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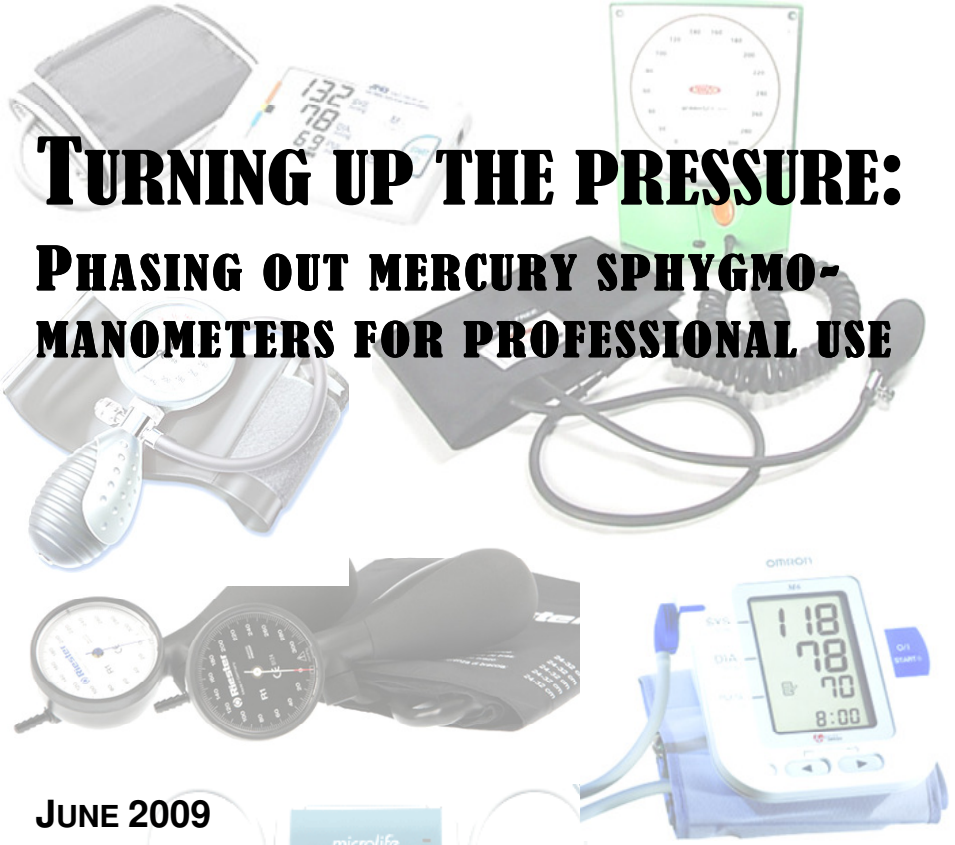

TURNING UP THE PRESSURE:

PHASING OUT MERCURY SPHYGMO-MANOMETERS FOR PROFESSIONAL USE

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Cover: The cover is a collage of some of the many mercury-free sphygmomanometers found on the EU market. The selection of photos for the cover in no way implies endorsement of these devices, nor does it imply any particular assurance of their performance, accuracy or validation.

This paper has been researched and prepared by Peter Maxson, Director, Concorde East/West Sprl, with all reasonable care and due diligence. The European Environmental Bureau (EEB) and author gratefully acknowledge financial and other support from the Garfield Foundation, the Sigrid Rausing Trust and the European Commission. Health Care Without Harm Europe provided special support for the hospital survey, and special thanks are also due to all hospital staff who so generously gave their time and care to respond to the questionnaires. Nevertheless, the paper does not necessarily reflect the official positions of any of these organisations, and the author accepts full responsibility for the analysis. Any third party who relies on information contained in this document, or her own interpretation thereof, does so at her own risk.

Executive Summary

Introduction

It is widely known that mercury is highly toxic, causing damage in particular to the nervous system, with the highest risk to humans occurring during the early development phases.

In response to European Union and global concerns about mercury pollution, the aim of the Community Mercury Strategy is to reduce mercury levels in the environment, and thereby reduce human exposure, by restricting mercury use, supply, and releases. These critical objectives were also key factors behind the recent 25th UNEP Governing Council Decision to begin negotiating a legally binding instrument on mercury, with the aim to have a treaty in place by 2013.

In line with the aims of restricting mercury uses and releases, the present study was commissioned by the European Environmental Bureau's "Zero Mercury Campaign." It deals with one key item of medical equipment – the blood pressure cuff, or sphygmomanometer – that continues to be a significant user of mercury in the EU, amounting to some 3-6 tonnes of mercury consumption per year. It highlights real-life experiences of European hospitals that purchase and use mercury-containing and mercury-free sphygmomanometers. By means of a survey of the experiences of a number of European hospitals, this study has observed that the transition to mercury-free medical devices for professional use is not just a question of technical and economic feasibility. Rather, the transition involves an interrelated but manageable set of issues that should be addressed in a coherent manner. The main issues requiring attention during the shift to mercury-free sphygmomanometers are summarised below.

Before proceeding, however, the sponsors and author of this report would like to express their heartfelt appreciation to all those who contributed their time and expertise to respond to the long list of survey questions. Those valuable contributions permitted a number of important issues to be clarified on the basis of real "hands-on" information rather than continued speculation.

Technical issues

The mercury sphygmomanometer has long been considered the "gold standard" of blood pressure measurements because all medical personnel have been trained to use it, the blood pressure readings are fairly reliable, it is often (mistakenly) believed that the device never needs to be calibrated, and it can be used universally – including in special clinical conditions such as arrhythmia, pre-eclampsia and certain vascular diseases where electronic sphygmomanometers may be less reliable.

While mercury-free semi-automated and automated (electronic) sphygmomanometers that measure blood pressure without a stethoscope are, in recent years, more commonly used than mercury devices, they have some limitations. This report focuses primarily on the "manual" mercury-free sphygmomanometers – used together with a stethoscope – that are direct substitutes for mercury sphygmomanometers. Such substitutes include the aneroid sphygmomanometer, which typically uses a pressure dial instead of a mercury manometer; the digital sphygmomanometer, which shows blood pressure readings on a

digital display; and the newer hybrid sphygmomanometer, which shows blood pressure readings on a non-mercury (e.g. liquid crystal display) column.

In past years, most manual mercury-free sphygmomanometers were subject to a range of problems such as unreliability, fragility, need for more frequent calibration, etc., that gave them a reputation for substandard performance. Even now, the reliability and performance of a sphygmomanometer depends to a large extent on the design and manufacture, although it may also be strongly influenced by the frequency of maintenance and calibration, the training and experience of the user, the manner in which it is used, etc.

While a number of manual mercury-free sphygmomanometers now on the market have been independently tested ("validated") and determined to be fully substitutable for mercury sphygmomanometers, some are more expensive to purchase and may have a shorter lifetime than a mercury sphygmomanometer. Combined with the reticence of some health care professionals to trust mercury-free instruments, some hospitals and especially general practitioners in some countries have been reluctant to adopt them.

Economic issues

A full life-cycle assessment of the economics (including external costs such as human health and environmental impacts) of mercury vs. mercury-free sphygmomanometers tends to come out modestly to strongly in favour of mercury-free devices, although such an assessment is heavily dependent on key assumptions of sphygmomanometer lifetime, as well as frequency and cost of calibration.

Moreover, the full life-cycle economics are favourable only in the case where the purchaser makes a well-informed decision and purchases a good quality, reasonably priced, validated and recommended mercury-free sphygmomanometer that does not require too frequent calibration. If this decision is not well-informed, then the purchaser will probably find his mercury-free decision to be somewhat more costly.

Hospital with very tight budgets more typically focus on the up-front purchase cost of a sphygmomanometer, and pay less attention to calibration, maintenance and lifetime considerations. However, even under these circumstances, low-budget hospitals are tending to replace mercury sphygmomanometers (after a long series of in-house repairs) with mercury-free alternatives when the mercury devices are no longer functional or repairable.

Human issues

Everyone who has been trained to use a manual sphygmomanometer and listen through a stethoscope to the sounds of the different stages of blood flow through the brachial artery knows that a certain amount of practice is required before becoming comfortable with the process. And even with practice and experience, errors in blood pressure readings are generally acknowledged. A number of factors other than the reliability of the sphygmomanometer may influence the reliability of the blood pressure reading, including the speed of deflation, an appropriately sized cuff, terminal digit preference, the "white coat effect," ambient noise, etc. There is no doubt that as a result of incorrect blood pressure readings, a certain number of patients have been prescribed blood pressure medicine they don't need.

The interviews carried out for this study have demonstrated that there is a need for better information among health care professionals. While most are well informed, some have insisted that mercury sphygmomanometers do not need to be calibrated unless they have

been damaged. In some cases individual health care professionals understand the need for calibration of all sphygmomanometers but reported that their health care facility does not consider it necessary either for technical or economic reasons . Some have confused calibration with validation. Some insist on the need for great accuracy in the sphygmomanometer while overlooking the considerable normal variations in blood pressure, as well as possible user errors.

Just as health care professionals need to understand better the limitations of the mercury sphygmomanometer, they should also understand the limitations of whatever mercury-free sphygmomanometer they may be working with. Has the particular model been validated? Are there certain clinical conditions for which it has not been validated? Is it susceptible to shock? Does it need to be calibrated every time it has been dropped? How susceptible is it to calibration drift, when was it last calibrated, and what is the recommended frequency of calibration? It is unreasonable to attribute to the sphygmomanometer all problems with blood pressure readings, while failing to also consider the knowledge of the user, and the proper care and use of the instrument.

It is useful to keep in mind that while the interviews carried out for this study focused on hospitals, general practitioners tend to work in a somewhat different environment. They may have worked for many years with a single mercury sphygmomanometer, and they may have relatively little familiarity with mercury-free alternatives. On the other hand, there is a greater chance, compared to a hospital, that the mercury sphygmomanometer has not been maintained or calibrated for many years. For numerous reasons – many of them very understandable and very human – there will remain a group of health care professionals who will be reticent to phase out the mercury sphygmomanometer, even as they become better informed about mercury-free sphygmomanometers.

Mercury waste issues

Less than half of the persons interviewed for this study understood that mercury wastes, when they occur, should be dealt with in a special manner and isolated from other wastes. Even so, many admitted that in practice, mercury wastes would be discarded in the same bins as other hazardous wastes. Other interviewees said that mercury wastes and infectious wastes were discarded in the same bins. And in about 30 percent of the interviews it was stated that mercury wastes would be discarded by the cleaning staff in the normal trash, as there was no particular awareness of any hazard from mercury.

Especially at health care facilities, hazardous waste management is a critical task not only because of the diversity and quantities of waste handled, but also because substandard practices have the potential to harm the reputation of the entire facility. Importantly, waste management takes place at the complex interface among individual human awareness, corporate procedures, government regulations and economic cost to the health care facility. As a result, where there is not constant vigilance, one will invariably uncover under-budgeted measures such as inadequate training, substandard waste management practices, etc.

The failure of a number of health care facilities to treat mercury (and probably other hazardous wastes) properly has other repercussions besides increasing the risks to human health and the environment. In this case, it also leads to an incomplete appreciation of the real cost of using mercury instruments, thereby further encouraging the continued use of mercury equipment.

Regulatory issues

It is often assumed that since they are medical devices, all sphygmomanometers on the EU market must be required to meet certain strict standards of quality and performance. However, the lack of EU-wide standards has contributed to the appearance on the EU market of a certain number of cheap, inferior products that have not only damaged the reputation of other mercury-free sphygmomanometers, but could also be dangerous to patients.

Many of the persons interviewed assumed that the "CE" label on a sphygmomanometer is a certification of the device's high level of performance – rather equivalent to a formal validation. They were unaware that under the Medical Devices Directive the CE label may be affixed to any device that meets all of the Directive's administrative requirements in order for the sphygmomanometer to be approved for use as a "clinical" device, which include independent oversight by a competent organisation.

As an important medical device, all sphygmomanometers should be tested against a range of EU-wide standards, calibration requirements should be transparent, etc. In this manner health care professionals may have full confidence in the performance of the mercury-free sphygmomanometers that meet the highest standard and are properly maintained. As concluded by the American Heart Association Council on High Blood Pressure Research (AHAC 2005): "Regulatory agencies should establish standards to ensure the use of validated devices, routine calibration of equipment, and the training and retraining of manual observers."

EU transition to mercury-free sphygmomanometers

While many health care facilities in different parts of the EU have been reducing their reliance on mercury devices for many years, for all of the reasons above the shift is not as rapid or as broad-based as it could be. Most of the hospitals in a few EU countries have completely phased out mercury sphygmomanometers – some of them more than ten years ago. Many hospitals in other countries are merely waiting for the old mercury instruments to wear out. A smaller number of hospitals insist that mercury sphygmomanometers are still necessary, or at least see no immediate need to phase them out.

This study highlights the need for further awareness-raising, and adoption of equipment performance standards, to facilitate the transition to mercury-free sphygmomanometers within the EU. This report and others also confirm that both health care institutions and governments have already effectively managed this transition, and can provide constructive experience in this regard. Moreover, a near-term phase-out of the marketing of any new mercury sphygmomanometers could still accommodate continued use of existing mercury equipment for some time, effectively providing a reasonable time period for such a transition.

In comparison to the present situation in the EU, a speedier transition to mercury-free sphygmomanometers is certainly feasible, and this study aims to contribute constructively to that debate.

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Phasing out mercury sphygmomanometers for professional use

1 Introduction

1.1 Purpose

The European Environmental Bureau (EEB) has commissioned this report as a contribution to the EU debate about phasing out the use of mercury in sphygmomanometers for healthcare and in other measuring devices for professional uses. The report will be presented at the conference, "EU mercury phase-out in measuring and control equipment", 18 June 2009, Brussels, organised jointly by the European Environmental Bureau, the Zero Mercury Working Group (ZMWG) and Health Care Without Harm Europe (HCWHE).

One of the key objectives of the EU Mercury Strategy, adopted in January 2005, is to reduce the amount of mercury circulating in society by cutting both supply and demand. On the demand side, the largest EU uses are for the chlor-alkali industry and dental amalgam. Another significant use is in measuring and control devices such as sphygmomanometers and porosimeters. At various points in the product life-cycle – during manufacture, during use or misuse, in the event of breakage or leaks, during the process of mercury waste management and disposal, at the end of the instrument's useful life, etc. – mercury can be released and present a risk to human health and the global environment, not to mention the diverse and significant costs of dealing with mercury in the product waste stream.

The aim of the report is to help inform the logical next step following the adoption of the EU Measuring Devices Directive 2007/51 in October 2007. That directive banned the use of mercury thermometers for consumer and professional uses, and it banned other measuring devices only for consumer uses. The European Commission is in the process of reviewing the availability and reliability of mercury-free alternatives that are technically and economically feasible to substitute for mercury-containing sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses. On the basis of this review the Commission will, if appropriate, present a legislative proposal by October 2009 to extend the restrictions.

1.2 Mercury toxicity

Mercury is a naturally occurring heavy metal that is linked to numerous health effects in humans and wildlife. It is a global priority pollutant, a persistent, bioaccumulative and toxic substance, and a potent neurotoxin, meaning that it damages the central nervous system. Among other effects, mercury exposure can adversely affect the brain, spinal

cord, kidneys and liver, and it easily crosses the placenta, where it can impair neurological development of the fetus.

Mercury in the environment can become more concentrated as it is ingested by larger and larger organisms and moves up the food chain, eventually accumulating in the bodies of humans and wildlife. Mercury travels long distances through the atmosphere, and has contaminated global food supplies at levels that can pose a significant risk to human health. Even the Arctic, which has no sources of mercury pollution, is experiencing dangerous levels of contamination in its marine mammals and other species that are part of the food chain.

For these reasons, mercury-containing products such as sphygmomanometers have come under increasing pressure to be phased out and replaced by mercury-free devices. The aim of the EU strategy is to reduce mercury levels in the environment and to reduce human exposure – especially by reducing mercury use, supply, and emissions. These considerations were also central to the 25th UNEP Governing Council Decision to begin negotiating a legally binding instrument on mercury, with the aim to have a treaty in place by 2013.

2 Background

2.1 General information

The diagnosis, management, treatment, epidemiology and research of hypertension is dependent on accurate and reliable measurement of blood pressure. Measurement of blood pressure is essential to classify individuals, to ascertain blood pressure related risk, and to guide management of health care (AHAC 2005). High blood pressure, or hypertension, can quietly damage the body for years before symptoms develop. It may be a risk factor for all of the following:

Damage to the arteries – healthy arteries are flexible, strong and elastic. Their inner lining is smooth so that blood flows freely, supplying vital organs and tissues with adequate nutrients and oxygen. With high blood pressure, the increased pressure of blood flowing through the arteries gradually can cause a variety of problems, such as arteriosclerosis, atherosclerosis and aneurism.

Damage to the heart – uncontrolled high blood pressure can damage the heart in a number of ways, such as coronary artery disease, enlarged left heart and heart failure.

Damage to the brain – the brain depends on a controlled and nourishing blood supply to function properly. High blood pressure can cause several problems, including transient ischemic attack, stroke, mild cognitive impairment and dementia.

Damage to the kidneys – the kidneys filter excess fluid and waste from the blood – a process that depends on healthy blood vessels. High blood pressure can injure both the blood vessels in and leading to the kidneys, causing several types of kidney disease (nephropathy), including kidney failure, kidney scarring and kidney artery aneurism. Having diabetes in addition to high blood pressure can worsen the damage.

Damage to the eyes – tiny, delicate blood vessels supply blood to the eyes. Like other vessels, they too can be damaged by high blood pressure, which can also cause fluid build-up under the retina and nerve damage.

High blood pressure emergencies – high blood pressure is typically a chronic condition that gradually causes damage over the years. In some cases, though, blood pressure rises so quickly and severely that it becomes a medical emergency requiring immediate treatment, often with hospitalization. As a medical emergency, high blood pressure can cause altered brain function, stroke, severe damage to the main coronary artery, seizures in pregnant women, unstable chest pain, heart attack, pulmonary edema, acute renal failure, etc.

If blood pressure is inaccurately measured, many people are at risk of being mislabelled as having hypertension and being given unnecessary treatment. With over 20% of the adult population suffering from hypertension, the consequences of inaccurate diagnosis carry serious implications for health care delivery and for society.

Purchasers unaware of the sphygmomanometer validation process often mistakenly assume that if a product reaches the marketplace, it must measure blood pressure accurately, which is not necessarily the case. This could have serious repercussions, for example, for patients who may be placed on a drug treatment program as a result of inaccurate blood pressure measurement (dabl 2009).

Over the last twenty or so years, the accuracy of the conventional technique of blood pressure measurement using a stethoscope and mercury sphygmomanometer has been questioned, and efforts have been made to improve the accuracy with automated devices – at least for the routine measurement of normal clinical conditions. During the same period, the phenomenon of "white coat hypertension" has been identified, whereby some subjects with apparently elevated blood pressure actually have normal, or reduced, blood pressure when the measurement is repeated away from the medical environment. This has focused attention on (automated) methods of measurement that provide profiles of blood pressure behaviour rather than relying on isolated measurements under circumstances that may in themselves influence the blood pressure (dabl 2009).

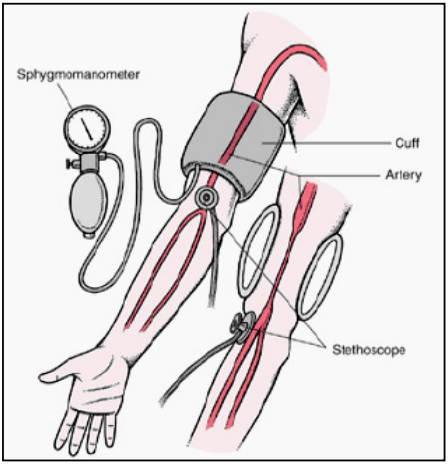
The most common method is ambulatory blood pressure measurement (ABPM), that has been developed to provide a profile of blood pressure over 24 hours. ABPM has gradually become indispensable to good clinical practice and should be available especially to patients diagnosed with hypertension. Self-measurement of blood pressure is therefore increasingly popular.

Meanwhile, the gradual phase-out of mercury from the clinical environment has also expanded the market for automated devices. Yet only a small number of the many automated blood pressure measuring devices on the market have been subjected to independent validation, and of those that have been so tested, less than half fulfil the validation criteria for accuracy. While not recommended for a number of special clinical conditions, a validated and recommended, automated sphygmomanometer is clearly becoming the "workhorse" of general blood pressure measurement.

At the same time, it stands to reason that the accuracy of blood pressure measuring devices should not be based solely on claims from manufacturers, so independent validation is needed. However, sphygmomanometer manufacturers understandably complain about the long and costly time lag between validation of a device and the publication of results in a scientific journal which, if positive, gives the device substantial credibility (and sales) in the marketplace (dabl 2009).

2.2 Mercury sphygmomanometers

Manual devices are used to measure blood pressure according to the original technique described by Riva Rocci and Korotkoff over a century ago. A mercury sphygmomanometer typically includes a mercury manometer, an upper arm cuff, and a manual inflation bulb with a pressure control valve, and requires the use of a stethoscope. The method relies on the auscultatory technique, in which a clinician determines systolic and diastolic blood pressures (SBP and DBP) by listening (auscultate) with his stethoscope for sounds (so-called Korotkoff sounds) over the brachial artery that characterize different stages of blood flow during cuff



deflation. This technique is usually referred to as conventional blood pressure measurement, or CBPM. Further details on sphygmomanometer function and use are provided in Appendix 1.

The accuracy of blood pressure measurement using the mercury sphygmomanometer relies heavily on taking multiple readings, having a relaxed patient (who has been sitting for at least several minutes before measurements are taken), and perhaps most importantly, a competent clinician (Watson and Lip 2006). The latter also needs to select an appropriate-sized cuff (80% of the upper arm circumference), to deflate the cuff at a relatively slow but continuous rate (2-3mm Hg/sec.) and to accurately auscultate and discriminate between the Korotkoff sounds to provide a reproducible reading (European Commission 2008).

Figure 1 – Traditional mercury sphygmomanometer

2.2.1 Advantages and disadvantages

The advantages and disadvantages of mercury sphygmomanometers have been extensively discussed in the medical literature. Compared to other measuring devices, the main advantages of the mercury sphygmomanometer are:

- a mercury manometer is relatively easy to use by people who are trained and practiced in using this instrument,
- it is relatively stable (i.e., it typically does not need to be calibrated more than once every two years),
- it may be used with virtually any medical condition,
- it is relatively easy to repair so that it may have a long lifetime,
- it is fairly easy to see when it is not functioning properly, and
- even the cheapest models may be expected to be reasonably reliable.

As a result, and certainly also because most medical personnel are so familiar with this instrument, it is still considered by many to be the “gold standard” for blood pressure measurements.

However, the various hazards and costs associated with the life-cycle of mercury in a sphygmomanometer may be significant (see Section 5), and are less and less acceptable to society in general. In addition, a big problem of mercury sphygmomanometers, and a major reason for their gradual phase-out – especially in hospitals – is that they are not able to generate automated measurements. Finally, as mentioned, there is evidence that the traditional auscultatory technique may lead to the misclassification of a certain number of individuals as hypertensive, and also to a failure to make a proper diagnosis (in some individuals) based on blood pressure measurements that may be normal in the clinical setting, but elevated at other times (AHAC 2005).

2.3 Mercury-free sphygmomanometers

Alternatives to mercury-containing sphygmomanometers on the market can roughly be divided into the following groups:

a. Equipment for blood pressure measurements based on the auscultatory technique described above:
   - Aneroid sphygmomanometers for manual reading;
   - Digital sphygmomanometers for manual reading;

b. Equipment for blood pressure measurements based on the oscillometric technique (which measures only mean arterial pressure and then uses software containing algorithms to calculate the systolic and diastolic values) or other techniques:
   - Semi-automated devices for clinical use and home- or self-assessment;
   - Automated blood pressure devices for hospital use.

2.3.1 Equipment based on the auscultatory technique

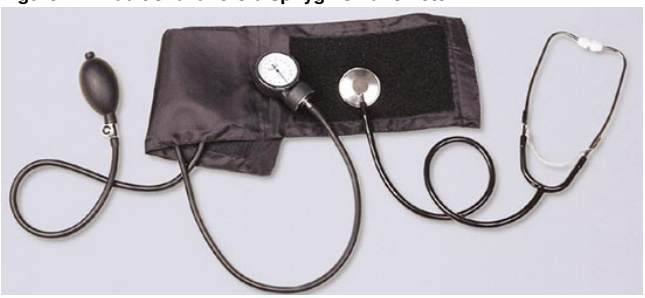
2.3.1.1 Aneroid

The manual aneroid sphygmomanometer works in a similar way to the mercury sphygmomanometer, but with an aneroid gauge that replaces the mercury manometer. While the accuracy and reliability of the aneroid manometer vary with the design and quality of the device, several aneroid mechanical sphygmomanometers have been validated for clinical use, meeting the criteria of the BHS protocol of the British Hypertension Society (BHS 2008). A list of validated aneroid sphygmomanometers for clinical use can be found on the dabl® Educational Trust website on blood pressure measurements (dabl 2009).

The dabl® Educational Trust website provides an overview of the results of validation tests by AAMI (Association for the Advancement of Medical Instrumentation), BHS (British Hypertension Society) and ESH (European Society of Hypertension). The most recent guidelines from the Task Force for the Management of Arterial Hypertension of the European Society for Hypertension (ESH) and of the European Society of Cardiology (ESC) specify that mercury-free devices can be used and will become increasingly important because of the gradual decrease in the use of mercury in the health care environment. However, the guidelines also insist that such mercury-free devices should

be validated according to standardised protocols (ESH/ESC 2007), and that the equipment should be calibrated periodically in line with manufacturer guidelines or legal requirements.

Figure 2 – Traditional aneroid sphygmomanometer



One drawback of aneroid manometers has traditionally been their susceptibility to shock. Better designs to deal with this sort of problem have recently appeared, e.g. the manufacturer Welch Allyn has introduced a new concept (DuraShock™) for an aneroid sphygmomanometer that is more shock-resistant than a conventional aneroid sphygmomanometer (Galligan *et al.* 2003). Similarly, the German producer Riester introduced in the second half of 2008 a shock-resistant aneroid sphygmomanometer, the R1 model, that is guaranteed to be shock-proof to a drop of up to 120 cm. Both manufacturers also provide the equipment with a 5-year calibration warranty (European Commission 2008).

Figure 3 – Riester R1 shock-proof aneroid sphygmomanometer

2.3.1.2 Manual digital

A relatively new type of "manual digital" sphygmomanometer marketed as an alternative to mercury sphygmomanometers and as a reference manometer, combines an electronic manometer with a dial for manual reading. One such device, manufactured by A.C. Cossor & Son (Surgical) Ltd in the UK, performs an auto-calibration to zero each time it is switched on, and meets the criteria of the International Protocol for blood pressure measuring devices in adults (BHS 2008). In particular it also displays the rate of cuff deflation, which is an important feature not possible in aneroid devices, nor in a mercury

column. Used with a stethoscope, this sphygmomanometer may also be used as a reference instrument. The U.S. producer Welch Allyn also provides sphygmomanometers with electronic manometers in the Maxistabil series.

Figure 4 – Two models of "manual digital" sphygmomanometer

Accoson Greenlight 300

Welch-Allyn Maxi Stabil 3

Manual blood pressure measurements (i.e., not based on oscillometry) are necessary for some specific clinical conditions including arrhythmia, pre-eclampsia and certain vascular diseases (IAG 2005). For this reason the UK Independent Advisory Group on Blood Pressure Monitoring in Clinical Practice recommends that calibrated manual mercury-free devices (which do not rely on oscillometry) should be available in all clinical areas in case they are needed to check any non-auscultatory blood pressure measurements on individual patients. In general, an aneroid sphygmomanometer should be calibrated according to the manufacturer's recommendation, or at least annually (IAG 2005; European Commission 2008).

Manual aneroid and digital sphygmomanometers are widely sold in the Member States for applications by general medical practitioners and in hospitals, which comprise the main market for sphygmomanometers today. An evaluation by the MHRA noted that the decreasing cost of automated devices, together with the improved reliability of aneroid devices and the introduction of manual digital sphygmomanometers, have been instrumental in the general reduction in the use of mercury sphygmomanometers (MHRA 2006; European Commission 2008).

2.3.2 Equipment based on the oscillometric or other technique

2.3.2.1 Semi-automated devices

Semi-automated electronic blood pressure devices have undergone extensive development during recent years, and a large number of different devices are marketed today. They typically use the oscillometric technique and include an electronic monitor with a pressure sensor, a digital display, an upper arm cuff and a hand-operated inflation bulb (European Commission 2008).

The semi-automated electronic devices are today standard for home/self assessment in many countries and are also widely used by general medical practitioners. The European Society of Hypertension has noted that for self-assessment, electronic devices using oscillometry are becoming more popular and are replacing the auscultatory technique. The electronic devices require less training and are easier to use by patients with infirmities such as arthritis and deafness. Equipment meeting the criteria of the BHS protocol of the British Hypertension Society is available at approximately the same price as that of a mercury sphygmomanometer (European Commission 2008).

Figure 5 – The Omron RX electronic sphygmomanometer for self blood pressure measurement at the wrist

2.3.2.2 Fully automated devices

For “fully” automated measurements in hospitals, more advanced equipment, which often combines the measurement of blood pressure with monitoring of temperature, heart rate and blood oxygen level, is often used. The majority of the devices currently available use the oscillometric method (MHRA 2006). The price of this advanced equipment may be up to 10 times the price of a mercury sphygmomanometer (Lassen and Maag 2006), but these advanced devices cannot be directly compared to mercury sphygmomanometers, as they have many more features (European Commission 2008).

The European Society of Hypertension Working Group on Blood Pressure Monitoring has stated, with regard to automated devices as alternatives to mercury sphygmomanometers, that an accurate automated sphygmomanometer capable of providing printouts of systolic and diastolic blood pressure, together with heart rate and

the time and date of measurement, should eliminate errors of interpretation, should end observer bias and terminal digit preference,[1] and should be used whenever possible (ESHWG 2005; European Commission 2008).

In spite of the accuracy of any given manometer, blood pressure measurements with manual equipment are not as reproducible as one would hope because many other factors influence the measurements. In recent guidelines on diagnostic blood pressure measurements, the Danish Hypertension Society concluded that both 24-hour measurements and blood pressure measurements at home are more reproducible and predict cardiovascular events more precisely than blood pressure measurements in the clinic (Bang *et al.* 2006, as cited in European Commission 2008).

2.3.3 Advantages and disadvantages of manual mercury-free instruments

In conclusion, the main advantages and disadvantages of manual mercury-free sphygmomanometers include:

- faster reading, in some cases
- avoidance of all hazards and costs of dealing with mercury
- advised to use a validated and recommended device
- aneroid may require more frequent calibration than a mercury sphygmomanometer, and digital less frequent
- all manual devices are prone to all the problems of the auscultatory technique, e.g. observer bias and terminal digit preference
- aneroid devices may be susceptible to calibration drift without this being apparent to the user (dabl 2009). This may be addressed by such devices as self-calibrating sphygmomanometers, etc.
- digital devices use batteries, which add to the cost and contribute to the waste problem.
- digital devices are based on oscillometry, which may not give proper blood pressure readings for certain medical conditions.

2.4 Sphygmomanometer summary

As discussed above, the many models of sphygmomanometer in use can be categorised in terms of inflation method, manometer type, need for stethoscope, blood pressure measurement frequency, placement of the pressure cuff, need for electrical current, etc. Table 1 below presents the main types of sphygmomanometer, while focusing on the different types of manual device with which this study is especially concerned.

For this study, the main mercury-free devices that will be compared with the mercury sphygmomanometer include:

- aneroid devices, portable, used with stethoscope, often require frequent calibration
- electronic (batteries), portable, used with stethoscope, may require less frequent calibration

[1] "Observer bias" may be described as the tendency for one's own biases to influence one's observations or measurements, especially when reading somewhat imprecise values. "Terminal digit preference" is a phenomenon whereby an observer rounds off a measurement to a digit of his or her choosing, often the terminal digit "zero" or "five."

- semi-automated (batteries), portable, based on oscillometry, validation with recommendation suggested; these will be considered along with the electronic devices since they are available within a relatively similar price range.

Table 1 – The many types of sphygmomanometer on the market

Basic models	Main categories	Inflation method		Manometer type				Stetho-scope used		Reading frequency		Pressure cuff placement			Batteries or mains required	
		Manual	Automated	Mercury	Aneroid	Electronic display	Electronic column	Yes	No	Discrete or intermittent	Continuous	Upper arm	Wrist	Finger	No	Yes
Manual	mercury	■		■				■		■		■			■	
	aneroid	■			■			■		■		■			■	
	digital	■				■		■		■		■				■
	hybrid	■					■	■		■		■				■
Automated and semi-automated	clinical (upper arm)		■			■			■		■	■				■
	clinical (finger)		■			■			■		■			■		■
	SBPM (upper arm)		■			■			■	■		■				■
	SBPM (wrist)		■			■			■	■			■			■
	SBPM (Community)		■			■			■	■		■				■
	ABPM (general)		■			■			■	■						■
	ABPM (continuous non-invasive)		■			■			■		■					■

2.5 Sphygmomanometers in the European Union

2.5.1 EU manufacturers and exporters

Mercury sphygmomanometers are manufactured by at least four manufacturers (all small or medium-sized) in the EU. One of the companies is specialised in sphygmomanometers, whereas the others are specialised in diagnostic instruments. Manufacture of mercury sphygmomanometers comprises a minor part of the total turnover of these enterprises, and all of them also manufacture mercury-free sphygmomanometers. Production for the EU market accounts for about 15% of the production of mercury sphygmomanometer; the remaining part being exported to countries outside the EU (European Commission 2008).

Beside these four manufacturers, at least two manufacturers are manufacturing mercury-free sphygmomanometers for manual measurement of blood pressure. These manufacturers would benefit from an increased market for mercury-free sphygmomanometers (European Commission 2008)

As mercury-free devices are already manufactured by the companies, the costs to the industry of increasing production of mercury-free alternatives are likely to be negligible (European Commission 2008).

A significant percentage of the mercury sphygmomanometers marketed in the EU are imported from Asia. According to a major EU manufacturer, imports account for the majority of the EU market, in particular in countries without domestic production of sphygmomanometers (European Commission 2008).

The manufacturers of manual mercury-free sphygmomanometers validated by BHS, AAMI and/or ESH include A&D Medical, Accoson, Heine, Microlife, PMS, and Welch-Allyn.

2.5.2 The EU sphygmomanometer market

Mercury sphygmomanometers manufactured in the EU typically contain 85 to 100 g mercury. According to information from various manufacturers, mercury sphygmomanometers account for approximately 10% of the total EU market for sphygmomanometers. According to the available information, the remaining purchasers of mercury sphygmomanometers are mostly general practitioners. Most hospitals in the EU Member States have phased out mercury sphygmomanometers, or are in the process of doing so (European Commission 2008), if not by a formal decision, then by an informal process of gradually replacing end-of-life mercury sphygmomanometers with mercury-free devices.

In the UK the sale of mercury sphygmomanometers fell from about 2,800 units in 2003 to about 1,800 units in 2006 containing a total of 0.15 tonne mercury (85 g mercury on average) and representing about 10% of the sphygmomanometer market. If these volumes were extrapolated on a per capita basis, the EU-wide consumption would be about 1.2 tonnes mercury (European Commission 2008).

It is estimated that mercury sphygmomanometers account for 5-15% of the blood pressure measuring equipment sold in Denmark in 2006, and the total mercury content is estimated at 12-28kg Hg/year (Lassen and Maag 2006). If these volumes were extrapolated on a per capita basis, the EU-wide consumption would be 1.1-2.6 tonnes mercury (European Commission 2008).

According to information submitted to the European Commission, the total number of mercury sphygmomanometers in use in Hungary is 29,000, which corresponds to a “stock” of approximately 2.0-2.5 tonnes mercury. No data on current sales in Hungary were provided (European Commission 2008).

2.5.3 EU mercury consumption and mass flow for sphygmomanometers

A German manufacturer estimated the EU-wide market for mercury sphygmomanometers at about 60,000 units (about 5-6 tonnes mercury), with the Italian and Eastern European markets as the major ones, supplied mostly by imported products. According to this manufacturer, in Italy and Eastern Europe the mercury sphygmomanometer comprises a significant part of the market, whereas in other parts of the EU it comprises no more than about 10% (European Commission 2008).

Considering the available data, total EU-wide annual mercury consumption in sphygmomanometers is estimated at 3-6 tonnes contained in 30,000 to 60,000 units. The sphygmomanometers are sold mainly to general practitioners. Mercury sphygmomanometers are no longer purchased by hospitals in the UK, Germany,

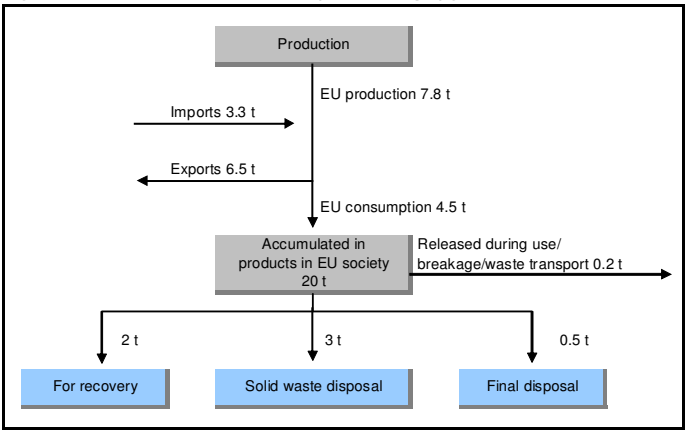
Denmark, France and Sweden, and the same is assumed to be true for most other Western European Member States (European Commission 2008).

Four manufacturers of mercury sphygmomanometers in the EU have been identified, but it cannot be excluded that a few additional manufacturers may be present in the EU. All four identified manufacturers also produce mercury-free sphygmomanometers. Several brands of mercury sphygmomanometers are imported from non-EU countries including Japan, USA and China. Imports account for the majority of the EU market, but in the UK and Germany (and maybe others) domestically produced sphygmomanometers dominate the market (European Commission 2008).

There is a significant export of mercury sphygmomanometers manufactured within the EU to countries outside the EU. European-made sphygmomanometers remain in demand outside the EU because they are considered by customers to be of higher quality, and they are more resistant to breakage and release of mercury. Based on available information, it is estimated that annual exports comprise at least 60,000-90,000 units, corresponding to 5-8 tonnes mercury (European Commission 2008).

Based on the previous estimates, and using the methodology developed for the recent EU Mercury Report (European Commission 2008), the following diagram roughly summarizes for the EU the mass flow of mercury used in sphygmomanometers.

Figure 6 – EU mass flow for mercury used in sphygmomanometers



2.5.4 Market trends for mercury sphygmomanometers in professional use

In response to external pressures to reduce the use of mercury, the Mayo Clinic (Rochester, Minnesota) began to replace mercury sphygmomanometers with mercury-free aneroid devices in the early 1990s. In order to address various technical concerns, in 1993 they instituted a maintenance protocol in order to ensure proper function and accuracy of the aneroid sphygmomanometers (Canzanello *et al.* 2001).

Many EU Countries have already replaced, or are considering replacing, mercury sphygmomanometers in professional use and health care. Latvia, Sweden, the Netherlands, Poland, Norway, Germany and Ireland are mostly mercury-free (EEB 2009).

In the UK, as mentioned above, mercury sphygmomanometers have been reduced to about 10% of the market for manual sphygmomanometers, and are sold almost entirely to general practitioners (European Commission 2008).

A Swedish investigation summarized the Swedish health care sector experience in phasing out mercury sphygmomanometers as follows: "*There were only positive experiences reported from the phase-out of mercury in the most widespread equipment called sphygmomanometers, which today is complete*" (Kemi and MK 2005). It was further concluded, "*There are no problems in diagnosing any condition using non-mercury sphygmomanometers including in the presence of arrhythmia, preeclampsia and in accelerated (malign) hypertension.*" … "*There is no evidence that the need for checks and calibrations cause practical problems or diagnostic problems. There are no reports of problems or inconveniences related to the change in routines.*"

To take just one example, the Karolinska University Hospital in Sweden has the largest department of cardiovascular and respiratory diseases in Scandinavia. It carries out 3,000 operations each year, including heart transplants and artificial hearts. It is a key facility to treat the most severe cardiac and vascular diseases. It accepts 1.3 million patients per year, it has 1,700 beds, and it carries out 54,800 laboratory analyses every day. It has not used mercury sphygmomanometers for more than 10 years (Karolinska 2009).

Appendix 2 provides many more examples from a report recently published by Health Care Without Harm.

For the many hospitals, especially in new EU Member States, where the budget is especially critical, it is very important to have good information about cost-effective (validated, reasonable cost, less frequent calibration requirement, etc.) mercury-free sphygmomanometers, so that money is not wasted on cheap, low quality models.

It is instructive to examine more closely the remaining market for mercury sphygmomanometers in the EU:

- In hospitals, the main users are those hospitals on a low budget, that tend to repair the existing equipment and make it last as long as possible. In most cases, these hospitals continue to use mercury sphygmomanometers that they have long held in inventory, but when these devices finally wear out, the hospitals generally replace them with mercury-free equipment. There are certainly also some smaller and more remote hospitals that continue to purchase mercury sphygmomanometers, but fewer and fewer.
- The majority of the market for mercury sphygmomanometers now seems to be comprised of general practitioners, typically older than the average health care specialist, who have always used mercury sphygmomanometers, who are very experienced in using them, who are completely convinced of the accuracy and reproducibility of their readings, who are very careful in their use so as to avoid accidents, who appreciate the low cost of these instruments, especially considering that calibration is probably infrequent (see details in Section 4.2), etc. It is not surprising that these users are not convinced of the value of phasing out the use of mercury.

It is also clear that the ongoing attraction of these users to mercury sphygmomanometers has little to do with the viability of mercury-free alternatives, and much more to do with cost, comfort and the reassuring habit of familiar practices.

3 The EEB survey questionnaire

3.1 Survey questionnaire

The questionnaire developed by the author and EEB to shed light on the main issues regarding phase-out of sphygmomanometers in the EU is attached as Appendix 3. It was carried out in eight countries during the month of April and the first part of May, 2009. The interviewers were selected by the EEB, and while various hospitals were targeted due to their large size, personal contacts were clearly important in arranging a number of interviews, and in encouraging the interviewees to speak frankly. However, because they chose to speak frankly, many interviewees were concerned that their hospital administration might not be comfortable with this process, and they preferred that their names and the name of their hospital should not be included in the final report. As a result it was decided to not put any interviewee or hospital names in the report.

The main purpose of the questionnaire was to gather case-based evidence of both the technical reliability and the economic feasibility of switching from mercury to mercury-free sphygmomanometers in health care. This questionnaire helped to guide the discussion and collect information on experiences and costs of hospitals that use either or both types of sphygmomanometer. Beyond the most evident cost data, the questionnaire made an effort to determine whether hospitals are aware of the full life-cycle costs of using instruments containing mercury.

3.1.1 Interviewees

Table 2 below summarises the number and responsibilities of the different hospital staff who agreed to provide information for this report. It may be seen that they represent a valuable cross-section of hospital activities, although there were not enough interviewees to furnish a comprehensive picture of the sphygmomanometer life-cycle at each hospital. Within the scope of this report, however, these interviews were adequate to provide valuable insights into many of the questions posed, and the insights obtained are evident throughout this report.

Table 2 – Interviewees and their responsibilities at EU hospitals

Position at hospital	Number of persons interviewed
Senior administrator	3
Administrator	3
Doctor	7
Nursing director	7
Nurse	8
Biomedical or technical specialist	7
Other staff (cleaning, security)	2
Total	**37**

3.1.2 Hospitals investigated

Table 3 provides information about the hospitals investigated in each of the eight countries selected, and specifically about their use of sphygmomanometers. Overall, nearly 90 percent of the sphygmomanometers used in these hospitals were found to be mercury-free, and 75 percent of the hospitals investigated no longer use mercury sphygmomanometers – some already for more than 10 years. At the bottom of the table, the same calculations are made with Germany excluded, since it could be argued that the large number of facilities and mercury-free sphygmomanometers in Germany excessively influence the rest of the data. Even with Germany excluded from the calculation, over 75 percent of the sphygmomanometers used in these hospitals were found to be mercury-free, and close to 50 percent of the hospitals investigated no longer use mercury sphygmomanometers.

Further details with regard to the information collected through the questionnaire and interviews are discussed later in the report.

Table 3 – Statistics on the hospitals investigated for this report

Country	Number of hospitals investigated	Number of beds*	Total sphygs*	Mercury sphygs*	Mercury-free sphygs*	Hospitals with only mercury-free sphygs
Czech Republic	4	3,279	1,235	838	397	0
France	4	4,035	1,120	12	1,100	3
Germany	29	16,000	4,000	0	4,000	29
Greece	2	1,050	190	120	70	0
Hungary	5	4,375	315	115	200	1
Italy	3	1810	480	240	240	1
Spain	5	2,785	860	0	860	5
United Kingdom	3	4,700	1,700	90	1,610	2
Total	**55**	**38,034**	**9,900**	**1,413**	**8,487**	**41**
Hg vs. Hg-free				14%	86%	75%
Total without Germany	26	22,034	5,900	1,413	4,487	12
Hg vs. Hg-free				24%	76%	46%

* Some estimates were made in cases where insufficient data were provided.
Source: Information received as a result of interviews carried out for this study.

3.2 Technical concerns

Virtually all of the sphygmomanometer users interviewed were eager to share their opinions and experiences, and those responses varied markedly. A selection of the statements made by interviewees about mercury sphygmomanometers includes the following:

- no problems
- air leakage, usually from rubber tubing, tubing connections or inflation bulb
- mercury leakage
- more susceptible to breakage
- more fragile if dropped

- slower measurement results
- hinders communication with the patient
- much bigger and heavier then aneroid devices
- environmental concerns
- high cost of calibration
- "loses" mercury
- "sometimes they don't operate"
- various maintenance problems
- too big, not portable
- no need for mercury sphygmomanometers
- less easy to use
- not portable
- technical quality is always getting worse
- needs more space
- needs horizontal surface at heart level
- needs regular cleaning
- slower and harder (than digital) to use
- no problem at all, "gold standard"

By contrast, a selection of the statements made by interviewees about mercury-free sphygmomanometers includes the following:

- they break more easily than mercury sphygmomanometers
- less reliable than mercury sphygmomanometers
- mercury sphygmomanometer necessary for some conditions
- no problems
- some air leaks
- accuracy is good
- aneroid sphygmomanometer is susceptible to damage
- automated devices not always accurate, especially when the patient moves
- different staff prefer diff. sphygmomanometers for different uses
- good for all ailments
- "digital ones" are inexact
- adequate precision
- much more portable (you can put it in your pocket)
- newer ones are especially reliable
- aneroid is less precise than mercury sphygmomanometer
- hospital very interested in the cheapest instrument; no problems
- "electronic sphygmomanometer is not so accurate" but other mercury-free are OK
- bad experience, not reliable
- have to wait 10 minutes between measurements, uses many batteries
- no problem if validated and calibrated, but I prefer the mercury sphygmomanometer
- similar problems as mercury sphygmomanometers, but less reliable
- one automated sphygmomanometer has many problems, but the advantage is that you don't need a stethoscope
- aneroid is OK for all needs
- similar risk of breakage but there is no mercury to spill
- with a mercury sphygmomanometer, the "zero" setting can be verified just by looking at the mercury column, but not with mercury-free

- in the case of arrhythmia, digital sphygmos sometimes do not register properly the "tones" of the blood pressure
- measurement is OK, but you need more strength to pump
- the accuracy depends on how sensitive your ear is
- automated auscultatory devices often cannot get readings, and can be inaccurate

It may only be concluded that these responses reflect issues more complex than the simple question of whether mercury-free sphygmomanometers can do the job. These comments reflect differences in instrument quality, in medical conditions of patients, in user training and expectations, in the level of attention to maintenance and calibration, etc.

The majority of interviewees were unaware that shock-resistant mercury-free sphygmomanometers are now available.

The vast majority of mercury-free (including automated) devices in routine use have not been subjected to validation tests; a British interviewee estimated that only about 10 percent have been so tested, although the percentage is much higher for manual.

There was significant confusion demonstrated by interviewees between validation and calibration. Many thought they are the same. Others understood the importance of calibration in theory, but confirmed that it is not done at all at their hospital unless there is an obvious problem with the function of the sphygmomanometer. Among interviewees who were aware of routine calibration at their hospitals, several mentioned that calibration is carried out using a mercury-free reference manometer.

One of the drawbacks of using cheap aneroid devices is that they are easily damaged, according to interviewees, and repairing them can be relatively expensive. If the damage is extensive, several interviewees pointed out that it may be cheaper to discard the damaged instrument and buy a new one. In hospitals where the budget is very tight, mercury sphygmomanometers are used as long as possible in order to avoid buying new (usually mercury-free) sphygmomanometers. The necessary repairs for a mercury sphygmomanometer are typically not expensive, and they can sometimes be kept in operation for up to 20 years. The median estimate by interviewees of the lifetime of a mercury sphygmomanometer was 8-10 years, although the typical lifetime reported from both hospitals in Greece was only 2-3 years. In some hospitals nurses are obliged to buy their own (normally mercury-free) sphygmomanometer. In this case they take better care of the instrument because they own it, but they are also likely to buy a cheap one that has not been validated. The lifetime of a cheap mercury-free sphygmomanometer most often cited was on the order of 1-2 years. A better quality aneroid device was estimated at around 4 years, and a good manual electronic instrument 5 years or more.

3.3 Phasing out mercury devices

Virtually all of the hospitals interviewed in Germany, Spain and France have phased out mercury sphygmomanometers – some for up to 10 years already. In fact, in Germany and Spain the interviewers were unable to find any hospitals that continue to use mercury sphygmomanometers. Only one large French hospital interviewed still has probably less than 10 wall-mounted mercury sphygmomanometers, and these are systematically replaced by mercury-free sphygmomanometers as the office space is reorganized, or if the mercury sphygmomanometer needs to be calibrated or repaired. The French CAHPP (Purchasing Agency for Private and Public Hospitals), which supplies more than 1,700 French medical centres, has for several years specified only mercury-free sphygmomanometers (CAHPP 2009).

The Czech hospitals interviewed said they try to repair their remaining mercury sphygmomanometers as long as possible, but when they are no longer usable, they are usually replaced with mercury-free. Some interviewees mentioned the tight budget as the excuse for using their mercury sphygmomanometers as long as possible. However, others were clearly convinced that the mercury sphygmomanometer is a more reliable and more accurate instrument than any of the mercury-free alternatives, and that any hazards of dealing with mercury are not significant.

One Greek hospital is also under heavy pressure to buy the cheapest sphygmomanometer, whatever model it might be. The other hospital does not feel any special urgency to shift to mercury-free. Their experiences with cheap mercury-free sphygmomanometers have not been very good, and they seemed to generally have the same reverence for mercury sphygmomanometers as some of the Czechs have.

Virtually all of the Hungarian hospitals interviewed also feel strong budget pressure, try to repair their remaining mercury sphygmomanometers, but noted that when the mercury sphygmomanometers can no longer be used, they will shift to mercury-free, especially as mercury sphygmomanometers are no longer available on the market.

Likewise, in the UK hospital still using mercury sphygmomanometers, they are also shifting to mercury-free as the mercury sphygmomanometers are put out of service, although one interviewee was convinced that no other instrument can equal a mercury sphygmomanometer. This hospital estimated that there is not any increased cost to the hospital overall as they shift to mercury-free.

Of three Italian hospitals interviewed, one has been mercury-free for the last two years; the second has not purchased mercury sphygmomanometers since 2005, but continues to use the remaining mercury sphygmomanometers in the hospital. And the third hospital in 2008 provided over 200 mercury sphygmomanometers to the staff just before a deadline for phasing them out. After April 2009 this hospital is no longer permitted to purchase mercury sphygmomanometers, but according to the present understanding they will continue to use the existing mercury sphygmomanometers as long as they can be kept in working condition.

3.4 Sphygmomanometer costs

As mentioned, some hospitals seek the cheapest devices they can find. Hungarian interviewees have sourced aneroid sphygmomanometers for €7-30, and digital sphygmomanometers for €8-28. Another found aneroid devices for €18 if purchased in lots of 20.

Standard prices cited by most interviewees were on the order of €40-60 for a validated mercury-free sphygmomanometer, although one well-informed interviewee noted that for a bit more it might be preferable to purchase a larger automated sphygmomanometer that would not be so easy to steal.

The cost of a mercury sphygmomanometer, where available, was generally cited at €50-80.

Calibration costs vary around €5-6 for an aneroid sphygmomanometer if carried out in the hospital itself, but up to €35 if outsourced to a service company. The calibration cost for a mercury sphygmomanometer, on the other hand, is closer to €30 (since it usually involves cleaning as well), and as high as €50 to calibrate a reference mercury sphygmomanometer.

These costs are factored into the overall cost analysis presented in Section 5.

3.5 Mercury waste issues

A few of the hospitals interviewed understood that mercury wastes, when they occur, should be dealt with in a special manner and isolated from other wastes, but most of these “aware” hospitals noted quite frankly that mercury wastes would be discarded in the same bins as other hazardous wastes (which in some countries is probably permitted by relevant regulations).

At the next level of awareness, it became clear in several interviews that hazardous wastes and infectious wastes are all discarded in the same bins.

At the lowest level of awareness, in about 30 percent of the hospitals interviewed, it was stated that mercury wastes would be discarded in the normal trash, as there was absolutely no awareness of any mercury hazard among the cleaning staff.

It is disturbing to hear of such relaxed attitudes about hazardous wastes, especially at health care facilities. But waste management takes place at the complex interface among individual awareness, corporate procedures, government regulations and economic cost to the hospital that generates the waste. As a result, where there is not constant vigilance, there will always be some efforts to deal with waste in a faster and less costly manner.

For this reason along with many others, toxics like mercury should be phased out wherever possible because there can never be a complete assurance that the waste will be properly managed. Despite the claims that are often heard from those generating toxic wastes, proper hazardous waste management is a far greater challenge than merely a training and management problem.

3.6 Questionnaire limitations

Considering the scope of the questions, the limited resources and various other constraints in carrying out this survey, there are a number of areas where some confusion and/or misinterpretation of the questionnaire responses may have occurred:

- Depending on the country, it was difficult to find interviewees who agreed to be named, so many interviews were carried out “off the record.”
- High-level administrators were often too busy to respond in detail to the questionnaire, so those working “in the trenches” were often interviewed. This resulted in valuable “unofficial” information about real sphygmomanometer use, but often lacked details of more general hospital policy on these issues.
- Even in the best of cases, it was necessary to identify several interviewees in order to get adequate responses to all of the questions. In the worst cases, many of the questions went unanswered in specific interviews.
- The level of knowledge of different interviewees varied greatly, and some appeared to respond to questions about which they had limited understanding.
- In retrospect, some questions were not as precise as they could have been, leading to interview responses that sometimes lacked the desired focus. For example, when discussing different types of mercury-free sphygmomanometers, it was not always evident whether interviewees were talking about aneroid, digital or automated models.
- The level of knowledge and experience of the interviewers was variable, so there were limits to discussion and clarification of some issues, and possibly occasional

errors in the interviewers' understanding or interpretation of responses to questions.

- The original English language questionnaire was translated into several other languages, and interviewee responses were interpreted, transcribed and translated back into English, permitting further opportunities for possible errors.

Nevertheless, any such faults are a very minor part of the whole, and the large body of information collected and transcribed through these interviews has proven to be a valuable contribution to the debate.

4 Technical sphygmomanometer issues

Mercury-containing sphygmomanometers used for home/self assessment and in hospitals have to a large extent been replaced by electronic devices based on the oscillometric technique. These are very convenient for most normal blood pressure measurements. However, as mentioned previously, sphygmomanometers based on the oscillometric technique should not be relied on for blood pressure determination in such "special conditions" as arteriosclerosis, arrhythmia, preeclampsia, *pulsus alternans*, and *pulsus paradoxus*. The discussion of available alternatives therefore focuses on sphygmomanometers that can measure all clinical conditions just as the mercury sphygmomanometer can do, i.e., using the auscultatory technique. The main difference is that the alternatives have replaced the mercury manometer with an aneroid or a digital/electronic manometer (European Commission 2008).

While the literature is full of interesting research on the technical aspects of sphygmomanometers and their use, the main challenges seem to fall under the following categories.

4.1 Sphygmomanometer accuracy and user errors

Everyone who has been trained to use a manual sphygmomanometer and listen through a stethoscope to the sounds of the different stages of blood flow through the brachial artery knows that a certain amount of practice is required before becoming comfortable with the process. And even with practice and experience, errors in blood pressure readings are generally acknowledged. A number of factors other than the reliability of the sphygmomanometer may influence the reliability of the blood pressure reading, including the speed of deflation, an appropriately sized cuff, terminal digit preference, the "white coat effect," ambient noise, etc.

Markandu *et al.* (2000) wrote in the *Journal of Human Hypertension* after examining 500 mercury sphygmomanometers and their tubes and pressure cuffs at a large London teaching hospital: "…*assessment of the technical knowledge needed to measure blood pressure by the auscultatory technique was also carried out amongst medical and nursing staff. This showed a considerable level of ignorance. These results [together with instrument deficiencies] inevitably lead to inaccurate measurement of blood pressure with serious consequences."*

Another research study in 2001 assessed the accuracy of mercury and aneroid sphygmomanometers in use in 231 English general practices (Rouse and Marshall 2001). Of 949 mercury and 513 aneroid sphygmomanometers, 9.2% gave readings that were more than 5mm Hg inaccurate, which is considered the limit of acceptable sphygmomanometer accuracy. It was not indicated how many of the inaccurate sphygmomanometers were mercury and how many were aneroid.

In another study, significant differences in the performance of various models of aneroid, mercury and automated devices were identified. It was concluded that a service model for improving the accuracy of blood pressure monitoring in primary care needs to take into account the current proliferation of pressure scale errors in these devices, the lack of regular control or calibration, and the poor quality of some of the devices in use (Coleman *et al.* 2005).

Still other research demonstrated that the mean initial automated reading (mm Hg) taken with the observer present (162±27/85±12) was similar to the mean manual blood pressure taken in duplicate (163±23/86+12). However, both values were higher ($P < 0.001$) than the mean of the next five readings taken with the automated recorder when the patient was resting quietly alone (142±21/80±12). Furthermore, women exhibited a greater fall in blood pressure than men did between the first and second test conditions. It was concluded that the use of an automated blood pressure recorder, by permitting the patient to relax apart from medical observation, can reduce the "white-coat effect" associated with readings taken by a manual sphygmomanometer (Myers 2006).

In a similar study, blood pressure readings taken at health clinics chronically overestimated the mercury sphygmomanometer readings, with a mean overestimation of 8.3mm for systolic BP and 7.1mm Hg for diastolic BP. Based on the clinic-based readings, 21% of patients were therefore misdiagnosed with uncontrolled hypertension. Health professionals should be aware of this potential difference when utilizing clinic-based BP values for making treatment decisions and/or assessing quality of care (Kim *et. al.* 2005).

Meanwhile, often lost in the discussion about device accuracy, though equally important, is the issue of measurement technique. A 2002 working meeting on blood pressure measurement in the United States highlighted numerous studies that found that basic measurement techniques, inappropriate cuff size, too rapid deflation, etc., were causing significant errors in measurement.

4.2 Calibration and maintenance

4.2.1 Calibration of mercury-free sphygmomanometers

Mercury-free sphygmomanometers have traditionally been more vulnerable to shock than mercury sphygmomanometers. While mercury-free sphygmomanometers may vary greatly in quality, depending on the design and manufacturer, this is an issue that has received particular attention as the health care industry moves away from mercury devices. Recent developments in shock-resistant design are generally not reflected in research carried out before 2004.

A number of mercury-free sphygmomanometers have been validated by the European Society for Hypertension and are considered highly reliable for blood pressure measurements. The main complaint about aneroid devices has been that they are less stable and need more frequent calibration. As confirmed by an independent advisory group for the Medicines and Healthcare Products Regulatory Agency in the UK (IAG 2005), calibration should be carried out annually or in line with the manufacturer's recommendation.

In Germany, the Bundeswehr (German Army) recommends checking aneroid sphygmomanometers every second year, although other hospitals may check them as often as twice a year in line with manufacturer recommendations. Still other German hospitals have confirmed that some aneroid sphygmomanometers may be used only until they have to be re-calibrated according to the national law, and at that time they are thrown away since the cost for calibration is nearly as expensive as a new sphygmomanometer. It would seem that in-hospital calibration could be much less expensive, although if these sphygmomanometers are used a lot, and if they are perhaps a bit fragile, it may be that they reach the end of their normal life in only two to three years.

In Sweden, where mercury sphygmomanometers have been phased out for many years, all blood pressure measuring equipment is recommended to be checked once a year and calibrated as necessary. Many manufacturers recommend to check the sphygmomanometers every second year, or whenever an aneroid sphygmomanometer that is not shock-resistant has been dropped (European Commission 2008).

4.2.2 Calibration and maintenance of mercury sphygmomanometers

It should be noted, however, that mercury sphygmomanometers also need regular calibration and maintenance, and have to be operated by trained personnel. Markandu *et al.* (2000) wrote in the *Journal of Human Hypertension* after examining 500 mercury sphygmomanometers and their tubes and pressure cuffs at a large London teaching hospital: "*More than half had serious problems that would have rendered them inaccurate in measuring blood pressure."*

Knight *et al.* (2001) found in a survey of 472 sphygmomanometers (of these, 75.4% were mercury devices) used in general practice in the UK that 69.1% of the mercury instruments and 95.7% of the aneroid instruments checked had no service records. A large proportion of mercury sphygmomanometers tested also had deficiencies likely to affect the reading if the recommended measurement technique were used. Despite the lack of service records, two-thirds of the mercury sphygmomanometers were accurate at all pressure levels. Only 38.8% of the aneroid instruments were accurate at all pressure levels tested.

In the Rouse and Marshall (2001) investigation of 949 mercury and 513 aneroid sphygmomanometers in England, nearly 100 sphygmomanometers of both kinds were in such a poor physical condition, e.g. with air leaks or dirty mercury, that the researcher suggested they be withdrawn from service. No practice had arrangements for routine maintenance and calibration of sphygmomanometers. Nationally, one of 54 practices had an arrangement for maintenance and calibration, whereas 34 of the 54 practices accepted calibration by drug companies on an irregular basis, and 19 had no service or had not calibrated their sphygmomanometers for years.

45 general practices within Lambeth, Southwark and Lewisham were visited during another investigation. A total of 279 mercury and mercury-free sphygmomanometers were calibrated using an accurate electronic reference pressure sensor. 17.9% (50 out of 279) of all surveyed devices showed errors in excess of the +/-3mm calibration threshold. 53.2% (33 out of 62) of aneroid devices were found to be reading in error by more than +/-3mm Hg compared with 7.8% (16 out of 217) of the mercury devices (Coleman *et al.* 2005).

As demonstrated above, until recently many sphygmomanometers have not been tested regularly, but there is an increasing awareness of the importance of regular calibration. As one example, more and more hospitals are using quality management systems (e.g. ISO 10001), and it is an integral part of the management system to regularly calibrate all medical equipment.

4.2.3 Mercury column not needed for calibration

It is important to recognize that no matter what type of blood pressure measurement device is used both aneroid and mercury sphygmomanometers must be calibrated regularly in order to avoid errors in blood pressure measurement and consequently the diagnosis and treatment of hypertension (WHO 2005).

One of the questions frequently raised is, even if we can do without mercury sphygmomanometers, is a mercury column still needed for calibration of mercury-free equipment in hospitals and clinics? In answering this question, the recommended calibration procedures of two manufacturers, Welch Allyn and AC Cossor & Son (Surgical) Ltd, are briefly reviewed.

4.2.3.1 Welch Allyn

The Welch Allyn DuraShock^{TM} is a shock resistant aneroid sphygmomanometer with an accuracy of +/-3mm Hg – similar to a mercury sphygmomanometer. This product line consists of four models of varying quality and price. The calibration warranties for these models range from 5 years for the cheapest "bronze" model to a lifetime warranty for the most expensive "platinum" model (Welch Allyn 2008a). (Similar equipment is now also available from the German manufacturer Riester.)

In spite of the calibration warranty, and despite the fact that the equipment also has a feature for a "quick check" of the calibration, Welch Allyn also recommends a full check of calibration at least every two years. Regarding the high quality equipment needed for a full check of the calibration, some have argued that for accurate blood pressure measurement the reference device used for calibration must be a mercury column or manometer (with a typical error of ±3 mm of mercury). Yet, when calibrating a device, the error of the reference pressure must be added to the specified accuracy of the instrument under test (±3mm Hg) to determine the working accuracy of a calibration set-up. As a result, if using a manometer (mercury column or aneroid gauge) rated at ±3.0mm Hg as a reference, one will be able to determine the accuracy of the gauge being tested to only ±6.0mm Hg. This is outside the accuracy range of ±5 mm of mercury typically desired by medical professionals (WMJ 2008).

For this reason, "Welch Allyn recommends using as sensitive as possible a pressure standard when performing calibration checks. A Setra Pressure Meter (part no. 2270-01), which is calibrated for ± 0.1mm Hg, or Netech (part no. 200-2000IN), which is calibrated for ± 1.0mm Hg, works well for this application." (Welch Allyn 2008b)

Thus it is evident that the manufacturers recommend that a digital manometer be used as the calibration standard rather than a mercury manometer. Both the Setra Pressure Meter and the Netech meter are digital pressure gauges. The Digimano 1000 from Netech is promoted specifically for calibrating sphygmomanometers and is sold with a "blood measure calibration kit" (Netech 2008). The meter has an accuracy of 0.25%. Therefore, it is clear that the most important requirement for calibrating a sphygmomanometer is an accurate pressure gauge. Any gauge used for the purpose of accurately measuring pressure in the relevant pressure range may be appropriate.

4.2.3.2 AC Cossor & Son

The Greenlight 300 sphygmomanometer from AC Cossor & Son (Surgical) Ltd is an electronic device that has been developed with the capability of calibrating other sphygmomanometers. According to the manufacturer, "*Due to its reliable accuracy, the Greenlight 300 is suitable for use as a reference manometer for checking the calibration of aneroid and mercury sphygmomanometers*" (Accoson 2008). A Pressure Cycle Test showed that the maximum indicated error both during the test and after 10,000 pressure cycles was +/- 0.8mm Hg, confirming compliance with both European and American standards, which specify a maximum error of +/- 3mm Hg (Accoson 2008).

The Greenlight 300 is designed to automatically self-calibrate to zero each time it is switched on. According to the manufacturer, the calibration of the Greenlight 300 need only be checked after four years. Other components such as the air control valve, cuff and tubing should be examined more frequently for signs of wear.

The available information suggests that good quality electronic pressure gauges, kept solely for calibration of sphygmomanometers, are at least as accurate as the traditional mercury column.

4.2.3.3 Other considerations

If the mercury column or sphygmomanometer is phased out, formal revision of the calibration assessment detailed by the device validation protocol of the British Hypertension Society would be required. A validation study incorporating such an amendment has previously been published (Coleman *et al.* 2008). In addition, it should be kept in mind that the cost of a digital reference device is substantially more than that of a mercury sphygmomanometer (presently about €700 vs. €60); also, a digital reference device may require yearly calibration at a cost of about €200 (de Greeff 2009), compared to around €50 for calibrating a reference mercury column.

4.3 Inaccurate manufacturer claims

In a 2005 investigation, 86 companies were found to be actively involved in the supply of 158 different models of sophisticated automated blood pressure device – 54 devices for use on the arm and 62 for use on the wrist. Following a request for further information, responses were received for 61% of the main category arm and wrist devices, and 80% of these provided claims for CE marking. Inconsistencies were found between claims for diagnostic suitability and claims for clinical validation. It was observed that a majority of the different models of sophisticated automated blood pressure devices available on the European Union market were not validated by clinical trial to one of the recognized protocols (Sims *et al*. 2005).

This confirms the importance of implementing EU-wide standards to ensure an acceptable level of quality in sphygmomanometers.

4.4 Mercury sphygmomanometer spillage, breakage and leakage

In some of the interviews carried out for this study there appeared to be some confusion between air leaks and metallic mercury leaks from sphygmomanometers. Furthermore, while breakage of mercury sphygmomanometers was reported to be quite frequent, it was sometimes not specifically noted how often such breakage led to mercury leaks or spills, and some interviewees were recalling . Therefore, not all of the interviews were reliable sources of information with regard to mercury spills.

At the Mayo Clinic in the U.S., 50 incidents were documented between 1993 and 1995 of significant leakage and spills from sphygmomanometers (WMJ 2008). The Mayo Clinic experience has been estimated to represent approximately three significant leaks or spills for every 100 sphygmomanometer-years, which is roughly consistent with the information gathered from the more reliable EU interviews for this study. Relevant cost estimates related to mercury spills and cleanup are discussed in Sections 5.4 and 5.5.

4.5 Validation

4.5.1 The validation process

The validation process needs to be more widely understood by sphygmomanometer purchasers and users. Of course the method of validation is important, but also its importance to the market value of the validated sphygmomanometer should be understood, the cost of validation that will be passed on to the purchaser, the delay in getting a sphygmomanometer to market because of the time it takes to carry out and publish a validation study, etc.

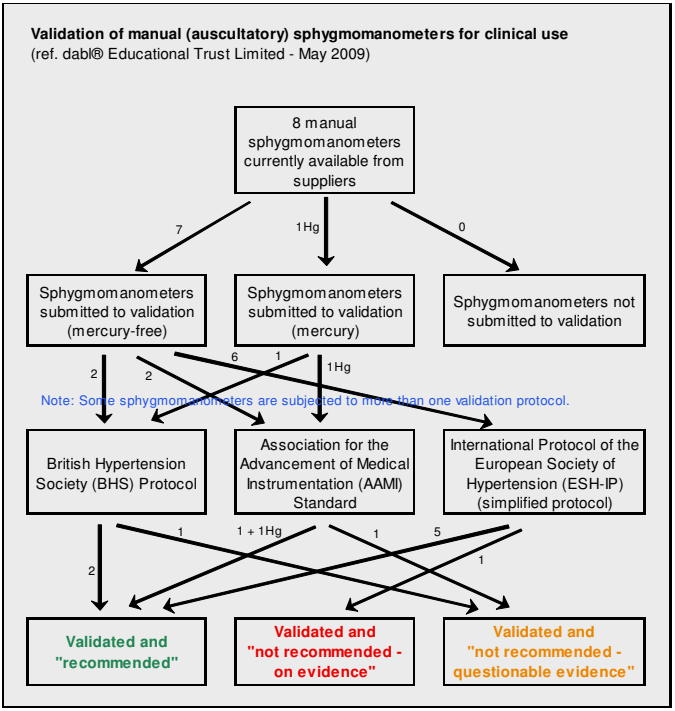
There is a large market for blood pressure measuring devices, not only in clinical medicine, but also with the public where the demand for self blood pressure measurement (SBPM) is growing rapidly. Device accuracy should always be of prime importance in selecting a blood pressure measuring device. However, the majority of devices available have not been evaluated independently for accuracy according to any of the three most widely used protocols: the British Hypertension Society (BHS) Protocol, the Association for the Advancement of Medical Instrumentation (AAMI) Standard, and more recently the International Protocol (IP) of the European Society of Hypertension (ESH). And the consumer often does not have the expertise or information to make a fully informed decision as to which device to purchase (dabl 2009).

Unfortunately for purchasers of sphygmomanometers, there is even some confusion over the meaning of the word “validation.” Some assume that a sphygmomanometer that has been “validated” has passed at least one of the three key performance protocols described above. However, many researchers (and the dabl® Educational Trust Limited website) take “validation” to mean only that a given device has been subjected to at least one of the validation protocols. Subsequently, if the sphygmomanometer happens to meet or exceed the protocol requirements, it is then “validated and recommended” under that protocol. As a result, one must be wary of claims that a given sphygmomanometer has merely been “validated,” as that does not necessarily mean it has passed the protocol tests.

The Association for the Advancement of Medical Instrumentation (AAMI) published a Standard for Electronic or Aneroid Sphygmomanometers in 1987, which included a protocol for the evaluation of the accuracy of devices, and this was followed in 1990 by the protocol of the British Hypertension Society (BHS); both protocols were revised in 1993. These protocols, which differed in detail, had a common objective, namely the standardisation of validation procedures to establish minimum standards of accuracy and performance, and to facilitate comparison of one device with another. A large number of blood pressure measuring devices have been evaluated according to one or both protocols. However, experience has demonstrated that the conditions imposed by the protocols are difficult to fulfil, and manufacturers complain about the long and costly time lag between validation of a device and the subsequent publication of the results. Therefore, the Working Group on Blood Pressure Monitoring of the European Society of Hypertension recently published a simplified protocol to facilitate validation. This simplified protocol sets the minimum approval standard necessary for a device to be used in clinical medicine, in the hope that in time most devices will be independently assessed for basic accuracy according to this protocol (dabl 2009).

Figure 7 below shows the process for manual sphygmomanometers that have been validated, and the results of those validations.

Figure 7 – Validation process for manual sphygmomanometers



4.5.2 Is a mercury column required for validation?

At present, there is no way to formally validate a sphygmomanometer against one of the established protocols (ESH-IP, AAMI or BHS) without the use of a classic mercury column, largely because the use of a mercury reference device is specifically required by the test protocol. However, since validation studies are performed in only a few centres around the world, very few mercury devices are used for this purpose. If necessary, they could be given a special exemption to use a mercury column or manometer, but in theory a mercury column is not even needed for this purpose.

It is very likely that validation with mercury-free devices will be permitted before long, following further research to determine/establish the equivalence of auscultatory mercury-free devices to current mercury sphygmomanometry. The three most widely used validation protocols all presently require any device being tested to be assessed against mercury sphygmomanometry as the reference standard (de Greeff 2009).

Possible mercury-free instruments that could be used as reference devices for validation would include aneroid, automated and hybrid devices. Aneroid and automated devices cannot be recommended as a reference standard due to concerns about consistent accuracy and calibration drift. A manual digital instrument (see Figure 4) could be a possible candidate. Likewise, the hybrid device (which is quite similar to the mercury sphygmomanometer but replaces the mercury column with an electronic transducer and

display) may prove its potential as a reference standard, as it enables auscultatory blood pressure measurements by reading pressures from an electronic (e.g. liquid crystal or LED) display. Further research needs to confirm whether observers read this digital display in the same manner as they would a mercury column, and indeed whether the dynamic of this display is similar to that of mercury falling during cuff deflation. Two hybrid devices are shown in Figure 8 below, one of which (Nissei DM-3000, which provides an LED display to mimic a mercury column during auscultatory blood pressure measurement) has recently been subjected to validation tests. The findings of this validation (i.e., whether the device is recommended or not) will be published in the near future (de Greeff 2009).

Figure 8 – Manual hybrid sphygmomanometers with LCD "columns"

A&D Medical UM-101

Nissei DM-1000

5 Real cost of mercury sphygmomanometers vs. mercury-free

5.1 Purchase cost

Prices for BHS-validated mercury-free sphygmomanometers range from about the same, to twice the price of mercury sphygmomanometers. The highest price is for the electronic/manual reference sphygmomanometer. In Germany, where there is a highly competitive market for sphygmomanometers, the price of a German-made mercury sphygmomanometer is approximately €60 (excl. VAT) for a general practitioner. The market price of an aneroid sphygmomanometer from the same manufacturer is about €50, and the shock-resistant aneroid sphygmomanometer a bit higher (European Commission 2008).

Prices of different models from the same manufacturer have been obtained in the UK. Desk models of Accoson sphygmomanometers can be purchased at the following prices (excl. VAT): Mercury sphygmomanometer about €63, conventional aneroid sphygmomanometer at the same price, Greenlight 300 sphygmomanometer at about €165. The Welch Allyn Maxi Stabil desk models are available at €89-215, depending on the model, whereas the Welch Allyn DuraShock™ is available at about the same price as the mercury sphygmomanometer (European Commission 2008).

Cheap "unbranded" mercury sphygmomanometers can be purchased at prices as low as €10-15, but these products are not considered to be viable alternatives to those discussed above (European Commission 2008). In most countries there is no law to prevent hospitals (or individual nurses) from legally purchasing such sphygmomanometers, which could be considered a potential health hazard.

The price of sphygmomanometers varies by performance and quality. As seen in Table 4 below, the "reference price" of a European mercury sphygmomanometer may be assumed to be €60, which is approximately the same price as a good quality shock-resistant aneroid sphygmomanometer. In contrast, a high-performance manual sphygmomanometer with electronic gauge may cost approximately €160, but it can also be used for calibration of other equipment. These purchase prices will be used for the overall comparison of manual sphygmomanometers in Section 5.8.

Table 4 lists a number of blood pressure measurement devices reviewed by the UK Department of Health, Medicines and Healthcare Products Regulatory Agency (MHRA 2006). The list includes indicative prices of the equipment on the UK market.

In order to compare the total life-cycle cost of a mercury sphygmomanometer with the cost of mercury-free alternatives, one must consider costs related to:

- compliance with regulations concerning mercury waste management
- need for special storage of used or damaged devices
- cleaning up after any mercury spill
- closing of the spill area during clean-up
- staff training with regard to the cleanup procedure, the disposal of contaminated equipment and hazardous waste management
- health costs of sick staff or patients exposed to mercury
- recycling or final disposal of hazardous waste; etc.

All of these cost elements are discussed in further detail below.

Table 4 – Comparison of blood pressure measuring devices

Equipment	Advantages	Disadvantages
Mercury sphygmomanometer (Price range £30–55)	'Gold standard', portable, good reliability, can be used on most patients.	• Contains toxic mercury leading to maintenance and disposal problems, as well as exposure in case of leakage or spill • Manual technique prone to observer bias • Requires clinical skill to operate
Aneroid sphygmomanometer (Price range £20–80)	Mercury-free, portable, can be used on most patients.	• Wear and mechanical shock to mechanism may result in incorrect readings • Requires regular calibration check • Manual technique prone to observer bias • Requires clinical skill
Electronic sphygmomanometer (Price range £30–140)	Mercury-free, portable, good reliability, can be used on most patients.	• Manual technique prone to observer bias • Requires clinical skill
Semi-automated and automated spot-check device (Price range £30–170)	Mercury-free, lightweight, compact, portable, easy to use, no observer bias.	• Originally designed for home use, and may not be suitable for all patients, particularly those with arrhythmias, pre-eclampsia and certain vascular diseases • Clinical validation recommended*
Wrist device (Price range £20–100)	As above, with increased patient comfort.	• As for automated device above • Readings are dependent on the relative positioning of the wrist to the heart • Tends to be less accurate than upper arm devices
Finger device (Price range £25–50)	As above.	• As for wrist device above, although measurement more peripheral and less reliable. • May not be suitable for patients with narrow or cold fingers.
Spot-check non-invasive blood pressure monitor (Price range £700–1,600) Automatic-cycling non-invasive blood pressure monitor (Price range £1,500–3,000)	• Mercury-free, no observer bias, portable, easy to use, designed for monitoring in clinical use • May include additional vital signs	• May not be suitable for all patients, particularly those with arrhythmias, pre-eclampsia and certain vascular diseases • Clinical validation recommended*
Ambulatory blood pressure monitor (Price range £1,000–2,000)	Mercury-free, lightweight, compact, designed for clinical use, records 24- hour blood pressure trend.	• Designed for ambulatory monitoring, not as a replacement for the mercury sphygmomanometer • Clinical validation recommended*
All prices are approximate and serve only as a guide to differentiate between types of instrument. *Clinical validation recommended by the Independent Advisory Group. **Source:** MHRA (2006)		

5.2 Calibration frequency and costs

A Swedish evaluation of mercury-free measuring devices conclude regarding the experience with use of mercury-free equipment: *"All blood pressure measuring equipment is recommended to be checked once a year and calibrated when necessary. There is no evidence that the need for checks and calibrations cause practical problems or diagnostic problems. There are no reports of problems or inconveniences related to the change in routines."*

Several guidelines recommend that sphygmomanometers should be calibrated every year or as specified by manufacturers. The UK Medical Devices Directive, e.g., requires measuring devices to be checked every year, whereas aneroid devices need to be checked every six months. This applies to conventional aneroid and not the newest types. The manufacturer of Greenlight 300 proposes to check the calibration only after 4 years. Instructions for the Welch Allyn DuraShock^{TM} suggest that the equipment should be calibrated at least every two years.

In hospitals calibration is often carried out by the technical department, whereas the calibration of equipment in general practices is done by specialised companies or, as is the case in the UK, by drug companies, providing this service for free as part of their customer service.

The cost of calibration in the UK, if undertaken by a service company, is approximately €30-35. With shipment the total costs would be approximately €40. It should be noted that this is nearly the same price as a new inexpensive aneroid sphygmomanometer. If the hospital technical service undertakes calibration of all equipment in the hospital, the cost will be lower.

For cheap aneroid sphygmomanometers that are not shock-resistant, the cost of calibration over the life of the meter would exceed the cost of the meter by many times if the equipment were calibrated every six months.

5.3 Maintenance and repair

If a hospital has a calibration schedule, routine maintenance is typically carried out at the same time, during which the basic functioning and integrity of the sphygmomanometer is checked. If there is no calibration schedule, then it is likely that there is no routine maintenance either. In this case, a sphygmomanometer will only be sent for control or repair if it has an evident problem.

Some repair, especially with regard to mercury sphygmomanometers, is carried out by the hospital technical service. This would include the cleaning, topping up and/or replacement of mercury, cleaning of the glass or plastic mercury column, etc. For all sphygmomanometers repair usually concerns replacement of damaged or leaking rubber tubing, cuffs, etc. If the damage is more extensive, it is more likely to be carried out by the service company unless the repair cost would approach the cost of a new sphygmomanometer, in which case the old one is simply discarded or used for spare parts.

For purposes of this analysis, since maintenance and repair frequency and costs are not well known, they are simply included with calibration costs.

5.4 Cleaning up spills

The personal interviews carried out for this study provided useful information on mercury spills, though not enough to reliably extrapolate to the EU as a whole.

During the interviews it was learned that actual mercury spills are not frequent, but nearly all interviewees had seen them. The frequency of spills has decreased in recent years since more sphygmomanometers now use a plastic mercury column rather than glass. For purposes of this analysis, Section 4.4 has estimated approximately three significant mercury leaks or spills for every 100 sphygmomanometer-years. At various hospitals cleanup time was estimated from two minutes (no special procedure) to about one hour (this was one of only three interviews during which it was suggested that the area should

be closed during cleanup), except for one case in which the fire brigade was called in response to a mercury spill.

One Hungarian interviewee noted that mercury spills usually only happen when health care personnel pump up the sphygmomanometer pressure too much and mercury spills out the top of the mercury column.

Based on the interviews, while most hospitals surveyed for this study provide basic training with regard to hospital waste management, many hospitals still using mercury sphygmomanometers do not appear to have a specific clean-up and safety procedure (or if there is a procedure, the staff seems to be unfamiliar with it) for dealing with mercury spills. In general such a procedure would involve evacuation of people, particular attention to any exposures, especially of more vulnerable individuals such as pregnant women and children, clean-up with a special spill kit or equivalent, adequate aeration of the area, etc.

In order to calculate a spill cleanup cost, it was assumed that a proper response could cover a large cost range from €50 to €1,000 or more, depending on the cost items included, with an average cost on the order of some €400.

5.5 Human exposures

Mercury sphygmomanometers pose a potential health risk if they are dropped/broken/leaking during normal use, during maintenance or in storage. The mercury vapour can be inhaled by visitors, patients, nurses, doctors and other hospital staff, and it may remain in the setting (on furniture or clothing, in the carpet or cracks in the floor) for a long time if not cleaned up properly. As with all mercury exposures, women of childbearing age, pregnant women, and young children are most susceptible. In this section the possible health and environmental costs of mercury releases to the air – releases related to spills as well as releases during eventual sphygmomanometer disposal – are addressed.

5.5.1 Exposure cost estimates

A previous economic analysis (EEB 2006) conservatively estimated annual EU health costs in the range of €25,000-30,000 per kg of atmospheric mercury emissions. The lower figure has been used for this study.

A European Commission-sponsored study (DHI 2005) of the impact of REACH[2] legislation estimated that the annual environmental costs of chemical emissions in the European Union likely approximate the direct health costs. Therefore, for combined health and environmental costs the figure of €40,000 per kg of atmospheric mercury emissions has been used for this study.

5.5.2 Exposures of health care professionals and patients

Mercury spills have been mentioned above. The main sources of potential exposure are related to mercury vapour releases in the health care facility, and atmospheric emissions during waste disposal of the spilled mercury. Based on an average of 80-100g mercury in a typical mercury sphygmomanometer, it is estimated here that about 5g Hg could be emitted to the atmosphere during the “lifetime” of a typical spill.

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[2] REACH (Registration, Evaluation and Authorisation of CHemicals) is the acronym for the eponymous EU Regulation on chemicals.

In the interviews carried out for this study, there were also a number of reports of oxidation of mercury in sphygmomanometers, dust or dirt in the manometer tube, air leaks, mercury "top up" required, etc. These are all indications of mercury vapour escaping to the outside air.

In one Czech hospital, of a total of about 180 mercury sphygmomanometers in use, one interviewee reported that about 40 of the sphygmomanometers need topping up every year, suggesting pervasive and continual slow mercury emissions to the air.

Among the several Hungarian hospitals interviewed, some10-20 percent of the mercury sphygmomanometers appeared to need mercury added each year, and in Greek hospitals around 2-3 percent.

There is no evidence that anyone has actually measured the ambient concentration of mercury in the air around a sphygmomanometer, or the mercury concentration in the air that is exhausted from the pressure cuff of a mercury sphygmomanometer. For this reason these possible emissions have not been estimated for this study. However, it is highly likely, depending on the model, age, use and maintenance of an instrument, that an elevated mercury level would be detected around a significant number of instruments that remain in use or in storage. This is not the sort of finding that would help the image of the health care sector, and should be one further reason to encourage phasing out these devices before such a finding is formally published.

5.5.3 Exposures of the public from waste disposal

Based on a recent report of mercury emissions to the atmosphere from the disposal of mercury-containing products, it may be estimated that at least 30 percent of the mercury in sphygmomanometers ends up in municipal waste, and approximately 5 percent of that mercury is probably emitted to the atmosphere. The relevant human health and environmental costs are included in Table 5 below.

5.6 Managing mercury waste

Issues of mercury waste management in health care facilities has been discussed at length in Section 3.5 above. Since each facility should have a comprehensive hazardous waste management programme, there is only an incremental cost required for storing and disposing of a mercury sphygmomanometer. This cost should include elements such as proper hazardous waste containment of used or broken devices, secure storage, and eventual recycling or proper disposal that minimises any releases and prevents mercury from entering the general waste stream. Lacking good data on such costs, it is estimated that they come to about €20-40 per mercury sphygmomanometer disposed of.

5.7 Cost issues for hospitals on tight budgets

A hospital with a tight budget is more likely to focus on the up-front purchase cost of a sphygmomanometer, and pay less attention to calibration, maintenance and lifetime considerations. In the absence of legislation, such a hospital is likely to replace mercury sphygmomanometers, after a long life of in-house repairs, with mercury-free sphygmomanometers only when the mercury devices are no longer functional or repairable.

However, since the under-budgeting of sphygmomanometer calibration, maintenance, etc., is not a sound basis for provision of quality health care, this low-budget option was not considered in the cost analysis below.

5.8 Overall cost comparison

Table 5 presents a rough overall cost comparison among the validated manual mercury and mercury-free instruments presented in the first three rows of Table 4.

Table 5 – Cost comparison between manual mercury and mercury-free sphygs for professional use

Cost-related inputs	Mercury	Aneroid	Digital	Notes
Average lifetime (years)	9	4	6	Rough estimates from documents and interviews
Equiv. sphygs consumed per yr.	0.11	0.25	0.17	One sphyg spread over its average lifetime
Purchase cost per sphyg (€)	60	60	160	Estimates from the text
Calibration and maintenance cost (€ per calib.)	30	30	40	Estimates (Hg €20-40; aneroid €20-40; digital €30-50) from the text
Calibration frequency (years per calibration)	2	1	3	While the calibration requirement differs among countries and devices, these ranges are recommended by BHS.
Staff training cost (Hg spill response) (€ per sphyg)	30	0	0	At ~10 euro per staff hour
Staff training cost (Hg spill, €/sphyg-yr.)	3	0	0	Staff training cost (spill) divided by sphyg lifetime
Staff training cost (sphyg use) (€ per sphyg)	20	20	30	At ~10 euro per staff hour
Staff training cost (sphyg use, €/sphyg-yr.)	2	2	3	Staff training cost (sphyg use) divided by sphyg lifetime
Spill cleanup cost (€ per spill)	400	0	0	Cost of spill kit, person-hours, spill area closure and cost of downtime, waste disposal, etc. (range €50-1000, est. average about €400).
Spill frequency (per sphyg-yr.)	0.03	0	0	Est. 3 significant Hg spills or leaks per 100 sphyg-years
Waste management cost (€/sphyg)	30	1	2	Cost of separate collection, special storage, recycling/disposal of Hg devices
Cost of human exposure, spill (€/kg Hg vaporised)	25,000	0	0	Spill-related costs (> €25,000 per kg Hg released to the atmosphere)
Cost of human & environmental exposure, waste (€/kg Hg vaporised)	40,000	0	0	Costs related to waste management (> €40,000 per kg Hg released to the atmosphere)
Social cost of change (€/sphyg)	0	2	3	Indicative (relatively insignificant) cost to individual health care providers obliged to change their habits
Equivalent cost (€ per sphyg-yr.)				
Equivalent purchase cost	7	15	27	Purchase cost/sphyg divided by sphyg lifetime
Equivalent calibr. & maint. cost + batteries	15	30	16	Calibration cost divided by frequency, plus estimated battery cost (€3) for electronic sphyg
Equivalent staff training cost	5	2	3	Staff training cost (spill response + sphyg use)
Equivalent spill cleanup cost	12	0	0	Spill cleanup cost * spill frequency
Equivalent waste management cost	3	0	0	Waste management cost/sphyg divided by sphyg lifetime
Equiv. human exposure cost (spill)	4	0	0	Hg vapour releases in clinic and via typical spill waste disposal; assume 5g Hg released per spill
Equivalent human & environment exposure cost (waste)	6	0	0	Other Hg vapour releases from dealing with Hg sphygs and wastes; assume ~30% of Hg in discarded sphygs goes to municipal waste, and ~5% of that reaches the atmosphere
Equivalent social cost	0	1	1	Social cost per sphyg divided by sphyg lifetime
Total cost (€ per sphyg-year)	**52**	**48**	**47**	

With regard to the generic instruments compared in Table 5, the mercury sphygmomanometer is assumed to be a standard, portable, reliable instrument. The aneroid sphygmomanometer is assumed to be a portable, reliable, “shock-proof” instrument. The electronic (digital) sphygmomanometer is assumed to be a portable, reliable, manual model.

While statistics on sphygmomanometer lifetime, staff training, cleanup costs and waste management procedures vary greatly from one country to another, the estimates below are based on the interviews and recent literature (sphygmomanometer lifetime), and/or on generally acceptable procedures (training, cleanup, maintenance, waste management).

Based on these assumptions, the overall cost comparison shows no special economic advantage for any of these alternatives. However, the calculation is extremely sensitive to the estimated lifetime of the sphygmomanometer, and to the frequency and cost of calibration. Since both of these variables depend heavily on the model of sphygmomanometer, the manner and frequency of use, etc., one can only conclude for certain from this cost comparison that:

1. a good quality, shock-proof aneroid sphygmomanometer that does not need to be calibrated more than once a year is almost certain to be more cost-effective than the alternatives; and
2. the overall comparative costs are so similar, the sphygmomanometer purchase decision should be based on other important concerns such as toxic content rather than the purchase cost.

The less detailed cost comparison (omitting external costs) carried out for the European Commission (European Commission 2008) concluded that the equivalent cost of the mercury sphygmomanometer is about 10 percent higher than the cost of a good quality shock-proof aneroid sphygmomanometer, while the equivalent cost of a “high-end electronic sphygmomanometer” is 50-60 percent higher than the aneroid sphygmomanometer.

In a study done by Kaiser Permanente, the largest not-for-profit Health Maintenance Organization (HMO) in the United States, it was determined that when associated life-cycle costs are included (waste management, liability, training, etc.), the total cost per unit of a good aneroid sphygmomanometer is about one-third that of a mercury-containing device (WMJ 2008). While that finding is even more compelling than the simple analysis carried out for this paper, it is clear that Kaiser Permanente identified the full life-cycle costs associated with using mercury-containing sphygmomanometers to be very significant. Taking its own advice, that HMO no longer purchases mercury sphygmomanometers.

6 EU exports of mercury sphygmomanometers

Along with the discussions about phasing out the use of mercury sphygmomanometers in the EU, there is a parallel concern about whether the export of mercury sphygmomanometers produced in the EU should also be phased out. In order to help illuminate this discussion, some of the arguments for and against exports are briefly reviewed below without assessing which arguments may have more merit.

6.1 Arguments in favour of exports

Arguments that have been advanced in support of the continued export of mercury sphygmomanometers include the following:

- many countries purchase EU mercury sphygmomanometers due to their high quality; if EU exports are no longer available, these countries will be obliged to purchase lower quality mercury sphygmomanometers from non-EU exporters;
- many mercury sphygmomanometers from non-EU exporters are less expensive, lower quality, less reliable, more fragile, shorter lifetime, requiring more frequent calibration, etc.;
- these lower quality sphygmomanometers will therefore be the cause of more mercury leaks and spills (i.e., human health exposures, waste disposal problems), compared to the present EU exports that are more expensive, use robust and shatterproof materials for the vulnerable components, and use better quality filter materials;
- because the non-EU sphygmomanometers are less stable and less reliable, patient care will also suffer if these sphygmomanometers are used, especially if the frequent calibration requirements are not respected, and this will lead to further significant human health costs that could be avoided if EU sphygmomanometer exports were allowed to continue;
- phasing out EU exports would reduce EU sales of sphygmomanometers and may lead to a loss of some jobs.

6.2 Arguments for banning exports

On the other hand, a number of alternative arguments may be advanced in support of an eventual phase-out of mercury sphygmomanometer exports:

- the EU should avoid double standards, i.e., imposing restrictions in the EU that it does not also support outside the EU. Mercury-containing products prohibited in the EU should not be exported to countries where they may not be properly regulated, and/or where their disposal may be poorly managed;
- the generally agreed global objectives for mercury are to reduce supply, demand and emissions. Those objectives are not advanced by continuing exports of mercury-containing sphygmomanometers from the EU;
- if third countries presently purchase the more expensive sphygmomanometers exported by the EU, then the purchase cost is not their chief concern. They should

be willing shift to mercury-free sphygmomanometers (also exported by EU manufacturers) if they are provided with better information, and if they are sure of the quality and reliability of mercury-free sphygmomanometers;

- if Argentina and the Philippines have already decided to shift to mercury-free sphygmomanometers, it should not be difficult for other countries to move in the same direction, especially with some encouragement from the EU;
- in parallel with an export ban, efforts should be enhanced worldwide to educate professionals, the public and government ministries about viable mercury-free alternatives.

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Appendices

Appendix 1 – The ABC's of sphygmomanometers

(Adapted from *http://en.wikipedia.org/wiki/sphygmomanometer*)

A sphygmomanometer or blood pressure meter is a device used to measure blood pressure, comprising an inflatable cuff to restrict blood flow, and a mercury or mechanical manometer to measure the pressure. It is always used in conjunction with a means to determine at what pressure blood flow is just starting, and at what pressure it is unimpeded. Manual sphygmomanometers are used in conjunction with a stethoscope.

A sphygmomanometer consists of an inflatable cuff, a measuring unit (the mercury manometer, or aneroid gauge), and inflation bulb and valve, for manual instruments.

Operation

The cuff is normally placed smoothly and snugly around the left arm, at roughly the same vertical height as the heart while the subject is seated with the arm supported. It is essential that the correct size of cuff is selected for the patient. Too small a cuff results in too high a pressure, whilst too large a cuff results in too low a pressure. The cuff is inflated until the artery is completely occluded. Listening with a stethoscope to the brachial artery at the elbow, the examiner slowly releases the pressure in the cuff. As the pressure in the cuffs falls, a "whooshing" or pounding sound (see below) is heard when blood flow first starts again in the artery. The pressure at which this sound began is noted and recorded as the systolic blood pressure. The cuff pressure is further released until the sound can no longer be heard. This is recorded as the diastolic blood pressure.

Reading the blood pressure

The unit of measurement of blood pressure is millimetres of mercury (mm Hg). Blood pressures are usually given as an even number. By observing the mercury in the column of a mercury manometer while slowly releasing the air pressure with a control valve, one can read the values of the blood pressure in mm Hg. The peak pressure in the arteries during the cardiac cycle is the systolic pressure, and the lowest pressure (at the resting phase of the cardiac cycle) is the diastolic pressure. A stethoscope is used in the auscultatory method. Systolic pressure ("first phase") is identified with the first of the continuous Korotkoff sounds. Diastolic is identified at the moment the Korotkoff sounds disappear ("fifth phase").

Types of sphygmomanometer

There are three types of sphygmomanometer:

- Manual sphygmomanometers, which require a stethoscope for auscultation. These should be operated by a trained person. Mercury manometers are considered to be the "gold standard" of measurement because their operation is reasonably reliable, these devices have long achieved an acceptable standard of quality and performance, and they may be used for determining blood pressure for high risk

patients including pregnant women. Mercury-free aneroid and electronic manual instruments of a high quality are now also available, but one needs to take care to distinguish them from lower quality instruments.

- Digital sphygmomanometers with manual or automated inflation. These are electronic, easy to operate and practical in noisy environments because they do not require a stethoscope. Many have not been validated for all patient groups (or at all), and the quality of different instruments may vary significantly. They measure mean arterial pressure (MAP) and use algorithms to calculate systolic and diastolic values. In this sense, they do not actually measure the blood pressure, but derive the readings. Digital oscillometric monitors are also challenged by "special conditions" for which they are not designed to be used, including arteriosclerosis, arrhythmia, preeclampsia, *pulsus alternans*, and *pulsus paradoxus*.
- Digital portable finger blood pressure monitors with automated inflation. These operate on the same principle as those above, although they are more portable and easy to operate, though less accurate. They are the smallest blood pressure monitors.

Appendix 2 – "End of an Era," excerpt from an HCWH report

From: J Harvie and J Karliner, "End of an Era: The Phase-out of Mercury-Based Blood Pressure Measurement Devices in the United States and its Implications for Europe and the Rest of the World," Health Care Without Harm, September 2008.

PART TWO – SUMMARY OF FINDINGS

1. THE EUROPEAN PARLIAMENT HAS MANDATED A REVIEW OF THE FEASIBILITY OF ALTERNATIVES TO MERCURY SPHYGMOMANOMETERS BY OCTOBER 2009[3]

> Of all mercury instrumentation used in health care, the mass of mercury deployed in mercury column sphygmomanometers (80 to 100g/unit) make them collectively one of the largest mercury reservoirs in the health care setting.

> The sphygmomanometer is also one of the most challenging devices to eliminate because of perceived or real issues with regard to the cost and accuracy of the alternatives.

> Health Care Without Harm decided to document the experience of the U.S. health care sector in addressing this question over the last decade to help inform the debate in the EU.

> We found that the U.S. healthcare community has experienced tremendous success in delivering safe, accurate, cost-effective mercury-free blood pressure measurement.

2. THE U.S. LEADS THE EUROPEAN UNION IN ADDRESSING THE PROBLEM OF MERCURY IN HEALTH CARE

> In both the U.S. and the EU, mercury thermometers are nearly completely phased out. In the U.S., this has been achieved largely through voluntary and state-level legislation. In Europe, this has been achieved through an EU-mandated ban.

> However, blood pressure devices (sphygmomanometers) are another story. While some countries, such as Sweden, have successfully eliminated mercury-based blood pressure devices, and a number of hospitals throughout the EU have done the same, the U.S. health care system is, based on available information, well out in front of the EU in this area of environmental health.

> This situation could change if the EU mandates a phase-out of mercury sphygmomanometers sales and export.

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[3] "By 3 October 2009 the Commission shall carry out a review of the availability of reliable safer alternatives that are technically and economically feasible for mercury-containing sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses." http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007 :257:0013:01:EN:HTML

3. HUNDREDS OF U.S. HOSPITALS HAVE SUCCESSFULLY PHASED-OUT MERCURY SPHYGMOMANOMETERS WITH ALTERNATIVES. THEY REPORT LITTLE OR NO PROBLEM WITH THE TRANSITION

> By 2001, over 600 hospitals had committed to end their use of mercury in healthcare through a

pledge developed by HCWH.

> In 2002, Practice GreenHealth (formerly Hospitals for a Healthy Environment, h2E) began an award program, the *Making Medicine Mercury Free Award*, for those hospitals that had virtually eliminated their use of all mercury. To date, over 250 hospitals have received this award.

> According to a 2005 survey of 554 health care facilities conducted by the American Hospital Association, 73 percent of respondents had removed all mercury sphygmomanometers.[4]

> Hospitals and hospital systems representing over 80 medical centers and more than 200,000 employees have provided HCWH with letters that detail the success of their mercury elimination programs.

4. GROUP PURCHASING ORGANIZATIONS (GPOS) SERVING THOUSANDS OF U.S. HOSPITALS NO LONGER PROCURE MERCURY-BASED MEDICAL DEVICES

> GPOs represent over $52 billion or 96 percent of all contract health care purchases made in the U.S.[5]

> In a 2005 survey of GPOs, three of the five largest U.S. GPOs had implemented mercury-free purchasing policies that ban items from contracts except where a non-mercury alternative is not available.[6]

> Overall, the sales of mercury-containing devices are decreasing, and those of non-mercury alternatives are increasing in the United States. During this market shift, GPOs have not experienced a decrease in total sales, which seems to indicate that consumers are not simply buying mercury-containing items from other vendors.

> This year, two of the largest GPOs in the United States sent letters to HCWH highlighting the market transformation away from mercury blood pressure devices.

5. TWELVE U.S. STATES ARE PHASING OUT MERCURY SPHYGMOMANOMETERS VIA LEGISLATIVE MANDATES

> In addition to voluntary initiatives undertaken by hospitals, health care systems and purchasing organizations, several state governments have pursued a legislative approach.

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[4] Cited in “Making Medicine Mercury Free: A 2005 Report on the Status of Virtual Mercury Elimination in the Health Care Sector,” Hospitals for a Healthy Environment, Arlington, 2005. http://www.h2e-online.org/docs/h2e2005MercuryReport.pdf

[5] Werner, Curt. “HPN Survey: GPO contract purchases top $54 billion in 2002” Health Purchasing News. June 2003.

[6] Cited in “Making Medicine Mercury Free: A 2005 Report on the Status of Virtual Mercury Elimination in the Health Care Sector,” Hospitals for a Healthy Environment, Arlington, 2005. http://www.h2e-online.org/docs/h2e2005MercuryReport.pdf

> Eleven States -the members of the Interstate Mercury Education and Reduction Clearinghouse (IMERC)- have enacted legislation regulating the sale and distribution of mercury-added sphygmomanometers.

> Three States -Rhode Island, Louisiana and Connecticut- have effectively banned mercury-based blood pressure devices by restrictions on the sale of products by mercury content.

> The other eight -California, Illinois, Maine, Massachusetts, Minnesota, New Hampshire, Vermont, and Washington- have restricted sphygmomanometer sales by name.

> In addition, the state of Michigan, which is not a member of IMERC, has enacted a ban on the sale of mercury-added sphygmomanometers, effective January 1, 2009.

> Together, these states account for approximately 30 percent of the U.S. population.

> Overall, between 2001 and 2007, the total amount of mercury sold in sphygmomanometers, as reported to IMERC-member states, has decreased by approximately 60 percent.

6. MANUFACTURERS, RESPONDING TO SHIFTING DEMAND, ARE PRODUCING THE ALTERNATIVES

> Two of the former leading U.S. based mercury blood pressure device manufacturers, Welch Allyn and Trimline Medical, have ended their production of mercury blood pressure devices.

7. PEER REVIEWED SCIENTIFIC STUDIES SHOW THAT THE ALTERNATIVES ARE ACCURATE

> Peer reviewed literature from the last decade shows that aneroid and digital sphygmomanometers are just as accurate as mercury-based devices.

> Mercury and non-mercury blood pressure devices provide accurate measurement as long as instruments are calibrated.

> It is imperative that the healthcare community and governments ensure that alternative devices are purchased from manufacturers that follow techniques and testing protocols that are independently certified.

> After considering the scientific evidence, a report produced by the World Health Organization (WHO) department addressing cardiovascular diseases concluded in 2005 that even in low resource settings, “in light of the toxicity of mercury, it is recommended that mercury blood pressure measuring devices be gradually phased out in favour of affordable, validated, professional electronic devices.”[7]

> WHO also points out that “international protocols for blood pressure measuring device validation have been released by the Association for the Advancement of Medical Instrumentation, the British Hypertension Society, and the European Society of Hypertension Working Group on Blood Pressure Measurement.”

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[7] “Affordable Technology: Blood Pressure Measuring Devices for Low Resource Settings,” Cardiovascular Diseases, World Health Organization, Geneva, 2005.

Appendix 3 – Questionnaire on sphygmomanometers

Questionnaire on mercury sphygmomanometers and mercury-free sphygmomanometers

Questionnaire completed by_____

Date_____

Time_____

Purpose of Questionnaire:

The purpose is to evaluate the 1) technical reliability and 2) economical feasibility of switching from mercury sphygmomanometers to mercury-free sphygmomanometers in health care. Therefore, do not waste too much time on discussions that do not help to clarify either of these two points.

This questionnaire is intended to guide the discussion and collect information on experiences and costs of hospitals that use either or both types of sphygmomanometer.

Please ensure at least that all questions highlighted in GREY are answered.

Questions:

Overview of sphygmomanometers at this hospital

1. Name and address of hospital.
2. For eventual comparison with other hospitals, how many beds are in this hospital?
3. Name and current job of (each) interviewee.
   - How long have you worked at this hospital?
   - If you have worked less than 5 years in their present job, did you have the same occupation before?
4. Do you use sphygmomanometers that contain / not contain mercury in this hospital?
   - If yes, approximately how many total sphygmomanometers are there in the hospital?
   - Approximately how many of that total are mercury sphygmomanometers, and how many are mercury-free?
   - What brands and models of mercury-free sphygmomanometers are used?
   - Do you use different models of mercury-free sphygmomanometer for different purposes in the hospital? If so, please explain.
   - Are your mercury-free sphygmomanometers certified or validated according to any international validation protocols, and do they meet the criteria of medical societies

(such as the British Hypertension Society, European Hypertension Society, the Association for the Advancement of Medical Instrumentation, etc.)?

5. Are sphygmomanometers an important "tool" (i.e. do you use them daily, weekly, monthly) in your own work?
   - If so, have you ever encountered any difficulties using mercury sphygmomanometers? If yes, could you please explain.
6. Alternatively, have you ever used mercury-free sphygmomanometers in clinical diagnosis and monitoring?
   - If so, have you ever encountered any difficulties using them, e.g. in dealing with specific medical conditions such as cardiac arrhythmias, preeclampsia, accelerated (malign) hypertension, diabetes, pregnancy or other vascular conditions? If so, please explain
7. In your opinion, are mercury sphygmomanometers necessary to properly treat any specific medical problems such as cardiac arrhythmias, preeclampsia, accelerated (malign) hypertension, diabetes, pregnancy or other vascular conditions?
8. In your opinion, do mercury-free sphygmomanometers give an accurate and reliable measurement or reading?
9. In your opinion, is there a faster or slower, better or worse performance if mercury sphygmomanometers are compared with mercury-free sphygmomanometers?
10. Is there any other practical information you would like to mention regarding your own experience or knowledge of sphygmomanometers?

Calibration practices

11. Is there a mandatory programme, procedure or schedule of maintenance or calibration for the sphygmomanometers in your hospital? If so, please describe briefly the maintenance schedule and frequency for:
    - mercury sphygmomanometers
    - mercury-free sphygmomanometers
12. What equipment (e.g. a mercury manometer or alternative standard) is needed for accurate calibration of sphygmomanometers, what is the calibration procedure and how often do they need to be calibrated? Are your instruments being calibrated on a regular basis and is a record kept?
    - mercury sphygmomanometers
    - mercury-free sphygmomanometers
13. In your opinion, are mercury sphygmomanometers needed for testing or calibrating any other blood pressure measuring devices?
14. Can you estimate/do you know the cost of calibrating a single sphygmomanometer? If not, is there a maintenance contract that covers maintenance and calibration of all sphygmomanometers at the hospital? Is there information on calibration costs contained in that contract?
    - mercury sphygmomanometers
    - mercury-free sphygmomanometers

Durability and ease of use

15. What is the lifetime of a typical sphygmomanometer? Do they just get too old at some point, or do they break before that time?
    - mercury sphygmomanometers
    - mercury-free sphygmomanometers
16. If you have sufficient experience, can you explain the advantages and disadvantages of mercury and mercury-free sphygmomanometers with regard to:
    - Time required for training to use the sphygmomanometer
    - Ease of use
    - Susceptibility to breakage or damage that would make them useless (lifetime of a typical mercury (free) sphygmomanometer)
    - Ability to maintain their setting between calibrations?
    - Susceptibility to shock (is this a common problem, and are there on the market shock-resistant mercury-free models?)
17. Do you have any suggestions to speed the transition from mercury sphygmomanometers to mercury-free sphygmomanometers?

Maintenance and spills

18. Is one of the staff trained to carry out maintenance on sphygmomanometers, or is this a job that is contracted to a service company?
    - mercury sphygmomanometers
    - mercury-free sphygmomanometers
19. Are you aware of any particular maintenance problems with regard to sphygmomanometers?
    - mercury sphygmomanometers
    - mercury-free sphygmomanometers
20. What is your experience with regard to breakage of mercury sphygmomanometers?
    - How many get broken in your hospital each year?
    - Are they always replaced with new mercury sphygmomanometers, or are they sometimes replaced with mercury-free sphygmomanometers?
    - Are you aware of breakage-resistant mercury sphygmomanometers available on the market?
21. What is your experience with regard to leaking mercury sphygmomanometers?
    - How often are leaks detected, i.e. how many leaks detected each year?
    - During maintenance, how often does mercury have to be added, i.e., how many each year?
22. What is your experience with spills from mercury sphygmomanometers?
    - Do spills occur only when a mercury sphygmomanometer breaks, or are there sometimes spills during maintenance or other circumstances?
23. When there is a mercury leak, spill, or breakage, what is the basic procedure for cleaning up any contaminated areas?
    - According to your procedure, is it necessary to close such areas during cleanup?

Waste

24. What is your disposal practice for mercury sphygmomanometers that are not broken?
25. What is your disposal practice for (broken) mercury sphygmomanometers and related waste?

- Is there a separate waste management system for mercury waste?
- How is hazardous waste managed in general?
- Are old mercury sphygmomanometers or mercury wastes held in temporary storage pending final disposal?

26. What are your mercury waste handling and transportation procedures?

Exposure risk

27. Are there any safety precautions required when using mercury sphygmomanometers at your hospital?
28. Is there any potential exposure to mercury vapour from intact or broken mercury sphygmomanometers for
    - hospital workers such as doctors, nurses and patients?
    - women of childbearing age, and young children?
29. Can you recall any mercury exposure events related to using mercury sphygmomanometers?
30. Are there any hospital situations (risk of aggressive movements by the patient, etc.) in which mercury sphygmomanometers should not be used?

Training

31. How is the staff trained to respond if a mercury sphygmomanometer is dropped or broken?
32. Do you train staff in general hazardous waste management?
33. Do you train staff how to safely dispose of broken mercury sphygmomanometers?
34. Have you ever observed a staff member incorrectly dealing with hazardous waste?
35. Do you believe your hospital's education and training program for dealing with hazardous waste is adequate?

Cost elements

36. What is the cost of purchasing a sphygmomanometer?
    - mercury sphygmomanometer
    - mercury-free sphygmomanometer with roughly equivalent features
37. If your hospital switched some mercury sphygmomanometers to mercury-free sphygmomanometers, are you aware of any specific cost savings (or cost increases) related to this switch?
38. Are you aware of any health care costs related to treating hospital staff for exposure to mercury from mercury sphygmomanometers?
39. Are you aware of any health care costs related to treating patients for exposure to mercury from mercury sphygmomanometers?
40. What is the estimated cost to train one staff person in hazardous waste management? How many staff members are trained in hazardous waste management?
    - what is the additional cost, if any, to train one staff person in mercury waste management, including what to do if a mercury sphygmomanometer is broken, leaking or spilled? How many staff members are given such additional training?

41. What is the estimated cost (not including staff time) of cleaning up a contaminated area and disposing of the waste in the event of a leak or spill from a mercury sphygmomanometer?
    - How much staff time would be typically involved?
    - What is the value of this staff time?
42. What is the estimated cost of having special infrastructure to deal with hazardous waste (such as ventilated temporary storage rooms)?
    - is there any additional hazardous waste infrastructure cost related to managing waste from mercury sphygmomanometers?
43. Are there any other identifiable costs or benefits at your hospital of using:
    - mercury sphygmomanometers
    - mercury-free sphygmomanometers
44. Is there anything else you would you like to add with regard to costs and effectiveness of sphygmomanometers or similar diagnostic instruments that we have not covered elsewhere in this questionnaire?

Other issues

Potentially useful documents you could ask for (optional):

- calibration certificates
- management of hazardous waste procedure
- clean up procedure in case of spillage, leakage, breakage
- training procedure

If possible, you could also take some pictures.