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Mercury-free blood pressure measurement equipment

– Experiences in the Swedish healthcare sector

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Preface

This report summarises the experiences of using mercury free blood pressure equipment in the Swedish health care sector. The study has been performed by Kemi & Miljö AB on commission by the Swedish Chemicals Inspectorate.

The European Commission presented in January 2005 a Community Strategy Concerning Mercury, with the aim to reduce mercury levels in the environment and to reduce human exposure by e.g. reducing emissions and the entry into circulation of mercury in society. In this strategy actions are proposed to restrict the marketing for consumer use and healthcare equipment of non-electrical or electronic measuring and control equipment containing mercury, such as thermometers and sphygmomanometers.

Since 1992 thermometers and other measuring instruments containing mercury, such as blood pressure equipment, may not be commercially manufactured or sold in Sweden. This study was commissioned in order to contribute with Swedish experiences in the process to work out marketing and use restrictions at the European level.

Sundbyberg, November 2005

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Executive Summary

Since 1992 thermometers and other measuring instruments containing mercury may not be commercially manufactured or sold in Sweden. During the years the National Chemicals Inspectorate has granted exemptions for strain gauges. This study summarises the experiences of using mercury free blood pressure equipment in the Swedish health care sector.

All heads of department of clinical physiology in Swedish hospitals were contacted and asked to report their experiences from the phase out of mercury in blood pressure equipment. They were specifically asked whether the phase out had caused any increased risks for patients. Information was also gathered from other experts such as researchers, technical committee representatives, representatives from procurement organisations and manufacturers.

The different methods for measuring blood pressure are described as well as their respective pros and cons. The study also describes where the equipment is manufactured, assembled and marketed.

The following experiences of using mercury free blood pressure equipment were found:

- There were only positive experiences reported from the phase out of mercury in the most wide spread equipment called sphygmomanometers, which today is complete.
- No negative medical, practical or economic experiences were found from the phase out of mercury containing sphygmomanometers.
- There are no problems in diagnosing any condition using non-mercury sphygmomanometers including in the presence of arrhythmias, preeclampsia and in accelerated (malign) hypertension.
- Fully functioning, economically competitive, non-mercury plethysmographic equipment is replacing the mercury containing strain-gauge equipment that is used for measuring blood pressure in fingers, toes and other specialty areas.
- The speed of the phase out of the strain gauge plethysmographic equipment is dependent mostly on the life span of the products that are going to be replaced. The non-mercury replacement technologies are for many uses just as good with the exception of a few specified medical conditions.
- It is estimated that within 4-5 years non-mercury plethysmographic equipment will be validated for all areas of use of strain gauges, clinical as well as research use. There is probably no technical obstacle for using non-mercury techniques for all areas of use once the proper validation is in place.

Sammanfattning

Sedan 1992 får inte termometrar och andra mätinstrument som innehåller kvicksilver tillverkas eller säljas i Sverige. Under åren har Kemikalieinspektionen beviljat dispens för trådtöjningsgivare. Den här rapporten sammanfattar erfarenheterna av att använda kvicksilverfria instrument för blodtrycksmätning inom den svenska sjukvården.

Alla klinikchefer inom klinisk fysiologi på svenska sjukhus kontaktades och ombads rapportera sina erfarenheter från utfasning av kvicksilver i instrument för blodtrycksmätning. De tillfrågades särskilt om utfasningen hade inneburit någon ökad risk för patienterna. Information inhämtades också från andra experter, så som forskare, representanter från tekniska kommittéer, representanter från upphandlingsorganisationer och tillverkare.

De olika metoderna för blodtrycksmätning beskrivs liksom deras fördelar och nackdelar. I rapporten beskrivs också var utrustningen tillverkas, monteras och marknadsförs.

Följande erfarenheter av att använda kvicksilverfria instrument för blodtrycksmätning identifierades:

- Det rapporterades enbart positiva erfarenheter från utfasningen av kvicksilver i det vanligaste förekommande instrumentet blodtrycksmanschett (sfygmomanometer), vilken idag är fullständig.
- Inga negativa medicinska, praktiska eller ekonomiska erfarenheter identifierades från utfasningen av kvicksilverinnehållande sfygmomanometrar.
- Det är inga problem att diagnostisera något sjukdomstillstånd vid användning av kvicksilverfria sfygmomanometrar, inklusive störning av hjärtats normala rytm (arytmi), havandeskapsförgiftning och accelererande högt blodtryck.
- Fullt fungerande, ekonomiskt jämförbara, kvicksilverfria mätinstrument ersätter kvicksilverinnehållande trådtöjningsgivare som används för mätning av blodtryck i fingrar, tår och andra specialområden (pletysmografer).
- Hastigheten på utfasningen av trådtöjningsgivarna beror huvudsakligen på livslängden hos de produkter som ska ersättas. Den kvicksilverfria ersättningsteknologin fungerar för många användningar lika bra, med undantag för ett fåtal specifika medicinska tillstånd.
- Inom 4-5 år bedöms de kvicksilverfria pletysmograferna vara validerade för alla användningsområden där man idag använder trådtöjningsgivare med kvicksilver, kliniskt såväl som inom forskningen. Det finns troligen inga tekniska hinder för att använda kvicksilverfria tekniker för alla användningsområden under förutsättning att en utvärdering är genomförd.

Introduction

Background

The European Commission presented in January 2005 a Community Strategy Concerning Mercury. The key aim is to reduce mercury levels in the environment and to reduce human exposure by e.g. reducing emissions and the entry into circulation of mercury in society by cutting supply and demand.

In this strategy actions are proposed to restrict the marketing for consumer use and healthcare equipment of non-electrical or electronic measuring and control equipment containing mercury, such as thermometers and sphygmomanometers. The European Commission has also proposed a ban against mercury in some of those products such as thermometers.

Since 1992 thermometers and other measuring instruments containing mercury may not be commercially manufactured or sold in Sweden. During the years the National Chemicals Inspectorate has granted exemptions for strain gauges, currently valid until 31 December 2006. For use in health care no other applications has been applied for. This study summarises the experiences of phasing out mercury containing blood pressure equipment in Sweden.

The study was commissioned by the Swedish Chemicals inspectorate and was executed by the Stockholm based consultancy firm Kemi & Miljö AB during September and October 2005. Kemi & Miljö has more than a decade's experience with the phase out of mercury in the health care sector.

Objective

This study firstly aims to describe the different techniques and areas of use for mercury and non mercury blood pressure measuring equipment. The study also describes the current use of blood pressure and blood flow measurement equipment, the Swedish market for such equipment including the product's countries of origin. Manufacturing of blood pressure measuring equipment is a globalised business and therefore the Swedish market is to a large extent a reflection of the European market.

The study also maps the experiences from phasing out mercury in sphygmomanometers and strain gauges in the Swedish health care sector. The experiences from using mercury free products are screened.

During the mapping of experiences questions have been put explicitly to find the potential negative experiences from using alternatives to mercury equipment.

Screening Methodology

All heads of department of clinical physiology in Swedish hospitals were contacted via e-mail. They were asked to describe what problems, if any, they had at their clinics that were related to mercury free blood pressure measuring equipment. They were also asked if there were any situations where they saw the need for equipment containing mercury.

A total of 31 clinics were contacted. Of those 31 clinics all perform examinations that require sphygmomanometers (se explanation further down). Some but not all perform the type of examinations that requires plethysmographic devices (se explanation further down). Six clinics spontaneously answered the mail. Three of those heads of department of clinical physiology were interviewed as a follow up to their answers. They referred to experiences from their own clinic and experiences from other clinics around the country.

The secretary of the Technical Committee of the Swedish Association for Clinical Physiology supplied valuable material to the study and was interviewed. He in turn gathered information from experts and predecessors, people with long experience that know the implications of using mercury and non-mercury equipment.

The medical equipment industry was contacted through the Swedish Medical Equipment Suppliers Organisation. That led to further interviews with equipment developers, manufacturers and suppliers. Medical technicians at hospitals and researchers that are specialised in the area were interviewed as well as representatives from procurement organisations.

For several reasons the information gathered for this report can with good confidence be said to cover the collected experiences from the Swedish health care sector. The replies from the heads of clinics were very similar and none of them indicated problems related to the phase out of mercury. Also, the Technical Committee mentioned above serves as a representative for all practitioners of clinical physiology.

Finally, after the introduction of the ban in 1992 no other applications for exemptions for the use of mercury in health care have been applied for other than for the strain gauges that are studied in detail in this report. This means that there has not been any need to continue using mercury equipment for other areas that are not covered in this report.

Blood pressure measurement equipment

Technical description and areas of use

Blood pressure can be measured by using a manometer in combination with:

1. a reading of the pulse (the oscillometric and auscultatory techniques)
2. by measuring how limbs change in size at different pressures (the plethysmographic method)
3. or by detecting the blood flow (Doppler technique).

I addition, limb blood flow can quantitatively be measured using the plethysmographic method.

Below is a short description of the methods and the equipments that are used.

Sphygmomanometers

• Mercury - This includes a mercury manometer, an upper arm cuff, a hand inflation bulb with a pressure control valve and requires the use of a stethoscope to listen to the Korotkoff sounds, the auscultatory technique - mercury dependent.

• Aneroid - This includes an aneroid gauge (a device relying on the expansion or contraction of air in a metal tube), an upper arm or a wrist cuff, a mechanical dial or electronic display. The device may be manual, semi- or fully automated. Depending on type it may rely on the auscultatory technique or the oscillometric technique - mercury free.

Sphygmomanometers are used exclusively for blood pressure measurements.

Plethysmographic devices

The plethysmographic devices include an electronic monitor and a cuff. Oscillometric, Doppler, photo cell or strain gauge techniques are used for blood pressure measurements. Strain gauge plethysmographic devices are also used for pure blood flow measurements. In that case the devices measure variations in the size of an organ or body part on the basis of the amount of blood passing through or are present in the body part. The description below about strain gauge relates both to blood flow and blood pressure measurements.

The **oscillometric** method relies on a pressure sensor and a microprocessor in place of the ear and detects variations in pressure oscillations due to arterial wall movement beneath an occluding cuff. Mercury free. The oscillometric technique can be suitable for ankle measurements.

The **Doppler** technique uses the Doppler effect to measure the velocity of red blood cells to determine blood flow at different pressure conditions. There are ultrasonic Doppler devices for big vessels, or laser Doppler devices for small measurement volumes. Mercury free. The **photo cell** technique registers changes in tissue colour at different pressure conditions. Mercury free. The Doppler and photo cell techniques are typically used for measurements in fingers and toes.

Common for the oscillometric, Doppler and photo cell techniques is that they do blood flow readings while another part of the device applies pressure. This is different from the strain gauge method**.** The **strain gauge** technique registers changes in electric conductivity in a tube that is attached around an organ. Both mercury and non mercury techniques exist. Strain gauge are in some places still used for finger and toe measurements but is being replaced by Doppler and photo cell equipments. The mercury strain gauge technique is the only validated method for blood flow measurements for certain kinds of arteriosclerosis.

Pros and cons for equipment in use for blood pressure measurement

Equipment	Areas of use	Advantages	Disadvantages
Mercury Sphygmomanometer	Not used is Sweden	Transportable, well understood by users, can be used on most normal patients.	Contains toxic substance leading to waste management problems, can be prone to observer bias.
Aneroid Sphygmomanometer	Default method for blood pressure measurement. Upper arm measurements is the most common method.	Mercury-free, easily transportable, well understood by users, easy to check calibration, can be used on most patients. Semi-automated and automated devices have no observer bias.	Manual devices can be prone to observer bias. Wear and mechanical shock to mechanism may result in incorrect readings. Requires regular calibration check.
Device relying on oscillometric, Doppler or photo cell methods	Mostly used for finger, toe ankle and wrist measurements.	Mercury-free, easy to use, no observer bias. Designed for clinical use.	Replacement cost is likely to restrict immediate acceptability. Not fully validated for all clinical and research applications.
Mercury device relying on strain gauge method	The only validated method for diagnosing certain kinds of arteriosclerosis	Easy to use, no observer bias. Large reference material.	Contains toxic substance leading to waste management problems.
Non-mercury device relying on strain gauge method	Not yet validated method	Easy to use, no observer bias	Contains no toxic substance but not yet validated method

Market

Countries of origin

The blood pressure measurement equipment is manufactured all over the world. Germany has a large medical equipment industry and is one of the major countries of origin. In Sweden as in many other European countries the blood pressure measurement equipment is either imported as finished products or parts are imported and assembled into finished products. The aneroid (non mercury) manometers used in the sphygmomanometers are manufactured in many parts of the world including Germany and South East Asia (mostly China but also Japan and others). The oscillometric devises are almost 100 % Chinese. Tillquist Med estimates that in total 80 % of their equipment is sourced from Germany. [1]

As the strain gauge, Doppler and photo cell equipments usually are products of quite high technical complexity they have parts that come from all over the world. A substantial amount of the parts come from South East Asia.[2]

Availability at EU level

There are plenty of brands of mercury free sphygmomanometers that can easily be obtained from major medical equipment suppliers, i.e. Omron, BOSCH + SOHN GMBH, AC Cossor & Son (Surgical) Ltd, Welch Allyn Medical Products, W.A Baum Co. Inc., American Diagnostic Corporation, Heine Optotechnik GMBH, Rudolf Riester GMBH and Trimline Medical Products.

There is a smaller market for plethysmographs such as the strain gauge or equivalent non-mercury blood flow monitors using laser-Doppler. Manufacturers that have been identified in this study include Moor Instruments in the UK, Hakanson in the US, Perimed AB and Elektromedicin AB in Sweden[3].

[1] Lars Echkerblom, Henry Ericson AB, and Håkan Wallmo, Tillquist Med, personal communication 10 October 2005.

[2] Björn Bakken, Perimed AB, personal communication October 3rd 2005.

[3] Björn Bakken, Perimed AB, personal communication October 3rd 2005.

Experiences with mercury free equipment

General

Swedish hospitals started phasing out mercury sphygmomanometers in the 1980's and the phase out is complete. Since 1998 only non-mercury techniques are used for all upper arm measurements. Mercury sphygmomanometers are occasionally still discovered at smaller private practitioners. When these are found the mercury containing pipe has oxidised and dust has clogged the filter and made the equipment totally unfit for its area of use.[4]

While, the often semi automatic, oscillometric devices are widely used for routine blood pressure checks the aneroid sphygmomanometers are used for more precise diagnosing of medical conditions.[5] Both the oscillometric and aneroid devises are well functioning for their area of use. The overall experience in Sweden is that mercury free blood pressure measuring equipment does not cause problems in clinical diagnosis and monitoring[6]. Since the mercury free equipment has proven to be reliable there is instead a great satisfaction in having eliminated mercury.

Sphygmomanometers

There is no evidence in this study that the elimination of mercury in sphygmomanometers in Sweden has caused problems in diagnosing any condition. Semi automatic oscillometric devices are for practical reasons often used for a first screening. Aneroid manometers with adequate maintenance and regular calibration have proved to be well fit for routine but also precise blood pressure measurements. This is also valid when arrhythmias are present and in diagnosing preeclampsia and accelerated (malign) hypertension.[7] The only difference from the equipment containing mercury is an increased need for calibration. All blood pressure measuring equipment is recommended to be checked once a year and calibrated when necessary. There is no evidence that the need for checks and calibrations cause practical problems or diagnostic problems. There are no reports of problems or inconveniences related to the change in routines.

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[4] Lars Eckerblom, Henry Ericson AB, personal communication 10 October 2005.

[5] Lars Eckerblom, Henry Ericson AB, personal communication 10 October 2005.

[6] Heads of Department of Clinical Physiology at Danderyd Hospital, Växjö Hospital, Norra Älvsborgs County Hospital, Helsingborgs Hospital Östra Hospital and S:t Görans Hospital, personal communication September 29th- October 6th 2005.

[7] Urban Niklasson, Technical Committee Secretary of Swedish Association for Clinical Physiology, S:t Görans sjukhus, personal communication, October 5th 2005.

Other Peer-reviewed studies[8] show that electronic and aneroid sphygmomanometers are accurate within acceptable clinical practice limits if calibrated regularly according to manufacturer directions. Mercury-free blood pressure measuring devices have been used by most major medical facilities and accepted by medical personnel for many years.

An American study[9] from 2003 concluded in summary that "Research on sphygmomanometers suggests that there are numerous good alternatives to mercury sphygmomanometers. Aneroid sphygmomanometers are cost competitive, have a long history in the field, and have been found acceptable by many hospitals."

In a UK study[10] an aneriod device achieved an A grade for both systolic and diastolic pressures and fulfilled the requirements of the Association for the Advancement of Medical Instrumentation. The mean and standard deviation for systolic and diastolic pressures respectively were -0.6 (4.6) mmHg and -1.3 (3.5) mmHg in sequential analysis, and -1.3 (2.2) mmHg and -1.9 (2.7) mmHg in simultaneous analysis. And the conclusion was that the The Maxi Stabil aneroid device could be recommended for use in an adult population.

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[8] N.D. Markandu *et al.*, "The Mercury Sphygmomanometers Should Be Abandoned Before it is Proscribed," *Journal of Human Hypertension* (2000) 14, 31-36; Vincent J. Canzanello *et al.*, "Are Aneroid Sphygmomanometers Accurate in Hospital and Clinic Settings?" *Archives of Internal Medicine*, March 12, 2001, 729-731.

[9] An Investigation of Alternatives to Mercury Containing Products. Prepared for Maine Department of Environmental Protection at Lowell Center for Sustainable Production, University of Massachusetts Lowell

[10] Reinders, Annemarie; Jones, Clare R; Cuckson, Alexandra C; Shennan, Andrew H. The Maxi Stabil 3: validation of an aneroid device according to a modified British Hypertension Society protocol. Blood Pressure Monitoring. 8(2):83-89, April 2003.

Strain gauge plethysmographs

The last remaining mercury containing equipment for measuring blood pressure and blood flow in Sweden is strain gauge plethysmographs.[11] The equipment is used for measuring blood pressure in fingers and in toes. The mercury equipments are now being successfully replaced by equipment using photo cell or laser-Doppler techniques. Strain gauge plethysmographs containing gallium and indium as a substitute for mercury also exist. At the clinics these techniques can satisfy all necessary kinds of diagnosis that previously needed mercury containing equipment.[12] [13] Clinics that have completely replaced mercury containing instruments with equipment using either laser-Doppler or ultrasound are completely satisfied and do not feel hampered in any way.[14] There is therefore no need for mercury plethysmographs for toe[15] and finger examinations or for measuring relative blood flow of arms and legs. Although most clinics have the mercury strain gauge plethysmograph equipment many of them do not use them regularly.

The reason why equipment containing mercury is still in use is mainly not medical but economical. The mercury containing tube is not very expensive and has a life span of around one year. But the tube is developed to function together with complex electronic measurement equipment that cost more than EUR 20 000 each and that has a life span of 10-15 years. The non-mercury products are fully competitive with mercury equipment on a price basis and on functionality. But clinics hesitate to invest in new equipment unless the existing equipment breaks down.

In some cases mercury containing equipment is still in use at specialist clinics and contribute to the diagnosis and monitoring of critical limb ischemia.[16] Specialist clinics are still dependent on them when monitoring certain kinds of arteriosclerosis.[17] The number of patients that depend on the use of mercury strain gauge techniques is not known but it is estimated that no more than 200 strain gauge tubes are needed annually for the whole of Sweden.

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[11] Urban Niklasson, Technical Committee Secretary of Swedish Association for Clinical Physiology, S:t Görans sjukhus, personal communication, October 5th 2005

[12] Jan Lundvall, Department of Clinical Physiology, Växjö Hospital, personal communication, September 27th 2005

[13] Mikael Öhman, Department of Clinical Physiology, Danderyd Hospital, personal communication September 29th 2005.

[14] Lars Brudin, Department of Clinical Physiology, Kalmar Hospital, personal communication September 29th 2005.

[15] Graaff JC, Ubbink D.T., Legemate D.A., de Haan R.J., Jacobs M.J.: The usefulness of a laser Doppler in the measurement of toe blood pressures. 2000, J Vasc Surg; 32:1172-9.

[16] Krister Kullenberg, Department of Clinical Physiology, Norra Älvsborgs County Hospital, personal communication.

[17] Urban Niklasson, Technical Committee Secretary of Swedish Association for Clinical Physiology, S:t Görans sjukhus, personal communication, October 5th 2005

Mercury strain gauge plethysmographs are mostly used for research purposes. There is today no alternative to mercury containing plethysmographs in research where absolute blood flow in arms and legs are examined.[18] That is because of the huge reference material that has been built up during the decades of use.

Research is ongoing to find alternatives.[19] Non-mercury methods exist and can probably work in a clinical use but before they can be fully implemented they need to be validated. One alternative non-mercury method has recently been validated[20] but several independent validations are necessary in order to clear out all known differences between the old and the new methods. It is estimated that within 4 to 5 years time a mercury free method can be used on a national basis for both clinical and research purposes.

[18] JOYNER MJ, DIETZ NM, SHEPHERD JT. From Belfast to Mayo and beyond: the use and future of plethysmography to study blood flow in human limbs. J Appl Physiol 91: 2431–2441, 2001.

[19] Kristoffersen, R: Evaluation of new transducer for venous occlusion plethysmography, 1999, Department of Physical Electronics, Norwegian university of Science and Technology and Department of Signals and systems, Chalmers University of Technology (thesis).

[20] Leslie SJ, Attinà T, Hultsch E, Bolscher L, Grossman M, Denvir MA and Webb DJ. Comparison of two plethysmography systems in assessment of forearm blood flow. Journal of Applied Physiology 96:1794-1799, 2004. First published Jan 29, 2004

Conclusions

The conclusions that can be drawn from contacts with a broad array of people with a deep knowledge in the area of blood pressure measuring in conjunction with up to date peer reviewed scientific studies[21] are:

- There were only positive experiences reported from the phase out of mercury in the most wide spread equipment called sphygmomanometers, which today is complete.
- No negative medical, practical or economic experiences were found from the phase out of mercury containing sphygmomanometers.
- There are no problems in diagnosing any condition using non-mercury sphygmomanometers including in the presence of arrhythmias, preeclampsia and in accelerated (malign) hypertension.
- Fully functioning, economically competitive, non-mercury plethysmographic equipment is replacing the mercury containing strain-gauge equipment that is used for measuring blood pressure in fingers, toes and other specialty areas.
- The speed of the phase out of the plethysmographic strain gauge equipment is dependent mostly on the life span of the products that are going to be replaced. The non-mercury replacement technologies are for many uses just as good with the exception of a few specified medical conditions.
- It is estimated that within 4-5 years non-mercury plethysmographic equipment will be validated for all areas of use of strain gauges, clinical as well as research use. There is probably no technical obstacle for using non-mercury techniques for all areas of use once the proper validation is in place.

[21] See ”Screening Methodology” and footnotes 1-20.

Glossary

Arrhythmias – An irregularity in the force or rhythm of the heartbeat.

Arteriosclerosis – A disease process, commonly called hardening of the arteries, which includes a variety of conditions that cause artery walls to thicken and lose elasticity.

Auscultation – The act of examination by listening to body sounds.

Hypertension – Blood pressure above the normal range.

Ischemia - Insufficient supply of blood and oxygen to a part of the body; often results from constriction or obstruction of a blood vessel.

Preeclampsia – A condition of hypertension occurring in pregnancy, typically indicated by fluid retention and high blood pressure.

Sphygmo – Greek, from sphugmos, pulsation

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