Report from the Conference

EU Mercury phase out in Measuring and Control Equipment

Brussels, June 2009

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Health Care Without Harm

zero Hg mercury working group

The European Environmental Bureau (EEB) is a federation of over 140 environmental citizens' organisations based in most EU Member States, most candidate and potential candidate countries as well as in a few neighbouring countries. These organisations range from local and national, to European and international.

EEB's aim is to protect and improve the environment by influencing EU policy, promoting sustainable development objectives and ensuring that Europe's citizens can play a part in achieving these goals. EEB stands for environmental justice and participatory democracy. Our office in Brussels was established in 1974 to provide a focal point for our members to monitor and respond to the EU's emerging environmental policy. In 2004, EEB, working with the Mercury Policy Project/Ban Mercury Working Group, launched the 'Zero Mercury' campaign.

Health Care Without Harm Europe (HCWH Europe) is the European branch of an international coalition of hospitals, medical professionals and environmental organisations working to transform the healthcare sector, without compromising patient safety or care, so that it is ecologically sustainable and no longer a source of harm to public health and the environment. The coalition has offices in Arlington, Brussels, Buenos Aires and Manila with over 470 members in 52 countries.

The Zero Mercury Working Group is an international coalition of over 80 Public interest non-governmental organisations from more than 42 countries from around the world formed in 2005 by the European Environmental Bureau and the Mercury Policy Project. The group's aim is to reach 'zero' emissions, demand and supply of mercury, from all sources we can control, towards eliminating mercury in the environment, at EU level and globally.

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REPORT FROM THE EEB CONFERENCE

EU MERCURY PHASE OUT IN MEASURING AND CONTROL EQUIPMENT

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European Environmental Bureau **Health Care Without Harm** **Zero Mercury Working Group**

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Table of Contents

I. Introduction and background 3
II. Conference Results 5
III. Agenda 9
IV. Sphygmomanometers in healthcare 11
1. EU restrictions of mercury use in measuring and control equipment – EC proposal 11
2. Industry's view on mercury in measuring devices - The global mercury crisis and the global hypertension crisis 15
Discussion 17
3. NGOs view and experiences on mercury-free measuring devices 21
4. Phasing out mercury sphygmomanometers for professional use 22
Discussion 27
5. To be or not to be Hg Free – that is the question! A case for the Mercury Free Hospital 27
6. The experience of Rezekne Hospital as a mercury-free hospital 30
7. Global developments and mercury in measuring devices 31
8. WHO policy and partnership 33
9. The Global Movement for Mercury Free Healthcare 39
Discussion 41
10. Phasing out of mercury sphygmomanometers in Poland 41
11. Swedish Policy for a Mercury Free Environment 42
12. UK concerns on mercury device restrictions 44
Discussion 44
V. Technical Panel Discussion 45
13. Perspective by a mercury-free hospital 45
14. Manufacturer's perspective 46
15. Clinical doctor's perspective (Presentation by Professor Peter Orris MD, University of Illinois, WHO Collaborating Center in Occupational and Environmental Health) 48
16. Validation expert's perspective 49
Panel discussion on calibration, validation and special cases 51
VI. Other measuring devices 52
18. Other Mercury Containing Devices or Applications of Concern 52
19. Mercury electrodes: Important applications of polarography and possible mercury-free alternatives 54
20. Views on other measuring devices from a Member State - Denmark 56
Discussion on other measuring devices 56
VII. List of Abbreviations 58
VIII. Pictures from the meeting 59
IX. Participants list 62

I. Introduction and background

Mercury is an extremely toxic metal that is now ubiquitous in the environment due to centuries of unchecked releases. When airborne, mercury is a transcontinental pollutant that, once deposited, bioaccumulates and bioconcentrates as it makes its way up the food chain. Exposure to mercury, even at low levels, has been linked to central nervous system damage, kidney and liver impairment, reproductive and development disorders, defects in fetuses and learning deficits.

Mercury is used extensively in many industry sectors such as in the chlor-alkali production, as well as in products – lamps, dental amalgams, switches and relays, as well as in equipment used for measuring and control purposes. Mercury containing sphygmomanometers are still used in European hospitals and by general practitioners and are therefore a source of mercury release to the environment and risk to health, when broken or leaking. However, these measuring devices all have comparable and suitable alternatives that do not contain mercury.

The European Commission (EC) Measuring devices directive (2007/51 EC) was adopted in 2007 and includes a ban on mercury in new fever thermometers for all uses (consumer and professional) by April 2009. The ban also covers all other measuring and control devices for consumer use only. According to the directive, the EC will release a report by October 2009 on the availability of mercury-free measuring and control devices (mainly sphygmomanometers) that are technically and economically feasible for professional use in healthcare.

In preparation for making its findings, the EC started collecting information mainly on the technical aspects, availability and reliability of mercury-free sphygmomanometers in healthcare. In addition, one of the EU scientific committees (SCENIHR – on Emerging and Newly Identified Health Risks), is expected to provide its opinion in autumn 2009 on the same issue.

Given these developments, the European Environmental Bureau (EEB), Zero Mercury Working Group (ZMWG) together with Health Care Without Harm Europe (HCWH) organised a conference to provide input into this important debate by fostering exchange of valuable information between experts and policy makers.

The objectives of the conference were to discuss:

- The technical and economic feasibility of hospitals and healthcare institutions transitioning to mercury-free sphygmomanometers;
- Experiences of stakeholders such as Member States and European hospitals that have phased out mercury containing measuring devices;
- The availability and adequacy of mercury-free measuring sphygmomanometers also for calibration, validation and special cases.

Background

- Mercury sphygmomanometers contain a large amount of mercury per unit (about 80g to 100g). The consumption of mercury in measuring equipment is estimated to be some 7-17 tonnes of mercury per year in the European Union. This total includes sphygmomanometers, in which there is approximately 3-6 tonnes of mercury distributed in 30,000 to 60,000 units.
- Risks associated with mercury sphygmomanometers emerge when they are broken, in case of spillage or leakage. Once released, mercury either can go airborne or, depending on the surface area permanently contaminate it, if not taken care properly and adversely affect staff and patients' health in the hospitals. Mercury sphygmomanometers also pose a risk to the environment and health when they enter the waste stream, when landfilled or incinerated.
- Alternatives to mercury sphygmomanometers do exist, such as aneroid or digital sphygmomanometers (based on the auscultatory technique) or semi-automated or automated blood pressure devices (based on the oscillometric technique). They are sold from many medical equipment suppliers. Many mercury-free models are validated and satisfy the criteria

of the professional medical organisations such as the British Hypertension Society and the European Society for Hypertension. They have been proven to have no problems in any kind of clinical diagnosis or monitoring – even for special medical conditions such as arrhythmia, pre-eclampsia, diabetes or hypertension and other vascular diseases.

- It was noted that generally mercury sphygmomanometers are less expensive than mercury-free alternatives. However, when other factors are taken into consideration such as mercury pollution and release, exposed staff and patients, special infrastructure, staff training, hazardous waste cleanup expenses, then the total cost of mercury-free alternatives is far cheaper. Studies have concluded that the overall real cost of a good aneroid sphygmomanometer is only about one third of a mercury sphygmomanometer.

II. Conference Results

Mercury-containing sphygmomanometers have traditionally been considered the 'gold standard' by healthcare practitioners. On the other hand, efforts are underway at European level and globally to reduce the use and emissions of mercury, especially where adequate alternatives exist.

As discussed in more detail below, a very interesting mix of participants attended the conference including: medical doctors, experts in validation and calibration issues, recyclers, manufacturers of measuring devices, trade unions, Member State representatives, hospital representatives, NGOs and representatives of United Nations organisations and EU institutions. They provided valuable information, and inspired an interesting and spirited debate.

The conference discussion and results are summarised below.

Different approaches and country practices

- One industry representative shared his perspective that since pollution from mercury sphygmomanometers is an inconsequential environmental release of mercury, this should not be used as the rationale for banning mercury sphygmomanometers and thereby risking the misdiagnosis of patients. Other techniques that measure pressure more accurately than with a mercury column are available, but these need validation and further study; therefore today there is no similarly accurate or better mercury-free alternative.

- Environmental NGOs position is that mercury-containing sphygmomanometers in healthcare, should be phased out since there are safe, precise and reliable alternatives available on the market which are already used in hospitals in many countries in Europe and around the world.

- The EEB commissioned study *"Turning up the pressure: phasing out mercury sphygmomanometers for professional use"*, presented at the conference, examined the difference of opinion among professionals with regard to the viability of mercury free sphygmomanometers. Interviews were carried out with hospitals and clinicians in 8 EU countries (Czech Republic, France, Germany, Greece, Hungary, Italy, Spain and the UK). A rough estimation of sphygmomanometers in use in these 55 hospitals was close to 10,000, of which about 15% were mercury sphygmomanometers and the rest mercury-free. It can therefore be seen that there is clearly a movement in the direction of mercury-free devices. Other important findings included the following:

  - This field research confirmed that many EU hospitals have already phased out mercury sphygmomanometers (some for more than ten years) and many others are in the process of phasing them out.
  - Concerns were expressed about the operational performance and maintenance required for the mercury sphygmomanometers; the fragility of the aneroid sphygmomanometers, their stability in case no regular calibration has taken place, and the fact that some hospitals may not follow the proper procedure of calibration. There is also a great lack of awareness on the availability of mercury-free and shock resistant models.
  - Cost issues were also a major factor; the purchasing budget is frequently separate from the maintenance budget, hospitals would often purchase inexpensive and sometimes lower quality sphygmomanometers – therefore contributing to the attitude among some professionals that they could not rely on the mercury-free sphygmomanometers.
  - Finally, it was noted that many hospitals do not adequately dispose of broken mercury sphygmomanometers or other mercury-containing waste. In some of the hospitals mercury is disposed of as normal trash or mixed with infectious waste or combined with other waste in a special bin.

- The view of several hospitals (which use mercury-free sphygmomanometers) is that it is technically possible and economically feasible to undergo the transition.
- The main constrains to switching to alternatives is that mercury is considered the gold standard and most long term clinical studies are based on that. Other barriers include the familiarity of healthcare professionals with mercury sphygmomanometers and their need for the existing validation protocols.
- Overall, sphygmomanometer comparative costs are very similar; therefore the purchase decision should be based on other important concerns such as toxic content and waste management practices rather than the initial purchase cost.
- There is still a debate on whether sphygmomanometers are still essential either for calibration purposes or for the treatment of special health conditions such as arrhythmia or pre-eclampsia. From one industry point of view, mercury sphygmomanometers are needed for these purposes. However, those who have undergone the transition stressed that the mercury-free alternatives are adequate for use.
- Many countries around the world are already in the process of phasing out the use of mercury devices in healthcare. As one example, Swedish hospitals converted to mercury-free alternatives in the early 1990s. However, before the transition took place, these were in close contact with experts, especially with the Swedish Society for Clinical Physiology to ensure that the alternatives functioned just as well.
- In the USA, at least 10 States have banned mercury in measuring devices including mercury in sphygmomanometers, with little or no opposition.
- The Philippines had an administrative order to phase out mercury from the healthcare sector across the country over two years including sphygmomanometers.
- In Argentina the Ministry of Health issued a Resolution (Feb. 2009) banning the purchase of all new mercury thermometers and sphygmomanometers in the healthcare system. Examples of phase outs also exist at provincial and municipal levels.
- Globally, world governments agreed that deliberations should start towards a global legally binding instrument in view of reducing mercury emissions, supply and demand globally. As part of this effort, it's envisioned that hospitals should begin to phase out mercury and increase efforts to reduce and where possible eliminate the amount of unnecessary mercury equipment.

Technical matters

- When it comes to making an accurate reading of any blood pressure device (whether mercury or mercury-free) of a patient it was generally agreed by conference participants that this is dependant on such factors as:
    - The skills of the measurer/operator/observer of applying the technique properly.
    - The quality of the product (whether it is validated or not, leaking cuff, tube, bulb or valve).
    - The patient (for example patient movement, patient position, stress, white coat effect, cuff sizing, variability of blood pressure, etc.)
    - Routine maintenance and calibration is needed for both devices in order to function at peak performance
- Calibration was extensively discussed. In this context it means that any sphygmomanometer is compared with a reference manometer to ensure that it measures accurately. During the process, the margin of error of the reference manometer is added to the margin of error of the mercury sphygmomanometer itself. Thus, there is a combined potential error, which means that the reference manometer should be as accurate as possible. For example: a mercury column could replace the digital gauge, but the accuracy of that device is +/- 3mm Hg. The accuracy of the aneroid is +/- 3 mm Hg. If that is added together you can only test to +/- 6mm Hg, which is not

adequate. Therefore, when you calibrating gauges with a digital pressure standard that is 0,1 mm Hg – then the total error can only be +/- 3,1 mm Hg maximum.

- As a result, mercury devices may not be needed for calibration of mercury free devices. Manufactures should be pushed to give simple calibration methodologies to be widely available.
- Validation is a more complex process carried out typically by academic researchers who publish their findings in a professional journal. They would take a specific model of sphygmomanometer in this case and validate it against a standard. At present, the validation of new blood pressure monitors should be performed using mercury devices. A few mercury sphygmomanometers might have to be retained in validation centres, which should be accredited to conduct delicate validation studies. However, this could be a temporary occurrence until validation protocols change their standard and use mercury-free devices for validation procedures.
- The "Gold Standard" does not necessarily mean an accurate blood pressure.
- Electronic devices are more reliable than expected, even in long-term use. Some electronic devices may be 10 times more accurate than the mercury column.
- Experts and hospitals affirmed that there are no special cases were mercury sphygmomanometers are still needed. Auscultatory mercury-free devices (e.g. aneroids) are currently needed in specific patient groups (arrhythmia, etc). However, in the future this might change.

Other measuring devices

- Concerning the other remaining mercury based measuring devices for professional and industrial uses (such as porosimeters, pycnometers, hydrometers), there is not much information available The consumption of mercury in measuring equipment in the EU is 7 to 17 tonnes per year.

- Within "miscellaneous uses," there is a large range of mercury consumed: between 15 and 114 tonnes per year, about two-thirds of which or more appears to be consumed in porosimetry and pycnometry.

- Porosimeters are used to measure the porosity of a sample (e.g. sintered filters, catalytic converters, fuel cells, bone replacement materials, ceramics, etc). The use of mercury porosimeters is about 10-100 tonnes distributed in about 1000-2000 units. There are various alternatives, but none ideal for certain substances and/or certain pore sizes. In addition, there are certain validation standards that would also have to be revised to move away from mercury porosimetry. It appears that 100% of the mercury in the porosimetry process can be recycled if this is done correctly.

- For other measuring devices still using mercury, NGOs believe that steps should be taken to ensure that 100% of the mercury used is recycled. Phase out of most of these devices appears feasible and needs to be further pursued.

In summary

In summary, EEB, HCWH and the ZMWG hope that this conference has contributed towards giving a clearer picture of how feasible it is to make the transition to mercury free measuring devices in the health care setting. It is imperative that this unnecessary use and release of mercury should seize since there are viable, suitable alternatives available already on the market.

The conference showed evidence from medical and technical experts, NGOs, hospital and Member states representatives that the shift to mercury-free sphygmomanometer use in clinical diagnosis and monitoring is fully possible, even when it comes to issues of accuracy, reliability, calibration and their use on special medical conditions such as arrhythmias and pre-eclampsia.

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III. Agenda

Time schedule	Title of presentation	Speaker
8:30	Registration	
9.00	Welcome - Short introduction to the morning session	Mrs. Doreen Fedrigo (EEB-Moderator)
9.05	EU restrictions of mercury use in measuring and control equipment – EC proposal	Sotiris Kiokias, EC DG Enterprise
9.25	Industry's view on mercury in measuring devices	Dave Osborn, Philips/COCIR
9.40	NGO position on mercury in measuring devices	Anna Lind, EEB
The transition to a mercury free health care		
10.00	Is the Healthcare sector ready for the transition?	Peter Maxson, Concorde East/West
10.25	Coffee break	
10.45 11.00	Experiences from EU Mercury-free Hospitals	- Paul Williams, Facilities Health And Safety Advisor, Heart Of England NHS Foundation Trust, UK - Mrs. Jelena Stepule, Rezekne Hospital, Latvia
11.30	Global developments and mercury in measuring devices	Desiree Narvaez, UNEP
11.45	WHO policy and partnership	Peter Orris MD, University of Illinois, WHO Collaborating Center in Occupational and Environmental Health
12.00	Global experiences from hospitals – US/Global South	Anja Leetz Health Care Without Harm
12.25	Discussion (Q&A) Morning session	
13.00	Lunch Break	
	Welcome back - Short introduction to the afternoon session	Mrs. Doreen Fedrigo (EEB-Moderator)
  14.15 14.30 14.45	Member states views – (National experiences in phasing out mercury from the healthcare sector) Discussion	-Dr Agnieszka Dudra, (PhD), Specialist Bureau for Chemical Substances and Preparations, Poland - Ulla Falk, KEMI, Sweden

15.00	Coffee Break	
15.15 15.50	*Panel Discussion:* Are Hg sphygmomanometers needed for calibration? Are there special cases were Hg sphygmos are still needed? Are non-mercury devices validated? o Discussion (Q&A) - afternoon session	• Heikki Terio, R&D Manager, Karolinska University Hospital • Thomas Grant, Director, Regional Category Management, Welch Allyn • Peter Orris MD, University of Illinois, WHO Collaborating Center in Occupational and Environmental Health • Mr. George Stergiou, MD, Associate Professor of Medicine Hypertension Center, Third University Department of Medicine, Sotiria Hospital, Athens
Other measuring devices and export		
16.10 16.20	Which other mercury containing devices such as porosimeters, etc shall be considered to be phased out? Current polarographic instrumentation and important application in industry and research Views from a Member state (Denmark) Discussion (Q&A)	Peter Maxson, Concord East/West Uwe Loyall, Manager, Competent Center Voltammetry, CVS and Stability Measuring Instruments, Metrohm International Headq. Frank Jensen, Special Advisor, Danish EPA
17.00	Overall conclusion – End of conference	Mrs. Doreen Fedrigo (EEB-Moderator)

IV. Sphygmomanometers in healthcare

1. EU restrictions of mercury use in measuring and control equipment – EC proposal

(Presentation by Mr Sotirios Kiokias, European Commission, DG Enterprise and Industry)

Directive 2007/51/EC[1] relating to restrictions on the marketing of certain measuring devices containing mercury, adopted on 25 September 2007 is an amendment of Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. This directive (76/769) is now part of REACH[2]´s Annex 17. [3]

According to 2007/51 the sale of mercury containing measuring devices for the general public has been banned with effect from April 2009 in order to reduce risks posed to human health through discharges of mercury to the environment from broken or discarded measuring devices. In this directive the mercury sphygmomanometers in health care were not restricted, because of some concerns raised in particular for the essential use of these devices, i.e. for the diagnosis of certain life-threatening diseases, such as arrhythmia, accelerated hypertension, pre-eclampsia, etc.

Following the discussion in the Parliament and the Council it has been decided that a review clause (Annex, 19(a), p-3) should be present in this directive:

«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...The Commission shall, if appropriate, present a legislative proposal to extend the restrictions…. »

To that end, the EC, preparing for this review, mainly focused their investigation on mercury based sphygmomanometers in health care considering the sensitive use and their wider applicability. There are indications from the COWI/Concorde[4] 2008 report that the EU wide annual mercury consumption is about 3-6 tonnes distributed in 30,000 to 60,000 units. DG Enterprise first tried to get a better idea of what the situation is on national level. Therefore, DG Enterprise prepared specific questionnaires for both the Members of the Limitation Working Group and the Medical Devices Experts Group. In these specific questionnaires input was asked concerning:

- Availability of alternatives to Hg-containing sphygmos in Member States and information as to whether, these are adequately validated, calibrated, etc.;
- Essential uses of Hg-containing sphygmos for the treatment of special medical conditions;
- Other Hg-based measuring devices used for professional & industrial uses.

The feedback received from the Medical Experts gave no clear consensus, as Malta, Finland, Germany, Hungary, United Kingdom and Italy claimed that mercury containing

[1] DIRECTIVE 2007/51/EC of the European Parliament and of the Council of 25 September 2007 amending Council Directive 76/769/EEC relating to restrictions on the marketing of certain measuring devices containing mercury, Official Journal L57, 3.10.2007, p.13.

[2] Registration, Evaluation, Authorisation and Restriction of Chemical substances. The new chemicals law (EC 1907/2006) entered into force on 1 June 2007.

[3] COMMISSION REGULATION (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII Official Journal L 164, 26.06.2009, p. 7.

[4] COWI/Concorde. "Options for reducing mercury use in products and applications, and the fate of mercury already circulating in society". December 2008

sphygmomanometers are still essential either for calibration purposes or the treatment of special health conditions, while Ireland, Netherlands, Poland and Sweden confirmed the existence of technically and economically feasible alternatives for all uses.

Within the Limitation Working Group – via the questionnaires and in meetings (October and December 2008), most responding Member States (Latvia, Sweden, Netherlands, Norway and France) claimed that mercury-containing sphygmomanometers are no longer necessary and have already been replaced. in health care . However, Germany and Italy mentioned that mercury based sphygmomanometers should be kept for calibration purposes. The United Kingdom and Finland opposed an EU ban of mercury devices noting that mercury containing sphygmomanometers are indispensable for validation purposes as well as for the treatment of certain medical conditions.

DG Enterprise also involved other stakeholders. The Environmental and Health NGOs (EEB, HEAL, Health Care Without Harm) showed a lot of interest in this topic, and submitted very interesting reports concerning the situation in the EU market as well as scientific publications and reports for worldwide initiatives. Industry representatives such as COCIR (European Committee of Radiological, Electromedical and Healthcare Industry) and AAMI (Association for Advancement of Medical Instrumentation) also sent some feedback to the Commission. Both associations claim that mercury based sphygmomanometers must not be banned from either practical use or from calibration purposes because they provide the most accurate reading possible today.

Significant input (e.g. socio-economic data, availability of alternatives) has also been provided by a 2008 study carried out by COWI and Concorde SA with the name **"***Options for reducing mercury use in products and applications, and the fate of mercury already circulating in society",* commissioned by DG-Environment in the framework of the Community Strategy on Mercury. In addition, DG Enterprise involved scientific organisations with expertise in the area such as the European Society of Hypertension (ESH) who informed that properly validated electronic instruments (but not the aneroid devices) could serve as reliable substitutes to mercury containing sphygmomanometers. ESH claims that automated devices are not accurate for blood measurements in patients with arrhythmia, and that mercury-sphygmomanometers are also still essential for the calibration of electronic devices.

The European Board and College of the Obstetrics and Gynaecology (EBCOG) is currently consulting the International Society for the Study of Hypertension in Pregnancy (ISSHP), in order to advice the Commission on the need for mercury-containing sphygmomanometers for the treatment of hypertension in obstetrics.

The EC review also covers the other remaining mercury based measuring devices for professional and industrial uses. Not much feedback has been received from Member States. Sweden and the Netherlands provided some general information about mercury-containing measuring devices used for research/analytical purposes, for some of which no alternatives may currently exist (such as polarographs, UV-spectrophotometers, gas regulators, gyroscopes, etc.). There is a good amount of information in the COWI/Concorde 2008 report with special reference to strain gauges, laboratory thermometers, porosimeters, pycnometers, hydrometers etc. Porosimeters comprises an important category of Hg-based measuring devices for industrial/professional uses. According to the COWI/Concorde report, mercury circulating in society in the EU 27 due to the use of mercury porosimeters is about 10-100 tonnes distributed in about 1000-2000 units.

The Commission organised a workshop in April 2009 in Brussels. COWI presented their study and informed that although alternatives are available for all applications, mercury-sphygmos are still sold mainly to medical practitioners. Both digital and aneroid "shock-proof" sphygmos for measuring blood pressure by the auscultatory method are available for all applications (their price ranges from <1 to 2.5 times the price of Hg-containing devices). Their main constraint is that Hg

equipment is still considered to be the "gold standard".

Presenting at the workshop, EEB and HCWH recalled the adverse effects of mercury on human health and reminded that several European countries have already replaced mercury containing sphygmos (e.g. Sweden, Denmark, the Netherlands) and underlined that several brands of available alternatives (mainly electronic devices) already exist in the EU market, many of which satisfy the criteria set by the British Hypertension Society (BHS) and the European Hypertension Society (EHS). Hg containing sphygmos also need to be calibrated regularly and are less accurate (± 3 mm/Hg) than the digital sphygmomanometers (± 0.1 mm/Hg).

COSSOR, an UK manufacturer of both mercury-free and mercury based sphygmomanometers, noted that it is important to distinguish between automated and manual methods. The best automated devices can have errors of 10% (mm/Hg) in 25% of readings. Manual electronic devices have an accuracy of 0.4mm/Hg compared with 3mm/Hg for Hg containing sphygmos. No electronic device has ever been shown to be out of calibration during the past 5 years. However, the inaccuracy of some aneroid devises could be a reason why some professionals still prefer to keep using the Hg containing sphygmos.

At the workshop, Sweden presented their experiences from Karolinska University Hospital referring to calibration procedures for both aneroid and automated/electronic blood pressure devices. Sweden was the first country adopting a policy to ban use of mercury in sphygmomanometers. Since 1991 there has been a policy in Sweden to use Hg-free measuring devises. However, it cannot be excluded that some old practitioners may still use mercury containing sphygmomanometers for blood pressure measurements.

A few other countries like Netherlands, Austria, Denmark and France claimed that they have positive experiences over a long period with the use of Hg-free sphygmos in their countries from the voluntary phase-out by hospitals. Italy and Germany supported a limited use of mercury containing sphygmos for calibration purposes, so that their use should be feasible only in certain calibration services at national level. UK and FI as well favored the continuation of Hg containing sphygmos in healthcare use, in particular for clinical validation purposes and for use by clinicians when automated oscillometric blood pressure monitors are inappropriate (e.g. arrhythmias, pre-eclampsia and certain vascular diseases).

Given the lack of information on other mercury containing devices for professional and industrial uses associated industry – porosimeter and polarographer - was invited and participated. Thermofisher (India), one of the key players in the field, informed about the Mercury Intrusion Porosimetry (MIP) claiming that this is a long-established and widely accepted method for determining with good accuracy the volume and pore size distribution. There are about 1000-1200 porosimeters used in the EU. The advantages of mercury based porosimeters are, according to Thermofisher:

- rapid measurement
- simple and relatively inexpensive instrumentation
- wide range of pore size –volume measurements

Around 5 kg of mercury is required for installation of the meter, while typically around 45-65 g mercury is used per analysis. Alternative techniques exist (Hg-free extrusion and intrusion porosimetry), but due to their limitations and according to the industry, mercury porosimetry is essential for large sectors of EU industry either for research or quality control purposes.

Metrohm, a producer of electrodes used in polarography explained that polarography, based on use of Hg electrodes, is a highly sensitive method for trace metal analysis. About 1200 polarographs are in operation worldwide; with 100 to 150 g per unit (total amount of Hg in use is about 200 kg).

Metrohm referred to the limitation of alternative techniques: (IC-ICP-MS, SPE-AAS): they have high purchase and running costs, limited mobility, laboratory infrastructure required etc. Modern instruments use significantly reduced amounts of mercury which is recycled hundred percent.

COWI/Concorde consultants confirmed the existence of medical-, ambient temperature-, laboratory-, contact- thermometers and hygrometers. There are mercury thermometers mainly used in laboratories and industrial settings. They referred to alternatives: Hg-free liquid-in-glass or dial thermometers available for all applications with a 1°C resolution. Electronic thermometers are available for nearly all applications at higher resolution. The main constraints of alternatives are higher costs and many laboratory standards are based on mercury containing thermometers.

The main conclusions of the workshop were:

- Concerning Hg-based measuring devices for professional and industrial uses:
  These mainly concern quite specialized and rather small-scale applications, which may not significantly contribute to exposure of consumers or environment to mercury. Although mercury content per instrument can be quite high (e.g. in porosimeters), the number of such devices in use in the EU is limited and they are typically used in labs with well-established control procedures. However, the actual level of mercury recycling should be investigated before any safe conclusion can be drawn.
- Concerning mercury-based sphygmomanometers:
  there is an ongoing tendency for substitution of mercury-containing sphygmos, and where such substitution has occurred the experience has been uniformly positive. Nevertheless, in some Member States where substitution has not yet occurred, concerns remain on calibration, validation, and on the treatment of certain medical cases, which could at least in part be due to user-related preferences and habits, as well as lack of knowledge or training for using mercury-free devices.

Considering the critical issue for the health and safety of patients, DG Enterprise requested (in April 2009) an opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) as crucial input for the COM review. DG-Enterprise asked SCENIHR to answer the following questions:

- Is there sufficient evidence to demonstrate that Hg-free blood pressure measuring devices (aneroid or electronic instruments) are reliable substitutes for Hg sphygmos?
- Have Hg-free sphygmos been adequately validated over a wide range of blood pressures, ages and clinical conditions and for the diagnosis of hypertension in specific clinical conditions (arrhythmia, pre-eclampsia in obstetrics etc.)?
- Are Hg containing sphygmos essential as reference devices for clinical validation protocols as well as for calibration of Hg-free sphygmos;
- Is SCENIHR aware of any adverse effects for patients' health due to the replacement of Hg containing sphygmos by Hg-free alternatives?

There was already a first meeting with SCENIHR (end May 2009) to clarify the terms of reference. Another one would take place at the end of June 2009. SCENIHR is going to review very carefully the alternatives to mercury sphygmomanometers not only within the same technique (auscultatory) but also taking the reliability between oscillometric and auscultatory techniques. It is premature at this place to say anything about the outcome of this opinion.

With respect to further steps of the preparation of the EC review:

DG-Enterprise will carefully consider the information from the April Mercury Workshop and the EEB/ZMWG/HCWH Mercury Conference (presentations and exchange of ideas/positions with

Member States and stakeholders on alternatives for Hg-sphygmomanometers and other measuring devices professional/industrial uses).

The opinion of the scientific committee (SCENIHR) is expected to be published at the end of September 2009 will serve as the main scientific input concerning the essential (or not) use of Hg-based sphygmos for the treatment of certain medical cases.

Finally, in October 2009, DG-Enterprise will prepare a summary report of the outcome of the review, which will be submitted to European Chemicals Agency (ECHA). ECHA will then evaluate in accordance with Article 69 (5) of REACH whether an amendment of the current Hg restrictions may be justified. If that will be the case, then the restriction procedure of REACH will be implemented.

2. Industry's view on mercury in measuring devices - The global mercury crisis and the global hypertension crisis

(Presentation by David Osborn, European Radiological, Electromedical and Healthcare IT Industry (COCIR), Philips Healthcare)

We have a global mercury crisis; but the question, which COCIR thinks that should be asked is: 'Do we want to significantly worsen the global hypertension crisis by banning mercury sphygmomanometers?'

The speaker clarified that he is not a doctor but an engineer, and has been working in health care since the late 80s. He works for Philips Healthcare and they do not make mercury sphygmomanometers, but only electronic automated ones. He is also the co-convener of the ISO/IEC international committee on sphygmomanometers, where they have just completed writing three standards covering this field this year.

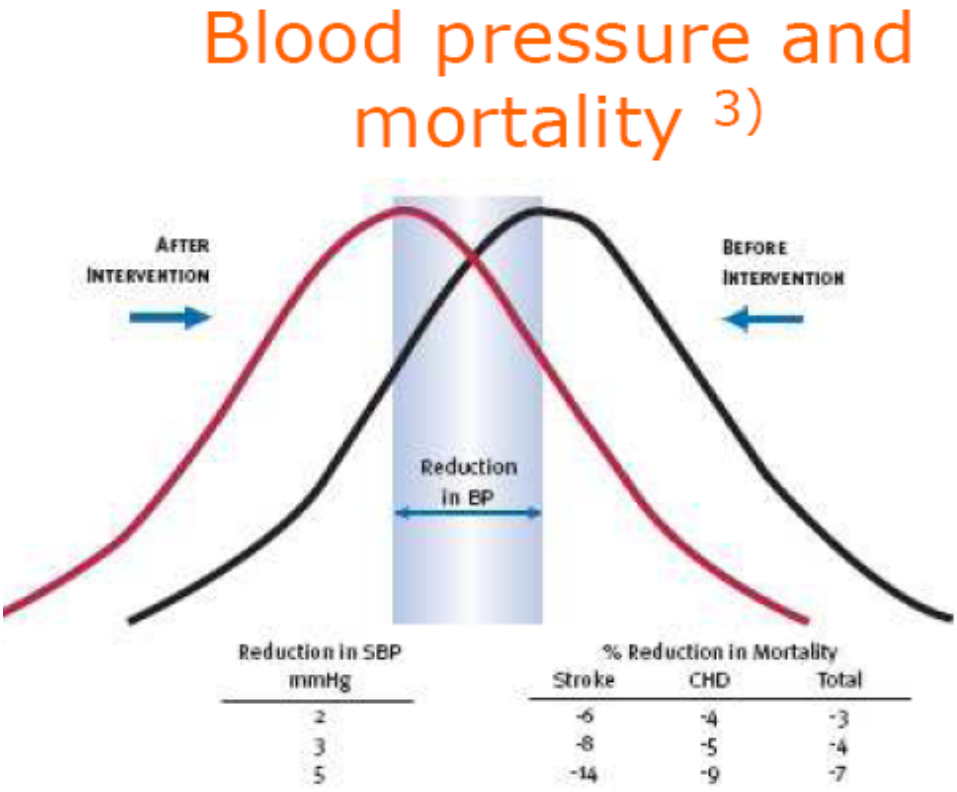
Mercury pollution from sphygmomanometers is an inconsequential source of mercury released into the environment in comparison to the lighting industry (such as compact fluorescents lights) and the electric power generation industry.

Hypertension is an absolute epidemic in the world today. In USA it is estimated that 25 to 30 % of adult Americans have hypertension while the estimate for Europe is 44%. High blood pressure is a significant cause of cardiovascular and renal disease and can lead to death. Hypertension is diagnosed by determining blood pressure. Blood pressure cannot be measured with a sphygmomanometer but only estimated. Blood pressure can only be measured with an indwelling catheter. There are many long-term studies on blood pressure where the consequences of high blood pressure have been examined. Blood pressure correlates to a variety of factors (e.g. obesity, exercise and diet). In all of these studies blood pressure was determined by moving columns of mercury (e.g. the Framingham Heart Study[5]). This is not a static measurement. The cuff is pumped and then the pressure is bled out of the cuff while the clinician is listening to sounds (first discovered by Prof. Korotkoff in Russia in the 1890s). At certain points when the blood first begins to flow and when the last sound is heard, is the determination of what we call systolic and diastolic blood pressure. This measurement or estimation is important because the long-term studies have shown a correlation to outcomes to health based upon these numbers.

There is no such thing as a calibration of a mercury sphygmomanometer unless you want to calibrate the meter stick, or unless you want to measure the purity of the mercury. It is a direct standard; it is the height of the mercury column (measured in millimeters) directly relating to a pressure. All other means are calibrated to that which means that they have an error. They have a

[5] http://www.framinghamheartstudy.org/

static error but more importantly, a dynamic error that is related to how a clinician estimates the blood pressure using a sphygmomanometer. They are looking at the moving column of mercury as they are listening to the blood sounds and also looking at the wiggle on the top of the mercury which relates to the pulsatile flow of the blood; and based upon their clinical training they determine what the pressure is as they hear those sounds. This is important because those estimations are related to the horizontal studies and to the speaker's knowledge there are no instruments that give the same number.



Change in blood pressure and mortality

The curve above, from the National Health Institute in the USA, shows the significance of very small changes in blood pressure as determined by a sphygmomanometer and the outcome for things like cardiovascular disease and stroke. Very small changes like 3 millimeters of mercury represent an 8% change in mortality to stroke. 44% of European adults are hypertensive. Small movements in the average blood pressure on population studies have very significant changes in the outcomes.

If a sphygmomanometer does not give the number that one expects it should give in treatment decisions, there is a misdiagnoses and mistreatment. There is intervention where there should not have been an intervention because the device measure is low, or there is intervention where it was not needed when the device measure is high. This results in poor outcomes, when people are treated that don't need to be treated and it could be about tens of millions of people – then there is a lot of added and unnecessary costs and most of the health systems in Europe are very cost sensitive.

With a three millimeter mercury error, to the high side, there will be a large number of patients that are either being treated when they did not need to be treated or large numbers of patients who were thought to be normal and where therefore not treated and now have these kinds of outcomes. These are scary numbers. A three millimeter error to the low side implies 8% more stroke, which is a high number. Thus, it becomes a very significant public policy issue.

All other sphygmomanometers have to be calibrated to a reference source in terms of their static measurement. Electronic sphygmomanometers use a different methodology to determine the blood pressure. Aneroid sphygmomanometers are the most likely candidate in a short term to replace mercury sphygmomanometers. Unless they have a very large dial, there is a source of error because the dial is too small. The source of error is on a 2-3 millimeter range. The new standard requires usability tests of aneroid sphygmomanometers to demonstrate the clinician can read them accurately enough to give a meaningful result. Since the determination is to a movement, you have not only a static but also a dynamic error relating to that movement. As mentioned earlier, you don't calibrate the mercury sphygmomanometer (unless you are looking at the metallic composition of the mercury) because it is the primary standard.

The real validation of sphygmomanometers comes from 20 to 35 years of outcome studies. The need to validate is validating the effect on the disease, the effect on patients over a long period of time that blood pressure has. Then you have to translate that to the means you are measuring it.

About special patient populations: the determination of blood pressure of patients with arrhythmia is virtually impossible. Even a moving column of mercury gives rather strange result because a person's blood pressure is chaotic. Thus, there is not a consistent pressure (to measure).

There is another significant issue that has been addressed in the standards that have been produced: pregnancy. We don't quite understand the mechanism yet but we do have a fair amount of published literature that shows that automated sphygmomanometers (or 90+% of them) are dramatically inaccurate in pregnant women exhibiting pre-eclampsia. That is very scary because the problem in pre-eclampsia is a dramatic rise in blood pressure and a potential cardiovascular collapse. The early warning signs on that is elevated blood pressure. If you use an automated sphygmomanometer that doesn't work in pre-eclampsia, it gives you invalid answers. The standard that was published in January addresses that issue by requiring automated devices that claimed to be suitable for use in pregnancy to be validated in a pre-eclamptive population, so that problem is solved. However, the ones on the market today – unless they have had this validation – should be treated as suspicious. Attention should be paid in cardiology areas where there are patients with arrhythmia. The automated systems don't work very well there. Philips makes such automated devices, but labels them on this issue. However, not all companies do that.

So the question from the speaker is: since the pollution from mercury sphygmomanometers is an inconsequential source of environmental release of mercury, do we really want to take the risk of misdiagnosing tens of millions of patients here in Europe by banning mercury sphygmomanometers? For those who are misdiagnosed on the low side that will lead to many pre-mature deaths.

Discussion

- COCIR/Philips commented that it is crucial to note that most of the electronic sphygmomanometers are using the oscillometric method and not the auscultation method. It is a different method and it gives a different number. It has the advantage that you don't need a skilled operator to take blood pressure. However, it gives a different number and many clinicians don't understand that.

  Answering to a corresponding question, COCIR/Philips further clarified that there are two classes of sphygmomanometers for common clinical usage: The non-automated sphygmomanometers, which means that you have a measuring element and rely on the skill of the clinician reading whatever the measuring device is to determine the blood pressure. The second, is the automated device, the preponderance of which use the oscillometric method which actually looks at the waveform of the pressure as the cuff is deflated and then looks at

the modulation of that and then does a calculation based upon the mean pressure determined from that, to synthesize a systolic and diastolic number.

A column of mercury is the gold measurement, i.e. a direct measure of pressure. For a mercury sphygmomanometer the sources of error are the positioning of the meter stick relative to the column of mercury and the metallic composition of the mercury solution (assuming that it is not dirty, broken, etc.). Hence, it is a direct measurement. An aneroid device can be made to be relatively accurate. However, they do drift, and if they are not properly made they will drift a lot in the initial use as the aneroid gage burns in – it takes about 10,000 pressure cycles for that to happen. But all quality aneroid devices have that done in a factory before they are built and calibrated. The issue isn't meteorological measurement accuracy. The issue is clinically based upon the correlation of patient outcomes and how you determine the pressure relative to those patient outcomes. And the significance here is that the horizontal studies didn't have an indwelling catheter. Further, COCIR/Philips commented that if we all had aortic catheters and had that measurements taken we would know what the pressure is accurate to a much greater degree. The issue here is how we have historically correlated auscultation to disease and determine when and how to treat patients based upon that determination. So if the measurement methodology is changed and if we don't adjust the data for that, then we don't treat the patients properly based upon the scientific outcome studies.

- University of Illinois, WHO Collaborating Center (WHO CC, UoI), who is approaching this discussion more from a clinicians approach, commented that it would be very interesting to research what the countries that don't use mercury sphygmomanometers (such as Sweden) have as rates of stroke and hypertension and how that compares to the rest of Europe to justify the final conclusion. He further noted that the Framingham study was carried out more than 40 years ago, and at the time there were some inaccuracies in the process, and is not clear how they have adjusted their data.

- Karolinska University Hospital argued that there is already a lot of uncertainty in the mercury measurement procedure. There are devices that are even more accurate than the mercury column for the measurement of any type of blood pressure problem. He further remarked that the calibration of the measurement device can be done with an accuracy of 0,2% of the full scale reading in millimetre mercury.

- COCIR/Philips agreed that the error the standard permits in an aneroid device is a lot and there are plenty of cardiologists of the ESH in particular who think that this is an outrageously high number.

  Blood pressure is not a static thing in human beings. Most people have a 7 or 8 millimeter modulation on their systolic pressure just due to respiration. When blood pressure is taken it takes about 20 seconds between maximum inflation and the point of diastolic pressure determination. That means the pressure has gone through one or two respiration cycles in that period, which is why in the cardiologists protocols, they call for taking 2, 3 or 4 sequential measurements over the course of a few minutes. There are a lot of steps to be taken to make a diagnostic determination of pressure.

  In a hospital, most of the pressure determinations are not for diagnostic purposes because you have got a critically ill patient or you have a patient in the operating theatre. There you are more looking at a trend and you can accept a more perfunctory measurement because you do not require a highly precise measurement. But if you are being screened for hypertension the more precise the measurement the better the results are going to be in terms of placing you in that population curve and deciding what treatment protocol is appropriate. And that is what is so concerning about those curves from the National Institute of Health: small changes would

make dramatic changes in how people are treated. And so if we have too much measurement uncertainty we are going to have outcomes that are not as good as they could otherwise be.

- COCIR/Philips observed that in the United States there are some States that have almost banned mercury sphygmomanometers. In some doctors offices it is probably about 50:50. In emergency rooms they use automated devices. They are not interested in hypertension diagnosis – they are doing a quick screening. In critical care and in the operating rooms they use 100% automated devices because they want determinations to be taken every 10 or 15 minutes or every hour and going automatically into the patient monitoring system. However, in cardiologists' office – there a lot of columns of mercury still existing.

- Mercury Policy Project (MPP) commented that in the USA there are more than 10 states that have banned mercury in measuring devices including mercury in sphygmomanometers and that there has been no opposition to those phase outs. The hospitals in the USA are not buying mercury sphygmomanometers to his knowledge. In these 10 states you are not allowed to purchase a mercury sphygmomanometer regardless whether you are in a hospital or in a private practice.

  MPP further commented on the issue above that COCIR/Philips are alleging that national governments and states who only allow mercury free sphygmomanometers are responsible for "wholesale mistreatment of the citizens" and that this may be result in pre-mature death of many Europeans and projected to the US as well. He considers these as pretty scary statements and question whether COCIR/Philips has engaged with these federal government and state authorities; since we are not just talking about Europe and the USA here, we are talking about countries around the world and these are very scary statements.

- COCIR/Philips commented that USA made a public policy decision without thinking about the consequences. There have been a number of papers written by members of the AAMI committee with which the speaker is associated. Some of the clinical individuals involved (some are renowned cardiologists on the committee) are very unhappy and believe that the consequences to public health will be very severe particularly given the epidemic of hypertension. It is a political process however, and frequently you have individuals with a political agenda and they are not necessarily interested in hearing the consequences of what they are doing. He does not want to accuse anyone but it is to him very scary that we don't have a correlation between some of these other methodologies and the moving column of mercury when the health decisions – as reported in the literature – are all based on a moving column of mercury.

- The European Commission (DG Enterprise and Industry) commented about the importance of having the appropriate cuff size. A lot of the historical, older measurements were done on narrow cuffs which do not give a very good reading. Now it has changed to wider cuffs: how does this affect the long-term studies?

- On the issue of cuff size, COCIR/Philips commented that unfortunately it is not clear that the long-term studies kept a record of cuff sizes. What they have been finding in the more recent research is that as long as the cuffs are not too narrow there is a pretty broad range that is acceptable. If the cuff is too narrow, if you look at the biophysics of the tissue compression, you are not getting the pressure from the surface down to where the artery is and you are going to overpressure the cuff relative to where the artery is. This becomes a bigger issue with more obese and very muscular patients. There is a lot that could be done to help to improve our knowledge.

- COCIR/Philips added that for all the automated devices the standard requires human clinical testing (about 85 patients with spread out arm size, gender, weight and such). You must compare that result to an auscultation. We are (the standard is) silent if that is done with a column of mercury or an aneroid but very clearly, the further you get away from the primary measurement the more error there is. But all automated sphygmomanometers are required to be clinically validated and if you claim special patient populations (e.g. pregnant women, children) then we (the standard) expect that validation to be done in the special patient population as well as the general population.

- COCIR/Philips also commented that removing mercury, for instance from thermometers for clinical use, is an appropriate thing to do because that is a direct measurement. It is a static measurement and it can be done adequately electronically as well.

  COCIR/Philips re-iterated that a sphygmomanometer does not measure blood pressure. It is estimating blood pressure using a method that has been around since the 1890s (with some modifications over time). The difficulty is that our treatment protocols are based upon that estimation. If we had 40-year outcome studies using something else then we could use that other means of estimating blood pressure and know what to do. Thus, the difficulty here is a correlation between what happens in human health - over a long period of time and over a wide variety of population – and estimate of this physical parameter.

- Welch Allyn commented that some digital pressure meters are 10-times more accurate than the typical mercury column. These digital pressure meters are generally used in manufacturing and calibration of sphygmomanometers. Mercury sphygmomanometers that are commonly available are specified +/- 3 millimeters of mercury as are our most auscultatory devices. So they are both equally accurate if properly maintained.

  However, COCIR/Philips commented that neither is good enough based upon the outcomes research. And for the aneroid that is a static comparison and no published research appears to exist showing that clinicians get the same answer with a good aneroid that they get with a good moving column. It would be interesting to look at the dynamic difference as well as the static difference. Most of the research has been in the meteorology lab making static measurements. Unfortunately that is not what systolic and diastolic blood pressure estimation is all about.

- Welch Allyn observed that the sphygmomanometer is just one part of a "system" to obtain auscultatory blood pressure readings. The sphygmomanometer is the (1) pressure sensor, and you also need a (2) blood pressure cuff to occlude the artery, a (3) stethoscope to pick up Korotkoff sounds, and lastly, a (4) well-trained human being to ensure proper technique has been observed, to interpret the Korotkoff sounds, and determine systolic and diastolic pressure. From the four major components of this system, the greatest source of error by far is technique related – human error. Consider the argument that mercury sphygmomanometers cannot be abandoned due to their historic role in clinical studies and the potential to make historic data comparisons difficult. The argument appears more emotional than scientific when you understand that mercury and aneroid sphygmomanometers are both equally accurate (+/- 3 mm Hg), and as pressure meters are just one part of a system (including the cuff, stethoscope, auscultatory technique, etc.). The evolution of blood-pressure cuff design/sizing and blood-pressure technique have had a much larger impact on historically-comparable blood pressure readings than the pressure meters themselves.

  COCIR/Philips added that the source of error is the patient because their pressure is varying over time and agreed with the assessment above made by Welch Allyn.

- COCIR/Philips explained that there is no question that we have some other techniques that measure pressure more accurately than with a column of mercury. However, such techniques should be correlated somehow to human health; and for that there is a need for real validation data and potentially some longitudinal data to make sense of it. At the very least you would need a wide range of clinical studies comparing the traditional auscultation and a moving column – which could be done on a double-headed system using the same cuff pulling those errors out. Nonetheless, COCIR/Philips commented that today we do not have a fully validated, similarly accurate or better mercury-free alternative.

3. NGOs view and experiences on mercury-free measuring devices

(Presentation by Dr. Anna Lind, European Environmental Bureau)

Mercury is highly toxic and exposure to it causes risk to human health and the environment. That is why the aim of the EU mercury strategy is to reduce mercury levels in the environment by reducing mercury use, supply and emissions. This is in line with what was discussed on the 25th UNEP Governing Council meeting where governments agreed that there is a need for a global legally binding instrument to tackle the mercury problem.

Mercury sphygmomanometers contain a large amount of mercury (about 80g - 100g) and are widely used in hospitals and practitioners' offices in the EU. The negative effects when using mercury sphygmomanometers emerge when these are broken, if they are dropped or if there is leakage. This causes risk to staff and patients in the hospitals. The toxic mercury vapour can be inhaled by bystanders (patients, doctors, nurses and other hospital staff) and remain in the setting for a long time (in the carpet or in furniture or in floor cracks) if not taken care properly. Women of childbearing age, pregnant women and children are most susceptible. It is also a risk to the environment when mercury sphygmomanometers enter the waste stream, either when land filled or incinerated. The positive effect of using mercury-free sphygmomanometers is, consequently, the reduced mercury burden in the society.

Furthermore negative cost effects are related with mercury containing sphygmomanometers especially in the event of breakage, leakage, spillage, considering that those are hazardous waste. Such costs (and staff time) are associated with the need for: special infrastructure/storage to deal with hazardous waste, closing down a room, special clean up procedure, cost to train staff in hazardous waste management as well as costs related to health care costs for treatment of hospital staff or patients for exposure to mercury.

On the other hand, there are suitable mercury free devices already available on the market. They are sold from many medical equipment suppliers, are validated and satisfy the criteria of the professional medical organisations such as the British Hypertension Society and the European Society for Hypertension. They have been proven to have no problems in any kind of clinical diagnosis or monitoring – even for special medical conditions such as arrhythmia, pre-eclampsia, diabetes or hypertension and other vascular diseases. Such mercury-free products are available from Welch Allyn, Microlife, SunTech Medical, American Diagnosis Corporation Trimline Medical Products, Omrori, Rudolf Riester, Heine Optotechnik, BOSCH + SOHN, Braun, Terumo, Seinex.

Aneroid sphygmomanometer

Many health care facilities in the EU have already done or are planning to do this transition, such as Sweden, Latvia, Poland and Ireland. These countries have only positive experiences with this transition. They have not reported problems in any kind of clinical diagnosis or monitoring – even for special medical diseases.

The above are also supported by the recent EEB commissioned study 'Turning up the pressure: phasing out mercury sphygmomanometers for professional use' which is presented by its author, further down. This study looked at hospitals in eight different countries in the EU and their experiences with mercury and mercury free sphygmomanometers, since many of them have already made the transition.

EEB´s position is that mercury-containing sphygmomanometers should be banned because there are safe, precise and reliable alternatives available on the market which are used in hospitals in different countries already.

Apart from the sphygmomanometers, there are also other measuring devices containing mercury such as porosimeters, pycnometers, etc. They all contain different amounts of mercury but collectively these become large amounts of mercury, which are circulating in society and can be released to the environment. Alternatives exist for almost all of those devices. The costs of mercury –free alternatives appear lower or similar to the cost of the mercury devices and in most cases the use of the mercury-containing devices is decreasing for different reasons.

Therefore for those other measuring devices still using mercury, at least 100% recycling of the mercury used should be ensured and phase out of most of these devices appears feasible and needs to be further pursued.

4. Phasing out mercury sphygmomanometers for professional use

(Presentation by Peter Maxson, Concorde East/West)

In 2008, COWI/Concorde East/West carried out a study for DG Environment where they evaluated the consumption of mercury in measuring equipment, estimated to be some 7-17 tonnes of mercury per year in the European Union. This total includes sphygmomanometers, in which there is approximately 3-6 tonnes of mercury.

The study *"Turning up the pressure: phasing out mercury sphygmomanometers for professional use"*[6] that was carried out for the EEB, examined the difference of opinion among professionals

[6] http://www.zeromercury.org/SphygReport_EEB_Final-A5_11Jun2009.pdf

with regard to the viability of mercury free sphygmomanometers. The questions that continue to arise are: Can mercury sphygmomanometers be completely eliminated from professional use, and if so, is the health care system actually ready for such a transition? As input to these questions, interviews were carried out with hospitals and clinicians in 8 countries (Czech Republic, France, Germany, Greece, Hungary, Italy, Spain and the UK). In total 37 persons were interviewed. The interviews with health care professionals are categorized as in the table below.

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

Table: Positions of healthcare professionals and numbers of people interviewed

In total, information was obtained for 55 hospitals representing a capacity of 38,000 beds. A rough estimation of sphygmomanometers in use in these 55 hospitals was close to 10,000, of which about 15% were mercury sphygmomanometers and the rest mercury-free. It can therefore be seen that there is clearly a movement in the direction of mercury-free. Whether the movement is faster or slower seems to depend on the country in question.

Hospitals with only mercury-free sphygmomanometers represented 75% of the total interviewed - but it would be more like 50% of the hospitals if Germany were to be removed from that calculation. Worthy of note is that the number of hospital beds per sphygmomanometer varies greatly in the countries examined: from something like one sphygmomanometer for 3 hospital beds in the UK, to one sphygmomanometer for 14 hospital beds in Hungary. In some countries like Greece, up to two-thirds of the sphygmomanometers that were found were mercury-containing ones; in Italy about half, whereas, in Denmark, Spain and France, zero or almost zero.

The main concerns that were voiced by the interviewees were that the aneroid sphygmomanometers are too fragile and are subject to shock. People have had bad experiences with some sphygs so they lacked confidence in the reliability of the mercury-free sphygmomanometers. Further, interviewees noted that by looking at the sphygmomanometer, it is impossible to know whether the calibration has shifted or how stable it is.

There is also a fair amount of confusion between calibration and validation. Some people wanted to see the CE-label on the sphygmomanometer to know that it was a valid instrument; others knew that calibration should be carried out but some hospitals did not necessarily follow the proper procedure because of cost reasons or a lack of awareness of the person who is responsible for it.

There is also a large lack of awareness. Many interviewees were not aware that there are shock resistant models of aneroid sphygmomanometers and they were not aware of the limitations of the

mercury ones or the difference in quality available among electronic and aneroid sphygmomanometers. Further, many people were not at all aware of the importance of routine calibration.

Cost issues were also a major factor in many hospitals. In some places the nurse is required to purchase his or her own sphygmomanometer. In that case, especially in the lower income countries, people were looking for the cheapest sphygmomanometer they could buy with the expectation that if the instrument was on the market the quality would be at least at a certain minimum level. In the hospital it was discovered that – because the purchasing budget is frequently separate from the maintenance budget, hospitals would also purchase inexpensive and sometimes lower quality sphygmomanometers – therefore contributing to the attitude among some of the professionals that they could not rely on the mercury-free sphygmomanometers that they were working with. The speaker underlined that an awareness raising process in the hospitals would be necessary, also as part of the legislative process we are currently undergoing.

Traditional mercury sphygmomanometer

In terms of waste, it was not a surprise that all hospital have a rigorous way of dealing with hospital waste in dividing waste among hazardous waste, infectious waste and municipal waste. However, when it comes to dealing with a mercury spill, the people dealing with the waste are not necessarily aware of the adequate procedure. In a number of interviews there were people who have seen mercury disposed as normal trash or - because they considered it as somewhat hazardous- put it together with the infectious waste or mixed with other waste in a special bin. However, it was typically not at all separated from other sorts of waste or dealt with in a way that would be considered appropriate.

Interviewees expressed various concerns about mercury sphygmomanometers such as frequent breaks of rubber tubes, air leakage, the mercury was dirty, that it had oxidized and it was difficult to read the mercury column through dirt on the inside of the tube. This indicates that there is a certain amount of air getting into the mercury column in some way and if that is true, it could be assumed that the mercury is also getting out in the ambient air in some manner. Various maintenance people also stated that you have to top up the mercury column on a routine basis – even if this is once a year – so something is happening to the mercury. A well maintained mercury column is quite a good instrument. However, it seems that in many of these hospitals they have not been maintained or calibrated as they should be.

In terms of waste, in the 2008 COWI/Concorde study it was discovered that the approximate recycling efficiency is something like 20% for all measuring equipment combined. With sphygmomanometers - because of the quantity of mercury in them – it is assumed that they are normally collected and recycled to a higher level of 30 to 35%. Another percentage could be disposed as hazardous waste in underground salt mines. However, it seems that something like 50% of the mercury in sphygmomanometers may still not be going to a proper disposal, which we should be concerned about.

Calibration of any sphygmomanometer means that it is compared with a reference manometer to ensure that the sphygmomanometer is functioning properly and measures accurately. During the calibration process the margin of error of the reference manometer is added to the margin of error of the mercury sphygmomanometer itself. Thus, there is a combined potential error which means that the reference manometer should be as accurate as possible to limit the overall error.

The frequency of calibration for a cheap aneroid sphygmomanometer has been suggested to be twice a year. There are good quality electronic auscultative devices on the market now that perhaps do not need to be calibrated more than once every 4 or 5 years.

COCIR/Philips commented earlier that mercury sphygmomanometers do not need to be calibrated. Theoretically this is probably true, but if one considers that maintenance includes cleaning, replacing cuffs, rubber tubing and such, then it is certainly true that mercury sphygmomanometers need to be looked at routinely. There have been studies that have looked at mercury sphygmomanometers and their actual use in a number of clinical areas and something like 20 or 25% of the mercury sphygmomanometers were not operating properly – which is a very high number and suggests the importance of routine maintenance and calibration of the mercury sphygmomanometers.

Validation is a more complex process carried out typically by academic researchers who publish their findings in a professional journal. They would take a specific model of sphygmomanometer in this case and validate it against a standard. There is a lack of clarity about the definition of validation. There have been people saying that if a sphygmomanometer is validated, it means that the sphygmomanometer has passed the various tests. Other people say that validation means only that the sphyg has been tested – regardless of whether it has passed the tests or not.

During the validation process a sphygmomanometer could be validated and recommended for use with adults. It could be validated and recommended for normal clinical cases but not for some special medical cases, or it could be validated and recommended for all adult uses.

If a sphygmomanometer has the CE marking it basically means that it "*demonstrates compliance with the Essential Requirements of the Medical Devices Directive*". Again, the fact that a sphygmomanometer has been validated does not mean that there is no need for maintenance or calibration.

A number of European countries have virtually phased out mercury sphygmomanometers. Some say, however, that the auscultatory technique is necessary to measure blood pressure in special clinical cases and that electronic equipment based on oscillometry is not necessarily reliable for these cases.

For this reason special attention is given to the main mercury-free devices that use the auscultatory technique: these are aneroid and digital manual devices.

The quality of the aneroid sphygmomanometers varies greatly; however there are models that have been validated and are of high quality. Digital manual sphygmomanometers are somewhat more

recent. They are typically more expensive, but they can be highly accurate and typically need less frequent calibration. In various places they are used as reference manometers in order to calibrate other sphygmomanometers.

Manual/digital sphygmomanometer

A detailed cross comparison regarding costs was carried out concerning these devices. However, it may not be useful to rely too much on these figures because the estimated lifetime and the calibration frequency of these sphygmomanometers are the overriding factors that make a difference in the overall costs. In conclusion, a validated shock-proof aneroid sphygmomanometer of good quality that does not need to be calibrated more than once a year will invariably be more cost-effective than the alternatives. The overall sphygmomanometer comparative costs are so similar that the purchase decision should be based on other important concerns such as toxic content and waste management practices rather than the initial purchase cost. This confirms more or less the Kaiser-Permanente study that concluded that the overall real cost of a good aneroid sphygmomanometer is only about one third of the cost of a mercury sphygmomanometer. The less comprehensive analysis that was prepared for the 2008 COWI/Concorde study for DG Environment showed again that the aneroid sphygmomanometers were something like 10% less costly than mercury sphygmomanometers, and the digital sphygmomanometers significantly more.

In terms of other barriers getting in the way of changing from mercury to mercury-free devices, it is clear that the long familiarity of health care professionals with mercury sphygmomanometers makes many people want to continue using what they are familiar with, and there is resistance from certain professional associations. Further, part of the difficulty is that many standards have been developed based upon the mercury manometer and the mercury column. General practitioners are typically a bit older and not so familiar with new techniques. What they have been using for a long time works fine for them, so they don't feel any urgent need to change.

Some MHRA (UK Medicines and Healthcare Products Regulatory Agency) reasons that were submitted to the European Commission for keeping mercury sphygmomanometers came to the speaker's attention and were:

- "the majority of blood pressure measurement devices on the market have not been validated for use with patients from special groups, e.g. arrhythmia, pre-eclampsia and certain vascular diseases".
- With regard to aneroid sphygmomanometers, they "drift out of calibration with the user being unaware. The displays of digital gauges are difficult to read as the numbers are continually changing during cuff deflation, and the ergonomics associated with freezing the

display at the correct points are different, leading to errors".

In the presenter's view these are valid points, but in response there are many sphygmomanometers that have been validated and recommended for special groups. To say that many sphygmomanometers have not been validated is not really a reason to keep mercury sphygmomanometers. Likewise aneroid sphygmomanometers need to be regularly calibrated, and various models that have been validated have been shown to be extremely accurate if they are maintained and calibrated properly. Finally, digital displays, where the numbers change on an LCD screen, are not necessary if they pose a problem for some people.

The question is not whether the phase out of mercury sphygmomanometers for professional use is viable, but whether the health care sector is ready to manage this change.

Discussion

- On a comment on what is the extent of and on whether there is available data on the effect from mercury used in mercury-sphygmomanometers, Concorde commented that there are numerous adverse health effects from mercury emissions and mercury releases. The effect on the environment is that there are releases to the waste stream, water and to air. Whether the mercury is coming from mercury sphygmomanometers-waste or whether it is coming from coal fired power plants, there is still unnecessary pollution and release to various environmental media which needs to be reduced, considering that this is feasible, even if this appears small in relation to other potential sources.

- In the cost calculation discussed on various studies as described in the Concorde report for EEB, there is an estimate on the overall health effect of certain releases or emissions of mercury. The number that is given there is based upon air emissions and this is what is figured into the cost calculation. That was based on numbers that were built up around discussions of emissions from coal fired power plants in the US from the past 5 or 6 years. In that sense the potential emissions from measuring devices are quantified.

- Concorde clarified further that on one of the websites[7] there are 8 models of sphygmomanometers that have been validated for use in all clinical cases. If it is only a matter of replacing the mercury column with an aneroid dial or some other manometer but keeping the auscultative approach in order to be able to listen to the appropriate sounds, there does not seem to be any intrinsic reason why one could not replace that manometer device with a mercury-free manometer. But when the validation studies are done the protocols say that those studies have to be done against the mercury column or against a mercury sphygmomanometer and so those non-mercury devices have been validated against mercury sphygmomanometers.

5. To be or not to be Hg Free – that is the question! A case for the Mercury Free Hospital

(Presentation by Paul Williams, Facilities Health and Safety Advisor, Heart of England NHS Foundation Trust, UK)

Mercury is being phased out in all types of equipment in 'Heart of England NHS Foundation Trust' hospitals. However, there are still some mercury containing instruments that have not been completely phased out. To be or not to be mercury free? This is the question hospitals have to face up to.

[7] http://www.dableducational.org/sphygmomanometers/devices_3_abpm.html

Heart of England NHS Foundation Trust is an inner city hospital with 10 000 staff and 1734 beds. . It is estimated that approximately 95% of the staff are not aware of the harmful effects of mercury.

There are a lot of problems linked to the use of mercury such as:

- Breakage of instruments
- Spillage Procedure – what to do when an instrument breaks?
- Location of kits
- Fire brigade call outs when spillage occurs
- Contaminating other waste streams
- Storage pending disposal
- Costs of disposal
- Costs of disposal kits

Some answers on how to remove mercury from our hospitals.

- Establish one person to have overall responsibility for managing use and disposal of mercury in the organization. They can coordinate, give advice, know where the spillage kits are, etc.
- Who pays for the mercury disposal and associated costs? Have a budget set up straight away so there is no arguing over who is going to pay.
- Have a responsible department. For instance, the speaker's pathology department has a dedicated chemical store which stores the mercury devices in a proper and correct manner.
- The spillage procedure – what to do in a spillage? Heart of England NHS Foundation Trust has clear guidance instructions on that.
- Knowing where the mercury is sent, so that it does not get sent to the third world or somewhere where it is not properly dealt with and disposed of. Ensure that correct legislative procedures are followed in the disposal process.

In case there is a spillage, the Heart of England NHS Foundation Trust hospital has spillage kits (see picture below) that are correctly labeled.

Mercury sent for disposal should be correctly packaged and labeled pending transportation.

The following are some considerations to make when replacing mercury devices with electronic alternatives:

- The costs of replacement.
- Establishing an inventory. This will provide listing of all equipment and detail such data as serial number, location of equipment, equipment type and the next testing date.
- Maintenance of Electrical items, especially PAT Testing. The electrical equipment has to be tested for its electrical functionability.
- Calibration.
- Use of calibration expiry date stamps.
- Responsibility for ensuring above.
  Who in the organization is going to be made responsible for making sure the rules are followed and determine what the rules are. Get the rules written down on who ultimately is responsible and to whom you should report to. Policy to be written and then monitored as to compliance.
- Training.

Special Mercury spill kit in case of breakage, leakage

Some substitutes to mercury devices:

- Heart of England NHS Foundation Trust uses tympanic thermometers which is an infra red method of measuring temperature in the ear. The Hospital has 200 of these in use which would cost £73.00 each. However because they are contracted to buy disposable covers for the instruments - the instruments are provided free of charge under the contract (in year ending 1.3.2009 1,280,800 covers were purchased costing £56,902.52). Calibration is done internally by trained medical engineers departments who have been trained on calibrating equipment by the companies. The calibrating equipment that is used also has to be calibrated and is sent away every 12 months.

- Electronic blood pressure machines
  They are multi functional and are not only used to measure blood pressure. They also give an electronic record which mercury blood pressure machines do not give. The average use is one per eight beds (~200 machines in use throughout the organisation). Mercury calibration devices are not used, instead an electronic one is used and there is a manual one supporting it as well. It is calibrated by the manufacturers annually. Colored out-of-date stickers are used and there is an electronic database where the information is kept. It is the manager's responsibility to make sure that the equipment is functional and not out of date.

In different instances, the electronic devices are used followed by the backup device. For hypertension and pre-eclampsia electronic device are supported by manual devices.

Training is particularly important:

- In use of all types of machines
- Training in calibrating equipment
- Training to recognize when to revert from electronic to manual – that can probably only come with experience. Knowing when the machine is not functioning or does not appear to be functioning correctly and when to step up to manual.
- Training on recognizing status of equipment i.e. that is out of calibration
- Training in mercury spillage procedures.

Arguments for retaining mercury devices:

- More personal in touch with patient
- Accuracy
- Cost of replacement
- Problems with cuff sizes for standard electric.

Arguments against retaining mercury devices:

- Environmental impact
- Health and Safety issues –spillages
- Ease of use
- Flexibility of some electrical equipment to perform multiple functions and also record measurements over a period of time.

6. The experience of Rezekne Hospital as a mercury-free hospital

(Presentation by Jelena Stepule, Rezekne Hospital, Latvia)

Rezekne Hospital is a multipurpose emergency medical health care institution with a total amount of 385 beds. The departments of the hospital provide medical assistance and services for more than 20 profiles. The Hospital serves residents of Rezekne city and region. In some profiles the hospital also serves people of other regions of Latgale, e.g. Ludza, Preili and Daugavpils. There are more than 130 000 inhabitants in the service area. Rezekne Hospital is a municipal state institution and employs 77 physicians, 220 nurses, 75 nurse assistants, 73 hospital attendants and 71 other workers.

There are 30 departments in the Hospital: Emergency medical assistance and patient receiving – room, Anesthesia and Intensive Care Unit, Necrology Division, children's department, Gynecologic and obstetric department, neurology and neurosurgery department, therapy department, traumatology department, Surgery department, Infectious diseases department Hemodialysis department, Pathology department, Sterilization department, Cabinet of blood, Pharmacy, Clinical Laboratory, Ray diagnostic department, Physical medical department.

Rezekne Hospital is involved as a pilot hospital in the UNDP/GEF project "*Demonstrating and Promoting Best Techniques and Practices for Reducing Health Care Waste to Avoid Environmental Releases of Dioxins and Mercury*".[8] The overall objective of the project is to reduce environmental releases of dioxins and mercury by demonstrating and promoting best techniques and practices for reducing and managing health care waste in a number of countries and regions. In the framework of the project the improvement of the waste management (collection, treatment and disposal) will be implemented in the hospital as well as the manual for the personnel will be developed and tested.

The hospital switched to mercury free thermometers three years ago. Mercury sphygmomanometers are not in use since 1998 - 2000 (and this refers to most of the hospitals in Latvia).
Problems with mercury use:

- Mercury evaporates at room temperature with a rate of 0.002 mg of 1cm^2 surface within 1 hour and the vapor has no color and fragrance.
- In the case of breakage the harmful substances (in the shape of small balls) are difficult to collect.
- Mercury is harmful to the environment and toxic to the body. While in the room it slowly evaporates. In humans the effects of inhalation may occur even after several years.

[8] http://www.gefmedwaste.org/article.php?list=type&type=3

The collection of mercury devices in Latvia is still under development. In the past (and in some cases even now) hospitals usually collected it in special containers or poured it out to the wastewaters.

Rezekne Hospital has a labor safety specialist who designs and presents employees with a variety of instructions to ensure staff carries out their work safely and properly. In 2005, the hospital developed an instruction manual "Waste Collection and Disposal in a Municipal Company with Limited Liability Rezekne Hospital". This instruction manual prescribes actions and measures in the case of breakage of mercury-containing units.

Since 1998 Rezekne Hospital does not use mercury sphygmomanometers any more. They were uncomfortable (as they were very large and fragile), they often got broken (the mercury often leaked onto the work table) and they took up to much place on the work surface.

Currently, the hospital uses mechanical sphygmomanometers which are safer and more comfortable in application and use. Two types of mercury-free sphygmomanometers are used in the hospital: mechanical and electronic type sphygmomanometers with monitors used in the intensive care unit.

Calibration and verification of the blood measure devices are carried out by the Outsources testing laboratory "RoLa" Ltd. The laboratory is certified according to the standard LVS EN ISO/IEC 17011:2004 once per year.

7. Global developments and mercury in measuring devices

(Presentation by Desiree M. Narvaez, Programme Officer at UNEP)

UNEP (United Nations Environment Programme) is the voice for the environment in the United Nations system. Its work on chemicals is based in Geneva. UNEP has been mandated by governments to protect human health and the global environment from the release of mercury and its compounds. The efforts began in 2001 when – especially EU countries – called for increased efforts to address the mercury issue on a global level. The goal is to minimize or, where possible, eliminate global anthropogenic mercury use and releases.

In 2005, measuring devices were the seventh largest sector of global mercury demand. The UNEP report on trade, demand and supply of mercury estimates that at least 150-350 metric tonnes of mercury are used on an annual basis in the measuring devices sector. When observing emissions of mercury by sector, the combustion of fossil fuels ranks the top (about 45%). Emissions from mercury containing measuring and control devices (which fall under the waste sector) are a minor fraction in this statistic. However, the estimates on mercury emissions from measuring devices are rather conservative. Two thirds of the overall global mercury emissions come from Asian (mainly India and China) sources. In Europe, the third biggest emitter of mercury, the biggest sector of emissions stems from coal burning. Waste incineration is an additional important source of mercury emissions in Europe.

The approach of UNEP is currently to work together with the manufacturers in reducing the supply and thus reducing the demand of mercury. In 2008, UNEP commissioned the Lowell Center of Massachusetts to carry out a study on the level of substitution and the experiences of technology change in different countries on the use of mercury free sphygmomanometers. Questionnaires were sent out and 13 countries responded.

The results of the study:

- In 5 developed/OECD countries substitutes were available and readily used ("Level 2" of substitution).
- In 5 developing countries substitutes were available but minimally used ("Level 1")
- In 3 developing countries there were no substitutes available ("Level 0")

General findings were that there was a special need to support developing countries (e.g. education, create a level playing field in terms of availability and accessibility, pricing of alternatives, etc.).

In 2003 UNEP´s Program on Mercury was established. It aims to:
- Support actions to prevent mercury pollution
- Evaluate long term global policy frameworks
- Work with stakeholders to reduce global mercury supply and demand

Additionally, the UNEP Governing Council in 2005 urged the UNEP Mercury Programme to initiate the Global Mercury Partnership working together on a voluntary basis with industry, science, professional associations, NGO´s and individuals, as an approach to reduce risk of mercury to human health and the environment.

During the UNEP Governing Council meeting in 25 February 2009 there was a breakthrough decision on initiating a legally binding instrument for mercury. This was supported by the newly elected government of the United States and an agreement (GC Decision 25/5) on a legally binding instrument for mercury by 2013 could be made. There will be the first intergovernmental negotiations in June 2010 which will continue in 2011 and 2012. A plenipotentiary conference of Parties will take place in 2013.

The first step is to convene an open ended working group in October 2009 where the working group will scope what the Intergovernmental Negotiating Committee (INC) process will cover. Governments will have to define the scope and negotiating priorities for the next INCs. Further, governments have to agree on the timeframe and the particular dates for the INCs.

In the interim, Governing Council requests (GC 25 paragraph 34) that UNEP should continue its existing work with its partners under the UNEP Global Mercury Partnership. Among the many areas of work, UNEP is requested to continue its work in reducing mercury in products and processes and raising awareness of mercury free alternatives and work towards synergies with mercury supply/storage initiatives as well as waste management activities.
UNEP's interim activities also include the Global Initiative co-led by WHO and Health Care without Harm (HCWH). The goal is to phase out the demand for mercury-containing fever thermometers and sphygmomanometers by at least 70% by 2017 and to shift the production of all mercury-containing fever thermometers and sphygmomanometers to accurate, affordable, and safer non-mercury alternatives.

UNEP aims to invite partners and increase participation of the UNEP Global Mercury Partnership (GMP). [9] Through the GMP – specifically the products partnership - UNEP will work with manufacturers to set standards, reduce mercury content and eventually phase out mercury in measuring and control devices. For UNEP it is very important to identify the manufacturers and collaborate with them. The OEWG[10] will be on 19-23 October 2009 in Bangkok, Thailand to prepare for the mercury negotiations. The EU (DG ENVI and DG Enterprise) may wish to submit recommendations to OEWG based on its experience in relation to mercury in measuring and control

[9] More information is available at http://www.chem.unep.ch/mercury/partnerships/new_partnership.htm.
[10] More information about the upcoming OEWG is available at http://www.chem.unep.ch/mercury/WGprep.1/Meeting.htm

devices and as a result of the current consultation.

8. WHO policy and partnership

(Presentation by Prof. Peter Orris, University of Illinois, WHO collaborating center)

The Great Lakes Centers for Environmental & Occupational Safety and Health University of Illinois is a WHO collaborating center, this is why the WHO Office in Geneva asked him to present the WHO position on this matter.

The presenter clarified that he comes to this issue as an occupational environmental physician concerned in the Great Lakes area about mercury content of fish and the implications of that for pregnant women and developing babies. He also has 30 year experience as an internist at Cook County Hospital. To his view there no longer is a need for mercury sphygmomanometers.

Health Care Without Harm asked a colleague and him to look at this issue and they have done a review of the medical literature coming at this from a medical end – the outcome is that we don't need mercury devices to secure accurate blood pressures in clinical practice.

An effective substitution strategy must include hazard characterization both of the material being substituted and the alternatives. There needs to be an understanding that people are at risk, that there are safer alternatives, and that there is a way of adopting these alternatives. Finally, that the costs of this substitution in its entirety, including the social costs involved, makes it worthwhile to go to the substitute. For instance, there is an absolutely astounding number of thermometers that get broken in hospitals every day. The mercury then spills on to the floor and remains in the clinical setting. An adequate cleaning up process is quite elaborated (see text box below). Without an adequate clean up procedure the material can be inhaled for prolonged periods. Health care workers are not reporting or not associating adverse health effects with these exposures. We must be missing a certain number of workers with pneumonititis related to this on a global level – and that is a very interesting hidden disease or hidden effect.

Contents of a Mercury spill Kit

1) Four to five zip lock-type bags
2) Trash bags (2 to 6 mm thick)
3) Plastic container with lid that seals (35 mm film canister for example)
4) Nitrile or latex gloves
5) Paper towels
6) Cardboard strips (or index cards often used for recipes in North America)
7) Eyedropper or syringe (without needle)
8) Duct or other sticky tape (12 inches or so)
9) Flashlight
10) Powdered sulfur or zinc (can this be easily obtained at a pharmacy)
11) Set of instructions with waste collection and disposal protocols

Cleanup Instructions

DO NOT USE A VACUUM CLEANER

1) Remove all jewelry from hands and wrists so the mercury does not combine (amalgamate) with the precious metals.

2) Change into old clothes and shoes that can be safely discarded should they happen to become contaminated.

3) Remove everyone from the area where cleanup will take place. Shut door of impacted area. Turn off interior ventilation system to avoid dispersing mercury vapour.

4) Mercury can be cleaned up easily from the following surfaces: wood, linoleum, tile and any other like surfaces. If a spill occurs on carpet, curtains, upholstery or other like surfaces, these contaminated items should be thrown away in accordance with the disposal means outlined below. Only cut and remove the affected portion of the contaminated carpet for disposal.

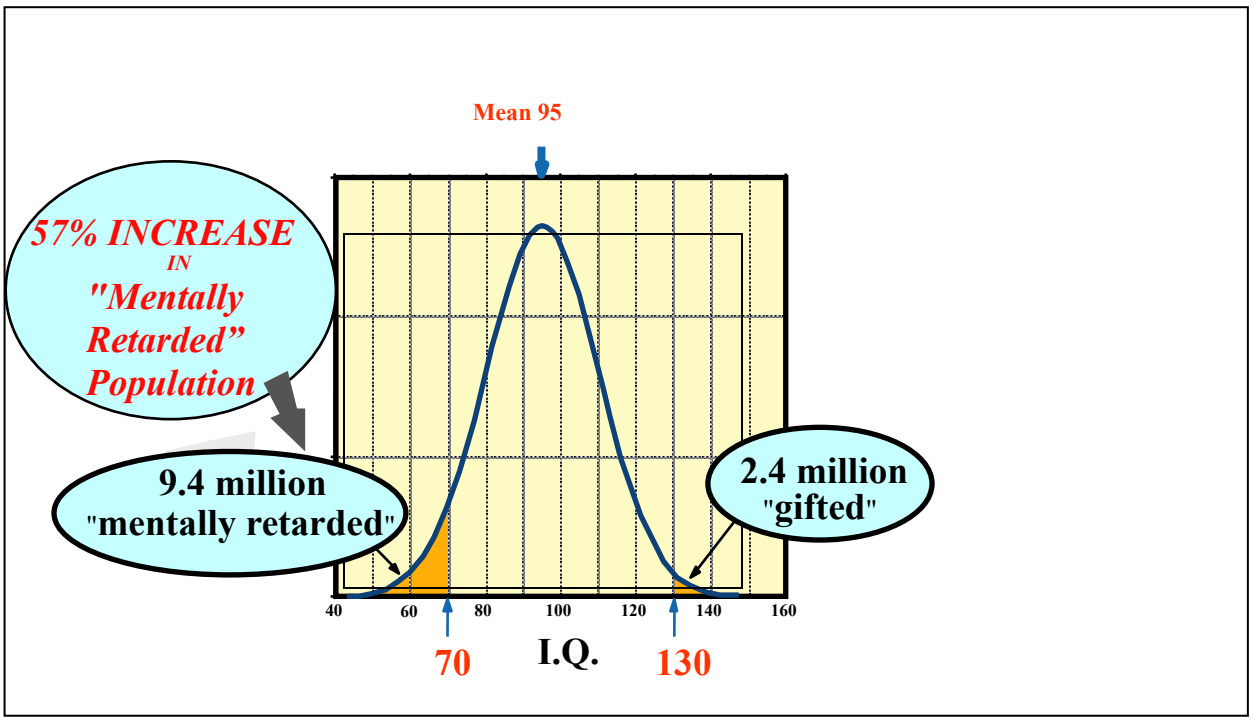
5) Put on rubber or latex gloves. If there are any broken pieces of glass or sharp objects, pick them up with care. Place all broken objects on a paper towel. Fold the paper towel and place in a zip lock bag. Secure the bag and label it.

6) Locate visible mercury beads. Use cardboard to gather mercury beads. Use slow sweeping motions to keep mercury from becoming uncontrollable. Take a flashlight, hold it at a low angle close to the floor in a darkened room and look for additional glistening beads of mercury that may be sticking to the surface or in small cracked areas of the surface. Note: Mercury can move surprising distances on hard and flat surfaces, so be sure to inspect the entire room when "searching."

7) Use the eyedropper or syringe to collect or draw up the mercury beads. Slowly and carefully transfer mercury into an unbreakable plastic container like a 35mm film canister with a locking or air tight lid (avoid using glass). Place container in zip lock bag. Make sure to label the bag. After you remove larger beads, use duct tape (or other sticky tape) to collect smaller hard-to-see beads. Place the duct tape in a zip lock bag and secure. Make sure to label the bag as directed by your local health or fire department.

The form of mercury that is the most toxic at low doses is the methylmercury. Methylmercury is the transformation of elemental mercury by microorganisms in the aquatic environment. Usually the methylmercury is then absorbed by fish and can be eaten by pregnant women or women in childbearing age who are particularly vulnerable to the toxic effects. This low does exposure is exquisitely toxic. The information from the Faroe Island Study [11]as well as other studies reveals that methylmercury is particularly toxic to the complex brain functions of fetuses and infants. Prenatal methylmercury exposure that increases the concentration of mercury in maternal hair by one micro gram per gram decreases the IQ in the offspring by 0,7 points. Now, 0,7 points or even 5 points is not a clinical entity that anybody sees in their office. Often patients do not notice it at that level. Therefore, this is a toxicity that is not seen in the individual but a toxicity that you can see on a population basis.

[11] 'Cognitive deficits in 7-year-old children with prenatal exposure to methylmercury' Grandjean, P., Weihe, P., White, R., Debes, F., Araki, S., Yokoyama, K.,, Murata, K., Sorenson, N., Dahl, R., Jorgenson, P., November 1997 *Neurotoxicology and teratology*. vol. 19, issue, 6, pp. 417-428.



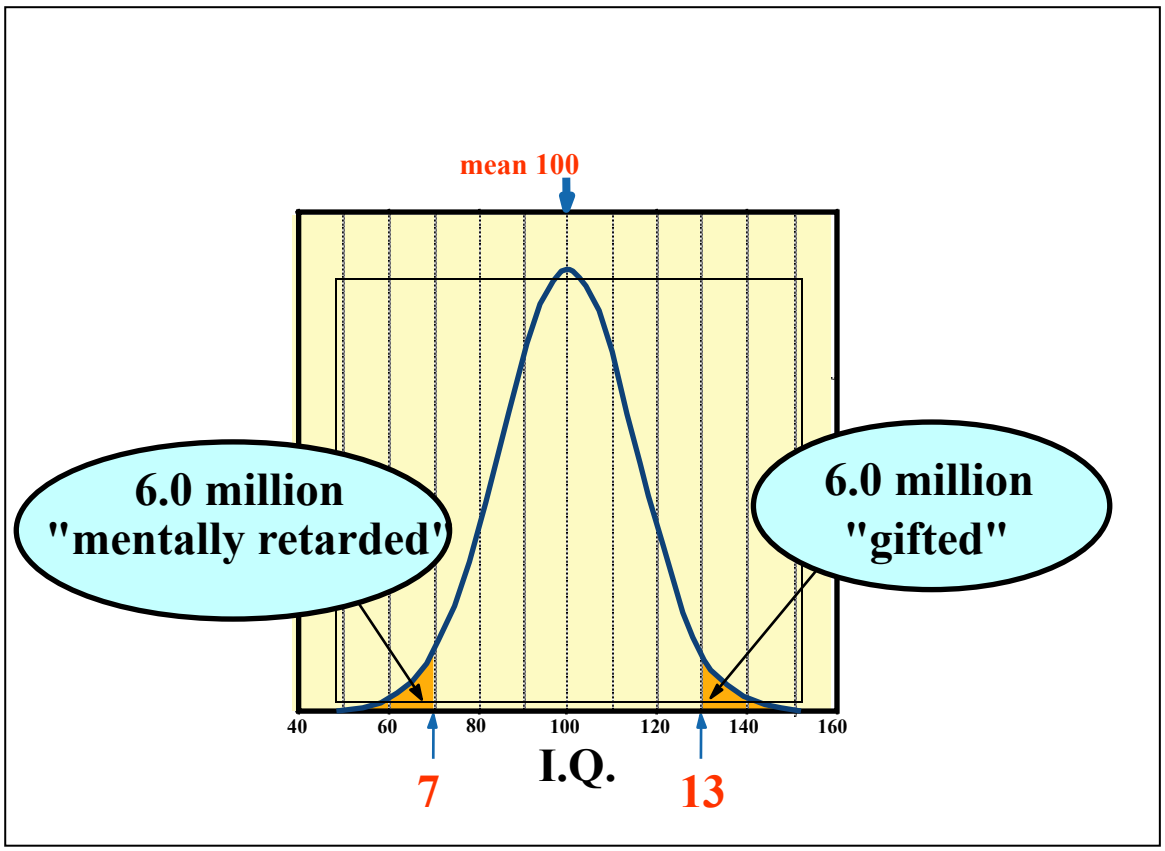
5 Point Decrease in Mean IQ

A few years ago it was estimated that IQ distribution for the USA (population: approximately 260 million) with a mean of 100, left about 6 million individuals with significant cognitive deficits who needed social support. That costs the society money as well as causing problems for the individual families. If that curve shifts down five points, or in other words: if you give this mercury to everybody born in the population, you then produce a substantial increase in people needing that social support. The estimate of lost productivity due to the mercury toxicity from all sources in the USA was done a few years ago by colleagues at Mount Sinai and it was estimated to be 8, 7 billion dollars annually.

When it comes to mercury in fish it is difficult to give advice to individual patients about what fish to stay away from. The trick is that we want the mercury out of the fish and not the fish out of the mother because fish is important for the intellectual development of the fetus and baby. Thus, it is better to go for alternatives that will not further expose people to mercury.

In 2005, the "Mercury in Health Care" policy paper from WHO noted that mercury in sphygmomanometers was the largest reservoir of mercury in health care. . It is not the dominant societal exposure to mercury – which is from coal power plants – but it is within our capacity to reduce the effect.

Having used mercury sphygmomanometers for about 25 years in practice the speaker can testify that the mercury column is not particularly easily read, even when it is cleaned and calibrated, and also you have to bring it over to the patient. The class around the column itself unfortunately lifts up, especially if you tinker with it and the mercury spills out at the bottom. This is why they have to keep coming around refilling the column with some regularity.



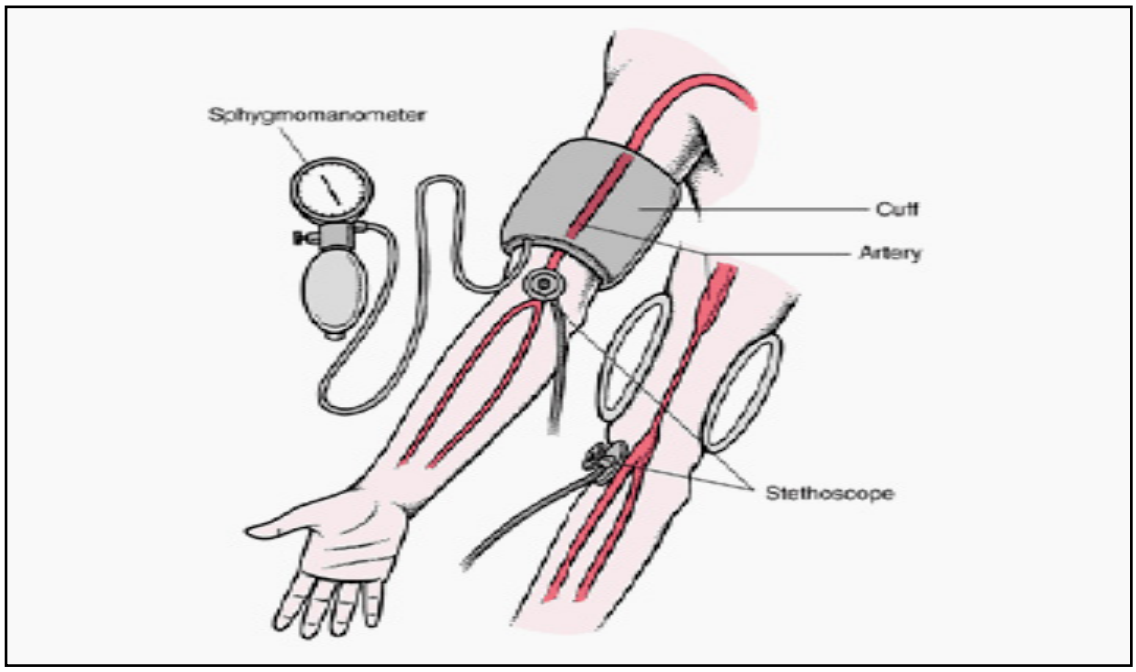
Effects of a small shift in IQ distribution in a population of 260

To calibrate these devices the pressure measuring end of it is taken of, the cuff and the tubing, etc – the device is then hooked up to two reading devices with a Y tube – one is a mercury manometer and the other is one of the other devices. Two different kinds of measuring manometers are thus needed to calibrate.

The American Heart Association stated some years ago that it is surprising that nearly 100 years after it was first discovered and subsequent recognition of its limited accuracy, the Korotkoff technique for measuring blood pressure has continued essentially unchanged. That is auscultation of the sounds produced by a beating heart as you hear it through a stethoscope. The "gold standard" for clinical blood pressure measurement has always been readings taken by a trained health care provider using a mercury sphygmomanometer and the Korotkoff sound technique. However, there is increasing evidence that this procedure may lead to the misclassification of a large numbers of individuals.

So what is the first and largest problem with the accuracy of this technique and this measurement? It is the person between the stethoscope ear pieces. If the person does not know what he/she should be listening for or if the person is not listening well then there will be mistakes.

There is an epidemiological study in which they tried to standardize across national settings and between a multitude of providers in a level of accuracy for epidemiology that you really don't have in clinical practice. In doing so you identify a number of errors and inter-observer biases that overwhelmed much of the rest of the inaccuracy.



Measuring blood pressure using a sphygmomanometer

Further, worthy to note is that there is a strong end-digit preference. People love "fives" and "zeros". In general very marked digit preferences were observed for both the conventional and the semi automatic measurements, being most prominent for the digit "0" (52% and 25%, respectively) followed by a preference for the digit "5" (19% and 15%). So this question about being 3 millimeters of mercury inaccurate really has long term effects on patients but on the clinical setting in most environments that degree of accuracy you just do not have.

The next thing discovered is that doctors scare patients with some regularity in the well known phenomena called the "white coat effect". This means that the blood pressure is going to be higher with the doctor reading the blood pressure than when the patient is sitting on their own. Use of an automated blood pressure recorder can eliminate some of the white coat effect associated with readings taken by a mercury sphygmomanometer.

On the "gold standard": A survey of blood pressure devices used in a large teaching hospital in London in 2000 gave us this series of problems that I have observed in my own hospital:

– 38 % (n=469 devices) were found to have dirty mercury columns.
– On 21 % of those, the markings were difficult to read due to oxidation of the mercury.
– 18 % had either an obscured mercury column or faded markings, and three devices were found to have leaking mercury.

Of note are the results of cuff inspection:

– 8% were "worn out", damaged or had splits
– 35% of Velcro cuffs did not stick well enough to resist bursting apart on inflation above 180 mm Hg
– Seven cuffs contained the wrong size bladder for the size of the cuff.

The electronic pressure gauges are more accurate and therefore better for Y tube calculation. These electronic pressure devices may be up to 5 or 10 fold more accurate than the mercury manometer.

Early Clinical Experience:
In Sweden they converted over in the late 1980s and early 1990s. On a survey approach of their hospitals: clinics found no problems with diagnosis or clinical care by using the aneroids. To clarify aneroid devices can be used for people with arrhythmias and other special medical conditions. This may not be true for oscilloscopic devices because they do the calculation of the diastolic and systolic pressure but it is true for the aneroids. Aneroids are good for all of these special medical conditions if they are calibrated and if they are maintained. Published experiences, such as from the Mayo Clinic in Rochester, confirm this.

When observing in Brazil or developing countries it was discovered that there were slight under-readings of the aneroid instruments (hypertension prevalence 30%, compared with 32% for digital and mercury). However, aneroid devices were preferred because they were easily used in clinical settings in the fields.

Electronic devices have to be calibrated as well. One study showed that 21% of patients were misdiagnosed with uncontrolled hypertension due to the lack of consistency and surveillance of calibration. In another study aneroid sphygmomanometers were less accurate than mercury based sphygmomanometers but again only in settings in which they were not adequately calibrated and maintained.

The next problem is that most of these products that are on the market are not externally validated by independent sources. Further, when models were tested they did not live up to the manufacturers promises.

The WHO 2005 position paper, on review of the literature, said that both mercury and aneroid sphygmomanometers have been in use for 100 years and when working properly either gives accurate results. Aneroid sphygmomanometers provide accurate pressure measurements when a proper maintenance protocol is followed (as is also true for the mercury devices).

In the short term the WHO is planning to develop a mercury cleanup and storage procedure. The WHO says that before final replacement has taken place, and to ensure that new devices conform with recommended validation protocols, health-care facilities will need to keep mercury as the "gold" standard to ensure proper calibration of sphygmomanometers. That was in 2005 and it is clear that this needs to be re-evaluated because this is no longer true given these electronic pressure standards.

In medium and long term, hospitals should begin to phase out mercury and assess their inventory. They should increase efforts to reduce the amount of unnecessary mercury equipment in general. And finally in the long term, they should look to ban mercury containing devices and promote the use of mercury-free alternatives.

The British Hypertension Society and others do some independent evaluation of the various models. There has been an explosion of reporting and materials in the literature both on the various manufacturers' models, the various trade names as well as the overall group and types. In 2008 the World Medical Association urged the elimination of mercury containing products for physicians in their offices as well as the larger clinics.

In sum:
- The "Gold Standard" does not necessarily mean an accurate blood pressure
- The greatest inaccuracies derive from the measurer
- The greatest variability is the patient (position, stress, variability of blood pressure, etc.)
- The product accuracy is often related to the manufacturer and the individual product
- When maintained & calibrated properly, nearly all inter-device variability is below 4mm of mercury

This understanding led WHO to partner with Health Care Without Harm under a United Nations Environment Program Products Partnership on mercury in 2008. This project has a series of step by step goals to urge the health sector to move away from mercury in its entirety.

About clinical practice in the USA: you can´t find a new hospital, a new large clinic or anything else that is buying mercury sphygmomanometers. Most physicians, when they phase out the old ones get the new mercury free ones.

9. The Global Movement for Mercury Free Healthcare

(Presentation by Anja Leetz, Healthcare Without Harm Europe /HCWH-E)

HCWH is a global network and takes its point of departure from the Hippocratic Oath: "First Do No Harm". HCWH looks at the connection between the care that health professionals are giving and the impact of this has on the environment. HCWH is a coalition of 480 organisations across the globe in 52 countries. Our goal is to transform the healthcare sector and raise awareness of the activities undertaken by the healthcare sector. HCWH focuses on issues such as medical waste incineration, mercury and PVC, green buildings, climate change in the healthcare sector.

What are HCWH's goals for mercury? The phase out in the healthcare industry globally and to replace mercury with viable cost effective alternatives. This is achieved by creating a broad coalition involving governments, hospitals and NGOs. HCWH are still looking for national governments and healthcare providers to join our efforts, see more on the website[12]

HCWH sees three main challenges concerning mercury. HCWH wants to replace mercury with devices that are:
- Accurate
- Affordable
- Unproblematic to dispose of

Studies that have been done in collaboration with the EEB have shown that there are alternatives, which are being used already.
HCWH began their mercury campaign in the USA in 1998. HCWH convinced top pharmacy chains to stop selling mercury containing thermometers. Further, HCWH worked with hospitals and associations to shift the market to stop purchasing mercury thermometers. It is now virtually impossible to buy a mercury thermometer in the USA. As a result of the work on thermometers HCWH moved onto sphygmomanometers.

HCWH produced the report "End of an Era"[13]– that documents the dramatic decline in the US of mercury sphygmomanometers in the past decade. It contains many statements from a variety of hospitals. Some of the report findings are:

[12] www.mercuryfreehealthcare.org
[13] http://www.noharm.org/lib/downloads/mercury/End_of_an_Era_Mercury.pdf

- According to a 2005 survey of 554 healthcare facilities, conducted by the American Hospital Association, 73 % of respondents had removed all mercury sphygmomanometers.
- According to the Interstate Mercury Education and Reduction Clearinghouse: one third of the US population is covered by mercury state level sphygmomanometer bans or restrictions.
- Group Purchasing Organisations(GPOs) represent over $52 billion or 96 % of all contract healthcare purchases made in the U.S. In a 2005 survey of GPOs, three of the five largest US GPOs had implemented mercury-free purchasing policies that ban items from contracts except where a non-mercury alternative is not available.
- Hospitals and hospital systems representing over 80 medical centres and more than 200,000 employees have provided HCWH with letters that detail the success of their mercury elimination programmes.

Kathy Gerwig Vice President of Kaiser Permanente, which is a non profit healthcare provider in the USA with 156,000 employees, said: "in the years since we made the change to mercury-free (aneroid) devices we have not had any issues with accuracy or other complaints."

A similar statement was made by Nancy Mulvihill, Vice President of the Covenant Health Systems: "In the more than three years that we have made the changes to aneroid units, and digital blood pressure units, we have not had any issues with accuracy …I hope … that you will be convinced as we were, that it is in the best interest of all concerned to eliminate mercury sphygmomanometers".

Mary Ellen Leciejewski of Catholic Healthcare West, a not-for-profit healthcare system composed of 41 hospitals, 68 clinics and 9 trauma centers stated: "I am writing to share our successful experience in the elimination of mercury blood pressure devices…As our experience has demonstrated, cost effective viable alternatives to mercury blood pressure measurement are available in the marketplace."

After the success in the USA, HCWH started to focus on the rest of the world. Now HCWH is looking at how to get mercury out of healthcare globally. Part of the strategy is to run workshops and work with developing countries on pilot projects for substituting mercury devices. As a result of that HCWH has policy initiatives on several levels. There are national policy models like in the Philippines. The Philippines had an administrative order to phase out mercury from the healthcare sector across the country over two years and this includes sphygmomanometers.

HCWH also had a big success in Argentina where the Ministry of Health issued a Resolution in February 2009 banning the purchase of all new mercury thermometers and sphygmomanometers in the healthcare system. On the municipal level there is the example of Buenos Aires, which has implemented a policy to phase out mercury from 33 public hospitals and 38 healthcare centres– the largest public health system in Argentina. The policy is 80 percent implemented. This is a model for large cities in developing countries and actually served as a sample for the national law in Argentina on banning mercury. Buenos Aires is a success story and now the country is ready to go forward and to follow the example of the city. Also Delhi (India) has developed a city-wide policy. Eleven government hospitals have either phased-out or are phasing out mercury thermometers and blood pressure devices from their facilities.

For provincial and state level policies there is the example of Kwa Zulu Natal in South Africa. Here again it is the policy replacing sphygmomanometers and thermometers.

In Europe there are many hospitals that have phased out mercury sphygmomanometers. Countries such as Sweden, Denmark and the Netherlands, have eliminated mercury from healthcare almost entirely. Europe has a mercury export ban. The goal should be to phase out mercury

sphygmomanometers and HCWH are working in a coalition to achieve their goal.

Discussion

- A validation expert from the Hypertension Center, University of Athens commented about the problems with mercury sphygmomanometers: The first problem is poor maintenance and the second problem is the observer-user not applying the auscultatory technique properly. Although these problems appear to be relevant for mercury-containing and aneroid sphygmomanometers, the oscillometric – the so called electronic devices – do not require an observer and are very stable in long-term use.

- In the last 15 years large outcome studies in hypertension (10 to 15,000 people followed for about 5 years) where all done with electronic devices. Thus, 15 years ago the scientists decided to use such devices, not in order to get rid of the mercury, but to prevent the observer error and thereby to improve the accuracy of blood pressure measurement.

- The Danish EPA commented that the Danish attempt of getting rid of mercury in the health care system has been totally voluntary, there really has been no hard pressure from the environmental side, and this demonstrates that the alternatives must be just as good as the traditional techniques.

- It was clarified that on the basis of the adopted directive on measuring devices (Oct. 2007) any barometers for the general public will be banned with effect in October 2009. This does not apply for barometers for professional use. A ban of the export of mercury containing devices is not part of the 2008 regulation – however this issue will be discussed as part of its review in the coming years.

- The representative of the UK Hospital pointed out that maintenance is an issue that needs to be considered when purchasing new equipment. A system needs to be in place to ensure the purchase of the new equipment is recorded and schedule put in place for its ongoing maintenance. Medical staff in the modern day has to cope with pressures of different responsibilities (handling waste, accounts, maintenance issues and taking care of patients). Therefore, when considering systems to implement consideration should be given to ease of use from both the maintenance team and also equipment users.

10. Phasing out of mercury sphygmomanometers in Poland

(Presentation by Dr. Agnieszka Dudra, Bureau for Chemical Substances and Preparations, Poland)

The Bureau for Chemical Substances and Preparations is an institution of government administration responsible for the control of placing chemical products on the market. Due to the legal basis the Bureau is a REACH competent authority which cooperates with ECHA and with the Commission in the implementation of the REACH regulation. It also cooperates with the office for registration of medicinal products and medical devices which is a competent authority for matters related to medical devices in Poland.

In Poland, the restriction on mercury was adopted and published in the regulation of the Minister of Economy which adjusted the polish law to the European directive 2007/51. The Bureau, on behalf of the Ministry of Health, states that chemicals management should ensure a high level of protection for human health and the environment, including the promotion of alternatives for dangerous substances.

In Poland it appears that health care institutions currently have limited access to mercury containing

sphygmomanometers. Health care institutions have largely phased out mercury containing sphygmomanometers and replaced them with both aneroid and electronic devices.

About the alternatives used in Poland: The electronic devices are more durable, can record results and do not depend on the experience of the person doing the measurements. There are two different types of electronic devices: wrist and fingers. These two devices do not comply with the BHS criteria. Therefore these devices can only be applied for home use. In the professional health care there is a solution that is often used: there is a possibility to use the Korotkoff technique in electronic devices. Mercury-free sphygmomanometers use a liquid crystal display instead of a mercury column and instead of a mercury manometer it uses a pressure dial. This solution is recommended by the polish institute for cardiology and it is very popular in Poland now.

In order to meet the criteria for hypertension measurements and in order to get suitability for clinical practice, the alternatives should be validated. In Poland the validation is done according to European standards. The devices are also calibrated. The calibration is performed against non-mercury reference manometers which are calibrated by the Central Office of Measures every two years.

In comparison to mechanical manometers, mercury sphygmomanometers are 3 or 4 times cheaper. Compared to electronic sphygmomanometers, mercury sphygmomanometers are 2 times cheaper in Poland. However, there are many advantages of electronic devices: they are more durable, can record results and do not depend on the experience of the person who carries out the measurement. The polish government has not conducted an economical analysis of a replacement of mercury sphygmomanometers with mercury-free ones, but in our opinion this is economically feasible. The Ministry of Health forecasted that the complete replacement can be expected by 2010.

11. Swedish Policy for a Mercury Free Environment

(Presentation by Ulla Falk, Senior Technical Officer, Swedish Chemicals Agency)

In the 1950s and 1960s there was research done in Sweden to see how mercury was transformed into different kind of components and how these components were distributed in the environment. Swedish people have long been aware of the risks of mercury, such as the risks involved if a thermometer is broken.

Due to the discovery of high levels of mercury in certain lakes in Sweden, there was a ban on the sale of fish from these lakes in the early 1970s. Twenty years later this had been further investigated and the national food administration recommended pregnant women to not eat certain fish species from fresh water. The rest of the population was recommended to eat fresh water fish only once a week.

In the 1990s the Swedish EPA was commissioned by the government to carry out some programs in order to see the state of the art of heavy metals in the marine environment, fresh water environment and the air. It was discovered that the levels of mercury in soil were 3-5 times higher in forests and arable fields. There were also increased levels of mercury in fish in lakes and also in some coastal areas in the Baltic Sea. The limit value set by the WHO and FAO was exceeded in half of the 100.000 lakes in Sweden. This means that 50.000 lakes contained mercury levels that exceeded the limit value. Further, it was estimated that Sweden emits 0,7 tonnes of mercury per year. There is a deposition of 4,2 tonnes per year originating from other regions of the world. It was concluded that Sweden had to reduce the deposition by 80% to reach safe levels. In order to do this it was evident that international action was needed. It is not only Sweden that has these problems – there are many regions in the world which may have even bigger problems than in Sweden.

The government concluded that there had to be a reduction in emissions and in 1992 a new regulation was put in place. It is the Swedish experience, that if you want to phase out a substance, a regulation is a vital basis for the work. Of course you can also work in parallel in other ways with voluntary elements and campaigns and project and so on, but as a basis, a legally binding instrument is very important. This regulation stated that measuring instruments – and then it was all kind of measuring instruments (including those in the health care sector) – and electrical components containing mercury may not be manufactured or sold in Sweden. These articles or goods may not be exported to third countries or imported to Sweden. Five years later it was added that mercury and its components may not be exported from Sweden. This is very important because once you export mercury or mercury containing articles to other parts of the world; you also export the mercury problem to the country.

Sweden knew that there was a hidden stock of mercury in the society but did not know where and in what amounts. The communities employed competent electricians who went out in the society and visited schools and business places and identified equipment or components containing mercury. Then they put a label on it so people knew that if this component was broken it had to be taken care of in a proper way.

There was another project where two dogs were trained to sniff out mercury; they were extremely effective and found mercury where you could not see it. They found it in water tubs, in sinks, etc. The dogs went through all the schools in Sweden and not only found mercury in the chemical store rooms but also in small cracks in the wooden floors in the class rooms. Mercury was found in many different places that you are not aware of, which is a bit scary. All the mercury that was in the laboratories in the schools was collected and taken care of properly. There was also a campaign where people could go to a pharmacy – for a period of 5 years – and bring their mercury containing fever thermometer and get a mercury-free one instead for free.

The speaker emphasized that in Sweden they are not prepared to risk the lives of people just to get a better environment – that is not the case. Thus, when the transition took place to alternative technologies they were examined first that they in fact function well. When the ban was introduced on measuring instruments, there was close contact with experts, especially with the Swedish Society for Clinical Physiology. Hospitals in Sweden started to phase out mercury containing instruments without the legally binding instrument because they were aware of the risks and therefore did not want them in the hospitals.

The phasing out of mercury sphygmomanometers started in the 1980s and is completed in Sweden since many years. Sweden now uses mainly aneroid sphygmomanometers for all kinds of measurements. The Swedish doctors have no negative experience at all – they are all positive. In 2004 the Chemicals Agency was commissioned by the government to investigate whether a general ban was possible in Sweden. Half a year later the Agency reported that it is possible. Since 1 June 2009 Sweden has a general ban on mercury, saying that:

"*Mercury, mercury compounds and preparations containing mercury shall not be placed on the Swedish market, used or exported from Sweden*" and "*Articles containing mercury shall not be placed in the Swedish market or exported from Sweden*".

This ban cannot target products that are within the scope of EU legislation which is the case e.g. for the RoHS directive on electrical and electronic equipment. However, what is not covered by EU legislation is covered by the Swedish ban.

There is a report on KEMI's website which discusses the alternatives to mercury containing blood pressure measuring instruments[14], as well as several other reports on mercury – also in English.

[14] www.kemi.se

12. UK concerns on mercury device restrictions

(Presentation of the UK position- slides as sent by DEFRA (Department for Environment, Food and Rural Affairs, UK)

The UK is not wedded to mercury measuring devices for healthcare and has reduced their use in recent years. However, mercury sphygmomanometers should be available for clinical validation purposes and used by clinicians when automated oscillometric blood pressure monitors are inappropriate. For example, in arrhythmias, pre-eclampsia and certain vascular disease cases.

It is well known that automated oscillometric blood pressure monitors are not appropriate for all patients, particularly those with arrhythmias, pre-eclampsia and certain vascular diseases; in these patients there is a change in the haemodynamics from the norm and algorithms used to calculate systolic and diastolic blood pressures are of unknown accuracy. Clinical validation protocols generally select patients with hypertension, but are otherwise normal. This means the majority of blood pressure measurement devices on the market have not been validated for use with patients from special groups.

The current advice from the Committee on Blood Pressure Monitoring in Clinical Practice is to use auscultation (manual sphygmomanometer) or arterial cannulation in those clinical conditions where oscillometry is inappropriate. In general, this means that either a mercury or aneroid sphygmomanometer should be used in this situation. However, it is well known that aneroid sphygmomanometers drift out of calibration and the user is unaware of this. There is evidence to show that calibration of aneroid gauges is often neglected.

Mercury sphygmomanometers are also used as the reference device for these clinical validation protocols (EN 1060-4, British Hypertension Society protocol and ANSI/AAMI SP10); validation is required as part of the CE marking process. New draft international standards do not specify reference device. Validation trials can last several months and problems may occur if aneroid sphygmomanometers are used -they drift out of calibration with the user unaware.

Further, displays of digital gauges are difficult to read as the numbers are continually changing during cuff deflation and the ergonomics associated with freezing the display at the correct points are different, leading to errors. An international consensus is required for the reference device to ensure results are comparable.

It is expected that the demand for mercury sphygmomanometers in the UK to continue to decrease as their use is governed by COSHH Regulations (Control of Substances Hazardous to Health). However, clinicians should have access to the device that is most appropriate for their needs.

Discussion

- The European Commission commented that it would have been good to have a clinical study or a long term study which shows that there has been either a decrease in patient mortality or and increase in patient mortality or no change. At present it is unfortunate that no such monitoring study has been made in countries that have phased-out Hg spygmos since many years ago (e.g. Sweden).

- EEB argued that as we saw from the study of Professor Orris (WHO CC, UoI), many countries have actually done the change to mercury-free sphygmomanometers on the ground with no problems. There is a need for more scientific data. However, if it is already happening around the world then we have to meet reality somewhere.

- The validation expert from the Hypertension Center, University of Athens commented that the

majority of blood pressure monitors are being used by patients at home, and the guideline by the European Society of Hypertension is that these should be electronic. Thus, the vast majority of blood pressure monitors in the community are electronic. He further pointed out that the best method to assess blood pressure is using 24-hour ambulatory blood pressure monitoring, which also is almost exclusively performed using electronic devices. Therefore, what is left are the office measurements. It is debatable whether time has come to ban mercury devices only or get rid of the auscultatory technique altogether. He noted that the auscultatory devices are problematic in the office (due to poor performance of physicians in applying the auscultatory technique), therefore a change should take place which is not only necessarily related to mercury.

V. Technical Panel Discussion

Are Hg sphygmomanometers needed for calibration? Are there special cases were Hg sphygmomanometers are still needed? Are non-mercury devices validated?

13. Perspective by a mercury-free hospital

(Presentation by Dr Heikki Terio, Research Manager, Karolinska University Hospital)

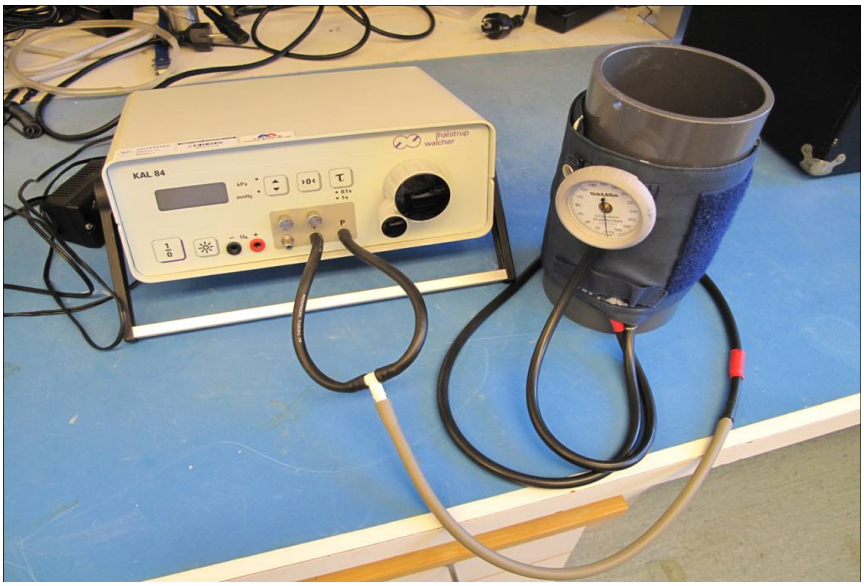
The speaker is a medical engineer and has been working in hospitals since 1983. Karolinska University Hospital is one of the largest in Europe. It has 1700 beds and 1,3 million visits per year. There are different quality systems – one of which is used in the clinical physiology which is certified by the Swedish Board for Accreditation and Conformity Assessment (SWEDAC). According to the certification Karolinska University hospital has measurement methods which are accredited and the Swedish authorities control these systems. They have the international norms which are used by the Swedish authorities for calibration. These are used to calibrate their own main norm in their hospitals. This working norm is used weekly or when it is needed to calibrate the actual aneroid blood pressure equipment or the automatic equipment. The accreditation that is used is ISO 17025. Karolinska hospital has the following measurement quantities that are accredited for:

- Mass
- Photometry
- Temperature
- Rotation velocity of centrifuges
- Pressure

During a static calibration of an aneroid blood pressure instrument, there is a check of tubing and of the manometer and also a leakage test. It takes about 30 minutes and costs about 30 Euros – these are internal costs of which the clinic is charged for.

In the hospital there is a certain procedure to calibrate the main norm, going from 0 to 300 mm of mercury and then again down from 300 to 0. There should be control tags when it is calibrated and when it needs to be calibrated again and this should appear in the inventory system. These systems are calibrated by external companies or the Swedish authorities. The procedure is almost the same as the one that is used for the working norms.

The calibration of the automatic or the electronic blood pressure measurement equipment is conducted in the same way. The difference is that there is a certain pulse rate that is used and goes on several levels to the systolic and diastolic pressures so that one can control that the algorithm that it really works and gives the right answer. Of course the pulse rate can also be changed, which means that it is possible to simulate arrhythmia cases.



Calibration of blood pressure machine

14. Manufacturer's perspective

(Presentation by Thomas Grant, Director, Regional Category Management, Welch Allyn, producer of Mercury-Free Sphygmomanometers)

Three questions will be addressed:

- Are there special cases were mercury sphygmomanometers are still needed?
- Are non-mercury devices validated – specifically aneroids?
- Are mercury sphygmomanometers needed for calibration?

What are the relative advantages of mercury free devices? Taking blood pressure is a system – it is not just the manometer. As the American Heart Association suggested in a task force around 1990, the errors derive from:

- faulty equipment
- observer bias
- the failure to standardize measurement technique.

What are the potential causes for error? There is a lot of confusion around this point.

Mercury is not a magic pressure meter. It is possible to get errors with mercury if the mercury is not at zero level or if the column is not vertical. Further, the manometer needs to be at eye level to prevent error due to parallax effect. Mercury manometers often suffer from lack of regular maintenance and can introduce error due to plugged filters and oxidized mercury.

Aneroid devices are also subject of error if they go out of calibration.

Automated devices have their own issues. For example, patient movement can be problematic, especially for devices that are of lower cost/quality. Further, loose cuff applications and user techniques are sources of error. Arrhythmia, pre-eclampsia can also cause errors.

Other causes of errors that are not specific to the technology itself are:

- Technique error: Inadequate training, patient position, cuff sizing and application, digit rounding, deflation speed. The largest errors come from humans.
- Equipment condition: Leaking cuff, tube, bulb or valve. Poor stethoscope sound quality.

What are the advantages of the different technologies and why have they been used for so long?

Mercury

- is a simple system
- it is accurate to +/- 3mm of mercury which is adequate for diagnosis
- it uses the auscultatory technique which allows diagnosis even in the case of arrhythmia and other special conditions
- it is a relatively low cost technology

For aneroids, similarly, they are:

- accurate to +/- 3mm of mercury
- it is mercury free
- the dials can be larger than use in a mercury column
- have the flexibility that it can be held close to the face for legibility
- it also uses the auscultatory technique
- it is also at a relatively low cost.

Automated devices:

- are mercury free
- are generally less accurate – about +/- 4mm
- Have the great advantage of reducing user technique errors. If you take the human factor out you can get more accurate readings, especially over a patient population. On a individual level there are always going to be cases where you may need to do a one-on-one physician auscultatory technique but when you are talking about general mass screenings you get more accurate results by using an automated device.
- have the advantage of using less-trained personnel. This can be a real advantage in areas that are developing and do not have as many physicians or trained nurses – or, for example, in the home.

In conclusion about the technologies: every technology has the potential to introduce error – especially if not properly maintained. High quality aneroid and mercury technology are both equally accurate – they are both +/- 3mm. Where labor is expensive and/or access to well trained personnel is limited, an automated device might be the best device.

Thus, the answer to the first question: Are there special cases were mercury sphygmomanometers are still needed? is: no.

The answer to the second question "Are non-mercury devices validated – specifically aneroids?"

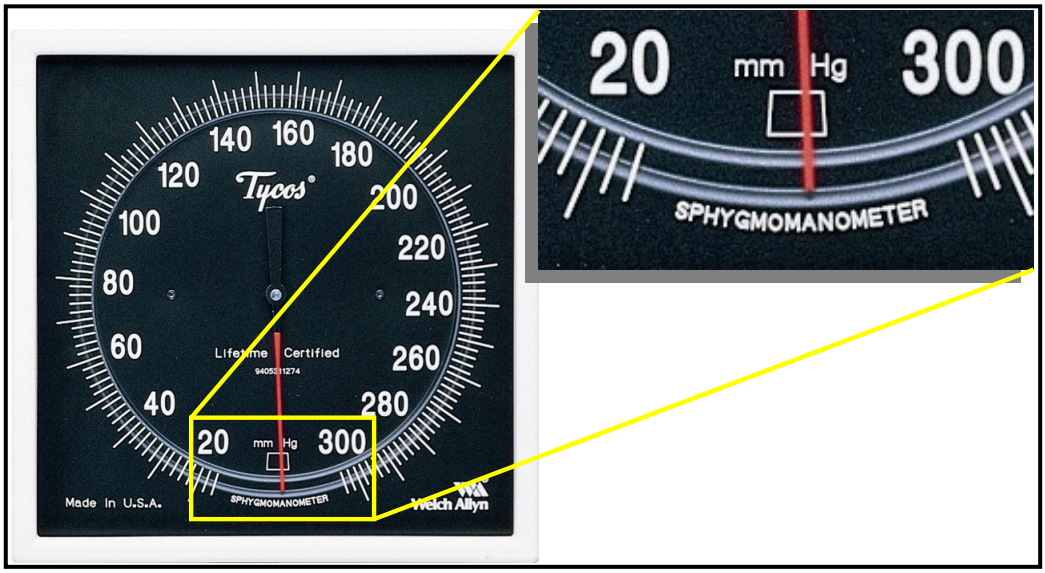
One thing to keep in mind is that there is a wide range of quality among these devices. There are big differences in quality depending on the manufacturer. There are a lot of low-cost, low-quality devices on the market. The same is true for digital devices: they range in quality from very low-cost home devices to very expensive ($10,000+) devices that you find in the hospitals. These devices all have varying degrees of capabilities and quality and they should not be thought of as being the same. All Welch Allyn brand devices are validated.

Several studies have been done that prove that aneroid technology is equal to mercury technology in terms of accuracy. Standards exist for the development of these technologies. Thus, for the question: Are non-mercury devices validated? - the answer is "yes".

The answer to the questions: "Are Hg sphygmomanometers needed for calibration?" The important thing to know when calibrating is that the error is additive. For example: a mercury column could replace the digital gauge, but the accuracy of that device is +/- 3mm Hg. The accuracy of the aneroid is +/- 3 mm Hg. If that is added together you can only test to +/- 6mm Hg which is not adequate. Manufacturers need their devices to be +/- 3mm Hg. Welch Allyn tests with extremely sensitive digital pressure meters and manufacture to +/- 2 mm Hg, so that when it goes out in the field it ensures +/- 3 mm Hg. Thus, when you are re-calibrating gauges with a digital pressure standard that is 0,1 mm Hg – then your total error can only be +/- 3,1 mm Hg maximum.

Aneroid sphygmomanometers – at least those who meet the standards – are all required to have this +/- 3 mm Hg of zero scale.

A study done in 1970 by Perlman et al, showed that if a gauge read zero at no pressure – 89% of the time it will be within the accuracy of +/- 3 throughout the whole scale. Therefore, this is a "quick check" of calibration, see picture below.



Check of calibration

Training and awareness are very important. The fact that clinicians think mercury is fail-safe and that it is always accurate no matter what – is a fallacy. Some clinicians think that an aneroid is accurate no matter where the needle is at zero pressure – that is a fallacy. There has to be a certain level of awareness, professionalism, and understanding about the equipment and technique you are using in order to get accurate measurements.

In conclusion, are mercury sphygmomanometers needed for calibration? The answer is: No.

15. Clinical doctor's perspective

(Presentation by Professor Peter Orris MD, University of Illinois, WHO Collaborating Center in Occupational and Environmental Health)

It is a misnomer that mercury sphygmomanometers are used for calibration – that is not their purpose. Mercury manometers can be used for calibration. There is no evidence that this is more accurate, in fact there is substantial evidence that it is less accurate.

Mercury sphygmomanometers are cheaper than the other alternatives. However, if you look at the

lifetime of the devices, it is not a significant factor when you are talking about health care in Europe. We can get rid of the mercury and the environmental issues involved. There is no application that you need mercury sphygmomanometers for and there is no use for it in calibration. In other words, from a purely technical point of view mercury sphygmomanometers should be removed.

16. Validation expert's perspective

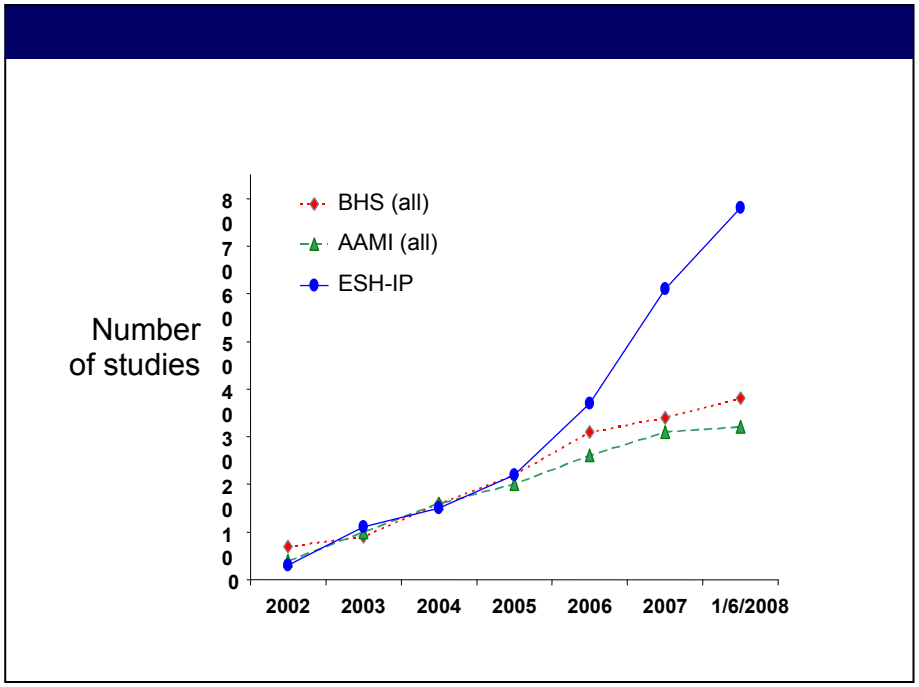
(Presentation by Dr. George S. Stergiou, MD, Associate Professor of Medicine, Hypertension Center, Third University Department of Medicine, Sotiria Hospital, Athens, Greece)

The speaker clarified that he is a doctor, performs validation studies and is involved in the development of validation protocols.

What does a "certified" blood pressure monitor mean? Blood pressure monitors are medical tools and deserves proper validation through the scientific community. Validation means that it fulfills one of these three protocols:

- AAMI Protocol (1987, 1993)
  American Association for the Advancement of Medical Instrumentation
- BHS Protocol (1990, 1993)
  British Hypertension Society
- International Protocol (2002, 2009)
  European Society of Hypertension Working Group on Blood Pressure Monitoring

A recent review of validation studies[15] showed that since 2005 the International Protocol has been used the most mainly due to its simplicity.



Validation studies performed according to ESH-IP, BHS and AAMI protocols (since ESH-IP publications 2002)

A validation procedure requires nine sequential measurements – two observers with mercury devices connected to each other (simultaneous measurements) to give 5 pairs of measurements and

[15] Stergiou G, Karpettas N, Atkins N, O'Brien E. Blood Pressure Monitoring 2009, in press.

a supervisor takes 4 measurements using the tested device in-between the sets of the observers' measurements. Patients are selected according to gender, age and blood pressure levels.

Particularly for the electronic (oscillometric) devices, further to the validation in the adults separate validation studies are needed in special populations, such as children, pregnancy, eclampsia, elderly and arrhythmia (particularly atrial filbrilation). In all these areas there are positive preliminary data with electronic devices, yet more information is needed.

A revised version of the European Society of Hypertension International Protocol will be in effect in January 2010. The revised protocol will have the most stringent criteria for device accuracy. Developments about validation studies can be found at www.dableducational.org. At present there are 18 accurate non-mercury devices for office measurement by the doctors, 69 for self-measurements by the patients at home, and 22 for the ambulatory monitoring. The picture below shows a non-mercury alternative device.

Accoson Greenlight 300. The first non-automated mercury-free blood pressure measurement device to pass the International Protocol

The answer to whether mercury sphygmomanometers are needed for new device validation is:"Yes". Currently, it is not possible to validate without mercury. However, mercury devices are only needed in a limited number of research centers around the world, which should be accredited to conduct delicate validation studies. The European and the British Society of Hypertension are looking now on criteria to accredit the validation centers. Alternatives of mercury devices for validation studies are also being examined. However, for the moment mercury is still needed. For example, a mercury-free non-electronic auscultatory device has the potential to be used in future validations.

It is a misconception that you can't measure with a "digital" screen with auscultation. It has been tested and published that it works, it is just a matter of observers getting used to it.

The answer to the question: are mercury-free auscultatory devices still needed? It is agreed that they are still needed at least in some cases (e.g. arrhythmias).

What is calibration? It is being used to mean to "check the accuracy of a device". It is also being used to mean "correcting, namely diagnose and repair the error". In this discussion calibration means only checking. In fact a mercury device cannot be used to calibrate electronic monitors; this

is difficult because the deflation rate of the electronic device is uncontrolled and usually too fast. Also, some device measure blood pressure during inflation. Thus, even if a mercury device is available, it can´t be used easily to calibrate an electronic device.

What is the purpose of calibration? Calibration is needed to ensure that the device retains its standards, and this procedure should be performed electronically.

The manufactures have designed the electronic devices for the life of up to 35.000 measurement cycles for home use and up to 100.000 cycles for office use. It appears that in long-term use these devices are more reliable than expected. There is a recommendation by the ISO (International Standardization Organization) that manometric checks should be performed every two years.

Another issue is that electronic devices measure blood pressure automatically – systolic and diastolic. They use a manufacturer-specific algorithm, which can not change because it is a software. It is installed in a micro processor and either works or not. It can not distort measurements. It either takes an accurate measurement or no measurement at all, exactly as it is the case with your electronic watch: it will not go five minutes forward. Thus, it is extremely unlikely that because of shock or temperature the algorithm will affect the measurement accuracy. The conclusion is that the algorithm is not a subject to calibration.

The electronic devices have accuracy problems related either to manometric error or to the companion components. In practice the manometric error does not appear to be an issue. There are published papers showing that even after a long-term use the manometric error is quite rare. What is quite common is the malfunction of cuffs, tubing and valves. How can these errors be checked? First, the electronic device will be able to tell you that there is a problem by giving an error sign. Second, low cost portable devices - which should be available in all hospitals - are able to check the manometric accuracy. The adjustment of a device requires more complex equipment and should be performed by the manufacturer.

Conclusion
- Electronic devices are more reliable than expected – even in long term use.
- Auscultatory mercury-free devices are currently needed in specific patient groups (arrhythmia, etc). However, in the future this might change.
- At present, the validation of new blood pressure monitors should be performed using mercury devices, until another reliable solution becomes available.
- Mercury devices are not needed for calibration. Manufactures should be pushed to give simple calibration methodologies to be widely available.

Panel discussion on calibration, validation and special cases

- The validation expert from the Hypertension Center, University of Athens commented that there are around 20 centers around the world for the validation studies and at present they need to use mercury. Currently, all the three validation protocols (American, British and European) accept only mercury as a reference. More research is needed to find reliable alternatives of mercury for validation. However, having mercury devices existing in only 20 scientific centers is not as bad as having mercury sphygmomanometers in every hospital.

  He further clarified that mercury devices do not need validation. It is the standard and reference. They only need maintenance and if they function well and with open bulb show at the zero point they are accurate.

- EEB commented that if the validation protocols changed in the future then the mercury-sphygmomanometers for the validation centers would not be needed.

- The validation expert from the Hypertension Center, University of Athens explained that the validation procedure allows a certain level of inaccuracy. Thus, the accurate devices are accepted to have a certain level of inaccuracy. This is the level of accuracy that is currently acceptable. In considering about replacing the mercury and use another reference (for validation), then a set of other more stringent criteria need to be established to ensure accuracy – but this has not yet been done. More research is needed to find reliable substitutes of mercury for validation studies. These will require extensive testing before being applied.

  He further clarified that all the evidence we now have about what is high blood pressure, what is the association with risk and what are the benefits of reducing blood pressure with treatment, have been mainly based on mercury device taken measurements - so this is the standard.

- Welch Allyn commented that the idea of mercury devices being more accurate than a well-maintained aneroid device is a fallacy. Typical mercury sphygmomanometers are accurate to +/- 3 mm Hg; mercury gauges are not more accurate than +/- 3 mm Hg unless designed with more resolution on the meniscus (although more rare today, higher resolution mercury devices can sometimes be found in test labs and are used mainly for calibration). Mercury is not an infallible standard – it is a simple pressure gauge and it is capable of error as well as any other pressure gauge.

- The validation expert from the Hypertension Center, University of Athens pointed out that one should clarify the difference between blood pressure "measurement" and blood pressure "assessment". One is: which is the instrument that tells me exactly what is the blood pressure level in the artery right now. And the other – the problem we have as doctors: what is the "usual" blood pressure of this individual, in general. Thus, one might obtain an accurate measurement but a completely wrong assessment. But if one has a wrong measurement from the start, then the assessment will also be wrong. So these are the different issues – but both should be taken into account.

- The European Commission, DG ENTR noted that validation is required as a part for the CE marking process for blood measuring devices in order to demonstrate compliance with the essential requirements of the Medical Devices Directive – so if one accepts that mercury based sphygmomanometers are essential as reference devices for clinical validation protocols then there is an issue here that needs to be clarified following consultation with SCENIHR.

VI. Other measuring devices

18. Other Mercury Containing Devices or Applications of Concern

(Presentation by Peter Maxson, Concorde East/West)

Other measuring devices that contain mercury should perhaps be further considered.

There are a number of measures of what should be a priority in terms of future regulation:

– Quantity of mercury consumed by the device
– Dispersal of mercury during use (before disposal)
– Availability of alternatives
– Cost of alternatives
– Extent of recycling with regard to a specific use
– Relevant waste management issues
– Economic, environmental and social impacts of phase-out compared to business as usual

The big question with many other devices, and until fairly recently with sphygmomanometers as well, is: How much information do we really have with which to make these decisions?

In the data that was gathered for the 2008 COWI/Concorde study for DG Environment, it was discovered that the consumption of mercury in measuring equipment is 7 to 17 tonnes, see table below. Most other mercury uses are already regulated in some manner except chemicals. Within "miscellaneous uses," there is a large range of mercury consumed: between 15 and 114 tonnes per year. This is largely because of the uncertainty in so many of the items that are included in this total. However, in this 15-114 tonnes, about two-thirds of it or more appears to be consumed in porosimetry and pycnometry.

Chlor-alkali production	160 - 190
Light sources	11 - 15
Batteries	7 - 25
Dental amalgams	90 - 110
Measuring equipment	7 - 17
Switches, relays, etc.	0.3 - 0.8
Chemicals	28 - 59
Miscellaneous uses	15 - 114
Total (round)	320 - 520

EU27+2 mercury consumption in industrial processes and products (tonnes/year) - 2007

Porosimetry is a major mercury user. The purpose of porosimeters is the measure of the porosity of a sample – that could be sintered filters, catalytic converters, fuel cells, bone replacement materials, ceramics, etc. The advantage of mercury is that it is a fast, reliable technique covering a wide range of pores from 0.003 µm to 400 µm.

There are various alternatives, but none is ideal for certain substances and/or certain pore sizes. Further, as in the case of sphygmomanometers, there are certain validation standards that would also have to be revised in order to move away from mercury porosimetry. After testing, about 4% of mercury remains in a typical sample, the rest is recovered for re-use by the company that is doing the testing. That means that over a period of time, testing 25 samples, you use 100% of your quantity of mercury in the machine. The question is what happens to the mercury that remains in the samples. Industry assures us that it is possible to recycle 100%. Due to the fact that this process is normally done in research labs, one would hope that a high rate of recycling is carried out – but there is no information to confirm that. For the research that was done for the 2008 COWI/Concorde study for DG Environment, there was an estimation of 25-30% of recycling in addition to a certain amount of mercury in samples that goes to final disposal – for example in salt mines in Germany. However, there is little real data to back up these numbers.

Looking at the other miscellaneous uses that were mentioned in the report, there were some mentions of esophageal dilators and gastrointestinal tubes that in the past frequently contained

mercury. This is an area where more information is needed. Also mentioned in the report are mercury vacuum pumps or displacement pumps. There are some reports of some of the former eastern European countries that have joined the EU that there are such pumps still in use in research areas in different parts of the EU. Again it is an area where there should be more research to see whether these applications remain, and whether something should be included in future regulation.

19. Mercury electrodes: Important applications of polarography and possible mercury-free alternatives

(Presentation by Uwe Loyall, Manager Competence Center Voltammetry, Metrohm International, Manufacturer of Polarography)

Polarography is an electrochemical analytical technique which is used in chemical labs, in universities, in industry. Metrohm uses mercury as a sensor electrode. Voltage is applied, and currents are measured to this sensor. It is mainly used to determine toxic traces and low concentrations of heavy metals such as lead, cadmium, chromium or mercury.

The center of the whole device is a glass vessel and three electrodes immersing in this glass vessel, including the mercury sensor. The mercury electrode is a glass capillary, from which a small mercury drop is extruded. In the glass vessel the sample we want to analyze is introduced. At the end of the determination the mercury drop falls off to the bottom of the vessel and from there it can be collected at the end of the measurement.

Filling of the electrode is typically 6 milliliters which is approximately 80g mercury. Under normal circumstances this will last for half a year to one year of every day use. Based on the consumption of mercury and estimated number of polarographs worldwide we assume that the total consumption is about 250 to 350kg worldwide.

Modern mercury drop electrode

All these mercury can be collected and recycled so there is no spill and no leakage of this mercury in the environment.

From a (mercury) life cycle perspective of the user: the mercury is purchased from a supplier, it is used in a lab, collected in a close container and finally returned to a recycler.

Alternatives: the technique is used for the determination of heavy metals. There are other techniques existing that have a similar application. They are either non-electric techniques – for example optical/spectroscopic techniques – or other sensors (with reduced mercury content or completely mercury-free sensors) using similar principals of measurement as polarography.

There are spectroscopic techniques that are very well established, which are usually the standard techniques in most of the labs worldwide. They are good for the majority of application. However, there are some limitations:

- Only total element concentration detection.
- High investments (purchase, running)
- Problems with some sample matrices (e.g. sea water, pure chemicals)
- Limited mobility
- Laboratory infrastructure required

Besides liquid mercury as a sensor there are other sensors existing, some of them are commercially available and some others are still in a research state. Typically they are based on carbon or on noble metals like gold or platinum. These sensors have quite severe restrictions – this is why most of them are only used in research fields and not in routine. If we look into industry we have nearly no users using such sensors because of the restrictions. Their advantages are that they can replace some mercury applications and they are sometimes even more sensitive than the mercury sensor. However, the most important restriction is that they are not as robust as the mercury sensor, so when it comes to reliability the classic electrode is better. The alternative sensors need more maintenance, show more interferences, require more operator skills and sometimes the alternatives even contain toxic metals like mercury.

About two thirds of Metrohm's users use mercury electrodes. Within these two thirds, half are for environmental control and in universities and the other half is used in the quality control in industry. A third of all of Metrohm's users use applications without any mercury electrode. It is expected that this part will increase in the future and the users of mercury will decrease because improvements of the quality of the alternative sensors. However, at the moment it is not possible to replace all these applications by mercury free sensors.

With polarography it measures mainly toxic heavy metals and also other electro chemically active substances but the main focus are heavy metals in:

- Environmental samples
  River, ground, sea water
- Biological samples
  Plant, animal material
- Industrial samples
  Impurities in pure chemicals (production control in industry)

In approved applications, only very few elements can be determined without any mercury. Speciation is quite important so it is important to know which chemical form the toxic chemical has. Since some forms are more toxic it is important to estimate the implication of the toxic metal on the biosphere. Polarography is one of the few means that can answer questions like that. With polarography it is possible to then assess how mobile the heavy metals are, do they stay where they are, do they move down a river, etc.

There are some alternative techniques. They are usually quite expensive because they couple a separation technique together with a detection technique. Furthermore, they can not answer all the questions. There is one application where there is so far not any alternative, the so-called complexation capacity. This is an application that characterizes the capability of natural waters to form heavy metal complexes. This parameter can be used to estimate the degree of bioavailability, thus the toxicity, of the heavy metals that are present in the water of a particular lake or river. Polarography can be used to answer such questions.

Polarography is also very widely used in sea water analysis because here the high salt concentration does not interfere in contrast to other techniques. Industry uses polarography in a few applications because the alternative techniques show severe problems.

Summary

- Polarography is a highly sensitive method for trace metal analysis
- It allows metal speciation which is not possible with standard alternative techniques
- Polarography has some unique applications in environmental research and industry
- Modern instruments use significantly reduced amounts of mercury
- The mercury can be recycled 100 %
- Metrohm assumes that the annual world-wide consumption is max. 350 kg

20. Views on other measuring devices from a Member State - Denmark

(Presentation by Frank Jensen, Special advisor, Danish EPA)

Denmark has a general ban on mercury since 1994 which covers mercury in its metallic form and its chemical compounds. However, it does not cover everything: there has to be more than 100ppm in the product. Denmark has experienced no problems with this mercury ban.

Exemptions:
- Used products or products in use are exempted from the ban, so that it is possible to continue to use them until their end of life
- Products regulated by other legislation.
- Products for research. For example, porosimeters which is only used by the national environmental institute
- Products for teaching (not for schools)

Thermometers and barometers were not allowed in industrial use but due to the interpretation by the Ministry of Justice, Denmark has lifted that ban hoping that the coming legislation of the European Commission will take care of this. There is a possibility in the Danish legislation to allow derogations but there is no application for the industrial use.

Discussion on other measuring devices

- The European Commission informed the audience that they have requested more information about the actual rate of recycling from the key manufacturers of porosimetry. Industry has to contact their EU customers (users of porosimeters) in order to distribute specific questionnaires (with feedback on the amount of Hg they used, recycle, dispose as waste etc. on annual basis as well as the associated costs) which should be filled and sent directly to EC for their further analysis. Therefore, in early September, the EC will have a better idea of the recycling level of mercury used in porosimetry to consider for the purposes of the review report.

- MICROMERITICs, a porosimeter manufacturer, commented that 100% of the mercury in the

porosimetry process can be recycled if this is done correctly.

- A recycler (specialized on mercury waste) confirmed that that the process of recycling mercury from porosimetry is a closed loop and 100% can be recycled. It is cleaned and given back to the customers. The amount they receive is differing between half a kilogram up to 100 kg each year and company. The amount is depending on the amount of used instruments and the using-frequency. The process is a closed loop in Germany and can therefore become a closed loop in Europe.

- European Commission, DG Enterprise confirmed that the EC is doing their best (through extensive consultation with all interested parties and with the upcoming opinion of SCENIHR on feasibility of substitution of healthcare sphygmos) to increase the knowledge base for the remaining uses of mercury in measuring devices intended for professional and industrial applications.

VII. List of Abbreviations

Abbreviation	Meaning
AAMI	Association for Advancement of Medical Instrumentation
BHS	British Hypertension Society
COCIR	European Committee of Radiological, Electromedical and Healthcare Industry
DG ENTR	Directorate General Enterprise and Industry, EC
DG ENV	Directorate General Environment, EC
EEB	European Environmental Bureau
EC	European Commission
ESH	European Society of Hypertension
EU	European Union
Hg	Chemical sign for Mercury
RoHS	Restriction of Hazardous Substances in EEE Directive (2002/95/EC)

VIII. Pictures from the meeting

(from left) Anna Lind (EEB), Peter Maxson (Concorde East/West), Doreen Fedrigo (EEB), Sotiris Kiokias (European Commission), Dave Osborn (COCIR/Philips)

Dave Osborn (COCIR/Philips)

Peter Maxson (Concorde East/West)

Paul Williams (Heart of England NHS Foundation Trust)

Jelena Stepule (Rezekne hospital)

Peter Orris (University of Illinois, WHO Collaborating Center)

Anna Lind (EEB)

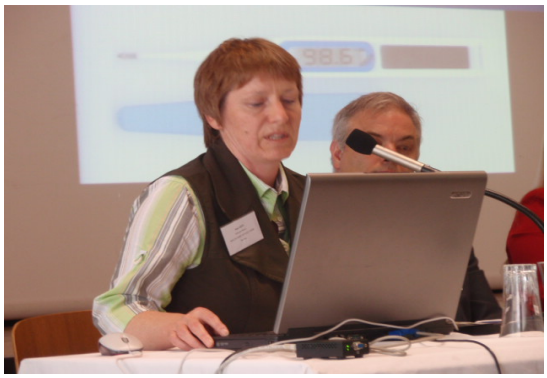
Desiree Narvaez (UNEP)

(from left) George Stergiou (Hypertension Centre), Heikki Terio (Karolinska University Hospital), Thomas Grant (Welch Allyn), Doreen Fedrigo (EEB), Peter Orris (WHO, University of Illinois)

Ulla Falk (KEMI), Agnieszka Dudra, (Bureau forChemical Substances and Preparations, Poland)

George Stergiou (Hypertension Centre)

General views of the conference, Goethe Institute, Brussels



Anja Leetz (Health Care Without Harm)

(from left) Heikki Terio (Karolinska University Hospital), Thomas Grant (Welch Allyn)

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Uwe Loyall (Metrohm)

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