Letter to the Editor

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Response to – Blood Pressure Monitoring 2011; 16:67–73

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The authors would like to comment on the manuscript by Stergiou *et al.* [1]. The authors make incorrect assumptions in both the introduction and conclusion of the article related to the significance of the European Society of Hypertension International Protocol (ESH-IP). In the article's introduction, the authors state that the ESH-IP 2002 is the most widely used protocol for noninvasive blood pressure (NIBP), and that 104 monitors were validated to the ESH-IP 2002 from its release until 2010. During the same period, the authors state that only 48 monitors were validated to the British Hypertension Society standard, and 38 monitors were validated to the Association for the Advancement of Medical Instrumentation (AAMI) standard. This may be true if you consider only published validations; however, in the same period all NIBP devices sold in the USA were required by the Food and Drug Administration to pass AAMI SP10, and all NIBP devices sold in Europe were expected to meet EN1060-4. This would include hundreds, if not thousands, of devices validated to the SP10 and EN1060-4 standards. The authors also claim that the reduced sample size, from 85 to 33 individuals, in the EHS-IP reduces the burden and cost of clinical validations. However, the regulatory authorities in the USA and Europe still require validation with the lengthier, more robust 85-subject protocols and all manufacturers selling into these markets need to perform the protocol as currently described in the recently released ANSI/AAMI/ISO 81060-2:2009 standard. During the development of 81060-2, the 33-subject protocol was reviewed, but was rejected because the ESH did not provide statistical justification for the reduced sample size. In the article's conclusion, the authors claim that the stricter requirements in the ESH-IP 2010 will allow more accurate devices on the market. However, as the ESH-IP 2010 is not a regulatory requirement in any country, it will have no influence on monitors that are legally permitted for sale.

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

References

1 Stergiou GS, Karpettas N, Atkins N, O'Brien E. Impact of applying the more stringent validation criteria of the revised European Society of Hypertension International Protocol 2010 on earlier validation studies. *Blood Press Monit* 2011; **16**:67–73.

The European Society of Hypertension International Protocol for the validation of blood pressure measuring devices in adults. Response to letter by Gallick D., Friedman B.A., Alpert B.S., Seller J.D., Quinn D.E., and Osborn D.

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Response to letter

We would like to respond to the criticisms made by members of the Sphygmomanometer Committee of the Association for the Advancement of Medical Instrumentation [1] regarding our article entitled 'Impact of applying the more stringent validation criteria of the revised European Society of Hypertension International Protocol 2010 on earlier validation studies' [2].

We note, to begin with, that the letter criticizing the European Society of Hypertension International Protocol (ESH-IP) is signed by six of the 21 members of the Association for the Advancement of Medical Instrumentation (AAMI) Sphygmomanometer Committee [3], five of whom are employees of leading manufacturers of blood pressure measuring devices [1].

The authors of the letter begin their criticism by stating: 'In the article's introduction, the authors state that the ESH-IP 2002 is the most widely used protocol for NIBP and that 104 monitors were validated to the ESH-IP 2002 from its release until 2010. During the same period, they state that only 48 monitors were validated to the BHS standard and 38 monitors were validated to the AAMI

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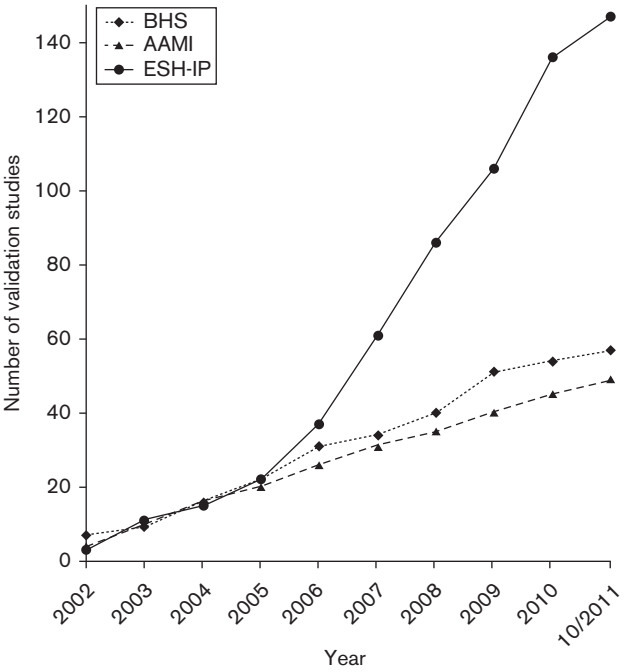
standard'. Although this statement cannot be refuted, the authors then go on to weaken its scientific veracity with estimates of device approval that cannot be verified: 'This may be true if you consider only published validations; however, in the same period all NIBP devices sold in the USA were required by the FDA to pass AAMI SP10, and all NIBP devices sold in Europe were expected to meet EN1060-4. This would include hundreds, if not thousands, of devices validated to the SP10 and EN1060-4 standards'. Of course we only considered published validations, which could be scrutinized in terms of their adherence to the protocol requirements. Depending on published evidence is the essence of good science and for the authors of the letter to state that 'hundreds, if not thousands' of devices were validated only goes to show that it is not possible even to numerically quantify, let alone critically assess, these unreferenced validation studies.

The authors of the letter then go on to criticize the fact that the ESH-IP requires only 33 participants versus 85 participants in the AAMI protocol. Indeed, the ESH-IP is based on analysis of 33 participants, but also on 99 blood pressure readings [4,5]. The ESH-IP was developed on the basis of the analysis and experience of the data from 19 previous validation studies carried out using the AAMI and the British Hypertension Society (BHS) protocols [6]. To examine this issue further, we have carried out a Monte Carlo analysis with device error distribution modeling based on these studies, which demonstrates the robustness of the participant selection criteria and the adequacy of the reduced sample size (unpublished data submitted for publication).

It should be remembered that the rationale for developing the ESH-IP was to simplify the validation procedure so as to facilitate wider use of the validation procedure by more centers throughout the world. In view of this reasonable objective, the concluding criticism of the letter is remarkable: 'However, since the ESH-IP 2010 is not a regulatory requirement in any country, it will have no influence on which monitors are legally permitted for sale'. This statement is not supported by the evidence as shown in the following updated graph of validation studies reported as PubMed papers or abstracts at meetings of the International, European or American Society of Hypertension, which illustrates the continuing popularity of the ESH-IP as the protocol of choice for validating blood pressure measuring devices worldwide; since 2002, 147 studies have been conducted according to the ESH-IP, whereas only 49 have used the AAMI protocol (Fig. 1).

The process of validating blood pressure measuring devices is complex and costly, and the more practical protocols are the more likely it is that the many devices being manufactured will be assessed for accuracy according to internationally agreed methodologies. It is important nonetheless to continue to explore various ways of improving the accuracy of devices on which so many important decisions depend in the management of hypertension [7].

Fig. 1



Cumulative graph of validation studies carried out according to the European Society of Hypertension International Protocol (ESH-IP) compared with the Association for the Advancement of Medical Instrumentation (AAMI) and the British Hypertension Society (BHS) protocols from 2002 (publication of ESH-IP) until October 2011.

Acknowledgements

Conflicts of interest

GS Stergiou has received honoraria for educational lectures from Omron and consultation fees from Microlife. Nikos Karpettas has nothing to declare. Neil Atkins is a shareholder and an employee of dabl Limited, Dublin, Ireland. Eoin O'Brien is a shareholder and a member of the board of dabl Limited, Dublin, Ireland.

References

1 Gallick D, Friedman BA, Alpert BS, Seller JD, Quinn DE, Osborn D. Letter. *Blood Press Monit* 2012; **17;** (in press).

2 Stergiou GS, Karpettas N, Atkins N, O'Brien E. Impact of applying the more stringent validation criteria of the revised European Society of Hypertension International Protocol 2010 on earlier validation studies. *Blood Press Monit* 2011; **16**:67–73.

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