protocols [34]. Moreover, it has been demonstrated in practice that validation studies can be performed in such a way as to satisfy the criteria of both protocols. It would seem timely, therefore, for the AAMI and BHS to join together in producing a revised common protocol for the validation of blood-pressure-measuring devices that might be acceptable as an international protocol. Indeed, one of the objectives of the Working Group of the European Society of Hypertension is to investigate the possibility of having a common protocol that would be accepted as the international standard for the validation of blood pressure measuring devices [35]. Such a protocol would be welcomed by manufacturers and by those involved in performing validation procedures. Representatives of the AAMI and BHS are in the process of exchanging views on the feasibility of producing a common protocol. This objective is being facilitated by analysis of data from 19 device-validation studies performed in the Blood Pressure Unit in Dublin to determine how the results would have been affected had sample sizes been smaller and recruitment ranges less stringent [36].

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 on the complex issue of device validation, 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 [34].

There are seven major areas in which the two protocols might be modified: pre-validation phases could be eliminated; recruitment and training of observers could be improved and made less difficult by using audio-visual technology to record comparative measurements; the range of blood pressures required for recruiting subjects for clinical validation could be relaxed; the numbers of subjects recruited could be reduced; 'hopeless' devices might be eliminated early in validation; analysis of results could be facilitated by the use of computer programs, and devices using a validated algorithm might not need to be re-validated, provided that integrity of this algorithm can be proven.

Eliminating pre-validation phases

The BHS protocol is divided into two parts [9]. Part I comprises the main validation procedure and has five phases: before-use calibration; 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 exercise and various postures; part II is performed only if the device obtains grade A or B during part I of validation. Assuming (as has been recommended above) that all devices for self-measurement have passed the Comité Européen 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 removal of the pre-validation phases would shorten the validation procedure greatly.

Observer participation

The most fallible component in measurement of blood pressure 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 period of the validation study. The Sphygmocorder has been designed to overcome these difficulties [37,38]. In this system, some components used to measure blood pressure have been combined with audio-visual recording technology to provide recorded data of the comparative measurements. 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 needs to be present to ensure that high-quality recordings are being attained and the recorded video tapes may later be checked by another trained observer and re-played by two trained observers if the sounds are unclear, 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 removes the expensive need to employ observers throughout the validation procedure and has greatly facilitated validation of devices [37,38]. The Sphygmocorder has been validated for accuracy against the trained human observer using the protocol of the BHS [37,38]. 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 [2]. Two developments towards this end are to be welcomed. First two CD-ROM are available for training and assessing observers [39,40]. Second, an observer kit with two connected observer stations, each with a mercury column, a steady-deflation mechanism and a recording facility is now available commercially (E.C. Med, Paris, France).

Reduction in number of subjects recruited

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 review the number of subjects required [36]. 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 [25,26,41–43]. The AAMI and BHS protocols both require a sample size of 85 subjects with three pairs of measurements on each. Original calculations of statistical power 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. Analysis of results of 19 validation studies has shown that reducing the number of subjects

recruited from 85 to 33 is possible without affecting the accuracy of the validation. 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 ranges shown in Table 1 and a device failing this phase is eliminated from further testing, whereas one passing it proceeds to a secondary phase, in which a further 18 subjects are recruited (making a total of 33), for whom comparisons must satisfy the criteria shown in Table 1. These alterations did not substantially alter the results of the validation studies examined, but they would have greatly simplified the validation process [36].

Relaxing the range of blood pressures

Experience has shown that recruiting subjects 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 unreliable. The relaxation of these requirements to those shown in Table 1 with an equal number of subjects being recruited to each range would facilitate the validation procedure without unduly affecting results [36].

Eliminating 'hopeless' devices

Examination of results of 19 previous validation studies shows that, if a device does not satisfy the criteria of the primary phase (Table 1), in which three pairs of measurements are performed on 15 subjects with blood pressures in the ranges shown in Table 1, it cannot satisfy the validation criteria and should be eliminated at this stage, whereas one passing the primary phase proceeds to the secondary phase, in which a further 18 subjects are recruited (making a total of 33). By eliminating 'hopeless' devices in this way, considerable time and expense could be saved.

Computer analysis

The data derived from validation have to be analysed and displayed graphically. A software program to provide a full statistical analysis and to plot the data according to the recommended criteria has been devised by R. De Gaudemaris (personal communication).

Integrity of algorithm and modification to design

The first BHS protocol emphasized the importance of manufacturers indicating by a change in model number any modifications made to blood pressure measuring devices. The revised BHS protocol, published in 1993, went further stipulating not only that manufacturers must indicate clearly all modifications to the technological and software components of automated devices by changing the device number but also that modified devices must be subjected to validation anew [9]. These stipulations were influenced by consequences that had resulted from changes made by manufacturers to the algorithms of devices for measuring ambulatory blood

Table 1 Synopsis of preliminary proposals for an 'international' validation protocol

Seven points of modification
- Eliminate pre-validation phases
- Use observer aids
  - Sphygmocorder
  - Colson kit
  - CD-ROMs for training
- Relax ranges of blood pressure for recruitment of subjects
- Reduce the number of subjects recruited
- Eliminate 'hopeless' devices
- Use computer analysis
- Check integrity of algorithm to avoid validation of devices with the same algorithm

Validation methodology
- Comparison with standard mercury sphygmomanometer
- Measurements performed on the arm by two trained and 'blinded' observers
- Double-Y stethoscope and two calibrated mercury-column sphygmomanometers connected to the same cuff, or use the Sphygmocorder
- Measurements performed according to simultaneous or sequential methodology

Requirements concerning range of blood pressure
- Primary phase: five subjects in each category (15 subjects)
- Secondary phase: 11 subjects in each category (33 subjects)

	Low	Medium	High
Systolic blood pressure (mmHg)	< 130	130–160	> 160
Diastolic blood pressure (mmHg)	< 60	80–100	> 100

Procedure
Sequential measurements are performed on the 15 first subjects. If the 45 comparisons satisfy at least one of the criteria shown in the table below, the evaluation is then performed on 18 other subjects; if not, the validation is stopped and the device rejected.
Evaluation criteria for devices using sequential same-arm measurement

Primary phase (15 subjects)	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
45 Comparisons must satisfy at least one of the following	20	30	35
Secondary phase (15 previous plus 18 new subjects)	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
99 Comparisons must satisfy at least two of the following	50	75	90
99 Comparisons must satisfy all of the following	45	70	85

pressure [44]. Manufacturers, however, have from time to time expressed the view that the BHS stipulations were not only unreasonable, in that they oblige the manufacturer to go to the unnecessary expense of having a device that has undergone some design modifications without alteration of the algorithm re-evaluated, but also counterproductive, in that they prohibit beneficial modification to design of a design, which need not involve adjusting an algorithm previously shown to have satisfied the criteria for accuracy of the protocol. There is validity in this viewpoint and, since the BHS protocol is at present undergoing revision, it would seem timely to debate the issue [44]. Might it be reasonable to remove this stipulation from the BHS protocol if a manufacturer of a device that satisfied the BHS criteria for accuracy, were prepared to provide first, independent evidence that the algorithm of the modified device is identical to that of the originally validated model; second, evidence that the proposed modifications cannot alter the performance of the algorithm; and third, a system of model numbering that would acknowledge a common algorithm and denote the feature of the modification? Perhaps manufacturers of blood-pressure-measuring devices would be prepared to say how these objectives might be achieved [44].

Other considerations

Devices should be able to identify errors related to arm movement or inadequate inflation of the cuff. Careful attention must also be given to validation of devices for special groups, such as the obese and the elderly. Subjects for whom validatory comparisons are not possible must not simply be excluded from the validation procedure, but rather included as subjects on whom the device would not operate. A revised validation protocol must also allow for innovative technology by predicting developments in the manufacture of automated devices. Similarly, a revised protocol must provide for the assessment of other haemodynamic measurements that are becoming important in cardiovascular assessment, such as heart rate, pulse pressure and motion logging, and further measurements, such as monitoring of silent ischaemia and pulse-wave velocity. Consideration should also be given to the way in which a completed validation report is published (in this regard, the journal *Blood Pressure Monitoring*, has become the repository for such studies).

State of the market

There is an enormous market for automated devices that permit self-measurement of blood pressure. In Germany, for example, 1.2 million such devices are sold annually [15]. In 1994, Ng and Small surveyed 423 automated devices, of which 161 were for the self-measurement of blood pressure [45]. Only a few of the many hundreds of models available worldwide have been subjected to independent validation. A review of the literature in 1998 to determine which automated devices for self-measurement of blood pressure had been validated according to the BHS and AAMI protocols showed that 10 such devices had been validated, of which one was deemed satisfactory according to the criteria of the BHS and standard AAMI protocols [46]. However, if the intra-arterial comparisons of the AAMI protocol and the new German protocol are accepted, a further two devices may be added [15] (Table 2).

In a validation study in 1990 using early versions of the BHS and AAMI protocols, all seven devices tested failed to satisfy the criteria for accuracy of either protocol, whereas the mercury sphygmomanometer was comfortably within the criteria of both protocols [7]. The Omron company is the first manufacturer of devices for self-measurement of blood pressure to have produced a device fulfilling the requirements of the BHS and AAMI protocols, insofar as we are aware. The Omron HEM-

Table 2 Automated blood-pressure-measuring devices for self-measurement available on the market that have been subjected to validation by the British Hypertension Society (BHS) and Association for the Advancement of Medical Instrumentation (AAMI) protocols [44].

Device	Mode	AAMI[a]	BHS[b]	Circumstance
Omron HEM-400C	Oscillometric	Failed	Failed	Rest
Philips HP5308	Auscultatory	Failed	Failed	Rest
Healthcheck CX-5 060020	Oscillometric	Failed	Failed	Rest
Nissei Analogue Monitor	Auscultatory	Failed	Failed	Rest
Philips HP5306/B	Oscillometric	Failed	Failed	Rest
Systema Dr MI-150	Oscillometric	Failed	Failed	Rest
Fortec Dr MI-100	Oscillometric	Failed	Failed	Rest
Omron HEM-705CP	Oscillometric	Passed	B/A	Rest
Philips HP5332	Oscillometric	Failed	C/A	Rest
Nissei DS-175	Oscillometric	Failed	D/A	Rest
Omron HEM 706	Oscillometric	Passed	B/C	Rest
Omron HEM 403C	Oscillometric	Passed	??	Protocol violation
Omron HEM-703CP	Oscillometric	Passed	Not applicable	Intra-arterial
Omron R3	Wrist	Passed	Not applicable	Intra-arterial/German

[a]Grades A–D according to BHS protocol; A, best agreement; D, worst agreement with mercury standard. Note that, for the first seven devices grading criteria had not been established even though BHS protocol was in operation. Criteria for fulfilment of BHS protocol: devices must achieve at least grade B/B. [b]Criteria for fulfilment of AAMI standard: mean difference $\leq$ 5 mmHg and SD $\leq$ 8 mmHg.

705CP device achieved acceptable grades of B for systolic blood pressure and A for diastolic blood pressure according to the BHS criteria and satisfied the criteria for accuracy of the AAMI protocol, whereas in the same study the Philips HP5332 and the Nissei DS-175 devices achieved unacceptable BHS grades and failed to satisfy the AAMI criteria for accuracy [8]. In another study, the Omron HEM 706 device achieved BHS grades B/C in the overall range of blood pressure and satisfied the AAMI criteria for accuracy [47]. The Omron HEM 403C device has also been evaluated according to the BHS protocol but the protocol was violated by substitution of the Hawksley random-zero sphygmomanometer for the standard mercury sphygmomanometer [48]. Devices assessed against the Hawksley sphygmomanometer may be disadvantaged and the C grades obtained both for systolic and for diastolic blood pressures with the Omron HEM 403C device are at best questionable [49]. The AAMI protocol permits direct intra-arterial comparison for a small number of subjects [10], whereas the BHS protocol does not allow intra-arterial comparison for a number of reasons, the most important of which is that values of systolic and diastolic blood pressure obtained by the direct technique are different from measurements obtained by indirect methods and clinical practice derives from data obtained by the indirect rather than the direct technique [9]. Using intra-arterial comparison, the Omron HEM-703CP device was shown to satisfy the criteria of the AAMI protocol [12]. The German protocol for validation also permits intra-arterial comparisons and, using this protocol [23], the Omron R3, a device that measures blood pressure oscillometrically on the wrist, has fulfilled the protocol's requirements [15].

Clearly, among the number of devices for self measurement on the market, few have satisfied independent validation criteria, so manufacturers must be encouraged to have their products evaluated according to recognized protocols. Moreover, the state of the market needs to be assessed regularly and the results made easily accessible to prospective purchasers.

Conclusions

The First Consensus Conference on Self Blood Pressure Measurement endorsed these proposals, which were based on the foregoing data and reasoning.

Proposal I

Automated devices for self measurement of blood pressure should provide blood pressures both in millimetres of mercury and in kilopascals so that users can become familiar with the latter units. (Strength of recommendation: D.)

Proposal II

Manufacturers should be encouraged to produce the 'adjustable cuff', which would be applicable to all adult arms, as originally proposed in 1996. (Strength of recommendation: B.)

Proposal III

Devices for self-measurement of blood pressure must have a European Commission certificate, which will attest to the safety and physical durability of such devices under a range of environmental conditions. (Strength of recommendation: D.)

Proposal IV

Devices for self-measurement of blood pressure should be subjected to independent tests of accuracy under clinical conditions, as recommended by the BHS and AAMI protocols. (Strength of recommendation: D.)

Proposal V

The AAMI and BHS should produce a common validation protocol that would effectively become an international protocol for the validation of all blood-pressure-measuring devices, including those used for self-measurement, and they should be encouraged to simplify validation procedures in order to make the performance of validation studies in a large number of centres feasible. (Strength of recommendation: D.)

Proposal VI

The Working Group on Blood Pressure Monitoring of the European Society of Hypertension should consider giving accreditation to laboratories with an interest and expertise in validation of devices. (Strength of recommendation: D.)

Proposal VII

An annual 'state-of-the-market' review should be published, possibly in association with consumer associations, listing devices for self-measurement of blood pressure on the market that have been independently validated. (Strength of recommendation: D.)

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Key to category of evidence (Shekelle PG, Woolf SH, Eccles M, Grimshaw J. Developing guidelines. *BMJ* 1999; **318**:593–596):

*Category IIb evidence from at least one other type of quasi-experimental study.

†Category IV evidence from expert committee reports or opinions or clinical experience of respected authorities, or both.