

Report of the Independent Advisory Group on Blood Pressure Monitoring in Clinical Practice

June 2005

Summary of recommendations

Recommendation 1

While mercury sphygmomanometers continue to be used, appropriate health and safety procedures should be maintained including the availability of mercury spillage kits. When mercury is decommissioned then its disposal should be performed in compliance with the appropriate regulations

Recommendation 2

Where aneroid gauges are used for sphygmomanometry their calibration accuracy should be regularly checked based on the manufacturer's recommendation or annually.

Recommendation 3

Where oscillometric blood pressure measurement is used, it should not be assumed that a CE marked blood pressure monitor is automatically suitable for use in the diagnosis of hypertension.

Recommendation 4

In those clinical conditions where oscillometry is inappropriate (e.g. arrhythmias, pre-eclampsia and certain vascular diseases) an alternative method of pressure measurement (auscultation, arterial cannulation) should be used.

Recommendation 5

The MHRA, in collaboration with the **Committee on Blood Pressure Monitoring in Clinical Practice**, should define acceptable performance criteria against which automated non-invasive blood pressure monitors should be evaluated. Evidence for compliance with these criteria should be obtained from properly conducted clinical trials. The population characteristics for which the device has been evaluated should be specifically included.

Recommendation 6

The NHS and other healthcare sectors should only purchase devices that meet the performance criteria in recommendation 5.

Recommendation 7

Auscultation as a method of determining blood pressure should continue to be taught to healthcare workers as appropriate. Calibrated non-mercury devices, which do not rely on oscillometry, should be made available in all clinical areas. These will be used to check oscillometric results and other non auscultatory alternative blood pressure measurement determination on individual patients. These devices should also be used in clinical conditions where these alternative methods may be inappropriate e.g. arrhythmia, pre-eclampsia or specific vascular disease.

Introduction

This report is compiled from a draft report from the **Committee on Blood Pressure Monitoring in Clinical Practice** prepared for the Medicines and Healthcare products Regulatory Agency (MHRA) along with additional evidence from members of the MHRA and recent changes in the environmental pressures within the European Union.

The **Committee on Blood Pressure Monitoring in Clinical Practice** was established by the Chief Medical Officer, Sir Liam Donaldson following concerns regarding the use of mercury sphygmomanometers in clinical practice. These concerns were based around environmental and health and safety issues of mercury in clinical care areas. These risks must be balanced against the accuracy and appropriateness of the alternatives.

The committee's remit was: 'To evaluate whether mercury sphygmomanometers should continue to be used or removed from the clinical environment: and to consider the alternative to mercury devices and the evidence regarding their accuracy'.

The committee's discussions covered three main areas:

- the environmental arguments for the removal of all mercury-containing devices from the clinical workplace
- the implications of phasing out manual mercury sphygmomanometers from clinical practice
- the need for appropriate validation of non-invasive blood pressure monitors.

The committee decided to widen its remit to include not just mercury sphygmomanometers but also to include all forms of non-invasive blood pressure monitors.

The committee concluded that it is important to distinguish between the different types of non-invasive blood pressure monitoring available. The majority of devices can be conveniently classified according to three main criteria:

- the method of cuff inflation – manual or automatic
- the method of detection of systolic and diastolic pressures – auscultation or alternative e.g. oscillometric
- the method of pressure display – mercury manometer, dial manometer or electronic.

The environmental arguments for the removal of all mercury-containing devices from the clinical workplace

1. Mercury is known to be an environmental pollutant. It has no beneficial metabolic function in any living organism and can have adverse effects. Mercury can be transported around the world by air admissions of elemental mercury. The majority of mercury released into the atmosphere is elemental mercury, and most of this comes from human sources. It is estimated that overall the releases of mercury from natural sources contributes about 2,500 tonnes per year compared to 3,600 from human sources (elemental mercury is transformed to methyl mercury on deposition and this is where it enters the aquatic ecosystems and hence easily accumulates into living organisms). Mercury contamination in the sea has resulted in human deaths.
2. It is not known how many mercury sphygmomanometers are used in the United Kingdom and it is possible that this has been in decline through the influence of health and safety directives. However, by estimating the use in one health authority, a report to the Department of the Environment in 1996 estimated that 120,000 sphygmomanometers is a reasonable estimate. If each instrument contains 85 grams of mercury then just over 10 tonnes of mercury exists in these devices.
3. It is not known how much this mercury contributes to the total UK waste stream but as far as the health service is concerned, mercury within manometers is likely to be a small contributor. Waste mercury also comes from the following sources:
 - hearing aid batteries
 - thermometers
 - barometers (eg use in radiotherapy physics for dosimetry)
 - dental amalgam
 - fluorescent tubes
4. Previous estimates have suggested that approximately 1 tonne of mercury per annum is released in the UK waste stream from clinical thermometers using similar assumptions. This contrasts with a recent estimate of 12,000 tonnes of mercury being released in Western Europe from decommissioning of mercury cells used in the chlor-alkali sector of industry. Overall in the UK there has been a significant fall in mercury emissions from 31.6 to 8.8 tonnes between 1990 and 2001. This is likely to correlate to improved controls on mercury cells as they are being replaced by diaphragm and membrane cells. There has also been a decline of coal use. Improved control of incinerators from 1997 onwards has resulted in a large reduction in waste emissions. It is therefore likely that the contribution that mercury from manometers makes to the total mercury waste load is insignificant in comparison to these other sources.

5. The World Health Organisation makes recommendations about mercury concentrations in air and water. In the UK, levels are far less than this and there have also been significant reductions in releases of mercury to the marine environment.
6. Current regulations (Control of Substances Hazardous to Health Regulations 2002) require exposure to mercury to be prevented where this is reasonably practicable i.e. usually by elimination, or adequately controlled where this is not possible. Mercury has an occupational exposure limit (currently 0.025mg/cubic metre in air) and is readily absorbed through the skin. Normal operation of sphygmomanometers should cause no ill health risks, but spillages of mercury can lead to significant exposure if not dealt with promptly and correctly.
7. The mechanisms whereby mercury disposal from manometers is achieved were investigated by members of the committee. Mercury is regarded legally as special waste (under the Special Waste Regulations 1996.) Individual hospital Trusts and organisations in the NHS such as PASA must look at the disposal options required to ensure compliance with the special waste regulations which should be cost neutral to the NHS. Waste management contractors will collect medical instruments from both hospitals and general practitioners' surgeries. The devices are usually passed on to commercial organisations that separate mercury from the instrument. The instrument itself will usually go to land fill although the metal and glass components may be recycled.
8. These organisations store the mercury until a sufficient quantity is amassed, which is then sold to refiners. After a triple refine the mercury can be sold as a commodity and is traded on the world market in an industry standard flask weighing 34.5 kilos with an approximate value of 200 US Dollars per flask. Occasionally it is sold directly to instrument manufacturers such as Accoson or Philips (for manometers and florescent tubing). The NHS Procurement Agency PASA also commissions contracts with mercury recycling companies who deal with issues such as disposal of florescent tubes from which they reclaim mercury.
9. These companies will also be involved in the recycling of mercury from manometers. The waste management industry appears to have plenty of capacity for handling mercury at this time.
10. The use and control of mercury (e.g. in batteries, paint) are regulated under a range of EU directives. Mercury and its compounds are known as 'priority hazardous substances'. The Paris Commission which administers the 1992 convention for the environmental protection of the North Sea Atlantic has also agreed a number of actions to reduce mercury emissions in the marine environment. Of note a report to the European Commission by a Risk Policy Analyst Limited in 2002

concluded that remaining mercury use in products such as dental amalgam, batteries, measurement instruments, lighting, electrical control and switching equipment was insignificant. The two areas where a reasonable reduction of mercury release into the environment could be achieved are from dental amalgam (via crematorium) and from measuring and control instruments, primarily thermometers. However the commission did not make proposals to curb the use of mercury in medical devices. In January 2005 the EU adopted the 'Community Strategy Concerning Mercury' (for further details see 'mercury in medical devices' on the MHRA website).

Conclusions

The environmental and health and safety issues concerning mercury have not yet resulted in an absolute requirement to stop its use in blood pressure manometers. It is however likely that the pressures to remove all uses of mercury in the clinical environment will increase and suitable alternatives to mercury sphygmomanometers should be introduced into the NHS and other healthcare sectors over the next few years.

Recommendation 1

While mercury sphygmomanometers continue to be used, appropriate health and safety procedures should be maintained including the availability of mercury spillage kits. When mercury is decommissioned then its disposal should be performed in compliance with the appropriate regulations (Appendix 1).

The implications of phasing out manual mercury sphygmomanometers from clinical practice

It is important to distinguish the two separate implications of phasing out manual mercury sphygmomanometers from clinical practice.

i) It is possible to retain conventional auscultation sphygmomanometry and replace the mercury in glass manometer with a dial gauge as in the aneroid devices in use or with an electronic display. Dial gauges are prone to damage from dropping with significant errors occurring both in zero and calibration.

Recommendation 2

Where aneroid gauges are used for sphygmomanometry their calibration accuracy should be regularly checked based on the manufacturer's recommendation or annually.

In practice the majority of areas that have already phased out mercury and aneroid gauge sphygmomanometry have moved to automated oscillometric devices for the measurement of blood pressure. This involves two fundamental changes to the way in which blood pressure is measured:

- the display of pressure changes from the mercury in glass or dial gauge manometer to an electronic display
- the detection of the systolic and diastolic pressures changes from auscultation and the recognition of Korotkoff sounds to oscillometry.

The first of these should not create major problems as modern electronic methods of pressure measurement can be made very accurate and stable. A minor concern is that reading an electronic display may not be equivalent to a mercury column, but this is not likely to introduce a substantial error. In addition the use of electronic displays facilitates the use of alarms and electronic recording of results.

ii) However, the need for appropriate validation of non-invasive blood pressure monitors has major implications for the measurement of blood pressure in clinical practice.

Oscillometry was introduced initially as a method for the automated, non-invasive measurement of blood pressure in the operating theatre, critical care unit etc. where rapid and significant changes in both systolic and diastolic pressures occur. High levels of accuracy and precision about a specific point are not required in this type of monitoring. The convenience of these devices is considerable and they may be fitted with alarms and in the future will communicate with electronic patient records.

Oscillometric devices were not originally introduced for the diagnosis of hypertension which requires a much greater accuracy and precision of measurement. A 10 mmHg increase in diastolic blood pressure is associated with a doubling of cardiovascular risk between the ages of 40 and 69 years of age. More than half of individuals aged 65 and over will have a blood pressure of greater than 160/95 mmHg. Even small errors in blood pressure determination could result in tens of thousands of patients being misclassified and therefore receiving treatment unnecessarily if blood pressure is overestimated or alternatively increasing their clinical risk if blood pressure is underestimated.

There is increasing evidence that oscillometric measurements of blood pressure may not achieve acceptable levels of accuracy and precision in certain disease states including arrhythmias and pre-eclampsia.

Commercially available oscillometric devices vary greatly in the level of accuracy and precision with which they measure blood pressure. All blood pressure monitors sold for use in the clinical environment (as opposed to use for exercise performance enhancement etc.) must be CE marked under the Medical Device Directive. There is no recognised specific standard of accuracy that must be achieved to obtain a CE mark. Manufacturers may

demonstrate compliance with the Essential Requirements of the Directive by applying the appropriate harmonised standard, e.g. EN 60601-2-30 or EN 1060. These standards recommend that devices are clinically validated to one of the recognised protocols (Appendix 2). However, the application of harmonised standards is voluntary and manufacturers may choose alternative methods of demonstrating compliance. CE marking therefore cannot be relied on to ensure suitable accuracy for clinical use.

Recommendation 3

Where oscillometric blood pressure measurement is used, it should not be assumed that a CE marked blood pressure monitor is automatically suitable for use in the diagnosis of hypertension

Recommendation 4

In those clinical conditions where oscillometry is inappropriate (e.g. arrhythmias, pre-eclampsia and certain vascular diseases) an alternative method of pressure measurement (auscultation, arterial cannulation) should be used.

Recommendation 5

The MHRA, in collaboration with the **Committee on Blood Pressure Monitoring in Clinical Practice**, should define acceptable performance criteria against which automated non-invasive blood pressure monitors should be evaluated. Evidence for compliance with these criteria should be obtained from properly conducted clinical trials. The population characteristics for which the device has been evaluated should be specifically included.

Recommendation 6

The NHS and other healthcare sectors should only purchase devices, which meet the performance criteria in recommendation 5.

Recommendation 7

Auscultation as a method of determining blood pressure should continue to be taught to healthcare workers as appropriate. Calibrated non-mercury devices, which do not rely on oscillometry, should be made available in all clinical areas. These will be used to check oscillometric results and other non auscultatory alternative blood pressure measurement determination on individual patients. These devices should also be used in clinical conditions where these alternative methods maybe inappropriate e.g. arrhythmia, pre-eclampsia or specific vascular disease.

Appendix 1

Special waste regulations

The Special Waste Regulations 1996 are intended to transpose the requirements of the European Hazardous Waste Directive (91/689/EEC) which sets out requirements for the controlled management of hazardous (special) waste. The Regulations set out procedures to be followed when disposing of, carrying and receiving hazardous waste. The Special Waste regulations 1996 have been amended by the Special Waste (Amendment) Regulations 1996, the Special Waste (Amendment) Regulations 1997 and the Special Waste (Amendment) (England and Wales) Regulations 2001. These can be found on the HMSO website at www.hmso.gov.uk

Appendix 2

Clinical trial protocols

The British Hypertension Society protocol for the evaluation of blood pressure measuring devices: O'Brien E, Petrie J, et al., Journal of Hypertension 1993, 11 (Suppl 2): S43-S62.

ANSI/AAMI SP10, American National Standard for electronic or automated sphygmomanometer, 2002. www.aami.org

DIN 58130: 1996, Non-invasive sphygmomanometers – Clinical Investigation, S Mieke, Deutsches Institut fuer Normung E.V. (German Institute for Standardisation). Available from BSI www.bsonline.bsi-global.com

Working Group on Blood Pressure Monitoring of the European Society of the Hypertension International Protocol for validation of blood pressure measuring devices in adults: E O' Brien, T Pickering, et al., Blood Pressure Monitoring 2002, 7:3-17

BS EN 1060-4: 2004 Non-invasive sphygmomanometers – Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers. Available from BSI www.bsonline.bsi-global.com