

COMMITTEE ON BLOOD PRESSURE MONITORING IN CLINICAL PRACTICE Minutes

Tuesday, 4 November 2003
Room 1213 Hannibal House, Elephant & Castle

Present:

Professor A Shennan (Chairman) (Director of the Maternal and Foetal Research Unit, St Thomas's 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)
Professor M de Swiet (Professor of Obstetric Medicine, UCH)
Dr M Roberts (Chemicals and GM Policy Division, Defra)
Dr S Ludgate (Clinical Director, MHRA)
Mr Jonathan Plumb (Nursing Adviser, MHRA)
Ms S Vincent (Senior Medical Device Specialist, MHRA)
Mr C Apps (Medical Device Specialist, MHRA)

Apologies:

Professor J Potter (Professor of Medicine for the Elderly, Glenfield Hospital)
Ms J Reilly (Health and Safety Executive)
Mr G Smith (Senior Medical Device Specialist, MHRA)

1. Welcome and Introductions

2. Outline of remit/background to committee (AS)

2.1. 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".

2.2. Conflicts of Interest

The chair reminded committee member's that conflicts of interest must be declared.

2.3. Publicity/Media

- A press release giving notice of this committee has been published.
- Minutes of this meeting will be published on the MHRA website.
- Any committee member becoming aware of publicity issues should let Professor Shennan and Dr Ludgate know.

2.4. Meetings

The committee aims to meet three or four times in the next six months and then make its recommendations.

3. Environmental issues around Mercury (MR)

Dr Michael Roberts presented a paper which brought out the following points:

- there are environmental pressures for the removal of Mercury, in that mercury is an environmental pollutant that can adversely affect wildlife, ecosystems, and humans. Elemental mercury can be transported globally via the atmosphere and so may affect regions without significant releases, such as the Arctic. Microbes in water can convert elemental mercury to methylmercury. Methylmercury may be considered more of a potential hazard than elemental mercury as it can be concentrated along food chains, accumulating in particularly high concentrations in some predatory fish, for example,
- mercury has the potential to cause serious harm to health and death in humans and as such is an emotive issue,
- the major remaining use of Mercury in the EU is in cells used in the production of chlorine (the chlor-alkali industry). These cells account for around 12,000 tonnes of mercury and are due to be phased out by 2020.

4. Health and Safety concerns in clinical practice

4.1. The following points were made:

- it is estimated that 120,000 Mercury Sphygmomanometers are present in the UK. Assuming that each of these devices contains 85g Mercury then the total mass of mercury in sphygmomanometers is 10.2 tonnes in the UK. This is considered to contribute a tiny proportion of total mercury emissions (which have fallen greatly in recent decades),
- all mercury sphygmomanometers are sealed systems. When used as intended there is no risk of exposure. Risks of exposure, however, do occur when devices are broken, serviced and decommissioned,
- the disposal of mercury in sphygmomanometers needs to be managed properly. Management of this process is outside the remit of this committee.

4.2. It was noted that there are a series of questions that need to be addressed in relation to the decommissioning of mercury sphygmomanometers and the disposal and processing of mercury.

5. Legislative pressure: the facts (MR)

5.1. DEFRA's view is that it is desirable to remove mercury for use in the clinical environment. This position however raises a number of questions in relation to mercury sphygmomanometers, both environmental and clinical.

5.2. There are a number of Directives and Conventions relating to mercury and the environment. Currently there are no legislative pressures for the removal of mercury

used in medical devices and, therefore, no legal reason not to recommend the continued use of mercury sphygmomanometers.

Action: Dr Roberts

To obtain information on the estimated total amount of mercury currently in clinical use in the UK, how the disposal of mercury is carried out and obtain figures on the amount of mercury disposed of over previous 10 years to establish trends.

6. Setting the Scene: the importance of BP measurements

6.1. Measuring BP accurately is essential in the diagnosis and management of hypertension since this is a major risk factor for stroke and coronary heart disease. A 10mmHg increase in diastolic blood pressure is associated with the increase by a factor of two in cardiovascular death between the ages of 40 and 69 years (Lancet 2002; 360:1903-13). More than 50% of people aged 65 and over are diagnosed with blood pressure greater than 160/95mmHg.

6.2. For a Grade A BHS validated device 5% readings may have an error greater than 15mmHg but this is partly due to the sequential methodology used. An error of 10mmHg or greater could potentially lead to the misclassification of 100,000 adults.

6.3. An increase in variability is observed in validation studies with automated devices compared with the variability of mercury sphygmomanometers. In the validation of automated devices in high-risk groups a large, systematic, error is more likely to be observed.

6.4. Training is required for all types of blood pressure measurement though there is more skill required to use a non-automated device that relies on observer auscultation. Observer error is difficult to quantify but is an issue that needs to be addressed. The mercury sphygmomanometer is still the “gold standard” but an automated device that mimics its operation is desirable to reduce observer error.

7. Current Accuracy requirement of BP devices:

7.1. Medical Devices must have the CE mark to be sold on the UK market. In order to obtain this manufacturers must demonstrate the device performs as they claim. Blood pressure measurement is a measuring function and therefore manufacturers require a Notified Body.

7.2. The requirements of the Directive are for sphygmomanometers underpinned by the relevant standard EN1060 series. However, the development and standards and changes in standards takes a relatively long time and, as such, regulation does not offer a timely method for controlling the accuracy of blood pressure monitoring devices.

7.3. Devices need validation. Most in clinical practice have not achieved this. Fewer still have achieved validation under special clinical circumstances such as arrhythmia or pre-eclampsia.

7.4. Validation may be associated with a number of problems:

- Validation is expensive.
- Comparisons of automated devices with mercury sphygmomanometers cannot be performed simultaneously. This is due to some systems deflating the cuff step-wise so Korotkoff sounds cannot be accurately detected. As a result validation protocols are based on consecutive measurements.
- Devices that pass modified validation protocols may receive a pass if the violation is deemed acceptable.
- Are the current gradings such as those deemed acceptable by the BHS grading acceptable in clinical practice?

7.5. BHS want to validate devices and provide each validated device with a BHS validated mark. Companies would pay for the validation of their devices, but the validation is undertaken by independent staff.

7.6. Currently validation, however, relies on the use of mercury sphygmomanometers, and this may be a problem if these are decommissioned. Validation in countries who have banned mercury sphygmomanometers is carried out using aneroid devices.

Actions: Whole Group for future meetings

Is sufficient consideration given to different cuff sizes in current protocols?

Validation of “special groups”.

Who can validate devices?

What protocols should be used?

8. Blood Pressure Measurement: Alternatives

8.1. Blood Pressure measurement is divided into the following categories:

- **Oscillometric (automatic):** Oscillometric devices measure cuff pressure and detect arterial wall oscillations. The Mean Arterial Pressure MAP and the systolic blood pressure are usually calculated. MAP approximates to the cuff pressure at which the amplitude of the arterial wall sensor output is a maximum. Systolic Blood Pressure (SBP) can be calculated as the cuff pressure at which the maximum increase of amplitude of oscillations in arterial wall occurs. Actual method of blood pressure determination varies according to each manufacturer and is not generic. Oscillometric devices are not suitable for use in “special groups”. For example in patients with arterial fibrillation.
- **Auscultatory (automatic):** Automated auscultatory devices use a microphone to measure Korotkoff sounds to record systolic and diastolic blood pressure.
- **Aneroid**
- **Mercury**

8.2. There is an educational issue of which device is appropriate in which circumstances, with an incorrect perception that training is not required for automated devices.

8.3. The static pressure calibration of automated blood pressure monitors is typically relatively accurate and stable. Algorithms that are used to interpret the readings in terms of diastolic and systolic pressures are generally not released by the manufacturers and can be expected to differ in different devices. Interaction between transducer and algorithms can cause different measurements. Manufacturers can alter algorithms without having to declare alterations.

Action: Whole Group

A future meeting is required to discuss special groups specifically.

9. Alternatives to Mercury: non-automated

9.1. Aneroid devices are similar to mercury sphygmomanometers, but instead of relying on a mercury column to measure pressure they use alternative methods traditionally a bellows system connected to a needle to indicate the pressure on a dial.

9.2. Traditionally aneroid devices have tended to drift with time and require regular calibration against a mercury sphygmomanometer. As a result clinicians tend to be sceptical about their reliability. Materials have been improved to decrease the drift over time and there may be a place for aneroid devices.

9.3. Aneroid devices eliminate the algorithm problem but are subject to observer error. Systematic errors may also be an issue, particular concerns are expressed about digital displays and wobbling needles. It was noted that a flicking needle was more difficult to read than a moving column of mercury. Aneroid devices still require validation but alternative protocols would be required.

10. Alternatives to Mercury: automated

See section 8.1.

In automated devices the static pressure calibration is generally accurate and stable. However, the main problem with accuracy occurs when the oscillometric signals are interpreted as diastolic and systolic pressures by means of a pre-programmed algorithm. Such devices have rarely been validated for “special circumstances”.

11. Special issues with pregnancy

This is an emotive issue, but affects relatively few patients. There are 6-7 deaths per annum of pre-eclampsia in UK. Some of these may be due to cardiovascular events and therefore only 1-2 deaths may be affected by the accuracy of BP measurement. However, pre-eclampsia is associated with an incidence of maternal and foetal morbidity and, therefore, accurate blood pressure measurement is important in the diagnosis and management of this condition. Systematic errors are seen in some automated devices in pre-eclampsia validation studies.

Action: Whole Group

Measurement of severe hypertension, as opposed to general population use, to be considered in a “special groups” meeting.

12. Current obligations of Health Service (AC)

12.1. Hospitals are tending to procure electronic devices. This is for a number of reasons:

- Most people regard removal of mercury a good idea.
- COSHH Regulations.
- Controls Assurance Standards.
- Electronic devices are perceived to be accurate.
- Automated devices are less time consuming and labour intensive and require less concentration.

12.2. There are no direct orders and no legal requirements to remove mercury sphygmomanometers from clinical practice. The perception of this in practice may be different.

12.3. It is acknowledged that different skills are required to operate the device and as mercury sphygmomanometers become less widespread the skills base will decrease.

13. Direction of recommendations

The following need to be addressed in future meetings:

- The circumstances in which mercury can be used in the long and short term.
- How removal of mercury can be performed in a responsible way.
- Validation of non-mercury devices and assessment of their accuracy.
- Environmental Issues.

Action: Whole Group at future meeting

14. Implementation

- The format of any decisions and deliberations taken by the Group will be decided at future meetings. Query Device Alert. Query other publications.

Action: Professor Shennan and whole Group

Structure of future meetings.

15. Involvement of other experts?

It was agreed that additional representatives should be sought from:

- Royal College of Anaesthetists.
- Royal College of Physicians.
- Royal College of Paediatrics and Child Health.

16. Any other business

Dr Ludgate to circulate expenses claims forms.

17. Dates of next meeting

Dates to be circulated.

PS 13.11.03-02