

COMMITTEE ON BLOOD PRESSURE MONITORING IN CLINICAL PRACTICE

Minutes

Wednesday, 10 March 2004
Room 1213 Hannibal House, Elephant & Castle

The Committee's Remit:

"To evaluate whether mercury sphygmomanometers should continue to be used or removed from the clinical environment; and to consider the alternatives to mercury devices and the evidence regarding their accuracy"

Committee:

Professor A Shennan (Chairman) (Director of the Maternal and Foetal Research Unit, St Thomas' Hospital)

Ms M Beevers (Vice Chair, Nurses' Hypertension Association)

Professor P Chowienczyk (Professor of Cardiovascular Pharmacology, St Thomas' Hospital)

Dr A J Coleman (Consultant Physicist, St Thomas' Hospital)

Dr T Clutton-Brock (Dept of Anaesthetics and Intensive Care Medicine, Birmingham)

Professor M de Swiet (Professor of Obstetric Medicine, UCH)

Dr S Dean (Clinical Director of ITU, St James's University Hospital)

Dr P McCartney (General Practitioner, Bristol)

Professor B Williams (Professor of Medicine, Leicester Royal Infirmary)

Professor J Potter (Professor of Medicine for the Elderly, Glenfield Hospital)

For this meeting only:

Dr A Sims (Clinical Scientist, Freeman Hospital Newcastle)

Dr P Bickford-Smith (Dept of Anaesthetics, Bradford Royal Infirmary)

MHRA:

Dr S Ludgate (Clinical Director, MHRA)

Mr G Smith (Senior Medical Device Specialist, MHRA)

Mr C Apps (Medical Device Specialist, MHRA)

1. Welcome and Introductions

1.1. Professor Shennan welcomed everyone to the meeting.

2. Apologies:

2.1. Apologies have been received from:

Dr M Roberts (Chemicals and GM Policy Division, Defra)

Dr B Gill (Peter Congdon Neonatal Unit, Leeds General Infirmary)

Ms J Reilly (Health and Safety Executive)

3. Review of Minutes of the Previous Meeting

3.1. Dr Clutton-Brock suggested that point 10.2 of the previous minutes be amended to reflect that intra-arterial blood pressure can be used as an alternative to non-

invasive techniques and not to give an 'accurate absolute value' of blood pressure. Dr Clutton-Brock also suggested the removal of the word hypertension in point 10.3.

4. Action Points

4.1. Dr Coleman reported the results of his survey (see point 12).

4.2. Dr Clutton-Brock and Mr Smith put forward classification criteria. Dr Bickford-Smith was invited to speak on classification.

5. Update on remit, summary of progress and aims of current meeting

5.1. The Chairman reminded the committee of its remit.

5.2. The Chairman reminded committee members that conflicts of interest must be declared.

5.3. The aims of previous meetings have been primarily about gathering information. The aim of this meeting is to gain consensus on the following four points with particular focus on patients in primary care:

- (i) use of mercury in clinical practice
- (ii) use of standards to achieve recommendations
- (iii) assessment of alternatives to mercury
- (iv) the group's recommendations

6. Summary of environmental issues

6.1. Environmental pressure is causing mercury to be phased out though there is currently no legal requirement to do so in clinical practice. Mercury in clinical practice currently makes up a very small proportion of the total mercury in use. Professor Shennan is satisfied that the environmental issues that the committee must consider have been covered sufficiently in previous meetings.

7. Health and safety issues

7.1. See point 12.

8. Focus of Report

8.1. Professor Williams suggested that the use of blood pressure monitors in primary care affects the largest group of patients and should therefore be the focus of the committee's report. Blood pressure monitoring in special groups should, nonetheless, be included in the report. Ms Beevers advised the group that GPs are currently using inappropriate machines to monitor blood pressure in some instances.

8.2. Currently blood pressure monitors used in clinical practice must comply with the Medical Devices Directive and be CE marked. No clinical trials are necessary to obtain the CE mark and standards are non-mandatory. Devices do not have to achieve a standard of blood pressure accuracy to gain the CE mark. The committee may

recommend MHRA involvement in developing standards. However, as regulator, the MHRA cannot recommend the use of particular CE marked devices over others.

8.3. Achieving accuracy through standards is a slow process. It was suggested that a more immediate solution is to produce guidelines for procurement and purchasing bodies advising which devices are fit for purpose. Clinical guidelines can be achieved through NICE. However this is unlikely to have an effect on devices purchased on the high street. The remit of the committee is not to prevent public access to inaccurate devices.

8.4. The group may recommend that the current system is not good enough. A recommendation could be made to the Department of Health that non-invasive blood pressure measuring devices must be accredited. A method of accreditation of existing devices would then need to be developed. A body would need to be identified to devise a list of accredited devices and be responsible for policing accreditation.

8.5. Professor Shennan advised the committee that if it recommended that there must be a mechanism to purchase validated devices, then it should propose such a mechanism.

8.6. It is important that the report strikes a balance between vague recommendations and being too prescriptive. It should include advice on calibration, maintenance, non-validated devices and warn that in some circumstances devices may not be accurate. The report must be forward thinking with regards to classification.

Action Point: Professor Shennan

To collate the previous three meetings and produce a draft for comments.

9. Classification of Devices

9.1. Dr Bickford-Smith addressed issues on classification and recommended that classification should be centred on the user's needs.

9.2. It was agreed that the mercury sphygmomanometer is the gold standard but is increasingly being replaced by non-mercury sphygmomanometers. Auscultation is a basic clinical skill that should be maintained by clinicians although it is believed that in the future it will be used less frequently and predominantly as a back up to automatic monitors.

9.3. There is a clinical need for assessment of non-mercury auscultatory devices and guidance on their calibration, service and maintenance.

10. Validation vs Simulation

10.1. It is generally believed that simulators serve a different purpose to validation in clinical practice. Simulators are used as a functional check and will not replace validation in the immediate future.

11. Validation Protocols

11.1. Mr Smith presented a summary of BHS, ESH and ANSI/AAMI validation protocols highlighting their strengths and weaknesses.

11.2. Professor Potter informed the group that BHS is setting up a validation service. Currently the BHS blood pressure monitoring committee judge peer reviewed publications from any source and endorse those of sufficient quality which then appear on their website. The BHS hope that the new validation service will provide manufacturers, for a fee, with a swifter route to achieving BHS validation. The previous system of endorsing all validation studies using recognised protocols will continue.

11.3. As an independent body, the BHS is well placed to recommend the use of certain devices. It is conceivable that some manufacturers may make claims of passing validation protocols, when the mechanism or quality of the investigation performed is below an acceptable level. The group believed that this would need to be policed but this should be the responsibility of a government body.

11.4. Dr Sims expressed concern of the potential for BHS becoming a monopoly as a result of what the committee may recommend.

12. Mercury turnover from sphygmomanometers

12.1. Dr Coleman presented the results of his survey into the current arrangements for the disposal of mercury sphygmomanometers and procurement of replacement devices by NHS bodies.

12.2. It was suggested that the committee's report should contain guidelines for the storage and removal of mercury in accordance with health and safety legislation, including a list of contractors and special waste management instructions together with guidance from the environment agency.

12.3. Currently a trend exists such that procurement bodies are replacing mercury sphygmomanometers with aneroid devices. The committee's recommendations should be targeted at procurement bodies.

13. Methods of dissemination

13.1. Mechanisms to inform government.

13.2. NICE involvement.

13.3. Involvement of PASA of purchasing validated devices.

13.4. Specially designed leaflets distributed through pharmacies and GP centres have the potential of advising public about the limitations of blood pressure monitors.

13.5. Publications such as the British Medical Journal.

13.6. MHRA advice.

13.7. Controls assurance.

14. AOB

14.1. Dr Bickford-Smith advised the group that a training CD Rom was available from the virtual College. Professor Potter pointed out that similar information was available on the BHS website.

15. Dates of next meetings

15.1. Wednesday 28th April.