

The dabl Educational Trust device equivalence procedure

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Manufacturers of blood pressure measuring devices that have previously been successfully validated for accuracy may make modifications to a device, which do not affect its measurement accuracy and should not require further validation. In this paper the procedure for manufacturers to declare the equivalence of a modified device with a device that has been validated earlier is described. *Blood Press Monit* 12:245–249 © 2007 Lippincott Williams & Wilkins.

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Introduction

The use of automated and semiautomated devices for the measurement of blood pressure is now commonplace in both clinical practice and research. The importance of proper validation for such devices is well established. It is almost 20 years since the Association for the Advancement of Medical Instrumentation published its first standard for electronic or aneroid sphygmomanometers [1]. This standard included a protocol for evaluating device accuracy. The British Hypertension Society published its own protocol in 1990 [2], which was revised in 1993 [3]. The Association for the Advancement of Medical Instrumentation has since published four revisions of its standard, the latest being in 2003 [4]. Experience with validation highlighted major difficulties in fulfilling the criteria of these protocols and, in 2002, the European Society of Hypertension published the International Protocol, which, by taking into account previous validation data, was able to overcome the procedural difficulties of the earlier protocols and still retain their statistical and methodological integrity [5]. This is now the protocol of choice for most validation studies [6].

From time to time, manufacturers have queried the necessity for devices that undergo minor modifications without any alteration to the measurement algorithm having to undergo a repeat validation [7]. Since establishing the website, www.dableducational.org, closer dialogue with manufacturers brought this problem to the attention of the dabl Educational Advisory Board (membership listed at the end of this paper), which has approved measures to determine device equivalence.

Device modification not affecting accuracy

The following areas of modification that should not affect the measuring accuracy of a device have been identified:

Device design

Devices for use in a clinical setting may be designed to stand alone on a desktop, to be movable on a stand or to be attached to a wall. Each design demands different features so as to optimize the display, button positions, cuff connections, battery access and so on. Self-measurement devices may be manufactured in a variety of styles to cater to different markets.

Functionality

Devices may be modified to provide a variety of new functions, such as plotting averages and trends, or the capability to store data separately for different family members. Some devices allow risk factor calculations together with blood pressure measurements. Totally unrelated functions such as clocks and calendars may also be provided.

Accessories

A number of versions of the same device may be provided, for example, a basic device, or a superior model with a printer, or a communications link to a personal computer or a modem, and some models may have a battery charger.

These different modifications may be denoted by different model names and numbers, which may vary from country to country. Clearly, it is neither desirable nor practical to subject a blood pressure measuring device that had earlier been successfully validated for accuracy, and which has now undergone such modifications, to a further full validation of accuracy, but it is necessary to ensure that the basic validated algorithm has not been altered by the modifications. The dabl Educational Trust has, therefore, drawn up a procedure whereby manufacturers can officially declare a device that has been modified to be identical in its measurement details to an existing validated model and whereby they can provide assurances that the measuring accuracy has not been altered.

The 'Declaration of Blood Pressure Measuring Device Equivalence' form

The form consists of two parts – Section A and Section B (Fig. 1).

Section A

Opening statement

The form commences with an opening statement, which reads as follows:

I (Name of a Company Director) Director of (Company name) hereby state that there are no differences that will affect blood pressure measuring accuracy between the (blood pressure measuring device for which validation is claimed) blood pressure measuring device and the (existing validated blood pressure measuring device) blood pressure measuring device, which has previously passed the (protocol name) protocol, the results of which were published as follows (full reference).

List of differences

The list of potential differences is headed 'The only differences between the devices involve the following components:'. Each difference is accompanied by yes and no check boxes. Wherever the item is not applicable (e.g. the 'Algorithm for Auscultatory Measurements' in an oscillometric device), both boxes are left blank. A 'no' is therefore a declaration that the item is relevant but is identical in both devices. A 'yes' indicates that it is relevant and that it is different between the devices. This section also allows the inclusion of an item, such as 'printing facilities', which may be present in one device and absent in the other. All items ticked 'yes' must be briefly explained.

The list is broken down into two main parts. Part I consists of items critical to blood pressure measurement and Part II lists items not critical to measurement.

Part I. Items critical to blood pressure measurement:

1. Algorithm for oscillometric measurements
2. Algorithm for auscultatory measurements
3. Artefact/error detection
4. Microphone(s)
5. Pressure transducer
6. Cuff or bladder
7. Inflation mechanism
8. Deflation mechanism

Items 1–3 refer to the algorithm and, if changed, the device must undergo validation. Items 4–7 refer to the physical items potentially required for blood pressure detection and, with the possible exception of minor variations in item 6, if changed, the device must undergo validation. Items 7 and 8 refer to the inflation and deflation mechanisms and, if changed, the device must undergo validation.

Part II. Items not critical to blood pressure measurement:

9. Model name or number
10. Casing
11. Display
12. Carrying/mounting facilities
13. Software other than algorithm
14. Memory capacity/number of stored measurements
15. Printing facilities
16. Communication facilities
17. Power supply

Apart from 'model name or number', a brief explanation is required after each question to show that the modified feature is simply an added extra that does not affect blood pressure detection. Item 9 is present to cover two specific instances: (i) where the same model is sold under different names in different jurisdictions and (ii) where a model is 'upgraded' but retains the same name. Items 10–12 refer to design modifications. Items 13 and 14 refer to functionality changes and items 16 and 17 refer to accessory changes. Finally, a general 'other facilities' item is included, with a space to enter any 'further relevant details' so that the manufacturer can expand on any changes not covered in the equivalence form.

Section B

This section requires the name and signature of a company director with the date, name, signature and address of a witness and the official company seal or stamp.

Manuals for the device for which equivalence is being claimed and for the device that has been validated must be submitted electronically.

Assessing 'Declaration of Blood Pressure Measuring Device Equivalence' forms

When a completed form is submitted, it undergoes the following assessment procedures:

Stage I: Initial Form Assessment

- The validated device is checked to ensure that it is listed as 'recommended' on www.dableducational.org [6].
- Items in Part I are checked as marked 'no' or are not marked as appropriate; the only permissible 'yes' is item 6 provided that any change can be guaranteed not to interfere with the algorithm function. Any other 'yes' would automatically mean the rejection of the declaration and a requirement for validation.
- Items in Part II that are marked 'yes' must be accompanied by an explanation, which may be expanded in the 'further relevant details' section or on the reverse of the form.

Table 1 Example of an accepted equivalence application

	Submitted device (1)	Validated device (2)
Devices	ABC-Plus	ABC
Images	<input type="checkbox"/>	<input type="checkbox"/>
Validation		BHS-A/A grading
Device 1 criteria	Memory: 30 measurements	Averaging facility
Same criteria	Averaging facility	Oscillometric measuring method
	Oscillometric measuring method	Printer Port
	Printer Port	Error code (1, 2, 3, 5 and 6)
	Error code (1, 2, 3, 5 and 6)	Cuffs: M (L as accessory)
Comparable criteria	Cuffs: M and L	Optional mains adapter
	Mains adapter	Optional printer kit
	Printer kit	Memory: 2 × 30 measurements – 2 persons monitor
Device 2 criteria		www.manufacturer.com/bpmonitors/abc
Web link	www.manufacturer.com/bpmonitors/abcplus	
Comments	The ABC-Plus has both cuffs, the printer kit and mains adapter supplied. The ABC allows for 2 users. As far as accuracy is concerned, these are clearly equivalent	
Recommendation	Accept	

The name of the devices and pictures have been removed. Comparison of the ABC-Plus with the ABC.

- If the form is properly completed with no items affecting the blood pressure measurement being ticked and if the manuals are available, the comparison criteria can now be set out.

Stage 2: Summary of submitted equivalence criteria

The next stage in the procedure is to summarize the criteria unique to the device being submitted for equivalence and the criteria identical to both devices. The latter includes: (i) accessories that are included in one device but are optional in the other, most commonly, nonstandard cuffs and mains adapters, which often have to be purchased as extras with a basic model but are included with a superior model; and (ii) the provision of error codes.

Stage 3: Checking the equivalence form against the criteria

If the declaration form is correctly completed and all the items in the 'submitted device criteria' and the 'validated device criteria' are correctly addressed and declared not to affect the measurement procedure itself, the declaration is accepted and the device can be regarded as equivalent to the validated device for blood pressure measurement accuracy. An example of a successful equivalence application is shown in Table 1.

If the declaration form has been incorrectly completed or if any items in the 'submitted device criteria' and the 'validated device criteria' have not been declared or correctly addressed with explanations, the declaration is rejected with an explanation. The manufacturer is free to submit a new form.

Experience

Equivalence forms for 13 devices have been received to date (August 2006). Seven devices were from one

manufacturer, four from another and two from a third. Of these 13 submissions, only one equivalence form was correctly completed, two were rejected and the remaining 10 were returned for corrections, further details or explanations. Of these, eight were resubmitted, of which seven were accepted. One device was subjected to validation and the results have been published.

Discussion

The importance of device modification for blood pressure measurement has been recognized for many years [7]. When device modifications are made without the user being aware of them, such modifications can have serious epidemiological and clinical consequences [7]. Short of demanding an independent validation of all new devices, it is difficult to overcome the problem, but, with an increasing array of devices on the market and with many only undergoing cosmetic modifications that do not interfere with measurement accuracy, it is clearly unreasonable for clinicians to demand costly and time-consuming validations of all new devices. By the same token, there is an obligation on the part of manufacturers to assure clinicians and other users of blood pressure measuring equipment that alterations to the device design have not compromised algorithm accuracy. The 'Declaration of Blood Pressure Measuring Device Equivalence' procedure initiated by the dabl Educational Trust is an attempt to reconcile this issue by inviting manufacturers to provide assurances for equivalence between devices by formally declaring that a nonvalidated device is identical to a validated device in all blood pressure measuring aspects and that any and all differences between the devices do not affect the accuracy of blood pressure measurement.

Experience to date with the equivalence issue is limited but it is evident that the process is more complicated than was originally anticipated and that the checking

procedure is quite an involved one. At the last meeting of the dabl Educational Trust Advisory Board in Madrid in June 2006, it was agreed that equivalence applications, when summarized as described in this paper, should be submitted to the advisory board for final approval. This process alerts manufacturers to the strict formalities of the procedure and also demonstrates that the results of applications for device equivalence are being circulated to the international experts on the advisory board.

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References

- 1 Association for the Advancement of Medical Instrumentation. *American National Standard. Electronic or automated sphygmomanometers ANSI/AAMI SP10-1987*. Arlington, VA: AAMI; 1987.
- 2 O'Brien E, Petrie J, Littler W, de Swiet M, Padfield PL, O'Malley K, *et al*. The British Hypertension Society protocol for the evaluation of automated and semi-automated blood pressure measuring devices with special reference to ambulatory systems. *J Hypertens* 1990; **8**:607-619.
- 3 O'Brien E, Petrie J, Littler WA, de Swiet M, Padfield PL, Altman D, *et al*. The British Hypertension Society protocol for the evaluation of blood pressure measuring devices. *J Hypertens* 1993; **11** (Suppl 2):S43-S63.
- 4 Association for the Advancement of Medical Instrumentation. *American National Standard. Manual, electronic or automated sphygmomanometers ANSI/AAMI SP10-2002/A1*. Arlington, VA: AAMI; 2003.
- 5 O'Brien E, Pickering T, Asmar R, Myers M, Parati G, Staessen J, *et al*, with the statistical assistance of Atkins N and Gerin W on behalf of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension. International protocol for validation of blood pressure measuring devices in adults. *Blood Press Monit* 2002; **7**:3-17.
- 6 dabl[®] Educational Trust: www.dableducational.org. Assessed 24th July 2006.
- 7 O'Brien E. Modification of blood pressure measuring devices and the protocol of the British Hypertension Society. *Blood Pressure Monit* 1999; **4**:53-54.